FDA U.S. FOOD & DRUG ADMINISTRATION

December 12, 2019

Aaron Siri
Siri & Glimstad LLP
200 Park Avenue 17th Floor
New York, NY 10166

In reply refer to file: F18-6746

Dear Mr. Siri,

This is in reply to your Freedom of Information Act request dated August 16, 2018, in which you requested "A copy of the report for each clinical trial relied upon by the FDA when approving PedvaxHIB in 1989." Your request was received in the Center for Biologics Evaluation and Research on August 17, 2019.

Enclosed are the documents that our search located.

We have withheld portions of pages under Exemption (b)(4), 5 U.S.C. § 522(b)(4). That exemption permits the withholding of trade secrets and commercial or financial information that was obtained from a person outside the government and that is privileged or confidential.

In addition, we have withheld portions of pages under Exemption (b)(6), 5 U.S.C. § 522(b)(6). That exemption protects information from disclosure when its release would cause a clearly unwarranted invasion of personal privacy. FOIA Exemption 6 is available to protect information in personnel or medical files and similar files. This requires a balancing of the public's right to disclosure against the individual's right to privacy.

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Office of the Assistant Secretary for Public Affairs
Room 729H
200 Independence Avenue, S.W.
Washington, DC 20201
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Please clearly mark both the envelope and your letter or email "**FDA** Freedom of Information Act Appeal."

If you would like to discuss our response before filing an appeal to attempt to resolve your dispute without going through the appeals process, please contact:

Beth Brockner-Ryan, Branch Chief
Center for Biologics Evaluation and Research (CBER)
Access Litigation and Freedom of Information Branch
U.S. Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002
E-mail:beth.brocknerryan@fda.hhs.gov
Main Line 240-402-7800
FOI Line 240-402-8008

You also have the right to contact:

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5630 Fishers Lane
Room-1050
Rockville, MD 20857
E-mail: FDAFOIA@fda.hhs.gov

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8601 Adelphi Road–OGIS
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Telephone: 202-741-5770
Toll-Free: 1-877-684-6448
Fax: 202-741-5769
E-mail: ogis@nara.gov

If you have any questions or if we can be of further assistance, please let us know by referencing the above file number. You can contact me by phone at 240-402-8008 or by e-mail at Beth.BrocknerRyan@fda.hhs.gov.

Sincerely,

Beth A. Brockner Ryan -S

Digitally signed by Beth A. Brockner Ryan -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=13000524 89, cn=Beth A. Brockner Ryan -S
Date: 2019.12.12 15:36:54 -05'00'

Beth Brockner Ryan
Chief, Access Litigation and Freedom of Information Branch

PRODUCT LICENSE APPLICATION

PLA-0002-XXX-HC48 vol. 2

Merck and Co., Inc.
Haemophilus b Conjugate Vaccine
(Meningococcal Protein Conjugate)

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ume Sequence No. 000194

87-C541 continued

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MERCK SHARP & DOHME RESEARCH LABORATORIES
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August 31, 1988

Paul D. Parkman, M.D., Director
Center for Biologics Evaluation and Research
ATTN: Division of Biological
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Parklawn Building - Room 9B-04
5600 Fishers Lane
Rockville, Maryland 20857

Serial No. 028

Dear Dr. Parkman:

BB-IND 1966: Haemophilus b Conjugate Vaccine
(Neisseria meningitidis Outer Membrane Protein Complex)

INFORMATION AMENDMENT - CLINICAL

We are submitting a status report of clinical information that has been generated thus far to support our license application for PEDVAX-HIB™ [Haemophilus b Conjugate Vaccine (Neisseria meningitidis Outer Membrane Protein Complex)]. This information also has been supplied to Dr. Arthur Elliott for submission as an amendment to the license application for this product.

Sincerely yours,

Kenneth R. Brown, M.D.
Group Director
Regulatory Affairs, Biologics

CS/ys
284H

Attachments (3)
Federal Express No. 9024437752
9024437763

Desk Copy: Dr. Carl Frasch, HFB-640, Bldg. 29, Room 124
Federal Express No. 9024437774

Clinical Report
in Support of a Product License Application

for

PEDVAX-HIB™

Haemophilus b Conjugate Vaccine
(Neisseria meningitidis Outer Membrane Protein Complex)

* This document is submitted in confidence to government health authorities for registration purposes only.

Information and data submitted herein contain trade secrets or priviledged or confidential information which are the property of Merck & Co., Inc.

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Haemophilus b Conjugate Vaccine
(Neisseria meningitidis Outer Membrane Protein Complex)

I. INTRODUCTION

Haemophilus influenzae type b (Hib) accounts for an estimated 12,000 cases of meningitis annually in the United States, primarily in children <5 years of age. Over time, children acquire natural immunity in the form of specific antibodies to the bacteria; hence, meningitis is uncommon beyond 5 years of age. The mortality rate from meningitis currently ranges from 5% to 8%. Up to 35% of survivors develop significant neurologic sequelae such as mental retardation and deafness despite antibiotic treatment. In addition to meningitis, Hib disease presents as other invasive infections, including epiglottitis, septicemia, cellulitis, septic arthritis, osteomyelitis, pneumonia, and pericarditis. The mortality rate from this group of clinical syndromes may be less than that from meningitis. Hib also accounts for about 5% of otitis media. It is estimated that about 20,000 cases of all Hib diseases occur annually in the United States with more than 95% of all clinical isolates being of serotype b.

The incidence of the disease is higher in certain groups including native Americans (Eskimos and American Indians), infants and young children who attend day-care facilities or are household contacts of other children with the infection, blacks, Hispanics, patients with asplenia (e.g., sickle cell disease) or antibody deficiency syndromes, and children of lower socioeconomic status.

Although Hib disease may occur in any age group, it is predominantly a disease of early childhood as shown in the following table, being relatively uncommon after 10 years of age. It is also relatively uncommon in the first month of life, with only about 1% of cases in infants below 2 months of age. The disease peaks between 6 to 12 months of age.

Age-Specific Incidence (%) of Hib Disease

Age (Months)	Proportion of Disease (%)
<12	47
12-<18	16
18-<24	12
>24	25

Children 17 months of age and younger, in whom 60-65% of cases occur, are at present unprotected because available Haemophilus b vaccines are licensed only for children 18 months of age and older. A vaccine that can protect children above and below 18 months of age, is needed.

Licensure of currently available Haemophilus b vaccines is based on their comparability or equivalence to a capsular polysaccharide vaccine which protected against invasive Haemophilus b infections among 24 to 71 month-old Finnish children in a double-blind, controlled field trial. Features of the vaccine utilized in the Finnish trial for which candidate vaccines for licensure have been evaluated, include:

(i) Acceptable safety and tolerability.

(ii) stimulation of anticapsular (anti-PRP) antibody levels known to be associated with protection ($\geq$0.15 to $\geq$1.0 µg/ml).

(iii) elicitation of functional activities of vaccine-induced antibodies against Hib bacteria such as complement-mediated bactericidal activity, opsonophagocytosis, and protection against infection in an infant rat model.

Haemophilus b Conjugate Vaccine (Neisseria meningitidis Outer Membrane Protein Complex) has been evaluated in clinical studies which were designed to demonstrate the above-listed features in recipients aged 2 to 11 months, 12 to 17 months, and $\geq$18 months. In addition, a bacterial polysaccharide immune globulin (BPIG) shown to be effective in preventing invasive Hib disease was compared with PRP-OMPC vaccine-induced antibodies from ach age group in in vitro and in vivo assays as described above.

Product Description and Rationale for Development

Haemophilus b Conjugate Vaccine (Neisseria meningitidis Outer Membrane Protein Complex) (PRP-OMPC) is prepared from the purified capsular polysaccharide (polyribosylribitol phosphate or PRP) of Hib (Ross strain). The capsular polysaccharide is covalently conjugated to an outer membrane protein complex of the B11 strain of N. meningitidis serogroup B. The choice of N. meningitidis as the carrier protein source is based on strong immunogenic properties including T-cell dependence of this vehicle protein complex and a possible protection against clinical meningococcal disease.

Clinical evaluation of PRP-OMPC vaccine was initiated with studies to assess:

(i) safety and tolerability

(ii) optimum route of administration: subcutaneous versus intramuscular.

(iii) preferred diluent for vaccine reconstitution: saline versus aluminum hydroxide.

(iv) optimum number and spacing of vaccine injections and frequency of administration of selected vaccine doses in different age groups.

Study #822 and the earlier segments of Studies #870 and #873 were designed to address those issues. Results from these studies stimulated further evaluation of other aspects, namely:

(i) An optimum vaccine dose (7.5 to 30 µg PRP) and administration schedule (1 month vs. 2 months between doses of vaccine in younger recipients) to induce satisfactory antibody response ($\geq$0.15 to >1.0 µg/ml range of polysaccharide anticapsular antibody) in approximately 90% of vaccinees.

(ii) Need and timing of booster vaccination.

Studies #870 and #873 were expanded to meet the new objectives, and Study #004 series and Study #008 were initiated to expand the database for the specified objectives, as well as to provide for the evaluation of safety and tolerability.

The compatibility of PRP-OMPC vaccine with concurrently administered pediatric vaccines such as DTP, OPV, MMR, was specifically investigated with respect to safety and tolerability, and immunogenicity of the individual vaccine antigens. Study #010 and #011 were set up for that purpose.

Serum samples obtained from subjects of vaccinees in each study series have been evaluated for total antibody content, (anti-PRP) IgG and IgM isotype as well as IgG_1 and IgG_2 subclasses. The functional activities of vaccine-induced antibodies have also been assessed with respect to both bactericidal and opsonic activities and to infant rat protection studies. Study #007 was designed to investigate such antibody responses and functional activities induced by licensed nonconjugated polysaccharide vaccines. This has provided a means of comparing PRP-OMPC to nonconjugated polysaccharide vaccines with respect to stimulation of antibodies and the functional activities of vaccine-induced antibodies.

Other aspects investigated either by special study protocols or by amendments to existing study protocols include:

(i) Vaccine immunogenicity in black children, including those with and without Km(1) immunoglobulin allotype markers.

(ii) Vaccine immunogenicity in Caucasian children including those with and without G23(m) immunoglobulin allotype markers (based on investigator's special evaluation in Study #873). Both groups of children are known to be hyporesponsive to Hib polysaccharide vaccines.

(iii) Priming induced by PRP-OMPC and elicited by boosting with either PRP-OMPC or with a licensed nonconjugated polysaccharide vaccine.

(iv) Immunogenicity of PRP-OMPC in children who contracted (and recovered from) invasive Haemophilus b disease despite previous immunization with licensed nonconjugated polysaccharide vaccines.

(v) Disposition of PRP-OMPC PRP antigen in serum and urine during the first 14 days following vaccination with PRP-OMPC vaccine and in recipients of other licensed nonconjugated and conjugated polysaccharide vaccines (in progress).

In the clinical evaluation of PRP-OMPC vaccine, attention has been specifically paid to the age groups $\geq$18 months, 12-17 months and <12 months in order to assess similarities or differences in the profiles of safety and immunogenicity.

This application is divided into the following sections:

I. INTRODUCTION
II. SUMMARY
III. DESCRIPTION OF PROCEDURES
IV. INTEGRATED SUMMARY OF SAFETY
V. INTEGRATED SUMMARY OF IMMUNOGENICITY
VI. OVERALL CONCLUSIONS ON SAFETY AND IMMUNOGENICITY
VII. INDIVIDUAL STUDY SUMMARIES AND TABLES
VIII. STATISTICAL METHODS
IX. REFERENCES/PUBLICATIONS

APPENDIX

Lot Numbers of Vaccine Used in Clinical Trials

Haemophilus b Conjugate Vaccine
(Neisseria meningitidis Outer Membrane Protein Complex)

Lots for the Haemophilus b Conjugate Vaccine (Neisseria meningitidis Outer Membrane Protein Complex) (PRP-OMPC) used in the clinical trials summarized in this report are identified by an alpha-numeric code consisting of two segments. In this report, all lots will be identified by the 5 digit suffix segment. The complete lot number for each lot of vaccine is listed below:

984 / C-K731

1002 / C-L466

1003 / C-L680

1018 / C-M679

1020 / C-N084

1069 / C-P241

1072 / 37359 / C-P298

1072 / 28616 / C-P298

1080 / C-P749

1085 / C-R132

SUMMARY

Haemophilus B Conjugate Vaccine
(Neisseria meningitidis Outer Membrane Protein Complex)

II. SUMMARY

Haemophilus B Conjugate Vaccine (Neisseria meningitidis Outer Membrane Protein Complex), PRP-OMPC has been evaluated in clinical studies of safety and tolerability, anti-PRP titer and subclass responses, and functional activities of vaccine-induced antibodies. The data presented herein were obtained using the vaccine formulation intended for commercial use, i.e., vaccine reconstituted with aluminum hydroxide diluent and administered by intramuscular injection. Results from early studies using other formulations (e.g. vaccine reconstituted with saline diluent) are presented in Section VII (Individual Study Summaries and Tables).

Data on PRP-OMPC were derived using 4 lots of vaccine, including 3 clinical consistency lots; data for polysaccharide vaccines were derived using 3 licensed, nonconjugated polysaccharide (PRP) vaccines (b-CAPSA®, HibVAX™, HIB-IMUNE®). Children 12 to 71 months of age received a single injection of PRP-OMPC. Infants less than 12 months of age were given 2 injections administered 2 months apart. Each dose of PRP-OMPC vaccine contained 15 mcg polysaccharide. Licensed, nonconjugated polysaccharide vaccines were administered in a single injection in 25 mcg doses; children immunized were $\geq$18 months of age. The number of children vaccinated as of May 16, 1988, the date of data cutoff for this report, and the number with specified data are shown in Table 1. Since studies are continuing, data on safety and immunogenicity are expected from additional vaccinees.

PRP-OMPC vaccine was generally administered alone except in a subset of vaccinees who received other pediatric vaccines (MMR, DTP plus OPV) concurrently but at separate sites with separate needles for injectable vaccines. These studies are in progress and the limited data available for this report are presented.

Vaccinees were evaluated for safety, tolerability and antibody responses. Safety data were obtained for 5 days postvaccination and were based on parents' entries made in a vaccination card provided. Injection site and systemic reactions were reported without regard to causality. Parents' observations recorded on the vaccination cards frequently included entries for intercurrent illnesses whose causal relationship to vaccination was unclear. Evaluation of antibody responses included total antibody determination by a radioimmunoassay (RIA) procedure, quantitation of antibody isotype (IgM, IgG), IgG subclasses, assays for complement-mediated bacteriolysis and opsonization, and passive protection of infant rats.

TABLE 1

Number of Subjects Vaccinated and Presenting Specified Data

Vaccine	Age	Number Vaccinated	Number of Subjects Evaluated for								
			Safety	Antibody Responses*					Bactericidal Activity	Opsonophagocytic Activity	Infant Rat Protection
				RIA	IgM	IgG	IgG_1	IgG_2			
PRP-OMPC	2–6 mo	777	577	248	49	49	49	21	52	22	8
	7–11 mo	300	213	121	27	27	27	15	38	13	6
	12–17 mo	476	369	182	79	78	72	43	94	47	5
	18–23 mo	249	195	110	42	42	47	23	55	18	—
	24–71 mo	361	273	148	60	59	60	32	69	30	—
Total		2163	1627	809	257	255	255	134	308	130	19
Polysaccaride Vaccines	18–23 mo	26	25	23	8	8	8	6	7	5	—
	24–71 mo	136	133	114	39	40	43	36	37	24	—
Total		162	158	137	47	48	51	42	44	29	—

*Only vaccinees with serum samples obtained 3 to 7 weeks after complete immunization are included.

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A. Safety and Tolerability

i. Comparison with Licensed Nonconugated Polysaccharide Vaccines in Children >18 Months of Age

The incidence of adverse reactions usually associated with Haemophilus influenzae type b (Haemophilus b) polysaccharide vaccines, namely, fever and injection site reactions reported approximately 6 hrs, 24 hrs and 48 hrs postvaccination appeared comparable between PRP-OMPC and PRP vaccines (Table 2).

TABLE 2

Percentage of 18-71 Month Old Vaccinees with Fever or Injection Site Reactions Reported

	PRP-OMPC				Nonconjugated Polysaccharide Vaccines*			
	No. of	% Reactions at			No. of	% Reactions at		
Type of Reaction	Subjects	6 hr	24 h	48 hr	Subjects	6 hr	24 h	48 hr
Fever >38.3°C	425	2.4	1.4	2.4	154	3.9	1.3	1.9
Erythema >2.5 cm diameter	457	0.2	0.6	0.4	157	0.6	0.6	0
Induration/Swelling >2.5 cm diameter	457	0.9	1.3	0.9	157	0.6	0	0

*Combined data for three nonconjugated polysaccharide vaccines.

Both PRP-OMPC and licensed polysaccharide vaccines were well tolerated in this age group, with no vaccine-associated serious adverse reactions reported. The types of reactions reported in PRP-OMPC vaccinees and those reported in polysaccharide vaccinees in this age group are shown in Table 3. Minor injection site reactions predominated. There were no significant differences in the incidences of systemic reactions reported between PRP-OMPC and PRP vaccines, with the exception of miscellaneous respiratory tract symptoms which in general were unrelated to vaccine.

TABLE 3

Reactions of >1% Incidence Reported in Children 18 to 71 Months of Age Immunized with PRP-OMPC or with Nonconjugated PRP Vaccines

	% Vacinees with Reaction Reported	
	PRP-OMPC (n=457)	Polysaccharide Vaccines (n=157)
Local (injection site)	33.3	13.3
Systemic		
Irritability	19.9	12.7
Sleepiness/Lethargy	14.1	12.1
Diarrhea	5.8	3.8
Rash	1.5	1.3
Fever (>38°C)	4.6	6.4
Miscellaneous Respiratory Tract Symptoms	4.1	0.6
Vomiting	1.3	2.5

ii. Concurrent Administration of PRP-OMPC with Routine Pediatric Vaccines

PRP-OMPC has been administered concurrently with MMR (n=23), and DTP plus OPV (n=21) vaccines at separate sites in separate syringes for injectable vaccines, to children ≥15 months of age in ongoing studies. No serious adverse reactions attributed to any of the vaccines have been reported when PRP-OMPC was given concurrently with the vaccines.

iii. Safety and Tolerability of PRP-OMPC Across Age Groups

There were no serious vaccine-related reactions reported for any of the vaccinees aged 2 months or older. Low grade fever, minor injection site reactions, and systemic reactions (often reflecting intercurrent illnesses or background conditions) were reported. Fever generally subsided within 3 days, and injection site reactions, within 5-7 days.

A. Safety and Tolerability (Cont.)

The incidence of fever and of injection site reactions over 48 hrs postvaccination are shown in Table 4. Any reactions/observations on intercurrent conditions over the same period are listed in Table 5 for children <12 months of age, and Table 6 for children ≥12 months of age. Comparative vaccine tolerability by vaccine lot was assessed separately in children who were randomly assigned to receive one of the clinical consistency lots of vaccine (see Section VI, Integrated Summary of Safety, for details). With the exception of erythema >1 inch diameter (which was reported in only one vaccine lot, 1072/C-P298, and not the rest) types and rates of reactions after the first versus the second injections (or reactions after single injections in ≥12 month olds compared with these rates) did not differ significantly.

TABLE 4

Percentage of Subjects with Fever or Local Reactions Following One Injection (12-71 mos of Age) or to Either of Two Injections of PRP-OMPC (2-11 mos. of Age)

		Reaction %							
		Injection 1				Injection 2			
Age Group	Reaction	No. of Subjects	6 hr	24 h	48 h	No. of Subjects	6 hr	24 hr	48 hr
2-11 mos	Fever >38.3°C	729	1	2	1	527	1	2	2
	Erythema >2.5 cm on diameter	774	.1	1	.4	568	.9	1.2	0.7
	Swelling/Induration >2.5 cm diameter	774	.5	1	1.2	568	.7	1.9	2.5
12-71 mos	Fever >38.3°C	743	2	2	1				
	Erythema >2.5 cm on diameter	813	.2	.6	.4				
	Swelling/Induration >2.5 cm diameter	813	.7	1.3	1.2				

TABLE 5

Reactions of >1% incidence Reported in
Infants 2 to 11 Months of Age During the 48 Hours
Following Immunization with PRP-OMPC Vaccine

	Incidence (%)	
	Injection 1 (n=790)	Injection 2 (n=584)
Local Reactions (Injection Site)		
Swelling ≤1 inch	12.0	14.7
Erythema ≤1 inch	18.1	17.5
Swelling >1 inch/Induration	1.9	4.5
Erythema >1 inch	1.3	1.5
Pain/Soreness	7.8	9.1
Systemic Reactions		
Irritability	27.3	25.0
Sleepiness/Lethargy	21.4	15.4
Warm to Touch	12.7	11.6
Diarrhea/Vomiting/Nausea	9.9	7.0
Teething	8.0	10.1
Crying	6.3	3.1
Respiratory Symptoms/Infection	5.7	6.8
Rash	1.9	2.9
Atopic Dermatitis (Diaper Rash)	1.4	1.2
Ear Infection/Otitis Media	1.1	2.4

n = Number of subjects with follow-up.

TABLE 6

Reactions of >1% Incidence Reported in Children 12 to 71 Months of Age During 48 Hours Following Immunization with PRP-OMPC Vaccine

	Incidence (%) Injection 1 (n=837)
Local Reactions (Injection Site)	
Swelling (≤1 inch)	10.4
Erythema (≤1 inch)	14.2
Swelling (>1 inch)/Induration	3.2
Pain/Soreness	19.5
Systemic Reactions	
Irritability	21.1
Sleepiness/Lethargy	13.7
Warm to Touch	9.7
Diarrhea/Vomiting/Nausea	8.0
Teething	5.5
Respiratory Symptoms/Infection	6.3
Crying	3.8
Rash	1.6
Ear Infection/Otitis Media	1.4
Atopic Dermatitis (Diaper rash)	1.3

n = Number of subjects with follow-up.

B. Immunogenicity

Table 7 presents anti-PRP responses to the four clinical vaccine lots by age, among children with prevaccination anti-PRP <0.15 mcg/ml. After one injection of vaccine, 99% (238/242) of <12 month old infants, and 99% (252/254) of ≥12 month old children responded with >0.15 mcg/ml anti-PRP. The percentages achieving >1.0 mcg/ml anti-PRP were 79% (189/241) and 89% (225/254) among age groups <12 months, and ≥12 months, respectively. After a second injection in infants <12 months of age, 89% (172/193) achieved >1.0 mcg/ml anti-PRP. The 12-17 month age group showed the lowest response among the ≥12 month age group that received a single dose. The functional activities of vaccine-induced antibodies were, however, demonstrated in the sera of more vaccinees in the 12-17 month age group after one injection of vaccine than those of <12 month vaccinees after two injections of vaccine, as shown later.

Anti-PRP responses in a subset of children randomly assigned to receive one of the three clinical consistency lots of vaccine are shown in Table 8. After adjusting for prevaccination anti-PRP levels for age groups, no significant differences among clinical consistency lots were observed with respect to level of anti-PRP responses and geometric mean fold rise in anti-PRP. Vaccinees in the 12-17 month age group responded with lower anti-PRP GMTs and geometric mean fold rises, among single dose recipients. Their responses were also lower than those of <12 month old children completing a 2-dose regimen. Neither sex nor race was a factor in anti-PRP responses to the clinical consistency lots of vaccine.

Antibody persistence and effect of re-injection of vaccine: Studies with the four lots of vaccine administered in 15 mcg doses are ongoing; antibody persistence is available in only a limited number of vaccinees. Persistence of vaccine-induced antibody assessed after a mean interval ranging from 12.8 to 13.1 months, in children initially immunized at the age of 2-11 months with early lots of vaccine in 7 mcg doses is shown in Table 9. Vaccine-induced anti-PRP persisted at >1.0 mcg/ml in 47% of vaccinees. A booster response followed re-injection of PRP-OMPC and injection of nonconjugated PRP vaccine.

Concurrent administration of PRP-OMPC with routine pediatric vaccines: In a limited number of children ≥15 months of age, PRP-OMPC has been administered concurrently with measles, mumps and rubella vaccines (n=23), and booster immunization with diphtheria and tetanus toxoids and pertussis and oral polio vaccines (n=21) to children ≥15 months of age. In the limited results available, no impairment of immune responses to the individual antigens tested was noted.

TABLE 7

Antibody Responses to PRP-OMPC Vaccine
in Infants and Children with Prevaccination
Antibody Levels ≤0.15 mcg/ml

Age (Months)	Postinjection 1*				Postinjection 2**			
	% With Anti-PRP		Geometric		% With Anti-PRP		Geometric	
	>0.15 mcg/ml	>1.0 mcg/ml	Mean Fold Rise	GMT (mcg/ml)	>0.15 mcg/ml	>1.0 mcg/ml	Mean Fold Rise	GMT (mcg/ml)
2-6	99 (145/147)	78 (114/147)	18.8	2.35	99 (120/121)	87 (105/121)	37.4	4.70
7-11	99 (93/94)	80 (75/94)	26.4	3.30	100 (72/72)	93 (67/72)	62.4	7.84
12-17	100 (129/129)	82 (106/129)	26.8	3.38				
18-23	98 (63/64)	97 (62/64)	57.9	7.16				
24-71	98 (60/61)	93 (57/61)	82.6	10.29				

* Responses measured 1 month postvaccination in children 12-71 months of age or 2 months postvaccination in infants 2-11 months of age.

** Responses measured 1 month after injection.

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TABLE 8

Antibody Responses* To Vaccine in Infants and Children Randomized to Receive One of Three PRP-OMPC Clinical Vaccine Lots

Lot	Age Group (Months)	No. of Subjects	% With Anti-PRP >0.15 mcg/ml Pre	% With Anti-PRP >0.15 mcg/ml Post*	% With Anti-PRP > 1.0 mcg/ml Pre	% With Anti-PRP > 1.0 mcg/ml Post*	Anti-PRP Geometric Mean Fold Rise	Anti-PRP GMT (mcg/ml) Pre	Anti-PRP GMT (mcg/ml) Post
1072/C-P298	2-6	11	36	100	0	82	25.1	<0.13	4.09
	7-11	5	20	100	0	80	45.9	<0.13	6.07
	12-17	16	44	100	0	88	22.7	0.14	4.33
	18-23	9	56	100	22	100	39.1	0.24	12.99
	24-71	12	67	100	50	100	23.3	0.77	21.49
1080/C-P749	2-6	8	13	100	0	88	31.6	<0.13	4.19
	7-11	5	20	100	0	100	63.2	<0.13	9.16
	12-17	13	23	100	0	62	14.6	<0.13	2.08
	18-23	9	56	100	0	100	40.2	0.14	7.75
	24-71	11	46	100	18	91	39.9	0.22	12.53
1085/C-R132	2-6	10	80	100	10	80	12.1	0.20	3.17
	7-11	5	20	100	0	100	43.8	<0.13	6.56
	12-17	11	18	100	0	100	23.0	<0.13	3.29
	18-23	12	58	100	17	92	42.5	0.20	11.16
	24-71	8	63	100	13	88	50.3	0.24	15.33

*Responses measured at 1 month after completion of scheduled vaccination regimen.

TABLE 9

Anti-PRP Persistence and Booster Responses in Infants Previously Immunized with PRP-OMPC Vaccine at 2 to 11 Months of Age

Booster Vaccine (Dose)	Mean Interval Between Primary Injection and Booster	Time	No. of Subjects	% With Anti-PRP >0.15 mcg/ml	% With Anti-PRP ≥ 1.0 mcg/ml	Anti-PRP Geometric Mean Fold Rise	Anti-PRP GMT (mcg/ml)
PRP-OMPC (7 mcg)	12.8	Pre	6	33	0	---	0.12
		Postdose 2*	6	100	83	8.3	1.57
		Prebooster	6	100	50	7.4	1.39
		Postbooster	6	100	100	>440.7	≥83.38
PRP (25 mcg)	13.1	Pre	11	27	0	---	0.09
		Postdose 2*	11	100	64	8.5	1.33
		Prebooster	11	91	45	6.6	0.97
		Postbooster	11	100	100	>184.1	≥28.85

*Two priming injections given one month apart.

000018

B. Immunogenicity (Cont.)

Immunoglobulin Isotype and Subclass Composition

PRP-OMPC vaccine induced both IgM and IgG anti-PRP. IgG response was predominantly IgG_1; children ≥18 months of age had modest IgG_2 response (Table 10).

TABLE 10

Isotype and Subclass Antibody Responses* to PRP-OMPC Vaccine

		IgM				IgG				IgG_1				IgG_2			
			GMT (mcg/ml)				GMT (mcg/ml)				GMT (mcg/ml)				GMT (mcg/ml)		
Vaccine	Age (months)	No. of Subjects	Pre	Post	GMFR**	No. of Subjects	Pre	Post	GMFR**	No. of Subjects	Pre	Post	GMFR**	No. of Subjects	Pre	Post	GMFR**
PRP-OMPC	2-6	38	<0.10	0.13	1.8	36	<0.10	1.03	8.7	40	<0.60	5.22	8.9	17	<0.25	<0.25	1.0
	7-11	24	<0.10	0.27	3.2	24	<0.10	1.77	17.7	21	<0.60	13.03	21.7	13	< .25	<0.25	1.0
	12-17	79	<0.10	0.65	5.2	78	<0.10	0.71	7.6	72	<0.60	3.94	7.4	43	<0.25	<0.25	1.0
	18-23	42	0.12	0.98	5.7	42	<0.10	2.57	21.9	47	<0.60	10.68	17.6	23	<0.25	<0.32	1.7
	≥24	60	0.20	1.38	5.7	59	<0.10	3.57	32.3	60	<0.60	14.61	23.7	32	<0.25	<0.41	2.0

* Total IgG values cannot be compared to IgG subclass values; IgM and IgG assays use (b) (4) antiglobulin conjugates while IgG subclass assays use monoclonal antiglobulin conjugates.

** Geometric mean fold rise

02000

B. Immunogenicity (Cont.)

Comparison with other Hib Vaccines

Data were obtained from children randomly assigned to receive one of three licensed nonconjugated polysaccharide (PRP) vaccines (b-CAPSA™: n=63; HIB-IMUNE®: n=48; HibVAX™: n=51) and a limited number (n=18) of serum samples from children vaccinated with ProHiBiT™, PRP-D. PRP-OMPC was significantly more immunogenic than nonconjugated PRP vaccines (combined data) in the ≥24 month age group as well as in 18-23 month age group ($p<0.1$) (Table 11). Anti-PRP GMT was higher in PRP-OMPC vaccinees than PRP-D vaccines in both age groups tested but the percentages of vaccinees achieving >1.0 mgc/ml anti-PRP were comparable.

In addition, <18 months of age, a single dose of PRP-OMPC vaccine given at 2 months of age has been shown to be more immunogenic than PRP-D after 3 doses given at 2, 4 and 6 months of age (Table 12).

Functional activities of PRP-OMPC vaccine-induced antibodies: Postvaccination sera from PRP-OMPC vaccinees in all age groups <12 months, 12-17 months and ≥18 months demonstrated biologic activities in in-vitro assays specific for bacteriolysis and opsonophagocytic activity (Table 13). The proportions of sera demonstrating ≥4 fold rise in bactericidal activity appeared to be age-dependent, being highest ≥18 months and lowest <12 months of age. Opsonophagocytic activity was independent of age. Both activities were demonstrated in higher proportions of vaccinee sera as anti-PRP levels increased. A similar pattern was observed with PRP and PRP-D vaccines.

Infant rat protection studies: PRP-OMPC vaccine-induced anti-PRP >1.0 mcg/ml conferred protection in an infant rat model for Hib bacteremia. Sera from vaccinees ≥12 months as well as vaccinees <12 months of age demonstrated protection in the model.

Antibody Responses to PRP-OMPC Vaccine in Special Populations

1. Children with impaired immune response to licensed nonconjugated PRP vaccines and to natural Hib infection.

   PRP-OMPC vaccine has been evaluated in a group of children >24 months of age who not only had impaired immune response to licensed nonconjugated PRP vaccines by developing invasive Hib infection, but also responded poorly to the infection with anti-PRP <1 mcg/ml. After recovery from the infection all such children (n=13) achieved anti-PRP >1 mcg/ml following the first injection of PRP-OMPC vaccine; only 4 of 13 (31%) who were randomly assigned to receive nonconjugated PRP vaccine achieved

B. Immunogenicity (Cont.)

>1.0 mcg/ml anti-PRP (Table 14). All 9 children with <1.0 mcg anti-PRP in this letter group achieved >1.0 mcg/ml antibody following a single injection of PRP-OMPC.

2. Children with genetically-based impaired immune response to PRP vaccines:

Children with impaired antibody response to nonconjugated PRP vaccines leading to increased susceptibility to invasive Hib infection due to lack of genetic markers (Km (1) immunoglobulin allotype in blacks and G2m(23) immunoglobulin allotype in whites) have been shown to have good anti-PRP response to PRP-OMPC vaccination (Table 15).

TABLE 11

Antibody Responses to a Single Dose of PRP-OMPC Conjugate Vaccine, Licensed PRP-D Conjugate Vaccine or PRP Nonconjugated Vaccines in Children 18-71 Months of Age with Prevaccination Antibody Levels ≤0.15 mcg/ml

Age (Months)	PRP-OMPC Vaccine			PRP Vaccine			PRP-D Vaccine		
	% With Anti-PRP		GMT	% With Anti-PRP		GMT	% With Anti-PRP		GMT
	≥0.15 mcg/ml	≥1.0 mcg/ml	(mcg/ml)	≥0.15 mcg/ml	≥1.0 mcg/ml	(mcg/ml)	≥0.15 mcg/ml	≥1.0 mcg/ml	(mcg/ml)
18-23	98 (63/64)	97 (62/64)	7.16	77 (10/13)	15 (2/13)	0.39	100 (1/ 1)	100 (1/ 1)	1.23
24-71	98 (60/61)	93 (57/61)	10.29	92 (43/47)	36 (17/47)	0.87	100 (10/10)	100 (10/10)	4.03

TABLE 12*

Comparative Immunogenicity of H. influenzae type b (Hib) Conjugate Vaccines (PRP-D/PRP-OMP) in Infants <6 Months of Age. JI Ward, C. Berkowitz, K. Burkhart, G. Brenneman, J. Pescetti, M. Marcy. Harbor-UCLA Medical Center, Torrance, CA; Arctic Investigations Lab, CDC, Anchorage, AK; Kaiser, Panorama City, CA.

We conducted 3 studies of the immunogenicity and safety of two Hib conjugate vaccines in 2 populations of infants. Three doses of PRP-D (Connaught) were given at 2, 4 and 6 months of age and bloods were obtained at 2, 4, 6 and 7-9 months. Two doses of PRP-OMP (Merck) were given at 2 and 4 months and sera obtained at 2, 4, and 6 months. All sera were assayed simultaneously by FDA standard RIA. GM levels (mg/ml) were:

Age (Dose)	PRP-OMP (CA) (n=27)	PRP-D (CA) (n=20)	PRP-D (AK) (n=13)
2 Months (Pre)	0.1	0.04	0.2
4 Months (Post 1)	1.77	0.04	0.05
6 Months (Post 2)	3.9	0.1	0.08
7 Months (Post 3)	NA	0.3	NA
9 Months (Post 3)	NA	NA	0.3

Even after 1 dose given 2 months, PRP-OMP was clearly more immunogenic than PRP-D after 3 doses given at 2, 4, and 6 months.

* Twenty-Eighth Conference on Antimicrobial Agents and Chemotherapy: Abstract #1128, 1988.

TABLE 13

Comparative Functional Activities of Antibodies
Induced by Different Hib Vaccines

Anti-PRP Antibody (mcg/ml)	Vaccine	Age (Mos)	PRP-OMPC Vaccine SBA* ≥4-Fold Rise	PRP-OMPC Vaccine OP+ 80% Bacterial Kill
>1.0-3.0	PRP-OMPC	<12	8/17 (47%)	3/4 (75%)
		12-17	21/28 (75%)	12/16 (75%)
		≥18.0	13/16 (81%)	4/3 (67%)
	PRP-D	>18.0	5/7 (71%)	ND
	PRP	≥18.0	2/13 (15%)	0/5 (0%)
>3.0-6.0	PRP-OMPC	<12	8/14 (57%)	3/4 (75%)
		12-17	19/23 (83%)	9/11 (82%)
		≥18.0	17/19 (89%)	4/5 (80%)
	PRP-D	≥18.0	3/4 (75%)	ND
	PRP	≥18.0	1/3 (33%)	2/3 (67%)
>6.0-25.0	PRP-OMPC	<12	24/35 (69%)	12/12 (100%)
		12-17	20/21 (95%)	9/10 (90%)
		≥18.0	31/35 (89%)	8/9 (89%)
	PRP-D	≥18.0	4/4 (100%)	ND
	PRP	≥18.0	11/18 (61%)	12/12 (100%)

*Serum Bactericidal Activity
+Opsonization/Bacterial Killing
ND Not Done

TABLE 14

Antibody Responses to PRP-OMPC Vaccine or
Licensed PRP Vaccines in Hyporesponders

Vaccine	Time	% with Anti-PRP >1.0 mcg/ml	% with Anti-PRP >2.0 mcg/ml	GMT mcg/ml (n)
PRP-OMPC	Pre	0 (0/13)	0 (0/13)	0.17 (13)
	Post 1	100 (13/13)	92 (12/13)	6.16 (13)
	Post 2	100 (13/13)	100 (13/13)	10.80 (13)
PRP	Pre	0 (0/13)	0 (0/13)	0.16 (13)
	Post	31 (4/13)	15 (2/13)	0.53 (13)

TABLE 15*

Antibody Responses to PRP-OMPC in Relation to
Km(1) and G2m(23) Allotypes in Infants and Children

Subjects (Age Range)	Allotype	No.	Mean Age (Mo.)	Capsular Polysaccharide Antibody Geo. Mean, mcg/mL Total	IgG
Whites (2-17 Mo.)	G2m(23) Pos.	29	9.6	2.4	1.1
	G2m(23) Neg.	9	6.4	2.6	1.5
Blacks (7-17 Mo.)	Km(1) Pos.	12	12.0	6.7	4.0
	Km(1) Neg.	13	12.7	6.1	4.1

Conclusions

PRP-OMPC vaccine in 15 mcg doses administered intramuscularly was well tolerated in children 12 to 71 months of age as well as infants 2-11 months of age.

No serious vaccine-related reactions have been reported.

In a limited number of children the safety profile of PRP-OMPC vaccine administered concurrently with MMR or DTP/OPV vaccines was unchanged and PRP-OMPC vaccine was well tolerated.

PRP-OMPC vaccine was highly immunogenic in children ≥18 months of age and younger children 2 to 17 months of age.

Virtually all children (99%) 12 months of age and older responded with anti-PRP antibody levels associated with short-term protection (>0.15 mcg/ml); 89% responded with levels associated with long-term protection (>1.0 mcg/ml) after a single 15 mcg (PRP) injection.

After completing a vaccination regimen consisting of two injections given 2 months apart, infants under 12 months of age responded with antibody levels similar to those in older children, i.e., 99% with >0.15 mcg/ml, 89% >1.0 mcg/ml.

Among Whites and Blacks antibody response was not affected by race. Studies in other racial populations are in progress.

PRP-OMPC vaccine induced IgG and IgM antibodies, with IgG class antibodies predominating. IgG subclass response was almost exclusively IgG_1, in infants under 12 months of age while older children showed a modest IgG_2 response in addition.

In a limited number of children initially immunized at the age of 2 to 11 months, PRP-OMPC vaccine-induced antibodies persisted at >0.15 mcg/ml in 94% and >1.0 mcg/ml in 47% of vaccinees approximately 1 year later.

The vaccine demonstrated a T-cell dependent memory effect, with significant increases in anti-PRP antibodies following booster injections.

Concurrent administration of the vaccine with MMR or with booster immunization of DTP and OPV has shown no impairment of antibody response to the individual antigens in ongoing studies.

Conclusions (Cont.)

Vaccine-induced antibodies demonstrated functional activities in in vitro assays specific for Hib bacteriolysis, bacterial opsonization and killing, and in an infant rat model for protection against Hib bacteremia.

PRP-OMPC vaccine was highly immunogenic in children with impaired immune response to either licensed nonconjugated polysaccharide vaccines, natural infection with Hib or both.

The vaccine was significantly more immunogenic in children 18 months of age and older than licensed nonconjugated polysaccharide vaccines. The antibody response to PRP-OMPC vaccine in children below 18 months of age, including 2 month old infants was also significantly higher than that of licensed nonconjugated polysaccharide vaccines in children 18 months of age and older.

PROCEDURES

Haemophilus b Conjugate Vaccine
(Neisseria meningitidis Outer Membrane Protein Complex)

III. DESCRIPTION OF PROCEDURES

A. Study Design

Clinical studies of Haemophilus b conjugate vaccine (Neisseria meningitidis outer membrane protein complex) (PRP-OMPC) involved only healthy children aged approximately 2 months to 5 years. To assure an even distribution of children across this age span, vaccinees were grouped into ages 2 to 6 months, 7 to 11 months, 12 to 17 months, 18 to 23 months and 24 to 71 months. The vaccination regimen consisted of two intramuscular injections given 2 months (42 to 70 days) apart in infants below 12 months of age and a single injection in children 12 months of age and older. Each dose of PRP-OMPC vaccine contained approximately 15 mcg PRP. Four clinical vaccine lots were used in the majority of studies: 1069/C-P241, 1072/C-P298, 1080/C-P749, 1085/C-R132, the latter three of which were manufactured for the purpose of demonstrating clinical consistency. In earlier studies conducted on a small scale, vaccine lots 984/C-K731, 1002/C-L466, 1003/C-L680, 1018/C-M679 and 1020/C-N084 were used, in vaccine doses ranging from 6 to 20 mcg polysaccharide.

Institutional Review Board approval and written parental informed consent were obtained prior to enrolling a child in any of the studies. Instruction on vaccine reconstitution, dosage and administration were provided to the investigator by protocol and discussed at site visits. Vaccine was initially stored frozen at -70°C, but later at 2-8°C, as was the diluent.

Blood samples were obtained prior to each injection and approximately 1 month after the second or after a single injection. Only assay results from blood samples obtained within 3 to 7 weeks of the second or only injection of vaccine were analyzed.

All vaccine recipients were observed for at least 15 minutes after vaccination for any immediate reactions. Safety was further evaluated by requiring parents to record their child's temperature and any reactions at the injection site or systemic complaints on the day of vaccination and for 5 days thereafter on Vaccination Report Cards. Serious adverse experiences in the 14 days following vaccination were required to be reported by the investigator. The report included the investigator's opinion on causality of the adverse experience.

Vaccine immunogenicity was evaluated by measuring total antibody to the capsular polysaccharide of Haemophilus influenzae type b (Hib) by a Farr type radiommunoassay. In a subset of vaccinees, functional antibody activity, including complement-mediated bactericidal activity, opsonization and intracellular killing of Hib bacteria, infant rat passive protection and immunoglobulin isotype and subclasses of IgG anti-PRP were determined.

B. Assays

Assays were performed at Merck Sharp & Dohme Laboratories, with the exception of opsonophagocytic assays which were done by Barry Gray, M.D., University of Alabama, Birmingham.

1. Serum Bactericidal Assay

(b) (4)

2. Opsonophagocytic Assay

(b) (4)

3. Infant Rat Passive Protection Test

(b) (4)

4. Radioimmunoassay for anti-PRP: CBER Method

Dilutions of human sera were incubated with extrinsically-labeled ^{125}I Hib polysaccharide. Antigen-antibody complexes were removed from solution by the addition of an equal volume of saturated ammonium sulfate. Samples were centrifuged and the antigen-antibody complexes in the precipitate were counted in a gamma counter. Radioactive count data were processed through a computer program (weighted 4-parameter logistic curve fitting procedure) and serum titers between 20 and 80% binding of the radiolabeled ^{125}I polysaccharide on the standard curve were considered positive.

5. ELISA (For Antibody Isotype and IgG Subclass)

(b) (4)

INTEGRATED SUMMARY
OF SAFETY

Haemophilus b Conjugate Vaccine
(Neisseria meningitidis Outer Membrane Protein Complex)

IV. INTEGRATED SUMMARY OF SAFETY

Vaccine safety and tolerability were assessed by monitoring postvaccination reactions. Immediately after each injection, children were observed for approximately 15 minutes. Thereafter, reactions were monitored using standardized cards containing specific parameters which were checked by the parents. Reactions for which feedback was required were temperature, injection site reactions (pain/soreness, swelling, redness) irritability, crying, tiredness/sleepiness, hives/rashes, wheezing, nausea, vomiting and diarrhea. Other reactions or conditions not specifically asked for were recorded by the parent in a space provided on the card. The duration of observation varied from 3 to 5 days after the day of vaccination. In addition, any adverse experience occurring within 14 days of vaccination, without regard to causal relationship to vaccination, was recorded. A study site staff member contacted the child's parents during the 24-48 hour period following vaccination. If a parent did not return the vaccination card, information obtained by telephone was used for safety evaluation.

These procedures were expected to insure that serious adverse experiences would not be missed, that reactions previously reported in association with Haemophilus influenzae type b (Hib) polysaccharide vaccines would be sought actively, and that pre-existing conditions were recognized e.g. teething, which would result in symptoms or signs that could be confused with those due to vaccination. This reliance on parental observation, however, resulted in multiple entries including those of a remote or doubtful causal relationship to vaccination.

Four vaccine lots (1069/C-P241, 1072/C-P298, 1080/C-P749, 1085/C-R132), the last three of which represent a clinical series, were used in most of the vaccinees reviewed for safety. Safety data were obtained from children immunized with previous vaccine lots which were also reconstituted and administered in a method similar to that used for the four current lots, i.e., aluminum hydroxide diluent and injection by intramuscular route.

As of May 16, 1988, a total of 2163 children had received at least one injection of the four vaccine lots or earlier lots noted above and outlined in Table 1.

TABLE 1

Age Distribution and Number of Children Immunized
With PRP-OMPC Vaccine

Age (mos.)	Vaccine Lot 1069/C-P241	1072/C-P298	1080/C-P749	1085/C-R132	Other	Total
2-6	196	250	178	47	106	777
7-11	71	99	72	22	36	300
12-17	92	132	185	26	41	476
18-23	46	70	112	21	0	249
24-71	91	158	87	25	0	361
Total Number Vaccinated	496	709	634	141	183	2163

Overall, vaccination with the four vaccine lots was well tolerated in all age groups (2-71 months). No serious vaccine-related adverse reactions were reported either after a single injection in children 12 months of age and older or after any of the two injections given 2 months apart in infants 2 to 11 months of age. In general, adverse reactions consisted of injection site soreness, and systemic reactions including low grade fever. Reactions were generally mild and transient. Fever subsided within 2 to 3 days, and injection site reactions within a week.

The incidence of fever and injection site reactions reported approximately 6 hours (Day 0), 24 hours (Day 1), and 48 hours (Day 2) postimmunization with all lots is shown in Table 2. The highest incidence of any local reaction was 3.7% (swelling >1 inch/induration) while that of fever >38.3°C (101°F) was 2.1%. Reactions and parents' observations reported within 48 hours of vaccination without regard to causal relationship to vaccination are listed under local reactions or systemic reactions by age group (Tables 3 and 4).

The safety profile of the vaccine in children ≥12 months of age was comparable to that in younger children. Moreover, within the 2-11 month age group, the vaccine safety profile after the first injection was comparable to that after the second injection.

Mild elevations in temperature were reported in some vaccinees over the 48 hour period. In infants 2 to 11 months of age, temperatures >38.3°C (101°F) were reported in 2.6% and 3.6% of vaccinees following Injection 1 and Injection 2 respectively (Table 5). In children 12-71 months of age, temperatures >38.3°C (101°F) were reported in 3.7% of vaccinees (Table 6).

Four children had temperatures >40°C (104°F). One child was diagnosed as having otitis media, one bronchitis, conjunctivitis plus otitis media, and one had influenza. The fourth child's temperature could not be verified. A list of serious adverse experiences temporally related to vaccination are shown the Appendix.

A. Clinical Vaccine Lots

Reaction incidences reported in 366 children randomized to three clinical lots of vaccine (1072/C-P298, 1080/C-P749, 1085/C-R132) are summarized in Tables 7-9. There were no significant differences among local or systemic reactions reported after the first injection with the exception of erythema >1 inch which was reported more frequently with lot 1072/C-P298 (5.9% <12 months and 1.9% ≥12 months versus 0% in the two age groups for other vaccine lots, $p<.05$). Following the second injection, no significant differences among reactions were detected in this smaller subset. Within this randomized group, rates of reported injection site reactions >1 inch diameter (erythema, swelling/induration) and fever >38.3°C (101°F) were compared between age groups ≥12 months and <12 months. Swelling/induration was reported significantly more often in the ≥12 month old children than infants.

B. Concurrent Administration with DTP/OPV or MMR

Studies are in progress to compare the safety, tolerability and immunogenicity of PRP-OMPC vaccine administered alone or concurrently with either measles, mumps, and rubella vaccine, or with diphtheria and tetanus toxoids and pertussis and oral poliovirus vaccines. No serious vaccine-related reactions have been reported to date. Data currently available are shown in Tables 10 and 11.

C. Multidose Study

A 15 mcg polysaccharide dose was chosen and used in clinical trials based on its optimum safety and immunogenicity as determined from previous studies in different doses. Reactions reported from on-going confirmatory studies on 7.5, 15 and 30 mcg doses are shown in Tables 12 and 13.

D. Comparative Polysaccharide Vaccines Study

Reactions reported in children 18-71 months of age immunized with a single injection of licensed polysaccharide vaccines (b-CAPSA®, n=63, HIB-IMUNE®, n=48, and HibVAX™, n=51) are compared with those immunized with PRP-OMPC vaccine in Table 14. Although the two classes of vaccines were not evaluated in a comparative study, the types and rates of reactions reported with PRP-OMPC were generally similar to those reported with nonconjugated polysaccharide vaccines, with the exception of pain and soreness which were reported more frequently with PRP-OMPC.

E. Conclusions

PRP-OMPC vaccine in 15 mcg doses was well tolerated in children 12 to 71 months of age as well as infants 2-11 months of age.

No serious vaccine-related reactions have been reported.

In a limited number of children the safety profile of PRP-OMPC vaccine administered concurrently with MMR or DTP/OPV vaccines was well tolerated.

TABLE 2

Percentage of Vaccinees With Fever or Injection Site Reactions
Following Immunization With Haemophilus b Conjugate Vaccine

Age	Reaction	Injection 1				Injection 2			
		No. of Subjects	6 Hr. Day 0	24 Hr. Day 1	48 Hr. Day 2	No. of Subjects	6 Hr. Day 0	24 Hr. Day 1	48 Hr. Day 2
2-11 Mo.	Fever >38.3°C (101°F)	729	1.0	1.5	0.9	527	1.3	1.5	1.9
	Swelling >1 inch diameter/ Induration	774	0.5	1.0	1.3	557	0.9	2.8	3.7
	Erythema >1 inch diameter	774	0.1	1.0	0.4	557	0.9	1.2	0.7
12-71 Mo.	Fever >38.3°C (101°F)	743	2.1	1.6	1.5	--	--	--	--
	Swelling >1 inch diameter/ Induration	813	1.1	2.5	1.8	--	--	--	--
	Erythema >1 inch diameter	813	0.2	0.6	0.4	--	--	--	--

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TABLE 3

Incidence of Clinical Reactions Reported in Infants 2 to 11 Months of Age During the 48 Hours Following Immunization with PRP-OMPC Vaccine

	Incidence (%)	
	Injection 1 (n=790)	Injection 2 (n=584)
Local Reactions (Injection Site)		
Swelling ≤1 inch	12.0	14.7
Erythema ≤1 inch	18.1	17.5
Swelling >1 inch/Induration	1.9	4.5
Erythema >1 inch	1.3	1.5
Pain/Soreness	7.8	9.1
Warmth, Injection Site	0.1	0.2
Infection, Injection Site	0.0	0.2
Systemic Reactions		
Irritability	27.3	25.0
Sleepiness/Lethargy	21.4	15.4
Warm to Touch	12.7	11.6
Diarrhea/Vomiting/Nausea	9.9	7.0
Teething	8.0	10.1
Crying	6.3	3.1
Respiratory Symptoms/Infection	5.7	6.8
Rash	1.9	2.9
Atopic Dermatitis (Diaper Rash)	1.4	1.2
Ear Infection/Otitis Media	1.1	2.4
Anorexia	0.9	0.9
Fever	0.6	0.7
Conjunctivitis	0.3	1.0
Constipation	0.5	0.2
Insomnia	0.5	0.3
Gastroenteritis, Noninfections	0.4	0.2
Eye Discharge	0.3	0.0
Hyperhydrosis	0.3	0.0
Polydipsia	0.3	0.0
Nervousness	0.1	0.7
Urticaria	0.0	0.5

n = Number of subjects with follow-up.

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TABLE 3 (CONT.)

Incidence of Clinical Reactions Reported in
Infants 2 to 11 Months of Age During the 48 Hours
Following Immunization with PRP-OMPC Vaccine

	Incidence (%)	
	Injection 1 (n=790)	Injection 2 (n=584)
Systemic Reactions (Cont.)		
Asthenia	0.1	0.2
Increased Appetite	0.0	0.2
Ataxia	0.0	0.2
Body Odor	0.1	0.0
Candidiasis	0.1	0.0
Contusion	0.0	0.2
Coxsackie Virus Infection	0.0	0.2
Dehydration	0.1	0.0
Dermatomycoses	0.1	0.0
Ear Fluid	0.0	0.2
Endophthalmitis	0.0	0.2
Eye Swelling	0.1	0.0
Facial Edema	0.0	0.2
Flatulence	0.1	0.0
Flushing	0.1	0.0
Flu-like Illness	0.0	0.2
Gastritis, Acute	0.0	0.2
Gastrointestinal Pain	0.1	0.0
Hyperkinesia	0.1	0.2
Infectious Gastroenteritis	0.1	0.2
Injection Site Pain	0.0	0.2
Lymphadenopathy	0.0	0.2
Miliaria Rubra	0.1	0.0
Oral Candidiasis	0.1	0.0
Otalgia	0.1	0.2
Otitis Externa	0.1	0.0

n = Number of subjects with follow-up.

TABLE 3 (CONT.)

Incidence of Clinical Reactions Reported in
Infants 2 to 11 Months of Age During the 48 Hours
Following Immunization with PRP-OMPC Vaccine

	Incidence (%)	
	Injection 1 (n=790)	Injection 2 (n=584)
Systemic Reactions (Cont.)		
Pruritus	0.1	0.0
Salivation Increased	0.0	0.2
Scleral Disorders	0.1	0.0
Serous Otitis Media	0.0	0.2
Skin Inflammation	0.1	0.0
Skin Texture Changes	0.0	0.2
Urinary Frequency	0.1	0.0
Urinary Tract Infections	0.0	0.2
Wolff-Parkinson-White Syndrome	0.1	0.2

n = Number of subjects with follow-up.

6233I/8
25AUG88

TABLE 4

Incidence of Clinical Reactions Reported in Children 12 to 71 Months of Age During 48 Hours Following Immunization with PRP-OMPC Vaccine

	Incidence (%) Injection 1 (n=837)
Local Reactions (Injection Site)	
Swelling (≤1 inch)	10.4
Erythema (≤1 inch)	14.2
Swelling (>1 inch)/Induration	3.2
Erythema (>1 inch)	0.6
Pain/Soreness	19.5
Stiffness/Tightness	0.2
Warmth, Injection Site	0.2
Ecchymosis, Injection Site	0.1
Inflammation, Injection Site	0.1
Systemic Reactions	
Irritability	21.1
Sleepiness/Lethargy	13.7
Warm to Touch	9.7
Diarrhea/Vomiting/Nausea	8.0
Teething	5.5
Respiratory Symptoms/Infection	6.3
Crying	3.8
Rash	1.6
Ear Infection/Otitis Media	1.4
Atopic Dermatitis (Diaper rash)	1.3
Fever	1.0
Anorexia	0.8
Sleep Disorders	0.5
Conjunctivitis	0.4
Limping	0.4
Infectious Gastroenteritis	0.4
Nervousness	0.4
Polydipsia	0.4

n = Number of subjects with follow-up.

TABLE 5

Percentages of Vaccinees (2-11 Months of Age)
with Elevated Temperatures During a Two-Day Period
Following 1363 Injections of PRP-OMPC Vaccine

Temperature	Post Injection 1 (n=772)	Post Injection 2 (n=553)
≥100°F (37.8°C)	8.5	9.6
≥101°F (38.3°C)	2.6	3.6
≥102°F (38.9°C)	1.3	1.3
≥103°F (39.4°C)	0.9	0.7

Fever, temperature not recorded, was reported in 1 case (Inj. 1) and 2 cases (Inj. 2).

n = Number of subjects with follow-up.

6233I/10
25AUG88

TABLE 6

Percentages of Vaccinees (12-71 Months of Age) with Elevated Temperatures During a Two-Day Period Following 896 Injections of PRP-OMPC Vaccine

Temperature	Post Injection (n=777)
≥100°F (37.8°C)	12.0
≥101°F (38.3°C)	3.7
≥102°F (38.9°C)	1.9
≥103°F (39.4°C)	0.6

Fever, temperature not recorded, was reported in 2 cases.

n = Number of subjects with follow-up.

6233I/11
25AUG88

TABLE 7

Clinical Reactions Reported at a Frequency of 2% or More
During Days 0 to 2 Following Injection of Hib Conjugate Vaccine
- Children Randomized to the Consistency Lots -

Lot: 1072/C-P298	2-11 Months Old				12-71 Months Old	
	Injection 1 (n=51)		Injection 2 (n=30)		Injection 1 (n=53)	
Clinical Reaction	No.	Reported (%)	No.	Reported (%)	No.	Reported (%)
Injection Site						
Swelling, ≤1 inch	6	11.8	2	6.7	8	15.1
Erythema, ≤1 inch	7	13.7	3	10.0	5	9.4
Swelling, >1 inch/Induration	0	0.0	2	6.7	2	3.8
Erythema, >1 inch	3	5.9	0	0.0	1	1.9
Pain/Soreness	5	9.8	1	3.3	6	11.3
Systemic						
Sleepiness/Lethargy	6	11.8	6	20.0	4	7.5
Fever	2	3.9	0	0.0	0	0.0
Warm to Touch	4	7.8	3	10.0	4	7.5
Diarrhea/Vomiting/Nausea	2	3.9	1	3.3	0	0.0
Teething	2	3.9	1	3.3	2	3.8
Irritability	11	21.6	7	23.3	8	15.1
Crying	3	5.9	1	3.3	0	0.0
Insomnia	2	3.9	0	0.0	0	0.0
Respiratory Symptoms/ Infection	3	5.9	1	3.3	3	5.7
Rash	0	0.0	1	3.3	1	1.9
Ear Infection/Otitis Media	1	2.0	3	10.0	1	1.9
Conjunctivitis	1	2.0	0	0.0	0	0.0

n = Number of subjects with follow-up.

6233I/12
25AUG88

TABLE 8

Clinical Reactions Reported at a Frequency of 2% or More
During Days 0 to 2 Following Injection of Hib Conjugate Vaccine
- Children Randomized to the Consistency Lots -

Lot: 1080/C-P749	2-11 Months Old				12-71 Months Old	
	Injection 1 (n=45)		Injection 2 (n=32)		Injection 1 (n=56)	
Clinical Reaction	No.	Reported (%)	No.	Reported (%)	No.	Reported (%)
Injection Site						
Swelling, ≤1 inch	4	8.9	3	9.4	4	7.1
Erythema, ≤1 inch	5	11.1	4	12.5	6	10.7
Swelling, >1 inch/Induration	0	0.0	1	3.1	1	1.8
Erythema, >1 inch	0	0.0	0	0.0	0	0.0
Pain/Soreness	2	4.4	1	3.1	7	12.5
Systemic						
Sleepiness/Lethargy	7	15.5	3	9.4	1	1.8
Warm to Touch	4	8.9	2	6.3	2	3.6
Diarrhea/Vomiting/Nausea	2	4.4	0	0.0	0	0.0
Teething	1	2.2	1	3.1	1	1.8
Constipation	1	2.2	0	0.0	0	0.0
Irritability	8	17.8	3	9.4	3	5.4
Nervousness	2	3.6	0	0.0	0	0.0
Crying	3	6.7	0	0.0	2	3.6
Hyperkinesia	1	2.2	0	0.0	0	0.0
Respiratory Symptoms/ Infection	2	4.4	0	0.0	1	1.8
Atopic Dermatitis (Diaper Rash)	1	2.2	0	0.0	2	3.6
Rash	2	4.4	0	0.0	1	1.8
Ear Infection/Otitis Media	0	0.0	1	3.1	0	0.0

n = Number of subjects with follow-up.

6233I/13
25AUG88

TABLE 9

Clinical Reactions Reported at a Frequency of 2% or More
During Days 0 to 2 Following Injection of Hib Conjugate Vaccine
- Children Randomized to the Consistency Lots -

Lot: 1085/C-R132	2-11 Months Old				12-71 Months Old	
	Injection 1 (n=48)		Injection 2 (n=35)		Injection 1 (n=54)	
Clinical Reaction	No.	Reported (%)	No.	Reported (%)	No.	Reported (%)
Injection Site						
Swelling, ≤1 inch	7	14.6	6	17.1	4	7.4
Erythema, ≤1 inch	7	14.6	5	14.3	7	13.0
Swelling, >1 inch/Induration	0	0.0	1	2.9	2	3.7
Erythema, >1 inch	0	0.0	0	0.0	0	0.0
Pain/Soreness	2	4.2	3	8.6	8	14.8
Systemic						
Sleepiness/Lethargy	5	10.4	5	14.3	4	7.4
Warm to Touch	6	12.5	1	2.9	1	1.9
Diarrhea/Vomiting/Nausea	3	6.3	0	0.0	1	1.9
Teething	0	0.0	2	5.7	1	1.9
Constipation	0	0.0	1	2.9	0	0.0
Irritability	13	27.1	3	8.6	10	18.5
Nervousness	0	0.0	0	0.0	2	5.7
Crying	0	0.0	1	2.9	1	1.9
Insomnia	1	2.1	0	0.0	0	0.0
Respiratory Symptoms/ Infection	1	2.1	2	5.7	0	0.0
Rash	2	4.2	0	0.0	0	0.0
Pruritus	1	2.1	0	0.0	0	0.0
Ear Infection/Otitis Media	0	0.0	1	2.9	1	1.9
Ear Fluid	0	0.0	1	2.9	0	0.0

n = Number of subjects with follow-up.

6233I/14
25AUG88

TABLE 10

Percentage of Vaccinees With Specified Injection Site or Systemic Reactions Reported Within 48 Hours of Having Received PRP-OMPC and MMR Vaccines Either Separately or Concurrently

	PRP-OMPC/MMR Concurrently		PRP-OMPC Followed by MMR 4 Weeks Later	
	PRP-OMPC (n=23)	MMR (n=23)	PRP-OMPC (n=22)	MMR (n=10)
Injection Site Reactions				
Swelling >1 inch	0.0	0.0	0.0	0.0
Erythema >1 inch	4.3	0.0	0.0	0.0
Pain/Soreness	13.0	0.0	4.5	10.0
	PRP-OMPC/MMR*			
Systemic Reactions				
Irritability	21.7		36.4	0.0
Sleepiness/Lethargy	8.7		9.1	10.0

n = Number of subjects with follow-up.

* Systemic reactions following concurrent administration were attributed to both vaccines.

6233I/15
25AUG88

TABLE 11

Percentage of Vaccinees With Specified Injection Site or Systemic Reactions Reported Within 48 Hours of Having Received PRP-OMPC and DTP/OPV Vaccines Either Separately or Concurrently

	PRP-OMPC/DPT/OPV Concurrently		PRP-OMPC Followed By DTP/OPV 4 Weeks Later	
	PRP-OMPC (n=21)	DTP/OPV (n=21)	PRP-OMPC (n=26)	DTP/OPV (n=16)
Injection Site Reactions				
Swelling >1 inch	0.0	0.0	0.0	0.0
Erythema >1 inch	0.0	0.0	0.0	0.0
Pain/Soreness	33.3	57.1	23.1	43.8
	PRP-OMPC/DTP/OPV*			
Systemic Reactions				
Irritability	71.4		34.6	25.0
SLeepiness/Lethargy	33.3		19.2	12.5

n = Number of subjects with follow-up.

* Systemic reactions following concurrent administration were attributed to both vaccines.

6233I/16
25AUG88

TABLE 12

Frequency of Specified Injection Site and Systemic Reactions
Reported Among Vaccinees (2-18 Months of Age)
For Two Days Following the One Injection at Three Dose Levels
With PRP-OMPC Vaccine

	7.5 mcg	15 mcg	30 mcg
Local (Injection Site)			
Swelling >1 inch	0.0 (0/71)	0.0 (0/49)	0.0 (0/13)
Erythema >1 inch	0.0 (0/71)	2.1 (1/49)	0.0 (0/13)
Pain/Soreness	9.9 (7/71)	0.0 (0/49)	0.0 (0/13)
Systemic			
Irritability	14.1 (10/71)	26.5 (13/49)	15.4 (2/13)
Sleepiness/Lethargy	14.1 (10/71)	10.2 (5/49)	7.7 (1/13)
Temperature			
>38.3°C (101°F)	1.7 (1/58)	7.5 (3/40)	0.0 (0/9)

6233I/17
25AUG88

TABLE 13

Frequency of Specified Injection Site and Systemic Reactions
Reported Among Vaccinees (19-59 Months of Age)
For Two Days Following the One Injection at Three Dose Levels
With PRP-OMPC Vaccine

	7.5 mcg	15 mcg	30 mcg
Local (Injection Site)			
Swelling >1 inch	0.0 (0/31)	0.0 (0/25)	0.0 (0/27)
Erythema >1 inch	0.0 (0/31)	0.0 (0/25)	0.0 (0/27)
Pain/Soreness	9.7 (3/31)	24.0 (6/25)	29.6 (8/27)
Systemic			
Irritability	12.9 (4/31)	12.0 (3/25)	3.7 (1/27)
Sleepiness/Lethargy	6.5 (2/31)	12.0 (3/25)	7.4 (2/27)
Temperature			
>38.3°C (101°F)	0.0 (0/25)	5.0 (1/20)	0.0 (0/25)

6233I/18
25AUG88

TABLE 14

Percentage of Vaccinees (18-71 Months of Age)
With Specified Injection Site and Systemic Reactions
for Two Days Following Injection With PRP-OMPC Vaccine
Compared With Licensed Polysaccharide Vaccine

Type of Complaint	% Vaccinees With Reported Reactions	
	Conjugate Vaccine	Polysaccharide Vaccine
Local (Injection Site)		
Swelling >1 inch	1.5 (7/468)	0.0 (0/158)
Erythema >1 inch	0.6 (3/468)	2.1 (1/158)
Pain/Soreness	25.0 (117/468)	12.0 (19/158)
Systemic		
Irritability	19.9 (93/468)	12.6 (20/158)
Sleepiness/Lethargy	14.1 (66/468)	12.0 (19/158)
Temperature		
>38.3°C (101°F)	4.6 (20/439)	6.4 (10/157)

6233I/19
25AUG88

APPENDIX

Serious Adverse Experiences Among Children Ages 2 to 71 Months Receiving
Haemophilus b Conjugate Vaccine (Neisseria meningitidis Outer Membrane Complex)

Study #	Case #	Vaccine Lot	Dose	Dates Administered	Date of Event	Date Reported to Merck	Summary of Event	Vaccine* Related
004-01	(b) (6)	1069/C-P241	15 mcg	(b) (6)	05/27/87	06/02/87	05/27/87: A 9-month old male had difficulty sleeping and had a runny nose beginning 05/27/87 for 2 days. He developed wheezing and a temperature of 100.7°F. The child recovered. Medical history - reactive airway disease; similar experience in 2/87 during RSV respiratory infection.	Definitely Not
004-01	(b) (6)	1069/C-P241	15 mcg	(b) (6)	(b) (6)	08/04/87	(b) (6): A 4-month old female, 1 month after the first dose of conjugate vaccine and 3 days after vaccination with DTP and OPV, was diagnosed with meningitis. The etiology of the meningitis was determined as nonbacterial and probably viral.	Definitely Not

*Clinical Investigator's Assessment

6233I/20
25AUG88

00052

APPENDIX (CONT.)

Serious Adverse Experiences Among Children Ages 2 to 71 Months Receiving
Haemophilus b Conjugate Vaccine (Neisseria meningitidis Outer Membrane Complex)

Study #	Case #	Vaccine Lot	Dose	Dates Administered	Date of Event	Date Reported to Merck	Summary of Event	Vaccine* Related
004-10	(b) (6)	1072/C-P298	15 mcg	(b) (6)	11/15/87	11/24/87	11/15/87: A 6-month old female developed cellulitis on the left side of her neck at the site of an insect bite. (b) (6): The child was hospitalized with diagnosis of cervical cellulitis. Blood and CSF cultures were negative. Urine antigen detection test for Haemophilus influenzae was negative. Probable staphylococcal cellulitis. She recovered without residual effects.	Probably Not
004-14	(b) (6)	1069/C-P241	15 mcg	(b) (6)	(b) (6)	09/24/87	(b) (6): A 5-month old female developed gastroenteritis. She was hospitalized with moderate dehydration and was treated with oral rehydration and Tylenol. (b) (6): The child was discharged. (b) (6): The child was rehospitalized with the same symptoms. (b) (6): After recovering, she again was discharged. No bacterial pathogens were isolated. Viral studies were not done.	Probably Not

*Clinical Investigator's Assessment

6233I/21
25AUG88

00053

APPENDIX (CONT.)

Serious Adverse Experiences Among Children Ages 2 to 71 Months Receiving
Haemophilus b Conjugate Vaccine (Neisseria meningitidis Outer Membrane Complex)

Study #	Case #	Vaccine Lot	Dose	Dates Administered	Date of Event	Date Reported to Merck	Summary of Event	Vaccine* Related
0004-14	(b) (6)	1072/C-P298	15 mcg	(b) (6)	12/11/87	01/22/88	12/11/87: A 3-month old female developed acute watery diarrhea with minimal dehydration, conjunctivitis, and an upper respiratory infection. (b) (6): The child was hospitalized and x-ray revealed right middle lobe pneumonia and bronchiolitis. The child subsequently recovered and was discharged.	Probably Not
0004-14	(b) (6)	1069/C-P241	15 mcg	(b) (6)	12/16/87	01/22/88	12/16/87: A 5-month old female experienced mild bronchiolitis, conjunctivitis, and temperature of 100.1°F rectal at time of administration of Dose 2. (b) (6): The child was hospitalized with a temperature of 102°F rectal and diagnosed as having asceptic meningitis. Blood and CSF cultures were negative, 36,500 WBC (59 poly, 30 lymph). The child has recovered.	Probably Not
0004-14	(b) (6)	1072/C-P298	15 mcg	(b) (6)	(b) (6)	03/15/88	(b) (6): A 2-month old female was hospitalized with URI. She was treated with Benadryl. (b) (6): The child was discharged and subsequently recovered.	Probably Not

*Clinical Investigator's Assessment

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25AUG88

APPENDIX (CONT.)

Serious Adverse Experiences Among Children Ages 2 to 71 Months Receiving
Haemophilus b Conjugate Vaccine (Neisseria meningitidis Outer Membrane Complex)

Study #	Case #	Vaccine Lot	Dose	Dates Administered	Date of Event	Date Reported to Merck	Summary of Event	Vaccine* Related
0004-14	(b) (6)	1072/C-P298	15 mcg	(b) (6)	(b) (6)	03/15/88	(b) (6): A 4-month old female was hospitalized for an upper respiratory infection. (b) (6): The child was discharged.	Definitely Not
0007-01	(b) (6)	HibVAX™	25 mcg	(b) (6)	(b) (6)	02/11/88	(b) (6): A 23-month old male was diagnosed as having otitis media and an E. coli urinary tract infection. (b) (6): The child was hospitalized. (b) (6): The child subsequently recovered and was discharged. Medical history of underlying obstructive neuropathy.	Probably Not
0008-02	(b) (6)	1072/C-P298	7.5 mcg	(b) (6)	05/22/88	06/14/88	05/22/88: A 9-month old male developed a fever of 103-104°. (b) (6): The child was hospitalized with maculo papular rash on face and body (confluent on back, chest, and groin), vomiting (1x) and temperature of 37.8°C rectal. (b) (6): Rash was disappearing and child was discharged.	No

*Clinical Investigator's Assessment

6233I/23
25AUG88

55000

APPENDIX (CONT.)

Serious Adverse Experiences Among Children Ages 2 to 71 Months Receiving
Haemophilus b Conjugate Vaccine (Neisseria meningitidis Outer Membrane Complex)

Study #	Case #	Vaccine Lot	Dose	Dates Administered	Date of Event	Date Reported to Merck	Summary of Event	Vaccine* Related
873	(b) (6)	1003/C-L680	7 mcg (in saline)	(b) (6)	12/15/84	12/21/84	(b) (6): A 10-month old female experienced no complications after receiving the first injection of vaccine. (b) (6): Four hours after receiving the second vaccine injection, she developed a temperature of 38.9°C. She was lethargic and anorexic but took fluids without difficulty. At the same time, her mother noted swelling and erythema over the anterior thigh surrounding the injection site, extending from above the knee to the groin. She refused to crawl or move the extremity. 12/16/84: The child's temperature was 37.5°C. She was using her leg, and the swelling and tenderness had subsided somewhat. Her improvement continued although she had an isolated temperature elevation of 38.6°C at approximately 32 hours after the injection. 12/17/84: The swelling was 90% resolved, and her temperature was 37.4°C (axillary). 12/22/84: The child was in good health.	Probably

*Clinical Investigator's Assessment

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25AUG88

APPENDIX (CONT.)

Serious Adverse Experiences Among Children Ages 2 to 71 Months Receiving
Haemophilus b Conjugate Vaccine (Neisseria meningitidis Outer Membrane Complex)

Study #	Case #	Vaccine Lot	Dose	Dates Administered	Date of Event	Date Reported to Merck	Summary of Event	Vaccine* Related
873	(b) (6)	1018/C-M679	18 mcg	(b) (6)	(b) (6)	06/02/86	(b) (6): Two days after receiving the Hib vaccine, a 7-month old female developed fever of 38.9°C and a 1 x 3.5 cm induration with erythema and tenderness at the injection site. 05/31/86: Her temperature increased to 39.2°C. (b) (6): The child had an axillary temperature of 37.4°C and a 2.5 x 1 cm induration without erythema or tenderness at the injection site. A faint, fine erythematous rash was present on the face, neck, upper torso and upper extremities. Laboratory analysis revealed ESR 18, WBC count 5,700, bands 2%, PMN's 5%, lymphocytes 93 with occasional atypical lymphs present and platelet count 315,000. Urinalysis revealed specific gravity 1.008, pH 6, protein and glucose were negative. 06/03/86: The child was without fever for more than 24 hours. 06/05/86: The rash had resolved. (b) (6): Upon physical examination, an approximately 2.5 x 2 cm area of nontender induration at the injection site was reported. Repeat laboratory analysis revealed ESR 13, WBC count 11,000, eosinophils 1%, PMN's 31%, lymphocytes 67%, monocytes 10% and platelet count 863,000. Viral cultures are negative.	Possibly

*Clinical Investigator's Assessment

6233I/25
25AUG88

APPENDIX (CONT.)

Serious Adverse Experiences Among Children Ages 2 to 71 Months Receiving
Haemophilus b Conjugate Vaccine (Neisseria meningitidis Outer Membrane Complex)

Study #	Case #	Vaccine Lot	Dose	Dates Administered	Date of Event	Date Reported to Merck	Summary of Event	Vaccine* Related
873	(b) (6)	1018/C-M679	18 mcg	(b) (6)	(b) (6)	06/02/86	(b) (6): A 5-month old male infant began high-pitched screaming approximately 4 hours after vaccination. He was unconsolable for 2 hours but then was fed and slept through the night. 06/01/86: At 6 a.m., he awoke screaming and was unconsolable for 10 hours. He ate in the morning but refused a bottle until 4 p.m. The infant slept between 4:30 p.m. and 7:00 p.m., but began crying again between 9:00 and 12:00 p.m. 06/02/86: After awakening, the infant was alert and playful. 06/13/86: The child was well.	Definitely

*Clinical Investigator's Assessment

6233I/26
25AUG88

Haemophilus b Conjugate Vaccine
(Neisseria meningitidis Outer Membrane Protein Complex)

V. INTEGRATED SUMMARY OF IMMUNOGENICITY

A. Vaccine-Induced Anti-PRP Antibodies

Capsular polysaccharide (PRP) antibody induced by Haemophilus b conjugate vaccine (Neisseria meningitidis outer membrane protein complex) (PRP-OMPC) was measured by radioimmunoassay (RIA) within Merck Sharp & Dohme Research Laboratories. The precise protective level of anti-PRP antibody in man is unknown; estimates range from 0.15 mcg/ml for short-term protection to ≥1.0 mcg/ml for long-term protection from invasive infection. Therefore, antibody responses to the vaccine are presented here in relation to these two levels. Antibody responses to PRP-OMPC vaccination were evaluated not only in children ≥18 months of age, an age group for which Hib vaccines are available commercially, but also in younger children 12 to 17 months and 2 to 11 months of age. These younger children and infants, being at a higher risk for invasive Hib disease, would benefit most from an immunogenic vaccine.

Anti-PRP responses among healthy infants and children 2 to 71 months of age receiving 15 mcg doses of lyophilized vaccine (lots 1069/C-P241, 1072/C-P298, 1080/C-P749, 1085/C-R132) reconstituted with aluminum hydroxide diluent and administered by intramuscular injection are summarized in Table 1. Infants less than 12 months of age received two injections of vaccine two months apart; older children received a single injection.

Ninety-nine percent of children (789/796) had protective antibody levels (>.15 mcg/ml) after one injection of vaccine, regardless of age at the time of vaccination. Ninety-one percent (397/437) of children 12 months of age or older had a level associated with long-term protection (>1.0 mcg/ml). One injection of vaccine induced antibody >1.0 mcg/ml in 78% (279/359) of infants less than 1 year old. After a second injection 90% (252/281) of infants 2 to 11 months of age achieved >1.0 mcg/ml anti-PRP antibody. The geometric mean fold rise in antibody levels after one injection of vaccine ranged from 13.5 to 48.1 in the age groups outlined in Table 1. After the second injection of vaccine in infants <12 months of age, further increases of 1.7 to 2.6 fold were seen. Geometric mean antibody titers following the last or a single injection of PRP-OMPC vaccine ranged from 3.76 mcg/ml to 16.6 mcg/ml.

A. Vaccine-Induced Anti-PRP Antibodies (Cont.)

Table 2 summarizes antibody responses to the four lots of the vaccine among a subset of children with nonprotective prevaccination levels, i.e., ≤0.15 mcg/ml. The responses of this subset of children to the vaccine were excellent. Ninety-nine percent (252/254) and 89% (225/254) of children ≥12 months of age responded with antibody levels >0.15 mcg/ml and >1.0 mcg/ml, respectively, after one injection of vaccine. Antibody levels >0.15 mcg/ml were achieved in 99% (238/242) of infants <12 months of age following one injection of vaccine, with 79% (189/241) developing antibody >1.0 mcg/ml. Following a second injection, 89% (172/193) achieved protective levels >1.0 mcg/ml. Among single dose recipients, antibody levels were higher in the 18 to 23 and 24 to 71 month age groups than the 12 to 17 month age group.

Tables 3 and 4 show the distribution of anti-PRP titers in all vaccinees and in the group of children with prevaccination anti-PRP levels ≤0.15 mcg/ml. Over 50% of children ≥2 months of age achieved anti-PRP titers of >3 mcg/ml upon completion of their scheduled vaccination regimen, including children with <0.15 mcg/ml anti-PRP levels prior to vaccination.

Comparison of Vaccine Lots

Randomized Studies

Three vaccine lots of PRP-OMPC (lots 1072/C-P298, 1080/C-P749, 1085/C-R132) of PRP-OMPC vaccine were evaluated extensively in clinical trials. In five study centers (Study #004-01, #004-05, #004-07, #004-08, #004-10), a subset of infants and children were randomized to the three lots stratified by vaccination regimen (one or two injections), to assess comparability of vaccine lots with respect to their immunogenicity, safety and tolerability.

A total of 366 infants and children were randomized to receive the three vaccine lots. Anti-PRP levels were measured in 145 of them after the second or only injection depending on age. The age, sex and race characteristics by vaccine lot in this subset of children were comparable (Table 5). No significant differences among recipients of the lots were observed with respect to the specified demographic features.

A. Vaccine-Induced Anti-PRP Antibodies (Cont.)

Vaccine-induced antibody responses of this subset of children are shown in Table 6. No significant differences were observed among the vaccine lots with respect to level of anti-PRP response (GMT) adjusting for prevaccination antibody levels across identical age categories. Geometric mean titers for all age groups combined were 7.65, 5.49, and 6.32 mcg/ml for vaccine lots 1072/C-P298, 1080/C-P249, and 1085/C-R132, respectively. There was also no significant difference among recipients by vaccine lot in the geometric mean fold rise in antibody from prevaccination levels (again adjusted for age category).

Following their second or only injection, all infants and children receiving any lot of vaccine had anti-PRP titers >0.15 mcg/ml. The proportion of children developing titers >1.0 mcg/ml was not significantly different for the three lots. Anti-PRP levels >1.0 mcg/ml were achieved in 86% (24/28), 84% (26/31) and 96% (22/23) of recipients of lots 1072/C-P298, 1080/C-P249 and 1085/C-R132, respectively (Table 7).

Multicenter Study

To reassess the conclusion that no differences are apparent among the lots, the three vaccine lots were compared across all 14 studies in which they were evaluated under a uniform protocol. Unlike in the randomized subset, the number of vaccinees in the 14 studies was large enough for analyses of results by vaccine lot and by age group. Tables 8 and 9 summarize the anti-PRP responses of infants and children who received one of the vaccine lots in the 14 studies, irrespective of randomization.

Anti-PRP titers approximately one month after the last injection of vaccine were compared adjusting for age and race among those children who had a prevaccination antibody level ≤0.15 mcg/ml. As noted earlier, no significant differences were found among the three vaccine lots with respect to: 1) the proportion of vaccinees who developed titers >1.0 mcg/ml, stratified by prevaccination titers of <0.15 or >.15 - 1.0 mcg/ml, and 2) the level of response (GMT). Overall geometric mean antibody titers ranged from 4.31 to 6.17 mcg/ml for all age groups combined. Anti-PRP levels >1.0 mcg/ml were achieved in 84% to 96% of vaccine recipients with prevaccination antibody levels ≤0.15 mcg/ml.

A. Vaccine-Induced Anti-PRP Antibodies (Cont.)

Age, Sex and Race

The effect of age at the time of the initial vaccination, sex and race was evaluated among vaccinees receiving Lot 1072/C-P298, 1080/C-P749 or 1085/C-R132. Among children who had prevaccination levels of anti-PRP antibody <1.0 mcg/ml, there was a significant difference among age groups with respect to the number of children developing titers above that level, stratified by prevaccination antibody titer ($p<0.05$). Antibody levels after the last injection of vaccine increased with age category within each vaccination regimen (one injection in children ≥12 months of age, two injections in those <12 months of age) as shown in Table 10. After one injection of vaccine, geometric mean titers of antibody among children with antibody levels <0.15 mcg/ml prior to vaccination ranged from 2.79 mcg/ml in 12 to 17 month old children to 8.28 mcg/ml in children 24 months of age or older. After two injections, GMTs ranged from 4.16 mcg/ml in infants to 2 to 6 months of age to 6.64 mcg/ml in infants 7 to 11 months of age. Antibody responses were lower in the 12 to 17 month age group than in the ≥18 month age group after a single injection of vaccine; the responses in the 12 to 17 month of age group were also lower than in infants <12 months of age after two injections.

Tables 11 and 12 summarize antibody responses by sex and race. The sex of the infant or child was not a significant factor. The responses of Blacks and Caucasians were not significantly different. However, there were insufficient data in the subset analyzed to evaluate Hispanics and American Indians in a comparable manner.

Regimen

Antibody responses were analyzed in all infants and children receiving one of the three lots of vaccine in the 14 studies conducted under a uniform protocol. All children regardless of age showed a significant increase ($p<0.01$) in anti-PRP after one injection of vaccine, with a geometric mean fold rise of 13.0 (range, 11.9 - 41.3) (Table 13). In children <12 months of age receiving two injections, the second injection induced anti-PRP levels significantly ($p<0.01$) above post first dose injection levels; the geometric mean fold rise was 2.1. The overall geometric mean fold rise from prevaccination level to the level following the second injection was 30.0 (range, 26-39).

A. Vaccine-Induced Anti-PRP Antibodies (Cont.)

Dose

The 15 mcg PRP dose currently in use has been chosen on the basis of optimum immunogenicity and safety when compared with other doses ranging from 6 mcg to 20 mcg (see Section VII. Individual Study Summaries, Study #822, #870, and #873). Confirmatory studies using additional doses are still in progress due to delayed start. In addition to different doses, the effect of two injections in children >12 months of age will be evaluated. No data are available for analysis at present.

Priming Effect of PRP-OMPC: Response to Booster Injection

A limited number of children who received one or more primary doses of early lots of PRP-OMPC vaccine at ages 2 to 11 months (Table 14) and ≥12 months (Table 15) have been given a booter dose of PRP-OMPC vaccine or licensed unconjugated PRP vaccine after a mean interval ranging from 11.2 to 13.3 months. [See Section VII, Individual Study Summaries, Study #873]. All children vaccinated in infancy with PRP-OMPC vaccine showed similar boosts in anti-PRP levels following receipt of either PRP-OMPC vaccine booster or a licensed unconjugated PRP vaccine booster (Table 15). Geometric mean titers increased >49 to >440 fold with PRP-OMPC vaccine and >52 to >184 fold with licensed unconjugated PRP vaccine from prebooster levels. The difference in antibody responses between these booster regimens was not significant.

Persistence of Antibody

Vaccine-induced antibody persisted at levels >1.0 mcg/ml in 47% of children initially immunized at 2 to 11 months of age (Table 14). In children initially immunized at ≥12 months of age, antibody levels of >1.0 mcg/ml were still measured in 40% of vaccinees (Table 15). Table 16 summarizes available data in a cohort of infants and children with antibody levels measured 6 to 10 months after receiving one injection of vaccine. Anti-PRP levels >0.15 mcg/ml were present in all children 6 to 10 months after the initial injection of vaccine. Anti-PRP levels >1.0 mcg/ml were maintained in 60% of children vaccinated at ≥12 months of age and in 74% vaccinated at <12 months of age.

A. Vaccine-Induced Anti-PRP Antibodies (Cont.)

Coadministration of PRP-OMPC and MMR Vaccine

In an ongoing study, antibody responses to PRP and to measles, mumps, and rubella following receipt of PRP-OMPC vaccine given alone or concurrently with measles, mumps, and rubella live virus vaccine (MMR) at separate sites, with separate needles have been measured in a limited number of children (Tables 17 and 18).

Preimmunization anti-PRP levels were comparable in the two groups. All children, regardless of vaccination regimen, achieved anti-PRP levels >0.15 mcg/ml. Eighty-nine percent of children receiving PRP-OMPC vaccine alone (4 weeks prior to MMR vaccination) and 94% of children receiving the vaccine concurrently with MMR achieved anti-PRP levels >1.0 mcg/ml. There were no statistically significant differences in antibody responses between recipients irrespective of vaccination regimen. A significant ($p \leq 0.01$) increase in level of anti-PRP (GMT) one month post PRP-OMPC vaccine injection was observed for both vaccination regimens with geometric mean fold rise of 18.1 and 22.8 in the 4 week apart and concurrent regimens, respectively.

In a limited number of children measles and mumps antibody titers were measured by hemagglutination inhibition assay and mumps antibody titers by ELISA assay. All of the vaccinees were initially seronegative for antibody to measles (<5), mumps (<2) and rubella (<8). One hundred percent of vaccinees who received MMR alone or concurrently with PRP-OMPC vaccine developed antibody to all three vaccine viruses one month after the vaccine injection. Geometric mean titers of antibody to measles, mumps and rubella were not significant different when MMR was administered alone or concurrently with PRP-OMPC vaccine.

Concurrent administration of PRP-OMPC vaccine and MMR did not significantly reduce antibody response to any of the individual vaccine antigens tested.

Coadministration of PRP-OMPC, DTP and OPV Vaccines

Antibody response to PRP, diphtheria and tetanus, following administration of PRP-OMPC vaccine concurrently with diptheria, tetanus, pertussis vaccine (DTP) and live oral trivalent poliovirus vaccine (OPV) or separately in a limited number of children, are shown in Tables 19 and 20. This study is currently in progress.

A. Vaccine-Induced Anti-PRP Antibodies (Cont.)

Preimmunization anti-PRP levels were comparable in the two groups. All children, regardless of vaccination regimen, achieved anti-PRP levels >0.15 mcg/ml. Ninety percent achieved levels of anti-PRP >1.0 mcg/ml following administration of vaccine alone compared to 88% receiving vaccine concurrently with DTP and OPV vaccines. A significant increase ($p \leq 0.01$) in anti-PRP titer (GMT) one month post PRP-OMPC vaccine was observed for both vaccination regimens.

The proportion of vaccinees with >4-fold rises in antibody to diphtheria and tetanus was 100% one month post DTP/OPV vaccination for both regimens. Geometric mean titers of antibody to diphtheria and tetanus one month after vaccination were not significantly different between the two regimens. Antibody determination for pertussis and polio antigens are not available at the present time but will be included in future reports.

Concurrent administration of PRP-OMPC vaccine did not significantly reduce antibody response to PRP, diptheria or tetanus.

Immunoglobulin Isotype and Subclass

PRP-OMPC vaccine induced both IgM and IgG class anti-PRP antibody response in infants and children 2 to 71 months of age. The IgG antibody response was predominantly IgG_1 in children 18 to 23 months of age and almost exclusively IgG_1 in children <18 months of age (Table 21).

Antibody Responses to PRP-OMPC Vaccine in Special Populations

PRP-OMPC vaccine has been evaluated in selected populations characterized by:

1. Impaired antibody response to nonconjugated PRP vaccine.

2. Prior invasive Hib disease.

3. Impaired antibody responses to natural infection with Hib.

4. Combinations of any of the above.

A. Vaccine-Induced Anti-PRP Antibodies (Cont.)

A group of 30 children 27 to 71 months of age who manifested characteristics mentioned above were randomized to receive a licensed nonconjugated PRP vaccine (n=16) or PRP-OMPC vaccine (n=14). All children had recovered from invasive Hib disease which they developed between ages 21 and 45 months despite previous immunization with a licensed nonconjugated PRP vaccine. In addition, after recovery from disease, anti-PRP antibody levels were <1 mcg/ml in all 30 subjects. Table 22 shows antibody responses following a single injection of a licensed nonconjugated PRP vaccine in one group of 13 children and to each of two injections of PRP-OMPC vaccine in the other group of 13 children. Preimmunization antibody levels were comparable in the two groups. After a single injection 31% (4/13) had >1.0 mcg/ml antibody level in the nonconjugated PRP vaccine group compared with 100% (13/13) in the PRP-OMPC vaccine group ($p<0.01$). A level of >2.0 mcg/ml antibody response was reported in 15% of nonconjugated PRP vaccinees versus 92% of PRP-OMPC vaccinees ($p<0.01$).

Children with postimmunization antibody level <2 mcg/ml in the licensed nonconjugated PRP vaccine arm of the study were next given two injections of PRP-OMPC vaccine. Eighty six percent (6/7) children responded with >2 mcg/ml antibody (Table 23).

Antibody Responses in Relation to Expression of Genetic Markers

Children immunized with PRP-OMPC vaccine have been evaluated independently by one of our investigators for antibody responses in relation to immunoglobulin allotypes among blacks [Km(1)] and whites [G2m(23)] and found to elicit good anti-PRP responses among all four groups with and without these markers (Table 24). Black children who do not express Km(1) immunoglobulin allotype and white children who do not express G2m(23) immunoglobulin allotype have been shown to have impaired immune responses to nonconjugated PRP vaccines, and to be at higher relative risk for invasive Hib disease.

A. Vaccine-Induced Anti-PRP Antibodies (Cont.)

COMPARISON OF PRP-OMPC VACCINE AND LICENSED NONCONJUGATED PRP VACCINE

A randomized study of immune responses among children 18 months of age and older was carried out to compare immune responses induced by licensed nonconjugated PRP vaccines versus PRP-OMPC vaccines. Serum samples from a limited number of children immunized with a licensed conjugate vaccine (ProHIBIT™, PRP-D) were also assayed. One hundred sixty-two (162) children aged 18 to 58 months were randomized to receive one of three licensed PRP vaccines (b-CAPSA®, HIB-IMUNE® and HibVAX™) in a single injection regimen in accordance with the manufacturer's package inserts. Immune responses were evaluated by comparing pre- and postimmunization values for total PRP antibody, isotype and subclasses of antibodies and assays for bacteriolysis and opsonization.

Children receiving the three licensed nonconjugated PRP vaccines were comparable with respect to median age, sex and race (Table 25). No significant differences between the vaccines were observed with respect to the number of children responding with: 1) >0.15 mcg/ml and >1.0 mcg/ml antibody levels (Table 26); 2) increases in antibody class and subclass; 3) increases demonstrated in functional assays in the limited data available. Therefore, results have been combined for licensed nonconjugated PRP vaccines for further comparisons with PRP-OMPC vaccine in the same age group.

Table 27 shows antibody responses in children 18 months of age and older following one dose of PRP-OMPC vaccine, nonconjugated PRP or conjugated PRP-D vaccines. PRP-OMPC vaccine was significantly more immunogenic than licensed nonconjugated PRP vaccines in children ≥24 months of age and in children 18 to 23 months of age regardless of prevaccination antibody level ($p<.01$). Eighty-six percent (124/45) of PRP-OMPC vaccine recipients 24 months of age and older achieved antibody levels >3 mcg/ml compared to 49% (56/114) of PRP vaccinees of the same age (Table 28). Antibody responses in the subset of children whose prevaccination anti-PRP levels were ≤0.15 mcg/ml are summarized in Table 29. Ninety-seven percent (62/64) of children ≥24 months and 93% (57/61) of children 18 to 23 months of age receiving PRP-OMPC vaccine who had antibody levels ≤0.15 mcg/ml prior to vaccination developed anti-PRP levels >1.0 mcg/ml. Only 36% (17/47) and 15% (2/13) of children who received licensed nonconjugated PRP vaccines in the comparable age groups achieved this level. A significantly higher level of antibody (GMT) was observed in both the 18 to 23 (7.16 mcg/ml) and ≥24 month (10.29 mcg/ml) age groups who received PRP-OMPC vaccine compared to those seen in PRP vaccine

A. Vaccine-Induced Anti-PRP Antibodies (Cont.)

recipients in the 18 to 23 (0.39 mcg/ml) and the ≥24 month (0.87 mcg/ml) age groups ($p<.01$).

In addition, antibody responses to PRP-OMPC vaccine in children below 18 months of age (12 to 17, 7 to 11, and 2 to 6 months) were significantly higher than those elicited by licensed nonconjugated PRP vaccines in children ≥24 months of age ($p<.01$) (Table 30). Following completion of the prescribed vaccination regimen 95% (119/125) of children ≥18 months of age and 86% (275/319) of children <18 months of age who had prevaccination levels that were considered nonprotective developed antibody levels >1.0 mcg/ml compared to 36% of children ≥24 months of age who received PRP vaccine.

The immunoglobulin isotypes and subclasses induced by licensed nonconjugated PRP vaccines in children ≥18 months of age showed a pattern of increases similar to that observed for PRP-OMPC vaccine in children ≥18 months of age (Table 31). However, PRP-OMPC vaccine induced significantly higher ($p\leq0.05$) rises in antibody classes (IgG, IgM) and in IgG_1 subclass in children ≥18 months of age then did licensed nonconjugated PRP vaccines in children ≥24 months of age.

TABLE 1

Antibody Responses of Infants and Children To PRP-OMPC Vaccine

Age (Months)	Prevaccintion % With Anti-PRP >0.15 mcg/ml	Prevaccintion % With Anti-PRP >1.0 mcg/ml	Prevaccintion GMT (mcg/ml)	Postinjection 1* % With Anti-PRP >0.15 mcg/ml	Postinjection 1* % With Anti-PRP >1.0 mcg/ml	Postinjection 1* Geometric Mean Fold Rise	Postinjection 1* GMT (mcg/ml)	Postinjection 2** % With Anti-PRP >0.15 mcg/ml	Postinjection 2** % With Anti-PRP >1.0 mcg/ml	Postinjection 2** Geometric Mean Fold Rise	Postinjection 2** GMT (mcg/ml)
2-6	38 (95/248)	2 (6/248)	<0.13	99 (236/239)	78 (186/239)	13.5	2.41	99 (186/187)	88 (164/187)	27.5	4.63
7-11	22 (26/121)	1 (1/121)	<0.13	98 (118/120)	78 (93/120)	19.6	2.91	100 (94/94)	94 (88/94)	49.0	7.41
12-17	29 (53/182)	2 (4/182)	<0.13	100 (182/182)	84 (152/182)	23.0	3.76				
18-23	43 (46/110)	5 (6/110)	0.14	99 (109/110)	96 (106/110)	43.1	8.88				
24-71	58 (84/145)	19 (28/145)	0.27	99 (144/145)	96 (139/145)	48.1	16.60				

* Responses measured 1 month postvaccination in children 12-71 months of age or 2 months postvaccination in infants 2-11 months of age.

** Responses measured 1 month after injection.

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TABLE 2

Antibody Responses To PRP-OMPC Vaccine
in Infants and Children with Prevaccination Antibody Levels ≤0.15 mcg/ml

Age (Months)	Postinjection 1*				Postinjection 2**			
	% With Anti-PRP >0.15 mcg/ml	% With Anti-PRP >1.0 mcg/ml	Geometric Mean Fold Rise	GMT (mcg/ml)	% With Anti-PRP >0.15 mcg/ml	% With Anti-PRP >1.0 mcg/ml	Geometric Mean Fold Rise	GMT (mcg/ml)
2–6	99 (145/147)	78 (114/147)	18.8	2.35	99 (120/121)	87 (105/121)	37.4	4.70
7–11	99 (93/94)	80 (75/94)	26.4	3.30	100 (72/72)	93 (67/72)	62.4	7.84
12–17	100 (129/129)	82 (106/129)	26.8	3.38				
18–23	98 (63/64)	97 (62/64)	57.9	7.16				
24–71	98 (60/61)	93 (57/61)	82.6	10.29				

* Responses measured 1 month postvaccination in children 12–71 months of age or 2 months postvaccination in infants 2–11 months of age.

** Responses measured 1 month after injection.

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00070

TABLE 3

Distribution of Antibody Responses to PRP-OMPC Vaccine

Age (Months)	No. of Injections	% With Anti-PRP Antibody (mcg/ml) >0.15	>1.0	>3.0	>6.0	>25.0
2-6	2	99 (186/187)	88 (164/187)	65 (122/187)	46 (85/187)	8 (15/187)
7-11	2	100 (94/94)	94 (88/94)	81 (76/94)	64 (60/94)	13 (12/94)
12-17	1	100 (182/182)	84 (152/182)	56 (102/182)	35 (63/182)	9 (16/182)
18-23	1	99 (109/110)	96 (106/110)	79 (87/110)	56 (61/110)	26 (29/110)
24-71	1	99 (144/145)	96 (139/145)	86 (124/145)	75 (109/145)	46 (67/145)

0544Z/14

00071

TABLE 4

Distribution of Antibody Responses to PRP-OMPC Vaccine
in Infants and Children with Prevaccination Antibody Levels ≤0.15 mcg/ml

Age (Months)	No. of Injections	% With Anti-PRP Antibody (mcg/ml)				
		>0.15	>1.0	>3.0	>6.0	>25.0
2-6	2	99 (120/121)	86 (104/121)	66 (80/121)	45 (54/121)	9 (11/121)
7-11	2	100 (72/72)	93 (67/72)	81 (58/72)	65 (47/72)	15 (11/72)
12-17	1	100 (129/129)	82 (106/129)	54 (69/129)	33 (43/129)	8 (10/129)
18-23	1	98 (63/ 64)	97 (62/ 64)	75 (48/ 64)	52 (33/ 64)	20 (13/ 64)
24-71	1	98 (60/ 61)	93 (57/ 61)	82 (50/ 61)	61 (37/ 61)	31 (19/ 61)

0544Z/15

TABLE 5

Distribution of Age, Sex and Race Among Infants and Children Randomized to Receive One of Three PRP-OMPC Clinical Vaccine Lots

	PRP-OMPC Vaccine		
	Lot 1072/C-P298 (n=125)	Lot 1080/C-P749 (n=120)	Lot 1085/C-R132 (n=121)
Age (Months)			
<12 Mos	(n=62)	(n=58)	(n=57)
Mean	5.1	6.0	5.4
Median	5.0	5.5	5.0
Range	2-11	1-11	2-11
≥12 Mos	(n=63)	(n=62)	(n=64)
Mean	20.2	22.2	23.5
Median	21.0	21.0	22.0
Range	12-52	12-58	12-64
Overall			
Mean	12.7	14.3	15.0
Median	12.0	12.0	12.0
Range	2-52	1-58	2-64
Sex (%)			
<12 Mos			
Males	56.5	39.7	59.6
Females	43.5	60.3	40.4
≥12 Mos			
Males	55.6	53.2	54.7
Females	44.4	46.8	45.3
Overall			
Males	56.0	46.7	57.0
Females	44.0	53.3	43.0
Race (%)			
<12 Mos			
Caucasian	72.6	67.2	71.9
Black	19.4	22.4	17.5
Hispanic	4.8	6.9	8.8
Other	3.2	3.4	1.8
≥12 Mos			
Caucasian	42.9	41.9	39.1
Black	47.6	50.0	45.3
Hispanic	7.9	6.5	10.9
Other	1.6	1.6	4.7
Overall			
Caucasian	57.6	54.2	54.5
Black	33.6	36.7	32.2
Hispanic	6.4	6.7	9.9
Other	2.4	2.5	3.3

0544Z/16

TABLE 6

Antibody Responses* in Infants and
Children Randomized to Receive One of Three PRP-OMPC Clinical Vaccine Lots

Lot	Age Group (Months)	No. of Subjects	% With Anti-PRP >0.15 mcg/ml pre	% With Anti-PRP >0.15 mcg/ml post*	% With Anti-PRP > 1.0 mcg/ml pre	% With Anti-PRP > 1.0 mcg/ml post*	Anti-PRP Geometric Mean Fold Rise	Anti-PRP GMT (mcg/ml) pre	Anti-PRP GMT (mcg/ml) post
1072/C-P298	2-6	11	36	100	0	82	25.1	<0.13	4.09
	7-11	5	20	100	0	80	45.9	<0.13	6.07
	12-17	16	44	100	0	88	22.7	0.14	4.33
	18-23	9	56	100	22	100	39.1	0.24	12.99
	24-71	12	67	100	50	100	23.3	0.77	21.49
1080/C-P749	2-6	8	13	100	0	88	31.6	<0.13	4.19
	7-11	5	20	100	0	100	63.2	<0.13	9.16
	12-17	13	23	100	0	62	14.6	<0.13	2.08
	18-23	9	56	100	0	100	40.2	0.14	7.75
	24-71	11	46	100	18	91	39.9	0.22	12.53
1085/C-R132	2-6	10	80	100	10	80	12.1	0.20	3.17
	7-11	5	20	100	0	100	43.8	<0.13	6.56
	12-17	11	18	100	0	100	23.0	<0.13	3.29
	18-23	12	58	100	17	92	42.5	0.20	11.16
	24-71	8	63	100	13	88	50.3	0.24	15.33

*Responses measured at 1 month after completion of scheduled vaccination regimen.

0544Z/17

TABLE 7

Antibody Responses* in Children 2 to 71 Months of Age
Randomized to Receive One of Three PRP-OMPC Clinical Vaccine Lots

Lot	% With Anti-PRP >1.0 mcg/ml Prevaccination Anti-PRP Level ≤0.15 mcg/ml	% With Anti-PRP >1.0 mcg/ml Prevaccination Anti-PRP Level >0.15-1.0 mcg/ml	Anti-PRP Geometric Mean Fold Rise	Anti-PRP GMT (mcg/ml)
1072/C-P298	86 (24/28)	94 (16/17)	27.3	7.65
1080/C-P749	84 (26/31)	85 (11/13)	30.4	5.49
1085/C-R132	96 (22/23)	84 (16/19)	28.8	6.32

* Responses measured 1 month after completion of scheduled vaccinaton regimen for combined ages 2 to 71 months.

0544Z/18

57000

TABLE 8

Antibody Response* To PRP-OMPC Clinical Vaccine Lots in All Infants and Children**

Lot	Age Group (Months)	No. of Subjects	% With Anti-PRP >0.15 mcg/ml pre	% With Anti-PRP >0.15 mcg/ml post	% With Anti-PRP > 1.0 mcg/ml pre	% With Anti-PRP > 1.0 mcg/ml post	Anti-PRP Geometric Mean Fold Rise	Anti-PRP GMT (mg/ml) pre	Anti-PRP GMT (mg/ml) post
1072/C-P298	2-6	60	40	98	0	88	30.6	0.14	5.10 (4.89)***
	7-11	27	33	100	4	85	27.0	<0.13	4.81 (4.68)
	12-17	52	33	100	2	85	20.6	<0.13	3.44 (2.85)
	18-23	28	54	100	7	100	40.1	0.19	10.22 (12.47)
	24-71	37	62	97	30	92	28.0	0.38	12.74 (6.47)
1080/C-P749	2-6	34	21	100	0	94	57.5	<0.13	3.55 (3.12)
	7-11	20	25	100	0	100	47.3	<0.23	9.10 (9.78)
	12-17	33	30	100	3	76	14.4	<0.13	2.46 (2.46)
	18-23	23	44	100	4	100	62.7	0.14	9.26 (4.28)
	24-71	16	38	100	19	79	25.1	0.18	15.88 (10.99)
1085/C-R132	2-6	10	80	100	10	88	12.1	0.20	3.17 (11.11)
	7-11	5	20	100	0	100	43.8	<0.13	6.56 (7.52)
	12-17	11	18	100	0	100	23.0	<0.13	3.29 (3.56)
	18-23	12	58	100	17	100	42.5	0.20	11.16 (8.26)
	24-71	8	63	100	13	80	50.3	0.24	15.33 (10.24)

*Responses measured at 1 month after completion of scheduled vaccination regimen.
**Including those who were not randomized to vaccine lots.
***Parenthesis represent subjects with prevaccination antibody levels ≤0.15 mcg/ml.

0544Z/19

TABLE 9

Antibody Responses* to PRP-OMPC Clinical Vaccine Lots

Lot	% With Anti-PRP >1.0 mcg/ml Prevaccination Anti-PRP Level ≤ 0.15 mcg/ml	% With Anti-PRP >1.0 mcg/ml Prevaccination Anti-PRP Level >0.15-1.0 mcg/ml	Anti-PRP Geometric Mean Fold Rise	Anti-PRP GMT** (mcg/ml)
1072/C-P298	84 (98/116)	95 (69/73)	27.8	4.74 (116)
1080/C-P749	86 (76/ 88)	88 (29/33)	31.3	4.31 (88)
1085/C-R132	96 (22/ 23)	84 (16/19)	28.8	6.17 (23)

* Results are expressed for combined ages 2 to 71 months after completion of scheduled regimen.

** Parentheses represent subjects with prevaccination antibody levels ≤0.15 mcg/ml.

0544Z/20

00077

TABLE 10

Antibody Response To PRP-OMPC Clinical Vaccine Lots* by Age Group

Age Groups (Months)	No. of Subjects	% With Anti-PRP >0.15 mcg/ml pre	% With Anti-PRP >0.15 mcg/ml post	% With Anti-PRP >1.0 mcg/ml pre	% With Anti-PRP >1.0 mcg/ml post	Anti-PRP Geometric Mean Fold Rise	Anti-PRP GMT (mcg/ml) pre	Anti-PRP GMT (mcg/ml) post
2-6	104	38	99	1	85	26.3	<0.13	4.33 (4.16)**
7-11	52	29	100	2	92	39.1	<0.13	6.33 (6.64)
12-17	96	30	100	2	83	18.5	<0.13	3.05 (2.79)
18-23	63	51	100	8	98	43.1	0.17	10.02 (7.45)
24-71	61	56	98	25	92	36.5	0.30	13.83 (8.28)

* Lots 1072/C-P298, 1080/C-P749 and 1085/C-R132

** Parentheses represent subjects with prevaccination antibody levels ≤0.15 mcg/ml.

0544Z/21

000788

TABLE 11

Antibody Responses* To PRP-OMPC Clinical Vaccine Lots** by Sex

Age Group (Months)	Sex	No. of Subjects	% With Anti-PRP > 0.15 mcg/ml pre	% With Anti-PRP > 0.15 mcg/ml post	% With Anti-PRP > 1.0 mcg/ml pre	% With Anti-PRP > 1.0 mcg/ml post	Anti-PRP Geometric Mean Fold Rise	Anti-PRP GMT (mcg/ml) pre	Anti-PRP GMT (mcg/ml) post
2-11	Female	77	27	99	1	90	30.7	<0.13	4.78 (4.60)***
	Male	79	42	100	1	85	29.4	<0.13	5.04 (5.36)
12-71	Female	100	42	100	10	89	33.5	0.16	7.61 (5.88)
	Male	120	44	99	10	91	24.8	0.16	5.73 (3.58)

* Responses measured 1 month after completion of scheduled vaccination regimen.
** Lots 1072/C-P298, 1080/C-P749 and 1085/C-R132
***Parentheses represent subjects with prevaccination antibody levels $\leq$0.15 mcg/ml.

0544Z/22

67000

TABLE 12

Antibody Responses* To PRP-OMPC Clinical Vaccine Lots** by Race

Age Group (Months)	Race	No. of Subjects	% With Anti-PRP > 0.15 mcg/ml pre	% With Anti-PRP > 0.15 mcg/ml post	% With Anti-PRP > 1.0 mcg/ml pre	% With Anti-PRP > 1.0 mcg/ml post	Anti-PRP Geometric Mean Fold Rise	Anti-PRP GMT (mcg/ml) pre	Anti-PRP GMT (mcg/ml) post
2-11	Caucasian	121	34	99	2	85	27.2	<0.13	4.42 (4.46)***
	Black	18	28	100	0	94	46.9	<0.13	6.67 (6.79)
	American Indian	6	17	100	0	100	63.3	<0.13	9.57 (9.81)
	Hispanic	6	67	100	0	83	21.9	0.21	5.64 (3.25)
	Other	5	60	100	0	100	38.7	0.15	7.68 (8.85)
12-71	Caucasian	110	34	100	9	88	28.8	0.13	5.89 (4.44)
	Black	91	54	99	9	91	31.5	0.19	7.55 (5.30)
	Hispanic	10	40	100	30	100	15.6	0.20	4.75 (2.37)
	American Indian	3	100	100	0	100	17.7	0.61	10.73
	Other	6	33	100	17	83	16.8	0.23	5.99 (2.83)

*Responses measured 1 month after completion of scheduled vaccination regimen.
**Lots 1072/C-P298, 1080/C-P749 and 1085/C-R132
***Parentheses represent subjects with prevaccination antibody levels ≤0.15 mcg/ml.

00080

TABLE 13

Antibody Responses Following One or
Two Injections of PRP-OMPC Clinical Vaccine Lots*

Age Group	No. of Subjects	No. of Injections	Anti-PRP Geometric Mean Fold Rise
2-6 Months	141	1	11.9
	104	2	26.3
7-11 Months	69	1	15.4
	52	2	39.1
12-17 Months	96	1	18.5
18-23 Months	63	1	43.1
24-71 Months	61	1	36.5

*Lots 1072/C-P298, 1080/C-P749 and 1085/C-R132

0544Z/24

TABLE 14

Booster Antibody Responses in Infants Previously Immunized With PRP-OMPC Vaccine at 2 to 11 months of Age

Booster Vaccine (Dose)	Mean Interval Between Primary Injection and Booster	Time	No. of Subjects	% With Anti-PRP >0.15 mcg/ml	% With Anti-PRP > 1.0 mcg/ml	Anti-PRP Geometric Mean Fold Rise	Anti-PRP GMT (mcg/ml)
PRP-OMPC (7 mcg)	12.8	Pre	6	33	0	---	0.12
		Postdose 2*	6	100	83	8.3	1.57
		Prebooster	6	100	50	7.4	1.39
		Postbooster	6	100	100	>440.7	≥83.38
PRP (25 mcg)	13.1	Pre	11	27	0	---	0.09
		Postdose 2*	11	100	64	8.5	1.33
		Prebooster	11	91	45	6.6	0.97
		Postbooster	11	100	100	>184.1	≥28.85

*Two priming injections given one month apart.

0544Z/25

2R000

TABLE 15

Booster Responses to PRP-OMPC Vaccine or Licensed Nonconjugated PRP Vaccine

Booster Vaccine (dose)	Mean Age (Months)	Mean Interval Between Primary Injection and Booster	Time	No. of Subjects	% With Anti-PRP >0.15 mcg/ml	% With Anti-PRP > 1.0 mcg/ml	Anti-PRP Geometric Mean Fold Rise	Anti-PRP GMT (mcg/ml)
PRP-OMPC	19.2	13.3 mo	Preboost	10	100	40	---	0.98
			Postboost	10	100	100	≥49.4	≥48.58
PRP	20.5	11.2 mo	Preboost	38	92	40	---	0.84
			Postboost	38	100	100	≥52.4	≥45.06

0544Z/26

000843

TABLE 16

Persistence of Vaccine -Induced Antibody Among a Cohort of Infants and Children Receiving PRP-OMPC Vaccine

Age Group (Months)	Time (Months)	% With Anti-PRP > 0.15 mcg/ml	% With Anti-PRP > 1.0 mcg/ml	Anti-PRP GMT (mcg/ml)
2-11	Pre	13 (3/23)	0 (0/23)	0.08
	3*	100 (23/23)	96 (22/23)	8.75
	6-10*	100 (23/23)	74 (17/23)	1.87
≥12	Pre	53 (23/43)	9 (4/43)	0.19
	1*	100 (43/43)	91 (39/43)	8.00
	6-10*	100 (43/43)	60 (26/43)	1.60

* Months after the first or only injection of vaccine.

TABLE 17

Anti-PRP Responses to a Single Dose of PRP-OMPC Vaccine
Given Alone or Currently With MMR Vaccine
in Children ≥15 Months of Age

Vaccination Regimen	Time	No. of Subjects	% With Anti-PRP >0.15 mcg/ml	% With Anti-PRP >1.0 mcg/ml	Anti-PRP GMT (mcg/ml)
Concurrent	Pre	17	47	0	0.14
	Post	17	100	94	4.63
4 Weeks Apart	Pre	18	22	6	0.11
	Post	18	100	89	3.04

TABLE 18

Antibody Responses to Individual Viral Vaccine Antigens Following Administration of MMR Vaccine Alone or Concurrently With PRP-OMPC Vaccine

Vaccination Regimen	Live, Attenuated Vaccine	No. of Subjects	Seroconversion Rate* to Specific Viral Antigen	Antibody GMT
Concurrent	Measles	16	100	76.6
	Mumps	14	100	43.9
	Rubella	16	100	94.5
4 Weeks Apart	Measles	8	100	160.0
	Mumps	8	100	65.2
	Rubella	8	100	117.4

*Responses measured 1 month after vaccination.

0544Z/29

TABLE 19

Anti-PRP Responses to a Single Dose of PRP-OMPC Vaccine Given Alone or Concurrently With DTP and OPV Vaccines in Children ≥17 Months of Age

Vaccination Regimen	Time	No. of Subjects	% With Anti-PRP >0.15 mcg/ml	% With Anti-PRP >1.0 mcg/ml	Anti-PRP GMT (mcg/ml)
Concurrent	Pre	16	25	6	0.11
	Post	16	100	88	5.02
4 Weeks Apart	Pre	19	21	0	0.08
	Post	19	100	90	6.51

TABLE 20

Antibody Responses to Diptheria and Tetanus Toxoids
Following Administration of DTP/OPV Vaccines Alone
or Concurrently With PRP-OMPC Vaccine

Vaccination Regimen	Toxoid	Time	No. of Subjects	Geometric Mean Fold Rise	GMT (U/ml)
Concurrent	Diptheria	Pre	16	--	0.46
		Post*	16	48.84	22.58
	Tetanus	Pre	16	--	0.21
		Post*	16	45.69	9.57
4 Weeks Apart	Diptheria	Pre	11	--	0.91
		Post*	11	21.72	19.68
	Tetanus	Pre	11	--	0.34
		Post*	11	25.08	8.48

*Responses measured 1 month postvaccination

0544Z/31

TABLE 21

Isotype and Subclass of Antibody Responses* to PRP-OMPC Vaccine

		IgM				Total IgG				IgG_1				IgG_2			
Vaccine	Age (months)	No. of Subjects	GMT (mcg/ml) Pre	Post	GMFR**	No. of Subjects	GMT (mcg/ml) Pre	Post	GMFR**	No. of Subjects	GMT (mcg/ml) Pre	Post	GMFR**	No. of Subjects	GMT (mcg/ml) Pre	Post	GMFR**
PRP-OMPC	2-6	38	<0.10	0.13	1.8	36	<0.10	1.03	8.7	40	<0.60	5.22	8.9	17	<0.25	<0.25	1.0
	7-11	24	<0.10	0.27	3.2	24	<0.10	1.77	17.7	21	<0.60	13.03	21.7	13	< .25	<0.25	1.0
	12-17	79	<0.10	0.65	5.2	78	<0.10	0.71	7.6	72	<0.60	3.94	7.4	43	<0.25	<0.25	1.0
	18-23	42	0.12	0.98	5.7	42	<0.10	2.57	21.9	47	<0.60	10.68	17.6	23	<0.25	<0.32	1.7
	≥24	60	0.20	1.38	5.7	59	<0.10	3.57	32.3	60	<0.60	14.61	23.7	32	<0.25	<0.41	2.0

* Total IgG values cannot be compared to IgG subclass values; IgM and IgG assays use (b) (4) antiglobulin conjugates while IgG subclass assays use monoclonal antiglobulin conjugates.

** Geometric mean fold rise

0544Z/32

00089

TABLE 22

Antibody Responses to PRP-OMPC Vaccine or
to Licensed Nonconjugated PRP Vaccines
in Known Nonconjugated PRP Vaccine Hyporesponders

Vaccine	Age	Time	% with Anti-PRP >1.0 mcg/ml	% with Anti-PRP >2.0 mcg/ml	Anti-PRP GMT mcg/ml (n)
PRP-OMPC	2-5 Yrs	Pre	0 (0/13)	0 (0/13)	0.17 (13)
		Post 1	100 (13/13)	92 (12/13)	6.16 (13)
		Post 2	100 (13/13)	100 (13/13)	10.80 (13)
PRP	2-4 Yrs	Pre	0 (0/13)	0 (0/13)	0.16 (13)
		Post	31 (4/13)	15 (2/13)	0.53 (13)

0544Z/33

TABLE 23

Antibody Responses to PRP-OMPC Vaccine or to Licensed Nonconjugated PRP Vaccine in Hyporesponders with <2 mcg/ml Following Re-Immunization with Licensed Nonconjugated PRP Vaccines

Time	% with Anti-PRP >1.0 mcg/ml	% with Anti-PRP >2.0 mcg/ml	Anti-PRP GMT (mcg/ml)
Prevaccination	0 (0/9)	0 (0/9)	0.14 (9)
Post PRP Injection 1	0 (0/8)	0 (0/8)	0.25 (8)
Post PRP-OMPC Injection 1	88 (7/8)	63 (5/8)	2.48 (8)
Post PRP-OMPC Injection 2	86 (6/7)	86 (6/7)	6.85 (7)

0544Z/34

TABLE 24

Antibody Responses to PRP-OMPC Vaccine in Relation to Km(1) and G2m(23) Allotypes in Infants and Children*

Subjects (Age Range)	Allotype	No. of Subjects	Mean Age (Mos.)	Anti PRP Geometric Mean (mcg/ml) Total	IgG
Whites (2-17 Mos.)	G2m(23) Pos	29	9.6	2.4	1.1
	G2m(23) Neg	9	6.4	2.6	1.5
Blacks (7-17 Mos.)	Km(1) Pos	12	12.0	6.7	4.0
	Km(1) Neg	13	12.7	6.1	4.1

* Lenoir, A. A., et al.: Response to Haemophilus influenzae type b (Hib) polysaccharide N. meningitidis outer membrane protein (PS-OMP) conjugate vaccine in relation to Km(1) and G2m(23) allotypes. Twenty-sixth Interscience Conference on Antimicrobial Agents and Chemotherapy (Abstract #216) 133, 1986.

0544Z/35

TABLE 25

Distribution by Age, Sex and Race of
Haemophilus b Licensed Nonconjugated PRP Vaccine Recipients

	b-CAPSA® (n=63)	Hib-IMUNE® (n=48)	HibVAX™ (n=51)
Age (%)			
≥24 Months	83	90	80
18-23 Months	17	10	20
Median Age	26.0	26.5	26.5
Sex (%)			
Male	54	69	51
Female	46	31	49
Race (%)			
Caucasian	16	17	8
Black	24	21	24
Hispanic	54	48	61
Other	6	15	8

0544Z/36

TABLE 26

Antibody Responses to Licensed Nonconjugated PRP Vaccines

Vaccine	Age Group (Months)	Time	No. of Subjects	% With Anti-PRP >.15 mcg/ml	% With Anti-PRP >1.0 mg/ml	Anti-PRP Geometric Mean Fold Rise	Anti-PRP GMT (mcg/ml)
b-CAPSA®	18-23	Pre	11	45	0	--	0.11
		Post	11	82	36	4.3	0.51
	≥ 24	Pre	41	51	15	--	0.21
		Post	41	98	66	15.0	4.03
HIB-IMUNE®	18-23	Pre	4	0	0	--	0.06
		Post	4	100	25	9.6	1.19
	≥ 24	Pre	39	67	23	--	0.33
		Post	39	97	54	7.5	2.71
HibVAX™	18-23	Pre	8	63	13	--	0.25
		Post	8	88	50	5.2	1.44
	≥ 24	Pre	34	59	18	--	0.21
		Post	34	94	62	10.6	2.55

0544Z/37

76000

TABLE 27

Antibody Responses to a Single Dose of PRP-OMPC Conjugate Vaccine, Licensed PRP-D Conjugate, or Nonconjugated PRP Vaccines

Age (Months)	Time	PRP-OMPC Vaccine No. of Subjects	PRP-OMPC Vaccine % With Anti-PRP >0.15 mcg/ml	PRP-OMPC Vaccine % With Anti-PRP >1.0 mcg/ml	PRP-OMPC Vaccine GMT (mcg/ml)	PRP Vaccine No. of Subjects	PRP Vaccine % With Anti-PRP >0.15 mcg/ml	PRP Vaccine % With Anti-PRP >1.0 mcg/ml	PRP Vaccine GMT (mcg/ml)	PRP-D Vaccine No. of Subjects	PRP-D Vaccine % With Anti-PRP >0.15 mcg/ml	PRP-D Vaccine % With Anti-PRP >1.0 mcg/ml	PRP-D Vaccine GMT (mcg/ml)
18–23	Pre	110	42	5	0.14	23	44 (0–63)*	4 (0–13)	0.13	2	50	0	0.16
	Post	110	99	96	8.88	23	87 (82–100)	39 (25–50)	0.85	2	100	100	4.03
24–71	Pre	145	58	19	0.27	114	59 (51–67)	18 (15–23)	0.25	16	44	0	0.12
	Post	145	99	96	16.60	114	97 (94–98)	61 (54–66)	3.1	16	100	100	6.37

*Range of response to b-CAPSA®, HIB-IMUNE®, or HibVAX™

0544Z/38

56000

TABLE 28

Distribution of Antibody Responses to PRP-OMPC Vaccine or to Other Licensed Hib Vaccines

Anti-PRP Titer	Age Group (Months)	% (Proportion) with Titer		
		PRP-OMPC Vaccine	PRP Vaccine	PRP-D Vaccine
>.15	≥ 24	99 (144/145)	97 (110/114)	100 (16/16)
	18-23	99 (109/110)	87 (20/23)	100 (2/2)
> 1	≥ 24	96 (139/145)	61 (69/114)	100 (16/16)
	18-23	96 (106/110)	39 (9/23)	100 (2/2)
> 3	≥ 24	86 (124/145)	49 (56/114)	63 (10/16)
	18-23	79 (87/110)	26 (6/23)	50 (1/2)
> 6	≥ 24	75 (109/145)	44 (50/114)	38 (6/16)
	18-23	56 (61/110)	22 (5/23)	50 (1/2)
> 25	≥ 24	46 (67/145)	24 (27/114)	19 (3/16)
	18-23	26 (29/110)	4 (1/23)	0 (0/2)

0544Z/39

TABLE 29

Antibody Responses to a Single Dose of PRP-OMPC Conjugate Vaccine,
Licensed PRP-D Conjugate Vaccine or PRP Nonconjugated Vaccines in
Children 18-71 Months of Age With Prevaccination Antibody Levels ≤0.15 mcg/ml

Age (Months)	PRP-OMPC Vaccine			PRP Vaccine			PRP-D Vaccine		
	% With Anti-PRP		GMT	% With Anti-PRP		GMT	% With Anti-PRP		GMT
	>0.15 mcg/ml	>1.0 mcg/ml	(mcg/ml)	>0.15 mcg/ml	>1.0 mcg/ml	(mcg/ml)	>0.15 mcg/ml	>1.0 mcg/ml	(mcg/ml)
18-23	98 (63/64)	97 (62/64)	7.16	77 (10/13)	15 (2/13)	0.39	100 (1/ 1)	100 (1/ 1)	1.23
24-71	98 (60/61)	93 (57/61)	10.29	92 (43/47)	36 (17/47)	0.87	100 (10/10)	100 (10/10)	4.03

0544Z/40

00097

TABLE 30

Antibody Responses to a Single Dose of PRP-OMPC Conjugate Vaccine, Licensed PRP-D Conjugate Vaccine or Nonconjugated PRP Vaccines in Infants and Children With Prevaccination Antibody Levels ≤0.15 mcg/ml

Age (Months)	No. of Injections	PRP-OMPC Vaccine % With Anti-PRP <0.15 mcg/ml	PRP-OMPC Vaccine % With Anti-PRP >1.0 mcg/ml	PRP-OMPC Vaccine GMT (mcg/ml)	PRP-D Vaccine % With Anti-PRP >0.15 mcg/ml	PRP-D Vaccine % With Anti-PRP >1.0 mcg/ml	PRP-D Vaccine GMT (mcg/ml)	PRP-D Vaccine % With Anti-PRP >0.15 mcg/ml	PRP-D Vaccine % With Anti-PRP >1.0 mcg/ml	PRP-D Vaccine GMT (mcg/ml)
2–6	1	99(145/147)	78 (114/147)	2.35						
	2	99(120/121)	87 (105/121)	4.70						
7–11	1	99 (93/94)	80 (75/94)	3.30						
	2	100 (72/72)	93 (67/72)	7.84						
12–17	1	100(129/129)	82 (106/129)	3.38						
18–23	1	98 (63/64)	97 (62/64)	7.16	77 (10/13)	15 (2/13)	0.39	100 (1/ 1)	100 (1/ 1)	1.23
24–71	1	98 (60/61)	93 (57/61)	10.29	92 (43/47)	36 (17/47)	0.87	100 (10/10)	100 (10/10)	4.03

0544Z/41

00098

TABLE 31

Isotype and Subclass Antibody Responses to PRP-OMPC Conjugate Vaccine, to Licensed PRP-D Conjugate and to Nonconjugated PRP Vaccines*

		Total IgM				Total IgG				Total IgG_1				Total IgG_2			
Vaccine	Age (months)	No. of Subjects	GMT (mcg/ml) Pre	Post	GMFR**	No. of Subjects	GMT (mcg/ml) Pre	Post	GMFR**	No. of Subjects	GMT (mcg/ml) Pre	Post	GMFR**	No. of Subjects	GMT (mcg/ml) Pre	Post	GMFR**
PRP-OMPC	2-6	38	<0.10	0.13	1.8	36	<0.10	1.03	8.7	40	<0.60	5.22	8.9	17	<0.25	<0.25	1.0
	7-11	24	<0.10	0.27	3.2	24	<0.10	1.77	17.7	21	<0.60	13.03	21.7	13	< .25	<0.25	1.0
	12-17	79	<0.10	0.65	5.2	78	<0.10	0.71	7.6	72	<0.60	3.94	7.4	43	<0.25	<0.25	1.0
	18-23	42	0.12	0.98	5.7	42	<0.10	2.57	21.9	47	<0.60	10.68	17.6	23	<0.25	<0.32	1.7
	≥24	60	0.20	1.38	5.7	59	<0.10	3.57	32.3	60	<0.60	14.61	23.7	32	<0.25	<0.41	2.0
PRP	18-23	8	0.18	0.46	2.2	8	<0.10	0.65	7.8	8	<0.60	>2.63	5.2	6	<0.25	0.33	1.9
	≥24	39	0.19	0.39	1.8	40	<0.10	1.04	9.5	43	<0.60	5.26	9.3	36	<0.25	0.44	2.3
PRP-D	18-23	---	---	---		---	---	---		2	<0.60	1.36		2	<0.25	<0.25	
	≥24	---	---	---		---	---	---		9	<0.60	3.30		9	<0.25	0.33	

* Total IgG values cannot be compared to IgG subclass values; IgM and IgG assays use (b) (4) antiglobulin conjugates while IgG subclass assays use monoclonal and antiglobulin conjugates.

** Geometric mean fold rise

0544Z/45

66000

Haemophilus b Conjugate Vaccine
(Neisseria meningitidis Outer Membrane Protein Complex)

B. Functional Activities of Vaccine-Induced Anti-PRP Antibodies

The precise mechanism by which Hib anti-PRP antibodies protect against invasive Hib disease has not been determined, nor has the precise role of the antibody class or subclasses of IgG. Although serum bactericidal and opsonophagocytic activities mediated by anti-PRP antibodies are considered important in protecting against disease, anti-PRP antibody levels do not consistently correlate with either; they seem to correlate best with the latter, however. In light of these observations, the functional activities of anti-PRP antibodies induced by PRP-OMPC vaccine have been evaluated and compared with those of antibodies induced by licensed nonconjugated polysaccharide (PRP) vaccines. The latter have been shown to confer protection from invasive Hib disease to children ≥18 months of age, as has a conjugate vaccine (ProHiBiT™ PRP-D) recently licensed for the same age group. For this purpose sera from PRP-OMPC vaccinees and licensed nonconjugated PRP vaccinees were obtained from clinical trials. Those from PRP-D vaccinees were obtained from children from whom investigators were interested in determining postimmunization antibody levels. In addition to these sera, functional activity was determined (data not shown) for a bacterial polysaccharide immune globulin (BPIG) prepared from the pooled plasma of adults immunized with, among other immunogens, a Merck Sharp & Dohme nonconjugated PRP vaccine. BPIG has been shown to protect 2 month old Apache Indian infants from invasive Hib disease for 3 months postinjection. All sera were assayed in the same laboratory. (Serum bactericidal activity at Merck Sharp & Dohme Research Laboratories; opsonophagocytic activity at the University of Alabama by Dr. Barry Gray.)

1. Bactericidal Activity

Serum samples from 137 children 18 to 71 months of age immunized with three licensed nonconjugated PRP vaccines (b-CAPSA®, n=52; HibVAX™, N=42; HIB-IMUNE®, n=43) were assayed for total antibody levels. Samples were also assayed for bactericidal activity and opsonophagocytic activity. No differences among the three vaccines were detected with respect to the parameters evaluated in the limited data available. Therefore, the results have been combined and data from licensed nonconjugated polysaccharide vaccines as a group are compared with those from PRP-OMPC vaccine and, in some instances, with PRP-D.

B. Functional Activities of Vaccine-Induced Anti-PRP Antibodies (Cont.)

Bactericidal activity, generally increased with increasing postimmunization antibody levels among PRP-OMPC vaccinees in all age groups (<12 months, 12 to 17 months, ≥18 months) (Figure 1). This trend was more apparent in vaccinees 18 months (Figure 1C). In the ≥18 month age group, bactericidal activity at ≥1:80 serum dilution was demonstrated by a greater proportion of sera from vaccinees immunized with PRP-OMPC vaccine than by sera from licensed nonconjugated PRP vaccinees (Figure 2). Sera from PRP-D vaccinees were too few for comparison with other sera.

Comparative bactericidal activities demonstrated by sera from children immunized with different vaccines are shown in Table 1.

TABLE 1

Bactericidal Activity Demonstrated by Immunization with PRP-OMPC and other Hib Vaccines*

Vaccine	Age (Months)	No. of Subjects	% with Bactericidal Activity at ≥1:80 Serum Dilution		% With ≥4-Fold Rise in Bactericidal Activity
			Pre	Post	
PRP-OMPC	<12	81 (55)	0 (0)	20 (25)	60 (62)
	12-17	94 (63)	0 (0)	36 (32)	76 (71)
	≥18	123 (62)	1 (0)	61 (55)	93 (94)
PRP	≥18	45 (17)	0 (0)	31 (18)	60 (41)
PRP-D	≥18	18 (11)	0 (0)	38 (27)	83 (73)

* Parentheses represent subjects with preimmunization antibody levels ≤0.15 mcg/ml.

B. Functional Activities of Vaccine-Induced Anti-PRP Antibodies (Cont.)

Preimmunization sera from virtually all children lacked bactericidal activity. Postimmunization sera from children immunized with the three different vaccines had bactericidal activity. Among PRP-OMPC vaccine recipients, sera from the three age groups <12 months (after two injections of vaccine), 12-17 months and ≥18 months demonstrated good bactericidal activity. The highest proportion of sera with bactericidal activity at ≥1:80 serum dilution or with the ≥4-fold rise in activity was from the ≥18 month age group and the lowest was from the <12 month age group.

Among ≥18 month age group the proportion of sera with ≥4-fold rise in bactericidal activity was highest in children immunized with PRP-OMPC vaccine (94%), followed by those immunized with PRP-D (73%), for the subset with ≤0.15 mcg/ml anti-PRP pre-immunization. PRP vaccine recipients had the lowest proportion of sera with ≥4-fold rise in bactericidal activity (41%).

2. Opsonophagocytic Activity

The percentages of vaccinees whose sera demonstrated bacterial opsonization and killing were not significantly different among the age groups <12 months (after two injections of vaccine), 12 to 17 months and ≥18 months immunized with PRP-OMPC vaccine (Table 2). In children ≥18 months of age no significant differences were observed in the degree of opsonization and bacterial killing demonstrated in pre- and postimmunization sera between PRP-OMPC vaccinees and PRP vaccinees.

TABLE 2

Bacterial Opsonization and Intracellular Killing by Undiluted Sera from Immunized Subjects

Vaccine	Age (Month)	No. of Subjects	% With >80% Bacterial Kill	
			Preimmunization	Postimmunization
PRP-OMPC	<12	23 (18)	0 (0)	84 (94)
	12-17	47 (35)	0 (0)	72 (71)
	≥18	37 (18)	5 (0)	91 (83)
PRP*	≥18	29 (8)	3 (0)	76 (88)

B. Functional Activities of Vaccine-Induced Anti-PRP Antibodies (Cont.)

Given ranges of anti-PRP induced by PRP-OMPC vaccine mediated bactericidal activity in an age-dependent fashion; a greater proportion of ≥ 18 month age group had ≥4-fold rise in bactericidal activity at a given antibody level than <18 month age group (Table 3). Children <12 months had the lowest proportion with ≥4-fold rise in bactericidal activity at the specified range of anti-PRP level. Opsonophagocytic activity, however, was comparable among the three age groups (<12, 12 to 17, ≥18 months) for a given range of PRP-OMPC vaccine-induced antibody levels. The proportion of vaccinees with bactericidal activity or opsonic activity increased as anti-PRP level increased.

Among ≥18 month old children, functional activities demonstrated were higher in a given range of anti-PRP induced by PRP-OMPC vaccine than that induced by licensed nonconjugated PRP vaccines. The functional activities were comparable for PRP-OMPC and PRP-D vaccinees. Moreover, ≤6 mcg/ml anti-PRP induced by PRP-OMPC vaccine in 12-17 month age group as well as <12 month age group had functional activities in a higher proportion of vaccinees than the same anti-PRP induced by licensed PRP vaccines. Thus the biologic function mediated by antibodies induced by PRP-OMPC vaccine is equivalent qualitatively to that mediated by antibody induced by licensed nonconjugated PRP vaccines, but is seen in a higher proportion of vaccinees.

TABLE 3

Comparative Functional Activities of Antibodies
Induced by Different Hib Vaccines

Anti-PRP Antibody (mcg/ml)	Vaccine	Age (Mos)	PRP-OMPC Vaccine SBA* ≥4-Fold Rise	PRP-OMPC Vaccine OP+ 80% Bacterial Kill
>1.0-3.0	PRP-OMPC	<12	8/17 (47%)	3/4 (75%)
		12-17	21/28 (75%)	12/16 (75%)
		≥18.0	13/16 (81%)	4/3 (67%)
	PRP-D	>18.0	5/7 (71%)	ND
	PRP	≥18.0	2/13 (15%)	0/5 (0%)
>3.0-6.0	PRP-OMPC	<12	8/14 (57%)	3/4 (75%)
		12-17	19/23 (83%)	9/11 (82%)
		≥18.0	17/19 (89%)	4/5 (80%)
	PRP-D	≥18.0	3/4 (75%)	ND
	PRP	≥18.0	1/3 (33%)	2/3 (67%)
>6.0-25.0	PRP-OMPC	<12	24/35 (69%)	12/12 (100%)
		12-17	20/21 (95%)	9/10 (90%)
		≥18.0	31/35 (89%)	8/9 (89%)
	PRP-D	≥18.0	4/4 (100%)	ND
	PRP	≥18.0	11/18 (61%)	12/12 (100%)

*Serum Bactericidal Activity
+Opsonization/Bacterial Killing
ND Not Done

B. Functional Activities of Vaccine-Induced Anti-PRP Antibodies (Cont.)

Infant Rat Protection Studies

In an infant rat model that evaluated complete protection from bacteremia as an endpoint, the protective efficacy of pre and postimmunization serum samples from a limited number of children immunized with PRP-OMPC vaccine was evaluated. Table 4 shows the protective efficacy of sera in relation to immunization. All preimmunization sera contained less than 1.0 mcg/ml anti-PRP antibody and did not protect infant rats from bacteremia. In contrast, postimmunization sera in children ≥12 months of age as well as younger infants, protected rats from bacteremia. More rats were protected with sera obtained after a second injection of vaccine in children <12 months of age than after the first injection.

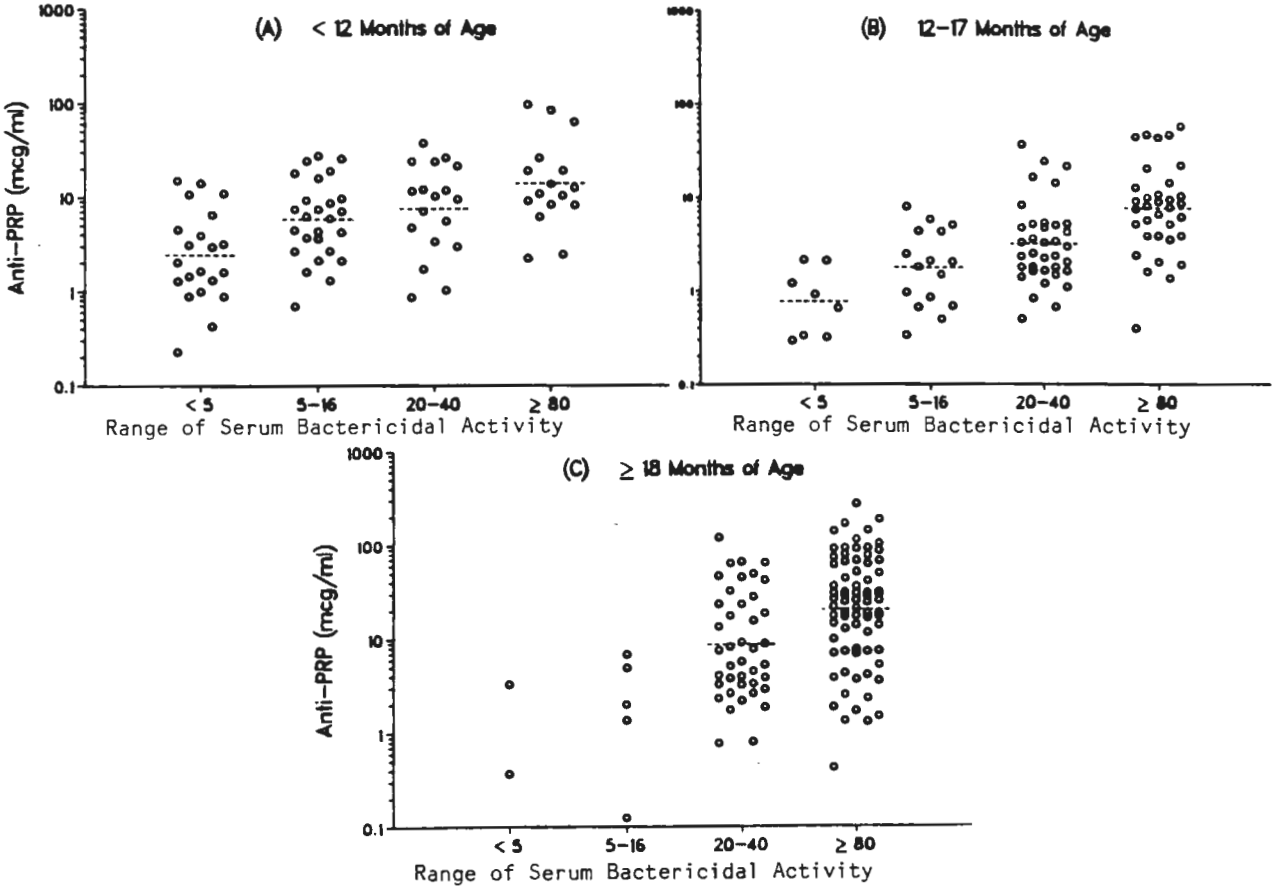
TABLE 4

Age (mos)	Time	Anti-PRP Antibody Levels GMT mcg/ml	No. >1.0 mcg/ml	No. of Rats Protected from Bacteremia (%)
<12	Pre	0.06	0/3 (0%)	0/12 (0%)
	Postinjection 1	1.63	1/3 (33%)	6/11 (55%)
	Postinjection 2	4.98	3/3 (100%)	11/12 (92%)
≥12	Pre	0.82	0/5 (0%)	0/15 (0%)
	Post	3.06	4/5 (85%)	11/19 (58%)

Haemophilus b Conjugate Vaccine
(Neisseria meningitidis Outer Membrane Protein Complex)

FIGURE 1

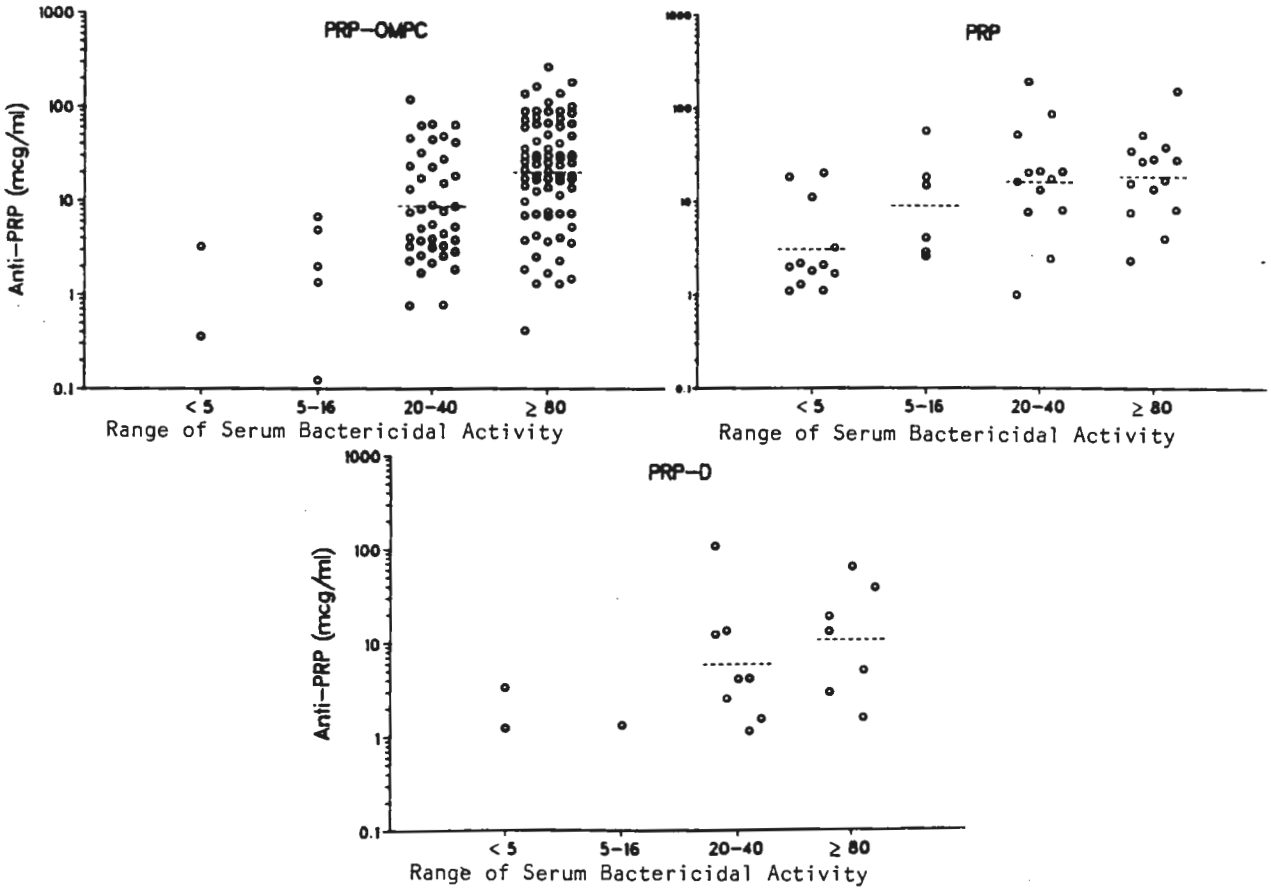
Bactericidal Activity in Relation to Anti-PRP
Antibody Levels in Children Immunized with PRP-OMPC



Haemophilus b Conjugate Vaccine
(Neisseria meningitidis Outer Membrane Protein Complex)

FIGURE 2

Bactericidal Activity in Relation to Anti-PRP Antibody Levels in Children ≥ 18 Months of Age



Haemophilus b Conjugate Vaccine
(Neisseria meningitidis Outer Membrane Protein Complex)

C. Conclusions

PRP-OMPC vaccine was highly immunogenic in children ≥18 months of age and younger children 2 to 17 months of age.

Virtually all children (99%) 12 months of age and older responded with anti-PRP antibody levels associated with short-term protection (>0.15 mcg/ml); 89% responded with levels associated with long-term protection (>1.0 mcg/ml) after a single 15 mcg (PRP) injection.

After completing a vaccination regimen consisting of two injections given 2 months apart, infants under 12 months of age responded with antibody levels similar to those in older children, i.e., 99% with >0.15 mcg/ml, 89% >1.0 mcg/ml.

Among Whites and Blacks antibody response was not affected by race. Studies in other racial populations are in progress.

PRP-OMPC vaccine induced IgG and IgM antibodies, with IgG class antibodies predominating. IgG subclass response was almost exclusively IgG_1, in infants under 12 months of age while older children showed a modest IgG_2 response in addition.

In a limited number of children initially immunized at the age of 2 to 11 months, PRP-OMPC vaccine-induced antibodies persisted at >0.15 mcg/ml in 94% and >1.0 mcg/ml in 47% of vaccinees approximately 1 year later.

The vaccine demonstrated a T-cell dependent memory effect, with significant increases in anti-PRP antibodies following booster injections.

Concurrent administration of the vaccine with MMR or with booster immunization of DTP and OPV has shown no impairment of antibody response to the individual antigens in ongoing studies.

Vaccine-induced antibodies demonstrated functional activities in in vitro assays specific for Hib bacteriolysis, bacterial opsonization and killing, and in an infant rat model for protection against Hib bacteremia.

C. Conclusions (Cont.)

PRP-OMPC vaccine was highly immunogenic in children with impaired immune response to either licensed nonconjugated polysaccharide vaccines, natural infection with Hib or both.

The vaccine was significantly more immunogenic in children 18 months of age and older than licensed nonconjugated polysaccharide vaccines. The antibody response to PRP-OMPC vaccine in children below 18 months of age, including 2 month old infants was also significantly higher than that of licensed nonconjugated polysaccharide vaccines in children 18 months of age and older.

OVERALL
CONCLUSIONS

Haemophilus b Conjugate Vaccine
(Neisseria meningitidis Outer Membrane Protein Complex)

VI. OVERALL CONCLUSIONS

A. Safety

Haemophilus b conjugate vaccine (Neisseria meningitidis Outer Membrane Complex) in a dose of 15 mcg polysaccharide reconstituted in aluminum hydroxide was well tolerated in children 12 to 71 months of age as well as infants 2 to 11 months of age. No serious adverse experience attributable to the vaccine at this dose was reported.

Side effects consisted primarily of injection site reactions, low grade fever and mild systemic reactions, the majority of which subsided within 2 to 3 days.

The types and rates of reactions were generally comparable to those that have been reported with Haemophilus b polysaccharide or conjugate vaccines in published literature.

The safety profile of PRP-OMPC administered concurrently with other pediatric vaccines such as measles, mumps and rubella vaccines or booster immunization with diphtheria and tetanus toxoids, and pertussis and oral polio vaccines, is currently under investigation. No serious adverse experience attributable to any of the mentioned vaccines has been reported to date.

B. Immunogenicity

PRP-OMPC vaccine was highly immunogenic in infants and children 2 to 71 months of age.

Virtually all children (99%) 12 months of age and older responded with anti-PRP antibody levels associated with short-term protection (>0.15 mcg/ml); 89% responded with antibody levels associated with long-term protection (>1.0 mcg/ml) after a single injection of vaccine containing 15 mcg of polysaccharide.

After completing a vaccination regimen consisting of two injections administered 2 months apart, infants under 12 months of age responded with antibody levels similar to those in older children, i.e., 99% with >0.15 mcg/ml, and 89% >1.0 mcg/ml anti-PRP antibody.

B. Immunogenicity (Cont.)

Antibody response was not affected by gender or by race among Whites and Blacks. Studies in other racial populations are in progress.

In a limited number of children who were initially immunized at the age of 2 to 11 months, vaccine-induced antibodies persisted at >0.15 mcg/ml in 94% and >1.0 mcg/ml in 47% of vaccinees approximately 1 year later.

The vaccine has demonstrated a T-cell-dependent memory effect, with significant increases in anti-PRP antibodies following re-injection approximately one year later. This booster response was observed in children with antibody levels <1.0 mcg/ml as well as those with levels ≥1.0 mcg/ml just prior to the re-injection. Accordingly, this immunologic memory mediated by PRP-OMPC may confer protection from Hib disease to infants and children whose initial postimmunization antibody levels are <1.0 mcg/ml.

The vaccine induced IgG and IgM antibodies, with IgG class antibodies predominating. IgG subclass response was almost exclusively IgG_1 in infants under 12 months of age while older children showed a modest IgG_2 response in addition to IgG_1.

Antibodies induced by the vaccine demonstrated functional activities in in vitro assays specific for Hib bacteriolysis, bacterial opsonization and killing, and in an infant rat model for protection against Hib bacteremia. These functional activities were observed in postimmunization sera of vaccines 12 months of age and older as well as vaccinees below 12 months of age.

Concurrent administration of the vaccine with measles mumps and rubella vaccine or with booster immunization of diphtheria and tetanus toxoids, and pertussis and oral polio vaccines has shown no impairment of antibody response to the individual antigens in ongoing studies.

The vaccine was highly immunogenic in:

1. children with impaired immune response to polysaccharide vaccines and who are at increased risk for invasive Hib disease, e.g., Blacks who do not express the Km(1) immunoglobulin allotype and Whites who do not express G2m(23) allotype.

2. children with impaired immune response to licensed polysaccharide vaccines, e.g., those who developed disease despite previous immunization with licensed polysaccharide vaccines.

3. children with impaired immune response to natural infection and subsequent re-challenge with a licensed polysaccharide vaccine.

B. Immunogenicity (Cont.)

PRP-OMPC was significantly more immunogenic than licensed unconjugated polysaccharide vaccines in children 18 months of age and older. Antibody responses to the vaccine in children below 18 months of age, including infants 2 months of age were also significantly higher than the responses to licensed unconjugated polysaccharide vaccines in children 18 months of age and older.

On the basis of increased antibody responses and demonstrable functional activities of vaccine-induced antibodies, PRP-OMPC should confer a higher degree of protection than licensed polysaccharide vaccines to children 18 months of age and older as well as to younger children and infants.

INDIVIDUAL STUDY
SUMMARIES

CLINICAL STUDIES OF HAEMOPHILUS b CONJUGATE VACCINE
(NEISSERIA MENINGITIDIS OUTER MEMBRANE PROTEIN COMPLEX) RECONSTITUTED IN SALINE (BBIND 1966)

STUDY NO.	INVESTIGATOR/ LOCATION	DATE INITIATED	STATUS	VACCINE LOT	VACCINE DOSE	VACCINE REGIMEN	NO. SUBJECTS VACCINATED	POPULATION (AGE)	TIME (MOS.)	% WITH ANTI-PRP >2-FOLD RISE	% WITH ANTI-PRP >.15 MCG/ ML	% WITH ANTI-PRP >1.0 MCG/ ML	GMT (MCG/ML)
001-01 (822)	Robert Weibel, M.D. Children's Hospital of Philadelphia 34th St. & Civic Blvd. Philadelphia, PA 19104	2/28/84	Complete	984/ C-K731	20 mcg/ saline	1 dose	6	21-60 yrs	0		100 (6/6)	50 (3/6)	1.975
									1	100 (6/6)	100 (6/6)	100 (6/6)	27.176
				984/ C-K731	10 mcg/ saline (n=5) or 20 mcg/ saline (n=3)	1 dose	8	12-71 mos	0		43 (3/7)	14 (1/7)	0.172**
									1	71 (5/7)	86 (6/7)	71 (5/7)	4.712
				984/ C-K731	10 mcg/ saline	1 dose or 2 doses at 0 and either 2 or 3 mos	13	2-11 mos	0		15 (2/13)	0 (0/13)	0.073
									1	69 (9/13)	85 (11/13)	38 (5/13)	0.722
									3-4	100 (5/5)	100 (5/5)	100 (5/5)	6.114
				1002/ C-L466	6 mcg/ saline (n=7) or 10 mcg/ saline (n=3)	0, 2 wks	11	2-6 mos	0		63 (5/8)	13 (1/8)	0.225**
									1.5	50 (4/8)	100 (8/8)	38 (3/8)	0.586
002-70 (870)	Edwin Anderson, M.D. Dept. of Medicine Marshall Univ. of Med. Huntingdon, WV	11/02/84	Complete	1002/ C-L466	10 mcg/ saline	0, 1 mo	15	2-6 mos	0		31 (4/13)	0 (0/13)	0.105
									2	100 (13/13)	100 (13/13)	92 (12/13)	2.284
									6-12	80 (4/5)	80 (4/5)	20 (1/5)	0.451
									13-23	63 (5/8)	75 (6/8)	13 (1/8)	0.357
003-73 (873)	Dan Granoff, M.D. St. Louis Children's Hospital 400 S. Kingshighway Blvd. St. Louis, MO	11/14/84	Complete	1003/ C-L680	7 mcg/ saline	0, 1 mo	10	2-11 mos	0		60 (6/10)	0 (0/10)	0.207
									1	71 (5/7)	100 (7/7)	29 (2/7)	1.018
									2	71 (5/7)	100 (7/7)	71 (5/7)	1.594
									7-10	43 (3/7)	100 (7/7)	29 (2/7)	0.653
									12-16	25 (2/8)	88 (7/8)	25 (2/8)	0.380
							3*	12-17 mos					

*Serology results are available for 3 or less vaccinees; therefore serology results are not included in this table.
**Serology data are combined due to small numbers.

6079I/1/29AUG88

CLINICAL STUDIES OF HAEMOPHILUS b CONJUGATE VACCINE
(NEISSERIA MENINGITIDIS OUTER MEMBRANE PROTEIN COMPLEX) RECONSTITUTED IN ALUM (BBIND 1966)

STUDY NO.	INVESTIGATOR/ LOCATION	DATE INITIATED	STATUS	VACCINE LOT	VACCINE DOSE	VACCINE REGIMEN	NO. SUBJECTS VACCINATED	POPULATION (AGE)	TIME (MOS.)	% WITH ANTI-PRP >2-FOLD RISE	% WITH ANTI-PRP >.15 MCG/ ML	% WITH ANTI-PRP >1.0 MCG/ ML	GMT (MCG/ML)
002-70 (870)	Edwin Anderson, M.D. Dept. of Medicine Marshall Univ. of Med. Huntingdon, WV	11/02/84	Complete	1018/ C-M679	13 mcg/ alum	0, 1 mo	14	2-6 mos	0		58 (7/12)	17 (2/12)	0.214
									2	50 (6/12)	100 (12/12)	42 (5/12)	0.903
0003-73 (873)	Dan Granoff, M.D. St. Louis Children's Hospital 400 S. Kingshighway Blvd. St. Louis, MO	11/14/84	Complete	1003/ C-L680	7 mcg/ alum	1 dose	6	23-43 yrs	0		67 (4/6)	67 (4/6)	0.915
									1	100 (6/6)	100 (6/6)	100 (6/6)	44.240
									6	80 (4/5)	100 (5/5)	100 (5/5)	25.115
				1003/ C-L680	7 mcg/ alum	0, 1 mo	29	2-11 mos	0		28 (8/29)	0 (0/29)	0.104
									1	70 (19/27)	89 (24/27)	44 (12/27)	0.866
									2	88 (21/24)	100 (24/24)	63 (15/24)	1.272
									7-10	63 (12/19)	100 (19/19)	32 (6/19)	0.674
									12-16	50 (9/18)	94 (17/18)	44 (8/18)	1.023
							10	12-17 mos	0		33 (3/9)	0 (0/9)	0.102
									1	100 (9/9)	100 (9/9)	89 (8/9)	3.092
									6-10	100 (6/8)	100 (6/6)	50 (3/6)	1.006
									12-16	100 (3/3)	100 (3/3)	67 (2/3)	3.076
				1018/ C-M679	13 mcg/ alum	0, 1 mo	28**	2-6 mos	0		31 (4/13)	0 (0/13)	0.102
									1	77 (10/13)	100 (13/13)	38 (5/13)	0.778
									2	92 (11/12)	100 (12/12)	50 (6/12)	1.216
				1018/ C-M679	13 mcg/ alum	0, 2 mos	26	2-6 mos	0		22 (5/23)	0 (0/23)	0.088
									2	81 (17/21)	100 (21/21)	43 (9/21)	1.001
									3	100 (23/23)	100 (23/23)	87 (20/23)	3.550

**Three children received only one dose.

6079I/2/29AUG88

CLINICAL STUDIES OF HAEMOPHILUS b CONJUGATE VACCINE
(NEISSERIA MENINGITIDIS OUTER MEMBRANE PROTEIN COMPLEX) RECONSTITUTED IN ALUM (BBIND 1966)

STUDY NO.	INVESTIGATOR/ LOCATION	DATE INITIATED	STATUS	VACCINE LOT	VACCINE DOSE	VACCINE REGIMEN	NO. SUBJECTS VACCINATED	POPULATION (AGE)	TIME (MOS.)	% WITH ANTI-PRP >2-FOLD RISE	% WITH ANTI-PRP >.15 MCG/ ML	% WITH ANTI-PRP >1.0 MCG/ ML	GMT (MCG/ML)
003-73 (873)	Dan Granoff, M.D. (Cont.)			1018/ C-M679 as a booster	6 mcg/ alum	booster dose as a a third injection one year after first dose	9	2-11 mos (1-2 yrs at boost)	Preboost Postboost	100 (9/9)	100 (9/9) 100 (9/9)	44 (4/9) 100 (9/9)	1.042 49.092
				PS** booster	25 mcg	booster dose as a third injection one year after first dose	21	2-11 mos (1-2 yrs at boost)	Preboost Postboost	100 (16/16)	88 (14/16) 100 (16/16)	38 (6/16) 100 (16/16)	0.669 20.297
							2*	12-17 mos (24-29 mos at boost)					
				PS** booster	25 mcg	booster dose as a second injection one year after first dose	4	2-11 mos (1-2 yrs at boost)	Preboost Postboost	100 (4/4)	75 (3/4) 100 (4/4)	0 (0/4) 100 (4/4)	0.216 24.236
							3*	12-17 mos 24-29 mos at boost)					
				1018/ C-M679/ PS**	6 mcg/ alum 25 mcg	dose 1 (0 mo) dose 2 (6 mos-1 yr)	25	2-11 mos (black children)	Preboost Postboost	100 (7/7)	100 (7/7) 100 (7/7)	29 (2/7) 100 (7/7)	0.858 117.975
							28	12-17 mos (black children)	Preboost Postboost	100 (7/7)	100 (7/7) 100 (7/7)	57 (4/7) 100 (7/7)	1.671 147.946
				1018/ C-M679	18 mcg/ alum	1 dose	3*	2-11 mos					

*Serology results are available for 3 or less vaccinees; therefore serology results are not included in this table.
**PS = polysaccharide

6079I/3/29AUG88

MULTICLINIC STUDY OF HEALTHY CHILDREN AND INFANTS RECEIVING HAEMOPHILUS B CONJUGATE VACCINE
(NEISSERIA MENINGITIDIS OUTER MEMBRANE PROTEIN COMPLEX) (BBIND 1966)

STUDY NO.	INVESTIGATOR/ LOCATION	DATE INITIATED	STATUS	VACCINE LOT	VACCINE DOSE	VACCINE REGIMEN	NO. SUBJECTS VACCINATED	POPULATION (AGE)	TIME (MOS.)	% WITH ANTI-PRP >2-FOLD RISE	% WITH ANTI-PRP >.15 MCG/ ML	% WITH ANTI-PRP >1.0 MCG/ ML	GMT (MCG/ML)
004-01	Catherine Wilfert,M.D. Duke University Medical Center P.O. Box 2951 Durham, N.C.	4/16/87	In progress	1069/ C-P241	15 mcg	0,2 mos	21	2-6 mos	0		57 (8/14)	7 (1/14)	0.153
									2	92 (12/13)	100 (13/13)	85 (11/13)	3.444
									3	92 (11/12)	100 (12/12)	83 (10/12)	5.182
							17	7-11 mos	0		13 (2/15)	0 (0/15)	0.089
									2	93 (14/15)	93 (14/15)	80 (12/15)	2.816
									3	100 (14/14)	100 (14/14)	100 (14/14)	10.152
						one dose	6	12-71 mos	0		20 (1/5)	0 (0/5)	0.075
									1	100 (5/5)	100 (5/5)	100 (5/5)	6.589
				1072/ C-P298	15 mcg	0,2 mos	15	1-6 mos	0		80 (4/5)	20 (1/5)	0.277
									2	80 (4/5)	100 (5/5)	80 (4/5)	2.685
									3	100 (2/2)	100 (2/2)	100 (2/2)	11.195
							3*	7-11 mos					
						one dose	5	12-71 mos	0		25 (1/5)	0 (0/4)	0.099
									1	100 (4/4)	100 (4/4)	75 (3/4)	3.303
				1080/ C-P749	15 mcg	0,2 mos	8*	2-6 mos					
							2*	7-11 mos					
						one dose	1*	23 mos					
				1085/ C-P132	15 mcg	0,2 mos	12*	1-6 mos					
						one dose	1*	17 mos					

*Serology results are available for 3 or less vaccinees; therefore serology results are not included in this table.

6079I/4/29AUG88

MULTICLINIC STUDY OF HEALTHY CHILDREN AND INFANTS RECEIVING HAEMOPHILUS B CONJUGATE VACCINE
(NEISSERIA MENINGITIDIS OUTER MEMBRANE PROTEIN COMPLEX) (BBIND 1966)

STUDY NO.	INVESTIGATOR/ LOCATION	DATE INITIATED	STATUS	VACCINE LOT	VACCINE DOSE	VACCINE REGIMEN	NO. SUBJECTS VACCINATED	POPULATION (AGE)	TIME (MOS.)	% WITH ANTI-PRP >2-FOLD RISE	% WITH ANTI-PRP >.15 MCG/ ML	% WITH ANTI-PRP >1.0 MCG/ ML	GMT (MCG/ML)
004-03	Kenneth Bromberg, M.D. SUNY Downstate Medical Center Dept. of Pediatrics 450 Clarkson Ave. Brooklyn, NY	5/4/87	In progress	1069/ C-P241	15 mcg	0,2 mos	7	2-6 mos	0		20 (1/5)	0 (0/5)	0.096
									2	100 (4/4)	100 (4/4)	100 (4/4)	2.781
									3	100 (3/3)	100 (3/3)	100 (3/3)	3.135
							12	7-11 mos	0		0 (0/4)	0 (0/4)	0.062
									2	100 (4/4)	100 (4/4)	100 (4/4)	5.416
									3	100 (4/4)	100 (4/4)	100 (4/4)	6.549
						one dose	13	12-71 mos	0		71 (5/7)	0 (0/7)	0.170
									1	86 (6/7)	100 (7/7)	71 (5/7)	4.195
				1080/ C-P749	15 mcg	0,2 mos	41	1-6 mos	0		45 (5/11)	0 (0/11)	0.124
									2	91 (10/11)	100 (11/11)	73 (8/11)	2.741
									3	100 (8/8)	100 (8/8)	75 (6/8)	3.153
							15	7-11 mos	0		75 (3/4)	0 (0/4)	0.190
									2	100 (4/4)	100 (4/4)	75 (3/4)	2.645
									3	100 (3/3)	100 (3/3)	100 (3/3)	13.555
						one dose	17*	12-71 mos					
004-04	Joel Ward, M.D. Harbor - UCLA Medical Center 1124 W. Carson Dr. Bldg. E-6 Torrance, CA	9/14/87	In progress	1069/ C-P241 or 1069/ C-P241	15 mcg	0,2 mos	44	1-6 mos	0		79 (27/34)	9 (3/34)	0.273
									2	81 (25/31)	100 (31/31)	65 (20/31)	1.946
									3	95 (20/21)	100 (21/21)	95 (20/21)	6.411
					15 mcg	0							
				1072/ C-P298	15 mcg	2 mos							
				1072/ C-P298	15 mcg	0, 2 mos	5	2-6 mos	0		25 (1/4)	0 (0/4)	0.095
									2	100 (4/4)	100 (4/4)	100 (4/4)	8.501
									3	100 (4/4)	100 (4/4)	100 (4/4)	11.339

*Serology results are available for 3 or less vaccinees; therefore serology results are not included in this table.

6079I/5/29AUG88

MULTICLINIC STUDY OF HEALTHY CHILDREN AND INFANTS RECEIVING HAEMOPHILUS B CONJUGATE VACCINE
(NEISSERIA MENINGITIDIS OUTER MEMBRANE PROTEIN COMPLEX) (BBIND 1966)

STUDY NO.	INVESTIGATOR/ LOCATION	DATE INITIATED	STATUS	VACCINE LOT	VACCINE DOSE	VACCINE REGIMEN	NO. SUBJECTS VACCINATED	POPULATION (AGE)	TIME (MOS.)	% WITH ANTI-PRP >2-FOLD RISE	% WITH ANTI-PRP >.15 MCG/ ML	% WITH ANTI-PRP >1.0 MCG/ ML	GMT (MCG/ML)
004-05	Eugene Shapiro, M.D. Yale University School of Medicine Dept. of Pediatrics P.O. Box 3333 New Haven, CT	5/20/86	In progress	1020/ C-N084	15 mcg	0,2 mos	10*	2-6 mos					
					20 mcg	one dose	3*	12-71 mos					
				1069/ C-P241	15 mcg	0,2 mos	11	2-6 mos	0		20 (2/10)	0 (0/10)	0.086
									2	90 (9/10)	100 (10/10)	80 (8/10)	3.370
									3	100 (10/10	100 (10/10)	100 (10/10)	5.914
									6-10	86 (6/7)	100 (7/7)	71 (5/7)	1.464
							4*	7-11 mos					
						one dose	24	12-71 mos	0		35 (8/23)	9 (2/23)	0.127
									1	100 (22/22)	91 (20/22)	100 (22/22)	15.727
									6-10	100 (6/6)	100 (6/6)	83 (5/6)	2.303
				1072/ C-P298	15 mcg	0,2 mos	25	2-6 mos	0		36 (4/11)	0 (0/11)	0.110
									2	92 (11/12)	100 (12/12)	83 (10/12)	1.733
									3	100 (7/7)	100 (7/7)	86 (6/7)	3.300
							16	7-11 mos	0		54 (7/13)	0 (0/13)	0.167
									2	69 (9/13)	92 (12/13)	46 (6/13)	1.385
									3	100 (9/9)	100 (9/9)	78 (7/9)	4.033

*Serology results are available for 3 or less vaccinees; therefore serology results are not included in this table.

MULTICLINIC STUDY OF HEALTHY CHILDREN AND INFANTS RECEIVING HAEMOPHILUS B CONJUGATE VACCINE
(NEISSERIA MENINGITIDIS OUTER MEMBRANE PROTEIN COMPLEX) (BBIND 1966)

STUDY NO.	INVESTIGATOR/ LOCATION	DATE INITIATED	STATUS	VACCINE LOT	VACCINE DOSE	VACCINE REGIMEN	NO. SUBJECTS VACCINATED	POPULATION (AGE)	TIME (MOS.)	% WITH ANTI-PRP >2-FOLD RISE	% WITH ANTI-PRP >.15 MCG/ ML	% WITH ANTI-PRP >1.0 MCG/ ML	GMT (MCG/ML)
004-05	Eugene Shapiro, M.D. (Cont.)					one dose	48	12-71 mos	0		40 (14/35)	17 (6/35)	0.187
									1	94 (32/34)	97 (33/34)	85 (29/34)	6.163
									6-10	88 (7/8)	100 (8/8)	50 (4/8)	1.785
				1080/ C-P749	15 mcg	0,2 mos	14	2-6 mos	0		0 (0/5)	0 (0/5)	0.062
									2	80 (4/5)	80 (4/5)	60 (3/5)	1.812
									3	100 (3/3)	100 (3/3)	67 (2/3)	5.282
							8*	7-11 mos					
						one dose	26	12-71 mos	0		43 (6/14)	7 (1/14)	0.144
									1	93 (13/14)	100 (14/14)	71 (10/14)	5.320
				1085/ C-R132	15 mcg	0,2 mos	12	2-6 mos	0		40 (2/5)	0 (0/5)	0.107
									2	100 (5/5)	100 (5/5)	60 (3/5)	0.965
									3	100 (4/4)	100 (4/4)	75 (3/4)	3.501
							8	7-11 mos	0		17 (1/6)	0 (0/6)	0.087
									2	100 (6/6)	100 (6/6)	67 (4/6)	3.425
									3	100 (3/3)	100 (3/3)	100 (3/3)	6.631
						one dose	28	12-71 mos	0		47 (7/15)	7 (1/15)	0.141
									1	100 (15/15)	100 (15/15)	93 (14/15)	4.699

*Serology results are available for 3 or less vaccinees; therefore serology results are not included in this table.

MULTICLINIC STUDY OF HEALTHY CHILDREN AND INFANTS RECEIVING HAEMOPHILUS B CONJUGATE VACCINE
(NEISSERIA MENINGITIDIS OUTER MEMBRANE PROTEIN COMPLEX) (BBIND 1966)

STUDY NO.	INVESTIGATOR/ LOCATION	DATE INITIATED	STATUS	VACCINE LOT	VACCINE DOSE	VACCINE REGIMEN	NO. SUBJECTS VACCINATED	POPULATION (AGE)	TIME (MOS.)	% WITH ANTI-PRP >2-FOLD RISE	% WITH ANTI-PRP >.15 MCG/ ML	% WITH ANTI-PRP >1.0 MCG/ ML	GMT (MCG/ML)
004-06	Robert Daum, M.D. Tulane Univ. School of Medicine Dept. of Pediatrics 1430 Tulane Ave. New Orleans, LA	6/11/86	In progress	1018/ C-M679	15 mcg	0	7	1-6 mos	0		33 (2/6)	0 (0/6)	0.115
									2	83 (5/6)	100 (6/6)	50 (3/6)	1.098
				PS**	25 mcg	2 mos			3	67 (4/6)	100 (6/6)	33 (2/6)	0.973
				1069/ C-P241	15 mcg	0,2 mos	15*	1-6 mos					
				1069/ C-P241	15 mcg	0	17*	1-6 mos					
				1080/ C-P749	15 mcg	2 mos							
004-07	Parvin Azimi, M.D. Children's Med. Ctr. 51st & Grove St. Oakland, CA	5/26/88	In progress	1069/ C-P241	15 mcg	0,2 mos	9*	1-6 mos					
							6*	7-11 mos					
						one dose	29	12-71 mos	0		21 (3/14)	0 (0/14)	0.085
									1	100 (14/14)	100 (14/14)	86 (12/14)	3.497
				1072/ C-P298	15 mcg	0,2 mos	22	2-6 mos	0		50 (4/8)	0 (0/8)	0.125
									2	100 (5/5)	100 (5/5)	80 (4/5)	2.131
									3	100 (5/5)	100 (5/5)	100 (5/5)	11.858
							8	7-11 mos	0		0 (0/4)	0 (0/4)	0.062
									2	75 (3/4)	100 (4/4)	100 (4/4)	1.766
									3	100 (4/4)	100 (4/4)	75 (3/4)	5.011

*Serology results are available for 3 or less vaccinees; therefore serology results are not included in this table.
**PS = polysaccharide

6079I/8/29AUG88

MULTICLINIC STUDY OF HEALTHY CHILDREN AND INFANTS RECEIVING HAEMOPHILUS B CONJUGATE VACCINE
(NEISSERIA MENINGITIDIS OUTER MEMBRANE PROTEIN COMPLEX) (BBIND 1966)

STUDY NO.	INVESTIGATOR/ LOCATION	DATE INITIATED	STATUS	VACCINE LOT	VACCINE DOSE	VACCINE REGIMEN	NO. SUBJECTS VACCINATED	POPULATION (AGE)	TIME (MOS.)	% WITH ANTI-PRP >2-FOLD RISE	% WITH ANTI-PRP >.15 MCG/ ML	% WITH ANTI-PRP >1.0 MCG/ ML	GMT (MCG/ML)
004-07	Parvin Azimi, M.D. (Cont.)					one dose	29	12-71 mos	0		50 (8/16)	0 (0/16)	0.135
									1	100 (16/16)	100 (16/16)	94 (15/16)	5.250
				1080/ C-P749	15 mcg	0,2 mos	3*	1-6 mos					
							6*	7-11 mos					
						one dose	14	12-71 mos	0		25 (1/4)	0 (0/4)	0.090
									1	100 (4/4)	100 (4/4)	100 (4/4)	7.259
				1085/ C-R132	15 mcg	0,2 mos	6*	2-6 mos					
							4*	7-11 mos					
						one dose	13*	12-71 mos					

*Serology results are available for 3 or less vaccinees; therefore serology results are not included in this table.

6079I/9/29AUG88

MULTICLINIC STUDY OF HEALTHY CHILDREN AND INFANTS RECEIVING HAEMOPHILUS B CONJUGATE VACCINE
(NEISSERIA MENINGITIDIS OUTER MEMBRANE PROTEIN COMPLEX) (BBIND 1966)

STUDY NO.	INVESTIGATOR/ LOCATION	DATE INITIATED	STATUS	VACCINE LOT	VACCINE DOSE	VACCINE REGIMEN	NO. SUBJECTS VACCINATED	POPULATION (AGE)	TIME (MOS.)	% WITH ANTI-PRP >2-FOLD RISE	% WITH ANTI-PRP >.15 MCG/ ML	% WITH ANTI-PRP >1.0 MCG/ ML	GMT (MCG/ML)
004-08	Jeffrey Blumer, M.D. Rainbow Babies and Children's Hospital 2101 Adelbert Road Cleveland, OH	5/28/87	In progress	1069/ C-P241	15 mcg	0,2 mos	3*	2-6 mos					
							4	7-11 mos	0		25 (1/4)	0 (0/4)	0.080
									2	75 (3/4)	75 (3/4)	100 (4/4)	3.638
									3	100 (4/4)	100 (4/4)	100 (4/4)	11.383
						one dose	25	12-71 mos	0		36 (9/25)	12 (3/25)	0.155
									1	100 (25/25)	100 (25/25)	96 (24/25)	20.932
				1072/ C-P298	15 mcg	0,2 mos	3*	2-6 mos					
							10	7-11 mos	0		20 (1/5)	0 (0/5)	0.076
									2	100 (5/5)	80 (4/5)	100 (5/5)	2.524
									3	100 (5/5)	100 (5/5)	100 (5/5)	3.890
						one dose	47	12-71 mos	0		50 (19/38)	11 (4/38)	0.191
									1	97 (37/38)	100 (38/38)	95 (36/38)	8.458
				1080/ C-P749	15 mcg	0,2 mos	2*	2-6 mos					
							3*	7-11 mos					
						one dose	10	12-71 mos	0		57 (4/7)	0 (0/7)	0.145
									1	100 (7/7)	100 (7/7)	100 (7/7)	8.269
				1085/ C-R132	15 mcg	0,2 mos	2*	2-6 mos					
							3*	7-11 mos					
						one dose	10	12-71 mos	0		50 (2/4)	0 (0/4)	0.155
									1	100 (4/4)	100 (4/4)	100 (4/4)	22.693

*Serology results are available for 3 or less vaccinees; therefore serology results are not included in this table.

6079I/10/29AUG88

MULTICLINIC STUDY OF HEALTHY CHILDREN AND INFANTS RECEIVING HAEMOPHILUS B CONJUGATE VACCINE
(NEISSERIA MENINGITIDIS OUTER MEMBRANE PROTEIN COMPLEX) (BBIND 1966)

STUDY NO.	INVESTIGATOR/ LOCATION	DATE INITIATED	STATUS	VACCINE LOT	VACCINE DOSE	VACCINE REGIMEN	NO. SUBJECTS VACCINATED	POPULATION (AGE)	TIME (MOS.)	% WITH ANTI-PRP >2-FOLD RISE	% WITH ANTI-PRP >.15 MCG/ ML	% WITH ANTI-PRP >1.0 MCG/ ML	GMT (MCG/ML)
004-09	Elia Ayoub, M.D. Dept. of Pediatrics Box J-296 JHMC Univ. of Florida Gainesville, FL	9/1/87	In progress	1069/ C-P241	15 mcg	0,2 mos	8	2-6 mos	0		0 (0/4)	0 (0/4)	0.078
									2	100 (4/4)	100 (4/4)	100 (4/4)	2.292
									3	100 (4/4)	100 (4/4)	100 (4/4)	7.297
							7	7-11 mos	0		0 (0/4)	0 (0/4)	0.062
									2	100 (4/4)	100 (4/4)	100 (4/4)	4.004
						one dose	13	12-71 mos	0		63 (5/8)	0 (0/8)	0.151
									1	100 (8/8)	100 (8/8)	100 (8/8)	14.706
				1080/ C-P749	15 mcg	0,2 mos	10*	2-6 mos					
							7*	7-11 mos					
						one dose	34	12-71 mos	0		29 (4/14)	7 (1/4)	0.110
									1	100 (14/14)	100 (14/14)	100 (14/14)	6.641
				1085/ C-R132	15 mcg	0,2 mos	1*	2-6 mos					
							2*	7-11 mos					
						one dose	2*	12-71 mos					

*Serology results are available for 3 or less vaccinees; therefore serology results are not included in this table.

6079I/11/29AUG88

MULTICLINIC STUDY OF HEALTHY CHILDREN AND INFANTS RECEIVING HAEMOPHILUS B CONJUGATE VACCINE
(NEISSERIA MENINGITIDIS OUTER MEMBRANE PROTEIN COMPLEX) (BBIND 1966)

STUDY NO.	INVESTIGATOR/ LOCATION	DATE INITIATED	STATUS	VACCINE LOT	VACCINE DOSE	VACCINE REGIMEN	NO. SUBJECTS VACCINATED	POPULATION (AGE)	TIME (MOS.)	% WITH ANTI-PRP >2-FOLD RISE	% WITH ANTI-PRP >.15 MCG/ ML	% WITH ANTI-PRP >1.0 MCG/ ML	GMT (MCG/ML)
004-10	Ziad Shehab, M.D. Univ. of Arizona Med. Ctr. Dept. of Pediatrics 1501 N. Campbell Ave. Tucson, AZ	4/29/87	In pro- gress	1069/ C-P241	15 mcg	0,2 mos	8	2-6 mos	0		14 (1/7)	0 (0/7)	0.072
									2	100 (6/6)	100 (6/6)	100 (6/6)	5.430
									3	100 (7/7)	100 (7/7)	100 (7/7)	7.970
							7	7-11 mos	0		14 (1/7)	0 (0/7)	0.069
									2	86 (6/7)	100 (7/7)	71 (5/7)	3.608
									3	100 (4/4)	100 (4/4)	100 (4/4)	10.293
						one dose	15	12-71 mos	0		60 (9/15)	33 (5/15)	0.437
									1	93 (14/15)	100 (15/15)	93 (14/15)	14.684
				1072/ C-P298	15 mcg	0,2 mos	30	1-6 mos	0		35 (8/23)	0 (0/23)	0.112
									2	90 (18/20)	100 (20/20)	60 (12/20)	1.310
									3	95 (21/22)	95 (21/22)	82 (18/22)	3.586
							8	7-11 mos	0		17 (1/6)	0 (0/6)	0.078
									2	100 (6/6)	100 (6/6)	67 (4/6)	1.995
									3	100 (5/5)	100 (5/5)	80 (4/5)	6.145
						one dose	28	12-71 mos	0		45 (10/22)	18 (4/22)	0.203
									1	100 (22/22)	100 (22/22)	91 (20/22)	6.775
				1080/ C-P749	15 mcg	0,2 mos	13	2-6 mos	0		20 (1/5)	0 (0/5)	0.091
									2	100 (4/4)	100 (4/4)	100 (4/4)	2.477
									3	100 (4/4)	100 (4/4)	100 (4/4)	4.316
							3*	7-11 mos					

*Serology results are available for 3 or less vaccinees; therefore serology results are not included in this table.

6079I/12/29AUG88

MULTICLINIC STUDY OF HEALTHY CHILDREN AND INFANTS RECEIVING HAEMOPHILUS B CONJUGATE VACCINE
(NEISSERIA MENINGITIDIS OUTER MEMBRANE PROTEIN COMPLEX) (BBIND 1966)

STUDY NO.	INVESTIGATOR/ LOCATION	DATE INITIATED	STATUS	VACCINE LOT	VACCINE DOSE	VACCINE REGIMEN	NO. SUBJECTS VACCINATED	POPULATION (AGE)	TIME (MOS.)	% WITH ANTI-PRP >2-FOLD RISE	% WITH ANTI-PRP >.15 MCG/ ML	% WITH ANTI-PRP >1.0 MCG/ ML	GMT (MCG/ML)
004-10	Ziad Shebab, M.D. (Cont.)					one dose	11	12-71 mos	0		14 (1/7)	14 (1/7)	0.130
									1	100 (7/7)	100 (7/7)	71 (5/7)	3.273
				1085/ C-R132	15 mcg	0,2 mos	13*	2-6 mos					
							3*	7-11 mos					
						one dose	12	12-71 mos	0		44 (4/9)	22 (2/9)	0.186
									1	100 (9/9)	89 (8/9)	100 (9/9)	10.039
004-11	Trudy Murphy, M.D. Univ. of Texas Health Science Ctr. Dept. of Pediatrics 5323 Harry Hines Blvd. Dallas, TX	5/21/87	In pro- gress	1069/ C-P241	15 mcg	0,2 mos	26	2-6 mos	0		33 (5/15)	0 (0/15)	0.109
									2	93 (14/15)	100 (15/15)	93 (14/15)	4.556
									3	92 (12/13)	100 (13/13)	92 (12/13)	7.017
									6-10	100 (6/6)	100 (6/6)	83 (5/6)	2.396

*Serology results are available for 3 or less vaccinees; therefore serology results are not included in this table.

6079I/13/29AUG88

MULTICLINIC STUDY OF HEALTHY CHILDREN AND INFANTS RECEIVING HAEMOPHILUS B CONJUGATE VACCINE
(NEISSERIA MENINGITIDIS OUTER MEMBRANE PROTEIN COMPLEX) (BBIND 1966)

STUDY NO.	INVESTIGATOR/ LOCATION	DATE INITIATED	STATUS	VACCINE LOT	VACCINE DOSE	VACCINE REGIMEN	NO. SUBJECTS VACCINATED	POPULATION (AGE)	TIME (MOS.)	% WITH ANTI-PRP >2-FOLD RISE	% WITH ANTI-PRP >.15 MCG/ ML	% WITH ANTI-PRP >1.0 MCG/ ML	GMT (MCG/ML)
004-12	Harry Keyserling, M.D. Dept. of Pediatrics Emory Univ. School of Medicine Atlanta GA	7/11/87	In progress	1069/ C-P241	15 mcg	0,2 mos	7	2-6 mos	0		33 (2/6)	0 (0/6)	0.139
									2	100 (6/6)	100 (6/6)	100 (6/6)	4.191
									3	100 (6/6)	100 (6/6)	100 (6/6)	8.083
							2*	7-11 mos					
						one dose	16	12-71 mos		no serology done; clinical followup only			
				1072/ C-P298	15 mcg	0,2 mos	17	2-6 mos	0		40 (6/15)	0 (0/15)	0.117
									2	87 (13/15)	93 (14/15)	80 (12/15)	2.979
									3	92 (12/13)	100 (13/13)	92 (12/13)	6.495
							4	7-11 mos	0		25 (1/4)	25 (1/4)	0.176
									2	75 (3/4)	100 (4/4)	100 (4/4)	4.562
									3	100 (4/4)	100 (4/4)	100 (4/4)	6.599
						one dose	13	12-71 mos		no serology done; clinical followup only			
				1080/ C-P749	15 mcg	0,2 mos	55	1-6 mos	0		14 (3/21)	0 (0/21)	0.077
									2	95 (20/21)	100 (21/21)	71 (15/21)	1.944
									3	100 (13/13)	100 (13/13)	77 (10/13)	3.416
							14	7-11 mos	0		17 (1/6)	0 (0/6)	0.073
									2	100 (6/6)	100 (6/6)	100 (6/6)	3.444
									3	100 (5/5)	100 (5/5)	100 (5/5)	10.412
						one dose	75	12-71 mos		no serology done; clinical followup only			
				1085/ C-R132	15 mcg	0,2 mos	3*	1-6 mos					
						one dose	6	12-71 mos		no serology done; clinical followup only			

*Serology results are available for 3 or less vaccinees; therefore serology results are not included in this table.

6079I/14/29AUG88

MULTICLINIC STUDY OF HEALTHY CHILDREN AND INFANTS RECEIVING HAEMOPHILUS B CONJUGATE VACCINE
(NEISSERIA MENINGITIDIS OUTER MEMBRANE PROTEIN COMPLEX) (BBIND 1966)

STUDY NO.	INVESTIGATOR/ LOCATION	DATE INITIATED	STATUS	VACCINE LOT	VACCINE DOSE	VACCINE REGIMEN	NO. SUBJECTS VACCINATED	POPULATION (AGE)	TIME (MOS.)	% WITH ANTI-PRP >2-FOLD RISE	% WITH ANTI-PRP >.15 MCG/ ML	% WITH ANTI-PRP >1.0 MCG/ ML	GMT (MCG/ML)
004-13	George Peter, M.D. Div. of Pediatric Infectious Diseases Rhode Island Hospital 593 Eddy Street Providence, RI	6/9/87	In progress	1069/ C-P241	15 mcg	0,2 mos	5*	7-11 mos					
						one dose	17	12-71 mos	0		19 (3/16)	0 (0/16)	0.088
									1	100 (16/16)	100 (16/16)	94 (15/16)	9.046
				1080/ C-P749	15 mcg	0,2 mos	5*	2-6 mos					
							5*	7-11 mos					
						one dose	15	12-71 mos	0		14 (1/7)	14 (1/7)	0.131
									1	86 (6/7)	100 (7/7)	100 (7/7)	4.011
004-14	Mathuram Santosham, M.D. The Johns Hopkins University Infectious Disease Research Ctr. P.O. Box 1240 Whiteriver, AZ	5/20/87	In progress	1069/ C-P241	15 mcg	0,2 mos	14	1-6 mos	0		22 (2/9)	0 (0/9)	0.124
									2	89 (8/9)	100 (9/9)	67 (6/9)	1.611
									3	100 (6/6)	100 (6/6)	67 (4/6)	3.079
						one dose	49	12-71 mos	0		63 (27/43)	12 (5/43)	0.244
									1	100 (40/40)	100 (40/40)	95 (38/40)	11.583
									6-10	88 (29/33)	100 (33/33)	67 (22/33)	1.644
				1072/ C-P298	15 mcg**	0,2 mos	69	1-6 mos	0		59 (10/17)	12 (2/17)	0.216
									2	82 (14/17)	100 (17/17)	88 (15/17)	3.569
									3	100 (6/6)	100 (6/6)	83 (5/6)	5.642
						one dose	28*	12-71 mos					
				1080/ C-P749	15 mcg	0,2 mos	17*	1-6 mos					
							36*	12-71 mos					

*Serology results are available for 3 or less vaccinees; therefore serology results are not included in this table.
**One additional child (age unknown) also received one dose of Lot C-P298.

6079I/15/29AUG88

MULTICLINIC STUDY OF HEALTHY CHILDREN AND INFANTS RECEIVING HAEMOPHILUS B CONJUGATE VACCINE
(NEISSERIA MENINGITIDIS OUTER MEMBRANE PROTEIN COMPLEX) (BBIND 1966)

STUDY NO.	INVESTIGATOR/ LOCATION	DATE INITIATED	STATUS	VACCINE LOT	VACCINE DOSE	VACCINE REGIMEN	NO. SUBJECTS VACCINATED	POPULATION (AGE)	TIME (MOS.)	% WITH ANTI-PRP >2-FOLD RISE	% WITH ANTI-PRP >.15 MCG/ ML	% WITH ANTI-PRP >1.0 MCG/ ML	GMT (MCG/ML)
004-15	Adnan Dajani, M.D. Wayne State Univ. School of Medicine Children's Hospital of Michigan 3901 Beaubien Blvd. Detroit, MI	4/20/87	In progress	1069/ C-P241	15 mcg	0,2 mos	6*	2-6 mos					
							7	7-11 mos	0		25 (1/4)	0 (0/4)	0.082
									2	100 (4/4)	100 (4/4)	100 (4/4)	3.687
									3	100 (4/4)	100 (4/4)	100 (4/4)	9.192
						one dose	12	12-71 mos	0		44 (4/9)	0 (0/9)	0.152
									1	100 (9/9)	100 (9/9)	100 (9/9)	6.355
				1080/ C-P749	15 mcg	0,2 mos	10*	2-6 mos					
							9	7-11 mos	0		20 (1/5)	0 (0/5)	0.077
									2	100 (5/5)	100 (5/5)	60 (3/5)	2.568
									3	100 (5/5)	100 (5/5)	100 (5/5)	5.516
						one dose	51	12-71 mos	0		50 (8/16)	6 (1/16)	0.165
									1	94 (15/16)	100 (16/16)	88 (14/16)	7.279

*Serology results are available for 3 or less vaccinees; therefore serology results are not included in this table.

CLINICAL STUDY OF HAEMOPHILUS b CONJUGATE VACCINE
(NEISSERIA MENINGITIDIS OUTER MEMBRANE PROTEIN COMPLEX) IN POLYSACCHARIDE VACCINE FAILURES (BBIND 1966)

STUDY NO.	INVESTIGATOR/ LOCATION	DATE INITIATED	STATUS	VACCINE LOT	VACCINE DOSE	VACCINE REGIMEN	NO. SUBJECTS VACCINATED	POPULATION (AGE)	TIME (MOS.)	% WITH ANTI-PRP >2-FOLD RISE	% WITH ANTI-PRP >.15 MCG/ ML	% WITH ANTI-PRP >1.0 MCG/ ML	GMT (MCG/ML)
006-01	Dan Granoff, M.D. St. Louis Children's Hospital 400 S. Kingshighway Blvd. St. Louis, MO	6/22/87	In Progress	1069/ C-P241	15 mcg	0,2 mos	8	12-71 mos	0		43 (3/7)	0 (0/7)	0.111
									2-3	100 (7/7)	100 (7/7)	100 (7/7)	8.568
									3-5	100 (7/7)	100 (7/7)	100 (7/7)	11.990
				1072/ C-P298	15 mcg	0,2 mos	8	12-71 mos	0		83 (5/6)	0 (0/6)	0.289
									2-3	100 (6/6)	100 (6/6)	100 (6/6)	4.188
									3-5	100 (4/4)	100 (4/4)	100 (4/4)	9.155
				PS** followed by 1069/ C-P241 or 1072/ C-P298 as a second dose	25 mcg 15 mcg 15 mcg	dose 1 (0 mo) 2 mos 2 mos	16	12-71 mos	0		62 (8/13)	0 (0/13)	0.167
									1-2	67 (8/12)	83 (10/12)	33 (4/12)	0.563
									3-5	100 (8/8)	100 (8/8)	88 (7/8)	2.478
									5-7	100 (7/7)	100 (7/7)	86 (6/7)	6.850

**PS = polysaccharide

6079I/17/29AUG88

COMPARATIVE STUDY OF HEALTHY CHILDREN RECEIVING POLYSACCHARIDE VACCINE (BBIND 1966)

STUDY NO.	INVESTIGATOR/ LOCATION	DATE INITIATED	STATUS	VACCINE LOT	VACCINE DOSE	VACCINE REGIMEN	NO. SUBJECTS VACCINATED	POPULATION (AGE)	TIME (MOS.)	% WITH ANTI-PRP >2-FOLD RISE	% WITH ANTI-PRP >.15 MCG/ ML	% WITH ANTI-PRP >1.0 MCG/ ML	GMT (MCG/ML)
007-01	Kwang Sik Kim, M.D. Children's Hospital of Los Angeles 4650 Sunset Blvd. Los Angeles, CA	10/14/87	In Progress	b-CAPSA® I	25 mcg	1 dose	11	18-23 mos 45 (5/11)	0 1	 82 (9/11)	45 (5/11) 36 (4/11)	0 (0/11) 0.512	0.111
							52	24-60 mos	0 1	 88 (36/41)	51 (21/41) 98 (40/41)	15 (6/41) 66 (27/41)	0.212 4.032
				Hib IMUNE®	25 mcg	1 dose	5	18-23 mos	0 1	 100 (4/4)	0 (0/4) 100 (4/4)	0 (0/4) 25 (1/4)	0.062 1.194
							41	24-60 mos	0 1	 64 (25/39)	67 (26/39) 97 (38/39)	23 (9/39) 54 (21/39)	0.332 2.714
				Hib Vax™	25 mcg	1 dose	10	18-23 mos	0 1	 50 (4/8)	63 (5/8) 88 (7/8)	13 (1/8) 50 (4/8)	0.251 1.436
							41	24-60 mos	0 1	 71 (24/34)	59 (20/34) 94 (32/34)	18 (6/34) 62 (21/34)	0.214 2.553

DOSE-RANGING STUDIES OF HEALTHY CHILDREN AND INFANTS RECEIVING HAEMOPHILUS B CONJUGATE VACCINE
(NEISSERIA MENINGITIDIS OUTER MEMBRANE PROTEIN COMPLEX) (BBIND 1966)

STUDY NO.	INVESTIGATOR/ LOCATION	DATE INITIATED	STATUS	VACCINE LOT	VACCINE DOSE	VACCINE REGIMEN	NO. SUBJECTS VACCINATED	POPULATION (AGE)	TIME (MOS.)	% WITH ANTI-PRP >2-FOLD RISE	% WITH ANTI-PRP >.15 MCG/ML	% WITH ANTI-PRP >1.0 MCG/ML	GMT (MCG/ML)
008-01	Kwang Sik Kim, M.D. Children's Hospital of Los Angeles 4650 Sunset Blvd. Los Angeles, CA	12/15/87	In progress	1072/ C-P298	7.5 mcg	0,2 mos	7*	2-6 mos					
						0,2 mos	4*	7-12 mos					
						0,2 mos	6*	12-18 mos					
						one dose	8	19-48 mos	0		14 (1/7)	0 (0/7)	0.1
									1	100 (7/7)	100 (7/7)	100 (7/7)	4.9
					15 mcg	0,2 mos	8*	2-6 mos					
							5*	7-12 mos					
							1*	13-18 mos					
						one dose	20	19-48 mos	0		0 (5/15)	0 (0/15)	0.1
									1	100 (15/15)	100 (15/15)	93 (14/15)	4.1
					30 mcg	0,2 mos	7*	2-6 mos					
							5*	7-12 mos					
							3*	13-18 mos					
						one dose	8	19-48 mos	0		33 (2/6)	16 (1/6)	0.9
									1	100 (6/6)	100 (6/6)	83 (5/6)	5.4

*Data are available for less than 4 individuals, therefore, data are not included in this table.

6079I/19/29AUG88

DOSE-RANGING STUDIES OF HEALTHY CHILDREN AND INFANTS RECEIVING HAEMOPHILUS B CONJUGATE VACCINE (*NEISSERIA MENINGITIDIS* OUTER MEMBRANE PROTEIN COMPLEX) (BBIND 1966)

STUDY NO.	INVESTIGATOR/ LOCATION	DATE INITIATED	STATUS	VACCINE LOT	VACCINE DOSE	VACCINE REGIMEN	NO. SUBJECTS VACCINATED	POPULATION (AGE)	TIME (MOS.)	% WITH ANTI-PRP >2-FOLD RISE	% WITH ANTI-PRP >.15 MCG/ML	% WITH ANTI-PRP >1.0 MCG/ML	GMT (MCG/ML)
008-02	Ram Yogev, M.D. Northwestern Univ. Med. School The Children's Memorial Hospital 2300 Children's Plaza Chicago, IL	1/20/88	In progress	1072/ C-P298	7.5 mcg	0,2 mos	25*	2-6 mos					
							27*	7-12 mos					
							8*	13-18 mos					
						one dose	24	19-59 mos	0		29 (5/17)	18 (3/17)	0.156
									1	100 (17/17)	100 (17/17)	94 (16/17)	4.917
					15 mcg	0,2 mos	17	2-6 mos	0		60 (3/5)	0 (0/5)	0.157
									2	100 (5/5)	100 (5/5)	80 (4/5)	2.289
									3	100 (4/4)	100 (4/4)	100 (4/4)	2.295
							16	7-12 mos	0		25 (1/4)	0 (0/4)	0.085
									2	100 (4/4)	100 (4/4)	75 (3/4)	1.720
									3	100 (4/4)	100 (4/4)	100 (4/4)	5.068
							8*	13-18 mos					
						one dose	24	19-59 mos	0		53 (9/17)	0 (0/17)	0.161
									1	100 (17/17)	100 (17/17)	94 (16/17)	9.625
					30 mcg	0,2 mos	6*	7-12 mos					
							1*	13-18 mos					
							21	19-59 mos	0		38 (6/16)	13 (2/16)	0.149
									1	100 (16/16)	100 (16/16)	94 (15/16)	18.125

*Data are available for less than 4 individuals, therefore, data are not included in this table.

6079I/20/29AUG88

INTERACTION STUDIES OF HEALTHY CHILDREN AND INFANTS RECEIVING HAEMOPHILUS B CONJUGATE VACCINE
(NEISSERIA MENINGITIDIS OUTER MEMBRANE PROTEIN COMPLEX) (BBIND 1966)

STUDY NO.	INVESTIGATOR/ LOCATION	DATE INITIATED	STATUS	VACCINE LOT	VACCINE DOSE	VACCINE REGIMEN	NO. SUBJECTS VACCINATED	POPULATION (AGE)	TIME (MOS.)	% WITH ANTI-PRP >2-FOLD RISE	% WITH ANTI-PRP >.15 MCG/ ML	% WITH ANTI-PRP >1.0 MCG/ ML	GMT (MCG/ML)
010-02	Ellen R. Wald, M.D. Children's Hospital of Pittsburgh 3705 5th Ave. at DeSoto St. Pittsburgh, PA	2/2/88	In Progress	1080/ C-P749 and MMR concur-rently	15 mcg	1 dose	23	13-22 mos	0		47 (8/17)	0 (0/17)	0.141
									1	94 (16/17)	100 (17/17)	94 (16/17)	4.630
				1080/ C-P749 and MMR 4 wks apart	15 mcg	1 dose	22	13-22 mos	0		22 (4/18)	6 (1/18)	0.110
									1	100 (18/18)	100 (18/18)	89 (16/18)	3.042
									2	100 (8/8)	100 (8/8)	88 (7/8)	2.438
011-01	Barry Dashefsky, M.D. Children's Hospital of Pittsburgh 3705 5th Ave. at DeSoto St. Pittsburgh, PA	2/2/88	In Progress	1080/ C-P749 DTP/OPV concur-rently	15 mcg	1 dose	23	17-24 mos	0		25 (4/16)	6 (1/16)	0.114
									1	100 (16/16)	100 (16/16)	88 (14/16)	5.020
				1080/ C-P749 DTP/OPV 4 wks apart	15 mcg	1 dose	26	17-24 mos	0		20 (4/20)	0 (0/20)	0.079
									1	95 (19/20)	95 (19/20)	85 (17/20)	5.161
									2	100 (12/12)	100 (12/12)	75 (9/12)	6.644

6079I/21/29AUG88

Haemophilus b Conjugate Vaccine
(Neisseria meningitidis Outer Membrane Protein Complex)

MULTICLINIC STUDY OF SAFETY AND IMMUNOGENICITY IN CHILDREN

Study 004-01 - Durham NC - Catherine Wilfert, M.D.

Healthy children and infants 1-71 months of age were entered in this study. Twenty children 2-6 months of age received two 15 mcg doses of Lot 1069/C-P241 two months apart. One additional child received only the first dose. One in fourteen (7%) had an antibody titer >1.0 mcg/ml prior to vaccination. The GMT prior to vaccination was 0.153 mcg/ml. One month after the second dose 83% (10/12) had antibody titers >1.0 mcg/ml. The GMT at that time for these 12 vaccinees was 5.182 mcg/ml. Seventeen children 7-11 months of age received two 15 mcg doses of the same lot two months apart. The GMT prevaccination was 0.089 mcg/ml. One month after the second dose, 100% (14/14) had developed antibody titers >1.0 mcg/ml. The GMT for those 14 at 3 months was 10.152 mcg/ml. Six children 12-71 months of age received a single 15 mcg dose of this lot. The GMT prior to vaccination was 0.075 mcg/ml. One month after vaccination 100% (5/5) had developed antibody titers >1.0 mcg/ml. The GMT at 1 month was 6.589 mcg/ml.

Eighteen children, fifteen 1-6 months of age and three 7-11 months of age received the first 15 mcg dose of Lot 1072/C-P298. Fifteen children received the second dose 2 months later. Prior to vaccination 14% (1/7) had an antibody titer >1.0 mcg/ml. The GMT prior to vaccination was 0.181 mcg/ml. Two months after the first dose 86% (6/7) had antibody titers >1.0 mcg/ml. The GMT for these vaccinees at this time was 3.177 mcg/ml. Five children 12-71 months of age received a single dose of this same lot. The prevaccination GMT was 0.099 mcg/ml. One month after vaccination 75% (3/4) had developed antibody titers >1.0 mcg/ml. The GMT for these vaccinees was 3.303 mcg/ml at 1 month.

Ten children 2-11 months of age received the first 15 mcg dose of Lot 1080/C-P749. Seven children received a second dose two months later. Serologic data for these vaccinees were not available at the time of data cutoff. Data are expected. One child (23 months old) received a single dose of this same lot. This child developed an antibody titer of 3.864 mcg/ml 1 month following vaccination.

Twelve children 1-6 months of age received the first dose of Lot 1085/C-P132. Nine children received the second injection. Available serologic data show that one child (1/1) developed an antibody titer >1.0 mcg/ml (1.751 mcg/ml). Additional data are expected. One child (17 months) received a single dose of this same lot. This child also developed antibody >1.0 mcg/ml (4.037 mcg/ml).

Serious adverse experiences were reported for two children. One child developed aseptic meningitis and one child developed bronchial spasms. Both of these events were felt to be unrelated to use of the vaccine by the investigator.

Study 004-03 - Brooklyn, NY - Kenneth Bromberg, M.D.

Healthy children and infants 1-71 months of age were entered in this study. Nineteen children 2-11 months of age received two 15 mcg doses of Lot 1069/C-P241 and 13 children 12-71 months of age received a single 15 mcg dose of Lot 1069/C-P241. Prior to vaccination the GMT was 0.079 mcg/ml for the 2-11 month age group and 0.170 mcg/ml for the 12-71 month age group. One month following the second dose 100% (7/7) in the 2-11 month age group had developed antibody titers >1.0 mcg/ml. One month following vaccination 71% (5/7) in the 12-71 month age group had antibody titers >1.0 mcg/ml. The GMT for these vaccinees was 4.776 mcg/ml in the 2-11 month age group one month following the second dose and 4.195 mcg/ml for the 12-71 month age group one month following vaccination.

Forty-one children 1-6 months of age and 15 children 7-11 months of age received the first 15 mcg dose of a two dose, two months apart, regimen of Lot 1080/C-P249. Twenty-eight children 1-6 months of age and 11 children 7-11 months of age received the second dose. The GMT prior to vaccination was 0.124 mcg/ml for the 1-6 month age group and 0.190 mcg/ml for the 7-11 month age group. One month following the second dose 75% (6/8) in the 1-6 month age group and 100% (3/3) in the 7-11 month age group had an antibody titer >1.0 mcg/ml. The GMT for these vaccinees at that time was 3.153 mcg/ml and 13.555 mcg/ml respectively. Seventeen children (12-71 months) received a single 15 mcg dose of this lot. The prevaccination GMT was 0.063 mcg/ml. Available data show that one of two children developed an antibody titer >1.0 mcg/ml at 1 month. The GMT was 1.999 mcg/ml at 1 month. Additional data are expected.

No serious adverse experiences were reported in this study.

Study 004-04 - Torrance, CA - Joel Ward, M.D.

Healthy children and infants 1-6 months of age were entered into the study. Forty-four children received two 15 mcg doses of vaccine two months apart. Thirty-two children received two doses of Lot 1069/C-P241 while 12 children received one dose of Lot 1069/C-P241 followed by one dose of Lot 1072/C-P298. Of the children with serologic data, 9% (3/34) had antibody titers >1.0 mcg/ml prior to vaccination. The prevaccination GMT was 0.273 mcg/ml. One to three months after the second dose, 95% (20/21) had antibody titers >1.0 mcg/ml. The GMT for these vaccinees at that time was 6.411 mcg/ml. Five children received two 15 mcg doses of Lot 1072/C-P298 two months apart. The prevaccination GMT was 0.095 mcg/ml. One to three months after the second dose, 100% (4/4) had antibody titers >1.0 mcg/ml. The GMT for the 4 vaccinees at that time was 11.339 mcg/ml.

No serious adverse experiences were reported in this study.

Study 005 - New Haven, CT - Eugene Shapiro, M.D.

Healthy children and infants 2-71 months of age entered this study. Ten children 2-6 months of age received one 15 mcg dose of Lot 1020/C-N084. Serologic data are not available for these children. Three children 12-71 months of age received a single 20 mcg dose of the same lot. The prevaccination GMT was 0.244 mcg/ml. One month following vaccination 3/3 children had developed antibody levels >1.0 mcg/ml. The GMT at 1 month was 12.817 mcg/ml.

Eleven children 2-6 months of age and 4 children 7-11 months of age received two 15 mcg doses of Lot 1069/C-P241 two months apart. The prevaccination GMT was 0.089 mcg/ml. One month following the second dose, 100% (13/13) had developed antibody titers >1.0 mcg/ml. The GMT for these 13 vaccinees at that time was 7.476 mcg/ml. Twenty-four children 12-71 months of age received a single dose of the same lot. Prior to vaccination 9% (2/23) had antibody titers >1.0 mcg/ml. The GMT was 0.127 mcg/ml. One month following vaccination 100% (22/22) had antibody titers >1.0 mcg/ml. The GMT at 1 month for the 22 vaccinees was 15.727 mcg/ml.

Twenty-five children 2-6 months of age received the first 15 mcg dose of Lot 1072/C-P298. Seventeen children received the second dose. The prevaccination GMT was 0.110 mcg/ml. One month following the second dose, 86% (6/7) had developed antibody titers >1.0 mcg/ml. The GMT at that time for the 7 vaccinees was 3.300 mcg/ml. Sixteen children 7-11 months of age received the first dose of Lot 1072/C-P298. Fifteen children received the second dose. The prevaccination GMT was 0.167 mcg/ml. One month following the second dose, 78% (7/9) had developed antibody titers >1.0 mcg/ml. The GMT at that time was 4.033 mcg/ml.

Forty-eight children 12-71 months of age received a single dose of this same lot. Prior to vaccination, 17% (6/35) had antibody levels >1.0 mcg/ml. The GMT was 0.187 mcg/ml. One month following vaccination, 85% (29/34) had antibody titers >1.0 mcg/ml. The GMT at 1 month was 6.163 mcg/ml.

Fourteen children 2-6 months of age and 8 children 7-11 months of age received the first 15 mcg dose of Lot 1080/C-P749. Thirteen children received the second dose. The prevaccination GMT was 0.069 mcg/ml. One month following the second dose, 75% (3/4) had developed antibody titers >1.0 mcg/ml. The GMT at that time for the 4 vaccinees was 6.405 mcg/ml. Twenty-six children received a single dose of this same lot. Prior to vaccination 7% (1/14) had an antibody titer >1.0 mcg/ml. The GMT was 0.144 mcg/ml. One month postvaccination 71% (10/14) had >1.0 mcg/ml. The GMT for the 14 vaccinees at 1 month was 5.320 mcg/ml.

Twenty children, twelve 2-6 months of age and eight 7-11 months of age, received the first 15 mcg dose of Lot 1085/C-R132. Sixteen children received the second dose two months later. The prevaccination GMT was 0.095 mcg/ml. One month following the second dose, 86% (6/7) had developed antibody levels >1.0 mcg/ml. The GMT at that time for the 7 vaccinees was 4.603 mcg/ml. Twenty-eight children 12-71 months of age received a single 15 mcg dose of the same lot. One child out of 15 had an antibody titer >1.0 mcg/ml prior to vaccination. The prevaccination GMT was 0.141 mcg/ml. One month following vaccination 93% (14/15) had antibody levels >1.0 mcg/ml. The GMT at that time was 4.699 mcg/ml for these 15 vaccinees.

No serious adverse experiences were reported in this study.

Study 004-06 - New Orleans, LA - Robert Daum, M.D.

Healthy children and infants 1-6 months of age were entered in this study. Six children received a single 15 mcg dose of Lot 1018/C-M679 followed by a single 25 mcg dose of polysaccharide vaccine. One additional child received only the first dose. The prevaccination GMT was 0.115 mcg/ml. Two months following the first dose, 50% (3/6) had an antibody titer > 1.0 mcg/ml. The GMT was 1.098 mcg/ml for the six vaccinees.

Fourteen children received two 15 mcg doses of Lot 1069/C-P241 two months apart and seventeen children received a single 15 mcg dose of Lot 1069/C-P241 followed by a single 15 mcg dose of Lot 1080/C-P749 at two months. One additional child received only a single dose (Lot 1069/C-P241) of the two-dose regimen. Serologic data were not available at the time of data cutoff. Data are expected.

Serious adverse experiences were reported for two patients in this study. One child developed dysplastic lung and another child developed cough and choking. The investigator felt that these experiences were unrelated to use of the vaccine.

Study 004-07 - Oakland, CA - Parvin Azimi, M.D.

Healthy children and infants 1-71 months of age were entered in this study. Fifteen children 1-11 months of age received the first 15 mcg dose of Lot 1069/C-P241. Fourteen children received the second dose two months later. Serologic data for three patients show that 2/3 developed antibody levels >1.0 mcg/ml 2 months after the first dose. Twenty-nine children 12-71 months of age received a single dose of the same lot. The prevaccination GMT was 0.085 mcg/ml. One month following vaccination 86% (12/14) had developed antibody titers >1.0 mcg/ml. The GMT at that time was 3.497 mcg/ml for those 14 subjects.

Thirty children 2-11 months of age received the first 15 mcg dose of Lot 1072/C-P298. Twenty-one children received the second dose 2 months later. The prevaccination GMT was 0.099 mcg/ml. One month after the second dose, 89% (8/9) had developed antibody levels >1.0 mcg/ml. The GMT at that time was 8.087 mcg/ml. Twenty-nine children 12-71 months of age received a single 15 mcg dose of the same lot. The prevaccination GMT was 0.135 mcg/ml. One month following vaccination, 94% (15/16) had developed antibody titers >1.0 mcg/ml. The GMT at 1 month for the 16 children was 5.250 mcg/ml.

Nine children 1-11 months of age received the first dose of Lot 1080/C-P749. Three children received the second injection 2 months later. Serologic data for one child show that the child developed an antibody level of 3.200 mcg/ml. Fourteen children 12-71 months of age received a single dose of the same lot. The prevaccination GMT was 0.090 mcg/ml. One month following vaccination, 100% (4/4) had antibody titers >1.0 mcg/ml. The GMT at 1 month was 7.259 mcg/ml for these 4 vaccinees.

Ten children 2-11 months of age received the first 15 mcg dose of Lot 1085/C-R132. Five children received the second injection 2 months later. Serologic data for 2 children show that both children developed an antibody level >1.0 mcg/ml 2 months after the first dose. The prevaccination GMT was 0.106 mcg/ml. The postvaccination GMT was 12.545 mcg/ml. Thirteen children 12-71 months of age received a single 15 mcg dose of the same lot. Serologic data for two children show that both children developed an antibody level >1.0 mcg/ml 1 month after vaccination. The prevaccination GMT was 0.140 mcg/ml. The postvaccination GMT was 20.358 mcg/ml.

No serious adverse experiences were reported in this study.

Study 004-08 - Cleveland, OH - Jeffrey Blumer, M.D.

Healthy children and infants 2-71 months of age were entered in this study. Seven children 2-11 months of age received two 15 mcg doses of Lot 1069/C-P241 two months apart. The prevaccination GMT was 0.081 mcg/ml. One month following the second dose, 100% (6/6) had developed antibody titers >1.0 mcg/ml. The GMT for these vaccinees at that time was 9.871 mcg/ml. Twenty-five children 12-71 months of age received a single 15 mcg dose of the same lot. Prior to vaccination 12% (3/25) had antibody titers >1.0 mcg/ml. The GMT was 0.155 mcg/ml. One month following vaccination 96% (24/25) had antibody levels >1.0 mcg/ml. The GMT at that time was 20.932 mcg/ml.

Thirteen children 2-11 months of age received the first 15 mcg dose of Lot 1072/C-P298. Eleven children received the second dose two months later. The prevaccination GMT was 0.087 mcg/ml. One month following the second dose, 100% (7/7) had developed antibody titers >1.0 mcg/ml. The GMT for the 7 vaccinees was 4.014 mcg/ml. Forty-seven children 12-71 months of age received a single dose of the same lot. Prior to vaccination 11% (4/38) had antibody levels >1.0 mcg/ml. The GMT was 0.191 mcg/ml. One month following vaccination 95% (36/38) had antibody titers >1.0 mcg/ml. The GMT at that time was 8.458 mcg/ml for the 38 vaccinees.

Five children 2-11 months of age received the first 15 mcg dose of Lot 1080/C-P749. Four children received the second injection 2 months later. Serologic data for two children show that they each developed antibody titers >1.0 mcg/ml one month following the second dose. The prevaccination GMT was 0.127 mcg/ml. The postvaccination GMT was 4.243 mcg/ml. Ten children 12-71 months of age received a single dose of the same lot. The prevaccination GMT was 0.145 mcg/ml. One month following vaccination 100% (7/7) had developed antibody levels >1.0 mcg/ml. The GMT at that time for those 7 children was 8.269 mcg/ml.

Five children 2-11 months of age received two 15 mcg doses of Lot 1085/C-R132 two months apart. The prevaccination GMT was 0.175 mcg/ml. Two months after the first dose, 3/3 children had developed antibody titers >1.0 mcg/ml. The GMT at that time was 4.406 mcg/ml. Ten children 12-71 months received a single 15 mcg dose of the same lot. The GMT prevaccination was 0.155 mcg/ml. One month following vaccination 100% (4/4) had antibody levels >1.0 mcg/ml. The GMT at that time was 22.693 mcg/ml.

No serious adverse experiences were reported in this study.

Study 004-09 - Gainesville, FL - Elia Ayoub, M.D.

Healthy children and infants 2-71 months of age entered this study. Fifteen children 2-11 months of age received the first 15 mcg dose of Lot 1069/C-P241. Eleven children received the second dose 2 months later. The prevaccination GMT was 0.070 mcg/ml. One month following the second dose, 100% (7/7) had developed antibody levels >1.0 mcg/ml. The GMT at 3 months for the 7 vaccinees was 6.645 mcg/ml. Thirteen children 12-71 months of age received a single dose of the same lot. The GMT prevaccination was 0.151 mcg/ml. One month following vaccination 100% (8/8) had developed antibody levels >1.0 mcg/ml. The GMT at that time was 14.706 mcg/ml for these 8 vaccines.

Seventeen children 2-11 months of age received the first 15 mcg dose of Lot 1080/C-P749. Nine children received the second dose two months later. Serologic data for two children showed that they developed antibody levels >1.0 mcg/ml 2 months after the first dose. The prevaccination GMT was 0.093 mcg/ml and the postvaccination GMT was 3.249 mcg/ml. Thirty-four children 12-71 months of age received a single 15 mcg dose of the same lot. The prevaccination GMT was 0.110 mcg/ml. One month following vaccination 100% (14/14) had developed antibody levels >1.0 mcg/ml. The GMT for the 14 vaccinees at 1 month was 6.641.

Three children 2-11 months of age and 2 children 12-71 months of age received one 15 mcg dose of Lot 1085/C-R132. Serologic data were not available for these subjects at the time of data cutoff. Data are expected.

No serious adverse experiences were reported in this study.

Study 004-10 - Tucson, AZ - Ziad Shehab, M.D.

Healthy children and infants 1-71 months of age were entered in this study. Eight children 2-6 months of age received two 15 mcg doses of vaccine 2 months apart. Seven children received Lot 1069/C-P241 while one child received one dose of that lot and one dose of Lot 1072/C-P298. The prevaccination GMT was 0.072 mcg/ml. One month following the second dose, 100% (7/7) had developed antibody titers >1.0 mcg/ml. The GMT at that time for the 7 vaccinees was 7.970 mcg/ml. Seven children 7-11 months of age received 2 doses of Lot 1069/C-P241 two months apart. The prevaccination GMT was 0.069 mcg/ml. One month following the second dose, 100% (4/4) had developed antibody titers >1.0 mcg/ml. The GMT at that time for the 4 vaccinees was 10.293 mcg/ml. Fifteen children 12-71 months of age received a single dose of this same lot. Prior to vaccination 33% (5/15) had antibody levels >1.0 mcg/ml. The GMT was 0.437 mcg/ml. One month following vaccination, 93% (14/15) had antibody titers >1.0 mcg/ml. The GMT at that time was 14.684 mcg/ml.

Thirty children 1-6 months of age received the first 15 mcg dose of Lot 1072/C-P298. Twenty five children received the second dose 2 months later. The prevaccination GMT was 0.112 mcg/ml. One month following the second dose, 82% (18/22) had developed antibody levels >1.0 mcg/ml. The GMT for the 22 vaccinees was 3.586 mcg/ml at that time. Eight children 7-11 months of age received the first dose of this same lot and 6 children received the second dose. The GMT prevaccination was 0.078 mcg/ml. One month following the second dose, 80% (4/5) had antibody levels >1.0 mcg/ml. The GMT at that time was 6.145 mcg/ml. Twenty-eight children 12-71 months of age received a single dose of this same lot. Prior to vaccination 18% (4/22) had antibody levels >1.0 mcg/ml. The prevaccination GMT was 0.203 mcg/ml. One month following vaccination, 91% (20/22) had antibody levels >1.0 mcg/ml. The GMT at 1 month for the 22 vaccinees was 6.775 mcg/ml.

Sixteen children 2-11 months of age received the first dose of Lot 1080/C-P749. Nine children received the second dose two months later. The GMT prevaccination was 0.082 mcg/ml. One month following the second dose, 100% (6/6) had developed antibody titers >1.0 mcg/ml. The GMT for the 6 vaccinees was 6.319 mcg/ml at that time. Eleven children 12-71 months of age received a single dose of this same lot. Prior to vaccination 14% (1/7) had antibody levels >1.0 mcg/ml. The GMT was 0.130 mcg/ml. One month following vaccination 71% (5/7) had titers >1.0 mcg/ml. The GMT at 1 month for those 7 vaccinees was 3.273 mcg/ml.

Sixteen children 2-11 months of age received the first 15 mcg dose of Lot 1085/C-R132. Ten children received the second dose two months later. The prevaccination GMT was 0.208 mcg/ml. One month following the second dose, 80% (4/5) had developed antibody levels >1.0 mcg/ml. The GMT at that time for these 5 vaccinees was 2.767 mcg/ml. Twelve children 12-71 months of age received a single dose of this same lot. The GMT prior to vaccination was 0.186 mcg/ml. One month following vaccination 100% (9/9) had developed antibody levels >1.0 mcg/ml. The GMT at 1 month was 10.039 mcg/ml.

A serious adverse experience was reported for one patient who developed cervical cellulitis. The investigator felt that the experience was unrelated to use of the vaccine.

Study 004-11 - Dallas, TX - Trudy Murphy, M.D.

Healthy children 2-6 months of age were entered in this study. Twenty-five children received two 15 mcg doses of Lot 1069/C-P241 two months apart. One additional child received only one dose. The prevaccination GMT was 0.109 mcg/ml. One month following the second dose, 92% (12/13) had developed antibody titers >1.0 mcg/ml. The GMT for all vaccinees at that time was 7.017 mcg/ml.

No serious adverse experiences were reported in this study.

Study 004-12 - Atlanta, GA - Harry Keyserling, M.D.

Healthy children and infants 1-71 months of age were entered in this study. Nine children 2-11 months of age received two 15 mcg doses of Lot 1069/C-P241. The prevaccination GMT was 0.124 mcg/ml. One month following the second dose, 100% (7/7) had developed antibody titers >1.0 mcg/ml. The GMT at that time was 8.760 mcg/ml. Sixteen children 7-11 months of age received a single dose of the same lot. Serologic data are not available; only clinical follow-up was completed for this age group.

Seventeen children 2-6 months of age received two 15 mcg doses of Lot 1072/C-P298. The prevaccination GMT was 0.117 mcg/ml. One month following the second dose, 92% (12/13) had developed antibody levels >1.0 mcg/ml. The GMT for the 13 vaccinees at that time was 6.495 mcg/ml. Four children 7-11 months of age received two 15 mcg doses of the same lot. One child had an antibody level >1.0 mcg/ml prior to vaccination. The GMT was 0.176 mcg/ml. One month following the second dose, 100% (4/4) had an antibody level >1.0 mcg/ml. The GMT at that time was 6.599 mcg/ml. Thirteen children 12-71 months of age received a single 15 mcg dose of the same lot. Serologic data are not available; only clinical follow-up was completed for this age group.

Fifty-five children 1-6 months of age received the first dose of Lot 1080/C-P749. Thirty-one children received the second dose two months later. The prevaccination GMT was 0.077 mcg/ml. One month following the second dose, 77% (10/13) had developed antibody titers >1.0 mcg/ml. The GMT at that time was 3.416 mcg/ml for the 13 vaccinees. Fourteen children 7-11 months of age received the first dose of the same lot. Seven children received the second dose two months later. The prevaccination GMT was 0.073 mcg/ml. One month following the second dose, 100% (5/5) had antibody titers >1.0 mcg/ml. The GMT at that time was 10.412 mcg/ml for these 5 vaccinees. Seventy-five children 12-71 months of age received a single 15 mcg dose of this same lot. Serologic data are not available; only clinical follow-up was completed for this age group.

Three children 1-6 months of age received the first dose of Lot 1085/C-R132 and 6 children 12-71 months of age received a single dose of the same lot. Serologic data are expected for the 1-6 month age group.

No serious adverse experiences were reported in this study.

Study 004-13 - Providence, RI - George Peter, M.D.

Healthy children 2-71 months of age were entered into this study. Four children 7-11 months old received two 15 mcg doses of Lot 1069/C-P241 two months apart. One additional child received only one dose. Available data show one child (1/1) developed antibody >1.0 mcg/ml one month after the second dose. Seventeen children 12-71 months of age received a single dose of Lot 1069/C-P241. The prevaccination GMT was 0.088 mcg/ml. One month following vaccination, 94%(15/16) had antibody levels >1.0 mcg/ml. The GMT for these 16 vaccinees at that time was 9.046 mcg/ml.

Ten children, five 2-6 months of age and five 7-11 months of age received the first 15 mcg dose of Lot 1080/C-P749. Seven of these 10 received their second dose two months later. The prevaccination GMT was 0.062 mcg/ml. One month following the second dose, 100% (3/3) had antibody titers >1.0 mcg/ml. The GMT for these 3 vaccinees at that time was 11.172 mcg/ml. Fifteen children 12-71 months old received a single dose of Lot 1080/C-P749. Fourteen percent (1/7) had antibody levels >1.0 mcg/ml prior to vaccination. The GMT was 0.131 mcg/ml. One month following vaccination, 100% (7/7) had >1.0 mcg/ml. The GMT at that time for the 7 vaccinees was 4.011 mcg/ml.

No serious adverse experiences were reported in this study.

Study 004-14 - White River, AZ - Mathuram Santosham, M.D.

Healthy children 1-6 months of age and 12-71 months of age were entered in this study. Fourteen children 1-6 months of age received the first 15 mcg dose of Lot 1069/C-P241. Eleven of these 14 also received the second injection two months later. The prevaccination GMT was 0.124 mcg/ml. One month following the second dose, 67% (4/6) had antibody levels >1.0 mcg/ml. The GMT for these 6 vaccinees at that time was 3.079 mcg/ml. Forty-nine children 12-71 months of age received a single dose of this same lot. Twelve percent (5/43) had >1.0 mcg/ml prior to vaccination. The GMT was 0.244 mcg/ml. One month following vaccination, 95% (38/40) had antibody titers >1.0 mcg/ml. The GMT for these 40 vaccinees at 1 month was 11.583 mcg/ml.

Sixty-nine children 1-6 months of age received one 15 mcg dose of Lot 1072/C-P298. Fifty-four of these 69 received the second injection two months later. Twelve percent (2/17) had antibody levels >1.0 mcg/ml prior to vaccination. The GMT was 0.216 mcg/ml. At 2 months following the first dose and 1 month following the second dose, the percentages with >1.0 mcg/ml were 88% (15/17) and 83% (5/6) respectively. The GMTs at these times were 3.569 and 5.642 mcg/ml respectively. Twenty-eight children 12-71 months of age received a single 15 mcg dose of Lot 1072/C-P298. Available data show that 3/3 children developed antibody titers >1.0 mcg/ml 1 month following vaccination.

Seventeen children 1-6 months of age received the first dose of Lot 1080/C-P749. No child received the second injection. Thirty-six children 12-71 months of age have received a single dose of Lot 1080/C-P749. Serologic data were not available at the time of data cutoff. Data are expected.

Serious adverse experiences were reported for five children in this study. A five-month old female developed gastroenteritis which the investigator felt was unrelated to use of the vaccine. A three-month old female developed diarrhea, bronchiolitis, and pneumonia, all of which were felt by the investigator to be probably unrelated to use of the vaccine. A five-month old female developed mild bronchiolitis, conjunctivitis, and aseptic meningitis. The investigator felt that these experiences were probably unrelated to use of the vaccine. A four-month old female developed an upper respiratory infection which the investigator thought was unrelated to use of the vaccine. A two-month old female developed an upper respiratory infection which the investigator thought was unrelated to use of the vaccine.

Study 004-15 - Detroit, MI - Adnan Dajani, M.D.

Healthy children and infants 2-71 months of age were entered in this study. Thirteen children 2-11 months of age received the first 15 mcg dose of a two dose regimen of Lot 1069/C-P241. Eleven children received the second injection 2 months later. The prevaccination GMT was 0.073 mcg/ml. One month following the second dose, 100% (7/7) had developed antibody titers >1.0 mcg/ml. The GMT for these 7 vaccinees at that time was 7.686 mcg/ml. Twelve children 12-71 months of age received a single dose of this same lot. The prevaccination GMT was 0.152 mcg/ml. One month following vaccination, 100% (9/9) had developed antibody titers > 1.0 mcg/ml. The GMT for these 9 vaccinees at one month was 6.355 mcg/ml.

Nineteen children 2-11 months of age received the first 15 mcg dose of a two dose regimen of Lot 1080/C-P749. Fifteen children received the second injection two months later. The prevaccination GMT was 0.071 mcg/ml. One month following the second dose, 88% (7/8) had antibody levels >1.0 mcg/ml. The GMT at that time was 3.734 mcg/ml. Fifty-one children 12-71 months of age received a single 15 mcg dose of this same lot. Six percent (1/16) had an antibody titer >1.0 mcg/ml prior to vaccination. The GMT was 0.165 mcg/ml. One month following vaccination, 88% (14/16) had >1.0 mcg/ml. The GMT at that time was 7.279 mcg/ml.

No serious adverse experiences were reported in this study.

STUDY 004-01

PROGRAM: Haemophilus b Conjugate Vaccine (Neisseria meningitidis Outer Membrane Protein Complex), Study 004-01

PURPOSE: To evaluate the safety and immunogenicity of Haemophilus b conjugate vaccine (Neisseria meningitidis outer membrane protein complex) in healthy infants and children 2 to 71 months of age.

VACCINE: Haemophilus b Conjugate Vaccine (Neisseria meningitidis Outer Membrane Protein Complex) (PRP-OMPC)

Lot 1069/C-P241 - (b) (4) mcg polysaccharide/ml
mcg meningococcal protein/ml

Lot 1072/C-P298 - mcg polysaccharide/ml
mcg meningococcal protein/ml

Lot 1080/C-P749 - mcg polysaccharide/ml
mcg meningococcal protein/ml

Lot 1085/C-R132 - mcg polysaccharide/ml
mcg meningococcal protein/ml

Aluminum hydroxide diluent
Lot (b) (4)

INVESTIGATOR: Catherine M. Wilfert, M.D.
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P.O. Box 2591
Durham, North Carolina 27710

SUB-INVESTIGATOR: Mary V. Moggio
Duke University Medical Centr
P.O. Box 2591
Durham, North Carolina

STUDY LOCATION: Durham Child Care Center
Gregson Street
Durham, North Carolina 27705

Chapel Hill Pediatric Associates
Chapel Hill, North Carolina 27514

DATE STUDY INITIATED: April 29, 1987

DATE STUDY COMPLETED: In progress.

STUDY POPULATION: Healthy infants 2 to 71 months of age are included in the study. A subset of infants and children are randomized to receive three clinical lots of vaccine (1072/C-P298, 1080/C-P749, 1085/C-R132).

STUDY PROCEDURE: Infants 2 to 11 months of age receive two injections of PRP-OMPC vaccine given 2 months, while children 12 months of age and older receive a single injection. Vaccine is reconstituted in aluminum hydroxide and administered by intramuscular route. The dose for each injection is 15 mcg of polysaccharide in the appropriate volume. Lot 1069/C-P241 is reconstituted to contain 15 mcg polysaccharide in 0.75 ml, while lots 1072/C-P288, 1080/C-P749 and 1085/C-R132 are reconstituted to contain 15 mcg polysaccharide in 0.5 ml.

The parent or guardian is required to record the vaccine recipient's temperature and any reactions at the injection site or systemic complaints for 5 days after each injection of vaccine. Unexpected or serious reactions are to be reported immediately to the study physician. Serious adverse experiences in the 14 days following each injection of vaccine are required to be reported by the investigator.

A blood sample is obtained prior to each injection of vaccine and 1 month after the last or a single injection of vaccine. Additional follow-up blood samples are obtained 7 to 10 months after the last injection of vaccine from infants 2 to 11 months of age and at 15 to 18 months postvaccination from children $\geq$12 months of age.

All serum samples are assayed for antibody to the capsular polysaccharide of Haemophilus influenzae type b by radioimmunoassay. Selected samples may be tested for bactericidal and opsonophagocytic activity, immunoglobulin isotype and subclass IgG. Opsonophagocytic assays are performed at the University of Alabama. All other assays are performed at Merck Sharp & Dohme Research Laboratories.

RESULTS: Demographic information and individual pre and postimmunization antibody data for each vaccine recipient are presented in Tables 1 and 2.

1. Current status:

Lot	Age	No. Vaccinated Injection 1	Injection 2
1069/C-P241	2-11 mos	38	37
	12-71 mos	6	--
1072/C-P298*	2-11 mos	18 (2)**	15 (1)
	12-71 mos	5	--
1080/C-P749	2-11 mos	10 (4)	7
	12-71 mos	1	--
1085/C-R132	2-11 mos	12 (6)	9 (4)
	12-71 mos	1	--

* Infants and childrn randomized to receive Lots 1072/C-P298, 1080/C-P749, and 1085/C-K132 are assigned Case Nos. (b) (6) .

** Parentheses represent additional children vaccinated who received other pediatric vaccines concurrently with PRP-OMPC vaccine. Their results are summarized separately.

2. Serologic results:

Anti-PRP responses prior to each injection of vaccine and 1 month after the last or single injection of vaccine are as follows:

Age	Time	% With Anti-PRP >0.15 mcg/ml	% With Anti-PRP >1.0 mcg/ml	GMT (mcg/ml) All Vaccinees
2-11 mos	Pre	42 (16/38)	8 (3/38)	0.14
	Post 1	97 (36/37)	81 (30/37)	2.90
	Post 2	100 (29/29)	93 (27/29)	7.28
12-71 mos	Pre	27 (3/11)	0 (0/11)	0.09
	Post	100 (11/11)	91 (10/11)	4.67

RESULTS (CONT.)

Antibody responses among all vaccine recipients are presented in Tables 3 and 4 by lot. Antibody responses among the subset of vaccinees randomized to receive Lots 1072/C-P298, 1080/C-P749 and 1085/C-R132 are shown in Tables 5 to 7. Serologic results are not yet available for the limited number of subjects receiving other pediatric vaccines in conjunction with PRP-OMPC vaccine.

3. Clinical results:

The incidence of selected injection site and systemic reactions occurring within 2 days after vaccination are as follows:

	% of Vaccines with Reaction		
	2-11 mos		12-71 mos
Type of Reaction	Injection 1	Injection 2	
Injection Site:			
Pain/Soreness	9 (6/65)	5 (3/59)	8 (1/13)
Erythema >1 inch	2 (1/65)	2 (1/59)	0 (0/13)
Swelling >1 inch	0 (0/65)	2 (1/59)	0 (0/13)
Induration	0 (0/65)	3 (2/59)	0 (0/13)
Systemic:			
Irritability	23 (15/65)	29 (17/59)	8 (1/13)
Sleepiness/Lethargy/ Fatigue	23 (15/65)	19 (11/59)	0 (0/13)

The frequencies of all clinical reactions and maximum temperatures occurring during the 5 days following each injection of vaccine are presented in Tables 8 to 10 by lot.

RESULTS:
(CONT.)

No serious or alarming reactions attributable to vaccine have been reported. Two serious adverse experiences definitely not related to vaccine were reported:

1) Case No. (b) (6), a 9 month old male infant, with a history of reactive airway disease developed an exacerbation of wheezing 1 day after receiving an initial dose of Lot 1069/C-P241. The infant required medical intervention in the physicians office but no hospital admission and recovered.

2) Case No. (b) (6), a 4 month old female infant, was diagnosed with meningitis 1 month after receiving an initial dose of Lot 1069/C-P241 and 3 days after vaccination with DTP and OPV vaccines. The etiology of the meningitis was determined to be nonbacterial and probably viral.

TABLE 1

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	CAUC	(b) (6)	2M	0	(b) (6)	001	PREBLEED				310				
					0		011	INJ 1	CP241	15 MCG						
					76		011	BLEED 1			05/	2814				
					76		021	INJ 2	CP241	15 MCG						
					112		021	BLEED 2			05/	5483				
	F	CAUC		9M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP241	15 MCG						
					62		011	BLEED 1				5861				
					62		021	INJ 2	CP241	15 MCG						
					100		021	BLEED 2				17234				
	M	CAUC		8M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP241	15 MCG						
					69		011	BLEED 1				5090				
					69		021	INJ 2	CP241	15 MCG						
					111		021	BLEED 2				24418				
	M	CAUC		6M	0		001	PREBLEED				< 125				0
					0		011	INJ 1	CP241	15 MCG						
					57		011	BLEED 1				5467				100
					57		021	INJ 2	CP241	15 MCG						
	M	BLAC		10M	0		001	PREBLEED			03/	< 125				
					0		011	INJ 1	CP241	15 MCG						
					71		011	BLEED 1			03/	6826				
					71		021	INJ 2	CP241	15 MCG						
					105		021	BLEED 2			03/	38492				
	M	CAUC		4M	0		001	PREBLEED				200				
					0		011	INJ 1	CP241	15 MCG						
					76		011	BLEED 1			05/	3105				
					76		021	INJ 2	CP241	15 MCG						
					112		021	BLEED 2			05/	5307				
	M	CAUC		4M	0		001	PREBLEED				< 125				0
					0		011	INJ 1	CP241	15 MCG						
					69		011	BLEED 1				1232				35
					69		021	INJ 2	CP241	15 MCG						
					104		021	BLEED 2				3906				

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	CAUC	(b) (6)	9M	0	(b) (6)	001	PREBLEED				< 125				
					0		011	INJ 1	CP241	15 MCG						
					63		011	BLEED 1				3061				
					63		021	INJ 2	CP241	15 MCG						
					98		021	BLEED 2				8961				
	F	CAUC		4M	0		011	INJ 1	CP241	15 MCG						
	F	CAUC		2M	0		001	PREBLEED				361				
					0		011	INJ 1	CP241	15 MCG						
					92		011	BLEED 1			05/	1936				
					92		021	INJ 2	CP241	15 MCG						
					125		021	BLEED 2			05/	3830				
	M	BLAC		2M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP241	15 MCG						
					62		011	BLEED 1				9957				
					62		021	INJ 2	CP241	15 MCG						
					91		021	BLEED 2				10032				
					285		071	BLEED 3				5550				
	M	CAUC		2M	0		001	PREBLEED				< 250				
					0		011	INJ 1	CP241	15 MCG						
					69		011	BLEED 1				7190				
					69		021	INJ 2	CP241	15 MCG						
					113		021	BLEED 2				8280				
	F	CAUC		3M	0		001	PREBLEED				211				
					0		011	INJ 1	CP241	15 MCG						
					63		011	BLEED 1				368				
					63		021	INJ 2	CP241	15 MCG						
					98		021	BLEED 2				654				
	M	CAUC		7M	0		001	PREBLEED				294				
					0		011	INJ 1	CP241	15 MCG						
					63		011	BLEED 1				4898				
					63		021	INJ 2	CP241	15 MCG						
					99		021	BLEED 2				20912				
	F	CAUC		2M	0		001	PREBLEED				< 125				

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	F	CAUC	(b) (6)	2M	0	(b) (6)	011	INJ 1	CP241	15 MCG						
					91		011	BLEED 1			05/	2229				
					91		021	INJ 2	CP241	15 MCG						
					133		021	BLEED 2			05/	5573				
	F	CAUC		7M	0		001	PREBLEED				568				
					0		011	INJ 1	CP241	15 MCG						
					69		011	BLEED 1				1675				
					69		021	INJ 2	CP241	15 MCG						
					124		021	BLEED 2				9778				
	F	CAUC		2M	0		001	PREBLEED				261				
					0		011	INJ 1	CP241	15 MCG						
					64		011	BLEED 1				1623				
					64		021	INJ 2	CP241	15 MCG						
					104		021	BLEED 2				1780				
	F	CAUC		3M	0		001	PREBLEED				216				
					0		011	INJ 1	CP241	15 MCG						
					64		011	BLEED 1				1002				
					64		021	INJ 2	CP241	15 MCG						
					92		021	BLEED 2				2340				
	F	CAUC		2M	0		001	PREBLEED				300				
					0		011	INJ 1	CP241	15 MCG						
					62		021	INJ 2	CP241	15 MCG						
					98		021	BLEED 1				6848				
	M	CAUC		2M	0		001	PREBLEED				647				
					0		011	INJ 1	CP241	15 MCG						
					62		011	BLEED 1				13855				
					62		021	INJ 2	CP241	15 MCG						
					98		021	BLEED 2				23580				
	F	CAUC		2M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP241	15 MCG						
					63		011	BLEED 1				9782				
					63		021	INJ 2	CP241	15 MCG						
					91		021	BLEED 2				8829				
	M	CAUC		10M	0		001	PREBLEED				< 125				

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	CAUC	(b) (6)	10M	0	(b) (6)	011	INJ 1	CP241	15 MCG						
					63		011	BLEED 1				616				
					63		021	INJ 2	CP241	15 MCG						
					98		021	BLEED 2				1841				
	M	CAUC		7M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP298	15 MCG						
					70		011	BLEED 1				1380				
					70		021	INJ 2	CP298	15 MCG						
					126		021	BLEED 2				2259				
	F	CAUC		5M	0		011	INJ 1	CP298	15 MCG						
	M	CAUC		4M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP298	15 MCG						
					83		011	BLEED 1			05/	1307				
					83		021	INJ 2	CP298	15 MCG						
					117		021	BLEED 2			05/	922				
	F	CAUC		3M	0		001	PREBLEED				203				
					0		011	INJ 1	CP298	15 MCG						
					56		011	BLEED 1				10590				
					56		021	INJ 2	CP298	15 MCG						
					96		021	BLEED 2				8170				
	M	CAUC		3M	0		001	PREBLEED				153				
					0		011	INJ 1	CP298	15 MCG						
					56		011	BLEED 1				4277				
					56		021	INJ 2	CP298	15 MCG						
					96		021	BLEED 2				15340				
	M	CAUC		6M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP298	15 MCG						
					76		011	BLEED 1			05/	524				
					76		021	INJ 2	CP298	15 MCG						
					121		021	BLEED 2			05/	1183				
	M	CAUC		2M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP298	15 MCG						
					77		011	BLEED 1			05/	9251				

00153

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	CAUC	(b) (6)	2M	77	(b) (6)	021	INJ 2	CP298	15 MCG						
					111		021	BLEED 2			05/	6482				
	F	CAUC		8M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP749	15 MCG						
					77		011	BLEED 1			05/	36677				
					77		021	INJ 2	CP749	15 MCG						
					107		021	BLEED 2			05/	88114				
	M	CAUC		2M	0		001	PREBLEED				1930		< 2		
					0		011	INJ 1	CR132	15 MCG						
					56		011	BLEED 1				1097		>= 32		
					56		021	INJ 2	CR132	15 MCG						
					84		021	BLEED 2				1751		>= 32		
	F	CAUC		2M	0		001	PREBLEED				1032				
					0		011	INJ 1	CP298	15 MCG						
					56		011	BLEED 1				1118				
					56		021	INJ 2	CP298	15 MCG						
	F	CAUC		3M	0		011	INJ 1	CR132	15 MCG						
					55		021	INJ 2	CR132	15 MCG						
	F	CAUC		3M	0		011	INJ 1	CP749	15 MCG						
					53		021	INJ 2	CP749	15 MCG						
	M	CAUC		2M	0		011	INJ 1	CP298	15 MCG						
	M	CAUC		8M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP241	15 MCG						
					63		011	BLEED 1				3453				
					63		021	INJ 2	CP241	15 MCG						
					90		021	BLEED 2				8986				
					301		071	BLEED 3				2774				
					301		091	INJ 3	CP241	15 MCG						
					330		091	BLEED 4				57198				
	M	CAUC		4M	0		001	PREBLEED			02/	< 125				
					0		011	INJ 1	CP241	15 MCG						
					63		011	BLEED 1			02/	19523				

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	CAUC	(b) (6)	4M	63	(b) (6)	021	INJ 2	CP241	15 MCG						
					91		021	BLEED 2			02/	17602				
	M	CAUC		6M	0		001	PREBLEED				< 125				0
					0		011	INJ 1	CP241	15 MCG						
					61		011	BLEED 1				35441				95
					61		021	INJ 2	CP241	15 MCG						
					90		021	BLEED 2				65753				99
	M	CAUC		7M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP241	15 MCG						
					66		011	BLEED 1				3493				
					66		021	INJ 2	CP241	15 MCG						
					108		021	BLEED 2				4106				
	M	CAUC		9M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP241	15 MCG						
					63		011	BLEED 1				< 125				
					63		021	INJ 2	CP241	15 MCG						
					88		021	BLEED 2				7133				
	M	CAUC		10M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP241	15 MCG						
					63		011	BLEED 1				3840				
					63		021	INJ 2	CP241	15 MCG						
					104		021	BLEED 2				17431				
	F	BLAC		2M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP241	15 MCG						
					56		011	BLEED 1				453				
					56		021	INJ 2	CP241	15 MCG						
					112		021	BLEED 2				4173				
	F	CAUC		9M	0		001	PREBLEED				130				0
					0		011	INJ 1	CP241	15 MCG						
					67		011	BLEED 1				22245				98
					67		021	INJ 2	CP241	15 MCG						
					91		021	BLEED 2				37592				
	M	CAUC		7M	0		001	PREBLEED				148				

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT		LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	CAUC	(b) (6)	7M	0	(b) (6)	011	INJ	1	CP241	15 MCG						
					63		011	BLEED	1				17402				
					63		021	INJ	2	CP241	15 MCG						
					99		021	BLEED	2				36218				
	F	CAUC		10M	0		001	PREBLEED					1465				
					0		011	INJ	1	CP241	15 MCG						
					73		011	BLEED	1			05/	7426				
					73		021	INJ	2	CP241	15 MCG						
					112		021	BLEED	2			05/	21240				
	F	CAUC		2M	0		001	PREBLEED					208				
					0		011	INJ	1	CP241	15 MCG						
					68		011	BLEED	1				5898				
					68		021	INJ	2	CP241	15 MCG						
					105		021	BLEED	2				6882				
	M	CAUC		7M	0		001	PREBLEED					< 125				
					0		011	INJ	1	CP241	15 MCG						
					70		011	BLEED	1				294				
					70		021	INJ	2	CP241	15 MCG						
					105		021	BLEED	2				1070				
	M	CAUC		8M	0		001	PREBLEED					< 125				
					0		011	INJ	1	CP241	15 MCG						
					70		011	BLEED	1				6117				
					70		021	INJ	2	CP241	15 MCG						
					98		021	BLEED	2				8053				
	F	CAUC		9M	0		001	PREBLEED					< 125				
					0		011	INJ	1	CP241	15 MCG						
					60		011	BLEED	1				5967				
					60		021	INJ	2	CP241	15 MCG						
					95		021	BLEED	2				15811				
	M	CAUC		2M	0		001	PREBLEED					< 125				
					0		011	INJ	1	CP241	15 MCG						
					74		011	BLEED	1			05/	998				
					84		021	INJ	2	CP241	15 MCG						
					111		021	BLEED	2			05/	5775				

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	F	CAUC	(b) (6)	2M	0	(b) (6)	001	PREBLEED				1070				
					0		011	INJ 1	CP241	15 MCG						
					62		011	BLEED 1				2594				
					62		021	INJ 2	CP241	15 MCG						
					97		021	BLEED 2				657				
	F	CAUC		9M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP298	15 MCG						
					57		011	BLEED 1				16967				
					57		021	INJ 2	CP298	15 MCG						
					137		021	BLEED 2				39837				
	F	CAUC		7M	0		001	PREBLEED				129				
					0		011	INJ 1	CP298	15 MCG						
					99		021	INJ 2	CP298	15 MCG						
					131		021	BLEED 1			05/	54694				
	M	CAUC		1M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP298	15 MCG						
					75		011	BLEED 1			05/	1801				
					75		021	INJ 2	CP298	15 MCG						
					106		021	BLEED 2			05/	5342				
	F	CAUC		2M	0		001	PREBLEED				1054				
					0		011	INJ 1	CP298	15 MCG						
					106		011	BLEED 1			05/	9463				
					106		021	INJ 2	CP298	15 MCG						
	F	CAUC		2M	0		001	PREBLEED				255				
					0		011	INJ 1	CP749	15 MCG						
					77		011	BLEED 1			05/	3723				
					77		021	INJ 2	CP749	15 MCG						
					104		021	BLEED 2			05/	4857				
	F	CAUC		5M	0		001	PREBLEED				250				
					0		011	INJ 1	CP298	15 MCG						
					80		011	BLEED 1			05/	14327				
					80		021	INJ 2	CP298	15 MCG						
	M	CAUC		2M	0		001	PREBLEED				< 125				

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	CAUC	(b) (6)	2M	0	(b) (6)	011	INJ 1	CR132	15 MCG						
					80		011	BLEED 1			05/	1831				
					80		021	INJ 2	CR132	15 MCG						
	M	CAUC		2M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CR132	15 MCG						
					80		011	BLEED 1			05/	10909				
					80		021	INJ 2	CR132	15 MCG						
	F	CAUC		5M	0		001	PREBLEED				361				
					0		011	INJ 1	CP298	15 MCG						
					67		011	BLEED 1				772				
					67		021	INJ 2	CP298	15 MCG						
	M	CAUC		2M	0		001	PREBLEED				988				
					0		011	INJ 1	CP749	15 MCG						
					55		011	BLEED 1				628				
					55		021	INJ 2	CP749	15 MCG						
	F	CAUC		2M	0		001	PREBLEED				141				
					0		011	INJ 1	CP298	15 MCG						
					55		011	BLEED 1				3568				
					55		021	INJ 2	CP298	15 MCG						
	M	BLAC		4M	0		011	INJ 1	CR132	15 MCG						
	F	CAUC		3M	0		011	INJ 1	CP749	15 MCG						
					53		021	INJ 2	CP749	15 MCG						
	M	CAUC		9M	0		011	INJ 1	CP749	15 MCG						
	M	CAUC		2M	0		011	INJ 1	CR132	15 MCG						

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB/DTP/OPV CONCURRENTLY
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	F	CAUC	(b) (6)	2M	0	(b) (6)	001	PREBLEED								
					0		011	INJ 1	CR132	15 MCG						
					105		011	BLEED 1								
					105		021	INJ 2	96646							
					105		021	INJ 2	CR132	15 MCG						
	M	CAUC		2M	0		011	INJ 1	CP749	15 MCG						
					119		021	INJ 2	91083							
					119		021	INJ 2	CP749	15 MCG						
	F	CAUC		2M	0		001	PREBLEED								
					0		011	INJ 1	CP749	15 MCG						
					52		011	BLEED 1								
					52		021	INJ 2	CP749	15 MCG						
					52		021	INJ 2	96646							
					52		021	INJ 2	78612							
	M	CAUC		2M	0		001	PREBLEED								
					0		011	INJ 1	CR132	15 MCG						
					52		011	BLEED 1								
					52		021	INJ 2	CR132	15 MCG						
					52		021	INJ 2	96642							
					52		021	INJ 2	71647							
	M	CAUC		1M	0		011	INJ 1	CR132	15 MCG						
					0		011	INJ 1	93656							
					0		011	INJ 1	96632							
					51		021	INJ 2	CR132	15 MCG						
					51		021	INJ 2	93656							
					51		021	INJ 2	75647							
	F	BLAC	(b) (6)	4M	0	(b) (6)	011	INJ 1	CR132	15 MCG						
					0		011	INJ 1	87661							
					0		011	INJ 1	72462							
					56		021	INJ 2	CR132	15 MCG						
					56		021	INJ 2	91083							
	F	CAUC		2M	0		011	INJ 1	CR132	15 MCG						
					66		021	INJ 2	CR132	15 MCG						
					66		021	INJ 2	91083							

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB/DTP/OPV CONCURRENTLY
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	F	CAUC	(b) (6)	2M	66	(b) (6)	021	INJ	2	75647						
	M	CAUC		2M	0		011	INJ	1	96646						
					0		011	INJ	1	75647						
					0		011	INJ	1	CP298	15 MCG					
					63		021	INJ	2	CP298	15 MCG					
					63		021	INJ	2	10383						
					63		021	INJ	2	75647						
	M	CAUC		4M	0		011	INJ	1	CR132	15 MCG					
					0		011	INJ	1	96646						
					0		011	INJ	1	75647						
	M	CAUC		2M	0		011	INJ	1	96646						
					0		011	INJ	1	75647						
					0		011	INJ	1	CP749	15 MCG					
	F	CAUC		4M	0		011	INJ	1	93656						
					0		011	INJ	1	75647						
					0		011	INJ	1	CP749	15 MCG					
	M	CAUC		2M	0		011	INJ	1	91083						
					0		011	INJ	1	75647						
					0		011	INJ	1	CP298	15 MCG					

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	F	CAUC	(b) (6)	17M	0	(b) (6)	001	PREBLEED				158		< 5		
					0		011	INJ 1	CP241	15 MCG						
					36		011	BLEED 1				5278		20		
	F	CAUC		14M	0		001	PREBLEED				< 125		< 5		
					0		011	INJ 1	CP298	15 MCG						
					36		011	BLEED 1				5329		>= 80		
	M	CAUC		22M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP241	15 MCG						
					35		011	BLEED 1				5029				
	M	CAUC		18M	0		001	PREBLEED			05/	214	05/	< 5		
					0		011	INJ 1	CP298	15 MCG						
					28		011	BLEED 1			03/	6951	03/	20		
	F	CAUC		17M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP298	15 MCG						
					29		011	BLEED 1				621				
	F	OTHE		12M	0		001	PREBLEED				< 125		< 5		
					0		011	INJ 1	CP241	15 MCG						
					37		011	BLEED 1				6833		80		
	M	CAUC		12M	0		001	PREBLEED				406		5		
					0		011	INJ 1	CP241	15 MCG						
					50		011	BLEED 1				18206		80		
	M	OTHE		14M	0		001	PREBLEED				< 125		< 5		0
					0		011	INJ 1	CP241	15 MCG						
					42		011	BLEED 1				8056		>= 80		100
	M	CAUC		13M	0		001	PREBLEED				< 125		< 5		
					0		011	INJ 1	CP241	15 MCG						
					35		011	BLEED 1				8498		20		
	M	CAUC		23M	0		001	PREBLEED				195		< 5		
					0		011	INJ 1	CP298	15 MCG						
					32		011	BLEED 1				2937		20		
	M	BLAC		23M	0		001	PREBLEED				220		5		

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ RIA	CODE/ SBA	CODE/ OPSO
(b) (6)	M	BLAC	(b) (6)	23M	0	(b) (6)	011	INJ 1	CP749	15 MCG			
					46		011	BLEED 1			3864	>= 80	
	F	CAUC		13M	0		001	PREBLEED			126		
					0		011	INJ 1	CP298	15 MCG			
					32		011	BLEED 1			12242		
	F	CAUC		17M	0		001	PREBLEED			< 125	< 5	
					0		011	INJ 1	CR132	15 MCG			
					31		011	BLEED 1			4037	>= 80	

00162

TABLE 2

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	IGG1	CODE/	IGG2	CODE/	IGGM	CODE/	IGG TOTAL
(b) (6)	M	CAUC	(b) (6)	2M	0	(b) (6)	001	PREBLEED				< 600		< 250		< 100		< 100
					0		011	INJ 1	CP241	15 MCG								
					76		011	BLEED 1			05/	4413	05/	< 250	05/	< 100	05/	471
					76		021	INJ 2	CP241	15 MCG								
					112		021	BLEED 2			05/	5461	05/	< 250	05/	< 100	05/	558
	F	CAUC		9M	0		001	PREBLEED				< 600		< 250		< 100		< 100
					0		011	INJ 1	CP241	15 MCG								
					62		011	BLEED 1				3150		< 250		< 100		414
					62		021	INJ 2	CP241	15 MCG								
					100		021	BLEED 2				11934		< 250		< 100		1033
	M	CAUC		8M	0		001	PREBLEED				< 600		< 250		< 100		< 100
					0		011	INJ 1	CP241	15 MCG								
					69		011	BLEED 1				3734		< 250		< 100		366
					69		021	INJ 2	CP241	15 MCG								
					111		021	BLEED 2				6879		511		< 100		1403
	M	CAUC		6M	0		001	PREBLEED				< 600		< 250		102		< 100
					0		011	INJ 1	CP241	15 MCG								
					57		011	BLEED 1				1287		< 250		< 100		314
					57		021	INJ 2	CP241	15 MCG								
	M	BLAC		10M	0		001	PREBLEED			03/	< 600			03/	< 100	03/	< 100
					0		011	INJ 1	CP241	15 MCG								
					71		011	BLEED 1			03/	4777			03/	102	03/	541
					71		021	INJ 2	CP241	15 MCG								
					105		021	BLEED 2			03/	9917			03/	2878	03/	2755
	M	CAUC		4M	0		001	PREBLEED				< 600				< 100		< 100
					0		011	INJ 1	CP241	15 MCG								
					76		011	BLEED 1			05/	5612			05/	< 100	05/	1386
					76		021	INJ 2	CP241	15 MCG								
					112		021	BLEED 2			05/	4187			05/	< 100	05/	833
	M	CAUC		4M	0		001	PREBLEED				< 600				< 100		< 100
					0		011	INJ 1	CP241	15 MCG								
					69		011	BLEED 1				1055				< 100		276
					69		021	INJ 2	CP241	15 MCG								
					104		021	BLEED 2				3786				< 100		952

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	IGG1	CODE/	IGG2	CODE/	IGGM	CODE/	IGG TOTAL
(b) (6)	M	CAUC	(b) (6)	9M	0	(b) (6)	001	PREBLEED				< 600				< 100		< 100
					0		011	INJ 1	CP241	15 MCG								
					63		011	BLEED 1				2636				< 100		451
					63		021	INJ 2	CP241	15 MCG								
					98		021	BLEED 2				10642				212		765
	F	CAUC		4M	0		011	INJ 1	CP241	15 MCG								
	F	CAUC		2M	0		001	PREBLEED				< 600				< 100		< 100
					0		011	INJ 1	CP241	15 MCG								
					92		011	BLEED 1			05/	1026			05/	< 100	05/	328
					92		021	INJ 2	CP241	15 MCG								
					125		021	BLEED 2			05/	1512			05/	< 100	05/	391
	M	BLAC		2M	0		001	PREBLEED								< 100		< 100
					0		011	INJ 1	CP241	15 MCG								
					62		011	BLEED 1								1132		1505
					62		021	INJ 2	CP241	15 MCG								
					91		021	BLEED 2								801	01/	QNS
	M	CAUC		2M	0		011	INJ 1	CP241	15 MCG								
					69		021	INJ 2	CP241	15 MCG								
	F	CAUC		3M	0		001	PREBLEED								< 100		< 100
					0		011	INJ 1	CP241	15 MCG								
					63		011	BLEED 1								< 100		195
					63		021	INJ 2	CP241	15 MCG								
					98		021	BLEED 2								< 100		195
	M	CAUC		7M	0		001	PREBLEED				< 600				< 100		< 100
					0		011	INJ 1	CP241	15 MCG								
					63		011	BLEED 1				21576				118		3551
					63		021	INJ 2	CP241	15 MCG								
					99		021	BLEED 2				5315				< 100		863
	F	CAUC		2M	0		001	PREBLEED								< 100		< 100
					0		011	INJ 1	CP241	15 MCG								
					91		021	INJ 2	CP241	15 MCG								
					133		021	BLEED 1							05/	284	05/	1138
	F	CAUC		7M	0		001	PREBLEED				< 600						

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ IGG1	CODE/ IGG2	CODE/ IGGM	CODE/IGG TOTAL
(b) (6)	F	CAUC	(b) (6)	7M	0	(b) (6)	011	INJ	1	CP241	15 MCG			
					69		011	BLEED	1		1518			
					69		021	INJ	2	CP241	15 MCG			
					124		021	BLEED	2		10194			
	F	CAUC		2M	0		001	PREBLEED			< 600			
					0		011	INJ	1	CP241	15 MCG			
					64		011	BLEED	1		913			
					64		021	INJ	2	CP241	15 MCG			
					104		021	BLEED	2		892			
	F	CAUC		3M	0		001	PREBLEED			< 600			
					0		011	INJ	1	CP241	15 MCG			
					64		011	BLEED	1		746			
					64		021	INJ	2	CP241	15 MCG			
					92		021	BLEED	2		5964			
	F	CAUC		2M	0		011	INJ	1	CP241	15 MCG			
					62		021	INJ	2	CP241	15 MCG			
	M	CAUC		2M	0		011	INJ	1	CP241	15 MCG			
					62		021	INJ	2	CP241	15 MCG			
	F	CAUC		2M	0		011	INJ	1	CP241	15 MCG			
					63		021	INJ	2	CP241	15 MCG			
	M	CAUC		10M	0		011	INJ	1	CP241	15 MCG			
					63		021	INJ	2	CP241	15 MCG			
	M	CAUC		7M	0		011	INJ	1	CP298	15 MCG			
					70		021	INJ	2	CP298	15 MCG			
	F	CAUC		5M	0		011	INJ	1	CP298	15 MCG			
	M	CAUC		4M	0		011	INJ	1	CP298	15 MCG			
					83		021	INJ	2	CP298	15 MCG			
	F	CAUC		3M	0		011	INJ	1	CP298	15 MCG			
					56		021	INJ	2	CP298	15 MCG			
	M	CAUC		3M	0		011	INJ	1	CP298	15 MCG			

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT		LOT	DOSE	CODE/	IGG1	CODE/	IGG2	CODE/	IGGM	CODE/IGG TOTAL
(b) (6)	M	CAUC	(b) (6)	3M	56	(b) (6)	021	INJ	2	CP298	15 MCG							
	M	CAUC		6M	0		011	INJ	1	CP298	15 MCG							
					76		021	INJ	2	CP298	15 MCG							
	M	CAUC		2M	0		011	INJ	1	CP298	15 MCG							
					77		021	INJ	2	CP298	15 MCG							
	F	CAUC		8M	0		001	PREBLEED					< 600				< 100	< 100
					0		011	INJ	1	CP749	15 MCG							
					77		011	BLEED	1			05/	8788			05/	1662	05/ 2911
					77		021	INJ	2	CP749	15 MCG							
					107		021	BLEED	2			05/	63843			05/	6065	05/ 26861
	M	CAUC		2M	0		001	PREBLEED					< 600				< 100	222
					0		011	INJ	1	CR132	15 MCG							
					56		011	BLEED	1				< 600				695	151
					56		021	INJ	2	CR132	15 MCG							
					84		021	BLEED	2				4549				193	287
	F	CAUC		2M	0		011	INJ	1	CP298	15 MCG							
					56		021	INJ	2	CP298	15 MCG							
	F	CAUC		3M	0		011	INJ	1	CR132	15 MCG							
					55		021	INJ	2	CR132	15 MCG							
	F	CAUC		3M	0		011	INJ	1	CP749	15 MCG							
					53		021	INJ	2	CP749	15 MCG							
	M	CAUC		2M	0		011	INJ	1	CP298	15 MCG							
	M	CAUC		8M	0		011	INJ	1	CP241	15 MCG							
					63		021	INJ	2	CP241	15 MCG							
					301		091	INJ	3	CP241	15 MCG							
	M	CAUC		4M	0		011	INJ	1	CP241	15 MCG							
					63		021	INJ	2	CP241	15 MCG							
	M	CAUC		6M	0		011	INJ	1	CP241	15 MCG							
					61		021	INJ	2	CP241	15 MCG							

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT		LOT	DOSE	CODE/	IGG1	CODE/	IGG2	CODE/	IGGM	CODE/IGG	TOTAL
(b) (6)	M	CAUC	(b) (6)	7M	0	(b) (6)	011	INJ	1	CP241	15 MCG								
					66		021	INJ	2	CP241	15 MCG								
	M	CAUC		9M	0		011	INJ	1	CP241	15 MCG								
					63		021	INJ	2	CP241	15 MCG								
	M	CAUC		10M	0		011	INJ	1	CP241	15 MCG								
					63		021	INJ	2	CP241	15 MCG								
	F	BLAC		2M	0		011	INJ	1	CP241	15 MCG								
					56		021	INJ	2	CP241	15 MCG								
	F	CAUC		9M	0		011	INJ	1	CP241	15 MCG								
					67		021	INJ	2	CP241	15 MCG								
	M	CAUC		7M	0		011	INJ	1	CP241	15 MCG								
					63		021	INJ	2	CP241	15 MCG								
	F	CAUC		10M	0		011	INJ	1	CP241	15 MCG								
					73		021	INJ	2	CP241	15 MCG								
	F	CAUC		2M	0		011	INJ	1	CP241	15 MCG								
					68		021	INJ	2	CP241	15 MCG								
	M	CAUC		7M	0		011	INJ	1	CP241	15 MCG								
					70		021	INJ	2	CP241	15 MCG								
	M	CAUC		8M	0		011	INJ	1	CP241	15 MCG								
					70		021	INJ	2	CP241	15 MCG								
	F	CAUC		9M	0		011	INJ	1	CP241	15 MCG								
					60		021	INJ	2	CP241	15 MCG								
	M	CAUC		2M	0		011	INJ	1	CP241	15 MCG								
					84		021	INJ	2	CP241	15 MCG								
	F	CAUC		2M	0		011	INJ	1	CP241	15 MCG								
					62		021	INJ	2	CP241	15 MCG								
	F	CAUC		9M	0		011	INJ	1	CP298	15 MCG								

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	IGG1	CODE/	IGG2	CODE/	IGGM	CODE/IGG TOTAL
(b) (6)	F	CAUC	(b) (6)	9M	57	(b) (6)	021	INJ 2	CP298	15 MCG							
	F	CAUC		7M	0		011	INJ 1	CP298	15 MCG							
					99		021	INJ 2	CP298	15 MCG							
	M	CAUC		1M	0		011	INJ 1	CP298	15 MCG							
					75		021	INJ 2	CP298	15 MCG							
	F	CAUC		2M	0		011	INJ 1	CP298	15 MCG							
					106		021	INJ 2	CP298	15 MCG							
	F	CAUC		2M	0		001	PREBLEED				< 600				< 100	< 100
					0		011	INJ 1	CP749	15 MCG							
					77		011	BLEED 1			05/	QNS			05/	< 100	05/ 774
					77		021	INJ 2	CP749	15 MCG							
					104		021	BLEED 2			05/	20120			05/	< 100	05/ 2756
	F	CAUC		5M	0		011	INJ 1	CP298	15 MCG							
					80		021	INJ 2	CP298	15 MCG							
	M	CAUC		2M	0		011	INJ 1	CR132	15 MCG							
					80		021	INJ 2	CR132	15 MCG							
	M	CAUC		2M	0		001	PREBLEED				< 600		< 250		< 100	< 100
					0		011	INJ 1	CR132	15 MCG							
					80		011	BLEED 1			05/	5727	05/	< 250	05/	< 100	05/ 584
					80		021	INJ 2	CR132	15 MCG							
	F	CAUC		5M	0		011	INJ 1	CP298	15 MCG							
					67		021	INJ 2	CP298	15 MCG							
	M	CAUC		2M	0		011	INJ 1	CP749	15 MCG							
					55		021	INJ 2	CP749	15 MCG							
	F	CAUC		2M	0		011	INJ 1	CP298	15 MCG							
					55		021	INJ 2	CP298	15 MCG							
	M	BLAC		4M	0		011	INJ 1	CR132	15 MCG							
	F	CAUC		3M	0		011	INJ 1	CP749	15 MCG							

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	IGG1	CODE/	IGG2	CODE/	IGGM	CODE/IGG TOTAL
(b) (6)	F	CAUC	(b) (6)	3M	53	(b) (6)	021	INJ	2	CP749	15 MCG						
	M	CAUC		9M	0		011	INJ	1	CP749	15 MCG						
	M	CAUC		2M	0		011	INJ	1	CR132	15 MCG						

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB/DTP/OPV CONCURRENTLY
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT		LOT	DOSE	CODE/	IGG1	CODE/	IGG2	CODE/	IGGM	CODE/IGG	TOTAL
(b) (6)																			
[redacted]	F	CAUC	(b) (6)	2M	0	(b) (6)	001	PREBLEED					< 600		< 250		< 100		< 100
					0		011	INJ	1	CR132	15 MCG								
					105		011	BLEED	1			05/	6344	05/	< 250	05/	< 100	05/	228
					105		021	INJ	2	96646									
					105		021	INJ	2	CR132	15 MCG								
	M	CAUC		2M	0		011	INJ	1	CP749	15 MCG								
					119		021	INJ	2	91083									
					119		021	INJ	2	CP749	15 MCG								
	F	CAUC		2M	0		011	INJ	1	CP749	15 MCG								
					52		021	INJ	2	CP749	15 MCG								
					52		021	INJ	2	96646									
					52		021	INJ	2	78612									
	M	CAUC		2M	0		011	INJ	1	CR132	15 MCG								
					52		021	INJ	2	CR132	15 MCG								
					52		021	INJ	2	96642									
					52		021	INJ	2	71647									
	M	CAUC		1M	0		011	INJ	1	CR132	15 MCG								
					0		011	INJ	1	93656									
					0		011	INJ	1	96632									
					51		021	INJ	2	CR132	15 MCG								
					51		021	INJ	2	93656									
					51		021	INJ	2	75647									
	F	BLAC		4M	0		011	INJ	1	CR132	15 MCG								
					0		011	INJ	1	87661									
					0		011	INJ	1	72462									
					56		021	INJ	2	CR132	15 MCG								
					56		021	INJ	2	91083									
	F	CAUC		2M	0		011	INJ	1	CR132	15 MCG								
					66		021	INJ	2	CR132	15 MCG								
					66		021	INJ	2	91083									
					66		021	INJ	2	75647									
	M	CAUC		2M	0		011	INJ	1	96646									
					0		011	INJ	1	75647									

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB/DTP/OPV CONCURRENTLY
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT		LOT	DOSE	CODE/	IGG1	CODE/	IGG2	CODE/	IGGM	CODE/IGG TOTAL
(b) (6)	M	CAUC	(b) (6)	2M	0	(b) (6)		011	INJ	1	CP298	15 MCG						
					63			021	INJ	2	CP298	15 MCG						
					63			021	INJ	2	10383							
					63			021	INJ	2	75647							
	M	CAUC		4M	0			011	INJ	1	CR132	15 MCG						
					0			011	INJ	1	96646							
					0			011	INJ	1	75647							
	M	CAUC		2M	0			011	INJ	1	96646							
					0			011	INJ	1	75647							
					0			011	INJ	1	CP749	15 MCG						
	F	CAUC		4M	0			011	INJ	1	93656							
					0			011	INJ	1	75647							
					0			011	INJ	1	CP749	15 MCG						
	M	CAUC		2M	0			011	INJ	1	91083							
					0			011	INJ	1	75647							
					0			011	INJ	1	CP298	15 MCG						

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	IGG1	CODE/	IGG2	CODE/	IGGM	CODE/IGG TOTAL
(b) (6)	F	CAUC	(b) (6)	17M	0	(b) (6)	001	PREBLEED				< 600		< 250		106	< 100
					0		011	INJ 1	CP241	15 MCG							
					36		011	BLEED 1				1586		287		629	444
	F	CAUC		14M	0		001	PREBLEED				< 600				188	< 100
					0		011	INJ 1	CP298	15 MCG							
					36		011	BLEED 1				3449				958	1008
	M	CAUC		22M	0		011	INJ 1	CP241	15 MCG							
	M	CAUC		18M	0		001	PREBLEED							05/	< 100	05/ 103
					0		011	INJ 1	CP298	15 MCG							
					28		011	BLEED 1							03/	QNS	03/ 3938
	F	CAUC		17M	0		011	INJ 1	CP298	15 MCG							
	F	OTHE		12M	0		001	PREBLEED				< 600		< 250		233	< 100
					0		011	INJ 1	CP241	15 MCG							
					37		011	BLEED 1				7122		669		773	1246
	M	CAUC		12M	0		001	PREBLEED				< 600		< 250		115	< 100
					0		011	INJ 1	CP241	15 MCG							
					50		011	BLEED 1				12395		336		238	3234
	M	OTHE		14M	0		001	PREBLEED				< 600				< 100	< 100
					0		011	INJ 1	CP241	15 MCG							
					42		011	BLEED 1				13195				802	2933
	M	CAUC		13M	0		001	PREBLEED				< 600				< 100	< 100
					0		011	INJ 1	CP241	15 MCG							
					35		011	BLEED 1				9973				156	1473
	M	CAUC		23M	0		011	INJ 1	CP298	15 MCG							
	M	BLAC		23M	0		001	PREBLEED				< 600				196	< 100
					0		011	INJ 1	CP749	15 MCG							
					46		011	BLEED 1				6295				829	731
	F	CAUC		13M	0		011	INJ 1	CP298	15 MCG							
	F	CAUC		17M	0		001	PREBLEED				< 600		< 250		< 100	< 100

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ IGG1	CODE/ IGG2	CODE/ IGGM	CODE/IGG TOTAL
(b) (6)	F	CAUC	(b) (6)	17M	0	(b) (6)	011	INJ	1	CR132	15 MCG			
					31		011	BLEED	1		4367	< 250	700	1050

TABLE 3

ANTIBODY RESPONSES

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB CONJUGATE
ASSAY : RIA
LOT NUMBER : CP241
DOSE : 15 MCG
POPULATION : HEALTHY CHILDREN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
1- 6 MOS.	PRE INJ	57 (8/ 14)	7 (1/ 14)			0.153 (14)
	MONTH 2	100 (13/ 13)	85 (11/ 13)	92 (12/ 13)	16.3	3.444 (13)
	MONTH 3	100 (12/ 12)	83 (10/ 12)	92 (11/ 12)	21.9	5.182 (12)
	MONTH 7-10	100 (1/ 1)	100 (1/ 1)	100 (1/ 1)	44.4	5.550 (1)
7-11 MOS.	PRE INJ	13 (2/ 15)	0 (0/ 15)			0.089 (15)
	MONTH 2	93 (14/ 15)	80 (12/ 15)	93 (14/ 15)	19.9	2.816 (15)
	MONTH 3	100 (14/ 14)	100 (14/ 14)	100 (14/ 14)	75.3	10.152 (14)
	MONTH 7-10	100 (1/ 1)	100 (1/ 1)	100 (1/ 1)	22.2	2.774 (1)
12-71 MOS.	PRE INJ	20 (1/ 5)	0 (0/ 5)			0.075 (5)
	MONTH 1	100 (5/ 5)	100 (5/ 5)	100 (5/ 5)	50.3	6.589 (5)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 4

A N T I B O D Y R E S P O N S E S

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB CONJUGATE
ASSAY : RIA
LOT NUMBER : CP298
DOSE : 15 MCG
POPULATION : HEALTHY CHILDREN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
1- 6 MOS.	PRE INJ	80 (4/ 5)	20 (1/ 5)			0.277 (5)
	MONTH 2	100 (5/ 5)	80 (4/ 5)	80 (4/ 5)	9.7	2.685 (5)
	MONTH 3	100 (2/ 2)	100 (2/ 2)	100 (2/ 2)	63.5	11.195 (2)
7-11 MOS.	PRE INJ	0 (0/ 2)	0 (0/ 2)			0.063 (2)
	MONTH 2	100 (2/ 2)	100 (2/ 2)	100 (2/ 2)	38.7	4.839 (2)
12-71 MOS.	PRE INJ	25 (1/ 4)	0 (0/ 4)			0.099 (4)
	MONTH 1	100 (4/ 4)	75 (3/ 4)	100 (4/ 4)	23.6	3.303 (4)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 5

ANTIBODY RESPONSES
CHILDREN RANDOMIZED TO CONSISTENCY LOTS - ALL

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB CONJUGATE
ASSAY : RIA
LOT NUMBER : CP298
DOSE : 15 MCG
POPULATION : HEALTHY CHILDREN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
1- 6 MOS.	PRE INJ	67 (2/ 3)	33 (1/ 3)			0.375 (3)
	MONTH 2	100 (3/ 3)	67 (2/ 3)	67 (2/ 3)	3.9	1.455 (3)
12-71 MOS.	PRE INJ	50 (1/ 2)	0 (0/ 2)			0.157 (2)
	MONTH 1	100 (2/ 2)	100 (2/ 2)	100 (2/ 2)	38.3	5.996 (2)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 6

ANTIBODY RESPONSES
CHILDREN RANDOMIZED TO CONSISTENCY LOTS - ALL

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB CONJUGATE
ASSAY : RIA
LOT NUMBER : CP749
DOSE : 15 MCG
POPULATION : HEALTHY CHILDREN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
1- 6 MOS.	PRE INJ	100 (1/ 1)	0 (0/ 1)			0.988 (1)
	MONTH 2	100 (1/ 1)	0 (0/ 1)	0 (0/ 1)	0.6	0.628 (1)
12-71 MOS.	PRE INJ	100 (1/ 1)	0 (0/ 1)			0.220 (1)
	MONTH 1	100 (1/ 1)	100 (1/ 1)	100 (1/ 1)	17.6	3.864 (1)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 7

A N T I B O D Y R E S P O N S E S
CHILDREN RANDOMIZED TO CONSISTENCY LOTS - ALL

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB CONJUGATE
ASSAY : RIA
LOT NUMBER : CR132
DOSE : 15 MCG
POPULATION : HEALTHY CHILDREN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
1- 6 MOS.	PRE INJ	100 (1/ 1)	100 (1/ 1)			1.930 (1)
	MONTH 2	100 (1/ 1)	100 (1/ 1)	0 (0/ 1)	0.6	1.097 (1)
	MONTH 3	100 (1/ 1)	100 (1/ 1)	0 (0/ 1)	0.9	1.751 (1)
12-71 MOS.	PRE INJ	0 (0/ 1)	0 (0/ 1)			0.063 (1)
	MONTH 1	100 (1/ 1)	100 (1/ 1)	100 (1/ 1)	32.3	4.037 (1)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 8
CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	38	
VACCINEES WITH NO COMPLAINTS :	18	(47.4 %)
VACCINEES WITH COMPLAINTS :	20	(52.6 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 38 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	9	23.7
ERYTHEMA, INJ. SITE (<=1 IN.)	7	18.4
PAIN/SORENESS, INJ. SITE	3	7.9
SWELLING, INJ. SITE (<=1 IN.)	2	5.3
ERYTHEMA, INJ. SITE (>1 INCH)	1	2.6
SYSTEMIC REACTIONS	19	50.0
IRRITABILITY	13	34.2
FATIGUE	9	23.7
WARM TO TOUCH	8	21.1
TEETHING	5	13.2
DIARRHEA	3	7.9
NASAL DISCHARGE	2	5.3
VOMITING	2	5.3
ANOREXIA	1	2.6
CONJUNCTIVITIS	1	2.6
CRYING	1	2.6
CRYING, EXCESSIVE	1	2.6
OTITIS MEDIA	1	2.6
RASH	1	2.6
UPPER RESPIRATORY INFECTION, NOS	1	2.6
WHEEZING	1	2.6

TABLE 8 (cont.)

C L I N I C A L C O M P L A I N T S B Y F R E Q U E N C Y

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 2	
TOTAL VACCINEES :	37	
VACCINEES WITH NO COMPLAINTS :	13	(36.1 %)
VACCINEES WITH COMPLAINTS :	23	(63.9 %)
VACCINEES WITH NO DATA :	1	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 36 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	7	19.4
SWELLING, INJ. SITE (<=1 IN.)	6	16.7
ERYTHEMA, INJ. SITE (<=1 IN.)	4	11.1
ERYTHEMA, INJ. SITE (>1 INCH)	1	2.8
INDURATION, INJECTION SITE	1	2.8
PAIN/SORENESS, INJ. SITE	1	2.8
WARMTH, INJECTION SITE	1	2.8
SYSTEMIC REACTIONS	23	63.9
IRRITABILITY	12	33.3
FATIGUE	8	22.2
TEETHING	5	13.9
WARM TO TOUCH	5	13.9
ANOREXIA	2	5.6
COMMON COLD	2	5.6
CONJUNCTIVITIS	2	5.6
DIARRHEA	2	5.6
PHARYNGITIS	2	5.6
CONTUSION	1	2.8
COUGH	1	2.8
COXSACKIE VIRUS INFECTION	1	2.8
FEVER	1	2.8
LYMPHADENOPATHY	1	2.8
NASAL DISCHARGE	1	2.8
NAUSEA	1	2.8
OTALGIA	1	2.8
OTITIS MEDIA	1	2.8
PROLONGED CRYING, >1/2 HR	1	2.8
UPPER RESPIRATORY INFECTION, NOS	1	2.8
URINARY TRACT INFECTIONS	1	2.8
WHEEZING	1	2.8

TABLE 8 (cont.)

C L I N I C A L C O M P L A I N T S B Y F R E Q U E N C Y

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
POPULATION : HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	6	
VACCINEES WITH NO COMPLAINTS :	1	(16.7 %)
VACCINEES WITH COMPLAINTS :	5	(83.3 %)
VACCINEES WITH NO DATA :	0	

CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 6 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	1	16.7
ERYTHEMA, INJ. SITE (<=1 IN.)	1	16.7
SYSTEMIC REACTIONS	5	83.3
IRRITABILITY	2	33.3
NASAL DISCHARGE	2	33.3
UPPER RESPIRATORY INFECTION, NOS	2	33.3
WARM TO TOUCH	2	33.3
BRONCHIOLITIS, ACUTE	1	16.7
BRONCHITIS, ACUTE	1	16.7
FATIGUE	1	16.7
FEVER	1	16.7
NASAL CONGESTION	1	16.7
OTITIS MEDIA	1	16.7

TABLE 8 (cont.)

C L I N I C A L C O M P L A I N T S B Y F R E Q U E N C Y

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	16	
VACCINEES WITH NO COMPLAINTS :	8	(53.3 %)
VACCINEES WITH COMPLAINTS :	7	(46.7 %)
VACCINEES WITH NO DATA :	1	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 15 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	3	20.0
PAIN/SORENESS, INJ. SITE	3	20.0
ERYTHEMA, INJ. SITE (<=1 IN.)	1	6.7
SYSTEMIC REACTIONS	7	46.7
FATIGUE	3	20.0
IRRITABILITY	3	20.0
PROLONGED CRYING, >1/2 HR	2	13.3
ATOPIC DERMATITIS	1	6.7
INSOMNIA	1	6.7
NASAL CONGESTION	1	6.7
TEETHING	1	6.7
UPPER RESPIRATORY INFECTION, NOS	1	6.7
WARM TO TOUCH	1	6.7

TABLE 8 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 2	
TOTAL VACCINEES :	14	
VACCINEES WITH NO COMPLAINTS :	4	(28.6 %)
VACCINEES WITH COMPLAINTS :	10	(71.4 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 14 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	4	28.6
ERYTHEMA, INJ. SITE (<=1 IN.)	2	14.3
PAIN/SORENESS, INJ. SITE	2	14.3
INDURATION, INJECTION SITE	1	7.1
SWELLING, INJ. SITE (<=1 IN.)	1	7.1
SYSTEMIC REACTIONS	10	71.4
IRRITABILITY	6	42.9
TEETHING	5	35.7
FATIGUE	3	21.4
PROLONGED CRYING, >1/2 HR	2	14.3
WARM TO TOUCH	2	14.3
ASTHENIA	1	7.1
COMMON COLD	1	7.1
NAUSEA	1	7.1
OTITIS MEDIA	1	7.1
UPPER RESPIRATORY INFECTION, NOS	1	7.1
VOMITING	1	7.1

TABLE 8 (cont.)

CLINICAL COMPLA..TS BY FREQUENCY

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
POPULATION : HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE	:	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES	:	5	
VACCINEES WITH NO COMPLAINTS	:	2	(40.0 %)
VACCINEES WITH COMPLAINTS	:	3	(60.0 %)
VACCINEES WITH NO DATA	:	0	

CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 5 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	1	20.0
PAIN/SORENESS, INJ. SITE	1	20.0
SYSTEMIC REACTIONS	3	60.0
TEETHING	2	40.0
COMMON COLD	1	20.0
WARM TO TOUCH	1	20.0

TABLE 8 (cont.)

C L I N I C A L C O M P L A I N T S B Y F R E Q U E N C Y

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	6	
VACCINEES WITH NO COMPLAINTS :	3	(50.0 %)
VACCINEES WITH COMPLAINTS :	3	(50.0 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 6 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	1	16.7
ERYTHEMA, INJ. SITE (<=1 IN.)	1	16.7
SYSTEMIC REACTIONS	3	50.0
CRYING	2	33.3
FATIGUE	2	33.3
ASTHENIA	1	16.7
DIARRHEA	1	16.7
DYSPNEA	1	16.7
FLATULENCE	1	16.7
IRRITABILITY	1	16.7
VOMITING	1	16.7
WARM TO TOUCH	1	16.7

TABLE 8 (cont.)

C L I N I C A L C O M P L A I N T S B Y F R E Q U E N C Y

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 2	
TOTAL VACCINEES :	5	
VACCINEES WITH NO COMPLAINTS :	4	(80.0 %)
VACCINEES WITH COMPLAINTS :	1	(20.0 %)
VACCINEES WITH NO DATA :	0	

CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 5 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	1	20.0
SWELLING, INJ. SITE (<=1 IN.)	1	20.0
SWELLING, INJ. SITE (>1 INCH)	1	20.0
SYSTEMIC REACTIONS	1	20.0
FATIGUE	1	20.0
OTITIS MEDIA	1	20.0

TABLE 8 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
POPULATION : HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	1	
VACCINEES WITH NO COMPLAINTS :	0	(0.0 %)
VACCINEES WITH COMPLAINTS :	1	(100.0 %)
VACCINEES WITH NO DATA :	0	

CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 1 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	0	0.0
SYSTEMIC REACTIONS	1	100.0
WARM TO TOUCH	1	100.0

TABLE 8 (cont.)

C L I N I C A L C O M P L A I N T S B Y F R E Q U E N C Y

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB CONJUGATE
LOT NUMBER : CR132
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	6	
VACCINEES WITH NO COMPLAINTS :	2	(33.3 %)
VACCINEES WITH COMPLAINTS :	4	(66.7 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 6 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	4	66.7
SWELLING, INJ. SITE (<=1 IN.)	3	50.0
PAIN/SORENESS, INJ. SITE	1	16.7
SYSTEMIC REACTIONS	1	16.7
COMMON COLD	1	16.7
FATIGUE	1	16.7
IRRITABILITY	1	16.7
RASH	1	16.7
WARM TO TOUCH	1	16.7

TABLE 8 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB CONJUGATE
LOT NUMBER : CR132
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 2	
TOTAL VACCINEES :	4	
VACCINEES WITH NO COMPLAINTS :	3	(75.0 %)
VACCINEES WITH COMPLAINTS :	1	(25.0 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 4 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	0	0.0
SYSTEMIC REACTIONS	1	25.0
EAR FLUID	1	25.0

TABLE 8 (cont.)

C L I N I C A L C O M P L A I N T S B Y F R E Q U E N C Y

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB CONJUGATE
LOT NUMBER : CR132
POPULATION : HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	1	
VACCINEES WITH NO COMPLAINTS :	1	(100.0 %)
VACCINEES WITH COMPLAINTS :	0	(0.0 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 1 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	0	0.0

TABLE 8 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB/DTP/OPV CONCURRENT
LOT NUMBER : CP298
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	2	
VACCINEES WITH NO COMPLAINTS :	1	(50.0 %)
VACCINEES WITH COMPLAINTS :	1	(50.0 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 2 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	1	50.0
PAIN/SORENESS, INJ. SITE	1	50.0

TABLE 8 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB/DTP/OPV CONCURRENT
LOT NUMBER : CP298
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB/DTP/OPV CONCURRENT INJECTION: 1	
TOTAL VACCINEES :	2	
VACCINEES WITH NO COMPLAINTS :	0	(0.0 %)
VACCINEES WITH COMPLAINTS :	2	(100.0 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 2 VACCINEES
SYSTEMIC REACTIONS	2	100.0
PROLONGED CRYING, >1/2 HR	2	100.0
IRRITABILITY	1	50.0
WARM TO TOUCH	1	50.0

TABLE 8 (cont.)

C L I N I C A L C O M P L A I N T S B Y F R E Q U E N C Y

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB/DTP/OPV CONCURRENT
LOT NUMBER : CP298
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE	:	HIB CONJUGATE INJECTION: 2	
TOTAL VACCINEES	:	1	
VACCINEES WITH NO COMPLAINTS	:	1	(100.0 %)
VACCINEES WITH COMPLAINTS	:	0	(0.0 %)
VACCINEES WITH NO DATA	:	0	
CLINICAL COMPLAINTS		NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 1 VACCINEES
LOCAL REACTIONS (INJECTION SITE)		0	0.0

TABLE 8 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB/DTP/OPV CONCURRENT
LOT NUMBER : CP298
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB/DTP/OPV CONCURRENT INJECTION: 2	
TOTAL VACCINEES :	1	
VACCINEES WITH NO COMPLAINTS :	0	(0.0 %)
VACCINEES WITH COMPLAINTS :	1	(100.0 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 1 VACCINEES
SYSTEMIC REACTIONS	1	100.0
FATIGUE	1	100.0
IRRITABILITY	1	100.0
WARM TO TOUCH	1	100.0

TABLE 8 (cont.)

C L I N I C A L C O M P L A I N T S B Y F R E Q U E N C Y

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB/DTP/OPV CONCURRENT
LOT NUMBER : CP749
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	4	
VACCINEES WITH NO COMPLAINTS :	3	(75.0 %)
VACCINEES WITH COMPLAINTS :	1	(25.0 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 4 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	0	0.0

TABLE 8 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB/DTP/OPV CONCURRENT
LOT NUMBER : CP749
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE	:	HIB CONJUGATE INJECTION: 2	
TOTAL VACCINEES	:	2	
VACCINEES WITH NO COMPLAINTS	:	2	(100.0 %)
VACCINEES WITH COMPLAINTS	:	0	(0.0 %)
VACCINEES WITH NO DATA	:	0	

CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 2 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	0	0.0

TABLE 8 (cont.)

C L I N I C A L C O M P L A I N T S B Y F R E Q U E N C Y

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB/DTP/OPV CONCURRENT
LOT NUMBER : CP749
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE	:	HIB/DTP/OPV CONCURRENT INJECTION: 2	
TOTAL VACCINEES	:	2	
VACCINEES WITH NO COMPLAINTS	:	1	(50.0 %)
VACCINEES WITH COMPLAINTS	:	1	(50.0 %)
VACCINEES WITH NO DATA	:	0	

CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 2 VACCINEES
SYSTEMIC REACTIONS	1	50.0
FATIGUE	1	50.0
NASAL CONGESTION	1	50.0

TABLE 8 (cont.)

C L I N I C A L C O M P L A I N T S B Y F R E Q U E N C Y

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB/DTP/OPV CONCURRENT
LOT NUMBER : CR132
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	6	
VACCINEES WITH NO COMPLAINTS :	4	(66.7 %)
VACCINEES WITH COMPLAINTS :	2	(33.3 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 6 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	1	16.7
SWELLING, INJ. SITE (<=1 IN.)	1	16.7

TABLE 8 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB/DTP/OPV CONCURRENT
LOT NUMBER : CR132
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB/DTP/OPV CONCURRENT INJECTION: 1	
TOTAL VACCINEES :	6	
VACCINEES WITH NO COMPLAINTS :	0	(0.0 %)
VACCINEES WITH COMPLAINTS :	3	(100.0 %)
VACCINEES WITH NO DATA :	3	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 3 VACCINEES
SYSTEMIC REACTIONS	3	100.0
IRRITABILITY	3	100.0
FATIGUE	2	66.7
WARM TO TOUCH	1	33.3

TABLE 8 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB/DTP/OPV CONCURRENT
LOT NUMBER : CR132
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 2	
TOTAL VACCINEES :	5	
VACCINEES WITH NO COMPLAINTS :	3	(60.0 %)
VACCINEES WITH COMPLAINTS :	2	(40.0 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 5 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	2	40.0
ERYTHEMA, INJ. SITE (<=1 IN.)	1	20.0
PAIN/SORENESS, INJ. SITE	1	20.0
SWELLING, INJ. SITE (<=1 IN.)	1	20.0

TABLE 8 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB/DTP/OPV CONCURRENT
LOT NUMBER : CR132
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB/DTP/OPV CONCURRENT INJECTION: 2	
TOTAL VACCINEES :	5	
VACCINEES WITH NO COMPLAINTS :	2	(40.0 %)
VACCINEES WITH COMPLAINTS :	3	(60.0 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 5 VACCINEES
SYSTEMIC REACTIONS	3	60.0
FATIGUE	2	40.0
IRRITABILITY	2	40.0
WARM TO TOUCH	2	40.0
COMMON COLD	1	20.0
NASAL DISCHARGE	1	20.0
SNEEZING	1	20.0
VOMITING	1	20.0

TABLE 9

CLINICAL COMPLAINTS

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (38 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5	COMPLAINTS
LOCAL REACTIONS	9 (23.7%)	4 (10.5%)	2 (5.3%)	1 (2.6%)	1 (2.6%)	1 (2.6%)	9 (23.7%)
ERYTHEMA, INJ. SITE (>1 INCH)	1 (2.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.6%)
ERYTHEMA, INJ. SITE (<=1 IN.)	6 (15.8%)	4 (10.5%)	2 (5.3%)	1 (2.6%)	1 (2.6%)	1 (2.6%)	7 (18.4%)
PAIN/SORENESS, INJ. SITE	2 (5.3%)	1 (2.6%)	1 (2.6%)	0 (0.0%)	0 (0.0%)	1 (2.6%)	3 (7.9%)
SWELLING, INJ. SITE (<=1 IN.)	1 (2.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.6%)	2 (5.3%)
SYSTEMIC	15 (39.5%)	12 (31.6%)	5 (13.2%)	5 (13.2%)	3 (7.9%)	3 (7.9%)	19 (50.0%)
BODY AS A WHOLE/SITE UNSPEC.	8 (21.1%)	8 (21.1%)	1 (2.6%)	2 (5.3%)	0 (0.0%)	1 (2.6%)	12 (31.6%)
FATIGUE	8 (21.1%)	3 (7.9%)	1 (2.6%)	2 (5.3%)	0 (0.0%)	1 (2.6%)	9 (23.7%)
WARM TO TOUCH	3 (7.9%)	5 (13.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.6%)	8 (21.1%)
DIGESTIVE SYSTEM	7 (18.4%)	5 (13.2%)	3 (7.9%)	2 (5.3%)	1 (2.6%)	1 (2.6%)	8 (21.1%)
ANOREXIA	1 (2.6%)	1 (2.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.6%)

TABLE 9 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (38 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
DIARRHEA	3 (7.9%)	1 (2.6%)	1 (2.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		3 (7.9%)
TEETHING	4 (10.5%)	2 (5.3%)	2 (5.3%)	2 (5.3%)	1 (2.6%)	1 (2.6%)		5 (13.2%)
VOMITING	2 (5.3%)	2 (5.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (5.3%)
NERVOUS SYSTEM & PSYCHIATRIC	10 (26.3%)	9 (23.7%)	2 (5.3%)	1 (2.6%)	1 (2.6%)	1 (2.6%)		14 (36.8%)
CRYING	1 (2.6%)	1 (2.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (2.6%)
CRYING, EXCESSIVE	1 (2.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (2.6%)
IRRITABILITY	8 (21.1%)	8 (21.1%)	2 (5.3%)	1 (2.6%)	1 (2.6%)	1 (2.6%)		13 (34.2%)
RESPIRATORY SYSTEM	2 (5.3%)	2 (5.3%)	2 (5.3%)	1 (2.6%)	1 (2.6%)	1 (2.6%)		3 (7.9%)
NASAL DISCHARGE	1 (2.6%)	2 (5.3%)	1 (2.6%)	1 (2.6%)	1 (2.6%)	1 (2.6%)		2 (5.3%)
UPPER RESPIRATORY INFECTION, NOS	1 (2.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (2.6%)
WHEEZING	0 (0.0%)	1 (2.6%)	1 (2.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (2.6%)
SKIN & SKIN APPENDAGE	0 (0.0%)	1 (2.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (2.6%)

TABLE 9 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (38 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
RASH	0 (0.0%)	1 (2.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (2.6%)
SPECIAL SENSES	1 (2.6%)	2 (5.3%)	1 (2.6%)	1 (2.6%)	1 (2.6%)	1 (2.6%)		2 (5.3%)
CONJUNCTIVITIS	0 (0.0%)	1 (2.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (2.6%)
OTITIS MEDIA	1 (2.6%)	1 (2.6%)	1 (2.6%)	1 (2.6%)	1 (2.6%)	1 (2.6%)		1 (2.6%)
VACCINEES WITH COMPLAINTS	17 (44.7%)	13 (34.2%)	7 (18.4%)	6 (15.8%)	4 (10.5%)	4 (10.5%)		20 (52.6%)
VACCINEES WITH NO COMPLAINTS	21 (55.3%)	25 (65.8%)	31 (81.6%)	32 (84.2%)	34 (89.5%)	34 (89.5%)		18 (47.4%)
TOTAL VACCINEES REPORTING	38	38	38	38	38	38		38
VACCINEES WITH NO DATA	0	0	0	0	0	0		0

TABLE 9 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (37 VACCINEES) - INJECTION: 2						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5	COMPLAINTS
LOCAL REACTIONS	4 (11.1%)	6 (16.7%)	3 (8.3%)	3 (8.3%)	2 (5.6%)	2 (5.7%)	7 (19.4%)
ERYTHEMA, INJ. SITE (>1 INCH)	1 (2.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.8%)
ERYTHEMA, INJ. SITE (<=1 IN.)	1 (2.8%)	4 (11.1%)	1 (2.8%)	1 (2.8%)	0 (0.0%)	0 (0.0%)	4 (11.1%)
INDURATION, INJECTION SITE	0 (0.0%)	1 (2.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.8%)
PAIN/SORENESS, INJ. SITE	1 (2.8%)	1 (2.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.8%)
SWELLING, INJ. SITE (<=1 IN.)	3 (8.3%)	5 (13.9%)	3 (8.3%)	3 (8.3%)	2 (5.6%)	2 (5.7%)	6 (16.7%)
WARMTH, INJECTION SITE	0 (0.0%)	1 (2.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.8%)
SYSTEMIC	14 (38.9%)	14 (38.9%)	13 (36.1%)	9 (25.0%)	9 (25.0%)	7 (20.0%)	23 (63.9%)
BODY AS A WHOLE/SITE UNSPEC.	6 (16.7%)	6 (16.7%)	4 (11.1%)	2 (5.6%)	3 (8.3%)	1 (2.9%)	11 (30.6%)
COXSACKIE VIRUS INFECTION	0 (0.0%)	1 (2.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.8%)
FATIGUE	5 (13.9%)	3 (8.3%)	2 (5.6%)	1 (2.8%)	2 (5.6%)	0 (0.0%)	8 (22.2%)

TABLE 9 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (37 VACCINEES) - INJECTION: 2						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5	COMPLAINTS
FEVER	0 (0.0%)	1 (2.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.8%)
HARM TO TOUCH	2 (5.6%)	3 (8.3%)	3 (8.3%)	1 (2.8%)	2 (5.6%)	1 (2.9%)	5 (13.9%)
DIGESTIVE SYSTEM	4 (11.1%)	5 (13.9%)	3 (8.3%)	3 (8.3%)	3 (8.3%)	3 (8.6%)	9 (25.0%)
ANOREXIA	1 (2.8%)	1 (2.8%)	1 (2.8%)	1 (2.8%)	0 (0.0%)	0 (0.0%)	2 (5.6%)
DIARRHEA	0 (0.0%)	1 (2.8%)	0 (0.0%)	1 (2.8%)	1 (2.8%)	1 (2.9%)	2 (5.6%)
NAUSEA	0 (0.0%)	0 (0.0%)	1 (2.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.8%)
TEETHING	3 (8.3%)	3 (8.3%)	2 (5.6%)	1 (2.8%)	2 (5.6%)	2 (5.7%)	5 (13.9%)
HEMIC & LYMPHATIC SYSTEM	0 (0.0%)	0 (0.0%)	1 (2.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.8%)
LYMPHADENOPATHY	0 (0.0%)	0 (0.0%)	1 (2.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.8%)
NERVOUS SYSTEM & PSYCHIATRIC	8 (22.2%)	5 (13.9%)	6 (16.7%)	3 (8.3%)	3 (8.3%)	0 (0.0%)	12 (33.3%)
IRRITABILITY	8 (22.2%)	5 (13.9%)	6 (16.7%)	3 (8.3%)	3 (8.3%)	0 (0.0%)	12 (33.3%)
PROLONGED CRYING, >1/2 HR	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.8%)	0 (0.0%)	1 (2.8%)

TABLE 9 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (37 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
RESPIRATORY SYSTEM	2 (5.6%)	3 (8.3%)	4 (11.1%)	3 (8.3%)	1 (2.8%)	1 (2.9%)		6 (16.7%)
COMMON COLD	2 (5.6%)	1 (2.8%)	1 (2.8%)	1 (2.8%)	1 (2.8%)	1 (2.9%)		2 (5.6%)
COUGH	0 (0.0%)	1 (2.8%)	1 (2.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (2.8%)
NASAL DISCHARGE	1 (2.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (2.8%)
PHARYNGITIS	0 (0.0%)	1 (2.8%)	1 (2.8%)	1 (2.8%)	0 (0.0%)	0 (0.0%)		2 (5.6%)
UPPER RESPIRATORY INFECTION, NOS	0 (0.0%)	1 (2.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (2.8%)
WHEEZING	0 (0.0%)	0 (0.0%)	1 (2.8%)	1 (2.8%)	0 (0.0%)	0 (0.0%)		1 (2.8%)
SKIN & SKIN APPENDAGE	0 (0.0%)	0 (0.0%)	1 (2.8%)	1 (2.8%)	0 (0.0%)	0 (0.0%)		1 (2.8%)
CONTUSION	0 (0.0%)	0 (0.0%)	1 (2.8%)	1 (2.8%)	0 (0.0%)	0 (0.0%)		1 (2.8%)
SPECIAL SENSES	1 (2.8%)	2 (5.6%)	2 (5.6%)	3 (8.3%)	2 (5.6%)	2 (5.7%)		3 (8.3%)
CONJUNCTIVITIS	1 (2.8%)	2 (5.6%)	2 (5.6%)	2 (5.6%)	2 (5.6%)	2 (5.7%)		2 (5.6%)
OTALGIA	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.8%)	0 (0.0%)	0 (0.0%)		1 (2.8%)

TABLE 9 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (37 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
OTITIS MEDIA	1 (2.8%)	1 (2.8%)	1 (2.8%)	1 (2.8%)	1 (2.8%)	1 (2.9%)		1 (2.8%)
UROGENITAL SYSTEM	1 (2.8%)	1 (2.8%)	1 (2.8%)	1 (2.8%)	1 (2.8%)	1 (2.9%)		1 (2.8%)
URINARY TRACT INFECTIONS	1 (2.8%)	1 (2.8%)	1 (2.8%)	1 (2.8%)	1 (2.8%)	1 (2.9%)		1 (2.8%)
VACCINEES WITH COMPLAINTS	15 (41.7%)	15 (41.7%)	14 (38.9%)	11 (30.6%)	10 (27.8%)	8 (22.9%)		23 (63.9%)
VACCINEES WITH NO COMPLAINTS	21 (58.3%)	21 (58.3%)	22 (61.1%)	25 (69.4%)	26 (72.2%)	27 (77.1%)		13 (36.1%)
TOTAL VACCINEES REPORTING	36	36	36	36	36	35		36
VACCINEES WITH NO DATA	1	1	1	1	1	2		1

TABLE 9 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (6 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5	COMPLAINTS
LOCAL REACTIONS	1 (16.7%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
ERYTHEMA, INJ. SITE (<=1 IN.)	1 (16.7%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
SYSTEMIC	5 (83.3%)	4 (66.7%)	4 (66.7%)	4 (66.7%)	5 (83.3%)	5 (83.3%)	5 (83.3%)
BODY AS A WHOLE/SITE UNSPEC.	2 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)	1 (16.7%)	3 (50.0%)
FATIGUE	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)	1 (16.7%)
FEVER	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)	1 (16.7%)
HARM TO TOUCH	2 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)	0 (0.0%)	2 (33.3%)
NERVOUS SYSTEM & PSYCHIATRIC	0 (0.0%)	0 (0.0%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	1 (16.7%)	2 (33.3%)
IRRITABILITY	0 (0.0%)	0 (0.0%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	1 (16.7%)	2 (33.3%)
RESPIRATORY SYSTEM	3 (50.0%)	3 (50.0%)	3 (50.0%)	3 (50.0%)	4 (66.7%)	4 (66.7%)	4 (66.7%)
BRONCHIOLITIS, ACUTE	0 (0.0%)	0 (0.0%)	1 (16.7%)	1 (16.7%)	1 (16.7%)	1 (16.7%)	1 (16.7%)

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TABLE 9 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (6 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
BRONCHITIS, ACUTE	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (16.7%)
NASAL CONGESTION	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)	1 (16.7%)		1 (16.7%)
NASAL DISCHARGE	1 (16.7%)	1 (16.7%)	1 (16.7%)	1 (16.7%)	2 (33.3%)	2 (33.3%)		2 (33.3%)
UPPER RESPIRATORY INFECTION, NOS	2 (33.3%)	2 (33.3%)	2 (33.3%)	2 (33.3%)	2 (33.3%)	2 (33.3%)		2 (33.3%)
SPECIAL SENSES	1 (16.7%)	1 (16.7%)	1 (16.7%)	1 (16.7%)	1 (16.7%)	1 (16.7%)		1 (16.7%)
OTITIS MEDIA	1 (16.7%)	1 (16.7%)	1 (16.7%)	1 (16.7%)	1 (16.7%)	1 (16.7%)		1 (16.7%)
VACCINEES WITH COMPLAINTS	5 (83.3%)	4 (66.7%)	4 (66.7%)	4 (66.7%)	5 (83.3%)	5 (83.3%)		5 (83.3%)
VACCINEES WITH NO COMPLAINTS	1 (16.7%)	2 (33.3%)	2 (33.3%)	2 (33.3%)	1 (16.7%)	1 (16.7%)		1 (16.7%)
TOTAL VACCINEES REPORTING	6	6	6	6	6	6		6
VACCINEES WITH NO DATA	0	0	0	0	0	0		0

TABLE 9 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (16 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
LOCAL REACTIONS	3 (20.0%)	1 (6.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		3 (20.0%)
ERYTHEMA, INJ. SITE (<=1 IN.)	1 (6.7%)	1 (6.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (6.7%)
PAIN/SORENESS, INJ. SITE	3 (20.0%)	1 (6.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		3 (20.0%)
SYSTEMIC	6 (40.0%)	1 (6.7%)	0 (0.0%)	0 (0.0%)	1 (6.7%)	2 (13.3%)		7 (46.7%)
BODY AS A WHOLE/SITE UNSPEC.	4 (26.7%)	1 (6.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		4 (26.7%)
FATIGUE	3 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		3 (20.0%)
WARM TO TOUCH	1 (6.7%)	1 (6.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (6.7%)
DIGESTIVE SYSTEM	1 (6.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (6.7%)
TEETHING	1 (6.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (6.7%)
NERVOUS SYSTEM & PSYCHIATRIC	3 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (6.7%)	2 (13.3%)		4 (26.7%)
INSOMNIA	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (6.7%)		1 (6.7%)

TABLE 9 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (16 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
IRRITABILITY	2 (13.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (6.7%)		3 (20.0%)
PROLONGED CRYING, >1/2 HR	1 (6.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (6.7%)	1 (6.7%)		2 (13.3%)
RESPIRATORY SYSTEM	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (6.7%)	1 (6.7%)		1 (6.7%)
NASAL CONGESTION	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (6.7%)	1 (6.7%)		1 (6.7%)
UPPER RESPIRATORY INFECTION, NOS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (6.7%)	1 (6.7%)		1 (6.7%)
SKIN & SKIN APPENDAGE	1 (6.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (6.7%)
ATOPIC DERMATITIS	1 (6.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (6.7%)
VACCINEES WITH COMPLAINTS	6 (40.0%)	1 (6.7%)	0 (0.0%)	0 (0.0%)	1 (6.7%)	2 (13.3%)		7 (46.7%)
VACCINEES WITH NO COMPLAINTS	9 (60.0%)	14 (93.3%)	15 (100.0%)	15 (100.0%)	14 (93.3%)	13 (86.7%)		8 (53.3%)
TOTAL VACCINEES REPORTING	15	15	15	15	15	15		15
VACCINEES WITH NO DATA	1	1	1	1	1	1		1

TABLE 9 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (14 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
LOCAL REACTIONS	3 (21.4%)	2 (14.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		4 (28.6%)
ERYTHEMA, INJ. SITE (<=1 IN.)	2 (14.3%)	1 (7.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (14.3%)
INDURATION, INJECTION SITE	0 (0.0%)	1 (7.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (7.1%)
PAIN/SORENESS, INJ. SITE	2 (14.3%)	1 (7.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (14.3%)
SWELLING, INJ. SITE (<=1 IN.)	0 (0.0%)	1 (7.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (7.1%)
SYSTEMIC	8 (57.1%)	7 (50.0%)	6 (46.2%)	6 (46.2%)	5 (38.5%)	5 (38.5%)		10 (71.4%)
BODY AS A WHOLE/SITE UNSPEC.	3 (21.4%)	2 (14.3%)	1 (7.7%)	1 (7.7%)	0 (0.0%)	0 (0.0%)		4 (28.6%)
ASTHENIA	0 (0.0%)	1 (7.1%)	1 (7.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (7.1%)
FATIGUE	2 (14.3%)	1 (7.1%)	1 (7.7%)	1 (7.7%)	0 (0.0%)	0 (0.0%)		3 (21.4%)
WARM TO TOUCH	1 (7.1%)	2 (14.3%)	1 (7.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (14.3%)
DIGESTIVE SYSTEM	4 (28.6%)	6 (42.9%)	4 (30.8%)	4 (30.8%)	4 (30.8%)	4 (30.8%)		6 (42.9%)

TABLE 9 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (14 VACCINEES) - INJECTION: 2						
	DAYS POST VACCINATION						NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5	
NAUSEA	0 (0.0%)	1 (7.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.1%)
TEETHING	4 (28.6%)	5 (35.7%)	4 (30.8%)	4 (30.8%)	4 (30.8%)	4 (30.8%)	5 (35.7%)
VOMITING	0 (0.0%)	1 (7.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.1%)
NERVOUS SYSTEM & PSYCHIATRIC	3 (21.4%)	4 (28.6%)	2 (15.4%)	3 (23.1%)	1 (7.7%)	1 (7.7%)	6 (42.9%)
IRRITABILITY	3 (21.4%)	2 (14.3%)	2 (15.4%)	3 (23.1%)	1 (7.7%)	1 (7.7%)	6 (42.9%)
PROLONGED CRYING, >1/2 HR	0 (0.0%)	2 (14.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (14.3%)
RESPIRATORY SYSTEM	0 (0.0%)	0 (0.0%)	1 (7.7%)	2 (15.4%)	1 (7.7%)	1 (7.7%)	2 (14.3%)
COMMON COLD	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.7%)	1 (7.7%)	1 (7.7%)	1 (7.1%)
UPPER RESPIRATORY INFECTION, NOS	0 (0.0%)	0 (0.0%)	1 (7.7%)	1 (7.7%)	0 (0.0%)	0 (0.0%)	1 (7.1%)
SPECIAL SENSES	0 (0.0%)	0 (0.0%)	1 (7.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.1%)
OTITIS MEDIA	0 (0.0%)	0 (0.0%)	1 (7.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.1%)
VACCINEES WITH COMPLAINTS	9 (64.3%)	8 (57.1%)	6 (46.2%)	6 (46.2%)	5 (38.5%)	5 (38.5%)	10 (71.4%)

TABLE 9 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (14 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
								**********
VACCINEES WITH NO COMPLAINTS	5 (35.7%)	6 (42.9%)	7 (53.8%)	7 (53.8%)	8 (61.5%)	8 (61.5%)		4 (28.6%)
TOTAL VACCINEES REPORTING	14	14	13	13	13	13		14
VACCINEES WITH NO DATA	0	0	1	1	1	1		0

TABLE 9 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (5 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5	COMPLAINTS
LOCAL REACTIONS	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)
PAIN/SORENESS, INJ. SITE	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)
SYSTEMIC	1 (20.0%)	1 (20.0%)	3 (60.0%)	2 (40.0%)	2 (40.0%)	2 (40.0%)	3 (60.0%)
BODY AS A WHOLE/SITE UNSPEC.	1 (20.0%)	1 (20.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)
WARM TO TOUCH	1 (20.0%)	1 (20.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)
DIGESTIVE SYSTEM	1 (20.0%)	1 (20.0%)	2 (40.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	2 (40.0%)
TEETHING	1 (20.0%)	1 (20.0%)	2 (40.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	2 (40.0%)
RESPIRATORY SYSTEM	0 (0.0%)	0 (0.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)
COMMON COLD	0 (0.0%)	0 (0.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)
VACCINEES WITH COMPLAINTS	2 (40.0%)	1 (20.0%)	3 (60.0%)	2 (40.0%)	2 (40.0%)	2 (40.0%)	3 (60.0%)
VACCINEES WITH NO COMPLAINTS	3 (60.0%)	4 (80.0%)	2 (40.0%)	3 (60.0%)	3 (60.0%)	3 (60.0%)	2 (40.0%)

TABLE 9 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (5 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5	COMPLAINTS
TOTAL VACCINEES REPORTING	5	5	5	5	5	5	5
VACCINEES WITH NO DATA	0	0	0	0	0	0	0

TABLE 9 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (6 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5	COMPLAINTS
LOCAL REACTIONS	1 (16.7%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
ERYTHEMA, INJ. SITE (<=1 IN.)	1 (16.7%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
SYSTEMIC	2 (33.3%)	3 (50.0%)	0 (0.0%)	2 (33.3%)	1 (16.7%)	1 (16.7%)	3 (50.0%)
BODY AS A WHOLE/SITE UNSPEC.	2 (33.3%)	2 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (33.3%)
ASTHENIA	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
FATIGUE	2 (33.3%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (33.3%)
WARM TO TOUCH	0 (0.0%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
DIGESTIVE SYSTEM	1 (16.7%)	1 (16.7%)	0 (0.0%)	1 (16.7%)	0 (0.0%)	1 (16.7%)	1 (16.7%)
DIARRHEA	1 (16.7%)	1 (16.7%)	0 (0.0%)	1 (16.7%)	0 (0.0%)	1 (16.7%)	1 (16.7%)
FLATULENCE	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)	1 (16.7%)
VOMITING	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)

TABLE 9 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (6 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
NERVOUS SYSTEM & PSYCHIATRIC	1 (16.7%)	1 (16.7%)	0 (0.0%)	1 (16.7%)	1 (16.7%)	0 (0.0%)		3 (50.0%)
CRYING	1 (16.7%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (33.3%)
IRRITABILITY	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)	1 (16.7%)	0 (0.0%)		1 (16.7%)
RESPIRATORY SYSTEM	1 (16.7%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (16.7%)
DYSPNEA	1 (16.7%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (16.7%)
VACCINEES WITH COMPLAINTS	2 (33.3%)	3 (50.0%)	0 (0.0%)	2 (33.3%)	1 (16.7%)	1 (16.7%)		3 (50.0%)
VACCINEES WITH NO COMPLAINTS	4 (66.7%)	3 (50.0%)	6 (100.0%)	4 (66.7%)	5 (83.3%)	5 (83.3%)		3 (50.0%)
TOTAL VACCINEES REPORTING	6	6	6	6	6	6		6
VACCINEES WITH NO DATA	0	0	0	0	0	0		0

TABLE 9 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (5 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
LOCAL REACTIONS	1 (20.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (20.0%)
SWELLING, INJ. SITE (>1 INCH)	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (20.0%)
SWELLING, INJ. SITE (<=1 IN.)	0 (0.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (20.0%)
SYSTEMIC	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)		1 (20.0%)
BODY AS A WHOLE/SITE UNSPEC.	0 (0.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (20.0%)
FATIGUE	0 (0.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (20.0%)
SPECIAL SENSES	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)		1 (20.0%)
OTITIS MEDIA	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)		1 (20.0%)
VACCINEES WITH COMPLAINTS	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)		1 (20.0%)
VACCINEES WITH NO COMPLAINTS	4 (80.0%)	4 (80.0%)	4 (80.0%)	4 (80.0%)	4 (80.0%)	4 (80.0%)		4 (80.0%)
TOTAL VACCINEES REPORTING	5	5	5	5	5	5		5

TABLE 9 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (5 VACCINEES) - INJECTION: 2						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5	COMPLAINTS
							**********
VACCINEES WITH NO DATA	0	0	0	0	0	0	0

TABLE 9 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (1 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5	**********
SYSTEMIC	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)
BODY AS A WHOLE/SITE UNSPEC.	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)
WARM TO TOUCH	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)
VACCINEES WITH COMPLAINTS	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)
VACCINEES WITH NO COMPLAINTS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
TOTAL VACCINEES REPORTING	1	1	1	1	1	1	1
VACCINEES WITH NO DATA	0	0	0	0	0	0	0

TABLE 9 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB CONJUGATE
LOT NUMBER : CR132
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (6 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5	COMPLAINTS
LOCAL REACTIONS	4 (66.7%)	3 (50.0%)	1 (16.7%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	4 (66.7%)
PAIN/SORENESS, INJ. SITE	1 (16.7%)	1 (16.7%)	1 (16.7%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
SWELLING, INJ. SITE (<=1 IN.)	3 (50.0%)	2 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (50.0%)
SYSTEMIC	1 (16.7%)	1 (16.7%)	1 (16.7%)	1 (16.7%)	1 (16.7%)	1 (16.7%)	1 (16.7%)
BODY AS A WHOLE/SITE UNSPEC.	1 (16.7%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
FATIGUE	1 (16.7%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
WARM TO TOUCH	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
NERVOUS SYSTEM & PSYCHIATRIC	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
IRRITABILITY	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
RESPIRATORY SYSTEM	0 (0.0%)	1 (16.7%)	1 (16.7%)	1 (16.7%)	1 (16.7%)	1 (16.7%)	1 (16.7%)
COMMON COLD	0 (0.0%)	1 (16.7%)	1 (16.7%)	1 (16.7%)	1 (16.7%)	1 (16.7%)	1 (16.7%)

TABLE 9 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB CONJUGATE
LOT NUMBER : CR132
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (6 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
SKIN & SKIN APPENDAGE	0 (0.0%)	0 (0.0%)	1 (16.7%)	1 (16.7%)	0 (0.0%)	0 (0.0%)		1 (16.7%)
RASH	0 (0.0%)	0 (0.0%)	1 (16.7%)	1 (16.7%)	0 (0.0%)	0 (0.0%)		1 (16.7%)
VACCINEES WITH COMPLAINTS	4 (66.7%)	3 (50.0%)	1 (16.7%)	1 (16.7%)	1 (16.7%)	1 (16.7%)		4 (66.7%)
VACCINEES WITH NO COMPLAINTS	2 (33.3%)	3 (50.0%)	5 (83.3%)	5 (83.3%)	5 (83.3%)	5 (83.3%)		2 (33.3%)
TOTAL VACCINEES REPORTING	6	6	6	6	6	6		6
VACCINEES WITH NO DATA	0	0	0	0	0	0		0

TABLE 9 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB CONJUGATE
LOT NUMBER : CR132
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (4 VACCINEES) - INJECTION: 2						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5	COMPLAINTS
SYSTEMIC	1 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (25.0%)
SPECIAL SENSES	1 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (25.0%)
EAR FLUID	1 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (25.0%)
VACCINEES WITH COMPLAINTS	1 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (25.0%)
VACCINEES WITH NO COMPLAINTS	3 (75.0%)	4 (100.0%)	3 (100.0%)	3 (100.0%)	3 (100.0%)	3 (100.0%)	3 (75.0%)
TOTAL VACCINEES REPORTING	4	4	3	3	3	3	4
VACCINEES WITH NO DATA	0	0	1	1	1	1	0

TABLE 9 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB CONJUGATE
LOT NUMBER : CR132
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (1 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5	COMPLAINTS
							**********
VACCINEES WITH COMPLAINTS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
VACCINEES WITH NO COMPLAINTS	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)
TOTAL VACCINEES REPORTING	1	1	1	1	1	1	1
VACCINEES WITH NO DATA	0	0	0	0	0	0	0

TABLE 10

MAXIMUM TEMPERATURES

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (38 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
NORMAL	4 (10.8%)	5 (13.9%)	6 (16.2%)	5 (14.3%)	6 (17.6%)	5 (14.3%)		4 (10.5%)
< 99	24 (64.9%)	18 (50.0%)	26 (70.3%)	21 (60.0%)	21 (61.8%)	24 (68.6%)		16 (42.1%)
99 - 99.9	7 (18.9%)	10 (27.8%)	5 (13.5%)	9 (25.7%)	6 (17.6%)	4 (11.4%)		12 (31.6%)
100 - 100.9	1 (2.7%)	3 (8.3%)	0 (0.0%)	0 (0.0%)	1 (2.9%)	1 (2.9%)		4 (10.5%)
101 - 101.9	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.9%)		1 (2.6%)
102 - 102.9	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (2.6%)
TEMPERATURE TAKEN	37 (97.4%)	36 (94.7%)	37 (97.4%)	35 (92.1%)	34 (89.5%)	35 (92.1%)		38 (100.0%)
TEMPERATURE NOT TAKEN	1 (2.6%)	2 (5.3%)	1 (2.6%)	3 (7.9%)	4 (10.5%)	3 (7.9%)		0 (0.0%)

TABLE 10 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (37 VACCINEES) - INJECTION 2							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
NORMAL	5 (13.9%)	5 (14.3%)	6 (16.7%)	6 (16.7%)	5 (14.7%)	5 (14.7%)		5 (13.9%)
< 99	21 (58.3%)	21 (60.0%)	23 (63.9%)	24 (66.7%)	22 (64.7%)	22 (64.7%)		16 (44.4%)
99 - 99.9	7 (19.4%)	6 (17.1%)	4 (11.1%)	5 (13.9%)	7 (20.6%)	6 (17.6%)		7 (19.4%)
100 - 100.9	3 (8.3%)	1 (2.9%)	1 (2.8%)	0 (0.0%)	0 (0.0%)	1 (2.9%)		5 (13.9%)
101 - 101.9	0 (0.0%)	1 (2.9%)	2 (5.6%)	1 (2.8%)	0 (0.0%)	0 (0.0%)		2 (5.6%)
103 - 103.9	0 (0.0%)	1 (2.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (2.8%)
TEMPERATURE TAKEN	36 (97.3%)	35 (94.6%)	36 (97.3%)	36 (97.3%)	34 (91.9%)	34 (91.9%)		36 (97.3%)
TEMPERATURE NOT TAKEN	1 (2.7%)	2 (5.4%)	1 (2.7%)	1 (2.7%)	3 (8.1%)	3 (8.1%)		1 (2.7%)

TABLE 10 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (6 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
NORMAL	1 (16.7%)	1 (16.7%)	1 (16.7%)	1 (16.7%)	1 (16.7%)	1 (16.7%)		1 (16.7%)
< 99	2 (33.3%)	2 (33.3%)	3 (50.0%)	3 (50.0%)	3 (50.0%)	2 (33.3%)		1 (16.7%)
99 - 99.9	1 (16.7%)	3 (50.0%)	2 (33.3%)	2 (33.3%)	1 (16.7%)	2 (33.3%)		1 (16.7%)
100 - 100.9	2 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)	1 (16.7%)		3 (50.0%)
TEMPERATURE TAKEN	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)		6 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)

TABLE 10 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (16 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
NORMAL	1 (6.7%)	2 (13.3%)	3 (21.4%)	5 (33.3%)	5 (35.7%)	5 (35.7%)		1 (6.7%)
< 99	8 (53.3%)	9 (60.0%)	10 (71.4%)	10 (66.7%)	8 (57.1%)	8 (57.1%)		7 (46.7%)
99 - 99.9	6 (40.0%)	4 (26.7%)	1 (7.1%)	0 (0.0%)	1 (7.1%)	1 (7.1%)		7 (46.7%)
TEMPERATURE TAKEN	15 (93.8%)	15 (93.8%)	14 (87.5%)	15 (93.8%)	14 (87.5%)	14 (87.5%)		15 (93.8%)
TEMPERATURE NOT TAKEN	1 (6.3%)	1 (6.3%)	2 (12.5%)	1 (6.3%)	2 (12.5%)	2 (12.5%)		1 (6.3%)

TABLE 10 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (14 VACCINEES) - INJECTION 2							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
NORMAL	1 (7.1%)	1 (7.1%)	2 (15.4%)	2 (15.4%)	2 (14.3%)	2 (15.4%)		1 (7.1%)
< 99	9 (64.3%)	7 (50.0%)	10 (76.9%)	11 (84.6%)	11 (78.6%)	10 (76.9%)		4 (28.6%)
99 - 99.9	3 (21.4%)	5 (35.7%)	0 (0.0%)	0 (0.0%)	1 (7.1%)	1 (7.7%)		7 (50.0%)
100 - 100.9	1 (7.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (7.1%)
103 - 103.9	0 (0.0%)	1 (7.1%)	1 (7.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (7.1%)
TEMPERATURE TAKEN	14 (100.0%)	14 (100.0%)	13 (92.9%)	13 (92.9%)	14 (100.0%)	13 (92.9%)		14 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	0 (0.0%)	1 (7.1%)	1 (7.1%)	0 (0.0%)	1 (7.1%)		0 (0.0%)

TABLE 10 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (5 VACCINEES) - INJECTION 1						
	DAYS POST VACCINATION						NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5	
NORMAL	0 (0.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	0 (0.0%)
< 99	4 (80.0%)	3 (60.0%)	4 (80.0%)	4 (80.0%)	4 (80.0%)	4 (80.0%)	4 (80.0%)
99 - 99.9	1 (20.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)
TEMPERATURE TAKEN	5 (100.0%)	5 (100.0%)	5 (100.0%)	5 (100.0%)	5 (100.0%)	5 (100.0%)	5 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

TABLE 10 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (6 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		MAX TEMP
< 99	3 (50.0%)	3 (50.0%)	4 (66.7%)	3 (50.0%)	3 (50.0%)	3 (50.0%)		1 (16.7%)
99 - 99.9	3 (50.0%)	3 (50.0%)	2 (33.3%)	3 (50.0%)	3 (50.0%)	3 (50.0%)		5 (83.3%)
TEMPERATURE TAKEN	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)		6 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)

TABLE 10 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (5 VACCINEES) - INJECTION 2							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
NORMAL	1 (20.0%)	1 (20.0%)	2 (40.0%)	2 (40.0%)	2 (40.0%)	2 (40.0%)		1 (20.0%)
< 99	2 (40.0%)	2 (40.0%)	2 (40.0%)	2 (40.0%)	2 (40.0%)	2 (40.0%)		1 (20.0%)
99 - 99.9	1 (20.0%)	2 (40.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)		2 (40.0%)
100 - 100.9	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (20.0%)
TEMPERATURE TAKEN	5 (100.0%)	5 (100.0%)	5 (100.0%)	5 (100.0%)	5 (100.0%)	5 (100.0%)		5 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)

TABLE 10 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (1 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
99 - 99.9	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (100.0%)		0 (0.0%)
101 - 101.9	0 (0.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	0 (0.0%)		0 (0.0%)
103 - 103.9	1 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (100.0%)
TEMPERATURE TAKEN	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)		1 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)

TABLE 10 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB CONJUGATE
LOT NUMBER : CR132
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (6 VACCINEES) - INJECTION 1						
	DAYS POST VACCINATION						NUMBER WITH
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5	MAX TEMP
< 99	3 (50.0%)	4 (66.7%)	4 (66.7%)	5 (83.3%)	5 (83.3%)	5 (83.3%)	3 (50.0%)
99 - 99.9	3 (50.0%)	2 (33.3%)	2 (33.3%)	1 (16.7%)	1 (16.7%)	1 (16.7%)	3 (50.0%)
TEMPERATURE TAKEN	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

TABLE 10 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB CONJUGATE
LOT NUMBER : CR132
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (4 VACCINEES) - INJECTION 2							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
NORMAL	1 (25.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)		1 (25.0%)
< 99	3 (75.0%)	3 (75.0%)	3 (75.0%)	3 (75.0%)	3 (75.0%)	3 (75.0%)		3 (75.0%)
TEMPERATURE TAKEN	4 (100.0%)	4 (100.0%)	4 (100.0%)	4 (100.0%)	4 (100.0%)	4 (100.0%)		4 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)

TABLE 10 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : WILFERT, CATHERINE
STUDY : 000401
VACCINE : HIB CONJUGATE
LOT NUMBER : CR132
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (1 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
< 99	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)
99 - 99.9	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (100.0%)	1 (100.0%)		1 (100.0%)
TEMPERATURE TAKEN	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)		1 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)

STUDY 004-03

PROGRAM: Haemophilus b Conjugate Vaccine (Neisseria meningitidis Outer Membrane Protein Complex), Study #0004-03.

PURPOSE: To evaluate the safety and immunogenicity of Haemophilus b Conjugate Vaccine (Neisseria meningitidis Outer Membrane Protein Complex) in healthy infants and children 2 months to 5 years of age.

VACCINE: Haemophilus b Conjugate Vaccine (Neisseria meningitidis Outer Membrane Protein Complex).

Lot 1069/C-P241 - (b) (4) mcg polysaccharide/ml
(b) (4) mcg meningococcal protein/ml
Lot 1080/C-P749 - (b) (4) mcg polysaccharide/ml
(b) (4) mcg meningococcal protein/ml

Diluent
Aluminum hydroxide diluent
Lot (b) (4)

INVESTIGATOR: Kenneth Bromberg, M.D.
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SUB-INVESTIGATOR: Stephen Ira Ajl, M.D.
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STUDY LOCATION: Department of Pediatrics
SUNY Downstate Medical Center
450 Clarkson Ave.
Brooklyn, New York 11203

DATE INITIATED: May 4, 1987

DATE COMPLETED: In progress.

STUDY POPULATION: Healthy infants and children 2 to 71 months of age are included in the study.

STUDY PROCEDURE: Infants 2 to 11 months of age receive 2 injections of the vaccine given 2 months apart, while children 12 months of age and older receive a single injection. Vaccine is reconstituted in aluminum hydroxide and administered by intramuscular route. The dose for each injection is 15 mcg polysaccharide in the appropriate volume - 0.75 ml for Lot 1069/C-P241 and 0.5 ml for Lot 1080/C-P749.

Parents or guardians are required to record the vaccinee's temperature and any systemic or injection site reactions for 5 days after each injection. Unexpected or serious reactions are to be reported immediately to the study physician.

A blood sample is obtained immediately before each injection and one month after the last (or only) injection. Additional samples are obtained 7 to 10 months after the last injection for infants 2 to 11 months of age and at 15 to 18 months postvaccination for children 12 to 71 months of age.

All serum samples are assayed by Merck Sharp & Dohme Research Laboratories for antibody to H. influenzae type b capsular polysaccharide by radioimmunoassay (RIA). Selected samples are also tested for serum bactericidal activity, quantitation of IgG_1 and IgG_2 subclass, and IgM and total IgG antibodies. Testing for opsonophagocytic activity was done at the University of Alabama.

RESULTS: Demographic information and individual pre and postvaccination antibody data for each vaccinee enrolled in the study is reported in Tables 1 and 2.

1. Number Vaccinated:

Lot	Age	Injection No. 1	Injection No. 2
1069/C-P241	2-11 mo.	19	19
	12-71 mo.	13	--
1080/C-P749	2-11 mo.	56	38
	12-71 mo.	17	--

2. Serologic Results

Antibody responses (RIA) prior to and after vaccination are as follows:

Age	Time	% With Anti-PRP >0.15 mcg Ab/ml	% With Anti-PRP >1.0 mcg Ab/ml	GMT (mcg Ab/ml) All Vaccinees
2-11 mo.	Pre	38 (9/24)	0 (0/24)	0.11
	2 mo.	100 (23/23)	83 (19/23)	3.07
	3 mo.	100 (18/18)	89 (16/18)	4.72
12-71 mo.	Pre	56 (5/9)	0 (0/9)	0.14
	1 mo.	100 (9/9)	67 (6/9)	3.56

RESULTS: (CONT.)

Antibody responses (by lot per age group) prior to vaccination through 10 months postvaccination are included in Tables 3 and 4.

3. Clinical Results:

The frequencies of selected injection site and systemic reactions during the 48 hours after vaccination are as follows:

	% Vaccinees with Reactions		
	2 - 11 Months of Age		12 - 71 Months of Age
Type of Reaction	Injection 1	Injection 2	Injection 1
Injection Site			
Erythema >1 inch	2.7 (2/74)	1.8 (1/56)	3.7 (1/27)
Swelling >1 inch	1.4 (1/74)	3.6 (2/56)	3.7 (1/27)
Pain/Soreness	9.5 (7/74)	12.5 (7/56)	14.8 (4/27)
Systemic			
Irritability	28.4 (21/74)	41.1 (23/56)	25.9 (7/27)
Sleepiness/ Lethargy/Fatigue	41.9 (31/74)	30.4 (17/56)	33.3 (9/27)

Reaction frequencies and maximum temperatures recorded during the five days following each injection of vaccine are reported in Tables 5-7.

No serious or alarming reactions attributable to the vaccine were reported.

TABLE 1

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : BROMBERG, KENNETH
STUDY : 000403
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	F	CAUC	(b) (6)	9M	0	(b) (6)	001	PREBLEED				< 125				
					0		011	INJ	1 CP241	15 MCG						
					63		011	BLEED	1			9182				
					63		021	INJ	2 CP241	15 MCG						
					93		021	BLEED	2			8419				
	M	CAUC		8M	0		011	INJ	1 CP241	15 MCG						
					56		021	INJ	2 CP241	15 MCG						
	M	CAUC		9M	0		011	INJ	1 CP241	15 MCG						
					133		021	INJ	2 CP241	15 MCG						
	F	BLAC		11M	0		011	INJ	1 CP241	15 MCG						
					49		021	INJ	2 CP241	15 MCG						
	M	CAUC		7M	0		011	INJ	1 CP241	15 MCG						
					83		021	INJ	2 CP241	15 MCG						
	M	CAUC		7M	0		011	INJ	1 CP241	15 MCG						
					83		021	INJ	2 CP241	15 MCG						
	M	CAUC		5M	0		001	PREBLEED				< 125				
					0		011	INJ	1 CP241	15 MCG						
					67		011	BLEED	1			8858				
					67		021	INJ	2 CP241	15 MCG						
					106		021	BLEED	2			4074				
	F	CAUC		2M	0		001	PREBLEED				< 125				
					0		011	INJ	1 CP241	15 MCG						
					56		011	BLEED	1			2269				
					56		021	INJ	2 CP241	15 MCG						
					105		021	BLEED	2			3479				
	M	CAUC		2M	0		011	INJ	1 CP241	15 MCG						
					44		021	INJ	2 CP241	15 MCG						
	F	OTHE		9M	0		011	INJ	1 CP241	15 MCG						
					84		021	INJ	2 CP241	15 MCG						
	M	OTHE		2M	0		001	PREBLEED				< 125				

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : BROMBERG, KENNETH
STUDY : 000403
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	OTHE	(b) (6)	2M	0	(b) (6)	011	INJ	1 CP241	15 MCG						
					55		011	BLEED	1			1726				
					55		021	INJ	2 CP241	15 MCG						
					84		021	BLEED	2			2174				
	F	CAUC		2M	0		011	INJ	1 CP241	15 MCG						
					64		021	INJ	2 CP241	15 MCG						
	F	BLAC		6M	0		001	PREBLEED				< 125				
					0		011	INJ	1 CP241	15 MCG						
					57		021	INJ	2 CP241	15 MCG						
					246		071	BLEED	1			6964				
	F	CAUC		8M	0		011	INJ	1 CP241	15 MCG						
					70		021	INJ	2 CP241	15 MCG						
	M	OTHE		8M	0		001	PREBLEED				< 125				
					0		011	INJ	1 CP241	15 MCG						
					57		011	BLEED	1			2050				
					57		021	INJ	2 CP241	15 MCG						
					94		021	BLEED	2			3347				
	M	OTHE		7M	0		001	PREBLEED				< 125				
					0		011	INJ	1 CP241	15 MCG						
					56		011	BLEED	1			5072				
					56		021	INJ	2 CP241	15 MCG						
					84		021	BLEED	2			6694				
	M	OTHE		10M	0		011	INJ	1 CP241	15 MCG						
					63		021	INJ	2 CP241	15 MCG						
	F	OTHE		9M	0		001	PREBLEED				< 125				
					0		011	INJ	1 CP241	15 MCG						
					56		011	BLEED	1			9010				
					56		021	INJ	2 CP241	15 MCG						
					100		021	BLEED	2			9751				
	M	CAUC		2M	0		001	PREBLEED				528				
					0		011	INJ	1 CP241	15 MCG						
					70		011	BLEED	1			1723				

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : BROMBERG, KENNETH
STUDY : 000403
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	CAUC	(b) (6)	2M	70	(b) (6)	021	INJ	2 CP241	15 MCG						
					127		021	BLEED	2			5186				
	M	CAUC		5M	0		011	INJ	1 CP749	15 MCG						
					77		021	INJ	2 CP749	15 MCG						
	M	CAUC		6M	0		011	INJ	1 CP749	15 MCG						
					63		021	INJ	2 CP749	15 MCG						
	M	CAUC		6M	0		001	PREBLEED				< 125				
					0		011	INJ	1 CP749	15 MCG						
					69		011	BLEED	1			1306				
					69		021	INJ	2 CP749	15 MCG						
					133		021	BLEED	2			5792				
	M	BLAC		8M	0		001	PREBLEED				261				
					0		011	INJ	1 CP749	15 MCG						
					56		011	BLEED	1			3386				
					56		021	INJ	2 CP749	15 MCG						
	M	CAUC		6M	0		001	PREBLEED				< 125				
					0		011	INJ	1 CP749	15 MCG						
					161		011	BLEED	1		05/	638				
					161		021	INJ	2 CP749	15 MCG						
					203		021	BLEED	2		05/	631				
	M	CAUC		7M	0		001	PREBLEED				< 125		< 2		8
					0		011	INJ	1 CP749	15 MCG						
					71		011	BLEED	1		05/	2202	05/	< 2	05/	100
					71		021	INJ	2 CP749	15 MCG						
					113		021	BLEED	2		05/	2097	05/	< 2	05/	99
	M	BLAC		9M	0		001	PREBLEED				< 125		< 2		
					0		011	INJ	1 CP749	15 MCG						
					49		011	BLEED	1			6497		< 2		
					49		021	INJ	2 CP749	15 MCG						
					81		021	BLEED	2			100105		>= 32		
	M	BLAC		7M	0		011	INJ	1 CP749	15 MCG						
					119		021	INJ	2 CP749	15 MCG						

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : BROMBERG, KENNETH
STUDY : 000403
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	OTHE	(b) (6)	8M	0	(b) (6)	011	INJ	1	CP749 15 MCG						
					62		021	INJ	2	CP749 15 MCG						
	F	CAUC		5M	0		001	PREBLEED				< 125				
					0		011	INJ	1	CP749 15 MCG						
					59		011	BLEED	1			914				
					59		021	INJ	2	CP749 15 MCG						
					108		021	BLEED	2			862				
	M	CAUC		1M	0		001	PREBLEED				< 125				D
					0		011	INJ	1	CP749 15 MCG						
					51		021	BLEED	1			7069				90
					51		021	INJ	2	CP749 15 MCG						
					84		021	BLEED	2			3805				92
	M	OTHE		3M	0		011	INJ	1	CP749 15 MCG						
					93		021	INJ	2	CP749 15 MCG						
	F	CAUC		3M	0		011	INJ	1	CP749 15 MCG						
					63		021	INJ	2	CP749 15 MCG						
	F	CAUC		2M	0		001	PREBLEED			05/	237				
					0		011	INJ	1	CP749 15 MCG						
					72		021	INJ	2	CP749 15 MCG						
					114		021	BLEED	1		05/	2545				
	F	CAUC		4M	0		001	PREBLEED				< 125		< 2		
					0		011	INJ	1	CP749 15 MCG						
					56		011	BLEED	1			14763		>= 32		
					56		021	INJ	2	CP749 15 MCG						
					85		021	BLEED	2			26685		>= 32		
	M	CAUC		2M	0		001	PREBLEED				< 125		< 2		14
					0		011	INJ	1	CP749 15 MCG						
					63		011	BLEED	1			2967		< 2		96
					63		021	INJ	2	CP749 15 MCG						
					110		021	BLEED	2			1647		< 2		92
	F	OTHE		8M	0		001	PREBLEED				457		< 2		
					0		011	INJ	1	CP749 15 MCG						

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : BROMBERG, KENNETH
STUDY : 000403
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	F	OTHE	(b) (6)	8M	63	(b) (6)	011	BLEED 1				3056		>= 32		
					63		021	INJ 2	CP749	15 MCG						
					105		021	BLEED 2				12262		>= 32		
	M	BLAC		2M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP749	15 MCG						
					77		021	INJ 2	CP749	15 MCG						
					126		021	BLEED 1			05/	35128				
	F	OTHE		4M	0		011	INJ 1	CP749	15 MCG						
	M	CAUC		7M	0		011	INJ 1	CP749	15 MCG						
					49		021	INJ 2	CP749	15 MCG						
	F	CAUC		5M	0		001	PREBLEED				305				
					0		011	INJ 1	CP749	15 MCG						
					54		011	BLEED 1				4011				
					54		021	INJ 2	CP749	15 MCG						
					98		021	BLEED 2				3545				
	F	CAUC		7M	0		001	PREBLEED				173				
					0		011	INJ 1	CP749	15 MCG						
					61		011	BLEED 1				728				
					61		021	INJ 2	CP749	15 MCG						
					96		021	BLEED 2				2029				
	M	OTHE		5M	0		001	PREBLEED				268				
					0		011	INJ 1	CP749	15 MCG						
					49		011	BLEED 1				3295				
					49		021	INJ 2	CP749	15 MCG						
					90		021	BLEED 2				13674				
	F	CAUC		4M	0		011	INJ 1	CP749	15 MCG						
					55		021	INJ 2	CP749	15 MCG						
	M	CAUC		5M	0		011	INJ 1	CP749	15 MCG						
					79		021	INJ 2	CP749	15 MCG						
	F	CAUC		5M	0		011	INJ 1	CP749	15 MCG						
					79		021	INJ 2	CP749	15 MCG						

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : BROMBERG, KENNETH
STUDY : 000403
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	F	CAUC	(b) (6)	4M	0	(b) (6)	011	INJ 1	CP749	15 MCG						
	F	CAUC		8M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP749	15 MCG						
					70		021	INJ 2	CP749	15 MCG						
					121		021	BLEED 1				< 125				
					191		071	BLEED 2				1086				
	F	BLAC		7M	0		011	INJ 1	CP749	15 MCG						
					57		021	INJ 2	CP749	15 MCG						
	F	BLAC		8M	0		011	INJ 1	CP749	15 MCG						
	F	CAUC		3M	0		011	INJ 1	CP749	15 MCG						
					56		021	INJ 2	CP749	15 MCG						
	F	CAUC		3M	0		001	PREBLEED				426				
					0		011	INJ 1	CP749	15 MCG						
					56		011	BLEED 1				15811				
					56		021	INJ 2	CP749	15 MCG						
					112		021	BLEED 2				15697				
	F	CAUC		2M	0		011	INJ 1	CP749	15 MCG						
					82		021	INJ 2	CP749	15 MCG						
	M	CAUC		1M	0		001	PREBLEED				298				
					0		011	INJ 1	CP749	15 MCG						
					63		011	BLEED 1				787				
					63		021	INJ 2	CP749	15 MCG						
					98		021	BLEED 2				1855				
	F	CAUC		6M	0		011	INJ 1	CP749	15 MCG						
					86		021	INJ 2	CP749	15 MCG						
	M	CAUC		2M	0		011	INJ 1	CP749	15 MCG						
					56		021	INJ 2	CP749	15 MCG						
	M	BLAC		9M	0		011	INJ 1	CP749	15 MCG						
	M	CAUC		10M	0		011	INJ 1	CP749	15 MCG						

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : BROMBERG, KENNETH
STUDY : 000403
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	CAUC	(b) (6)	1M	0	(b) (6)	001	PREBLEED				< 125				
					0		011	INJ 1	CP749	15 MCG						
					51		011	BLEED 1				3769				
					51		021	INJ 2	CP749	15 MCG						
	M	CAUC		6M	0		011	INJ 1	CP749	15 MCG						
	F	CAUC		5M	0		011	INJ 1	CP749	15 MCG						
					56		021	INJ 2	CP749	15 MCG						
	F	BLAC		2M	0		011	INJ 1	CP749	15 MCG						
	M	CAUC		4M	0		001	PREBLEED				178				
					0		011	INJ 1	CP749	15 MCG						
					56		011	BLEED 1				286				
					56		021	INJ 2	CP749	15 MCG						
					91		021	BLEED 2				754				
	F	CAUC		2M	0		011	INJ 1	CP749	15 MCG						
					62		021	INJ 2	CP749	15 MCG						
	M	CAUC		3M	0		011	INJ 1	CP749	15 MCG						
	F	OTHE		3M	0		011	INJ 1	CP749	15 MCG						
					58		021	INJ 2	CP749	15 MCG						
	F	CAUC		2M	0		011	INJ 1	CP749	15 MCG						
	M	BLAC		4M	0		011	INJ 1	CP749	15 MCG						
	F	BLAC		3M	0		011	INJ 1	CP749	15 MCG						
	M	CAUC		3M	0		011	INJ 1	CP749	15 MCG						
	F	CAUC		2M	0		011	INJ 1	CP749	15 MCG						
	M	CAUC		2M	0		011	INJ 1	CP749	15 MCG						
	M	CAUC		3M	0		011	INJ 1	CP749	15 MCG						
	F	CAUC		2M	0		011	INJ 1	CP749	15 MCG						

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : BROMBERG, KENNETH
STUDY : 000403
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	BLAC	(b) (6)	9M	0	(b) (6)		011 INJ	1	CP749	15 MCG					
	M	BLAC		7M	0			011 INJ	1	CP749	15 MCG					

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : BROMBERG, KENNETH
STUDY : 000403
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	F	CAUC	(b) (6)	13M	0	(b) (6)	001	PREBLEED				177				
					0		011	INJ 1	CP241	15 MCG						
					43		011	BLEED 1				11298				
	F	BLAC		17M	0		001	PREBLEED				213		< 5		
					0		011	INJ 1	CP241	15 MCG						
					35		011	BLEED 1				9861		>= 80		
	F	CAUC		13M	0		001	PREBLEED				432		< 5		
					0		011	INJ 1	CP241	15 MCG						
					42		011	BLEED 1				670		5		
	M	OTHE		16M	0		001	PREBLEED				1867		20		
					0		011	INJ 1	CP241	15 MCG						
					59		011	BLEED 1				4820		80		
	M	CAUC		12M	0		001	PREBLEED				< 125		< 5		
					0		011	INJ 1	CP241	15 MCG						
					42		011	BLEED 1				3039		20		
	M	CAUC		16M	0		001	PREBLEED				763		5		
					0		011	INJ 1	CP241	15 MCG						
					55		011	BLEED 1				11627		80		
	F	BLAC		16M	0		001	PREBLEED				192				
					0		011	INJ 1	CP241	15 MCG						
					42		011	BLEED 1				956				
	M	CAUC		18M	0		001	PREBLEED				< 125		< 5		
					0		011	INJ 1	CP241	15 MCG						
					45		011	BLEED 1				23575		20		
	F	CAUC		23M	0		001	PREBLEED				127		< 5		
					0		011	INJ 1	CP749	15 MCG						
					68		011	BLEED 1				30901		80		
	F	CAUC		19M	0		001	PREBLEED				332				
					0		011	INJ 1	CP241	15 MCG						
					29		011	BLEED 1				4469				
	M	CAUC		15M	0		011	INJ 1	CP241	15 MCG						

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : BROMBERG, KENNETH
STUDY : 000403
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	F	CAUC	(b) (6)	19M	0	(b) (6)	011	INJ 1	CP241	15 MCG						
	M	CAUC		13M	0		011	INJ 1	CP241	15 MCG						
	F	HISP		17M	0		001	PREBLEED				127		< 5		0
					0		011	INJ 1	CP749	15 MCG						
					84		011	BLEED 1				1704		20		99
	F	CAUC		13M	0		011	INJ 1	CP749	15 MCG						
					239		071	BLEED 1				9389				
	M	OTHE		12M	0		011	INJ 1	CP241	15 MCG						
	F	BLAC		16M	0		001	PREBLEED				< 125		< 5		16
					0		011	INJ 1	CP749	15 MCG						
					54		011	BLEED 1				21050		>= 80		100
	M	CAUC		23M	0		011	INJ 1	CP749	15 MCG						
	F	CAUC		24M	0		001	PREBLEED				137		< 5		20
					0		011	INJ 1	CP749	15 MCG						
					56		011	BLEED 1				6952		20		100
	M	BLAC		16M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP749	15 MCG						
					44		011	BLEED 1				4667				
	M	HISP		16M	0		011	INJ 1	CP749	15 MCG						
	M	CAUC		12M	0		001	PREBLEED				162		< 5		
					0		011	INJ 1	CP749	15 MCG						
					56		011	BLEED 1				1670		20		
	F	CAUC		13M	0		011	INJ 1	CP749	15 MCG						
	F	CAUC		14M	0		011	INJ 1	CP749	15 MCG						
	F	CAUC		12M	0		001	PREBLEED				< 125		< 5		48
					0		011	INJ 1	CP749	15 MCG						
					28		011	BLEED 1				856		5		96

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : BROMBERG, KENNETH
STUDY : 000403
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	F	CAUC	(b) (6)	22M	0	(b) (6)	011	INJ	1 CP749	15 MCG						
	F	BLAC		12M	0		011	INJ	1 CP749	15 MCG						
	M	CAUC		15M	0		001	PREBLEED				307				
					0		011	INJ	1 CP749	15 MCG						
					19		011	BLEED	1			13535				
	M	BLAC		17M	0		011	INJ	1 CP749	15 MCG						
	M	BLAC		3Y	0		011	INJ	1 CP749	15 MCG						

TABLE 2

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : BROMBERG, KENNETH
STUDY : 000403
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT		LOT	DOSE	CODE/ IGG1	CODE/ IGG2	CODE/ IGGM	CODE/IGG TOTAL
(b) (6)	F	CAUC	(b) (6)	9M	0	(b) (6)	011	INJ	1	CP241	15 MCG				
					63		021	INJ	2	CP241	15 MCG				
	M	CAUC		8M	0		011	INJ	1	CP241	15 MCG				
					56		021	INJ	2	CP241	15 MCG				
	M	CAUC		9M	0		011	INJ	1	CP241	15 MCG				
					133		021	INJ	2	CP241	15 MCG				
	F	BLAC		11M	0		011	INJ	1	CP241	15 MCG				
					49		021	INJ	2	CP241	15 MCG				
	M	CAUC		7M	0		011	INJ	1	CP241	15 MCG				
					83		021	INJ	2	CP241	15 MCG				
	M	CAUC		7M	0		011	INJ	1	CP241	15 MCG				
					83		021	INJ	2	CP241	15 MCG				
	M	CAUC		5M	0		001	PREBLEED				< 600			
					0		011	INJ	1	CP241	15 MCG				
					67		011	BLEED	1			7446			
					67		021	INJ	2	CP241	15 MCG				
					106		021	BLEED	2			4408			
	F	CAUC		2M	0		001	PREBLEED				< 600			
					0		011	INJ	1	CP241	15 MCG				
					56		011	BLEED	1			5070			
					56		021	INJ	2	CP241	15 MCG				
					105		021	BLEED	2			4775			
	M	CAUC		2M	0		011	INJ	1	CP241	15 MCG				
					44		021	INJ	2	CP241	15 MCG				
	F	OTHE		9M	0		011	INJ	1	CP241	15 MCG				
					84		021	INJ	2	CP241	15 MCG				
	M	OTHE		2M	0		011	INJ	1	CP241	15 MCG				
					55		021	INJ	2	CP241	15 MCG				
	F	CAUC		2M	0		011	INJ	1	CP241	15 MCG				

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : BROMBERG, KENNETH
STUDY : 000403
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT		LOT	DOSE	CODE/ IGG1	CODE/ IGG2	CODE/ IGGM	CODE/IGG TOTAL
(b) (6)	F	CAUC	(b) (6)	2M	64	(b) (6)	021	INJ	2	CP241	15 MCG				
	F	BLAC		6M	0		011	INJ	1	CP241	15 MCG				
					57		021	INJ	2	CP241	15 MCG				
	F	CAUC		8M	0		011	INJ	1	CP241	15 MCG				
					70		021	INJ	2	CP241	15 MCG				
	M	OTHE		8M	0		011	INJ	1	CP241	15 MCG				
					57		021	INJ	2	CP241	15 MCG				
	M	OTHE		7M	0		011	INJ	1	CP241	15 MCG				
					56		021	INJ	2	CP241	15 MCG				
	M	OTHE		10M	0		011	INJ	1	CP241	15 MCG				
					63		021	INJ	2	CP241	15 MCG				
	F	OTHE		9M	0		011	INJ	1	CP241	15 MCG				
					56		021	INJ	2	CP241	15 MCG				
	M	CAUC		2M	0		011	INJ	1	CP241	15 MCG				
					70		021	INJ	2	CP241	15 MCG				
	M	CAUC		5M	0		011	INJ	1	CP749	15 MCG				
					77		021	INJ	2	CP749	15 MCG				
	M	CAUC		6M	0		011	INJ	1	CP749	15 MCG				
					63		021	INJ	2	CP749	15 MCG				
	M	CAUC		6M	0		011	INJ	1	CP749	15 MCG				
					69		021	INJ	2	CP749	15 MCG				
	M	BLAC		8M	0		011	INJ	1	CP749	15 MCG				
					56		021	INJ	2	CP749	15 MCG				
	M	CAUC		6M	0		011	INJ	1	CP749	15 MCG				
					161		021	INJ	2	CP749	15 MCG				
	M	CAUC		7M	0		001	PREBLEED				< 600	< 250	< 100	< 100
					0		011	INJ	1	CP749	15 MCG				

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : BROMBERG, KENNETH
STUDY : 000403
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	IGG1	CODE/	IGG2	CODE/	IGGM	CODE/	IGG TOTAL
(b) (6)	M	CAUC	(b) (6)	7M	71	(b) (6)	011	BLEED 1			05/	2233	05/	< 250	05/	263	05/	988
					71		021	INJ 2	CP749	15 MCG								
					113		021	BLEED 2			05/	3119	05/	< 250	05/	159	05/	554
	M	BLAC		9M	0		001	PREBLEED				< 600		< 250		133		< 100
					0		011	INJ 1	CP749	15 MCG								
					49		011	BLEED 1				43276		278		367		9375
					49		021	INJ 2	CP749	15 MCG								
					81		021	BLEED 2				95177		486		1653		41189
	M	BLAC		7M	0		011	INJ 1	CP749	15 MCG								
					119		021	INJ 2	CP749	15 MCG								
	M	OTHE		8M	0		D11	INJ 1	CP749	15 MCG								
					62		021	INJ 2	CP749	15 MCG								
	F	CAUC		5M	0		001	PREBLEED				< 600		< 250				
					0		011	INJ 1	CP749	15 MCG								
					59		011	BLEED 1				1617		< 250				
					59		021	INJ 2	CP749	15 MCG								
					108		021	BLEED 2				1226		< 250				
	M	CAUC		1M	0		001	PREBLEED				< 600		< 250		< 100		< 100
					0		011	INJ 1	CP749	15 MCG								
					51		021	BLEED 1				5281		< 250		260		872
					51		021	INJ 2	CP749	15 MCG								
					84		021	BLEED 2				6927		< 250		136		237
	M	OTHE		3M	0		011	INJ 1	CP749	15 MCG								
					93		021	INJ 2	CP749	15 MCG								
	F	CAUC		3M	0		011	INJ 1	CP749	15 MCG								
					63		021	INJ 2	CP749	15 MCG								
	F	CAUC		2M	0		011	INJ 1	CP749	15 MCG								
					72		021	INJ 2	CP749	15 MCG								
	F	CAUC		4M	0		001	PREBLEED				< 600		< 250		< 100		119
					0		011	INJ 1	CP749	15 MCG								
					56		011	BLEED 1				6988		267		6395		459

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : BROMBERG, KENNETH
STUDY : 000403
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ IGG1	CODE/ IGG2	CODE/ IGGM	CODE/IGG TOTAL
(b) (6)	F	CAUC	(b) (6)	4M	56	(b) (6)	021	INJ 2	CP749	15 MCG				
					85		021	BLEED 2			20206	397	2038	969
	M	CAUC		2M	0		001	PREBLEED			< 600	< 250	< 100	< 100
					0		011	INJ 1	CP749	15 MCG				
					63		011	BLEED 1			693	< 250	< 100	103
					63		021	INJ 2	CP749	15 MCG				
					110		021	BLEED 2			1780	< 250	257	300
	F	OTHE		8M	0		001	PREBLEED			< 600	< 250	163	< 100
					0		011	INJ 1	CP749	15 MCG				
					63		011	BLEED 1			5954	418	1165	1496
					63		021	INJ 2	CP749	15 MCG				
					105		021	BLEED 2			24500	762	2522	4601
	M	BLAC		2M	0		011	INJ 1	CP749	15 MCG				
					77		021	INJ 2	CP749	15 MCG				
	F	OTHE		4M	0		011	INJ 1	CP749	15 MCG				
	M	CAUC		7M	0		011	INJ 1	CP749	15 MCG				
					49		021	INJ 2	CP749	15 MCG				
	F	CAUC		5M	0		001	PREBLEED			< 600	< 250	< 100	< 100
					0		011	INJ 1	CP749	15 MCG				
					54		011	BLEED 1			3060	< 250	534	484
					54		021	INJ 2	CP749	15 MCG				
					98		021	BLEED 2				< 250	360	1423
	F	CAUC		7M	0		001	PREBLEED			< 600		< 100	< 100
					0		011	INJ 1	CP749	15 MCG				
					61		011	BLEED 1			761		< 100	141
					61		021	INJ 2	CP749	15 MCG				
					96		021	BLEED 2			6539		331	947
	M	OTHE		5M	0		001	PREBLEED					< 100	< 100
					0		011	INJ 1	CP749	15 MCG				
					49		011	BLEED 1					359	458
					49		021	INJ 2	CP749	15 MCG				
					90		021	BLEED 2					225	6369

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : BROMBERG, KENNETH
STUDY : 000403
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ IGG1	CODE/ IGG2	CODE/ IGGM	CODE/IGG TOTAL
(b) (6)	F	CAUC	(b) (6)	4M	0	(b) (6)	011	INJ 1	CP749	15 MCG				
					55		021	INJ 2	CP749	15 MCG				
	M	CAUC		5M	0		011	INJ 1	CP749	15 MCG				
					79		021	INJ 2	CP749	15 MCG				
	F	CAUC		5M	0		011	INJ 1	CP749	15 MCG				
					79		021	INJ 2	CP749	15 MCG				
	F	CAUC		4M	0		011	INJ 1	CP749	15 MCG				
	F	CAUC		8M	0		001	PREBLEED			< 600			
					0		011	INJ 1	CP749	15 MCG				
					70		021	INJ 2	CP749	15 MCG				
					121		021	BLEED 1			1297			
	F	BLAC		7M	0		011	INJ 1	CP749	15 MCG				
					57		021	INJ 2	CP749	15 MCG				
	F	BLAC		8M	0		011	INJ 1	CP749	15 MCG				
	F	CAUC		3M	0		011	INJ 1	CP749	15 MCG				
					56		021	INJ 2	CP749	15 MCG				
	F	CAUC		3M	0		001	PREBLEED					< 100	< 100
					0		011	INJ 1	CP749	15 MCG				
					56		011	BLEED 1					164	3062
					56		021	INJ 2	CP749	15 MCG				
	F	CAUC		2M	0		011	INJ 1	CP749	15 MCG				
					82		021	INJ 2	CP749	15 MCG				
	M	CAUC		1M	0		001	PREBLEED			746		< 100	131
					0		011	INJ 1	CP749	15 MCG				
					63		011	BLEED 1			2271		< 100	277
					63		021	INJ 2	CP749	15 MCG				
					98		021	BLEED 2					< 100	830
	F	CAUC		6M	0		011	INJ 1	CP749	15 MCG				
					86		021	INJ 2	CP749	15 MCG				

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : BROMBERG, KENNETH
STUDY : 000403
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT		LOT	DOSE	CODE/ IGG1	CODE/ IGG2	CODE/ IGGM	CODE/IGG TOTAL
(b) (6)	M	CAUC	(b) (6)	2M	0	(b) (6)	011	INJ	1	CP749	15 MCG				
					56		021	INJ	2	CP749	15 MCG				
	M	BLAC		9M	0		011	INJ	1	CP749	15 MCG				
	M	CAUC		10M	0		011	INJ	1	CP749	15 MCG				
	M	CAUC		1M	0		011	INJ	1	CP749	15 MCG				
					51		021	INJ	2	CP749	15 MCG				
	M	CAUC		6M	0		011	INJ	1	CP749	15 MCG				
	F	CAUC		5M	0		011	INJ	1	CP749	15 MCG				
					56		021	INJ	2	CP749	15 MCG				
	F	BLAC		2M	0		011	INJ	1	CP749	15 MCG				
	M	CAUC		4M	0		011	INJ	1	CP749	15 MCG				
					56		021	INJ	2	CP749	15 MCG				
	F	CAUC		2M	0		011	INJ	1	CP749	15 MCG				
					62		021	INJ	2	CP749	15 MCG				
	M	CAUC		3M	0		011	INJ	1	CP749	15 MCG				
	F	OTHE		3M	0		011	INJ	1	CP749	15 MCG				
					58		021	INJ	2	CP749	15 MCG				
	F	CAUC		2M	0		011	INJ	1	CP749	15 MCG				
	M	BLAC		4M	0		011	INJ	1	CP749	15 MCG				
	F	BLAC		3M	0		011	INJ	1	CP749	15 MCG				
	M	CAUC		3M	0		011	INJ	1	CP749	15 MCG				
	F	CAUC		2M	0		011	INJ	1	CP749	15 MCG				
	M	CAUC		2M	0		011	INJ	1	CP749	15 MCG				
	M	CAUC		3M	0		011	INJ	1	CP749	15 MCG				

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : BROMBERG, KENNETH
STUDY : 000403
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	IGG1	CODE/	IGG2	CODE/	IGGM	CODE/IGG TOTAL
(b) (6)	F	CAUC	(b) (6)	2M	0	(b) (6)	011	INJ 1	CP749	15 MCG							
	M	BLAC		9M	0		011	INJ 1	CP749	15 MCG							
	M	BLAC		7M	0		011	INJ 1	CP749	15 MCG							

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : BROMBERG, KENNETH
STUDY : 000403
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ IGG1	CODE/ IGG2	CODE/ IGGM	CODE/IGG TOTAL
(b) (6)	F	CAUC	(b) (6)	13M	0	(b) (6)	011	INJ 1	CP241	15 MCG				
	F	BLAC		17M	0		001	PREBLEED			< 600		< 100	< 100
					0		011	INJ 1	CP241	15 MCG				
					35		011	BLEED 1			17835		4804	4590
	F	CAUC		13M	0		001	PREBLEED			< 600		129	< 100
					0		011	INJ 1	CP241	15 MCG				
					42		011	BLEED 1			10499		494	1698
	M	OTHE		16M	0		001	PREBLEED			< 600		275	< 100
					0		011	INJ 1	CP241	15 MCG				
					59		011	BLEED 1			< 600		492	108
	M	CAUC		12M	0		001	PREBLEED			< 600		< 100	< 100
					0		011	INJ 1	CP241	15 MCG				
					42		011	BLEED 1			3047		< 100	435
	M	CAUC		16M	0		001	PREBLEED			< 600		317	< 100
					0		011	INJ 1	CP241	15 MCG				
					55		011	BLEED 1			24027		2356	2756
	F	BLAC		16M	0		001	PREBLEED			< 600		137	< 100
					0		011	INJ 1	CP241	15 MCG				
					42		011	BLEED 1			6361		1031	1047
	M	CAUC		18M	0		001	PREBLEED			< 600		< 100	< 100
					0		011	INJ 1	CP241	15 MCG				
					45		011	BLEED 1			14885		230	2127
	F	CAUC		23M	0		001	PREBLEED			< 600	< 250		
					0		011	INJ 1	CP749	15 MCG				
					68		011	BLEED 1			6368	868		
	F	CAUC		19M	0		011	INJ 1	CP241	15 MCG				
	M	CAUC		15M	0		011	INJ 1	CP241	15 MCG				
	F	CAUC		19M	0		011	INJ 1	CP241	15 MCG				
	M	CAUC		13M	0		011	INJ 1	CP241	15 MCG				

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : BROMBERG, KENNETH
STUDY : 000403
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ IGG1	CODE/ IGG2	CODE/ IGGM	CODE/IGG TOTAL
(b) (6)	F	HISP	(b) (6)	17M	0	(b) (6)	001	PREBLEED			< 600	< 250	114	< 100
					0		011	INJ 1	CP749	15 MCG				
					84		011	BLEED 1			2696	< 250	305	334
	F	CAUC		13M	0		011	INJ 1	CP749	15 MCG				
	M	OTHE		12M	0		011	INJ 1	CP241	15 MCG				
	F	BLAC		16M	0		001	PREBLEED			< 600	< 250	< 100	< 100
					0		011	INJ 1	CP749	15 MCG				
					54		011	BLEED 1			12077	711	676	2603
	M	CAUC		23M	0		011	INJ 1	CP749	15 MCG				
	F	CAUC		24M	0		001	PREBLEED			< 600		250	< 100
					0		011	INJ 1	CP749	15 MCG				
					56		011	BLEED 1			16585		1415	4609
	M	BLAC		16M	0		001	PREBLEED					< 100	< 100
					0		011	INJ 1	CP749	15 MCG				
					44		011	BLEED 1					< 100	431
	M	HISP		16M	0		011	INJ 1	CP749	15 MCG				
	M	CAUC		12M	0		001	PREBLEED			< 600	< 250	201	< 100
					0		011	INJ 1	CP749	15 MCG				
					56		011	BLEED 1			1820	< 250	482	430
	F	CAUC		13M	0		011	INJ 1	CP749	15 MCG				
	F	CAUC		14M	0		011	INJ 1	CP749	15 MCG				
	F	CAUC		12M	0		001	PREBLEED			< 600	< 250	< 100	< 100
					0		011	INJ 1	CP749	15 MCG				
					28		011	BLEED 1			3742	< 250	265	568
	F	CAUC		22M	0		011	INJ 1	CP749	15 MCG				
	F	BLAC		12M	0		011	INJ 1	CP749	15 MCG				
	M	CAUC		15M	0		011	INJ 1	CP749	15 MCG				

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : BROMBERG, KENNETH
STUDY : 000403
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ IGG1	CODE/ IGG2	CODE/ IGGM	CODE/IGG TOTAL
(b) (6)	M	BLAC	(b) (6)	17M	0	(b) (6)	011	INJ	1	CP749 15 MCG				
	M	BLAC		3Y	0		011	INJ	1	CP749 15 MCG				

TABLE 3

ANTIBODY RESPONSES

INVESTIGATOR : BROMBERG, KENNETH
STUDY : 000403
VACCINE : HIB CONJUGATE
ASSAY : RIA
LOT NUMBER : CP241
DOSE : 15 MCG
POPULATION : HEALTHY CHILDREN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
1- 6 MOS.	PRE INJ	20 (1/ 5)	0 (0/ 5)			0.096 (5)
	MONTH 2	100 (4/ 4)	100 (4/ 4)	100 (4/ 4)	15.5	2.781 (4)
	MONTH 3	100 (3/ 3)	100 (3/ 3)	100 (3/ 3)	25.1	3.135 (3)
	MONTH 7-10	100 (1/ 1)	100 (1/ 1)	100 (1/ 1)	55.7	6.964 (1)
7-11 MOS.	PRE INJ	0 (0/ 4)	0 (0/ 4)			0.062 (4)
	MONTH 2	100 (4/ 4)	100 (4/ 4)	100 (4/ 4)	43.3	5.416 (4)
	MONTH 3	100 (4/ 4)	100 (4/ 4)	100 (4/ 4)	52.4	6.549 (4)
12-71 MOS.	PRE INJ	71 (5/ 7)	0 (0/ 7)			0.170 (7)
	MONTH 1	100 (7/ 7)	71 (5/ 7)	86 (6/ 7)	20.3	4.195 (7)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 4

ANTIBODY RESPONSES

INVESTIGATOR : BROMBERG, KENNETH
STUDY : 000403
VACCINE : HIB CONJUGATE
ASSAY : RIA
LOT NUMBER : CP749
DOSE : 15 MCG
POPULATION : HEALTHY CHILDREN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
1- 6 MOS.	PRE INJ	45 (5/ 11)	0 (0/ 11)			0.124 (11)
	MONTH 2	100 (11/ 11)	73 (8/ 11)	91 (10/ 11)	15.1	2.741 (11)
	MONTH 3	100 (8/ 8)	75 (6/ 8)	100 (8/ 8)	17.6	3.153 (8)
7-11 MOS.	PRE INJ	75 (3/ 4)	0 (0/ 4)			0.190 (4)
	MONTH 2	100 (4/ 4)	75 (3/ 4)	100 (4/ 4)	11.7	2.645 (4)
	MONTH 3	100 (3/ 3)	100 (3/ 3)	100 (3/ 3)	63.2	13.555 (3)
12-71 MOS.	PRE INJ	0 (0/ 2)	0 (0/ 2)			0.063 (2)
	MONTH 1	100 (2/ 2)	50 (1/ 2)	100 (2/ 2)	16.0	1.999 (2)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 5
CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : BROMBERG, KENNETH
STUDY : 000403
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	19	
VACCINEES WITH NO COMPLAINTS :	4	(21.1 %)
VACCINEES WITH COMPLAINTS :	15	(78.9 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 19 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	7	36.8
ERYTHEMA, INJ. SITE (<=1 IN.)	5	26.3
SWELLING, INJ. SITE (<=1 IN.)	4	21.1
INDURATION, INJECTION SITE	2	10.5
SYSTEMIC REACTIONS	14	73.7
IRRITABILITY	6	31.6
FATIGUE	5	26.3
TEETHING	5	26.3
ANOREXIA	1	5.3
ATOPIC DERMATITIS	1	5.3
COUGH	1	5.3
CRYING	1	5.3
INSOMNIA	1	5.3
NASAL DISCHARGE	1	5.3
PROLONGED CRYING, >1/2 HR	1	5.3
RASH	1	5.3
SKIN INFLAMMATION	1	5.3
VOMITING	1	5.3

TABLE 5 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : BROMBERG, KENNETH
STUDY : 000403
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 2	
TOTAL VACCINEES :	19	
VACCINEES WITH NO COMPLAINTS :	5	(26.3 %)
VACCINEES WITH COMPLAINTS :	14	(73.7 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 19 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	5	26.3
ERYTHEMA, INJ. SITE (<=1 IN.)	3	15.8
SWELLING, INJ. SITE (<=1 IN.)	2	10.5
INDURATION, INJECTION SITE	1	5.3
SYSTEMIC REACTIONS	13	68.4
IRRITABILITY	10	52.6
FATIGUE	4	21.1
DIARRHEA	2	10.5
TEETHING	2	10.5
WARM TO TOUCH	2	10.5
ANOREXIA	1	5.3
COMMON COLD	1	5.3
EAR INFECTION, NOS	1	5.3
VOMITING	1	5.3

TABLE 5 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : BROMBERG, KENNETH
STUDY : 000403
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
POPULATION : HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	13	
VACCINEES WITH NO COMPLAINTS :	1	(7.7 %)
VACCINEES WITH COMPLAINTS :	12	(92.3 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 13 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	4	30.8
PAIN/SORENESS, INJ. SITE	4	30.8
ERYTHEMA, INJ. SITE (<=1 IN.)	1	7.7
ERYTHEMA, INJ. SITE (>1 INCH)	1	7.7
SWELLING, INJ. SITE (<=1 IN.)	1	7.7
SWELLING, INJ. SITE (>1 INCH)	1	7.7
WARMTH, INJECTION SITE	1	7.7
SYSTEMIC REACTIONS	12	92.3
IRRITABILITY	7	53.8
FATIGUE	5	38.5
TEETHING	5	38.5
DIARRHEA	4	30.8
PROLONGED CRYING, >1/2 HR	3	23.1
WARM TO TOUCH	3	23.1
NASAL DISCHARGE	2	15.4
UPPER RESPIRATORY INFECTION, NOS	2	15.4
VOMITING	2	15.4
ANOREXIA	1	7.7
APATHY	1	7.7
CONJUNCTIVITIS	1	7.7
COUGH	1	7.7
EPISTAXIS	1	7.7
NASAL CONGESTION	1	7.7
OTITIS MEDIA	1	7.7
PHARYNGITIS	1	7.7
RASH	1	7.7

TABLE 5 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : BROMBERG, KENNETH
STUDY : 000403
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	56	
VACCINEES WITH NO COMPLAINTS :	10	(18.2 %)
VACCINEES WITH COMPLAINTS :	45	(81.8 %)
VACCINEES WITH NO DATA :	1	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 55 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	26	47.3
ERYTHEMA, INJ. SITE (<=1 IN.)	16	29.1
SWELLING, INJ. SITE (<=1 IN.)	11	20.0
PAIN/SORENESS, INJ. SITE	7	12.7
ERYTHEMA, INJ. SITE (>1 INCH)	3	5.5
INDURATION, INJECTION SITE	1	1.8
SWELLING, INJ. SITE (>1 INCH)	1	1.8
SYSTEMIC REACTIONS	40	72.7
FATIGUE	27	49.1
IRRITABILITY	21	38.2
WARM TO TOUCH	9	16.4
TEETHING	7	12.7
PROLONGED CRYING, >1/2 HR	6	10.9
COMMON COLD	4	7.3
DIARRHEA	2	3.6
NASAL CONGESTION	2	3.6
VOMITING	2	3.6
ANOREXIA	1	1.8
CRYING, EXCESSIVE	1	1.8
FEVER	1	1.8
RASH	1	1.8
WHEEZING	1	1.8

TABLE 5 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : BROMBERG, KENNETH
STUDY : 000403
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 2	
TOTAL VACCINEES :	38	
VACCINEES WITH NO COMPLAINTS :	8	(21.6 %)
VACCINEES WITH COMPLAINTS :	29	(78.4 %)
VACCINEES WITH NO DATA :	1	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 37 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	17	45.9
ERYTHEMA, INJ. SITE (<=1 IN.)	10	27.0
SWELLING, INJ. SITE (<=1 IN.)	10	27.0
PAIN/SORENESS, INJ. SITE	7	18.9
INDURATION, INJECTION SITE	2	5.4
SWELLING, INJ. SITE (>1 INCH)	2	5.4
ERYTHEMA, INJ. SITE (>1 INCH)	1	2.7
SYSTEMIC REACTIONS	24	64.9
IRRITABILITY	16	43.2
FATIGUE	14	37.8
WARM TO TOUCH	9	24.3
TEETHING	8	21.6
VOMITING	5	13.5
DIARRHEA	2	5.4
PROLONGED CRYING, >1/2 HR	2	5.4
ANOREXIA	1	2.7
ATAXIA	1	2.7
COMMON COLD	1	2.7
COUGH	1	2.7
FEVER	1	2.7
INSOMNIA	1	2.7
NASAL CONGESTION	1	2.7
NASAL DISCHARGE	1	2.7
NAUSEA	1	2.7
NERVOUSNESS	1	2.7
SALIVATION INCREASE	1	2.7
WHEEZING	1	2.7

TABLE 5 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : BROMBERG, KENNETH
STUDY : 000403
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
POPULATION : HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	17	
VACCINEES WITH NO COMPLAINTS :	4	(28.6 %)
VACCINEES WITH COMPLAINTS :	10	(71.4 %)
VACCINEES WITH NO DATA :	3	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 14 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	3	21.4
ERYTHEMA, INJ. SITE (<=1 IN.)	2	14.3
SWELLING, INJ. SITE (<=1 IN.)	2	14.3
SYSTEMIC REACTIONS	10	71.4
FATIGUE	6	42.9
COUGH	3	21.4
IRRITABILITY	3	21.4
COMMON COLD	2	14.3
TEETHING	2	14.3
VOMITING	2	14.3
DIARRHEA	1	7.1
NASAL DISCHARGE	1	7.1
SALIVATION INCREASE	1	7.1
STRIDOR	1	7.1
VIRUS INFECTION	1	7.1
WARM TO TOUCH	1	7.1
WHEEZING	1	7.1

TABLE 6

CLINICAL COMPLAINTS

INVESTIGATOR : BROMBERG, KENNETH
STUDY : 000403
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (19 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
LOCAL REACTIONS	3 (15.8%)	7 (36.8%)	5 (26.3%)	4 (21.1%)	3 (15.8%)	2 (10.5%)		7 (36.8%)
ERYTHEMA, INJ. SITE (<=1 IN.)	2 (10.5%)	5 (26.3%)	2 (10.5%)	1 (5.3%)	1 (5.3%)	0 (0.0%)		5 (26.3%)
INDURATION, INJECTION SITE	0 (0.0%)	1 (5.3%)	1 (5.3%)	1 (5.3%)	1 (5.3%)	1 (5.3%)		2 (10.5%)
SWELLING, INJ. SITE (<=1 IN.)	2 (10.5%)	4 (21.1%)	3 (15.8%)	3 (15.8%)	2 (10.5%)	1 (5.3%)		4 (21.1%)
SYSTEMIC	5 (26.3%)	10 (52.6%)	9 (47.4%)	6 (31.6%)	6 (31.6%)	8 (42.1%)		14 (73.7%)
BODY AS A WHOLE/SITE UNSPEC.	3 (15.8%)	4 (21.1%)	2 (10.5%)	1 (5.3%)	1 (5.3%)	1 (5.3%)		5 (26.3%)
FATIGUE	3 (15.8%)	4 (21.1%)	2 (10.5%)	1 (5.3%)	1 (5.3%)	1 (5.3%)		5 (26.3%)
DIGESTIVE SYSTEM	2 (10.5%)	4 (21.1%)	4 (21.1%)	3 (15.8%)	3 (15.8%)	4 (21.1%)		6 (31.6%)
ANOREXIA	1 (5.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (5.3%)
TEETHING	2 (10.5%)	3 (15.8%)	3 (15.8%)	3 (15.8%)	3 (15.8%)	4 (21.1%)		5 (26.3%)
VOMITING	0 (0.0%)	1 (5.3%)	1 (5.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (5.3%)

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : BROMBERG, KENNETH
STUDY : 000403
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (19 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5	COMPLAINTS
NERVOUS SYSTEM & PSYCHIATRIC	2 (10.5%)	3 (15.8%)	4 (21.1%)	2 (10.5%)	2 (10.5%)	2 (10.5%)	7 (36.8%)
CRYING	1 (5.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (5.3%)
INSOMNIA	1 (5.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (5.3%)
IRRITABILITY	1 (5.3%)	2 (10.5%)	4 (21.1%)	2 (10.5%)	2 (10.5%)	2 (10.5%)	6 (31.6%)
PROLONGED CRYING, >1/2 HR	0 (0.0%)	1 (5.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (5.3%)
RESPIRATORY SYSTEM	0 (0.0%)	1 (5.3%)	1 (5.3%)	1 (5.3%)	1 (5.3%)	1 (5.3%)	1 (5.3%)
COUGH	0 (0.0%)	1 (5.3%)	1 (5.3%)	1 (5.3%)	1 (5.3%)	1 (5.3%)	1 (5.3%)
NASAL DISCHARGE	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (5.3%)	1 (5.3%)	1 (5.3%)
SKIN & SKIN APPENDAGE	0 (0.0%)	1 (5.3%)	2 (10.5%)	1 (5.3%)	1 (5.3%)	1 (5.3%)	3 (15.8%)
ATOPIC DERMATITIS	0 (0.0%)	0 (0.0%)	1 (5.3%)	1 (5.3%)	1 (5.3%)	1 (5.3%)	1 (5.3%)
RASH	0 (0.0%)	1 (5.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (5.3%)
SKIN INFLAMMATION	0 (0.0%)	0 (0.0%)	1 (5.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (5.3%)

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : BROMBERG, KENNETH
STUDY : 000403
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (19 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		**********
VACCINEES WITH COMPLAINTS	7 (36.8%)	12 (63.2%)	12 (63.2%)	8 (42.1%)	8 (42.1%)	10 (52.6%)		15 (78.9%)
VACCINEES WITH NO COMPLAINTS	12 (63.2%)	7 (36.8%)	7 (36.8%)	11 (57.9%)	11 (57.9%)	9 (47.4%)		4 (21.1%)
TOTAL VACCINEES REPORTING	19	19	19	19	19	19		19
VACCINEES WITH NO DATA	0	0	0	0	0	0		0

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : BROMBERG, KENNETH
STUDY : 000403
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (19 VACCINEES) - INJECTION: 2						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5	COMPLAINTS
LOCAL REACTIONS	1 (5.6%)	5 (26.3%)	5 (26.3%)	2 (10.5%)	2 (10.5%)	2 (10.5%)	5 (26.3%)
ERYTHEMA, INJ. SITE (<=1 IN.)	0 (0.0%)	3 (15.8%)	2 (10.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (15.8%)
INDURATION, INJECTION SITE	1 (5.6%)	1 (5.3%)	1 (5.3%)	1 (5.3%)	1 (5.3%)	1 (5.3%)	1 (5.3%)
SWELLING, INJ. SITE (<=1 IN.)	0 (0.0%)	2 (10.5%)	2 (10.5%)	1 (5.3%)	1 (5.3%)	1 (5.3%)	2 (10.5%)
SYSTEMIC	10 (55.6%)	7 (36.8%)	6 (31.6%)	4 (21.1%)	2 (10.5%)	2 (10.5%)	13 (68.4%)
BODY AS A WHOLE/SITE UNSPEC.	3 (16.7%)	2 (10.5%)	3 (15.8%)	2 (10.5%)	0 (0.0%)	0 (0.0%)	4 (21.1%)
FATIGUE	3 (16.7%)	2 (10.5%)	3 (15.8%)	2 (10.5%)	0 (0.0%)	0 (0.0%)	4 (21.1%)
WARM TO TOUCH	1 (5.6%)	1 (5.3%)	1 (5.3%)	1 (5.3%)	0 (0.0%)	0 (0.0%)	2 (10.5%)
DIGESTIVE SYSTEM	1 (5.6%)	3 (15.8%)	3 (15.8%)	1 (5.3%)	1 (5.3%)	1 (5.3%)	4 (21.1%)
ANOREXIA	0 (0.0%)	1 (5.3%)	1 (5.3%)	1 (5.3%)	0 (0.0%)	0 (0.0%)	1 (5.3%)
DIARRHEA	0 (0.0%)	1 (5.3%)	2 (10.5%)	1 (5.3%)	1 (5.3%)	1 (5.3%)	2 (10.5%)

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : BROMBERG, KENNETH
STUDY : 000403
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (19 VACCINEES) - INJECTION; 2							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		
TEETHING	1 (5.6%)	1 (5.3%)	1 (5.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (10.5%)
VOMITING	0 (0.0%)	1 (5.3%)	1 (5.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (5.3%)
NERVOUS SYSTEM & PSYCHIATRIC	6 (33.3%)	5 (26.3%)	3 (15.8%)	1 (5.3%)	0 (0.0%)	0 (0.0%)		10 (52.6%)
IRRITABILITY	6 (33.3%)	5 (26.3%)	3 (15.8%)	1 (5.3%)	0 (0.0%)	0 (0.0%)		10 (52.6%)
RESPIRATORY SYSTEM	1 (5.6%)	1 (5.3%)	1 (5.3%)	1 (5.3%)	1 (5.3%)	1 (5.3%)		1 (5.3%)
COMMON COLD	1 (5.6%)	1 (5.3%)	1 (5.3%)	1 (5.3%)	1 (5.3%)	1 (5.3%)		1 (5.3%)
SPECIAL SENSES	0 (0.0%)	1 (5.3%)	1 (5.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (5.3%)
EAR INFECTION, NOS	0 (0.0%)	1 (5.3%)	1 (5.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (5.3%)
VACCINEES WITH COMPLAINTS	10 (55.6%)	9 (47.4%)	8 (42.1%)	6 (31.6%)	4 (21.1%)	4 (21.1%)		14 (73.7%)
VACCINEES WITH NO COMPLAINTS	8 (44.4%)	10 (52.6%)	11 (57.9%)	13 (68.4%)	15 (78.9%)	15 (78.9%)		5 (26.3%)
TOTAL VACCINEES REPORTING	18	19	19	19	19	19		19

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : BROMBERG, KENNETH
STUDY : 000403
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (19 VACCINEES) - INJECTION: 2						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5	COMPLAINTS
VACCINEES WITH NO DATA	1	0	0	0	0	0	0

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : BROMBERG, KENNETH
STUDY : 000403
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (13 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
LOCAL REACTIONS	4 (30.8%)	2 (15.4%)	1 (7.7%)	1 (7.7%)	1 (7.7%)	1 (7.7%)		4 (30.8%)
ERYTHEMA, INJ. SITE (>1 INCH)	0 (0.0%)	1 (7.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (7.7%)
ERYTHEMA, INJ. SITE (<=1 IN.)	1 (7.7%)	1 (7.7%)	1 (7.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (7.7%)
PAIN/SORENESS, INJ. SITE	4 (30.8%)	2 (15.4%)	1 (7.7%)	1 (7.7%)	0 (0.0%)	0 (0.0%)		4 (30.8%)
SWELLING, INJ. SITE (>1 INCH)	1 (7.7%)	1 (7.7%)	1 (7.7%)	1 (7.7%)	1 (7.7%)	0 (0.0%)		1 (7.7%)
SWELLING, INJ. SITE (<=1 IN.)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.7%)		1 (7.7%)
WARMTH, INJECTION SITE	0 (0.0%)	1 (7.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (7.7%)
SYSTEMIC	8 (61.5%)	7 (53.8%)	5 (38.5%)	5 (38.5%)	7 (53.8%)	7 (53.8%)		12 (92.3%)
BODY AS A WHOLE/SITE UNSPEC.	3 (23.1%)	2 (15.4%)	0 (0.0%)	0 (0.0%)	2 (15.4%)	1 (7.7%)		5 (38.5%)
FATIGUE	3 (23.1%)	2 (15.4%)	0 (0.0%)	0 (0.0%)	2 (15.4%)	1 (7.7%)		5 (38.5%)
WARM TO TOUCH	1 (7.7%)	2 (15.4%)	0 (0.0%)	0 (0.0%)	1 (7.7%)	0 (0.0%)		3 (23.1%)

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : BROMBERG, KENNETH
STUDY : 000403
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (13 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5	
DIGESTIVE SYSTEM	5 (38.5%)	5 (38.5%)	4 (30.8%)	4 (30.8%)	5 (38.5%)	4 (30.8%)	7 (53.8%)
ANOREXIA	0 (0.0%)	1 (7.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.7%)
DIARRHEA	0 (0.0%)	0 (0.0%)	1 (7.7%)	1 (7.7%)	4 (30.8%)	1 (7.7%)	4 (30.8%)
TEETHING	4 (30.8%)	5 (38.5%)	4 (30.8%)	4 (30.8%)	3 (23.1%)	4 (30.8%)	5 (38.5%)
VOMITING	1 (7.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.7%)	0 (0.0%)	2 (15.4%)
NERVOUS SYSTEM & PSYCHIATRIC	4 (30.8%)	4 (30.8%)	1 (7.7%)	0 (0.0%)	2 (15.4%)	2 (15.4%)	8 (61.5%)
APATHY	0 (0.0%)	1 (7.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.7%)
IRRITABILITY	4 (30.8%)	4 (30.8%)	0 (0.0%)	0 (0.0%)	2 (15.4%)	2 (15.4%)	7 (53.8%)
PROLONGED CRYING, >1/2 HR	2 (15.4%)	0 (0.0%)	1 (7.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (23.1%)
RESPIRATORY SYSTEM	1 (7.7%)	1 (7.7%)	0 (0.0%)	1 (7.7%)	1 (7.7%)	3 (23.1%)	4 (30.8%)
COUGH	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.7%)	1 (7.7%)	1 (7.7%)	1 (7.7%)
EPISTAXIS	0 (0.0%)	1 (7.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.7%)

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : BROMBERG, KENNETH
STUDY : 000403
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (13 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
NASAL CONGESTION	1 (7.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (7.7%)
NASAL DISCHARGE	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.7%)	1 (7.7%)	2 (15.4%)		2 (15.4%)
PHARYNGITIS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.7%)		1 (7.7%)
UPPER RESPIRATORY INFECTION, NOS	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.7%)	1 (7.7%)	2 (15.4%)		2 (15.4%)
SKIN & SKIN APPENDAGE	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.7%)	0 (0.0%)		1 (7.7%)
RASH	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.7%)	0 (0.0%)		1 (7.7%)
SPECIAL SENSES	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.7%)		1 (7.7%)
CONJUNCTIVITIS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.7%)		1 (7.7%)
OTITIS MEDIA	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.7%)		1 (7.7%)
VACCINEES WITH COMPLAINTS	8 (61.5%)	7 (53.8%)	5 (38.5%)	5 (38.5%)	7 (53.8%)	7 (53.8%)		12 (92.3%)
VACCINEES WITH NO COMPLAINTS	5 (38.5%)	6 (46.2%)	8 (61.5%)	8 (61.5%)	6 (46.2%)	6 (46.2%)		1 (7.7%)
TOTAL VACCINEES REPORTING	13	13	13	13	13	13		13

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : BROMBERG, KENNETH
STUDY : 000403
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (13 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
								**********
VACCINEES WITH NO DATA	0	0	0	0	0	0		0

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : BROMBERG, KENNETH
STUDY : 000403
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (56 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		
LOCAL REACTIONS	9 (16.4%)	23 (41.8%)	13 (23.6%)	9 (16.4%)	6 (10.9%)	5 (9.1%)		26 (47.3%)
ERYTHEMA, INJ. SITE (>1 INCH)	0 (0.0%)	2 (3.6%)	1 (1.8%)	0 (0.0%)	1 (1.8%)	0 (0.0%)		3 (5.5%)
ERYTHEMA, INJ. SITE (<=1 IN.)	5 (9.1%)	15 (27.3%)	7 (12.7%)	4 (7.3%)	1 (1.8%)	1 (1.8%)		16 (29.1%)
INDURATION, INJECTION SITE	0 (0.0%)	0 (0.0%)	1 (1.8%)	1 (1.8%)	1 (1.8%)	1 (1.8%)		1 (1.8%)
PAIN/SORENESS, INJ. SITE	4 (7.3%)	4 (7.3%)	2 (3.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		7 (12.7%)
SWELLING, INJ. SITE (>1 INCH)	1 (1.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (1.8%)
SWELLING, INJ. SITE (<=1 IN.)	4 (7.3%)	10 (18.2%)	7 (12.7%)	7 (12.7%)	4 (7.3%)	4 (7.3%)		11 (20.0%)
SYSTEMIC	21 (38.2%)	28 (50.9%)	19 (34.5%)	18 (32.7%)	15 (27.3%)	15 (27.3%)		40 (72.7%)
BODY AS A WHOLE/SITE UNSPEC.	12 (21.8%)	23 (41.8%)	11 (20.0%)	6 (10.9%)	4 (7.3%)	4 (7.3%)		30 (54.5%)
FATIGUE	11 (20.0%)	19 (34.5%)	10 (18.2%)	5 (9.1%)	3 (5.5%)	3 (5.5%)		27 (49.1%)
FEVER	1 (1.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (1.8%)

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TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : BROMBERG, KENNETH
STUDY : 000403
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (56 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5	
HARM TO TOUCH	2 (3.6%)	8 (14.5%)	1 (1.8%)	1 (1.8%)	1 (1.8%)	1 (1.8%)	9 (16.4%)
DIGESTIVE SYSTEM	6 (10.9%)	5 (9.1%)	6 (10.9%)	5 (9.1%)	5 (9.1%)	5 (9.1%)	11 (20.0%)
ANOREXIA	1 (1.8%)	1 (1.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.8%)
DIARRHEA	1 (1.8%)	0 (0.0%)	1 (1.8%)	0 (0.0%)	0 (0.0%)	1 (1.8%)	2 (3.6%)
TEETHING	4 (7.3%)	3 (5.5%)	5 (9.1%)	5 (9.1%)	5 (9.1%)	4 (7.3%)	7 (12.7%)
VOMITING	1 (1.8%)	1 (1.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (3.6%)
NERVOUS SYSTEM & PSYCHIATRIC	9 (16.4%)	11 (20.0%)	8 (14.5%)	8 (14.5%)	4 (7.3%)	4 (7.3%)	23 (41.8%)
CRYING, EXCESSIVE	1 (1.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.8%)
IRRITABILITY	7 (12.7%)	10 (18.2%)	8 (14.5%)	8 (14.5%)	4 (7.3%)	4 (7.3%)	21 (38.2%)
PROLONGED CRYING, >1/2 HR	2 (3.6%)	4 (7.3%)	2 (3.6%)	1 (1.8%)	0 (0.0%)	0 (0.0%)	6 (10.9%)
RESPIRATORY SYSTEM	2 (3.6%)	2 (3.6%)	2 (3.6%)	3 (5.5%)	4 (7.3%)	5 (9.1%)	6 (10.9%)
COMMON COLD	1 (1.8%)	1 (1.8%)	1 (1.8%)	2 (3.6%)	3 (5.5%)	2 (3.6%)	4 (7.3%)

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : BROMBERG, KENNETH
STUDY : 000403
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (56 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
NASAL CONGESTION	1 (1.8%)	1 (1.8%)	1 (1.8%)	1 (1.8%)	1 (1.8%)	2 (3.6%)		2 (3.6%)
WHEEZING	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.8%)		1 (1.8%)
SKIN & SKIN APPENDAGE	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.8%)	1 (1.8%)	0 (0.0%)		1 (1.8%)
RASH	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.8%)	1 (1.8%)	0 (0.0%)		1 (1.8%)
VACCINEES WITH COMPLAINTS	24 (43.6%)	36 (65.5%)	25 (45.5%)	24 (43.6%)	18 (32.7%)	17 (30.9%)		45 (81.8%)
VACCINEES WITH NO COMPLAINTS	31 (56.4%)	19 (34.5%)	30 (54.5%)	31 (56.4%)	37 (67.3%)	38 (69.1%)		10 (18.2%)
TOTAL VACCINEES REPORTING	55	55	55	55	55	55		55
VACCINEES WITH NO DATA	1	1	1	1	1	1		1

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : BROMBERG, KENNETH
STUDY : 000403
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (38 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
LOCAL REACTIONS	8 (23.5%)	15 (40.5%)	11 (29.7%)	10 (27.0%)	9 (24.3%)	9 (24.3%)		17 (45.9%)
ERYTHEMA, INJ. SITE (>1 INCH)	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (2.7%)
ERYTHEMA, INJ. SITE (<=1 IN.)	6 (17.6%)	8 (21.6%)	5 (13.5%)	4 (10.8%)	2 (5.4%)	1 (2.7%)		10 (27.0%)
INDURATION, INJECTION SITE	0 (0.0%)	1 (2.7%)	1 (2.7%)	2 (5.4%)	1 (2.7%)	1 (2.7%)		2 (5.4%)
PAIN/SORENESS, INJ. SITE	5 (14.7%)	4 (10.8%)	3 (8.1%)	1 (2.7%)	1 (2.7%)	1 (2.7%)		7 (18.9%)
SWELLING, INJ. SITE (>1 INCH)	1 (2.9%)	2 (5.4%)	2 (5.4%)	1 (2.7%)	1 (2.7%)	1 (2.7%)		2 (5.4%)
SWELLING, INJ. SITE (<=1 IN.)	4 (11.8%)	7 (18.9%)	5 (13.5%)	7 (18.9%)	7 (18.9%)	7 (18.9%)		10 (27.0%)
SYSTEMIC	13 (38.2%)	20 (54.1%)	11 (29.7%)	9 (24.3%)	8 (21.6%)	6 (16.2%)		24 (64.9%)
BODY AS A WHOLE/SITE UNSPEC.	7 (20.6%)	13 (35.1%)	5 (13.5%)	4 (10.8%)	2 (5.4%)	1 (2.7%)		15 (40.5%)
FATIGUE	6 (17.6%)	10 (27.0%)	3 (8.1%)	3 (8.1%)	2 (5.4%)	0 (0.0%)		14 (37.8%)
FEVER	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)		1 (2.7%)

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : BROMBERG, KENNETH
STUDY : 000403
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (38 VACCINEES) - INJECTION: 2						
	DAYS POST VACCINATION						NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5	
HARM TO TOUCH	3 (8.8%)	4 (10.8%)	3 (8.1%)	3 (8.1%)	1 (2.7%)	1 (2.7%)	9 (24.3%)
DIGESTIVE SYSTEM	3 (8.8%)	10 (27.0%)	8 (21.6%)	7 (18.9%)	7 (18.9%)	5 (13.5%)	11 (29.7%)
ANOREXIA	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
DIARRHEA	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	1 (2.7%)	D (0.0%)	2 (5.4%)
NAUSEA	0 (0.0%)	1 (2.7%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
SALIVATION INCREASE	0 (0.0%)	1 (2.7%)	1 (2.7%)	1 (2.7%)	1 (2.7%)	0 (0.0%)	1 (2.7%)
TEETHING	3 (8.8%)	7 (18.9%)	8 (21.6%)	7 (18.9%)	7 (18.9%)	5 (13.5%)	8 (21.6%)
VOMITING	0 (0.0%)	3 (8.1%)	2 (5.4%)	0 (0.0%)	1 (2.7%)	0 (0.0%)	5 (13.5%)
NERVOUS SYSTEM & PSYCHIATRIC	10 (29.4%)	12 (32.4%)	1 (2.7%)	3 (8.1%)	2 (5.4%)	2 (5.4%)	18 (48.6%)
ATAXIA	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
INSOMNIA	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)
IRRITABILITY	10 (29.4%)	11 (29.7%)	1 (2.7%)	3 (8.1%)	1 (2.7%)	1 (2.7%)	16 (43.2%)

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : BROMBERG, KENNETH
STUDY : 000403
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (38 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		
NERVOUSNESS	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (2.7%)
PROLONGED CRYING, >1/2 HR	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	1 (2.7%)	1 (2.7%)		2 (5.4%)
RESPIRATORY SYSTEM	0 (0.0%)	2 (5.4%)	3 (8.1%)	1 (2.7%)	2 (5.4%)	1 (2.7%)		4 (10.8%)
COMMON COLD	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)		1 (2.7%)
COUGH	0 (0.0%)	1 (2.7%)	1 (2.7%)	1 (2.7%)	1 (2.7%)	1 (2.7%)		1 (2.7%)
NASAL CONGESTION	0 (0.0%)	0 (0.0%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (2.7%)
NASAL DISCHARGE	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)	0 (0.0%)		1 (2.7%)
WHEEZING	0 (0.0%)	1 (2.7%)	1 (2.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (2.7%)
VACCINEES WITH COMPLAINTS	14 (41.2%)	26 (70.3%)	17 (45.9%)	14 (37.8%)	14 (37.8%)	12 (32.4%)		29 (78.4%)
VACCINEES WITH NO COMPLAINTS	20 (58.8%)	11 (29.7%)	20 (54.1%)	23 (62.2%)	23 (62.2%)	25 (67.6%)		8 (21.6%)
TOTAL VACCINEES REPORTING	34	37	37	37	37	37		37

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : BROMBERG, KENNETH
STUDY : 000403
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (38 VACCINEES) - INJECTION: 2						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5	COMPLAINTS
VACCINEES WITH NO DATA	4	1	1	1	1	1	1

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : BROMBERG, KENNETH
STUDY : 000403
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (17 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5	COMPLAINTS
LOCAL REACTIONS	2 (14.3%)	2 (14.3%)	1 (7.1%)	1 (7.1%)	1 (7.1%)	1 (7.1%)	3 (21.4%)
ERYTHEMA, INJ. SITE (<=1 IN.)	1 (7.1%)	1 (7.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (14.3%)
SWELLING, INJ. SITE (<=1 IN.)	2 (14.3%)	1 (7.1%)	1 (7.1%)	1 (7.1%)	1 (7.1%)	1 (7.1%)	2 (14.3%)
SYSTEMIC	6 (42.9%)	5 (35.7%)	5 (35.7%)	4 (28.6%)	5 (35.7%)	6 (42.9%)	10 (71.4%)
BODY AS A WHOLE/SITE UNSPEC.	2 (14.3%)	4 (28.6%)	2 (14.3%)	0 (0.0%)	0 (0.0%)	1 (7.1%)	6 (42.9%)
FATIGUE	2 (14.3%)	4 (28.6%)	2 (14.3%)	0 (0.0%)	0 (0.0%)	1 (7.1%)	6 (42.9%)
VIRUS INFECTION	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.1%)	1 (7.1%)
HARM TO TOUCH	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.1%)	1 (7.1%)
DIGESTIVE SYSTEM	3 (21.4%)	2 (14.3%)	2 (14.3%)	2 (14.3%)	2 (14.3%)	4 (28.6%)	5 (35.7%)
DIARRHEA	0 (0.0%)	0 (0.0%)	1 (7.1%)	1 (7.1%)	1 (7.1%)	1 (7.1%)	1 (7.1%)
SALIVATION INCREASE	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.1%)	1 (7.1%)

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : BROMBERG, KENNETH
STUDY : 000403
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (17 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
TEETHING	2 (14.3%)	1 (7.1%)	1 (7.1%)	1 (7.1%)	1 (7.1%)	1 (7.1%)		2 (14.3%)
VOMITING	1 (7.1%)	1 (7.1%)	1 (7.1%)	0 (0.0%)	0 (0.0%)	1 (7.1%)		2 (14.3%)
NERVOUS SYSTEM & PSYCHIATRIC	1 (7.1%)	1 (7.1%)	1 (7.1%)	2 (14.3%)	2 (14.3%)	1 (7.1%)		3 (21.4%)
IRRITABILITY	1 (7.1%)	1 (7.1%)	1 (7.1%)	2 (14.3%)	2 (14.3%)	1 (7.1%)		3 (21.4%)
RESPIRATORY SYSTEM	2 (14.3%)	1 (7.1%)	2 (14.3%)	2 (14.3%)	3 (21.4%)	3 (21.4%)		4 (28.6%)
COMMON COLD	1 (7.1%)	1 (7.1%)	2 (14.3%)	1 (7.1%)	1 (7.1%)	1 (7.1%)		2 (14.3%)
COUGH	1 (7.1%)	0 (0.0%)	1 (7.1%)	1 (7.1%)	2 (14.3%)	2 (14.3%)		3 (21.4%)
NASAL DISCHARGE	1 (7.1%)	1 (7.1%)	1 (7.1%)	1 (7.1%)	1 (7.1%)	1 (7.1%)		1 (7.1%)
STRIDOR	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.1%)		1 (7.1%)
WHEEZING	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.1%)		1 (7.1%)
VACCINEES WITH COMPLAINTS	6 (42.9%)	6 (42.9%)	5 (35.7%)	4 (28.6%)	5 (35.7%)	6 (42.9%)		10 (71.4%)
VACCINEES WITH NO COMPLAINTS	8 (57.1%)	8 (57.1%)	9 (64.3%)	10 (71.4%)	9 (64.3%)	8 (57.1%)		4 (28.6%)

00290

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : BROMBERG, KENNETH
STUDY : 000403
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (17 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
TOTAL VACCINEES REPORTING	14	14	14	14	14	14		14
VACCINEES WITH NO DATA	3	3	3	3	3	3		3

TABLE 7

MAXIMUM TEMPERATURES

INVESTIGATOR : BROMBERG, KENNETH
STUDY : 000403
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (19 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
< 99	15 (88.2%)	13 (68.4%)	17 (94.4%)	17 (89.5%)	18 (94.7%)	18 (94.7%)		13 (68.4%)
99 - 99.9	2 (11.8%)	6 (31.6%)	1 (5.6%)	2 (10.5%)	0 (0.0%)	1 (5.3%)		5 (26.3%)
100 - 100.9	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (5.3%)	0 (0.0%)		1 (5.3%)
TEMPERATURE TAKEN	17 (89.5%)	19 (100.0%)	18 (94.7%)	19 (100.0%)	19 (100.0%)	19 (100.0%)		19 (100.0%)
TEMPERATURE NOT TAKEN	2 (10.5%)	0 (0.0%)	1 (5.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)

00202

TABLE 7 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : BROMBERG, KENNETH
STUDY : 000403
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (19 VACCINEES) - INJECTION 2							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
NORMAL	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (5.3%)	1 (5.6%)	1 (5.3%)		0 (0.0%)
< 99	10 (76.9%)	13 (68.4%)	15 (78.9%)	16 (84.2%)	15 (83.3%)	16 (84.2%)		11 (57.9%)
99 - 99.9	2 (15.4%)	4 (21.1%)	2 (10.5%)	0 (0.0%)	1 (5.6%)	1 (5.3%)		5 (26.3%)
100 - 100.9	1 (7.7%)	2 (10.5%)	0 (0.0%)	1 (5.3%)	0 (0.0%)	0 (0.0%)		1 (5.3%)
101 - 101.9	0 (0.0%)	0 (0.0%)	1 (5.3%)	0 (0.0%)	0 (0.0%)	1 (5.3%)		0 (0.0%)
102 - 102.9	0 (0.0%)	0 (0.0%)	1 (5.3%)	0 (0.0%)	1 (5.6%)	0 (0.0%)		1 (5.3%)
103 - 103.9	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (5.3%)	0 (0.0%)	0 (0.0%)		1 (5.3%)
TEMPERATURE TAKEN	13 (68.4%)	19 (100.0%)	19 (100.0%)	19 (100.0%)	18 (94.7%)	19 (100.0%)		19 (100.0%)
TEMPERATURE NOT TAKEN	6 (31.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (5.3%)	0 (0.0%)		0 (0.0%)

TABLE 7 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : BROMBERG, KENNETH
STUDY : 000403
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (13 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		MAX TEMP
NORMAL	0 (0.0%)	0 (0.0%)	1 (8.3%)	1 (7.7%)	1 (7.7%)	1 (7.7%)		0 (0.0%)
< 99	8 (80.0%)	10 (76.9%)	10 (83.3%)	10 (76.9%)	8 (61.5%)	9 (69.2%)		7 (53.8%)
99 - 99.9	2 (20.0%)	2 (15.4%)	1 (8.3%)	1 (7.7%)	2 (15.4%)	1 (7.7%)		2 (15.4%)
100 - 100.9	0 (0.0%)	1 (7.7%)	0 (0.0%)	0 (0.0%)	1 (7.7%)	0 (0.0%)		1 (7.7%)
101 - 101.9	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.7%)	0 (0.0%)	1 (7.7%)		2 (15.4%)
103 - 103.9	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.7%)	1 (7.7%)		1 (7.7%)
TEMPERATURE TAKEN	10 (76.9%)	13 (100.0%)	12 (92.3%)	13 (100.0%)	13 (100.0%)	13 (100.0%)		13 (100.0%)
TEMPERATURE NOT TAKEN	3 (23.1%)	0 (0.0%)	1 (7.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)

TABLE 7 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : BROMBERG, KENNETH
STUDY : 000403
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (56 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
NORMAL	2 (6.3%)	2 (3.7%)	2 (3.6%)	2 (3.6%)	2 (3.8%)	2 (4.0%)		2 (3.6%)
< 99	29 (90.6%)	47 (87.0%)	51 (92.7%)	51 (92.7%)	46 (88.5%)	47 (94.0%)		44 (80.0%)
99 - 99.9	1 (3.1%)	5 (9.3%)	2 (3.6%)	1 (1.8%)	4 (7.7%)	1 (2.0%)		8 (14.5%)
100 - 100.9	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.8%)	0 (0.0%)	0 (0.0%)		1 (1.8%)
TEMPERATURE TAKEN	32 (57.1%)	54 (96.4%)	55 (98.2%)	55 (98.2%)	52 (92.9%)	50 (89.3%)		55 (98.2%)
TEMPERATURE NOT TAKEN	24 (42.9%)	2 (3.6%)	1 (1.8%)	1 (1.8%)	4 (7.1%)	6 (10.7%)		1 (1.8%)

TABLE 7 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : BROMBERG, KENNETH
STUDY : 000403
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (38 VACCINEES) - INJECTION 2							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
NORMAL	2 (7.7%)	2 (5.6%)	3 (8.3%)	3 (8.8%)	4 (11.1%)	4 (11.8%)		2 (5.6%)
< 99	22 (84.6%)	29 (80.6%)	31 (86.1%)	29 (85.3%)	29 (80.6%)	28 (82.4%)		25 (69.4%)
99 - 99.9	2 (7.7%)	5 (13.9%)	0 (0.0%)	1 (2.9%)	2 (5.6%)	1 (2.9%)		7 (19.4%)
100 - 100.9	0 (0.0%)	0 (0.0%)	2 (5.6%)	0 (0.0%)	0 (0.0%)	1 (2.9%)		1 (2.8%)
101 - 101.9	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.9%)	1 (2.8%)	0 (0.0%)		1 (2.8%)
TEMPERATURE TAKEN	26 (68.4%)	36 (94.7%)	36 (94.7%)	34 (89.5%)	36 (94.7%)	34 (89.5%)		36 (94.7%)
TEMPERATURE NOT TAKEN	12 (31.6%)	2 (5.3%)	2 (5.3%)	4 (10.5%)	2 (5.3%)	4 (10.5%)		2 (5.3%)

TABLE 7 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : BROMBERG, KENNETH
STUDY : 000403
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (17 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
< 99	8 (100.0%)	13 (76.5%)	14 (87.5%)	13 (81.3%)	13 (86.7%)	13 (76.5%)		10 (58.8%)
99 - 99.9	0 (0.0%)	4 (23.5%)	1 (6.3%)	1 (6.3%)	1 (6.7%)	1 (5.9%)		3 (17.6%)
100 - 100.9	0 (0.0%)	0 (0.0%)	1 (6.3%)	1 (6.3%)	1 (6.7%)	1 (5.9%)		2 (11.8%)
101 - 101.9	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (6.3%)	0 (0.0%)	2 (11.8%)		2 (11.8%)
TEMPERATURE TAKEN	8 (47.1%)	17 (100.0%)	16 (94.1%)	16 (94.1%)	15 (88.2%)	17 (100.0%)		17 (100.0%)
TEMPERATURE NOT TAKEN	9 (52.9%)	0 (0.0%)	1 (5.9%)	1 (5.9%)	2 (11.8%)	0 (0.0%)		0 (0.0%)

STUDY 004-04

PROGRAM: Haemophilus b Conjugate Vaccine (Neisseria meningitidis Outer Membrane Protein Complex), Study 004-04

PURPOSE: To evaluate the safety and immunogenicity of Haemophilus b conjugate vaccine (Neisseria meningitidis outer membrane protein complex) in healthy infants 2 months of age.

VACCINE: Haemophilus b Conjugate Vaccine (Neisseria meningitidis Outer Membrane Protein Complex) (PRP-OMPC)

Lot 1069/C-P241 - (b) (4) mcg polysaccharide/ml
(b) (4) mcg meningococcal protein/ml
Lot 1072/C-P298 - (b) (4) mcg polysaccharide/ml
(b) (4) mcg meningococcal protein/ml

Aluminum hydroxide diluent
Lot (b) (4)

INVESTIGATOR: Joel I. Ward, M.D.
Harbor-UCLA Medical Center
Torrance, California

SUB-INVESTIGATOR: Carol Berkowitz, M.D.
Harbor-UCLA Medical Center
Torrance, California

STUDY LOCATION: Research and Education Institute
Harbor-UCLA Medical Center
Torrance, California

Kaiser-Permanente Medical Center
Panorama City, California

DATE STUDY INITIATED: September 14, 1987

DATE STUDY COMPLETED: In progress.

STUDY POPULATION: Healthy infants 2 months of age are included in the study.

STUDY PROCEDURE: Infants receive two injections of PRP-OMPC vaccine given 2 months. Vaccine is reconstituted in aluminum hydroxide and administered by intramuscular route. The dose for each injection is 15 mcg of polysaccharide in the appropriate volume. Lot 1069/C-P241 is reconstituted to contain 15 mcg polysaccharide in 0.75 ml, while 1080/C-P749 is reconstituted to contain 15 mcg polysaccharide in 0.5 ml/.

The parent or guardian is required to record the vaccine recipient's temperature and any reactions at the injection site or systemic complaints for 5 days after each injection of vaccine. Unexpected or serious reactions are to be reported immediately to the study physician. Serious adverse experiences in the 14 days following each injection of vaccine are required to be reported by the investigator.

A blood sample is obtained prior to each injection of vaccine and 1 and 7-10 months after the last injection of vaccine. All serum samples are assayed for antibody to the capsular polysaccharide of Haemophilus influenzae type b by radioimmunoassay. Selected samples may be tested for bactericidal and opsonophagocytic activity, immunoglobulin isotype and subclass IgG. Opsonophagocytic assays are performed at the University of Alabama. All other assays are performed at Merck Sharp & Dohme Research Laboratories.

RESULTS: Demographic information and individual pre and postimmunization antibody data for each vaccine recipient are presented in Table 1.

1. Current status:

Lot	No. Vaccinated	
	Injection 1	Injection 2
1069/C-P241	44	32
1072/C-P298	5	17

Thirty-two infants received two injections of Lot 1069/C-P241 and 5 children received two injections of Lot 1072/C-P298. Twelve infants (case nos. (b) (6) (b) (6)) received mixed lots with Lot 1069 as injection 1 and 1072 as injection 2.

2. Serologic results:

Anti-PRP responses prior to each injection of vaccine and 1 month after the last injection of vaccine are as follows:

Time	% With Anti-PRP		GMT (mcg/ml)
	>0.15 mcg/ml	>1.0 mcg/ml	All Vaccinees
Pre	74 (28/38)	8 (3/38)	0.25
Post 1	100 (35/35)	69 (24/35)	2.30
Post 2	100 (37/37)	89 (33/37)	5.38

Antibody responses by lot are presented in Table 2-5. If vaccine recipients received mixed lots, responses after the second injection are excluded from summaries by lot. As most second injections were administered outside the 42-70 acceptable day range, antibody responses are summarized two ways. In Tables 2-3, infants are excluded if their second vaccination and/or serum samples fall outside the standard day range. In Tables 4-5 and in the above summary tables the day ranges are expanded to include the majority of children vaccinated.

RESULTS: (CONT.)

3. Clinical results:

The incidence of selected injection site and systemic reactions occurring within 2 days after vaccination are as follows:

Type of Reaction	% of Vaccines with Reaction Injection 1	Injection 2
Injection Site:		
Pain/Soreness	18 (9/49)	6 (3/49)
Erythema >1 inch	0 (0/49)	2 (1/49)
Swelling >1 inch	0 (0/49)	2 (1/49)
Induration	0 (0/49)	2 (1/49)
Systemic:		
Irritability	25 (12/49)	27 (13/49)
Sleepiness/Lethargy/ Fatigue	20 (10/49)	16 (8/49)

The frequencies of all clinical reactions and maximum temperatures occurring during the 5 days following each injection of vaccine by lot are presented in Tables 6-8 by lot.

No serious or alarming reactions attributable to vaccine have been reported.

PROGRAM: Haemophilus b Conjugate Vaccine (Neisseria meningitidis Outer Membrane Protein Complex), Study 004-04 Addendum

PURPOSE: To evaluate the safety and immunogenicity of Haemophilus b conjugate vaccine (Neisseria meningitidis outer membrane protein complex) administered in conjunction with other routine pediatric vaccines in children 15 to 18 months of age.

VACCINES:

1. Haemophilus b Conjugate Vaccine (Neisseria meningitidis Outer Membrane Protein Complex) (PRP-OMPC)

   Lot 1080/C-P749 - (b) (4) mcg polysaccharide/ml
   mcg meningococcal protein/ml

   Aluminum hydroxide diluent
   Lot (b) (4)

2. Measles, Mumps and Rubella Virus Vaccine

   MMR®II
   Merck Sharp & Dohme
   Lot 0331P

3. Diptheria and Tetanus Toxoids and Pertussis Vaccine (DTP)

   TRI-IMMUNOL®
   Lederle Laboratories
   Lot 187-664

4. Poliovirus Vaccine, Live Oral Trivalent (OPV)

   ORIMUNE®
   Lederle Laboratories
   Lot 0560B

INVESTIGATOR: Joel I. Ward, M.D.
Harbor-UCLA Medical Center
Torrance, California

SUB-INVESTIGATOR: Carol Berkowitz, M.D.
Harbor-UCLA Medical Center
Torrance, California

STUDY LOCATION: Research and Education Institute
Harbor-UCLA Medical Center
Torrance, California

Kaiser-Permanente Medical Center
Panorama City, California

DATE STUDY INITIATED: August, 1988

DATE STUDY COMPLETED: In progress.

STUDY POPULATION: Healthy children 15 to 18 months of age are included in the study.

STUDY PROCEDURE: Children are randomized to receive PRP-OMPC vaccine concurrently with MMR, DTP and OPV vaccines or alone at 15 or 18 months of age. Approximately 25 children are assigned to each regimen.

Children receive a single 0.5 ml (15 mcg polysaccharide) injection of PRP-OMPC vaccine reconstituted in aluminum hydroxide and administered by intramuscular route at 15 or 18 months of age. A single 0.5 ml subcutaneous injection of MMR vaccine, a 0.5 ml intramuscular injection of DTP vaccine, and a 0.5 ml oral dose of OPV vaccine (at separate sites) are given at the same time or 3 months earlier (at 15 months of age) or 3 months later (at 18 months of age).

The parent or guardian is required to record the vaccine recipient's temperature and any reactions at the injection site or systemic complaints for 5 days after each injection of vaccine. Unexpected or serious reactions are to be reported immediately to the study physician. Serious adverse experiences in the 14 days following each injection of vaccine are required to be reported by the investigator.

STUDY PROCEDURE: (CONT.)

A blood sample is obtained prior to and 1 month after each injection of vaccine. All serum samples are assayed for antibody to the capsular polysaccharide of Haemophilus influenzae type b by radioimmunoassay. Selected samples may be tested for bactericidal and opsonophagocytic activity, immunoglobulin isotype and subclass IgG. A subset of serum samples are assayed for measles and rubella virus antibody by hemagglutination inhibition assay, mumps virus antibody by ELISA, and antibody to diphtheria and tetanus toxoid, pertussis and polio virus.

RESULTS:

The study has been initiated. Results are not yet available.

TABLE 1

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : WARD, JOEL
STUDY : 000404
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	CAUC	(b) (6)	2M	-7	(b) (6)	001	PREBLEED				136				
					0		011	INJ 1	CP241	15 MCG						
					77		011	BLEED 1			05/	797				
					77		021	INJ 2	CP298	15 MCG						
					140		021	BLEED 2			05/	267				
	M	CAUC		2M	0		001	PREBLEED				174				
					0		011	INJ 1	CP241	15 MCG						
					53		011	BLEED 1				344				
					53		021	INJ 2	CP298	15 MCG						
					102		021	BLEED 2				377				
	M	HISP		2M	0		001	PREBLEED				150				
					0		011	INJ 1	CP241	15 MCG						
					103		021	INJ 2	CP241	15 MCG						
					152		021	BLEED 1			05/	23510				
	M	CAUC		2M	0		001	PREBLEED				241				
					0		011	INJ 1	CP241	15 MCG						
					47		011	BLEED 1				9930				
					47		021	INJ 2	CP298	15 MCG						
					101		021	BLEED 2				23931				
	M	HISP		2M	0		001	PREBLEED				157				
					0		011	INJ 1	CP241	15 MCG						
					56		011	BLEED 1				831				
					67		021	INJ 2	CP298	15 MCG						
					126		021	BLEED 2				14408				
	M	HISP		2M	0		001	PREBLEED				204				
					0		011	INJ 1	CP241	15 MCG						
					73		011	BLEED 1			05/	1529				
					73		021	INJ 2	CP298	15 MCG						
					118		021	BLEED 2			05/	1767				
	F	CAUC		2M	0		001	PREBLEED				544				
					0		011	INJ 1	CP241	15 MCG						
					91		011	BLEED 1			05/	628				
					91		021	INJ 2	CP298	15 MCG						
					138		021	BLEED 2			05/	7167				

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : WARD, JOEL
STUDY : 000404
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	F	HISP	(b) (6)	1M	-7	(b) (6)	001	PREBLEED				281				
					0		011	INJ 1	CP241	15 MCG						
					97		011	BLEED 1			05/	11867				
					97		021	INJ 2	CP241	15 MCG						
					147		021	BLEED 2			05/	3928				
	F	HISP		2M	0		001	PREBLEED				143				
					0		011	INJ 1	CP241	15 MCG						
					59		011	BLEED 1				340				
					59		021	INJ 2	CP298	15 MCG						
					115		021	BLEED 2				2825				
	F	HISP		2M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP241	15 MCG						
					55		011	BLEED 1				457				
					55		021	INJ 2	CP298	15 MCG						
					102		021	BLEED 2				1019				
	M	CAUC		2M	-7		001	PREBLEED				< 125				
					0		011	INJ 1	CP241	15 MCG						
					85		011	BLEED 1			05/	1007				
					85		021	INJ 2	CP241	15 MCG						
					127		021	BLEED 2			05/	4597				
	F	BLAC		2M	0		001	PREBLEED				268				
					0		011	INJ 1	CP241	15 MCG						
					65		011	BLEED 1				31398				
					65		021	INJ 2	CP298	15 MCG						
					112		021	BLEED 2				34585				
	M	CAUC		2M	-2		001	PREBLEED				320				
					0		011	INJ 1	CP241	15 MCG						
					81		011	BLEED 1			05/	722				
					81		021	INJ 2	CP241	15 MCG						
					124		021	BLEED 2			05/	4109				
	F	CAUC		2M	0		001	PREBLEED				556				
					0		011	INJ 1	CP241	15 MCG						
					75		011	BLEED 1			05/	3280				
					75		021	INJ 2	CP241	15 MCG						

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : WARD, JOEL
STUDY : 000404
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	F	CAUC	(b) (6)	2M	126	(b) (6)	021	BLEED	2		05/	18255				
	F	HISP		1M	-8		001	PREBLEED				1070				
					0		011	INJ	1 CP241	15 MCG						
					90		011	BLEED	1		05/	857				
					90		021	INJ	2 CP241	15 MCG						
					132		021	BLEED	2		05/	7257				
	F	HISP		1M	-8		001	PREBLEED				622				
					0		011	INJ	1 CP241	15 MCG						
					79		011	BLEED	1		05/	2147				
					79		021	INJ	2 CP241	15 MCG						
					121		021	BLEED	2		05/	11864				
	M	HISP		2M	0		001	PREBLEED				294				
					0		011	INJ	1 CP241	15 MCG						
					57		011	BLEED	1			1670				
					57		021	INJ	2 CP241	15 MCG						
					108		021	BLEED	2			30049				
	M	CAUC		1M	0		001	PREBLEED				128				
					0		011	INJ	1 CP241	15 MCG						
					77		011	BLEED	1		05/	4573				
					77		021	INJ	2 CP298	15 MCG						
					127		021	BLEED	2		05/	3231				
	M	HISP		1M	-9		001	PREBLEED				135				
					0		011	INJ	1 CP241	15 MCG						
					75		011	BLEED	1		05/	17923				
					83		021	INJ	2 CP241	15 MCG						
					126		021	BLEED	2		05/	14764				
	M	BLAC		2M	0		001	PREBLEED				256				
					0		011	INJ	1 CP241	15 MCG						
					111		011	BLEED	1		05/	6954				
					111		021	INJ	2 CP241	15 MCG						
					184		021	BLEED	2		05/	2841				
	M	CAUC		2M	0		001	PREBLEED				298				
					0		011	INJ	1 CP241	15 MCG						

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : WARD, JOEL
STUDY : 000404
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	CAUC	(b) (6)	2M	70	(b) (6)	011	BLEED 1				829				
					70		021	INJ 2	CP241	15 MCG						
					121		021	BLEED 2				1299				
	F	CAUC		2M	0		001	PREBLEED				382				
					0		011	INJ 1	CP241	15 MCG						
					70		011	BLEED 1				7604				
					70		021	INJ 2	CP241	15 MCG						
					121		021	BLEED 2				4721				
	M	BLAC		3M	-1		001	PREBLEED				242				
					0		011	INJ 1	CP241	15 MCG						
					60		011	BLEED 1				514				
					60		021	INJ 2	CP298	15 MCG						
					116		021	BLEED 2				844				
	F	CAUC		2M	0		001	PREBLEED				348				
					0		011	INJ 1	CP241	15 MCG						
					82		011	BLEED 1			05/	4662				
					82		021	INJ 2	CP241	15 MCG						
					125		021	BLEED 2			05/	11154				
	F	HISP		2M	0		001	PREBLEED				489				
					0		011	INJ 1	CP241	15 MCG						
					70		011	BLEED 1				431				
					70		021	INJ 2	CP298	15 MCG						
					113		021	BLEED 2				6206				
	M	OTHE		2M	-8		001	PREBLEED				< 125				
					0		011	INJ 1	CP241	15 MCG						
					105		011	BLEED 1			05/	2574				
					105		021	INJ 2	CP241	15 MCG						
					174		021	BLEED 2			05/	4789				
	F	CAUC		2M	-11		001	PREBLEED				< 125				
					0		011	INJ 1	CP241	15 MCG						
					72		011	BLEED 1			05/	3287				
					72		021	INJ 2	CP241	15 MCG						
					114		021	BLEED 2			05/	37988				
	F	HISP		2M	0		001	PREBLEED				3537				

00308

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : WARD, JOEL
STUDY : 000404
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	F	HISP	(b) (6)	2M	0	(b) (6)	011	INJ	1	CP241	15 MCG					
					59		011	BLEED	1			1987				
					59		021	INJ	2	CP241	15 MCG					
					101		021	BLEED	2			1589				
	F	HISP		1M	0		001	PREBLEED				241				
					0		011	INJ	1	CP241	15 MCG					
					88		011	BLEED	1			1395	05/			
					88		021	INJ	2	CP241	15 MCG					
					136		021	BLEED	2			2533	05/			
	M	OTHE		1M	-10		001	PREBLEED				2600				
					0		011	INJ	1	CP241	15 MCG					
					98		011	BLEED	1			2838	05/			
					98		021	INJ	2	CP241	15 MCG					
					133		021	BLEED	2			7361	05/			
	F	HISP		1M	-9		001	PREBLEED				410				
					0		011	INJ	1	CP241	15 MCG					
					102		011	BLEED	1			8157	05/			
					102		021	INJ	2	CP241	15 MCG					
					145		021	BLEED	2			41302	05/			
	F	BLAC		2M	0		011	INJ	1	CP241	15 MCG					
					76		011	BLEED	1			5050	05/			
					76		021	INJ	2	CP241	15 MCG					
					122		021	BLEED	2			13949	05/			
	M	CAUC		1M	-14		001	PREBLEED				266				
					0		011	INJ	1	CP241	15 MCG					
					84		011	BLEED	1			585	05/			
					84		021	INJ	2	CP241	15 MCG					
					124		021	BLEED	2			1960	05/			
	M	BLAC		2M	-17		001	PREBLEED				143				
					0		011	INJ	1	CP241	15 MCG					
					87		011	BLEED	1			4567	05/			
					87		021	INJ	2	CP241	15 MCG					
					121		021	BLEED	2			1746	05/			
	M	HISP		2M	-12		001	PREBLEED				1627				

60300

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : HARD, JOEL
STUDY : 000404
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	HISP	(b) (6)	2M	0	(b) (6)	011	INJ	1	CP241	15 MCG					
					86		011	BLEED	1			05/ 3627				
					86		021	INJ	2	CP241	15 MCG					
					136		021	BLEED	2			05/ 4265				
	F	OTHE		2M	-7		001	PREBLEED				173				
					0		011	INJ	1	CP241	15 MCG					
					85		011	BLEED	1			05/ 5275				
					85		021	INJ	2	CP241	15 MCG					
					148		021	BLEED	2			05/ 3956				
	F	CAUC		2M	0		001	PREBLEED				151				
					0		011	INJ	1	CP241	15 MCG					
					120		011	BLEED	1			05/ 3554				
					120		021	INJ	2	CP241	15 MCG					
					161		021	BLEED	2			05/ 9862				
	F	CAUC		2M	-15		001	PREBLEED				225				
					0		011	INJ	1	CP241	15 MCG					
					72		011	BLEED	1			05/ 1313				
					72		021	INJ	2	CP241	15 MCG					
					118		021	BLEED	2			05/ 1177				
	M	HISP		2M	-14		001	PREBLEED				150				
					0		011	INJ	1	CP241	15 MCG					
					71		011	BLEED	1			05/ 3319				
					71		021	INJ	2	CP241	15 MCG					
					120		021	BLEED	2			05/ 4172				
	F	OTHE		2M	0		011	INJ	1	CP241	15 MCG					
					75		021	INJ	2	CP241	15 MCG					
					121		021	BLEED	1			05/ 1407				
	M	HISP		3M	-25		001	PREBLEED				< 125				
					0		011	INJ	1	CP298	15 MCG					
					58		011	BLEED	1			4285				
					58		021	INJ	2	CP298	15 MCG					
					98		021	BLEED	2			8622				
	M	CAUC		1M	0		001	PREBLEED				216				

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : WARD, JOEL
STUDY : 000404
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	CAUC	(b) (6)	1M	0	(b) (6)	011	INJ	1	CP241	15 MCG					
					81		011	BLEED	1			05/	2355			
					81		021	INJ	2	CP241	15 MCG					
	M	CAUC		1M	0		001	PREBLEED					162			
					0		011	INJ	1	CP241	15 MCG					
					73		011	BLEED	1			05/	1746			
					73		021	INJ	2	CP241	15 MCG					
					120		021	BLEED	2			05/	1869			
	F	CAUC		1M	0		001	PREBLEED					199			
					0		011	INJ	1	CP241	15 MCG					
					71		011	BLEED	1			05/	2080			
					71		021	INJ	2	CP241	15 MCG					
					119		021	BLEED	2			05/	732			
	M	HISP		2M	0		001	PREBLEED					245			
					0		011	INJ	1	CP241	15 MCG					
					68		011	BLEED	1				5304			
					68		021	INJ	2	CP241	15 MCG					
					118		021	BLEED	2				16686			
	F	CAUC		2M	0		001	PREBLEED					< 125			
					0		011	INJ	1	CP298	15 MCG					
					86		011	BLEED	1			05/	7989			
					86		021	INJ	2	CP298	15 MCG					
					115		021	BLEED	2			05/	8232			
	F	BLAC		2M	0		001	PREBLEED					< 125			
					0		011	INJ	1	CP298	15 MCG					
					85		011	BLEED	1			05/	28188			
					85		021	INJ	2	CP298	15 MCG					
					126		021	BLEED	2			05/	27130			
	M	CAUC		2M	0		001	PREBLEED					167			
					0		011	INJ	1	CP298	15 MCG					
					62		011	BLEED	1				2732			
					62		021	INJ	2	CP298	15 MCG					
					105		021	BLEED	2				10161			
	M	HISP		2M	0		001	PREBLEED					127			

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : WARD, JOEL
STUDY : 000404
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	HISP	(b) (6)	2M	0	(b) (6)	011	INJ	1	CP298	15 MCG					
					44		011	BLEED	1			8489				
					44		021	INJ	2	CP298	15 MCG					
					86		021	BLEED	2			7284				

00312

TABLE 2
ANTIBODY RESPONSES

INVESTIGATOR : WARD, JOEL
STUDY : 000404
VACCINE : HIB CONJUGATE
ASSAY : RIA
LOT NUMBER : CP241
DOSE : 15 MCG
POPULATION : HEALTHY CHILDREN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
1- 6 MOS.	PRE INJ	100 (5/ 5)	20 (1/ 5)			0.493 (5)
	MONTH 2	100 (5/ 5)	80 (4/ 5)	80 (4/ 5)	5.2	2.565 (5)
	MONTH 3	100 (1/ 1)	100 (1/ 1)	0 (0/ 1)	0.4	1.589 (1)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 3
ANTIBODY RESPONSES

INVESTIGATOR : WARD, JOEL
STUDY : 000404
VACCINE : HIB CONJUGATE
ASSAY : RIA
LOT NUMBER : CP298
DOSE : 15 MCG
POPULATION : HEALTHY CHILDREN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
1- 6 MOS.	PRE INJ	33 (1/ 3)	0 (0/ 3)			0.110 (3)
	MONTH 2	100 (3/ 3)	100 (3/ 3)	100 (3/ 3)	33.5	4.632 (3)
	MONTH 3	100 (3/ 3)	100 (3/ 3)	100 (3/ 3)	62.2	8.609 (3)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 4

A N T I B O D Y R E S P O N S E S
EXPANDED DAY RANGES

INVESTIGATOR : WARD, JOEL
STUDY : 000404
VACCINE : HIB CONJUGATE
ASSAY : RIA
LOT NUMBER : CP241
DOSE : 15 MCG
POPULATION : HEALTHY CHILDREN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
1- 6 MOS.	PRE INJ	79 (27/ 34)	9 (3/ 34)			0.273 (34)
	WEEKS 6-13	100 (31/ 31)	65 (20/ 31)	81 (25/ 31)	6.6	1.946 (31)
	WEEKS 14-23	100 (21/ 21)	95 (20/ 21)	95 (20/ 21)	18.7	6.419 (21)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 5

ANTIBODY RESPONSES
EXPANDED DAY RANGES

INVESTIGATOR : WARD, JOEL
STUDY : 000404
VACCINE : HIB CONJUGATE
ASSAY : RIA
LOT NUMBER : CP298
DOSE : 15 MCG
POPULATION : HEALTHY CHILDREN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
1- 6 MOS.	PRE INJ	25 (1/ 4)	0 (0/ 4)			0.095 (4)
	WEEKS 6-13	100 (4/ 4)	100 (4/ 4)	100 (4/ 4)	63.0	8.501 (4)
	WEEKS 14-23	100 (4/ 4)	100 (4/ 4)	100 (4/ 4)	84.0	11.339 (4)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 6

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : WARD, JOEL
STUDY : 000404
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	44	
VACCINEES WITH NO COMPLAINTS :	10	(22.7 %)
VACCINEES WITH COMPLAINTS :	34	(77.3 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 44 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	22	50.0
ERYTHEMA, INJ. SITE (<=1 IN.)	12	27.3
SWELLING, INJ. SITE (<=1 IN.)	11	25.0
PAIN/SORENESS, INJ. SITE	9	20.5
SYSTEMIC REACTIONS	25	56.8
IRRITABILITY	12	27.3
FATIGUE	11	25.0
WARM TO TOUCH	8	18.2
DIARRHEA	3	6.8
PROLONGED CRYING, >1/2 HR	3	6.8
VOMITING	3	6.8
CONSTIPATION	2	4.5
BODY ODOR	1	2.3
CRYING, EXCESSIVE	1	2.3
GASTROINTESTINAL PAIN	1	2.3
NASAL CONGESTION	1	2.3
NAUSEA	1	2.3
WHEEZING	1	2.3

TABLE 6 (cont.)
CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : WARD, JOEL
STUDY : 000404
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 2	
TOTAL VACCINEES :	32	
VACCINEES WITH NO COMPLAINTS :	6	(18.8 %)
VACCINEES WITH COMPLAINTS :	26	(81.3 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 32 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	18	56.3
SWELLING, INJ. SITE (<=1 IN.)	11	34.4
ERYTHEMA, INJ. SITE (<=1 IN.)	8	25.0
PAIN/SORENESS, INJ. SITE	3	9.4
ERYTHEMA, INJ. SITE (>1 INCH)	1	3.1
SWELLING, INJ. SITE (>1 INCH)	1	3.1
SYSTEMIC REACTIONS	20	62.5
WARM TO TOUCH	9	28.1
FATIGUE	8	25.0
IRRITABILITY	8	25.0
PROLONGED CRYING, >1/2 HR	4	12.5
TEETHING	4	12.5
VOMITING	4	12.5
RASH	3	9.4
UPPER RESPIRATORY INFECTION, NOS	3	9.4
CRYING, EXCESSIVE	1	3.1
DIARRHEA	1	3.1
NASAL DISCHARGE	1	3.1
NAUSEA	1	3.1
WHEEZING	1	3.1

TABLE 6 (cont.)
CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : WARD, JOEL
STUDY : 000404
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	5	
VACCINEES WITH NO COMPLAINTS :	2	(40.0 %)
VACCINEES WITH COMPLAINTS :	3	(60.0 %)
VACCINEES WITH NO DATA :	0	

CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 5 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	0	0.0
SYSTEMIC REACTIONS	3	60.0
IRRITABILITY	2	40.0
CRYING, EXCESSIVE	1	20.0
NAUSEA	1	20.0
OTITIS MEDIA	1	20.0
VOMITING	1	20.0

TABLE 6 (cont.)
CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : WARD, JOEL
STUDY : 000404
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 2	
TOTAL VACCINEES :	17	
VACCINEES WITH NO COMPLAINTS :	3	(17.6 %)
VACCINEES WITH COMPLAINTS :	14	(82.4 %)
VACCINEES WITH NO DATA :	0	

CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 17 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	9	52.9
ERYTHEMA, INJ. SITE (<=1 IN.)	7	41.2
SWELLING, INJ. SITE (<=1 IN.)	3	17.6
SWELLING, INJ. SITE (>1 INCH)	2	11.8
INDURATION, INJECTION SITE	1	5.9
SYSTEMIC REACTIONS	8	47.1
IRRITABILITY	5	29.4
TEETHING	2	11.8
WARM TO TOUCH	2	11.8
CRYING, EXCESSIVE	1	5.9
FATIGUE	1	5.9
NASAL CONGESTION	1	5.9
NAUSEA	1	5.9
UPPER RESPIRATORY INFECTION, NOS	1	5.9
VOMITING	1	5.9

TABLE 7

CLINICAL COMPLAINTS

INVESTIGATOR : WARD, JOEL
STUDY : 000404
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (44 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
LOCAL REACTIONS	16 (36.4%)	15 (34.1%)	7 (15.9%)	4 (9.1%)	3 (6.8%)	2 (4.5%)		22 (50.0%)
ERYTHEMA, INJ. SITE (<=1 IN.)	6 (13.6%)	8 (18.2%)	4 (9.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		12 (27.3%)
PAIN/SORENESS, INJ. SITE	8 (18.2%)	4 (9.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		9 (20.5%)
SWELLING, INJ. SITE (<=1 IN.)	6 (13.6%)	9 (20.5%)	5 (11.4%)	4 (9.1%)	3 (6.8%)	2 (4.5%)		11 (25.0%)
SYSTEMIC	18 (40.9%)	16 (36.4%)	10 (22.7%)	9 (20.5%)	3 (6.8%)	1 (2.3%)		25 (56.8%)
BODY AS A WHOLE/SITE UNSPEC.	10 (22.7%)	8 (18.2%)	4 (9.1%)	6 (13.6%)	1 (2.3%)	0 (0.0%)		15 (34.1%)
FATIGUE	6 (13.6%)	8 (18.2%)	3 (6.8%)	3 (6.8%)	0 (0.0%)	0 (0.0%)		11 (25.0%)
WARM TO TOUCH	5 (11.4%)	3 (6.8%)	2 (4.5%)	3 (6.8%)	1 (2.3%)	0 (0.0%)		8 (18.2%)
DIGESTIVE SYSTEM	5 (11.4%)	4 (9.1%)	2 (4.5%)	2 (4.5%)	1 (2.3%)	0 (0.0%)		8 (18.2%)
CONSTIPATION	1 (2.3%)	0 (0.0%)	1 (2.3%)	1 (2.3%)	0 (0.0%)	0 (0.0%)		2 (4.5%)
DIARRHEA	1 (2.3%)	3 (6.8%)	0 (0.0%)	1 (2.3%)	0 (0.0%)	0 (0.0%)		3 (6.8%)

TABLE 7 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : WARD, JOEL
STUDY : 000404
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (44 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5	COMPLAINTS
GASTROINTESTINAL PAIN	1 (2.3%)	1 (2.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.3%)
NAUSEA	1 (2.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.3%)
VOMITING	2 (4.5%)	0 (0.0%)	1 (2.3%)	0 (0.0%)	1 (2.3%)	0 (0.0%)	3 (6.8%)
NERVOUS SYSTEM & PSYCHIATRIC	8 (18.2%)	5 (11.4%)	6 (13.6%)	4 (9.1%)	1 (2.3%)	1 (2.3%)	13 (29.5%)
CRYING, EXCESSIVE	1 (2.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.3%)
IRRITABILITY	7 (15.9%)	5 (11.4%)	6 (13.6%)	4 (9.1%)	1 (2.3%)	1 (2.3%)	12 (27.3%)
PROLONGED CRYING, >1/2 HR	0 (0.0%)	1 (2.3%)	1 (2.3%)	0 (0.0%)	0 (0.0%)	1 (2.3%)	3 (6.8%)
RESPIRATORY SYSTEM	0 (0.0%)	2 (4.5%)	1 (2.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (4.5%)
NASAL CONGESTION	0 (0.0%)	1 (2.3%)	1 (2.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.3%)
WHEEZING	0 (0.0%)	1 (2.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.3%)
SKIN & SKIN APPENDAGE	1 (2.3%)	1 (2.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.3%)
BODY ODOR	1 (2.3%)	1 (2.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.3%)

TABLE 7 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : WARD, JOEL
STUDY : 000404
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (44 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		**********
VACCINEES WITH COMPLAINTS	26 (59.1%)	26 (59.1%)	16 (36.4%)	12 (27.3%)	6 (13.6%)	3 (6.8%)		34 (77.3%)
VACCINEES WITH NO COMPLAINTS	18 (40.9%)	18 (40.9%)	28 (63.6%)	32 (72.7%)	38 (86.4%)	41 (93.2%)		10 (22.7%)
TOTAL VACCINEES REPORTING	44	44	44	44	44	44		44
VACCINEES WITH NO DATA	0	0	0	0	0	0		0

TABLE 7 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : WARD, JOEL
STUDY : 000404
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (32 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
LOCAL REACTIONS	10 (31.3%)	15 (46.9%)	9 (28.1%)	5 (15.6%)	5 (15.6%)	5 (15.6%)		18 (56.3%)
ERYTHEMA, INJ. SITE (>1 INCH)	1 (3.1%)	1 (3.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (3.1%)
ERYTHEMA, INJ. SITE (<=1 IN.)	4 (12.5%)	7 (21.9%)	4 (12.5%)	1 (3.1%)	1 (3.1%)	1 (3.1%)		8 (25.0%)
PAIN/SORENESS, INJ. SITE	2 (6.3%)	3 (9.4%)	1 (3.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		3 (9.4%)
SWELLING, INJ. SITE (>1 INCH)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.1%)	1 (3.1%)	1 (3.1%)		1 (3.1%)
SWELLING, INJ. SITE (<=1 IN.)	4 (12.5%)	9 (28.1%)	6 (18.8%)	3 (9.4%)	3 (9.4%)	3 (9.4%)		11 (34.4%)
SYSTEMIC	19 (59.4%)	12 (37.5%)	9 (28.1%)	9 (28.1%)	4 (12.5%)	4 (12.5%)		20 (62.5%)
BODY AS A WHOLE/SITE UNSPEC.	9 (28.1%)	6 (18.8%)	5 (15.6%)	3 (9.4%)	1 (3.1%)	1 (3.1%)		11 (34.4%)
FATIGUE	6 (18.8%)	5 (15.6%)	2 (6.3%)	1 (3.1%)	0 (0.0%)	0 (0.0%)		8 (25.0%)
WARM TO TOUCH	4 (12.5%)	4 (12.5%)	3 (9.4%)	3 (9.4%)	1 (3.1%)	1 (3.1%)		9 (28.1%)
DIGESTIVE SYSTEM	6 (18.8%)	4 (12.5%)	3 (9.4%)	2 (6.3%)	2 (6.3%)	2 (6.3%)		8 (25.0%)

TABLE 7 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : WARD, JOEL
STUDY : 000404
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (32 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		
DIARRHEA	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.1%)	1 (3.1%)		1 (3.1%)
NAUSEA	1 (3.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (3.1%)
TEETHING	3 (9.4%)	3 (9.4%)	2 (6.3%)	1 (3.1%)	1 (3.1%)	1 (3.1%)		4 (12.5%)
VOMITING	3 (9.4%)	2 (6.3%)	1 (3.1%)	1 (3.1%)	0 (0.0%)	0 (0.0%)		4 (12.5%)
NERVOUS SYSTEM & PSYCHIATRIC	8 (25.0%)	4 (12.5%)	2 (6.3%)	2 (6.3%)	0 (0.0%)	0 (0.0%)		10 (31.3%)
CRYING, EXCESSIVE	1 (3.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (3.1%)
IRRITABILITY	6 (18.8%)	4 (12.5%)	2 (6.3%)	1 (3.1%)	0 (0.0%)	0 (0.0%)		8 (25.0%)
PROLONGED CRYING, >1/2 HR	3 (9.4%)	0 (0.0%)	0 (0.0%)	1 (3.1%)	0 (0.0%)	0 (0.0%)		4 (12.5%)
RESPIRATORY SYSTEM	4 (12.5%)	2 (6.3%)	2 (6.3%)	2 (6.3%)	1 (3.1%)	1 (3.1%)		5 (15.6%)
NASAL DISCHARGE	1 (3.1%)	0 (0.0%)	0 (0.0%)	D (0.0%)	0 (0.0%)	0 (0.0%)		1 (3.1%)
UPPER RESPIRATORY INFECTION, NOS	2 (6.3%)	2 (6.3%)	2 (6.3%)	2 (6.3%)	1 (3.1%)	1 (3.1%)		3 (9.4%)
WHEEZING	1 (3.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (3.1%)

TABLE 7 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : WARD, JOEL
STUDY : 000404
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (32 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		
SKIN & SKIN APPENDAGE	2 (6.3%)	1 (3.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		3 (9.4%)
RASH	2 (6.3%)	1 (3.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		3 (9.4%)
VACCINEES WITH COMPLAINTS	23 (71.9%)	20 (62.5%)	14 (43.8%)	10 (31.3%)	8 (25.0%)	8 (25.0%)		26 (81.3%)
VACCINEES WITH NO COMPLAINTS	9 (28.1%)	12 (37.5%)	18 (56.3%)	22 (68.8%)	24 (75.0%)	24 (75.0%)		6 (18.8%)
TOTAL VACCINEES REPORTING	32	32	32	32	32	32		32
VACCINEES WITH NO DATA	0	0	0	0	0	0		0

TABLE 7 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : WARD, JOEL
STUDY : 000404
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (5 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS **********
SYSTEMIC	2 (40.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	2 (40.0%)		3 (60.0%)
DIGESTIVE SYSTEM	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)		1 (20.0%)
NAUSEA	0 (0.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)		1 (20.0%)
VOMITING	1 (20.0%)	0 (0.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)		1 (20.0%)
NERVOUS SYSTEM & PSYCHIATRIC	2 (40.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)		3 (60.0%)
CRYING, EXCESSIVE	1 (20.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (20.0%)
IRRITABILITY	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)		2 (40.0%)
SPECIAL SENSES	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)		1 (20.0%)
OTITIS MEDIA	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)		1 (20.0%)
VACCINEES WITH COMPLAINTS	2 (40.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	2 (40.0%)		3 (60.0%)
VACCINEES WITH NO COMPLAINTS	3 (60.0%)	4 (80.0%)	4 (80.0%)	4 (80.0%)	4 (80.0%)	3 (60.0%)		2 (40.0%)

TABLE 7 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : WARD, JOEL
STUDY : 000404
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (5 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
TOTAL VACCINEES REPORTING	5	5	5	5	5	5		5
VACCINEES WITH NO DATA	0	0	0	0	0	0		0

TABLE 7 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : WARD, JOEL
STUDY : 000404
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (17 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		
LOCAL REACTIONS	4 (23.5%)	4 (23.5%)	4 (23.5%)	2 (11.8%)	2 (11.8%)	2 (11.8%)		9 (52.9%)
ERYTHEMA, INJ. SITE (<=1 IN.)	4 (23.5%)	4 (23.5%)	3 (17.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		7 (41.2%)
INDURATION, INJECTION SITE	0 (0.0%)	0 (0.0%)	1 (5.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (5.9%)
SWELLING, INJ. SITE (>1 INCH)	0 (0.0%)	0 (0.0%)	1 (5.9%)	2 (11.8%)	2 (11.8%)	1 (5.9%)		2 (11.8%)
SWELLING, INJ. SITE (<=1 IN.)	2 (11.8%)	1 (5.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (5.9%)		3 (17.6%)
SYSTEMIC	6 (35.3%)	6 (35.3%)	4 (23.5%)	2 (11.8%)	2 (11.8%)	2 (11.8%)		8 (47.1%)
BODY AS A WHOLE/SITE UNSPEC.	2 (11.8%)	0 (0.0%)	1 (5.9%)	1 (5.9%)	0 (0.0%)	0 (0.0%)		3 (17.6%)
FATIGUE	0 (0.0%)	0 (0.0%)	1 (5.9%)	1 (5.9%)	0 (0.0%)	0 (0.0%)		1 (5.9%)
WARM TO TOUCH	2 (11.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (11.8%)
DIGESTIVE SYSTEM	2 (11.8%)	3 (17.6%)	3 (17.6%)	2 (11.8%)	2 (11.8%)	1 (5.9%)		3 (17.6%)
NAUSEA	0 (0.0%)	1 (5.9%)	1 (5.9%)	1 (5.9%)	1 (5.9%)	0 (0.0%)		1 (5.9%)

TABLE 7 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : HARD, JOEL
STUDY : 000404
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (17 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
TEETHING	2 (11.8%)	2 (11.8%)	2 (11.8%)	1 (5.9%)	1 (5.9%)	1 (5.9%)		2 (11.8%)
VOMITING	0 (0.0%)	1 (5.9%)	1 (5.9%)	1 (5.9%)	1 (5.9%)	0 (0.0%)		1 (5.9%)
NERVOUS SYSTEM & PSYCHIATRIC	3 (17.6%)	3 (17.6%)	2 (11.8%)	1 (5.9%)	0 (0.0%)	1 (5.9%)		6 (35.3%)
CRYING, EXCESSIVE	0 (0.0%)	1 (5.9%)	1 (5.9%)	1 (5.9%)	0 (0.0%)	0 (0.0%)		1 (5.9%)
IRRITABILITY	3 (17.6%)	2 (11.8%)	1 (5.9%)	0 (0.0%)	0 (0.0%)	1 (5.9%)		5 (29.4%)
RESPIRATORY SYSTEM	1 (5.9%)	2 (11.8%)	1 (5.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (11.8%)
NASAL CONGESTION	0 (0.0%)	1 (5.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (5.9%)
UPPER RESPIRATORY INFECTION, NOS	1 (5.9%)	1 (5.9%)	1 (5.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (5.9%)
VACCINEES WITH COMPLAINTS	9 (52.9%)	10 (58.8%)	7 (41.2%)	3 (17.6%)	3 (17.6%)	4 (23.5%)		14 (82.4%)
VACCINEES WITH NO COMPLAINTS	8 (47.1%)	7 (41.2%)	10 (58.8%)	14 (82.4%)	14 (82.4%)	13 (76.5%)		3 (17.6%)
TOTAL VACCINEES REPORTING	17	17	17	17	17	17		17

TABLE 7 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : WARD, JOEL
STUDY : 000404
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (17 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
VACCINEES WITH NO DATA	0	0	0	0	0	0		0

TABLE 8

MAXIMUM TEMPERATURES

INVESTIGATOR : WARD, JOEL
STUDY : 000404
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (44 VACCINEES) - INJECTION 1						
	DAYS POST VACCINATION						NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5	
< 99	37 (86.0%)	41 (93.2%)	43 (97.7%)	42 (95.5%)	43 (97.7%)	42 (97.7%)	34 (77.3%)
99 - 99.9	5 (11.6%)	3 (6.8%)	1 (2.3%)	1 (2.3%)	0 (0.0%)	1 (2.3%)	8 (18.2%)
100 - 100.9	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.3%)	0 (0.0%)	0 (0.0%)	1 (2.3%)
103 - 103.9	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.3%)	0 (0.0%)	0 (0.0%)
104 - 104.9	1 (2.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.3%)
TEMPERATURE TAKEN	43 (97.7%)	44 (100.0%)	44 (100.0%)	44 (100.0%)	44 (100.0%)	43 (97.7%)	44 (100.0%)
TEMPERATURE NOT TAKEN	1 (2.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.3%)	0 (0.0%)

TABLE 8 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : HARD, JOEL
STUDY : 000404
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (32 VACCINEES) - INJECTION 2							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
< 99	26 (81.3%)	26 (81.3%)	25 (78.1%)	28 (90.3%)	27 (84.4%)	29 (93.5%)		19 (59.4%)
99 - 99.9	5 (15.6%)	6 (18.8%)	6 (18.8%)	3 (9.7%)	4 (12.5%)	2 (6.5%)		10 (31.3%)
101 - 101.9	1 (3.1%)	0 (0.0%)	1 (3.1%)	0 (0.0%)	1 (3.1%)	0 (0.0%)		3 (9.4%)
TEMPERATURE TAKEN	32 (100.0%)	32 (100.0%)	32 (100.0%)	31 (96.9%)	32 (100.0%)	31 (96.9%)		32 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.1%)	0 (0.0%)	1 (3.1%)		0 (0.0%)

TABLE 8 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : WARD, JOEL
STUDY : 000404
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (5 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
< 99	4 (80.0%)	2 (40.0%)	5 (100.0%)	5 (100.0%)	5 (100.0%)	4 (80.0%)		2 (40.0%)
99 - 99.9	0 (0.0%)	3 (60.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (20.0%)
100 - 100.9	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (20.0%)
101 - 101.9	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)		1 (20.0%)
TEMPERATURE TAKEN	5 (100.0%)	5 (100.0%)	5 (100.0%)	5 (100.0%)	5 (100.0%)	5 (100.0%)		5 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)

TABLE 8 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : WARD, JOEL
STUDY : 000404
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (17 VACCINEES) - INJECTION 2							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
< 99	13 (81.3%)	15 (88.2%)	17 (100.0%)	16 (94.1%)	16 (94.1%)	16 (94.1%)		13 (76.5%)
99 - 99.9	3 (18.8%)	2 (11.8%)	0 (0.0%)	1 (5.9%)	1 (5.9%)	1 (5.9%)		4 (23.5%)
TEMPERATURE TAKEN	16 (94.1%)	17 (100.0%)	17 (100.0%)	17 (100.0%)	17 (100.0%)	17 (100.0%)		17 (100.0%)
TEMPERATURE NOT TAKEN	1 (5.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)

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Comparative Immunogenicity of H.influenzae type b (Hib) Conjugate Vaccines (PRP-D/PRP-OMP) in Infants < 6 Months of Age.

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We conducted 3 studies of the immunogenicity and safety of two Hib conjugate vaccines in 2 populations of infants. Three doses of PRP-D (Connaught) were given at 2, 4 and 6 months of age and bloods were obtained at 2, 4, 6 and 7-9 months. Two doses of PRP-OMP (Merck) were given at 2 and 4 months and sera obtained at 2, 4, and 6 months. All sera were assayed simultaneously by FDA standard RIA. GM levels (ug/ml) were:

Age (dose)	PRP-OMP(CA) (N=27)	PRP-D(CA) (N=20)	PRP-D(AK) (N=13)
2 months (pre)	0.1	0.04	0.2
4 months (post-1)	1.77	0.04	0.05
6 months (post-2)	3.9	0.1	0.08
7 months (post-3)	NA	0.3	NA
9 months (post-3)	NA	NA	0.3

Even after 1 dose given at 2 months, PRP-OMP was clearly more immunogenic than PRP-D after 3 doses given at 2, 4 and 6 months.

STUDY 004-05

PROGRAM: Haemophilus b Conjugate Vaccine (Neisseria meningitidis Outer Membrane Protein Complex), Study #0004-05.

PURPOSE: To evaluate the safety and immunogenicity of Haemophilus b Conjugate Vaccine (Neisseria meningitidis Outer Membrane Protein Complex) in healthy infants and children 2 months to 5 years of age.

VACCINE: Haemophilus b Conjugate Vaccine (Neisseria meningitidis Outer Membrane Protein Complex).

Lot 1020/C-N084 - (b) (4) mcg polysaccharide/ml
(b) (4) mcg meningococcal protein/ml
Lot 1069/C-P241 - (b) (4) mcg polysaccharide/ml
(b) (4) mcg meningococcal protein/ml
Lot 1072/C-P298 - (b) (4) mcg polysaccaride/ml
(b) (4) mcg meningococcal protein/ml
Lot 1080/C-P749 - (b) (4) mcg polysaccharide/ml
(b) (4) mcg meningococcal protein/ml
Lot 1085/C-R132 - (b) (4) mcg polysaccharide/ml
(b) (4) mcg meningococcal protein/ml

Diluent
Aluminum hydroxide diluent
Lot (b) (4)

INVESTIGATOR: Eugene Shapiro, M.D.
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STUDY LOCATION: Primary Care Center
Yale-New Haven Hospital
20 York Street
New Haven, Connecticut 06510-8064

DATE INITIATED: May 20, 1986

DATE COMPLETED: In progress.

STUDY POPULATION: Healthy infants and children 2 to 71 months of age are included in the study. A subset of infants and children were randomized to receive the three clinical lots of vaccine (1072/C-P298, 1080/C-P749, 1085/C-R132).

STUDY PROCEDURE: Infants 2 to 6 months of age received a single 0.75 ml (15 mcg polysaccharide) intramuscular injection, while children 12 to 17 months of age received a single 1.0 ml (20 mcg polysaccharide) intramuscular injection of Lot 1020/C-N084 reconstituted in aluminum hydroxide.

Infants 2 to 11 months of age receive 2 injections of the vaccine given 2 months apart, while children 12 months of age and older receive a single injection. Vaccine is reconstituted in aluminum hydroxide and administered by intramuscular route. The dose for each injection is 15 mcg polysaccharide in the appropriate volume - 0.75 ml for Lot 1069/C-P241 and 0.5 ml for Lots 1072/C-P298, 1080/C-P749, and 1085/C-R132.

Parents or guardians are required to record the vaccinee's temperature and any systemic or injection site reactions for 5 days after each injection. Unexpected or serious reactions are to be reported immediately to the study physician.

A blood sample is obtained immediately before each injection and one month after the last (or only) injection. Additional samples are obtained 7 to 10 months after the last injection for infants 2 to 11 months of age and at 15 to 18 months postvaccination for children 12 to 71 months of age.

All serum samples are assayed by Merck Sharp & Dohme Research Laboratories for antibody to H. influenzae type b capsular polysaccharide by radioimmunoassay (RIA). Selected samples are also tested for serum bactericidal activity, quantitation of IgG_1 and IgG_2 subclass, and IgM and total IgG antibodies. Testing for opsonophagocytic activity was done at the University of Alabama.

RESULTS: Demographic information and individual pre and postvaccination antibody data for each vaccinee enrolled in the study is reported in Tables 1 and 2.

1. Number Vaccinated:

Lot	Age	Injection No. 1	Injection No. 2
1020/C-N084 (15 mcg)	2-11 mo.	10	5*
1020/C-N084 (20 mcg)	12-71 mo.	3	--
1069/C-P241	2-11 mo.	15	15
	12-71 mo.	24	--
1072/C-P298	2-11 mo.	41	32
	12-71 mo.	48	--
1080/C-P749	2-11 mo.	22	13
	12-71 mo.	26	--
1085/C-R132	2-11 mo.	20	16
	12-71 mo.	28	--

* PRP (Three of these infants later received Lot 1069/C-P241 and will be excluded from this summary.)

Children randomized to receive the clinical lots were assigned case numbers (b) (6). One child (case no. (b) (6)) received mixed lots - Lot 1072/C-P298 as injection 1 and Lot 1085/C-R132 as injection 2.

2. Serologic Results

Antibody responses (RIA) prior to and after vaccination are as follows:

Dose	Age	Time	% With Anti-PRP >0.15 mcg Ab/ml	% With Anti-PRP >1.0 mcg Ab/ml	GMT (mcg Ab/ml) All Vaccinees
15 mcg	2-11 mo.	Pre	30 (17/57)	0 (0/57)	0.10
		2 mo.	96 (55/57)	68 (39/57)	2.01
		3 mo.	100 (41/41)	88 (36/41)	5.07
15 mcg	12-71 mo.	Pre	40 (35/87)	11 (10/87)	0.15
		1 mo.	99 (84/85)	86 (73/85)	7.31
20 mcg	12-71 mo.	Pre	100 (3/3)	0 (0/3)	0.24
		1 mo.	100 (3/3)	100 (3/3)	12.82

RESULTS: (CONT.)

Antibody responses (by lot per age group) prior to vaccination through 13 months postvaccination are included in Tables 3-7. Responses for children randomized to receive the clinical lots are shown in Tables 8-10. If vaccine recipients received mixed lots, they were excluded from summaries by lot.

3. Clinical Results:

The frequencies of selected injection site and systemic reactions during the 48 hours after vaccination are as follows:

		% Vaccinees with Reactions		
		2 - 11 Months of Age		12 - 71 Months of Age
Dose	Type of Reaction	Injection 1	Injection 2	Injection 1
15 mcg	Injection Site			
	Erythema >1 inch	0.0 (0/105)	1.4 (1/70)	0.8 (1/27)
	Swelling >1 inch	0.0 (0/105)	1.4 (1/70)	0.8 (1/27)
	Pain/Soreness	0.0 (0/105)	1.4 (1/70)	6.3 (8/27)
	Systemic			
	Irritability	15.2 (16/105)	10.0 (7/70)	7.9 (10/127)
	Sleepiness/ Lethargy/Fatigue	3.8 (4/105)	4.3 (3/70)	0.8 (1/127)
20 mcg	Injection Site			
	Erythema >1 inch	NA	NA	0.0 (0/3)
	Swelling >1 inch	NA	NA	0.0 (0/3)
	Pain/Soreness	NA	NA	66.7 (2/3)
	Systemic			
	Irritability	NA	NA	0.0 (0/3)
	Sleepiness/ Lethargy/Fatigue	NA	NA	0.0 (0/3)

NA = Not Applicable

Reaction frequencies and maximum temperatures recorded during the five days following each injection of vaccine are reported in Tables 11-13.

No serious or alarming reactions attributable to the vaccine were reported.

TABLE 1

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	BLAC	(b) (6)	6M	0	(b) (6)	001	PREBLEED				132				
					0		011	INJ 1	CN084	15 MCG						
					58		011	BLEED 1				9409				
	M	CAUC		3M	0		001	PREBLEED				367				
					0		011	INJ 1	CN084	15 MCG						
					48		011	BLEED 1				792				
					98		081	INJ 2	POLYS	25 MCG						
					141		081	BLEED 2				35223				
					441		081	BLEED 3				7770				
	M	CAUC		5M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CN084	15 MCG						
					46		011	BLEED 1				346				
					99		081	INJ 2	POLYS	25 MCG						
					137		081	BLEED 2				1840				
					416		081	BLEED 3				< 125				
					416		091	INJ 3	CP241	15 MCG						
					459		091	BLEED 4				5506				
	F	CAUC		6M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CN084	15 MCG						
					44		011	BLEED 1				651				
					95		081	INJ 2	POLYS	25 MCG						
					140		081	BLEED 2				5313				
					380		081	BLEED 3				439				
					380		091	INJ 3	CP241	15 MCG						
					420		091	BLEED 4				7525				
	F	HISP		4M	0		001	PREBLEED				148				
					0		011	INJ 1	CN084	15 MCG						
					44		011	BLEED 1				358				
					104		081	INJ 2	POLYS	25 MCG						
					139		081	BLEED 2				631				
	M	BLAC		3M	0		001	PREBLEED				151				
					0		011	INJ 1	CN084	15 MCG						
					33		011	BLEED 1				15954				
	F	BLAC		3M	0		001	PREBLEED				< 125				

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	F	BLAC	(b) (6)	3M	0	(b) (6)	011	INJ	1	CN084	15 MCG					
					33		011	BLEED	1			3337				
	M	CAUC		4M	0		001	PREBLEED				< 125				
					0		011	INJ	1	CN084	15 MCG					
					447		071	BLEED	1			1179				
					447		091	INJ	2	CP298	15 MCG					
					469		091	BLEED	2			180567				
	F	CAUC		4M	0		011	INJ	1	CN084	15 MCG					
	M	CAUC		4M	0		001	PREBLEED				231				
					0		011	INJ	1	CN084	15 MCG					
					30		011	BLEED	1			1018				
					30		081	INJ	2	POLYS	25 MCG					
					58		081	BLEED	2			1122				
					301		081	BLEED	3			3145				
					301		091	INJ	3	CP241	15 MCG					
					370		091	BLEED	4			2332				
	F	CAUC		4M	0		001	PREBLEED				< 125		< 5		
					0		011	INJ	1	CP241	15 MCG					
					60		011	BLEED	1			4637		5		
					60		021	INJ	2	CP241	15 MCG					
					90		021	BLEED	2			4350		5		
					277		071	BLEED	3			1686				
	F	CAUC		2M	0		001	PREBLEED				< 125		< 5		
					0		011	INJ	1	CP241	15 MCG					
					66		011	BLEED	1			1862		20		
					66		021	INJ	2	CP241	15 MCG					
					101		021	BLEED	2			4879		20		
					300		071	BLEED	3			1242				
	M	CAUC		7M	0		001	PREBLEED				< 125				
					0		011	INJ	1	CP241	15 MCG					
					77		011	BLEED	1			7602	05/			
					77		021	INJ	2	CP241	15 MCG					
					107		021	BLEED	2			13718	05/			
					330		071	BLEED	3			596	D5/			

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	F	CAUC	(b) (6)	6M	0	(b) (6)	001	PREBLEED				159		< 5		
					0		011	INJ 1	CP241	15 MCG						
					72		011	BLEED 1			05/	1162	05/	40		
					72		021	INJ 2	CP241	15 MCG						
					98		021	BLEED 2			05/	12318	05/	160		
					300		071	BLEED 3			05/	984				
	M	CAUC		6M	0		001	PREBLEED				145		< 2		
					0		011	INJ 1	CP241	15 MCG						
					63		011	BLEED 1				262		< 2		
					63		021	INJ 2	CP241	15 MCG						
					98		021	BLEED 2				1468		< 2		
					301		071	BLEED 3				626				
	F	CAUC		4M	0		001	PREBLEED				225		< 2		
					0		011	INJ 1	CP241	15 MCG						
					57		011	BLEED 1				819		< 2		
					57		021	INJ 2	CP241	15 MCG						
					97		021	BLEED 2				1027		< 2		
					273		071	BLEED 3				190				
	M	OTHE		4M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP241	15 MCG						
					61		011	BLEED 1				4034				
					61		021	INJ 2	CP241	15 MCG						
					89		021	BLEED 2				10800				
					266		071	BLEED 3				1439				
	F	CAUC		2M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP241	15 MCG						
					62		011	BLEED 1				8164				
					62		021	INJ 2	CP241	15 MCG						
					97		021	BLEED 2				9658				
					255		071	BLEED 3				2576				
	M	CAUC		10M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP241	15 MCG						
					62		011	BLEED 1				4169				
					62		021	INJ 2	CP241	15 MCG						
					93		021	BLEED 2				7823				

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	CAUC	(b) (6)	10M	307	(b) (6)	071	BLEED 3				899				
	F	CAUC		5M	0		001	PREBLEED				< 125				0
					0		011	INJ 1	CP241	15 MCG						
					69		011	BLEED 1				15235				92
					69		021	INJ 2	CP241	15 MCG						
					97		021	BLEED 2				16862				92
					302		071	BLEED 3				15621				
	M	HISP		6M	0		001	PREBLEED				190				
					0		011	INJ 1	CP241	15 MCG						
					62		011	BLEED 1				4864				
					62		021	INJ 2	CP241	15 MCG						
					105		021	BLEED 2				5318				
	M	CAUC		9M	0		001	PREBLEED				245				
					0		011	INJ 1	CP241	15 MCG						
					63		011	BLEED 1				16662				
					63		021	INJ 2	CP241	15 MCG						
					104		021	BLEED 2				15687				
					288		071	BLEED 3				5962				
	F	CAUC		6M	0		001	PREBLEED				< 125				34
					0		011	INJ 1	CP241	15 MCG						
					63		011	BLEED 1				1878				98
					63		021	INJ 2	CP241	15 MCG						
					94		021	BLEED 2				4898				97
	M	HISP		8M	0		001	PREBLEED				< 125				23
					0		011	INJ 1	CP241	15 MCG						
					62		011	BLEED 1				4534				92
					62		021	INJ 2	CP241	15 MCG						
					84		021	BLEED 2				35486				98
					224		071	BLEED 3				6781				
	M	CAUC		5M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP241	15 MCG						
					70		011	BLEED 1				22270				
					70		021	INJ 2	CP241	15 MCG						
					105		021	BLEED 2				35692				

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	CAUC	(b) (6)	9M	0	(b) (6)	001	PREBLEED				248		< 5		
					0		011	INJ 1	CP298	15 MCG						
					57		011	BLEED 1				3389		< 5		
					57		021	INJ 2	CP298	15 MCG						
					96		021	BLEED 2				8897		5		
	F	CAUC		5M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP298	15 MCG						
					62		011	BLEED 1				2069				
					62		021	INJ 2	CP298	15 MCG						
					98		021	BLEED 2				1980				
	M	CAUC		9M	0		001	PREBLEED				363				
					0		011	INJ 1	CP298	15 MCG						
					63		011	BLEED 1				665				
					63		021	INJ 2	CP298	15 MCG						
					97		021	BLEED 2				4568				
	F	BLAC		9M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP298	15 MCG						
					65		011	BLEED 1				433				
					65		021	INJ 2	CP298	15 MCG						
					105		021	BLEED 2				478				
					231		071	BLEED 3				371				
	F	BLAC		6M	0		001	PREBLEED				< 125		< 5		4
					0		011	INJ 1	CP298	15 MCG						
					62		011	BLEED 1				1862		20		98
					62		021	INJ 2	CP298	15 MCG						
					113		021	BLEED 2				3178		20		99
	F	CAUC		2M	0		001	PREBLEED				296				
					0		011	INJ 1	CP298	15 MCG						
					61		011	BLEED 1				5942				
					61		021	INJ 2	CP298	15 MCG						
					126		021	BLEED 2				10690				
	F	CAUC		7M	0		001	PREBLEED				< 125		< 5		
					0		011	INJ 1	CP298	15 MCG						
					68		011	BLEED 1				887		< 5		

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	F	CAUC	(b) (6)	7M	68	(b) (6)	021	INJ 2	CP298	15 MCG						
					120		021	BLEED 2			05/	6418	05/	5		
	F	CAUC		5M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP298	15 MCG						
					80		011	BLEED 1			05/	7167				
					80		021	INJ 2	CP298	15 MCG						
					108		021	BLEED 2			05/	8881				
	F	BLAC		8M	0		001	PREBLEED				149		< 2		
					0		011	INJ 1	CP298	15 MCG						
					56		011	BLEED 1				954		8		
					56		021	INJ 2	CP298	15 MCG						
					146		021	BLEED 2				3190		< 2		
	F	CAUC		3M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP298	15 MCG						
					71		011	BLEED 1			05/	9351				
					71		021	INJ 2	CP298	15 MCG						
					111		021	BLEED 2			05/	12955				
	M	CAUC		8M	0		001	PREBLEED				700				
					0		011	INJ 1	CP298	15 MCG						
					67		011	BLEED 1				1112				
					67		021	INJ 2	CP298	15 MCG						
					109		021	BLEED 2				4509				
	M	CAUC		4M	0		001	PREBLEED				254				7
					0		011	INJ 1	CP298	15 MCG						
					70		011	BLEED 1				2401				24
					70		021	INJ 2	CP298	15 MCG						
					99		021	BLEED 2				3828				54
	M	CAUC		4M	0		001	PREBLEED				292				
					0		011	INJ 1	CP298	15 MCG						
					67		011	BLEED 1				4403				
					67		021	INJ 2	CP298	15 MCG						
					101		021	BLEED 2				6123				
	F	CAUC		8M	0		001	PREBLEED				< 125		< 5		45

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	F	CAUC	(b) (6)	8M	0	(b) (6)	011	INJ 1	CP298	15 MCG						
					64		011	BLEED 1				9717		5		
					64		021	INJ 2	CP298	15 MCG						
					97		021	BLEED 2				10506		20		100
	M	CAUC		4M	0		001	PREBLEED				< 125		< 5		14
					0		011	INJ 1	CP298	15 MCG						
					74		011	BLEED 1			05/	3375	05/	20		
					74		021	INJ 2	CP298	15 MCG						
					105		021	BLEED 2			05/	7951	05/	20	05/	100
	F	CAUC		7M	0		001	PREBLEED				< 125		< 5		
					0		011	INJ 1	CP298	15 MCG						
					59		011	BLEED 1				8590		< 5		
					59		021	INJ 2	CP298	15 MCG						
					91		021	BLEED 2				18625		5		
	M	HISP		10M	0		001	PREBLEED				386		< 5		47
					0		011	INJ 1	CP298	15 MCG						
					63		011	BLEED 1				5103		20		85
					63		021	INJ 2	CP298	15 MCG						
					91		021	BLEED 2				8474		>= 80		100
	F	BLAC		8M	0		001	PREBLEED				229		< 2		
					0		011	INJ 1	CP298	15 MCG						
					68		011	BLEED 1				< 125		< 2		
					68		021	INJ 2	CP298	15 MCG						
					108		021	BLEED 2				2189		8		
	M	CAUC		7M	0		001	PREBLEED				235				
					0		011	INJ 1	CP298	15 MCG						
					56		011	BLEED 1				749				
					56		021	INJ 2	CP298	15 MCG						
					91		021	BLEED 2				887				
	F	BLAC		11M	0		001	PREBLEED				< 125		< 2		
					0		011	INJ 1	CP749	15 MCG						
					91		011	BLEED 1				12261		< 2		
	F	BLAC		5M	0		011	INJ 1	CP749	15 MCG						

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ RIA	CODE/ SBA	CODE/ OPSO
(b) (6)	M	CAUC	(b) (6)	6M	0	(b) (6)	011	INJ	1 CP298	15 MCG			
	M	CAUC		2M	0		011	INJ	1 CP298	15 MCG			
	M	CAUC		4M	0		011	INJ	1 CP298	15 MCG			
	F	HISP		6M	0		011	INJ	1 CP749	15 MCG			
	M	CAUC		5M	0		011	INJ	1 CP298	15 MCG			
	M	HISP		3M	0		011	INJ	1 CP749	15 MCG			
	M	BLAC		2M	0		011	INJ	1 CR132	15 MCG			
	M	HISP		5M	0		011	INJ	1 CR132	15 MCG			
	M	CAUC		2M	0		011	INJ	1 CP298	15 MCG			
	M	CAUC		5M	0		011	INJ	1 CP298	15 MCG			
	M	CAUC		5M	0		011	INJ	1 CR132	15 MCG			
	M	CAUC		4M	0		011	INJ	1 CP749	15 MCG			
	F	CAUC		9M	0		011	INJ	1 CP749	15 MCG			
	F	CAUC		9M	0		011	INJ	1 CR132	15 MCG			
	F	CAUC		6M	0		011	INJ	1 CR132	15 MCG			
	F	BLAC		5M	0		011	INJ	1 CP298	15 MCG			
	M	CAUC		2M	0		011	INJ	1 CP749	15 MCG			
	M	CAUC		6M	0		011	INJ	1 CP749	15 MCG			
	F	BLAC		8M	0		011	INJ	1 CP298	15 MCG			
					63		021	INJ	2 CP298	15 MCG			
	F	BLAC		10M	0		011	INJ	1 CR132	15 MCG			

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ RIA	CODE/ SBA	CODE/ OPSO
(b) (6)	F	BLAC	(b) (6)	10M	62	(b) (6)	021	INJ 2	CR132	15 MCG			
	F	CAUC		6M	0		011	INJ 1	CP298	15 MCG			
					63		021	INJ 2	CP298	15 MCG			
	F	CAUC		6M	0		011	INJ 1	CP749	15 MCG			
	F	CAUC		4M	0		001	PREBLEED			151		
					0		011	INJ 1	CP298	15 MCG			
					64		011	BLEED 1			1038		
					64		021	INJ 2	CP298	15 MCG			
	M	CAUC		4M	0		011	INJ 1	CR132	15 MCG			
					67		021	INJ 2	CR132	15 MCG			
	M	CAUC		2M	0		001	PREBLEED			< 125		
					0		011	INJ 1	CP749	15 MCG			
					63		011	BLEED 1			7058		
					63		021	INJ 2	CP749	15 MCG			
	F	CAUC		6M	0		001	PREBLEED			< 125		
					0		011	INJ 1	CR132	15 MCG			
					58		011	BLEED 1			412		
					58		021	INJ 2	CR132	15 MCG			
	F	CAUC		8M	0		001	PREBLEED			< 125		
					0		011	INJ 1	CR132	15 MCG			
					63		011	BLEED 1			29354		
					63		021	INJ 2	CR132	15 MCG			
	M	CAUC		3M	0		001	PREBLEED			< 125		
					0		011	INJ 1	CP298	15 MCG			
					63		011	BLEED 1			569		
					63		021	INJ 2	CP298	15 MCG			
	F	CAUC		9M	0		001	PREBLEED			< 125		
					0		011	INJ 1	CR132	15 MCG			
					70		011	BLEED 1			690		
					70		021	INJ 2	CR132	15 MCG			
	M	CAUC		10M	0		001	PREBLEED			< 125		

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	CAUC	(b) (6)	10M	0	(b) (6)	011	INJ 1	CP749	15 MCG						
					62		011	BLEED 1				356				
					62		021	INJ 2	CP749	15 MCG						
	M	BLAC		7M	0		001	PREBLEED				422				
					0		011	INJ 1	CP298	15 MCG						
					63		011	BLEED 1				463				
					63		021	INJ 2	CP298	15 MCG						
	M	CAUC		4M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP749	15 MCG						
					58		011	BLEED 1				774				
					58		021	INJ 2	CP749	15 MCG						
	M	CAUC		2M	0		001	PREBLEED				< 125		< 5		
					0		011	INJ 1	CR132	15 MCG						
					61		011	BLEED 1				1160		20		
					61		021	INJ 2	CR132	15 MCG						
					89		021	BLEED 2				8558		>= 80		
	M	CAUC		6M	0		001	PREBLEED				< 125		< 5		
					0		011	INJ 1	CR132	15 MCG						
					56		011	BLEED 1				2063		< 5		
					56		021	INJ 2	CR132	15 MCG						
					84		021	BLEED 2				14435		< 5		
	M	HISP		9M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP298	15 MCG						
					56		011	BLEED 1				8153				
					56		021	INJ 2	CP298	15 MCG						
	M	CAUC		2M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP749	15 MCG						
					88		011	BLEED 1			05/	394				
					88		021	INJ 2	CP749	15 MCG						
	F	CAUC		5M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP749	15 MCG						
					63		011	BLEED 1				7252				
					63		021	INJ 2	CP749	15 MCG						

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	F	CAUC	(b) (6)	5M	98	(b) (6)	021	BLEED 2				17992				
	F	CAUC		5M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP298	15 MCG						
					68		011	BLEED 1				6698				
					68		021	INJ 2	CP298	15 MCG						
					95		021	BLEED 2				7686				
	F	BLAC		9M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP749	15 MCG						
					87		011	BLEED 1			05/	4467				
					87		021	INJ 2	CP749	15 MCG						
	M	CAUC		5M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP298	15 MCG						
					67		011	BLEED 1				2890				
					67		021	INJ 2	CP298	15 MCG						
					102		021	BLEED 2				5094				
	F	CAUC		9M	0		001	PREBLEED				< 125		< 5		
					0		011	INJ 1	CR132	15 MCG						
					59		011	BLEED 1				4981		5		
					59		021	INJ 2	CR132	15 MCG						
					91		021	BLEED 2				7685		5		
	F	CAUC		8M	0		001	PREBLEED				125				
					0		011	INJ 1	CR132	15 MCG						
					68		011	BLEED 1				479				
					68		021	INJ 2	CR132	15 MCG						
					98		021	BLEED 2				2938				
	M	CAUC		5M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP749	15 MCG						
					69		011	BLEED 1				< 125				
					69		021	INJ 2	CP749	15 MCG						
					104		021	BLEED 2				300				
	F	CAUC		2M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP298	15 MCG						
					64		011	BLEED 1				1724				

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	F	CAUC	(b) (6)	2M	64	(b) (6)	021	INJ	2	CR132	15 MCG					
					97		021	BLEED	2			4081				
	F	CAUC		6M	0		001	PREBLEED				< 125				
					0		011	INJ	1	CP749	15 MCG					
					79		011	BLEED	1			320				
					79		021	INJ	2	CP749	15 MCG					
					126		021	BLEED	2			710				
	M	HISP		7M	0		001	PREBLEED				< 125		< 2		43
					0		011	INJ	1	CR132	15 MCG					
					56		011	BLEED	1			3106		8		95
					56		021	INJ	2	CR132	15 MCG					
					84		021	BLEED	2			12915		>= 32		100
	M	BLAC		9M	0		001	PREBLEED				< 125				
					0		011	INJ	1	CP749	15 MCG					
					72		011	BLEED	1			3949				
					72		021	INJ	2	CP749	15 MCG					
					110		021	BLEED	2			9606				
	F	CAUC		3M	0		001	PREBLEED				< 125		< 5		
					0		011	INJ	1	CR132	15 MCG					
					78		011	BLEED	1			683		< 5		
					78		021	INJ	2	CR132	15 MCG					
					104		021	BLEED	2			732		< 5		
	F	CAUC		4M	0		001	PREBLEED				270		< 2		17
					0		011	INJ	1	CP298	15 MCG					
					75		011	BLEED	1			188		< 2		41
					75		021	INJ	2	CP298	15 MCG					
					108		021	BLEED	2			536		< 2		40
	F	CAUC		6M	0		001	PREBLEED				< 125				
					0		011	INJ	1	CP298	15 MCG					
					61		011	BLEED	1			1221				
					61		021	INJ	2	CP298	15 MCG					
					92		021	BLEED	2			864				
	M	CAUC		5M	0		001	PREBLEED				< 125				

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	CAUC	(b) (6)	5M	0	(b) (6)	011	INJ 1	CR132	15 MCG						
					83		011	BLEED 1			05/	1259				
					83		021	INJ 2	CR132	15 MCG						
	M	BLAC		10M	0		001	PREBLEED				127				
					0		011	INJ 1	CP749	15 MCG						
					64		011	BLEED 1				3988				
					64		021	INJ 2	CP749	15 MCG						
					93		021	BLEED 2				11419				
	F	CAUC		5M	0		001	PREBLEED				139		< 2		
					0		011	INJ 1	CP298	15 MCG						
					69		011	BLEED 1				184		< 2		
					69		021	INJ 2	CP298	15 MCG						
					106		021	BLEED 2				2716		8		
	M	HISP		7M	0		001	PREBLEED				222				
					0		011	INJ 1	CR132	15 MCG						
					70		011	BLEED 1				10753				
					70		021	INJ 2	CR132	15 MCG						
	M	HISP		10M	0		001	PREBLEED				281		< 2		
					0		011	INJ 1	CP749	15 MCG						
					77		011	BLEED 1			05/	1094	05/	< 2		
					77		021	INJ 2	CP749	15 MCG						
					112		021	BLEED 2			05/	7050	05/	8		
	M	CAUC		10M	0		011	INJ 1	CP298	15 MCG						
					80		021	INJ 2	CP298	15 MCG						
	M	CAUC		6M	0		001	PREBLEED				284		< 2		
					0		011	INJ 1	CR132	15 MCG						
					65		011	BLEED 1				800		< 2		
					65		021	INJ 2	CR132	15 MCG						
					98		021	BLEED 2				899		< 2		
	F	BLAC		8M	0		011	INJ 1	CP298	15 MCG						
	M	CAUC		5M	0		001	PREBLEED				254				
					0		011	INJ 1	CP298	15 MCG						

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	CAUC	(b) (6)	5M	63	(b) (6)	011	BLEED 1				992				
	F	CAUC		9M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP749	15 MCG						
					141		011	BLEED 1			05/	4314				
					141		021	INJ 2	CP749	15 MCG						
	M	CAUC		2M	0		001	PREBLEED				205		< 2		0
					0		011	INJ 1	CR132	15 MCG						
					58		011	BLEED 1				1059				
					58		021	INJ 2	CR132	15 MCG						
					98		021	BLEED 2				1352		< 2		100
	M	CAUC		5M	0		001	PREBLEED				< 125		< 2		0
					0		011	INJ 1	CP749	15 MCG						
					62		011	BLEED 1				7899		>= 32		100
					62		021	INJ 2	CP749	15 MCG						
					96		021	BLEED 2				27303		>= 32		98

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ RIA	CODE/ SBA	CODE/ OPSO
(b) (6)	M	CAUC	(b) (6)	13M	0	(b) (6)	001	PREBLEED			165		
					0		011	INJ 1	CN084	20 MCG			
					28		011	BLEED 1			13189		
					371		071	BLEED 2			2463		
	F	CAUC		17M	0		001	PREBLEED			549		
					0		011	INJ 1	CN084	20 MCG			
					35		011	BLEED 1			17102		
					377		071	BLEED 2			3351		
	F	CAUC		16M	0		001	PREBLEED			160		
					0		011	INJ 1	CN084	20 MCG			
					33		011	BLEED 1			9334		
					370		071	BLEED 2			1246		
	M	HISP		2Y	0		001	PREBLEED			< 125	< 5	
					0		011	INJ 1	CP241	15 MCG			
					36		011	BLEED 1			29106	80	
	M	BLAC		23M	0		001	PREBLEED			< 125	< 5	
					0		011	INJ 1	CP241	15 MCG			
					48		011	BLEED 1			21197	160	
	F	BLAC		24M	0		001	PREBLEED			235	< 5	
					0		011	INJ 1	CP241	15 MCG			
					28		011	BLEED 1			276759	320	
	M	BLAC		2Y	0		001	PREBLEED			168	< 5	
					0		011	INJ 1	CP241	15 MCG			
					28		011	BLEED 1			31604	160	
					258		071	BLEED 2			5768		
	F	HISP		2Y	0		001	PREBLEED			1542	80	
					0		011	INJ 1	CP241	15 MCG			
					28		011	BLEED 1			25180	>= 320	
					217		071	BLEED 2			3599		
	F	HISP		14M	0		001	PREBLEED			< 125	< 5	
					0		011	INJ 1	CP241	15 MCG			
					32		011	BLEED 1			4812	20	

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	BLAC	(b) (6)	22M	0	(b) (6)	001	PREBLEED				845		< 5		
					0		011	INJ 1	CP241	15 MCG						
					53		011	BLEED 1				14473		>= 80		
					238		071	BLEED 2				3318				
	F	BLAC		2Y	0		001	PREBLEED				< 125		< 5		
					0		011	INJ 1	CP241	15 MCG						
					28		011	BLEED 1				189390		640		
	F	BLAC		13M	0		001	PREBLEED				< 125		< 5		
					0		011	INJ 1	CP241	15 MCG						
					44		011	BLEED 1				680		20		
	M	BLAC		12M	0		001	PREBLEED				< 125		< 5		
					0		011	INJ 1	CP241	15 MCG						
					28		011	BLEED 1				10366		80		
	M	CAUC		23M	0		001	PREBLEED				< 125		< 5		
					0		011	INJ 1	CP241	15 MCG						
					28		011	BLEED 1				7125		80		
	M	BLAC		2Y	0		001	PREBLEED				< 125		< 5		
					0		011	INJ 1	CP241	15 MCG						
					28		011	BLEED 1				5363		80		
					280		071	BLEED 2				1667				
	M	BLAC		3Y	0		011	INJ 1	CP241	15 MCG						
	M	CAUC		2Y	0		001	PREBLEED				1034		5		
					0		011	INJ 1	CP241	15 MCG						
					33		011	BLEED 1				67071		320		
	M	CAUC		18M	0		001	PREBLEED				< 125		< 5		
					0		011	INJ 1	CP241	15 MCG						
					33		011	BLEED 1				65764		20		
	F	CAUC		12M	0		001	PREBLEED				< 125		< 5		
					0		011	INJ 1	CP241	15 MCG						
					34		011	BLEED 1				2412		20		
	M	CAUC		13M	0		001	PREBLEED				< 125		< 5		

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	CAUC	(b) (6)	13M	0	(b) (6)	011	INJ 1	CP241	15 MCG						
					41		011	BLEED 1				693		5		
					245		071	BLEED 2				2785				
	M	BLAC		2Y	0		001	PREBLEED				559				
					0		011	INJ 1	CP241	15 MCG						
					30		011	BLEED 1				15580				
	M	CAUC		12M	0		001	PREBLEED				< 125		< 5		
					0		011	INJ 1	CP241	15 MCG						
					26		011	BLEED 1				3478		20		
	F	HISP		24M	0		001	PREBLEED				168		< 5		
					0		011	INJ 1	CP241	15 MCG						
					28		011	BLEED 1				68489		>= 80		
	M	CAUC		20M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP241	15 MCG						
					36		011	BLEED 1				2701				
					210		071	BLEED 2				467				
	F	CAUC		12M	0		001	PREBLEED				565		5		
					0		011	INJ 1	CP241	15 MCG						
					41		011	BLEED 1				49650		80		
	M	BLAC		17M	0		001	PREBLEED				< 125		< 5		
					0		011	INJ 1	CP241	15 MCG						
					33		011	BLEED 1				45805		>= 80		
	F	CAUC		16M	0		001	PREBLEED				< 125		< 5		
					0		011	INJ 1	CP241	15 MCG						
					34		011	BLEED 1				37796		20		
	F	CAUC		17M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP298	15 MCG						
					39		011	BLEED 1				37700				
	M	CAUC		16M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP298	15 MCG						
					30		011	BLEED 1				771				

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	CAUC	(b) (6)	16M	188	(b) (6)	071	BLEED 2				561				
	M	CAUC		12M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP298	15 MCG						
					31		011	BLEED 1				3334				
	M	HISP		22M	0		001	PREBLEED				< 125		< 5		
					0		011	INJ 1	CP298	15 MCG						
					30		011	BLEED 1				2659		20		
					190		071	BLEED 2				877				
	F	CAUC		20M	0		001	PREBLEED				< 125		< 5		
					0		011	INJ 1	CP298	15 MCG						
					29		011	BLEED 1				29307		>= 80		
	F	CAUC		18M	0		001	PREBLEED				< 125				23
					0		011	INJ 1	CP298	15 MCG						
					29		011	BLEED 1				27823				99
	M	CAUC		13M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP298	15 MCG						
					22		011	BLEED 1				2800				
					186		071	BLEED 2				805				
	F	BLAC		2Y	0		001	PREBLEED				511		< 5		
					0		011	INJ 1	CP298	15 MCG						
					28		011	BLEED 1				14115		>= 80		
	F	BLAC		3Y	0		011	INJ 1	CP298	15 MCG						
	M	BLAC		3Y	0		001	PREBLEED				189		< 5		
					0		011	INJ 1	CP298	15 MCG						
					66		011	BLEED 1				9926		80		
					156		071	BLEED 2				2044				
	M	BLAC		2Y	0		001	PREBLEED				< 125				36
					0		011	INJ 1	CP298	15 MCG						
					58		011	BLEED 1				15640				98
	M	CAUC		16M	0		001	PREBLEED				< 125				31

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	CAUC	(b) (6)	16M	0	(b) (6)	011	INJ 1	CP298	15 MCG						
					38		011	BLEED 1				1931				93
					214		071	BLEED 2				583				
	M	BLAC		3Y	0		001	PREBLEED				131		5		46
					0		011	INJ 1	CP298	15 MCG						
					28		011	BLEED 1				< 125		5		48
					154		071	BLEED 2				359				
	F	CAUC		15M	0		001	PREBLEED				< 125				25
					0		011	INJ 1	CP298	15 MCG						
					29		011	BLEED 1				7743				97
	F	BLAC		12M	0		001	PREBLEED				127				20
					0		011	INJ 1	CP298	15 MCG						
					28		011	BLEED 1				9612				99
	M	BLAC		12M	0		001	PREBLEED				290				43
					0		011	INJ 1	CP298	15 MCG						
					47		011	BLEED 1				4820				95
	M	HISP		12M	0		001	PREBLEED				1812				53
					0		011	INJ 1	CP298	15 MCG						
					34		011	BLEED 1				9791				96
	M	BLAC		24M	0		001	PREBLEED				1021		20		88
					0		011	INJ 1	CP298	15 MCG						
					24		011	BLEED 1				30316		320		99
					210		071	BLEED 2				3866				
	F	BLAC		12M	0		001	PREBLEED				210				36
					0		011	INJ 1	CP298	15 MCG						
					30		011	BLEED 1				1361				54
					196		071	BLEED 2				2357				
	M	BLAC		2Y	0		001	PREBLEED				559		5		
					0		011	INJ 1	CP298	15 MCG						
					75		011	BLEED 1				25786		20		
	M	CAUC		12M	0		001	PREBLEED				< 125				28

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	CAUC	(b) (6)	12M	0	(b) (6)	011	INJ 1	CP298	15 MCG						
					35		011	BLEED 1				1886				90
	M	CAUC		14M	0		001	PREBLEED				231				15
					0		011	INJ 1	CP298	15 MCG						
					36		011	BLEED 1				550				61
					155		071	BLEED 2				2092				
	M	BLAC		22M	0		011	INJ 1	CR132	15 MCG						
	M	CAUC		12M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP298	15 MCG						
					202		071	BLEED 1				5112				
	M	CAUC		15M	0		001	PREBLEED				< 125				43
					0		011	INJ 1	CR132	15 MCG						
					32		011	BLEED 1				8082				65
	M	HISP		20M	0		001	PREBLEED				1700		< 5		
					0		011	INJ 1	CP298	15 MCG						
					34		011	BLEED 1				15746		20		
	M	CAUC		2Y	0		011	INJ 1	CP749	15 MCG						
	F	CAUC		2Y	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP749	15 MCG						
					141		071	BLEED 1				1879				
	M	BLAC		22M	0		001	PREBLEED				< 125		< 5		
					0		011	INJ 1	CR132	15 MCG						
					35		011	BLEED 1				3735		>= 80		
	M	BLAC		2Y	0		001	PREBLEED				4424		20		
					0		011	INJ 1	CP298	15 MCG						
					49		011	BLEED 1				14762		80		
	M	HISP		23M	0		011	INJ 1	CP298	15 MCG						
	F	CAUC		12M	0		001	PREBLEED				305		< 5		20
					0		011	INJ 1	CP749	15 MCG						

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	F	CAUC	(b) (6)	12M	29	(b) (6)	011	BLEED	1			507		5		98
	M	BLAC		2Y	0		011	INJ	1	CR132 15 MCG						
	M	CAUC		17M	0		001	PREBLEED				< 125		< 5		37
					0		011	INJ	1	CP749 15 MCG						
					37		011	BLEED	1			1649		20		100
	M	CAUC		3Y	0		001	PREBLEED				8089		20		100
					0		011	INJ	1	CP749 15 MCG						
					37		011	BLEED	1			50099		20		100
	F	CAUC		2Y	0		001	PREBLEED				651		< 5		22
					0		011	INJ	1	CR132 15 MCG						
					28		011	BLEED	1			36625		>= 80		100
	M	BLAC		2Y	0		001	PREBLEED				7774		< 5		
					0		011	INJ	1	CP298 15 MCG						
					35		011	BLEED	1			64815		20		
					168		071	BLEED	2			9588				
	M	BLAC		12M	0		001	PREBLEED				< 125				
					0		011	INJ	1	CP298 15 MCG						
					133		011	BLEED	1			14464				
	F	HISP		12M	0		011	INJ	1	CR132 15 MCG						
	M	CAUC		12M	0		001	PREBLEED				233		< 5		
					0		011	INJ	1	CR132 15 MCG						
					29		011	BLEED	1			2548		20		
	M	CAUC		12M	0		001	PREBLEED				< 125		< 2		36
					0		011	INJ	1	CP298 15 MCG						
					83		011	BLEED	1		05/	2247	05/	< 2	05/	100
	M	BLAC		16M	0		001	PREBLEED				278		< 5		
					0		011	INJ	1	CP298 15 MCG						
					31		011	BLEED	1			5128		20		
	F	BLAC		2Y	0		001	PREBLEED				231		< 5		40

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	F	BLAC	(b) (6)	2Y	0	(b) (6)	011	INJ	1	CP749	15 MCG					
					28		011	BLEED	1			769		20		74
	F	CAUC		24M	0		001	PREBLEED				228		< 5		43
					0		011	INJ	1	CR132	15 MCG					
					50		011	BLEED	1			7924		20		98
	M	CAUC		14M	0		001	PREBLEED				< 125				
					0		011	INJ	1	CP749	15 MCG					
					147		071	BLEED	1			827				
	F	CAUC		17M	0		001	PREBLEED				381		< 5		
					0		011	INJ	1	CP298	15 MCG					
					47		011	BLEED	1			61146		>= 80		
	M	BLAC		2Y	0		001	PREBLEED				166		< 5		4
					0		011	INJ	1	CR132	15 MCG					
					43		011	BLEED	1			3805		20		95
	F	BLAC		22M	0		001	PREBLEED				415		< 5		
					0		011	INJ	1	CP298	15 MCG					
					49		011	BLEED	1			4119		20		
	F	CAUC		20M	0		001	PREBLEED				< 125		< 5		22
					0		011	INJ	1	CR132	15 MCG					
					34		011	BLEED	1			9232		20		100
	M	BLAC		2Y	0		001	PREBLEED				< 125		< 5		
					0		011	INJ	1	CP749	15 MCG					
					28		011	BLEED	1			44430		>= 80		
	F	CAUC		15M	0		001	PREBLEED				152		< 5		44
					0		011	INJ	1	CP749	15 MCG					
					35		011	BLEED	1			2385		20		99
	M	CAUC		24M	0		001	PREBLEED				< 125		< 5		
					0		011	INJ	1	CP749	15 MCG					
					39		011	BLEED	1			1888		20		
	F	CAUC		2Y	0		001	PREBLEED				< 125		< 5		

00362

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	F	CAUC	(b) (6)	2Y	0	(b) (6)	011	INJ 1	CP749	15 MCG						
					38		011	BLEED 1				5019		5		
	M	CAUC		17M	0		001	PREBLEED				< 125		< 5		
					0		011	INJ 1	CP298	15 MCG						
					33		011	BLEED 1				16931		20		
	M	CAUC		19M	0		001	PREBLEED				< 125		< 5		
					0		011	INJ 1	CR132	15 MCG						
					35		011	BLEED 1				3638		>= 80		
	M	CAUC		16M	0		001	PREBLEED				301		< 5		20
					0		011	INJ 1	CR132	15 MCG						
					39		011	BLEED 1				2106		5		95
	F	BLAC		2Y	0		001	PREBLEED				< 125		< 5		
					0		011	INJ 1	CP298	15 MCG						
					43		011	BLEED 1				47282		20		
	M	HISP		12M	0		001	PREBLEED				< 125		< 5		29
					0		011	INJ 1	CR132	15 MCG						
					28		011	BLEED 1				4396		5		100
	F	BLAC		23M	0		001	PREBLEED				154		< 5		36
					0		011	INJ 1	CP749	15 MCG						
					28		011	BLEED 1				74680		>= 80		98
	F	BLAC		23M	0		001	PREBLEED				179		< 5		
					0		011	INJ 1	CR132	15 MCG						
					28		011	BLEED 1				791		20		
	F	CAUC		13M	0		011	INJ 1	CP298	15 MCG						
	M	BLAC		13M	0		001	PREBLEED				< 125		< 5		
					0		011	INJ 1	CP298	15 MCG						
					32		011	BLEED 1				1422		20		
	F	BLAC		12M	0		001	PREBLEED				< 125		< 2		26
					0		011	INJ 1	CP749	15 MCG						
					33		011	BLEED 1				926		< 2		34

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	BLAC	(b) (6)	20M	0	(b) (6)	001	PREBLEED				< 125		< 5		
					0		011	INJ 1	CP298	15 MCG						
					42		011	BLEED 1				46290		20		
	F	BLAC		2Y	0		001	PREBLEED				523		< 5		33
					0		011	INJ 1	CP749	15 MCG						
					29		011	BLEED 1				80280		>= 80		100
	M	BLAC		24M	0		001	PREBLEED				< 125		< 5		
					0		011	INJ 1	CR132	15 MCG						
					69		011	BLEED 1				3048		20		
	F	BLAC		4Y	0		001	PREBLEED				4873		20		
					0		011	INJ 1	CP298	15 MCG						
					24		011	BLEED 1				105068		320		
	M	BLAC		20M	0		001	PREBLEED				3096		< 5		
					0		011	INJ 1	CR132	15 MCG						
					63		011	BLEED 1				2224		< 5		
	M	BLAC		2Y	0		011	INJ 1	CP749	15 MCG						
	F	BLAC		21M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP749	15 MCG						
					56		011	BLEED 1				70465				
	F	BLAC		21M	0		001	PREBLEED				< 125		< 5		
					0		011	INJ 1	CP298	15 MCG						
					28		011	BLEED 1				7628		20		
	M	CAUC		15M	0		001	PREBLEED				< 125		< 5		
					0		011	INJ 1	CR132	15 MCG						
					42		011	BLEED 1				1505		5		
	F	BLAC		16M	0		011	INJ 1	CR132	15 MCG						
	M	BLAC		14M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP749	15 MCG						
					35		011	BLEED 1				275				
	M	BLAC		14M	0		001	PREBLEED				< 125				

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	BLAC	(b) (6)	14M	0	(b) (6)		011 INJ 1	CP298	15 MCG						
					35			011 BLEED 1				190				
	M	BLAC		24M	0			001 PREBLEED				2749		< 5		
					0			011 INJ 1	CR132	15 MCG						
					28			011 BLEED 1				7463		>= 80		
	M	CAUC		23M	0			001 PREBLEED				< 125		< 5		
					0			011 INJ 1	CR132	15 MCG						
					28			011 BLEED 1				7892		>= 80		
	F	BLAC		21M	0			001 PREBLEED				< 125				
					0			011 INJ 1	CP298	15 MCG						
					72			011 BLEED 1				1605				
	F	CAUC		24M	0			011 INJ 1	CP749	15 MCG						
	M	BLAC		22M	0			001 PREBLEED				960				
					0			011 INJ 1	CP298	15 MCG						
					28			011 BLEED 1				47339				
	M	CAUC		12M	0			001 PREBLEED				< 125				
					0			011 INJ 1	CP749	15 MCG						
					28			011 BLEED 1				9178				
	F	CAUC		16M	0			001 PREBLEED				< 125				
					0			011 INJ 1	CP298	15 MCG						
					33			011 BLEED 1				532				
	F	CAUC		12M	0			001 PREBLEED				< 125				
					0			011 INJ 1	CP298	15 MCG						
					41			011 BLEED 1				1200				
	M	CAUC		23M	0			001 PREBLEED				194		< 5		
					0			011 INJ 1	CR132	15 MCG						
					31			011 BLEED 1				31003		>= 80		
	M	CAUC		12M	0			001 PREBLEED				< 125		< 5		
					0			011 INJ 1	CR132	15 MCG						
					46			011 BLEED 1				1662		20		

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	BLAC	(b) (6)	12M	0	(b) (6)	001	PREBLEED				< 125				
					0		011	INJ	1 CP749	15 MCG						
					35		011	BLEED	1			32065				
	F	BLAC		2Y	0		011	INJ	1 CP749	15 MCG						
	M	BLAC		2Y	0		011	INJ	1 CP749	15 MCG						
	M	HISP		2Y	0		011	INJ	1 CR132	15 MCG						
	F	BLAC		23M	0		011	INJ	1 CP298	15 MCG						
	F	BLAC		12M	0		011	INJ	1 CR132	15 MCG						
	M	BLAC		14M	0		011	INJ	1 CP749	15 MCG						
	M	CAUC		12M	0		011	INJ	1 CP298	15 MCG						
	F	CAUC		12M	0		011	INJ	1 CR132	15 MCG						
	F	HISP		22M	0		011	INJ	1 CR132	15 MCG						
	M	HISP		12M	0		011	INJ	1 CP749	15 MCG						
	M	CAUC		19M	0		011	INJ	1 CP298	15 MCG						
	M	HISP		12M	0		011	INJ	1 CP298	15 MCG						
	F	BLAC		12M	0		011	INJ	1 CP749	15 MCG						
	M	CAUC		12M	0		011	INJ	1 CP749	15 MCG						
	F	CAUC		17M	0		011	INJ	1 CR132	15 MCG						
	F	BLAC		15M	0		011	INJ	1 CR132	15 MCG						

TABLE 2

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT		LOT	DOSE	CODE/ IGG1	CODE/ IGG2	CODE/ IGGM	CODE/IGG TOTAL
(b) (6)	M	BLAC	(b) (6)	6M	0	(b) (6)	011	INJ	1	CN084	15 MCG				
	M	CAUC		3M	0		011	INJ	1	CN084	15 MCG				
					98		081	INJ	2	POLYS	25 MCG				
	M	CAUC		5M	0		011	INJ	1	CN084	15 MCG				
					99		081	INJ	2	POLYS	25 MCG				
					416		091	INJ	3	CP241	15 MCG				
	F	CAUC		6M	0		011	INJ	1	CN084	15 MCG				
					95		081	INJ	2	POLYS	25 MCG				
					380		091	INJ	3	CP241	15 MCG				
	F	HISP		4M	0		011	INJ	1	CN084	15 MCG				
					104		081	INJ	2	POLYS	25 MCG				
	M	BLAC		3M	0		011	INJ	1	CN084	15 MCG				
	F	BLAC		3M	0		011	INJ	1	CN084	15 MCG				
	M	CAUC		4M	0		011	INJ	1	CN084	15 MCG				
					447		091	INJ	2	CP298	15 MCG				
	F	CAUC		4M	0		011	INJ	1	CN084	15 MCG				
	M	CAUC		4M	0		011	INJ	1	CN084	15 MCG				
					30		081	INJ	2	POLYS	25 MCG				
					301		091	INJ	3	CP241	15 MCG				
	F	CAUC		4M	0		001	PREBLEED				< 600		< 100	< 100
					0		011	INJ	1	CP241	15 MCG				
					60		011	BLEED	1			6450		< 100	854
					60		021	INJ	2	CP241	15 MCG				
					90		021	BLEED	2			6262		< 100	1196
	F	CAUC		2M	0		001	PREBLEED				< 600	< 250	< 100	< 100
					0		011	INJ	1	CP241	15 MCG				
					66		011	BLEED	1			2313	< 250	< 100	720
					66		021	INJ	2	CP241	15 MCG				
					101		021	BLEED	2			6477	< 250	< 100	1902

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	IGG1	CODE/	IGG2	CODE/	IGGM	CODE/	IGG TOTAL
(b) (6)	M	CAUC	(b) (6)	7M	0	(b) (6)	001	PREBLEED				< 600		< 250		< 100		< 100
					0		011	INJ 1	CP241	15 MCG								
					77		011	BLEED 1			05/	7612	05/	< 250	05/	< 100	05/	3598
					77		021	INJ 2	CP241	15 MCG								
					107		021	BLEED 2			05/	12193	05/	258	05/	< 100	05/	7212
	F	CAUC		6M	0		001	PREBLEED				< 600		< 250		< 100		< 100
					0		011	INJ 1	CP241	15 MCG								
					72		011	BLEED 1			05/	3653	05/	< 250	05/	110	05/	417
					72		021	INJ 2	CP241	15 MCG								
					98		021	BLEED 2			05/	5964	05/	< 250	05/	643	05/	1339
	M	CAUC		6M	0		001	PREBLEED				< 600		< 250		< 100		< 100
					0		011	INJ 1	CP241	15 MCG								
					63		011	BLEED 1				670		< 250		< 100		210
					63		021	INJ 2	CP241	15 MCG								
					98		021	BLEED 2				2266		< 250		< 100		488
	F	CAUC		4M	0		001	PREBLEED				< 600				< 100		< 100
					0		011	INJ 1	CP241	15 MCG								
					57		011	BLEED 1				3033				145		348
					57		021	INJ 2	CP241	15 MCG								
					97		021	BLEED 2				3213				147		543
	M	OTHE		4M	0		001	PREBLEED				< 600				< 100		< 100
					0		011	INJ 1	CP241	15 MCG								
					61		011	BLEED 1				4163				279		364
					61		021	INJ 2	CP241	15 MCG								
					89		021	BLEED 2				11914				144		690
	F	CAUC		2M	0		001	PREBLEED				< 600				< 100		< 100
					0		011	INJ 1	CP241	15 MCG								
					62		011	BLEED 1				6830				< 100		893
					62		021	INJ 2	CP241	15 MCG								
					97		021	BLEED 2				10697				< 100		1610
	M	CAUC		10M	0		011	INJ 1	CP241	15 MCG								
					62		021	INJ 2	CP241	15 MCG								
	F	CAUC		5M	0		011	INJ 1	CP241	15 MCG								

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ IGG1	CODE/ IGG2	CODE/ IGGM	CODE/IGG TOTAL
(b) (6)	F	CAUC	(b) (6)	5M	69	(b) (6)	021	INJ 2	CP241	15 MCG				
	M	HISP		6M	0		011	INJ 1	CP241	15 MCG				
					62		021	INJ 2	CP241	15 MCG				
	M	CAUC		9M	0		011	INJ 1	CP241	15 MCG				
					63		021	INJ 2	CP241	15 MCG				
	F	CAUC		6M	0		011	INJ 1	CP241	15 MCG				
					63		021	INJ 2	CP241	15 MCG				
	M	HISP		8M	0		011	INJ 1	CP241	15 MCG				
					62		021	INJ 2	CP241	15 MCG				
	M	CAUC		5M	0		011	INJ 1	CP241	15 MCG				
					70		021	INJ 2	CP241	15 MCG				
	M	CAUC		9M	0		001	PREBLEED			< 600	< 250	< 100	< 100
					0		011	INJ 1	CP298	15 MCG				
					57		011	BLEED 1			10663	< 250	< 100	2024
					57		021	INJ 2	CP298	15 MCG				
					96		021	BLEED 2			22885	< 250	136	5100
	F	CAUC		5M	0		001	PREBLEED			< 600	< 250	< 100	< 100
					0		011	INJ 1	CP298	15 MCG				
					62		011	BLEED 1			4358	1144	< 100	1511
					62		021	INJ 2	CP298	15 MCG				
					98		021	BLEED 2			2529	845	< 100	757
	M	CAUC		9M	0		001	PREBLEED			< 600	< 250	< 100	< 100
					0		011	INJ 1	CP298	15 MCG				
					63		011	BLEED 1			2402	< 250	< 100	284
					63		021	INJ 2	CP298	15 MCG				
					97		021	BLEED 2			9787	< 250	< 100	862
	F	BLAC		9M	0		001	PREBLEED				< 250	< 100	< 100
					0		011	INJ 1	CP298	15 MCG				
					65		011	BLEED 1				< 250	194	258
					65		021	INJ 2	CP298	15 MCG				
					105		021	BLEED 2				< 250	179	360

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	IGG1	CODE/	IGG2	CODE/	IGGM	CODE/	IGG TOTAL
(b) (6)	F	BLAC	(b) (6)	6M	0	(b) (6)	001	PREBLEED				< 600		< 250		< 100		< 100
					0		011	INJ 1	CP298	15 MCG								
					62		011	BLEED 1				1641		< 250		< 100		333
					62		021	INJ 2	CP298	15 MCG								
					113		021	BLEED 2				880		< 250		< 100		< 100
	F	CAUC		2M	0		001	PREBLEED				< 600						
					0		011	INJ 1	CP298	15 MCG								
					61		011	BLEED 1				27062						
					61		021	INJ 2	CP298	15 MCG								
					126		021	BLEED 2				7834						
	F	CAUC		7M	0		001	PREBLEED				< 600		< 250				
					0		011	INJ 1	CP298	15 MCG								
					68		011	BLEED 1				1812		< 250				
					68		021	INJ 2	CP298	15 MCG								
					120		021	BLEED 2			05/	15137		< 250				
	F	CAUC		5M	0		001	PREBLEED				< 600				< 100		< 100
					0		011	INJ 1	CP298	15 MCG								
					80		011	BLEED 1			05/	7506				166	05/	1142
					80		021	INJ 2	CP298	15 MCG								
					108		021	BLEED 2			05/	8742			05/	< 100	05/	1462
	F	BLAC		8M	0		001	PREBLEED				< 600						
					0		011	INJ 1	CP298	15 MCG								
					56		011	BLEED 1				714						
					56		021	INJ 2	CP298	15 MCG								
					146		021	BLEED 2				970						
	F	CAUC		3M	0		001	PREBLEED				< 600				< 100		< 100
					0		011	INJ 1	CP298	15 MCG								
					71		011	BLEED 1			05/	11910				466	05/	1122
					71		021	INJ 2	CP298	15 MCG								
					111		021	BLEED 2			05/	17511			05/	< 100	05/	1050
	M	CAUC		8M	0		011	INJ 1	CP298	15 MCG								
					67		021	INJ 2	CP298	15 MCG								
	M	CAUC		4M	0		011	INJ 1	CP298	15 MCG								

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT		LOT	DOSE	CODE/	IGG1	CODE/	IGG2	CODE/	IGGM	CODE/IGG TOTAL
(b) (6)	M	CAUC	(b) (6)	4M	70	(b) (6)	021	INJ	2	CP298	15 MCG							
	M	CAUC		4M	0		011	INJ	1	CP298	15 MCG							
					67		021	INJ	2	CP298	15 MCG							
	F	CAUC		8M	0		011	INJ	1	CP298	15 MCG							
					64		021	INJ	2	CP298	15 MCG							
	M	CAUC		4M	0		011	INJ	1	CP298	15 MCG							
					74		021	INJ	2	CP298	15 MCG							
	F	CAUC		7M	0		011	INJ	1	CP298	15 MCG							
					59		021	INJ	2	CP298	15 MCG							
	M	HISP		10M	0		011	INJ	1	CP298	15 MCG							
					63		021	INJ	2	CP298	15 MCG							
	F	BLAC		8M	0		001	PREBLEED					< 600					
					0		011	INJ	1	CP298	15 MCG							
					68		011	BLEED	1				< 600					
					68		021	INJ	2	CP298	15 MCG							
					108		021	BLEED	2				1862					
	M	CAUC		7M	0		011	INJ	1	CP298	15 MCG							
					56		021	INJ	2	CP298	15 MCG							
	F	BLAC		11M	0		001	PREBLEED					< 600				< 100	< 100
					0		011	INJ	1	CP749	15 MCG							
					91		011	BLEED	1				21365				< 100	2342
	F	BLAC		5M	0		011	INJ	1	CP749	15 MCG							
	M	CAUC		6M	0		011	INJ	1	CP298	15 MCG							
	M	CAUC		2M	0		011	INJ	1	CP298	15 MCG							
	M	CAUC		4M	0		011	INJ	1	CP298	15 MCG							
	F	HISP		6M	0		011	INJ	1	CP749	15 MCG							
	M	CAUC		5M	0		011	INJ	1	CP298	15 MCG							

00371

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ IGG1	CODE/ IGG2	CODE/ IGGM	CODE/IGG TOTAL
(b) (6)	M	HISP	(b) (6)	3M	0	(b) (6)	011	INJ	1	CP749	15 MCG			
	M	BLAC		2M	0		011	INJ	1	CR132	15 MCG			
	M	HISP		5M	0		011	INJ	1	CR132	15 MCG			
	M	CAUC		2M	0		011	INJ	1	CP298	15 MCG			
	M	CAUC		5M	0		011	INJ	1	CP298	15 MCG			
	M	CAUC		5M	0		011	INJ	1	CR132	15 MCG			
	M	CAUC		4M	0		011	INJ	1	CP749	15 MCG			
	F	CAUC		9M	0		011	INJ	1	CP749	15 MCG			
	F	CAUC		9M	0		011	INJ	1	CR132	15 MCG			
	F	CAUC		6M	0		011	INJ	1	CR132	15 MCG			
	F	BLAC		5M	0		011	INJ	1	CP298	15 MCG			
	M	CAUC		2M	0		011	INJ	1	CP749	15 MCG			
	M	CAUC		6M	0		011	INJ	1	CP749	15 MCG			
	F	BLAC		8M	0		011	INJ	1	CP298	15 MCG			
					63		021	INJ	2	CP298	15 MCG			
	F	BLAC		10M	0		011	INJ	1	CR132	15 MCG			
					62		021	INJ	2	CR132	15 MCG			
	F	CAUC		6M	0		011	INJ	1	CP298	15 MCG			
					63		021	INJ	2	CP298	15 MCG			
	F	CAUC		6M	0		011	INJ	1	CP749	15 MCG			
	F	CAUC		4M	0		011	INJ	1	CP298	15 MCG			
					64		021	INJ	2	CP298	15 MCG			
	M	CAUC		4M	0		011	INJ	1	CR132	15 MCG			

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	IGG1	CODE/	IGG2	CODE/	IGGM	CODE/IGG TOTAL
(b) (6)	M	CAUC	(b) (6)	4M	67	(b) (6)	021	INJ	2 CR132	15 MCG							
	M	CAUC		2M	0		011	INJ	1 CP749	15 MCG							
					63		021	INJ	2 CP749	15 MCG							
	F	CAUC		6M	0		011	INJ	1 CR132	15 MCG							
					58		021	INJ	2 CR132	15 MCG							
	F	CAUC		8M	0		011	INJ	1 CR132	15 MCG							
					63		021	INJ	2 CR132	15 MCG							
	M	CAUC		3M	0		011	INJ	1 CP298	15 MCG							
					63		021	INJ	2 CP298	15 MCG							
	F	CAUC		9M	0		011	INJ	1 CR132	15 MCG							
					70		021	INJ	2 CR132	15 MCG							
	M	CAUC		10M	0		011	INJ	1 CP749	15 MCG							
					62		021	INJ	2 CP749	15 MCG							
	M	BLAC		7M	0		011	INJ	1 CP298	15 MCG							
					63		021	INJ	2 CP298	15 MCG							
	M	CAUC		4M	0		011	INJ	1 CP749	15 MCG							
					58		021	INJ	2 CP749	15 MCG							
	M	CAUC		2M	0		001	PREBLEED								< 100	< 100
					0		011	INJ	1 CR132	15 MCG							
					61		011	BLEED	1							< 100	365
					61		021	INJ	2 CR132	15 MCG							
					89		021	BLEED	2							568	2629
	M	CAUC		6M	0		001	PREBLEED								< 100	< 100
					0		011	INJ	1 CR132	15 MCG							
					56		011	BLEED	1							< 100	305
					56		021	INJ	2 CR132	15 MCG							
					84		021	BLEED	2							< 100	783
	M	HISP		9M	0		011	INJ	1 CP298	15 MCG							
					56		021	INJ	2 CP298	15 MCG							

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ IGG1	CODE/ IGG2	CODE/ IGGM	CODE/IGG TOTAL
(b) (6)	M	CAUC	(b) (6)	2M	0	(b) (6)	011	INJ 1	CP749	15 MCG				
					88		021	INJ 2	CP749	15 MCG				
	F	CAUC		5M	0		011	INJ 1	CP749	15 MCG				
					63		021	INJ 2	CP749	15 MCG				
	F	CAUC		5M	0		011	INJ 1	CP298	15 MCG				
					68		021	INJ 2	CP298	15 MCG				
	F	BLAC		9M	0		011	INJ 1	CP749	15 MCG				
					87		021	INJ 2	CP749	15 MCG				
	M	CAUC		5M	0		011	INJ 1	CP298	15 MCG				
					67		021	INJ 2	CP298	15 MCG				
	F	CAUC		9M	0		001	PREBLEED					< 100	< 100
					0		011	INJ 1	CR132	15 MCG				
					59		011	BLEED 1					435	1024
					59		021	INJ 2	CR132	15 MCG				
					91		021	BLEED 2					445	413
	F	CAUC		8M	0		001	PREBLEED					< 100	< 100
					0		011	INJ 1	CR132	15 MCG				
					68		011	BLEED 1					< 100	< 100
					68		021	INJ 2	CR132	15 MCG				
					98		021	BLEED 2					178	124
	M	CAUC		5M	0		011	INJ 1	CP749	15 MCG				
					69		021	INJ 2	CP749	15 MCG				
	F	CAUC		2M	0		011	INJ 1	CP298	15 MCG				
					64		021	INJ 2	CR132	15 MCG				
	F	CAUC		6M	0		011	INJ 1	CP749	15 MCG				
					79		021	INJ 2	CP749	15 MCG				
	M	HISP		7M	0		001	PREBLEED			< 600	< 250	< 100	< 100
					0		011	INJ 1	CR132	15 MCG				
					56		011	BLEED 1			2460	< 250	600	404
					56		021	INJ 2	CR132	15 MCG				

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ IGG1	CODE/ IGG2	CODE/ IGGM	CODE/IGG TOTAL
(b) (6)	M	HISP	(b) (6)	7M	84	(b) (6)	021	BLEED 2			15528	< 250	1966	1457
	M	BLAC		9M	0		011	INJ 1	CP749	15 MCG				
					72		021	INJ 2	CP749	15 MCG				
	F	CAUC		3M	0		001	PREBLEED					< 100	237
					0		011	INJ 1	CR132	15 MCG				
					78		011	BLEED 1					< 100	238
					78		021	INJ 2	CR132	15 MCG				
					104		021	BLEED 2					< 100	306
	F	CAUC		4M	0		011	INJ 1	CP298	15 MCG				
					75		021	INJ 2	CP298	15 MCG				
	F	CAUC		6M	0		001	PREBLEED			< 600			
					0		011	INJ 1	CP298	15 MCG				
					61		011	BLEED 1			1585			
					61		021	INJ 2	CP298	15 MCG				
					92		021	BLEED 2			742			
	M	CAUC		5M	0		011	INJ 1	CR132	15 MCG				
					83		021	INJ 2	CR132	15 MCG				
	M	BLAC		10M	0		001	PREBLEED			< 600		< 100	< 100
					0		011	INJ 1	CP749	15 MCG				
					64		011	BLEED 1			5840		181	2097
					64		021	INJ 2	CP749	15 MCG				
					93		021	BLEED 2			15398		904	5271
	F	CAUC		5M	0		001	PREBLEED			< 600			
					0		011	INJ 1	CP298	15 MCG				
					69		011	BLEED 1			< 600			
					69		021	INJ 2	CP298	15 MCG				
					106		021	BLEED 2			2781			
	M	HISP		7M	0		011	INJ 1	CR132	15 MCG				
					70		021	INJ 2	CR132	15 MCG				
	M	HISP		10M	0		001	PREBLEED			< 600		< 100	< 100
					0		011	INJ 1	CP749	15 MCG				

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	IGG1	CODE/	IGG2	CODE/	IGGM	CODE/	IGG TOTAL
(b) (6)	M	HISP	(b) (6)	10M	77	(b) (6)	011	BLEED 1			05/	< 600			05/	< 100	05/	283
					77		021	INJ 2	CP749	15 MCG								
					112		021	BLEED 2			05/	7839			05/	373	05/	523
	M	CAUC		10M	0		011	INJ 1	CP298	15 MCG								
					80		021	INJ 2	CP298	15 MCG								
	M	CAUC		6M	0		001	PREBLEED				< 600		< 250		< 100		< 100
					0		011	INJ 1	CR132	15 MCG								
					65		011	BLEED 1				< 600		< 250		< 100		< 100
					65		021	INJ 2	CR132	15 MCG								
					98		021	BLEED 2				651		< 250		< 100		141
	F	BLAC		8M	0		011	INJ 1	CP298	15 MCG								
	M	CAUC		5M	0		001	PREBLEED				< 600						
					0		011	INJ 1	CP298	15 MCG								
					63		011	BLEED 1				1143						
	F	CAUC		9M	0		011	INJ 1	CP749	15 MCG								
					141		021	INJ 2	CP749	15 MCG								
	M	CAUC		2M	0		001	PREBLEED				< 600		< 250		< 100		< 100
					0		011	INJ 1	CR132	15 MCG								
					58		011	BLEED 1			01/	QNS	01/	QNS		< 100	01/	QNS
					58		021	INJ 2	CR132	15 MCG								
					98		021	BLEED 2				2501		< 250		< 100		541
	M	CAUC		5M	0		001	PREBLEED				< 600		< 250		< 100		< 100
					0		011	INJ 1	CP749	15 MCG								
					62		011	BLEED 1				23185		< 250		388		4202
					62		021	INJ 2	CP749	15 MCG								
					96		021	BLEED 2				73842		< 250		285		11349

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ IGG1	CODE/ IGG2	CODE/ IGGM	CODE/IGG TOTAL
(b) (6)	M	CAUC	(b) (6)	13M	0	(b) (6)	011	INJ 1	CN084	20 MCG				
	F	CAUC		17M	0		011	INJ 1	CN084	20 MCG				
	F	CAUC		16M	0		011	INJ 1	CN084	20 MCG				
	M	HISP		2Y	0		001	PREBLEED				< 250		
					0		011	INJ 1	CP241	15 MCG				
					36		011	BLEED 1				707		
	M	BLAC		23M	0		001	PREBLEED				< 250		
					0		011	INJ 1	CP241	15 MCG				
					48		011	BLEED 1				1010		
	F	BLAC		24M	0		001	PREBLEED			< 600	< 250	464	< 100
					0		011	INJ 1	CP241	15 MCG				
					28		011	BLEED 1			491977	705	1883	78540
	M	BLAC		2Y	0		011	INJ 1	CP241	15 MCG				
	F	HISP		2Y	0		001	PREBLEED			< 600	< 250	2900	< 100
					0		011	INJ 1	CP241	15 MCG				
					28		011	BLEED 1			1244	293	9255	666
	F	HISP		14M	0		011	INJ 1	CP241	15 MCG				
	M	BLAC		22M	0		011	INJ 1	CP241	15 MCG				
	F	BLAC		2Y	0		001	PREBLEED			< 600	< 250	132	< 100
					0		011	INJ 1	CP241	15 MCG				
					28		011	BLEED 1			514219	882	1928	27150
	F	BLAC		13M	0		001	PREBLEED			< 600		< 100	< 100
					0		011	INJ 1	CP241	15 MCG				
					44		011	BLEED 1			< 600		< 100	< 100
	M	BLAC		12M	0		001	PREBLEED			< 600		< 100	< 100
					0		011	INJ 1	CP241	15 MCG				
					28		011	BLEED 1			14250		457	7333
	M	CAUC		23M	0		001	PREBLEED			< 600	< 250		

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	IGG1	CODE/	IGG2	CODE/	IGGM	CODE/IGG TOTAL
(b) (6)	M	CAUC	(b) (6)	23M	0	(b) (6)	011	INJ 1	CP241	15 MCG							
					28		011	BLEED 1				3085		< 250			
	M	BLAC		2Y	0		001	PREBLEED				< 600		< 250			
					0		011	INJ 1	CP241	15 MCG							
					28		011	BLEED 1				1656		< 250			
	M	BLAC		3Y	0		011	INJ 1	CP241	15 MCG							
	M	CAUC		2Y	0		011	INJ 1	CP241	15 MCG							
	M	CAUC		18M	0		011	INJ 1	CP241	15 MCG							
	F	CAUC		12M	0		011	INJ 1	CP241	15 MCG							
	M	CAUC		13M	0		011	INJ 1	CP241	15 MCG							
	M	BLAC		2Y	0		001	PREBLEED				< 600		< 250			
					0		011	INJ 1	CP241	15 MCG							
					30		011	BLEED 1				5959		963			
	M	CAUC		12M	0		011	INJ 1	CP241	15 MCG							
	F	HISP		24M	0		011	INJ 1	CP241	15 MCG							
	M	CAUC		20M	0		011	INJ 1	CP241	15 MCG							
	F	CAUC		12M	0		011	INJ 1	CP241	15 MCG							
	M	BLAC		17M	0		011	INJ 1	CP241	15 MCG							
	F	CAUC		16M	0		011	INJ 1	CP241	15 MCG							
	F	CAUC		17M	0		011	INJ 1	CP298	15 MCG							
	M	CAUC		16M	0		001	PREBLEED				< 600		< 250		< 100	< 100
					0		011	INJ 1	CP298	15 MCG							
					30		011	BLEED 1				< 600		< 250		203	176
	M	CAUC		12M	0		001	PREBLEED				< 600		< 250		< 100	< 100

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	IGG1	CODE/	IGG2	CODE/	IGGM	CODE/IGG TOTAL
(b) (6)	M	CAUC	(b) (6)	12M	0	(b) (6)	011	INJ 1	CP298	15 MCG							
					31		011	BLEED 1				6751		< 250		423	562
	M	HISP		22M	0		001	PREBLEED				< 600		< 250		< 100	< 100
					0		011	INJ 1	CP298	15 MCG							
					30		011	BLEED 1				< 600		< 250		894	1316
	F	CAUC		20M	0		001	PREBLEED				< 600		< 250		< 100	< 100
					0		011	INJ 1	CP298	15 MCG							
					29		011	BLEED 1				52730		379		2011	11062
	F	CAUC		18M	0		001	PREBLEED				< 600		< 250		155	< 100
					0		011	INJ 1	CP298	15 MCG							
					29		011	BLEED 1				30990		396		1038	10954
	M	CAUC		13M	0		001	PREBLEED				< 600		< 250		< 100	< 100
					0		011	INJ 1	CP298	15 MCG							
					22		011	BLEED 1				1118		< 250		412	375
	F	BLAC		2Y	0		001	PREBLEED				< 600		< 250		< 100	< 100
					0		011	INJ 1	CP298	15 MCG							
					28		011	BLEED 1				2750		< 250		1146	560
	F	BLAC		3Y	0		011	INJ 1	CP298	15 MCG							
	M	BLAC		3Y	0		001	PREBLEED				< 600		< 250		< 100	< 100
					0		011	INJ 1	CP298	15 MCG							
					66		011	BLEED 1				1986		1470		548	1341
	M	BLAC		2Y	0		001	PREBLEED				< 600		< 250			
					0		011	INJ 1	CP298	15 MCG							
					58		011	BLEED 1				12538		514			
	M	CAUC		16M	0		001	PREBLEED				< 600		< 250		< 100	< 100
					0		011	INJ 1	CP298	15 MCG							
					38		011	BLEED 1				1827		< 250		441	373
	M	BLAC		3Y	0		001	PREBLEED				< 600		< 250		203	< 100
					0		011	INJ 1	CP298	15 MCG							
					28		011	BLEED 1				< 600		< 250		283	< 100

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	IGG1	CODE/	IGG2	CODE/	IGGM	CODE/IGG TOTAL
(b) (6)	F	CAUC	(b) (6)	15M	0	(b) (6)	001	PREBLEED				< 600		< 250		< 100	< 100
					0		011	INJ 1	CP298	15 MCG							
					29		011	BLEED 1				17972		910		371	1812
	F	BLAC		12M	0		001	PREBLEED				< 600		< 250		202	< 100
					0		011	INJ 1	CP298	15 MCG							
					28		011	BLEED 1				1723		354		1647	394
	M	BLAC		12M	0		001	PREBLEED				< 600		< 250		< 100	< 100
					0		011	INJ 1	CP298	15 MCG							
					47		011	BLEED 1				4488		< 250		1199	605
	M	HISP		12M	0		001	PREBLEED				< 600		< 250		937	< 100
					0		011	INJ 1	CP298	15 MCG							
					34		011	BLEED 1				6815		< 250		1795	837
	M	BLAC		24M	0		001	PREBLEED				< 600		< 250		< 100	< 100
					0		011	INJ 1	CP298	15 MCG							
					24		011	BLEED 1				24019		381		2539	9524
	F	BLAC		12M	0		001	PREBLEED						< 250			
					0		011	INJ 1	CP298	15 MCG							
					30		011	BLEED 1						< 250			
	M	BLAC		2Y	0		001	PREBLEED				< 600				< 100	< 100
					0		011	INJ 1	CP298	15 MCG							
					75		011	BLEED 1				34192				303	3296
	M	CAUC		12M	0		001	PREBLEED						< 250			
					0		011	INJ 1	CP298	15 MCG							
					35		011	BLEED 1						< 250			
	M	CAUC		14M	0		001	PREBLEED						< 250			
					0		011	INJ 1	CP298	15 MCG							
					36		011	BLEED 1						< 250			
	M	BLAC		22M	0		011	INJ 1	CR132	15 MCG							
	M	CAUC		12M	0		011	INJ 1	CP298	15 MCG							
	M	CAUC		15M	0		001	PREBLEED				< 600					

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	IGG1	CODE/	IGG2	CODE/	IGGM	CODE/IGG TOTAL
(b) (6)	M	CAUC	(b) (6)	15M	0	(b) (6)	011	INJ 1	CR132	15 MCG							
					32		011	BLEED 1				9060					
	M	HISP		20M	0		001	PREBLEED				< 600				1573	165
					0		011	INJ 1	CP298	15 MCG							
					34		011	BLEED 1				9434				6284	2423
	M	CAUC		2Y	0		011	INJ 1	CP749	15 MCG							
	F	CAUC		2Y	0		011	INJ 1	CP749	15 MCG							
	M	BLAC		22M	0		001	PREBLEED				< 600		< 250			
					0		011	INJ 1	CR132	15 MCG							
					35		011	BLEED 1				3958		< 250			
	M	BLAC		2Y	0		001	PREBLEED				< 600				116	156
					0		011	INJ 1	CP298	15 MCG							
					49		011	BLEED 1				4859				193	1007
	M	HISP		23M	0		011	INJ 1	CP298	15 MCG							
	F	CAUC		12M	0		001	PREBLEED				< 600		< 250		< 100	< 100
					0		011	INJ 1	CP749	15 MCG							
					29		011	BLEED 1				2070		< 250		703	505
	M	BLAC		2Y	0		011	INJ 1	CR132	15 MCG							
	M	CAUC		17M	0		001	PREBLEED				< 600		< 250		399	< 100
					0		011	INJ 1	CP749	15 MCG							
					37		011	BLEED 1				4159		< 250		618	667
	M	CAUC		3Y	0		001	PREBLEED				1379		385		784	559
					0		011	INJ 1	CP749	15 MCG							
					37		011	BLEED 1				14923		1562		1620	10671
	F	CAUC		2Y	0		001	PREBLEED				< 600		< 250		462	< 100
					0		011	INJ 1	CR132	15 MCG							
					28		011	BLEED 1				18943		< 250		983	6473
	M	BLAC		2Y	0		001	PREBLEED				3336				< 100	669

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	IGG1	CODE/	IGG2	CODE/	IGGM	CODE/IGG TOTAL
(b) (6)	M	BLAC	(b) (6)	2Y	0	(b) (6)	011	INJ 1	CP298	15 MCG							
					35		011	BLEED 1				48289				< 100	16237
	M	BLAC		12M	0		011	INJ 1	CP298	15 MCG							
	F	HISP		12M	0		011	INJ 1	CR132	15 MCG							
	M	CAUC		12M	0		001	PREBLEED				233		< 250		105	< 100
					0		011	INJ 1	CR132	15 MCG							
					29		011	BLEED 1				2548		< 250		2035	231
	M	CAUC		12M	0		001	PREBLEED				< 600				< 100	< 100
					0		011	INJ 1	CP298	15 MCG							
					83		011	BLEED 1			05/	1107			05/	< 100	05/ 156
	M	BLAC		16M	0		001	PREBLEED				< 600				< 100	< 100
					0		011	INJ 1	CP298	15 MCG							
					31		011	BLEED 1				< 600				632	524
	F	BLAC		2Y	0		001	PREBLEED				< 600		< 250		< 100	< 100
					0		011	INJ 1	CP749	15 MCG							
					28		011	BLEED 1				< 600		< 250		< 100	< 100
	F	CAUC		24M	0		001	PREBLEED				< 600		< 250		378	134
					0		011	INJ 1	CR132	15 MCG							
					50		011	BLEED 1				4563		612		548	1909
	M	CAUC		14M	0		011	INJ 1	CP749	15 MCG							
	F	CAUC		17M	0		001	PREBLEED				< 600					
					0		011	INJ 1	CP298	15 MCG							
					47		011	BLEED 1				138032					
	M	BLAC		2Y	0		001	PREBLEED				< 600		< 250		< 100	< 100
					0		011	INJ 1	CR132	15 MCG							
					43		011	BLEED 1				7586		< 250		1053	825
	F	BLAC		22M	0		001	PREBLEED				< 600				< 100	< 100
					0		011	INJ 1	CP298	15 MCG							
					49		011	BLEED 1				4652				268	826

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ IGG1	CODE/ IGG2	CODE/ IGGM	CODE/IGG TOTAL
(b) (6)	F	CAUC	(b) (6)	20M	0	(b) (6)	001	PREBLEED			< 600	< 250	304	< 100
					0		011	INJ 1	CR132	15 MCG				
					34		011	BLEED 1			31865	580	1550	1778
	M	BLAC		2Y	0		001	PREBLEED			< 600	< 250	483	< 100
					0		011	INJ 1	CP749	15 MCG				
					28		011	BLEED 1			7783	< 250	2288	6033
	F	CAUC		15M	0		001	PREBLEED			< 600	< 250	146	< 100
					0		011	INJ 1	CP749	15 MCG				
					35		011	BLEED 1			13488	< 250	1182	5988
	M	CAUC		24M	0		001	PREBLEED			< 600	< 250	258	< 100
					0		011	INJ 1	CP749	15 MCG				
					39		011	BLEED 1			2180	< 250	641	438
	F	CAUC		2Y	0		001	PREBLEED			< 600	< 250	< 100	< 100
					0		011	INJ 1	CP749	15 MCG				
					38		011	BLEED 1			6443	299	< 100	1884
	M	CAUC		17M	0		001	PREBLEED					689	< 100
					0		011	INJ 1	CP298	15 MCG				
					33		011	BLEED 1					828	6722
	M	CAUC		19M	0		001	PREBLEED			< 600	< 250	109	< 100
					0		011	INJ 1	CR132	15 MCG				
					35		011	BLEED 1			< 600	< 250	1434	< 100
	M	CAUC		16M	0		001	PREBLEED			< 600	< 250	< 100	< 100
					0		011	INJ 1	CR132	15 MCG				
					39		011	BLEED 1			< 600	< 250	< 100	615
	F	BLAC		2Y	0		011	INJ 1	CP298	15 MCG				
	M	HISP		12M	0		001	PREBLEED			< 600	< 250	< 100	< 100
					0		011	INJ 1	CR132	15 MCG				
					28		011	BLEED 1			4826	< 250	219	< 100
	F	BLAC		23M	0		001	PREBLEED			< 600	< 250	< 100	< 100
					0		011	INJ 1	CP749	15 MCG				

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	IGG1	CODE/	IGG2	CODE/	IGGM	CODE/IGG TOTAL
(b) (6)	F	BLAC	(b) (6)	23M	28	(b) (6)	011	BLEED 1				296476		838		485	11845
	F	BLAC		23M	0		001	PREBLEED				< 600		< 250		< 100	< 100
					0		011	INJ 1	CR132	15 MCG							
					28		011	BLEED 1				1523		< 250		286	139
	F	CAUC		13M	0		011	INJ 1	CP298	15 MCG							
	M	BLAC		13M	0		001	PREBLEED				< 600				< 100	< 100
					0		011	INJ 1	CP298	15 MCG							
					32		011	BLEED 1				4535				621	839
	F	BLAC		12M	0		001	PREBLEED				< 600				< 100	< 100
					0		011	INJ 1	CP749	15 MCG							
					33		011	BLEED 1				< 600				271	< 100
	M	BLAC		20M	0		011	INJ 1	CP298	15 MCG							
	F	BLAC		2Y	0		001	PREBLEED				< 600		< 250		< 100	< 100
					0		011	INJ 1	CP749	15 MCG							
					29		011	BLEED 1				261141		671		1129	109935
	M	BLAC		24M	0		001	PREBLEED								261	< 100
					0		011	INJ 1	CR132	15 MCG							
					69		011	BLEED 1								1264	4239
	F	BLAC		4Y	0		011	INJ 1	CP298	15 MCG							
	M	BLAC		20M	0		001	PREBLEED								425	1859
					0		011	INJ 1	CR132	15 MCG							
					63		011	BLEED 1								1270	1358
	M	BLAC		2Y	0		011	INJ 1	CP749	15 MCG							
	F	BLAC		21M	0		011	INJ 1	CP749	15 MCG							
	F	BLAC		21M	0		011	INJ 1	CP298	15 MCG							
	M	CAUC		15M	0		001	PREBLEED								< 100	< 100
					0		011	INJ 1	CR132	15 MCG							

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	IGG1	CODE/	IGG2	CODE/	IGGM	CODE/IGG TOTAL
(b) (6)	M	CAUC	(b) (6)	15M	42	(b) (6)	011	BLEED	1							416	132
	F	BLAC		16M	0		011	INJ	1 CR132	15 MCG							
	M	BLAC		14M	0		011	INJ	1 CP749	15 MCG							
	M	BLAC		14M	0		011	INJ	1 CP298	15 MCG							
	M	BLAC		24M	0		001	PREBLEED								176	206
					0		011	INJ	1 CR132	15 MCG							
					28		011	BLEED	1							1345	1260
	M	CAUC		23M	0		001	PREBLEED				< 125				6296	< 100
					0		011	INJ	1 CR132	15 MCG							
					28		011	BLEED	1			7892				4670	7063
	F	BLAC		21M	0		011	INJ	1 CP298	15 MCG							
	F	CAUC		24M	0		011	INJ	1 CP749	15 MCG							
	M	BLAC		22M	0		011	INJ	1 CP298	15 MCG							
	M	CAUC		12M	0		011	INJ	1 CP749	15 MCG							
	F	CAUC		16M	0		011	INJ	1 CP298	15 MCG							
	F	CAUC		12M	0		011	INJ	1 CP298	15 MCG							
	M	CAUC		23M	0		001	PREBLEED								< 100	< 100
					0		011	INJ	1 CR132	15 MCG							
					31		011	BLEED	1							3551	56980
	M	CAUC		12M	0		001	PREBLEED								< 100	< 100
					0		011	INJ	1 CR132	15 MCG							
					46		011	BLEED	1							2528	4556
	M	BLAC		12M	0		011	INJ	1 CP749	15 MCG							
	F	BLAC		2Y	0		011	INJ	1 CP749	15 MCG							
	M	BLAC		2Y	0		011	INJ	1 CP749	15 MCG							

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ IGG1	CODE/ IGG2	CODE/ IGGM	CODE/IGG TOTAL
(b) (6)	M	HISP	(b) (6)	2Y	0	(b) (6)		011 INJ	1	CR132 15 MCG				
	F	BLAC		23M	0			011 INJ	1	CP298 15 MCG				
	F	BLAC		12M	0			011 INJ	1	CR132 15 MCG				
	M	BLAC		14M	0			011 INJ	1	CP749 15 MCG				
	M	CAUC		12M	0			011 INJ	1	CP298 15 MCG				
	F	CAUC		12M	0			011 INJ	1	CR132 15 MCG				
	F	HISP		22M	0			011 INJ	1	CR132 15 MCG				
	M	HISP		12M	0			011 INJ	1	CP749 15 MCG				
	M	CAUC		19M	0			011 INJ	1	CP298 15 MCG				
	M	HISP		12M	0			011 INJ	1	CP298 15 MCG				
	F	BLAC		12M	0			011 INJ	1	CP749 15 MCG				
	M	CAUC		12M	0			011 INJ	1	CP749 15 MCG				
	F	CAUC		17M	0			011 INJ	1	CR132 15 MCG				
	F	BLAC		15M	0			011 INJ	1	CR132 15 MCG				

TABLE 3
ANTIBODY RESPONSES

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
ASSAY : RIA
LOT NUMBER : CN084
DOSE : 15 MCG
POPULATION : HEALTHY CHILDREN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
1- 6 MOS.	PRE INJ	0 (0/ 1)	0 (0/ 1)			0.063 (1)
12-71 MOS.	PRE INJ	100 (3/ 3)	0 (0/ 3)			0.244 (3)
	MONTH 1	100 (3/ 3)	100 (3/ 3)	100 (3/ 3)	52.6	12.817 (3)
	MONTH 12-13	100 (3/ 3)	100 (3/ 3)	100 (3/ 3)	8.9	2.175 (3)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 4
ANTIBODY RESPONSES

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
ASSAY : RIA
LOT NUMBER : CP241
DOSE : 15 MCG
POPULATION : HEALTHY CHILDREN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
1- 6 MOS.	PRE INJ	20 (2/ 10)	0 (0/ 10)			0.086 (10)
	MONTH 2	100 (10/ 10)	80 (8/ 10)	90 (9/ 10)	24.0	3.370 (10)
	MONTH 3	100 (10/ 10)	100 (10/ 10)	100 (10/ 10)	42.2	5.914 (10)
	MONTH 7-10	100 (7/ 7)	71 (5/ 7)	86 (6/ 7)	10.5	1.464 (7)
7-11 MOS.	PRE INJ	33 (1/ 3)	0 (0/ 3)			0.099 (3)
	MONTH 2	100 (3/ 3)	100 (3/ 3)	100 (3/ 3)	43.5	6.804 (3)
	MONTH 3	100 (3/ 3)	100 (3/ 3)	100 (3/ 3)	104.4	16.330 (3)
	MONTH 7-10	100 (3/ 3)	67 (2/ 3)	100 (3/ 3)	21.2	3.312 (3)
12-71 MOS.	PRE INJ	35 (8/ 23)	9 (2/ 23)			0.127 (23)
	MONTH 1	100 (22/ 22)	91 (20/ 22)	100 (22/ 22)	84.1	15.727 (22)
	MONTH 6-9	100 (6/ 6)	83 (5/ 6)	100 (6/ 6)	8.4	2.303 (6)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 5

ANTIBODY RESPONSES

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
ASSAY : RIA
LOT NUMBER : CP298
DOSE : 15 MCG
POPULATION : HEALTHY CHILDREN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
1- 6 MOS.	PRE INJ	36 (4/ 11)	0 (0/ 11)			0.110 (11)
	MONTH 2	100 (12/ 12)	83 (10/ 12)	92 (11/ 12)	11.1	1.733 (12)
	MONTH 3	100 (7/ 7)	86 (6/ 7)	100 (7/ 7)	20.8	3.300 (7)
7-11 MOS.	PRE INJ	54 (7/ 13)	0 (0/ 13)			0.167 (13)
	MONTH 2	92 (12/ 13)	46 (6/ 13)	69 (9/ 13)	6.7	1.385 (13)
	MONTH 3	100 (9/ 9)	78 (7/ 9)	100 (9/ 9)	16.9	4.033 (9)
	MONTH 7-10	100 (1/ 1)	0 (0/ 1)	100 (1/ 1)	3.0	0.371 (1)
12-71 MOS.	PRE INJ	40 (14/ 35)	17 (6/ 35)			0.187 (35)
	MONTH 1	97 (33/ 34)	85 (29/ 34)	94 (32/ 34)	22.5	6.163 (34)
	MONTH 6-9	100 (8/ 8)	50 (4/ 8)	88 (7/ 8)	6.1	1.785 (8)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 6

ANTIBODY RESPONSES

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
ASSAY : RIA
LOT NUMBER : CP749
DOSE : 15 MCG
POPULATION : HEALTHY CHILDREN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
1- 6 MOS.	PRE INJ	0 (0/ 5)	0 (0/ 5)			0.062 (5)
	MONTH 2	80 (4/ 5)	60 (3/ 5)	80 (4/ 5)	16.7	1.812 (5)
	MONTH 3	100 (3/ 3)	67 (2/ 3)	100 (3/ 3)	42.3	5.282 (3)
7-11 MOS.	PRE INJ	0 (0/ 2)	0 (0/ 2)			0.089 (2)
	MONTH 2	100 (2/ 2)	50 (1/ 2)	100 (2/ 2)	9.5	1.192 (2)
	MONTH 3	100 (1/ 1)	100 (1/ 1)	100 (1/ 1)	89.9	11.419 (1)
12-71 MOS.	PRE INJ	43 (6/ 14)	7 (1/ 14)			0.144 (14)
	MONTH 1	100 (14/ 14)	71 (10/ 14)	93 (13/ 14)	24.9	5.320 (14)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 7

ANTIBODY RESPONSES

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
ASSAY : RIA
LOT NUMBER : CR132
DOSE : 15 MCG
POPULATION : HEALTHY CHILDREN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
1- 6 MOS.	PRE INJ	40 (2/ 5)	0 (0/ 5)			0.107 (5)
	MONTH 2	100 (5/ 5)	60 (3/ 5)	100 (5/ 5)	5.9	0.965 (5)
	MONTH 3	100 (4/ 4)	75 (3/ 4)	100 (4/ 4)	20.2	3.501 (4)
7-11 MOS.	PRE INJ	17 (1/ 6)	0 (0/ 6)			0.087 (6)
	MONTH 2	100 (6/ 6)	67 (4/ 6)	100 (6/ 6)	24.9	3.425 (6)
	MONTH 3	100 (3/ 3)	100 (3/ 3)	100 (3/ 3)	53.1	6.631 (3)
12-71 MOS.	PRE INJ	47 (7/ 15)	7 (1/ 15)			0.141 (15)
	MONTH 1	100 (15/ 15)	93 (14/ 15)	100 (15/ 15)	23.1	4.699 (15)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 8

ANTIBODY RESPONSES
CHILDREN RANDOMIZED TO CONSISTENCY LOTS - ALL

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
ASSAY : RIA
LOT NUMBER : CP298
DOSE : 15 MCG
POPULATION : HEALTHY CHILDREN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
1- 6 MOS.	PRE INJ	17 (1/ 6)	0 (0/ 6)			0.083 (6)
	MONTH 2	100 (6/ 6)	67 (4/ 6)	83 (5/ 6)	8.9	1.170 (6)
	MONTH 3	100 (4/ 4)	75 (3/ 4)	100 (4/ 4)	24.1	3.096 (4)
7-11 MOS.	PRE INJ	50 (1/ 2)	0 (0/ 2)			0.162 (2)
	MONTH 2	100 (2/ 2)	50 (1/ 2)	50 (1/ 2)	8.5	1.943 (2)
12-71 MOS.	PRE INJ	50 (8/ 16)	25 (4/ 16)			0.292 (16)
	MONTH 1	100 (16/ 16)	88 (14/ 16)	94 (15/ 16)	23.1	9.541 (16)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 9

A N T I B O D Y R E S P O N S E S
CHILDREN RANDOMIZED TO CONSISTENCY LOTS - ALL

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
ASSAY : RIA
LOT NUMBER : CP749
DOSE : 15 MCG
POPULATION : HEALTHY CHILDREN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
1- 6 MOS.	PRE INJ	0 (0/ 5)	0 (0/ 5)			0.062 (5)
	MONTH 2	80 (4/ 5)	60 (3/ 5)	80 (4/ 5)	16.7	1.812 (5)
	MONTH 3	100 (3/ 3)	67 (2/ 3)	100 (3/ 3)	42.3	5.282 (3)
7-11 MOS.	PRE INJ	0 (0/ 2)	0 (0/ 2)			0.089 (2)
	MONTH 2	100 (2/ 2)	50 (1/ 2)	100 (2/ 2)	9.5	1.192 (2)
	MONTH 3	100 (1/ 1)	100 (1/ 1)	100 (1/ 1)	89.9	11.419 (1)
12-71 MOS.	PRE INJ	43 (6/ 14)	7 (1/ 14)			0.144 (14)
	MONTH 1	100 (14/ 14)	71 (10/ 14)	93 (13/ 14)	24.9	5.320 (14)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 10

ANTIBODY RESPONSES
CHILDREN RANDOMIZED TO CONSISTENCY LOTS - ALL

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
ASSAY : RIA
LOT NUMBER : CR132
DOSE : 15 MCG
POPULATION : HEALTHY CHILDREN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
1- 6 MOS.	PRE INJ	40 (2/ 5)	0 (0/ 5)			0.107 (5)
	MONTH 2	100 (5/ 5)	60 (3/ 5)	100 (5/ 5)	5.9	0.965 (5)
	MONTH 3	100 (4/ 4)	75 (3/ 4)	100 (4/ 4)	20.2	3.501 (4)
7-11 MOS.	PRE INJ	17 (1/ 6)	0 (0/ 6)			0.087 (6)
	MONTH 2	100 (6/ 6)	67 (4/ 6)	100 (6/ 6)	24.9	3.425 (6)
	MONTH 3	100 (3/ 3)	100 (3/ 3)	100 (3/ 3)	53.1	6.631 (3)
12-71 MOS.	PRE INJ	47 (7/ 15)	7 (1/ 15)			0.141 (15)
	MONTH 1	100 (15/ 15)	93 (14/ 15)	100 (15/ 15)	23.1	4.699 (15)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 11

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
LOT NUMBER : CN084
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	10	
VACCINEES WITH NO COMPLAINTS :	7	(70.0 %)
VACCINEES WITH COMPLAINTS :	3	(30.0 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 10 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	0	0.0
SYSTEMIC REACTIONS	3	30.0
IRRITABILITY	3	30.0
FATIGUE	2	20.0
NASAL DISCHARGE	1	10.0
WARM TO TOUCH	1	10.0

TABLE 11 (cont.)

C L I N I C A L C O M P L A I N T S B Y F R E Q U E N C Y

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
LOT NUMBER : CN084
POPULATION : HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	3	
VACCINEES WITH NO COMPLAINTS :	1	(33.3 %)
VACCINEES WITH COMPLAINTS :	2	(66.7 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 3 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	2	66.7
PAIN/SORENESS, INJ. SITE	2	66.7
SYSTEMIC REACTIONS	1	33.3
VOMITING	1	33.3

TABLE 11 (cont.)
CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	15	
VACCINEES WITH NO COMPLAINTS :	13	(86.7 %)
VACCINEES WITH COMPLAINTS :	2	(13.3 %)
VACCINEES WITH NO DATA :	0	

CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 15 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	1	6.7
ERYTHEMA, INJ. SITE (<=1 IN.)	1	6.7
SYSTEMIC REACTIONS	1	6.7
IRRITABILITY	1	6.7

TABLE 11 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 2	
TOTAL VACCINEES :	15	
VACCINEES WITH NO COMPLAINTS :	11	(73.3 %)
VACCINEES WITH COMPLAINTS :	4	(26.7 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 15 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	2	13.3
ERYTHEMA, INJ. SITE (<=1 IN.)	1	6.7
SWELLING, INJ. SITE (<=1 IN.)	1	6.7
SYSTEMIC REACTIONS	4	26.7
IRRITABILITY	4	26.7
FATIGUE	1	6.7
PROLONGED CRYING, >1/2 HR	1	6.7
WARM TO TOUCH	1	6.7

TABLE 11 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
POPULATION : HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	24	
VACCINEES WITH NO COMPLAINTS :	22	(91.7 %)
VACCINEES WITH COMPLAINTS :	2	(8.3 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 24 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	1	4.2
SWELLING, INJ. SITE (<=1 IN.)	1	4.2
SYSTEMIC REACTIONS	1	4.2
FATIGUE	1	4.2
IRRITABILITY	1	4.2

00300

TABLE 11 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	41	
VACCINEES WITH NO COMPLAINTS :	27	(67.5 %)
VACCINEES WITH COMPLAINTS :	13	(32.5 %)
VACCINEES WITH NO DATA :	1	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 40 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	9	22.5
ERYTHEMA, INJ. SITE (<=1 IN.)	7	17.5
SWELLING, INJ. SITE (<=1 IN.)	5	12.5
SYSTEMIC REACTIONS	6	15.0
IRRITABILITY	5	12.5
INSOMNIA	2	5.0
CRYING	1	2.5
FATIGUE	1	2.5

TABLE 11 (cont.)

C L I N I C A L C O M P L A I N T S B Y F R E Q U E N C Y

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 2	
TOTAL VACCINEES :	32	
VACCINEES WITH NO COMPLAINTS :	25	(86.2 %)
VACCINEES WITH COMPLAINTS :	4	(13.8 %)
VACCINEES WITH NO DATA :	3	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 29 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	2	6.9
SWELLING, INJ. SITE (>1 INCH)	2	6.9
ERYTHEMA, INJ. SITE (>1 INCH)	1	3.4
SYSTEMIC REACTIONS	3	10.3
IRRITABILITY	3	10.3

TABLE 11 (cont.)
CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
POPULATION : HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	48	
VACCINEES WITH NO COMPLAINTS :	36	(76.6 %)
VACCINEES WITH COMPLAINTS :	11	(23.4 %)
VACCINEES WITH NO DATA :	1	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 47 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	7	14.9
SWELLING, INJ. SITE (<=1 IN.)	5	10.6
ERYTHEMA, INJ. SITE (<=1 IN.)	4	8.5
ERYTHEMA, INJ. SITE (>1 INCH)	1	2.1
SWELLING, INJ. SITE (>1 INCH)	1	2.1
SYSTEMIC REACTIONS	7	14.9
IRRITABILITY	6	12.8
CRYING	1	2.1
HYPERKINESIA	1	2.1
VOMITING	1	2.1

TABLE 11 (cont.)
CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	22	
VACCINEES WITH NO COMPLAINTS :	14	(70.0 %)
VACCINEES WITH COMPLAINTS :	6	(30.0 %)
VACCINEES WITH NO DATA :	2	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 20 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	4	20.0
ERYTHEMA, INJ. SITE (<=1 IN.)	2	10.0
SWELLING, INJ. SITE (<=1 IN.)	2	10.0
SYSTEMIC REACTIONS	3	15.0
IRRITABILITY	2	10.0
CRYING	1	5.0
FATIGUE	1	5.0

TABLE 11 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 2		
TOTAL VACCINEES :	13		
VACCINEES WITH NO COMPLAINTS :	12	(100.0 %)	
VACCINEES WITH COMPLAINTS :	0	(0.0 %)	
VACCINEES WITH NO DATA :	1		
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 12 VACCINEES	
LOCAL REACTIONS (INJECTION SITE)	0	0.0	

TABLE 11 (cont.)
CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
POPULATION : HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1
TOTAL VACCINEES :	26
VACCINEES WITH NO COMPLAINTS :	20 (76.9 %)
VACCINEES WITH COMPLAINTS :	6 (23.1 %)
VACCINEES WITH NO DATA :	0

CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 26 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	5	19.2
PAIN/SORENESS, INJ. SITE	4	15.4
SWELLING, INJ. SITE (<=1 IN.)	2	7.7
ERYTHEMA, INJ. SITE (<=1 IN.)	1	3.8
SYSTEMIC REACTIONS	2	7.7
CRYING	1	3.8
IRRITABILITY	1	3.8
NERVOUSNESS	1	3.8

TABLE 11 (cont.)

C L I N I C A L C O M P L A I N T S B Y F R E Q U E N C Y

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
LOT NUMBER : CR132
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	20	
VACCINEES WITH NO COMPLAINTS :	14	(70.0 %)
VACCINEES WITH COMPLAINTS :	6	(30.0 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 20 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	3	15.0
ERYTHEMA, INJ. SITE (<=1 IN.)	2	10.0
SWELLING, INJ. SITE (<=1 IN.)	1	5.0
SYSTEMIC REACTIONS	6	30.0
IRRITABILITY	5	25.0
WARM TO TOUCH	3	15.0
DIARRHEA	1	5.0
INSOMNIA	1	5.0
RASH	1	5.0

TABLE 11 (cont.)
C L I N I C A L C O M P L A I N T S B Y F R E Q U E N C Y

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
LOT NUMBER : CR132
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 2	
TOTAL VACCINEES :	16	
VACCINEES WITH NO COMPLAINTS :	10	(71.4 %)
VACCINEES WITH COMPLAINTS :	4	(28.6 %)
VACCINEES WITH NO DATA :	2	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 14 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	3	21.4
ERYTHEMA, INJ. SITE (<=1 IN.)	3	21.4
SWELLING, INJ. SITE (<=1 IN.)	3	21.4
PAIN/SORENESS, INJ. SITE	1	7.1
SYSTEMIC REACTIONS	2	14.3
FATIGUE	2	14.3

TABLE 11 (cont.)
C L I N I C A L C O M P L A I N T S B Y F R E Q U E N C Y

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
LOT NUMBER : CR132
POPULATION : HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	28	
VACCINEES WITH NO COMPLAINTS :	23	(85.2 %)
VACCINEES WITH COMPLAINTS :	4	(14.8 %)
VACCINEES WITH NO DATA :	1	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 27 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	3	11.1
ERYTHEMA, INJ. SITE (<=1 IN.)	2	7.4
PAIN/SORENESS, INJ. SITE	2	7.4
SWELLING, INJ. SITE (<=1 IN.)	1	3.7
SYSTEMIC REACTIONS	2	7.4
IRRITABILITY	2	7.4

TABLE 12

CLINICAL COMPLAINTS

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (15 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
LOCAL REACTIONS	1 (6.7%)	1 (6.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (6.7%)
ERYTHEMA, INJ. SITE (<=1 IN.)	1 (6.7%)	1 (6.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (6.7%)
SYSTEMIC	1 (6.7%)	1 (6.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (6.7%)
NERVOUS SYSTEM & PSYCHIATRIC	1 (6.7%)	1 (6.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (6.7%)
IRRITABILITY	1 (6.7%)	1 (6.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (6.7%)
VACCINEES WITH COMPLAINTS	2 (13.3%)	2 (13.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (13.3%)
VACCINEES WITH NO COMPLAINTS	13 (86.7%)	13 (86.7%)	15 (100.0%)	15 (100.0%)	15 (100.0%)	15 (100.0%)		13 (86.7%)
TOTAL VACCINEES REPORTING	15	15	15	15	15	15		15
VACCINEES WITH NO DATA	0	0	0	0	0	0		0

TABLE 12 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (15 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
LOCAL REACTIONS	2 (13.3%)	1 (6.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (13.3%)
ERYTHEMA, INJ. SITE (<=1 IN.)	1 (6.7%)	1 (6.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (6.7%)
SWELLING, INJ. SITE (<=1 IN.)	1 (6.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (6.7%)
SYSTEMIC	3 (20.0%)	2 (13.3%)	1 (6.7%)	1 (6.7%)	0 (0.0%)	0 (0.0%)		4 (26.7%)
BODY AS A WHOLE/SITE UNSPEC.	1 (6.7%)	2 (13.3%)	1 (6.7%)	1 (6.7%)	0 (0.0%)	0 (0.0%)		2 (13.3%)
FATIGUE	0 (0.0%)	1 (6.7%)	1 (6.7%)	1 (6.7%)	0 (0.0%)	0 (0.0%)		1 (6.7%)
WARM TO TOUCH	1 (6.7%)	1 (6.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (6.7%)
NERVOUS SYSTEM & PSYCHIATRIC	3 (20.0%)	2 (13.3%)	1 (6.7%)	1 (6.7%)	0 (0.0%)	0 (0.0%)		4 (26.7%)
IRRITABILITY	3 (20.0%)	2 (13.3%)	1 (6.7%)	1 (6.7%)	0 (0.0%)	0 (0.0%)		4 (26.7%)
PROLONGED CRYING, >1/2 HR	0 (0.0%)	1 (6.7%)	1 (6.7%)	1 (6.7%)	0 (0.0%)	0 (0.0%)		1 (6.7%)
VACCINEES WITH COMPLAINTS	3 (20.0%)	2 (13.3%)	1 (6.7%)	1 (6.7%)	0 (0.0%)	0 (0.0%)		4 (26.7%)

TABLE 12 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (15 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS **********
VACCINEES WITH NO COMPLAINTS	12 (80.0%)	13 (86.7%)	14 (93.3%)	14 (93.3%)	15 (100.0%)	15 (100.0%)		11 (73.3%)
TOTAL VACCINEES REPORTING	15	15	15	15	15	15		15
VACCINEES WITH NO DATA	0	0	0	0	0	0		0

TABLE 12 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (24 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		
LOCAL REACTIONS	0 (0.0%)	0 (0.0%)	1 (4.2%)	1 (4.2%)	1 (4.2%)	1 (4.2%)		1 (4.2%)
SWELLING, INJ. SITE (<=1 IN.)	0 (0.0%)	0 (0.0%)	1 (4.2%)	1 (4.2%)	1 (4.2%)	1 (4.2%)		1 (4.2%)
SYSTEMIC	1 (4.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (4.2%)
BODY AS A WHOLE/SITE UNSPEC.	1 (4.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (4.2%)
FATIGUE	1 (4.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (4.2%)
NERVOUS SYSTEM & PSYCHIATRIC	1 (4.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (4.2%)
IRRITABILITY	1 (4.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (4.2%)
VACCINEES WITH COMPLAINTS	1 (4.2%)	0 (0.0%)	1 (4.2%)	1 (4.2%)	1 (4.2%)	1 (4.2%)		2 (8.3%)
VACCINEES WITH NO COMPLAINTS	23 (95.8%)	24 (100.0%)	23 (95.8%)	23 (95.8%)	23 (95.8%)	23 (95.8%)		22 (91.7%)
TOTAL VACCINEES REPORTING	24	24	24	24	24	24		24

TABLE 12 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (24 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
VACCINEES WITH NO DATA	0	0	0	0	0	0		0

TABLE 12 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (41 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5	COMPLAINTS
LOCAL REACTIONS	6 (15.0%)	4 (10.0%)	3 (7.5%)	3 (7.5%)	3 (7.5%)	3 (7.5%)	9 (22.5%)
ERYTHEMA, INJ. SITE (<=1 IN.)	4 (10.0%)	3 (7.5%)	2 (5.0%)	2 (5.0%)	2 (5.0%)	2 (5.0%)	7 (17.5%)
SWELLING, INJ. SITE (<=1 IN.)	3 (7.5%)	3 (7.5%)	2 (5.0%)	2 (5.0%)	2 (5.0%)	2 (5.0%)	5 (12.5%)
SYSTEMIC	6 (15.0%)	1 (2.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	6 (15.0%)
BODY AS A WHOLE/SITE UNSPEC.	1 (2.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.5%)
FATIGUE	1 (2.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.5%)
NERVOUS SYSTEM & PSYCHIATRIC	5 (12.5%)	1 (2.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	5 (12.5%)
CRYING	1 (2.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.5%)
INSOMNIA	2 (5.0%)	1 (2.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (5.0%)
IRRITABILITY	5 (12.5%)	1 (2.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	5 (12.5%)
VACCINEES WITH COMPLAINTS	11 (27.5%)	5 (12.5%)	3 (7.5%)	3 (7.5%)	3 (7.5%)	3 (7.5%)	13 (32.5%)

TABLE 12 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (41 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		**********
VACCINEES WITH NO COMPLAINTS	29 (72.5%)	35 (87.5%)	37 (92.5%)	37 (92.5%)	37 (92.5%)	37 (92.5%)		27 (67.5%)
TOTAL VACCINEES REPORTING	40	40	40	40	40	40		40
VACCINEES WITH NO DATA	1	1	1	1	1	1		1

TABLE 12 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (31 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
LOCAL REACTIONS	1 (3.6%)	1 (3.6%)	1 (3.6%)	2 (7.1%)	2 (7.1%)	2 (7.1%)		2 (7.1%)
ERYTHEMA, INJ. SITE (>1 INCH)	1 (3.6%)	1 (3.6%)	1 (3.6%)	1 (3.6%)	0 (0.0%)	0 (0.0%)		1 (3.6%)
SWELLING, INJ. SITE (>1 INCH)	1 (3.6%)	1 (3.6%)	1 (3.6%)	2 (7.1%)	2 (7.1%)	2 (7.1%)		2 (7.1%)
SYSTEMIC	3 (10.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		3 (10.7%)
NERVOUS SYSTEM & PSYCHIATRIC	3 (10.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		3 (10.7%)
IRRITABILITY	3 (10.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		3 (10.7%)
VACCINEES WITH COMPLAINTS	4 (14.3%)	1 (3.6%)	1 (3.6%)	2 (7.1%)	2 (7.1%)	2 (7.1%)		4 (14.3%)
VACCINEES WITH NO COMPLAINTS	24 (85.7%)	27 (96.4%)	27 (96.4%)	26 (92.9%)	26 (92.9%)	26 (92.9%)		24 (85.7%)
TOTAL VACCINEES REPORTING	28	28	28	28	28	28		28
VACCINEES WITH NO DATA	3	3	3	3	3	3		3

TABLE 12 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (48 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5	
LOCAL REACTIONS	7 (14.9%)	5 (10.6%)	5 (10.6%)	3 (6.4%)	3 (6.4%)	3 (6.4%)	7 (14.9%)
ERYTHEMA, INJ. SITE (>1 INCH)	1 (2.1%)	1 (2.1%)	1 (2.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.1%)
ERYTHEMA, INJ. SITE (<=1 IN.)	4 (8.5%)	3 (6.4%)	3 (6.4%)	2 (4.3%)	2 (4.3%)	2 (4.3%)	4 (8.5%)
SWELLING, INJ. SITE (>1 INCH)	1 (2.1%)	1 (2.1%)	1 (2.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.1%)
SWELLING, INJ. SITE (<=1 IN.)	5 (10.6%)	4 (8.5%)	4 (8.5%)	3 (6.4%)	3 (6.4%)	3 (6.4%)	5 (10.6%)
SYSTEMIC	7 (14.9%)	1 (2.1%)	1 (2.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	7 (14.9%)
OIGESTIVE SYSTEM	0 (0.0%)	1 (2.1%)	1 (2.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.1%)
VOMITING	0 (0.0%)	1 (2.1%)	1 (2.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.1%)
NERVOUS SYSTEM & PSYCHIATRIC	7 (14.9%)	0 (0.0%)	1 (2.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	7 (14.9%)
CRYING	1 (2.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.1%)
HYPERKINESIA	1 (2.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.1%)

TABLE 12 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (48 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
IRRITABILITY	6 (12.8%)	0 (0.0%)	1 (2.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		6 (12.8%)
VACCINEES WITH COMPLAINTS	11 (23.4%)	6 (12.8%)	6 (12.8%)	3 (6.4%)	3 (6.4%)	3 (6.4%)		11 (23.4%)
VACCINEES WITH NO COMPLAINTS	36 (76.6%)	41 (87.2%)	41 (87.2%)	44 (93.6%)	44 (93.6%)	44 (93.6%)		36 (76.6%)
TOTAL VACCINEES REPORTING	47	47	47	47	47	47		47
VACCINEES WITH NO DATA	1	1	1	1	1	1		1

TABLE 12 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (22 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
LOCAL REACTIONS	4 (20.0%)	4 (20.0%)	2 (10.0%)	2 (10.0%)	2 (10.0%)	2 (10.0%)		4 (20.0%)
ERYTHEMA, INJ. SITE (<=1 IN.)	2 (10.0%)	2 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (10.0%)
SWELLING, INJ. SITE (<=1 IN.)	2 (10.0%)	2 (10.0%)	2 (10.0%)	2 (10.0%)	2 (10.0%)	2 (10.0%)		2 (10.0%)
SYSTEMIC	3 (15.0%)	1 (5.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		3 (15.0%)
BODY AS A WHOLE/SITE UNSPEC.	1 (5.0%)	1 (5.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (5.0%)
FATIGUE	1 (5.0%)	1 (5.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (5.0%)
NERVOUS SYSTEM & PSYCHIATRIC	3 (15.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		3 (15.0%)
CRYING	1 (5.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (5.0%)
IRRITABILITY	2 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (10.0%)
VACCINEES WITH COMPLAINTS	6 (30.0%)	4 (20.0%)	2 (10.0%)	2 (10.0%)	2 (10.0%)	2 (10.0%)		6 (30.0%)
VACCINEES WITH NO COMPLAINTS	14 (70.0%)	16 (80.0%)	18 (90.0%)	18 (90.0%)	18 (90.0%)	18 (90.0%)		14 (70.0%)

TABLE 12 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (22 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		**********
TOTAL VACCINEES REPORTING	20	20	20	20	20	20		20
VACCINEES WITH NO DATA	2	2	2	2	2	2		2

TABLE 12 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (13 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		**********
VACCINEES WITH COMPLAINTS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)
VACCINEES WITH NO COMPLAINTS	12 (100.0%)	12 (100.0%)	12 (100.0%)	12 (100.0%)	12 (100.0%)	12 (100.0%)		12 (100.0%)
TOTAL VACCINEES REPORTING	12	12	12	12	12	12		12
VACCINEES WITH NO DATA	1	1	1	1	1	1		1

TABLE 12 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (26 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
LOCAL REACTIONS	5 (19.2%)	3 (11.5%)	1 (3.8%)	1 (3.8%)	1 (3.8%)	1 (3.8%)		5 (19.2%)
ERYTHEMA, INJ. SITE (<=1 IN.)	1 (3.8%)	1 (3.8%)	1 (3.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (3.8%)
PAIN/SORENESS, INJ. SITE	4 (15.4%)	2 (7.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		4 (15.4%)
SWELLING, INJ. SITE (<=1 IN.)	2 (7.7%)	2 (7.7%)	1 (3.8%)	1 (3.8%)	1 (3.8%)	1 (3.8%)		2 (7.7%)
SYSTEMIC	1 (3.8%)	1 (3.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (7.7%)
NERVOUS SYSTEM & PSYCHIATRIC	1 (3.8%)	1 (3.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (7.7%)
CRYING	1 (3.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (3.8%)
IRRITABILITY	1 (3.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (3.8%)
NERVOUSNESS	0 (0.0%)	1 (3.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (3.8%)
VACCINEES WITH COMPLAINTS	6 (23.1%)	3 (11.5%)	1 (3.8%)	1 (3.8%)	1 (3.8%)	1 (3.8%)		6 (23.1%)
VACCINEES WITH NO COMPLAINTS	20 (76.9%)	23 (88.5%)	25 (96.2%)	25 (96.2%)	25 (96.2%)	25 (96.2%)		20 (76.9%)

TABLE 12 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (26 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
TOTAL VACCINEES REPORTING	26	26	26	26	26	26		26
VACCINEES WITH NO DATA	0	0	0	0	0	0		0

TABLE 12 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
LOT NUMBER : CR132
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (20 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5	COMPLAINTS
LOCAL REACTIONS	2 (10.0%)	2 (10.0%)	2 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (15.0%)
ERYTHEMA, INJ. SITE (<=1 IN.)	2 (10.0%)	2 (10.0%)	1 (5.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (10.0%)
SWELLING, INJ. SITE (<=1 IN.)	0 (0.0%)	0 (0.0%)	1 (5.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (5.0%)
SYSTEMIC	6 (30.0%)	4 (20.0%)	2 (10.0%)	1 (5.0%)	0 (0.0%)	0 (0.0%)	6 (30.0%)
BODY AS A WHOLE/SITE UNSPEC.	3 (15.0%)	1 (5.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (15.0%)
WARM TO TOUCH	3 (15.0%)	1 (5.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (15.0%)
OIGESTIVE SYSTEM	1 (5.0%)	1 (5.0%)	1 (5.0%)	1 (5.0%)	0 (0.0%)	0 (0.0%)	1 (5.0%)
DIARRHEA	1 (5.0%)	1 (5.0%)	1 (5.0%)	1 (5.0%)	0 (0.0%)	0 (0.0%)	1 (5.0%)
NERVOUS SYSTEM & PSYCHIATRIC	3 (15.0%)	3 (15.0%)	1 (5.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	5 (25.0%)
INSOMNIA	0 (0.0%)	1 (5.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (5.0%)
IRRITABILITY	3 (15.0%)	3 (15.0%)	1 (5.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	5 (25.0%)

TABLE 12 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
LOT NUMBER : CR132
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (20 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		
SKIN & SKIN APPENDAGE	1 (5.0%)	1 (5.0%)	1 (5.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (5.0%)
RASH	1 (5.0%)	1 (5.0%)	1 (5.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (5.0%)
VACCINEES WITH COMPLAINTS	6 (30.0%)	4 (20.0%)	3 (15.0%)	1 (5.0%)	0 (0.0%)	0 (0.0%)		6 (30.0%)
VACCINEES WITH NO COMPLAINTS	14 (70.0%)	16 (80.0%)	17 (85.0%)	19 (95.0%)	20 (100.0%)	20 (100.0%)		14 (70.0%)
TOTAL VACCINEES REPORTING	20	20	20	20	20	20		20
VACCINEES WITH NO DATA	0	0	0	0	0	0		0

TABLE 12 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
LOT NUMBER : CR132
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (16 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
LOCAL REACTIONS	3 (21.4%)	3 (21.4%)	2 (14.3%)	2 (14.3%)	2 (14.3%)	2 (14.3%)		3 (21.4%)
ERYTHEMA, INJ. SITE (<=1 IN.)	3 (21.4%)	3 (21.4%)	2 (14.3%)	2 (14.3%)	2 (14.3%)	2 (14.3%)		3 (21.4%)
PAIN/SORENESS, INJ. SITE	1 (7.1%)	1 (7.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (7.1%)
SWELLING, INJ. SITE (<=1 IN.)	3 (21.4%)	3 (21.4%)	2 (14.3%)	2 (14.3%)	2 (14.3%)	2 (14.3%)		3 (21.4%)
SYSTEMIC	1 (7.1%)	2 (14.3%)	1 (7.1%)	1 (7.1%)	0 (0.0%)	0 (0.0%)		2 (14.3%)
BODY AS A WHOLE/SITE UNSPEC.	1 (7.1%)	2 (14.3%)	1 (7.1%)	1 (7.1%)	0 (0.0%)	0 (0.0%)		2 (14.3%)
FATIGUE	1 (7.1%)	2 (14.3%)	1 (7.1%)	1 (7.1%)	0 (0.0%)	0 (0.0%)		2 (14.3%)
VACCINEES WITH COMPLAINTS	3 (21.4%)	4 (28.6%)	3 (21.4%)	3 (21.4%)	2 (14.3%)	2 (14.3%)		4 (28.6%)
VACCINEES WITH NO COMPLAINTS	11 (78.6%)	10 (71.4%)	11 (78.6%)	11 (78.6%)	12 (85.7%)	12 (85.7%)		10 (71.4%)
TOTAL VACCINEES REPORTING	14	14	14	14	14	14		14

TABLE 12 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
LOT NUMBER : CR132
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (16 VACCINEES) - INJECTION: 2						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5	COMPLAINTS
VACCINEES WITH NO DATA	2	2	2	2	2	2	2

TABLE 12 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
LOT NUMBER : CR132
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (28 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
LOCAL REACTIONS	3 (11.1%)	1 (3.7%)	1 (3.8%)	1 (3.8%)	1 (3.8%)	1 (3.8%)		3 (11.1%)
ERYTHEMA, INJ. SITE (<=1 IN.)	2 (7.4%)	1 (3.7%)	1 (3.8%)	1 (3.8%)	1 (3.8%)	1 (3.8%)		2 (7.4%)
PAIN/SORENESS, INJ. SITE	2 (7.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (7.4%)
SWELLING, INJ. SITE (<=1 IN.)	1 (3.7%)	1 (3.7%)	1 (3.8%)	1 (3.8%)	1 (3.8%)	1 (3.8%)		1 (3.7%)
SYSTEMIC	2 (7.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (7.4%)
NERVOUS SYSTEM & PSYCHIATRIC	2 (7.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (7.4%)
IRRITABILITY	2 (7.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (7.4%)
VACCINEES WITH COMPLAINTS	4 (14.8%)	1 (3.7%)	1 (3.8%)	1 (3.8%)	1 (3.8%)	1 (3.8%)		4 (14.8%)
VACCINEES WITH NO COMPLAINTS	23 (85.2%)	26 (96.3%)	25 (96.2%)	25 (96.2%)	25 (96.2%)	25 (96.2%)		23 (85.2%)
TOTAL VACCINEES REPORTING	27	27	26	26	26	26		27

TABLE 12 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
LOT NUMBER : CR132
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (28 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5	COMPLAINTS
VACCINEES WITH NO DATA	1	1	2	2	2	2	1

TABLE 13

MAXIMUM TEMPERATURES

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (15 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
NORMAL	15 (100.0%)	14 (93.3%)	15 (100.0%)	15 (100.0%)	15 (100.0%)	15 (100.0%)		14 (93.3%)
99 - 99.9	0 (0.0%)	1 (6.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (6.7%)
TEMPERATURE TAKEN	15 (100.0%)	15 (100.0%)	15 (100.0%)	15 (100.0%)	15 (100.0%)	15 (100.0%)		15 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)

TABLE 13 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (15 VACCINEES) - INJECTION 2							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
NORMAL	15 (100.0%)	15 (100.0%)	15 (100.0%)	15 (100.0%)	15 (100.0%)	15 (100.0%)		15 (100.0%)
TEMPERATURE TAKEN	15 (100.0%)	15 (100.0%)	15 (100.0%)	15 (100.0%)	15 (100.0%)	15 (100.0%)		15 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)

TABLE 13 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (24 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
NORMAL	24 (100.0%)	23 (95.8%)	24 (100.0%)	24 (100.0%)	24 (100.0%)	24 (100.0%)		23 (95.8%)
100 - 100.9	0 (0.0%)	1 (4.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (4.2%)
TEMPERATURE TAKEN	24 (100.0%)	24 (100.0%)	24 (100.0%)	24 (100.0%)	24 (100.0%)	24 (100.0%)		24 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)

TABLE 13 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (41 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
NORMAL	40 (100.0%)	40 (100.0%)	40 (100.0%)	40 (100.0%)	40 (100.0%)	40 (100.0%)		40 (100.0%)
TEMPERATURE TAKEN	40 (97.6%)	40 (97.6%)	40 (97.6%)	40 (97.6%)	40 (97.6%)	40 (97.6%)		40 (97.6%)
TEMPERATURE NOT TAKEN	1 (2.4%)	1 (2.4%)	1 (2.4%)	1 (2.4%)	1 (2.4%)	1 (2.4%)		1 (2.4%)

TABLE 13 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (31 VACCINEES) - INJECTION 2							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
NORMAL	27 (96.4%)	27 (96.4%)	27 (96.4%)	27 (96.4%)	27 (96.4%)	27 (96.4%)		27 (96.4%)
99 - 99.9	1 (3.6%)	0 (0.0%)	1 (3.6%)	1 (3.6%)	1 (3.6%)	1 (3.6%)		0 (0.0%)
100 - 100.9	0 (0.0%)	1 (3.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (3.6%)
TEMPERATURE TAKEN	28 (90.3%)	28 (90.3%)	28 (90.3%)	28 (90.3%)	28 (90.3%)	28 (90.3%)		28 (90.3%)
TEMPERATURE NOT TAKEN	3 (9.7%)	3 (9.7%)	3 (9.7%)	3 (9.7%)	3 (9.7%)	3 (9.7%)		3 (9.7%)

TABLE 13 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (48 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
NORMAL	47 (97.9%)	48 (100.0%)	48 (100.0%)	48 (100.0%)	48 (100.0%)	48 (100.0%)		47 (97.9%)
100 - 100.9	1 (2.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (2.1%)
TEMPERATURE TAKEN	48 (100.0%)	48 (100.0%)	48 (100.0%)	48 (100.0%)	48 (100.0%)	48 (100.0%)		48 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)

TABLE 13 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (22 VACCINEES) - INJECTION 1						
	DAYS POST VACCINATION						NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5	
NORMAL	19 (90.5%)	20 (95.2%)	20 (95.2%)	21 (100.0%)	21 (100.0%)	21 (100.0%)	19 (90.5%)
< 99	1 (4.8%)	1 (4.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
99 - 99.9	1 (4.8%)	0 (0.0%)	1 (4.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (9.5%)
TEMPERATURE TAKEN	21 (95.5%)	21 (95.5%)	21 (95.5%)	21 (95.5%)	21 (95.5%)	21 (95.5%)	21 (95.5%)
TEMPERATURE NOT TAKEN	1 (4.5%)	1 (4.5%)	1 (4.5%)	1 (4.5%)	1 (4.5%)	1 (4.5%)	1 (4.5%)

TABLE 13 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (13 VACCINEES) - INJECTION 2							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
NORMAL	12 (100.0%)	12 (100.0%)	12 (100.0%)	12 (100.0%)	12 (100.0%)	12 (100.0%)		12 (100.0%)
TEMPERATURE TAKEN	12 (92.3%)	12 (92.3%)	12 (92.3%)	12 (92.3%)	12 (92.3%)	12 (92.3%)		12 (92.3%)
TEMPERATURE NOT TAKEN	1 (7.7%)	1 (7.7%)	1 (7.7%)	1 (7.7%)	1 (7.7%)	1 (7.7%)		1 (7.7%)

TABLE 13 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (26 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
NORMAL	26 (100.0%)	26 (100.0%)	26 (100.0%)	26 (100.0%)	26 (100.0%)	26 (100.0%)		26 (100.0%)
TEMPERATURE TAKEN	26 (100.0%)	26 (100.0%)	26 (100.0%)	26 (100.0%)	26 (100.0%)	26 (100.0%)		26 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)

TABLE 13 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
LOT NUMBER : CR132
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (20 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
NORMAL	18 (94.7%)	17 (85.0%)	19 (95.0%)	19 (95.0%)	20 (100.0%)	20 (100.0%)		17 (85.0%)
100 - 100.9	1 (5.3%)	2 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (5.0%)
103 - 103.9	0 (0.0%)	1 (5.0%)	1 (5.0%)	1 (5.0%)	0 (0.0%)	0 (0.0%)		2 (10.0%)
TEMPERATURE TAKEN	19 (95.0%)	20 (100.0%)	20 (100.0%)	20 (100.0%)	20 (100.0%)	20 (100.0%)		20 (100.0%)
TEMPERATURE NOT TAKEN	1 (5.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)

TABLE 13 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
LOT NUMBER : CR132
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (16 VACCINEES) - INJECTION 2							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
NORMAL	13 (92.9%)	13 (92.9%)	14 (100.0%)	14 (100.0%)	14 (100.0%)	14 (100.0%)		12 (85.7%)
99 - 99.9	1 (7.1%)	1 (7.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (14.3%)
TEMPERATURE TAKEN	14 (87.5%)	14 (87.5%)	14 (87.5%)	14 (87.5%)	14 (87.5%)	14 (87.5%)		14 (87.5%)
TEMPERATURE NOT TAKEN	2 (12.5%)	2 (12.5%)	2 (12.5%)	2 (12.5%)	2 (12.5%)	2 (12.5%)		2 (12.5%)

TABLE 13 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : SHAPIRO, EUGENE D.
STUDY : 000405
VACCINE : HIB CONJUGATE
LOT NUMBER : CR132
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (28 VACCINEES) - INJECTION 1						
	DAYS POST VACCINATION						NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5	
NORMAL	27 (100.0%)	27 (100.0%)	27 (100.0%)	27 (100.0%)	27 (100.0%)	27 (100.0%)	27 (100.0%)
TEMPERATURE TAKEN	27 (96.4%)	27 (96.4%)	27 (96.4%)	27 (96.4%)	27 (96.4%)	27 (96.4%)	27 (96.4%)
TEMPERATURE NOT TAKEN	1 (3.6%)	1 (3.6%)	1 (3.6%)	1 (3.6%)	1 (3.6%)	1 (3.6%)	1 (3.6%)

Pediatric Research April 1987
Volume 21, #4, Part 2
Program Issue APS-SPR
Infectious Diseases
Page 334A Abstract 963

† 963 **IMMUNOLOGIC PRIMING OF INFANTS WITH A SINGLE DOSE OF H. INFLUENZAE TYPE B (Hib) POLYSACCHARIDE-N. MENINGITIDIS OUTER MEMBRANE PROTEIN (PS-OMP) CONJUGATE VACCINE.** Eugene D. Shapiro, James C. Pramberg, Robert S. Daum, Yale and Tulane U. Schools of Medicine, Depts. of Pediatrics, New Haven and New Orleans.

In a trial of its immunogenicity, 13 children from 2-6 months of age received a single dose of PS-OMP conjugate vaccine. Titers of antibody against Hib capsular PS(PRP) one month after immunization were determined at Merck Laboratories by radioimmunoassay with the use of ^{125}I extrinsic labelled antigen. All 13 children had <0.4ug of antibody/ml before receiving PS-OMP vaccine and 6/13 (46%) had ≥1.0ug/ml after a single dose (geometric mean: 5.2ug/ml).

Because additional PS-OMP vaccine was not available and previous work suggested that the conjugate vaccine may prime infants to respond to plain PRP we administered PRP vaccine to all 7 children with <0.1ug of antibody/ml after PS-OMP vaccine and to 4 children with >1.0ug of antibody/ml after PS-OMP vaccine. Of the 7 children with <1.0ug of antibody/ml (geometric mean: 0.4ug/ml), 4 (57%) developed ≥1.0ug of antibody/ml (geometric mean: 5.2ug/ml) one month after "boosting" with PRP vaccine. Of the four children with >1.0ug of antibody/ml after PS-OMP vaccine, the titers of antibody one month after "boosting" with PRP vaccine increased in one child (from 19.6 to 31.2ug/ml), changed little in one child (from 1.0 to 1.1ug/ml) and decreased in two children (from 1.3 to 0.4ug/ml and from 1.5 to 0.4ug/ml, respectively). We conclude that the antibody responses of young infants to a single dose of PS-OMP conjugate vaccine vary: titers of antibody ≥1.0ug/ml develop in some infants, others are primed to achieve ≥1.0ug/ml after subsequent "boosting" with PRP vaccine, while others fail to have a substantial response.

Twenty-eighth Interscience Conference
Antimicrobial Agents and Chemotherapy
23-26 October 1988 Los Angeles, CA

Abstracts of the 1988 ICAAC
Page 293 No. 1031

Immunogenicity of H. Influenzae Type b (Hib) Polysaccharide-N. Meningitidis Outer Membrane Protein (PS-OMP) Conjugate Vaccine in Infants and Young Children. E.D. SHAPIRO*, L.A. CAPOBIANCO, M.Q. ZITT. Yale School of Medicine, New Haven, CT.

In an on-going study Hib PS-OMP conjugate vaccine (Merck, Sharp & Dohme) was administered in 1 dose to children ≥12 mos. of age and in 2 doses (separated by 2 mos.) to children 2-11 mos. of age. Concentrations of antibody against Hib capsular PS (PRP) in serum before each dose of the vaccine and at follow-up 1 month after immunization were determined at Merck Laboratories by radioimmunoassay with ^{125}I extrinsic labelled antigen. The results, expressed as the geometric mean (GM) concentration of anti-PRP antibody/ml. and the proportion of subjects with concentrations ≥1.0 ug/ml, for Groups I (ages 2-11 mos;median=6 mos; N=43), II (ages 12-23 mos;median=14 mos;N=52), and III (ages ≥24 mos;median=26 mos;N=31) are shown below:

	Anti-PRP Antibody (ug/ml)					
Grp	Before 1st Dose		Before 2nd Dose			
	GM	≥1.0	GM	≥1.0	GM	≥1.0
I	0.17	0/43(0%)	2.34	32/43(74%)	5.30	38/43(80%)
II	0.19	3/52(6%)	-	-	5.89	46/52(89%)
III	0.32	6/31(19%)	-	-	16.07	28/31(90%)

There were no substantial differences in the responses by race or to different lots of the vaccine and no serious and few minor adverse reactions occurred. This Hib PS-OMP vaccine is highly immunogenic in infants and young children.

PRODUCT LICENSE APPLICATION

PLA-0002-XXX-HC48 vol. 3

Merck and Co., Inc.
Haemophilus b Conjugate Vaccine
(Meningococcal Protein Conjugate)

8-5-8

DCC Volume Sequence No. 000195

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August 31, 1988

Clinical Report
in Support of a Product License Application
for
PEDVAX-HIB™
Haemophilus b Conjugate Vaccine
(*Neisseria meningitidis* Outer Membrane Protein Complex)

Volume 2 of 4

Merck Sharp & Dohme Research Laboratories

Rec'd in DPC 8/31/88

STUDY 004-06

PROGRAM: Haemophilus b Conjugate Vaccine (Neisseria meningitidis Outer Membrane Protein Complex), Study 004-06

PURPOSE: To evaluate the safety and immunogenicity of Haemophilus b conjugate vaccine (Neisseria meningitidis outer membrane protein complex) in healthy infants 2 months of age.

VACCINE: Haemophilus b Conjugate Vaccine (Neisseria meningitidis Outer Membrane Protein Complex) (PRP-OMPC)

Lot 1018/C-M679 - (b) (4) mcg polysaccharide/ml
mcg meningococcal protein/ml
Lot 1069/C-P241 - mcg polysaccharide/ml
mcg meningococcal protein/ml
Lot 1080/C-P749 - mcg polysaccharide/ml
mcg meningococcal protein/ml

Aluminum hydroxide diluent
Lot (b) (4)

INVESTIGATOR: Robert S. Daum, M.D.
Department of Pediatrics
Tulane University Medical Center
1430 Tulane Avenue
New Orleans, Louisiana

SUB-INVESTIGATORS: Charles A. Welborn, M.D.
James C. Pramberg, M.D.
Gerard A. Ballanco, M.D.

STUDY LOCATION: Tulane University Medical Center
New Orleans, Louisiana

Lallie Kemp Charity Hospital
Independence, Louisiana

Rothchild Pediatric Group
Metairie, Louisiana

DATE STUDY INITIATED: June 11, 1986

DATE STUDY COMPLETED: In progress.

STUDY POPULATION: Healthy infants 2 months of age are included in the study.

STUDY PROCEDURE: Infants receive two injections of PRP-OMPC vaccine 2 months apart. Vaccine is reconsituted in aluminum hydroxide and administered by intramuscular route. The dose for each injection is 15 mcg of polysaccharide in the appropriate volume. Lots 1018/C-M679 and 1069/C-P241 are reconstituted to contain 15 mcg of polysaccharide in 0.75 ml, while 1080/C-P749 is reconstituted to contain 15 mcg polysaccharide in 0.5 ml.

The parent or guardian is required to record the vaccine recipient's temperature and any reactions at the injection site or systemic complaints for 5 days after each injection of vaccine. Unexpected or serious reactions are to be reported immediately to the study physician. Serious adverse experiences in the 14 days following each injection of vaccine are required to be reported by the investigator.

A blood sample is obtained from all vaccinees immediately prior to each injection of vaccine and 1 and 8-14 months after the last injection. Urine samples are also obtained from all study participants prior to each injection of vaccine. In addition, blood and urine samples are obtained 2-3 and 7 days after the first injection of vaccine from one-half of vaccinees and 2-3 and 7 days after the second injection from the other half of vaccinees.

All serum samples are assayed for antibody to the capsular polysaccharide of Haemophilus influenzae type b by radioimmunoassay at Merck Sharp & Dohme Research Laboratories or by (b) (4) [redacted]. Serum obtained at 2-3 and 7 days postvaccination and urine samples are assayed for Haemophilus influenzae type b antigen by latex particle agglutination by (b) (4) [redacted]. Selected samples may also be tested for bactericidal and opsonophagocytic activity, immunoglobulin isotype and subclass IgG. Opsonophagocytic assays are performed at the University of Alabama. All other assays are performed at Merck Sharp & Dohme Research Laboratories.

RESULTS: Demographic information and individual pre and postimmunization antibody data for each vaccine recipient are presented in Table 1.

1. Current status:

Lot	No. Vaccinated Inj. 1	Inj. 2
1018/C-M679	7	6*
1069/C-P241	32	14
1080/C-P749	0	17**

* Licensed polysaccharide vaccine (25 mcg PRP) was administered to these 6 infants rather than PRP-OMPC vaccine.

** All 17 infants received Lot 1069/C-P241 as injection 1 and Lot 1080/C-P749 as injection 2 (Lot 1080 was reconstituted improperly for 11 infants (case nos. (b) (6) (b) (6)) who received a 12 mcg dose.

2. Serologic results:

Anti-PRP responses prior to and 1 month after vaccination among infants receiving one injection of PRP-OMPC vaccine (Lot 1018/C-P749) and a second injection of PRP vaccine are as follows:

Time	% With Anti-PRP >0.15 mcg/ml	>1.0 mcg/ml	GMT (mcg/ml) All Vaccinees
Pre	33 (2/6)	0 (0/6)	0.12
Post PRP-OMPC	100 (6/6)	50 (3/6)	1.10
Post PRP	100 (6/6)	33 (2/6)	0.97

Antibody response summary statistics for infants receiving Lot 1018/C-M679 are presented in Table 2. Serologic results are not yet available for infants receiving Lots 1069/C-P241 and/or 1080/C-P749 and from whom serum samples were collected at 2-3 and 7 days postvaccination. Testing for antigenemia and antigenuria is in progress.

RESULTS (CONT.)

3. Clinical results:

The incidence of selected injection site and systemic reactions occurring within 2 days after vaccination are as follows:

	% of Vaccinees with Reaction			
	Lot 1018		Lot 1069/1080	
Type of Reaction	Inj. 1	Inj. 2 (PRP)	Inj. 1	Inj. 2
Injection Site:				
Pain/Soreness	29 (2/7)	NA	0 (0/32)	3 (1/31)
Erythema >1 inch	0 (0/7)	NA	0 (0/32)	0 (0/31)
Swelling >1 inch	0 (0/7)	NA	0 (0/32)	0 (0/31)
Induration	0 (0/7)	NA	0 (0/32)	0 (0/31)
Systemic:				
Irritability	29 (2/7)	NA	19 (6/32)	16 (5/31)
Sleepiness/Lethargy/ Fatigue	57 (4/7)	NA	28 (9/32)	19 (6/31)

The frequency of all clinical reactions and maximum temperatures occurring during the 5 days following each injection of vaccine are presented in Tables 3-5 by lot.

No serious or alarming reactions attributable to vaccine have been reported.

TABLE 1

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : DAUM, ROBERT S.
STUDY : 000406
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ RIA	CODE/ SBA	CODE/ OPSO
(b) (6)	F	CAUC	(b) (6)	2M	0	(b) (6)	011	INJ	1	CP241 15 MCG			
					75		021	INJ	2	CP241 15 MCG			
	M	CAUC		1M	0		011	INJ	1	CP241 15 MCG			
					70		021	INJ	2	CP241 15 MCG			
	F	CAUC		2M	0		011	INJ	1	CP241 15 MCG			
					61		021	INJ	2	CP241 15 MCG			
	F	CAUC		1M	0		011	INJ	1	CP241 15 MCG			
					87		021	INJ	2	CP241 15 MCG			
	M	CAUC		1M	0		011	INJ	1	CP241 15 MCG			
					73		021	INJ	2	CP241 15 MCG			
	M	CAUC		2M	0		011	INJ	1	CP241 15 MCG			
					53		021	INJ	2	CP241 15 MCG			
	F	CAUC		1M	0		011	INJ	1	CP241 15 MCG			
					75		021	INJ	2	CP241 15 MCG			
	F	CAUC		2M	0		011	INJ	1	CP241 15 MCG			
					72		021	INJ	2	CP241 15 MCG			
	F	CAUC		2M	0		011	INJ	1	CP241 15 MCG			
					62		021	INJ	2	CP241 15 MCG			
	M	CAUC		2M	0		011	INJ	1	CP241 15 MCG			
					58		021	INJ	2	CP241 15 MCG			
	M	CAUC		2M	0		011	INJ	1	CP241 15 MCG			
					140		021	INJ	2	CP749 15 MCG			
	M	CAUC		2M	0		011	INJ	1	CP241 15 MCG			
					76		021	INJ	2	CP241 15 MCG			
	M	CAUC		1M	0		011	INJ	1	CP241 15 MCG			
					66		021	INJ	2	CP241 15 MCG			
	M	CAUC		2M	0		011	INJ	1	CP241 15 MCG			

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : DAUM, ROBERT S.
STUDY : 000406
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ RIA	CODE/ SBA	CODE/ OPSO
(b) (6)	M	CAUC	(b) (6)	2M	78	(b) (6)		021 INJ	2	CP749	12 MCG		
	F	CAUC		2M	0			011 INJ	1	CP241	15 MCG		
					61			021 INJ	2	CP241	15 MCG		
	M	CAUC		1M	0			011 INJ	1	CP241	15 MCG		
					78			021 INJ	2	CP749	12 MCG		
	F	CAUC		2M	0			011 INJ	1	CP241	15 MCG		
	M	CAUC		2M	0			011 INJ	1	CP241	15 MCG		
					59			021 INJ	2	CP241	15 MCG		
	M	CAUC		2M	0			011 INJ	1	CP241	15 MCG		
					56			021 INJ	2	CP749	12 MCG		
	M	CAUC		2M	0			011 INJ	1	CP241	15 MCG		
					83			021 INJ	2	CP749	12 MCG		
	F	CAUC		2M	0			011 INJ	1	CP241	15 MCG		
					63			021 INJ	2	CP749	12 MCG		
	F	CAUC		1M	0			011 INJ	1	CP241	15 MCG		
					78			021 INJ	2	CP749	12 MCG		
	F	CAUC		2M	0			011 INJ	1	CP241	15 MCG		
					57			021 INJ	2	CP749	12 MCG		
	F	CAUC		1M	0			011 INJ	1	CP241	15 MCG		
					85			021 INJ	2	CP749	15 MCG		
	F	CAUC		2M	0			011 INJ	1	CP241	15 MCG		
					60			021 INJ	2	CP749	12 MCG		
	F	CAUC		2M	0			011 INJ	1	CP241	15 MCG		
					57			021 INJ	2	CP749	12 MCG		
	F	CAUC		2M	0			011 INJ	1	CP241	15 MCG		
					56			021 INJ	2	CP749	12 MCG		
	M	CAUC		2M	0			011 INJ	1	CP241	15 MCG		

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : DAUM, ROBERT S.
STUDY : 000406
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT		LOT	DOSE	CODE/ RIA	CODE/ SBA	CODE/ OPSO
(b) (6)	M	CAUC	(b) (6)	2M	54	(b) (6)	021	INJ	2	CP749	12 MCG			
	M	CAUC		2M	0		011	INJ	1	CP241	15 MCG			
					62		021	INJ	2	CP749	15 MCG			
	M	CAUC		2M	0		011	INJ	1	CP241	15 MCG			
					77		021	INJ	2	CP749	15 MCG			
	M	CAUC		1M	0		011	INJ	1	CP241	15 MCG			
					60		021	INJ	2	CP749	15 MCG			
	M	CAUC		2M	0		011	INJ	1	CP241	15 MCG			
					59		021	INJ	2	CP749	15 MCG			
	M	CAUC		1M	0		001	PREBLEED				< 125		
					0		011	INJ	1	CM679	13 MCG			
					63		011	BLEED	1			1307		
					63		081	INJ	2	POLYS	25 MCG			
					112		081	BLEED	2			395		
	M	BLAC		1M	0		001	PREBLEED				271		
					0		011	INJ	1	CM679	13 MCG			
					56		011	BLEED	1			19606		
					56		081	INJ	2	POLYS	25 MCG			
					105		081	BLEED	2			31231		
	F	CAUC		2M	0		001	PREBLEED				< 125		
					0		011	INJ	1	CM679	13 MCG			
					63		011	BLEED	1			1547		
					63		081	INJ	2	POLYS	25 MCG			
					105		081	BLEED	2			409		
	M	CAUC		1M	0		001	PREBLEED				< 125		
					0		011	INJ	1	CM679	13 MCG			
					63		011	BLEED	1			189		
					63		081	INJ	2	POLYS	25 MCG			
					105		081	BLEED	2			2205		
	M	CAUC		2M	0		011	INJ	1	CM679	13 MCG			
	F	CAUC		1M	0		001	PREBLEED				254		

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : DAUM, ROBERT S.
STUDY : 000406
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	F	CAUC	(b) (6)	1M	0	(b) (6)	011	INJ	1	CM679	13 MCG					
					63		011	BLEED	1			518				
					63		081	INJ	2	POLYS	25 MCG					
					105		081	BLEED	2			302				
	M	CAUC		1M	0		001	PREBLEED				135				
					0		011	INJ	1	CM679	13 MCG					
					63		011	BLEED	1			452				
					63		081	INJ	2	POLYS	25 MCG					
					105		081	BLEED	2			253				

TABLE 2

A N T I B O D Y R E S P O N S E S

INVESTIGATOR : DAUM, ROBERT S.
STUDY : 000406
VACCINE : HIB CONJUGATE - LOT 1018/C-M679
ASSAY : RIA
POPULATION : HEALTHY CHILDREN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
1- 2 MOS.	PRE INJ	33 (2/ 6)	0 (0/ 6)			0.115 (6)
	MONTH 2	100 (6/ 6)	50 (3/ 6)	83 (5/ 6)	6.8	1.098 (6)
	MONTH 3*	100 (6/ 6)	33 (2/ 6)	67 (4/ 6)	6.0	0.973 (6)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

* POST PRP

TABLE 3
CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : DAUM, ROBERT S.
STUDY : 000406
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	32	
VACCINEES WITH NO COMPLAINTS :	16	(50.0 %)
VACCINEES WITH COMPLAINTS :	16	(50.0 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 32 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	0	0.0
SYSTEMIC REACTIONS	16	50.0
FATIGUE	9	28.1
IRRITABILITY	6	18.8
DIARRHEA	2	6.3
UPPER RESPIRATORY INFECTION, NOS	2	6.3
HARM TO TOUCH	2	6.3
PROLONGED CRYING, >1/2 HR	1	3.1
VOMITING	1	3.1
WHEEZING	1	3.1

TABLE 3 (cont.)
CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : DAUM, ROBERT S.
STUDY : 000406
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 2	
TOTAL VACCINEES :	14	
VACCINEES WITH NO COMPLAINTS :	11	(78.6 %)
VACCINEES WITH COMPLAINTS :	3	(21.4 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 14 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	0	0.0
SYSTEMIC REACTIONS	3	21.4
DIARRHEA	1	7.1
FATIGUE	1	7.1
IRRITABILITY	1	7.1
NERVOUSNESS	1	7.1
UPPER RESPIRATORY INFECTION, NOS	1	7.1

TABLE 3 (cont.)

C L I N I C A L C O M P L A I N T S B Y F R E Q U E N C Y

INVESTIGATOR : DAUM, ROBERT S.
STUDY : 000406
VACCINE : HIB CONJUGATE
LOT NUMBER : CM679
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	7	
VACCINEES WITH NO COMPLAINTS :	0	(0.0 %)
VACCINEES WITH COMPLAINTS :	7	(100.0 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 7 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	5	71.4
ERYTHEMA, INJ. SITE (<=1 IN.)	3	42.9
PAIN/SORENESS, INJ. SITE	2	28.6
REACTION, LOCAL	2	28.6
SYSTEMIC REACTIONS	5	71.4
FATIGUE	4	57.1
IRRITABILITY	2	28.6
WARM TO TOUCH	1	14.3

TABLE 3 (cont.)
CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : DAUM, ROBERT S.
STUDY : 000406
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 2	
TOTAL VACCINEES :	17	
VACCINEES WITH NO COMPLAINTS :	11	(64.7 %)
VACCINEES WITH COMPLAINTS :	6	(35.3 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 17 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	1	5.9
PAIN/SORENESS, INJ. SITE	1	5.9
SYSTEMIC REACTIONS	6	35.3
FATIGUE	5	29.4
IRRITABILITY	4	23.5
DIARRHEA	1	5.9
UPPER RESPIRATORY INFECTION, NOS	1	5.9
WARM TO TOUCH	1	5.9

TABLE 4

CLINICAL COMPLAINTS

INVESTIGATOR : DAUM, ROBERT S.
STUDY : 000406
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (32 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5	**********
SYSTEMIC	10 (31.3%)	12 (37.5%)	5 (15.6%)	4 (12.5%)	2 (6.3%)	1 (3.1%)	16 (50.0%)
BODY AS A WHOLE/SITE UNSPEC.	6 (18.8%)	7 (21.9%)	4 (12.5%)	3 (9.4%)	0 (0.0%)	0 (0.0%)	11 (34.4%)
FATIGUE	4 (12.5%)	6 (18.8%)	3 (9.4%)	2 (6.3%)	0 (0.0%)	0 (0.0%)	9 (28.1%)
WARM TO TOUCH	2 (6.3%)	1 (3.1%)	1 (3.1%)	1 (3.1%)	0 (0.0%)	0 (0.0%)	2 (6.3%)
DIGESTIVE SYSTEM	3 (9.4%)	1 (3.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (9.4%)
DIARRHEA	2 (6.3%)	1 (3.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (6.3%)
VOMITING	1 (3.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.1%)
NERVOUS SYSTEM & PSYCHIATRIC	4 (12.5%)	3 (9.4%)	2 (6.3%)	1 (3.1%)	1 (3.1%)	0 (0.0%)	6 (18.8%)
IRRITABILITY	4 (12.5%)	3 (9.4%)	2 (6.3%)	1 (3.1%)	1 (3.1%)	0 (0.0%)	6 (18.8%)
PROLONGED CRYING, >1/2 HR	0 (0.0%)	0 (0.0%)	1 (3.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.1%)
RESPIRATORY SYSTEM	1 (3.1%)	3 (9.4%)	2 (6.3%)	2 (6.3%)	1 (3.1%)	1 (3.1%)	3 (9.4%)

TABLE 4 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : DAUM, ROBERT S.
STUDY : 000406
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (32 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
UPPER RESPIRATORY INFECTION, NOS	1 (3.1%)	2 (6.3%)	2 (6.3%)	2 (6.3%)	1 (3.1%)	1 (3.1%)		2 (6.3%)
WHEEZING	0 (0.0%)	1 (3.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (3.1%)
VACCINEES WITH COMPLAINTS	10 (31.3%)	12 (37.5%)	5 (15.6%)	4 (12.5%)	2 (6.3%)	1 (3.1%)		16 (50.0%)
VACCINEES WITH NO COMPLAINTS	22 (68.8%)	20 (62.5%)	27 (84.4%)	28 (87.5%)	30 (93.8%)	31 (96.9%)		16 (50.0%)
TOTAL VACCINEES REPORTING	32	32	32	32	32	32		32
VACCINEES WITH NO DATA	0	0	0	0	0	0		0

TABLE 4 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : DAUM, ROBERT S.
STUDY : 000406
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (14 VACCINEES) - INJECTION: 2						
	DAYS POST VACCINATION						NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5	**********
SYSTEMIC	2 (14.3%)	2 (14.3%)	1 (7.1%)	1 (7.1%)	0 (0.0%)	1 (7.7%)	3 (21.4%)
BODY AS A WHOLE/SITE UNSPEC.	0 (0.0%)	1 (7.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.1%)
FATIGUE	0 (0.0%)	1 (7.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.1%)
DIGESTIVE SYSTEM	1 (7.1%)	1 (7.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.1%)
DIARRHEA	1 (7.1%)	1 (7.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.1%)
NERVOUS SYSTEM & PSYCHIATRIC	2 (14.3%)	2 (14.3%)	1 (7.1%)	1 (7.1%)	0 (0.0%)	0 (0.0%)	2 (14.3%)
IRRITABILITY	1 (7.1%)	1 (7.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.1%)
NERVOUSNESS	1 (7.1%)	1 (7.1%)	1 (7.1%)	1 (7.1%)	0 (0.0%)	0 (0.0%)	1 (7.1%)
RESPIRATORY SYSTEM	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.7%)	1 (7.1%)
UPPER RESPIRATORY INFECTION, NOS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.7%)	1 (7.1%)
VACCINEES WITH COMPLAINTS	2 (14.3%)	2 (14.3%)	1 (7.1%)	1 (7.1%)	0 (0.0%)	1 (7.7%)	3 (21.4%)

TABLE 4 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : DAUM, ROBERT S.
STUDY : 000406
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (14 VACCINEES) - INJECTION: 2						
	DAYS POST VACCINATION						NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5	**********
VACCINEES WITH NO COMPLAINTS	12 (85.7%)	12 (85.7%)	13 (92.9%)	13 (92.9%)	13 (100.0%)	12 (92.3%)	11 (78.6%)
TOTAL VACCINEES REPORTING	14	14	14	14	13	13	14
VACCINEES WITH NO DATA	0	0	0	0	1	1	0

004706

TABLE 4 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : DAUM, ROBERT S.
STUDY : 000406
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (6 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
SYSTEMIC	2 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (33.3%)
BODY AS A WHOLE/SITE UNSPEC.	2 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (33.3%)
FATIGUE	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (16.7%)
WARM TO TOUCH	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (16.7%)
DIGESTIVE SYSTEM	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (16.7%)
DIARRHEA	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (16.7%)
NERVOUS SYSTEM & PSYCHIATRIC	2 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (33.3%)
IRRITABILITY	2 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (33.3%)
VACCINEES WITH COMPLAINTS	2 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (33.3%)
VACCINEES WITH NO COMPLAINTS	4 (66.7%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)		4 (66.7%)
TOTAL VACCINEES REPORTING	6	6	6	6	6	6		6

TABLE 4 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : DAUM, ROBERT S.
STUDY : 000406
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (6 VACCINEES) - INJECTION: 2						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5	COMPLAINTS
VACCINEES WITH NO DATA	0	0	0	0	0	0	0

TABLE 5

MAXIMUM TEMPERATURES

INVESTIGATOR : DAUM, ROBERT S.
STUDY : 000406
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (32 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		WITH MAX TEMP
NORMAL	0 (0.0%)	0 (0.0%)	1 (3.1%)	2 (6.3%)	2 (6.3%)	2 (6.3%)		0 (0.0%)
< 99	28 (87.5%)	27 (84.4%)	30 (93.8%)	30 (93.8%)	29 (90.6%)	27 (84.4%)		21 (65.6%)
99 - 99.9	1 (3.1%)	4 (12.5%)	1 (3.1%)	0 (0.0%)	1 (3.1%)	3 (9.4%)		8 (25.0%)
100 - 100.9	3 (9.4%)	1 (3.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		3 (9.4%)
TEMPERATURE TAKEN	32 (100.0%)	32 (100.0%)	32 (100.0%)	32 (100.0%)	32 (100.0%)	32 (100.0%)		32 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)

TABLE 5 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : DAUM, ROBERT S.
STUDY : 000406
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (14 VACCINEES) - INJECTION 2							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
NORMAL	0 (0.0%)	0 (0.0%)	1 (7.1%)	1 (7.1%)	1 (7.1%)	1 (7.1%)		0 (0.0%)
< 99	13 (92.9%)	14 (100.0%)	13 (92.9%)	13 (92.9%)	13 (92.9%)	13 (92.9%)		13 (92.9%)
99 - 99.9	1 (7.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (7.1%)
TEMPERATURE TAKEN	14 (100.0%)	14 (100.0%)	14 (100.0%)	14 (100.0%)	14 (100.0%)	14 (100.0%)		14 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)

004644

TABLE 5 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : DAUM, ROBERT S.
STUDY : 000406
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (6 VACCINEES) - INJECTION 2						
	DAYS POST VACCINATION						NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5	
< 99	5 (83.3%)	4 (66.7%)	6 (100.0%)	5 (83.3%)	6 (100.0%)	6 (100.0%)	3 (50.0%)
99 - 99.9	1 (16.7%)	2 (33.3%)	0 (0.0%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	3 (50.0%)
TEMPERATURE TAKEN	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

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† 963 **IMMUNOLOGIC PRIMING OF INFANTS WITH A SINGLE DOSE OF H. INFLUENZAE TYPE B (Hib) POLYSACCHARIDE-N. MENINGITIDIS OUTER MEMBRANE PROTEIN (PS-OMP) CONJUGATE VACCINE.** Eugene D. Shapiro, James C. Pramberg, Robert S. Daum, Yale and Tulane U. Schools of Medicine, Depts. of Pediatrics, New Haven and New Orleans.

In a trial of its immunogenicity, 13 children from 2-6 months of age received a single dose of PS-OMP conjugate vaccine. Titers of antibody against Hib capsular PS(PRP) one month after immunization were determined at Merck Laboratories by radioimmunoassay with the use of ^{125}I extrinsic labelled antigen. All 13 children had <0.4ug of antibody/ml before receiving PS-OMP vaccine and 6/13 (46%) had ≥1.0ug/ml after a single dose (geometric mean: 5.2ug/ml).

Because additional PS-OMP vaccine was not available and previous work suggested that the conjugate vaccine may prime infants to respond to plain PRP we administered PRP vaccine to all 7 children with <0.1ug of antibody/ml after PS-OMP vaccine and to 4 children with >1.0ug of antibody/ml after PS-OMP vaccine. Of the 7 children with <1.0ug of antibody/ml (geometric mean: 0.4ug/ml), 4 (57%) developed ≥1.0ug of antibody/ml (geometric mean: 5.2ug/ml) one month after "boosting" with PRP vaccine. Of the four children with >1.0ug of antibody/ml after PS-OMP vaccine, the titers of antibody one month after "boosting" with PRP vaccine increased in one child (from 19.6 to 31.2ug/ml), changed little in one child (from 1.0 to 1.1ug/ml) and decreased in two children (from 1.3 to 0.4ug/ml and from 1.5 to 0.4ug/ml, respectively). We conclude that the antibody responses of young infants to a single dose of PS-OMP conjugate vaccine vary: titers of antibody ≥1.0ug/ml develop in some infants, others are primed to achieve ≥1.0ug/ml after subsequent "boosting" with PRP vaccine, while others fail to have a substantial response.

STUDY 004-07

PROGRAM: Haemophilus b Conjugate Vaccine (Neisseria meningitidis Outer Membrane Protein Complex), Study #0004-07.

PURPOSE: To evaluate the safety and immunogenicity of Haemophilus b Conjugate Vaccine (Neisseria meningitidis Outer Membrane Protein Complex) in healthy infants and children 2 months to 5 years of age.

VACCINE: Haemophilus b Conjugate Vaccine (Neisseria meningitidis Outer Membrane Protein Complex).

Lot 1069/C-P241 - (b) (4) mcg polysaccharide/ml
(b) (4) mcg meningococcal protein/ml
Lot 1072/C-P298 - (b) (4) mcg polysaccaride/ml
(b) (4) mcg meningococcal protein/ml
Lot 1080/C-P749 - (b) (4) mcg polysaccharide/ml
(b) (4) mcg meningococcal protein/ml
Lot 1085/C-R132 - (b) (4) mcg polysaccharide/ml
(b) (4) mcg meningococcal protein/ml

Diluent
Aluminum hydroxide diluent
Lot (b) (4)

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SUB-INVESTIGATOR: Ann Margaret Petru, M.D.
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STUDY LOCATION: Children's Hospital Medical Center
747 Fifty-Second Street
Oakland, California 94609

DATE INITIATED: May 26, 1987

DATE COMPLETED: In progress.

STUDY POPULATION: Healthy infants and children 2 to 71 months of age are included in the study. A subset of infants and children were randomized to receive the three clinical lots of vaccine (1072/C-P298, 1080/C-P749, 1085/C-R132).

STUDY PROCEDURE: Infants 2 to 11 months of age receive 2 injections of the vaccine given 2 months apart, while children 12 months of age and older receive a single injection. Vaccine is reconstituted in aluminum hydroxide and administered by intramuscular route. The dose for each injection is 15 mcg polysaccharide in the appropriate volume - 0.75 ml for Lot 1069/C-P241 and 0.5 ml for Lots 1072/C-P298, 1080/C-P749, and 1085/C-R132.

Parents or guardians are required to record the vaccinee's temperature and any systemic or injection site reactions for 5 days after each injection. Unexpected or serious reactions are to be reported immediately to the study physician.

A blood sample is obtained immediately before each injection and one month after the last (or only) injection. Additional samples are obtained 7 to 10 months after the last injection for infants 2 to 11 months of age and at 15 to 18 months postvaccination for children 12 to 71 months of age.

All serum samples are assayed by Merck Sharp & Dohme Research Laboratories for antibody to H. influenzae type b capsular polysaccharide by radioimmunoassay (RIA). Selected samples are also tested for serum bactericidal activity, quantitation of IgG_1 and IgG_2 subclass, and IgM and total IgG antibodies. Testing for opsonophagocytic activity was done at the University of Alabama.

RESULTS: Demographic information and individual pre and postvaccination antibody data for each vaccinee enrolled in the study is reported in Tables 1 and 2.

1. Number Vaccinated:

Lot	Age	Injection No. 1	Injection No. 2
1069/C-P241	2-11 mo.	15	14
	12-71 mo.	29	--
1072/C-P298	2-11 mo.	30	21
	12-71 mo.	29	--
1080/C-P749	2-11 mo.	9	3
	12-71 mo.	14	--
1085/C-R132	2-11 mo.	10	5
	12-71 mo.	13	--

Children randomized to receive the clinical lots were assigned case numbers (b) (6).

2. Serologic Results

Antibody responses (RIA) prior to and after vaccination are as follows:

Age	Time	% With Anti-PRP >0.15 mcg Ab/ml	% With Anti-PRP >1.0 mcg Ab/ml	GMT (mcg Ab/ml) All Vaccinees
2-11 mo.	Pre	32 (6/19)	0 (0/19)	0.10
	2 mo.	100 (14/14)	79 (11/14)	2.79
	3 mo.	100 (12/12)	92 (11/12)	6.38
12-71 mo.	Pre	36 (13/36)	0 (0/36)	0.11
	1 mo.	100 (36/36)	92 (33/36)	5.01

Antibody responses (by lot per age group) prior to vaccination through 10 months postvaccination are included in Tables 3-6. Responses for children randomized to receive the clinical lots are shown in Tables 7-9.

RESULTS: (CONT.)

3. Clinical Results:

The frequencies of selected injection site and systemic reactions during the 48 hours after vaccination are as follows:

	% Vaccinees with Reactions		
	2 - 11 Months of Age		12 - 71 Months of Age
Type of Reaction	Injection 1	Injection 2	Injection 1
Injection Site			
Erythema >1 inch	3.9 (2/51)	0.0 (0/31)	0.0 (0/61)
Swelling >1 inch	2.0 (1/51)	0.0 (0/31)	1.6 (1/61)
Pain/Soreness	11.8 (6/51)	19.4 (6/31)	18.0 (11/61)
Systemic			
Irritability	27.5 (14/51)	35.5 (11/31)	24.6 (15/61)
Sleepiness/ Lethargy/Fatigue	11.8 (6/51)	22.6 (7/31)	18.0 (11/61)

Reaction frequencies and maximum temperatures recorded during the five days following each injection of vaccine are reported in Tables 10-12.

No serious or alarming reactions attributable to the vaccine were reported.

TABLE 1

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	HISP	(b) (6)	7M	0	(b) (6)	001	PREBLEED				< 125				
					0		011	INJ 1	CP241	15 MCG						
					63		021	INJ 2	CP241	15 MCG						
					321		071	BLEED 1				1932				
	F	BLAC		9M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP241	15 MCG						
					61		011	BLEED 1				12832				
					61		021	INJ 2	CP241	15 MCG						
					306		071	BLEED 2				2549				
	M	BLAC		9M	-15		001	PREBLEED				< 125				
					0		011	INJ 1	CP241	15 MCG						
					122		011	BLEED 1			05/	1493				
					122		021	INJ 2	CP241	15 MCG						
	M	OTHE		3M	0		001	PREBLEED				140				
					0		011	INJ 1	CP241	15 MCG						
					119		011	BLEED 1			05/	1451				
					119		021	INJ 2	CP241	15 MCG						
	F	BLAC		2M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP241	15 MCG						
					100		011	BLEED 1			05/	7966				
					100		021	INJ 2	CP241	15 MCG						
	M	BLAC		2M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP241	15 MCG						
					100		011	BLEED 1			05/	3171				
					100		021	INJ 2	CP241	15 MCG						
	F	BLAC		4M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP241	15 MCG						
					78		011	BLEED 1			05/	12803				
					78		021	INJ 2	CP241	15 MCG						
	F	CAUC		1M	0		001	PREBLEED				662				
					0		011	INJ 1	CP241	15 MCG						
					63		011	BLEED 1				3016				
					63		021	INJ 2	CP241	15 MCG						

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	F	CAUC	(b) (6)	1M	98	(b) (6)	021	BLEED	2			7465				
	M	BLAC		8M	0		001	PREBLEED				1514				
					0		011	INJ	1 CP241	15 MCG						
					83		011	BLEED	1		05/	4510				
					83		021	INJ	2 CP241	15 MCG						
	F	OTHE		6M	0		001	PREBLEED				158				
					0		011	INJ	1 CP241	15 MCG						
					71		011	BLEED	1		05/	9085				
					71		021	INJ	2 CP241	15 MCG						
					105		021	BLEED	2		05/	12537				
	F	OTHE		6M	0		001	PREBLEED				185				
					0		011	INJ	1 CP241	15 MCG						
					71		011	BLEED	1		05/	23696				
					71		021	INJ	2 CP241	15 MCG						
					105		021	BLEED	2		05/	11501				
	F	BLAC		7M	0		011	INJ	1 CP241	15 MCG						
	F	OTHE		6M	0		001	PREBLEED				< 125				
					0		011	INJ	1 CP241	15 MCG						
					105		011	BLEED	1		05/	3524				
					105		021	INJ	2 CP241	15 MCG						
	F	BLAC		8M	0		001	PREBLEED				< 125				
					0		011	INJ	1 CP241	15 MCG						
					41		011	BLEED	1		05/	507				
					41		021	INJ	2 CP241	15 MCG						
					83		021	BLEED	2		05/	6277				
	M	CAUC		4M	0		001	PREBLEED				< 125				
					0		011	INJ	1 CP241	15 MCG						
					63		011	BLEED	1			672				
					63		021	INJ	2 CP241	15 MCG						
					106		021	BLEED	2			1298				
	F	BLAC		9M	0		011	INJ	1 CP298	15 MCG						
	M	OTHE		3M	0		001	PREBLEED				< 125		< 5		

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	OTHE	(b) (6)	3M	0	(b) (6)	011	INJ	1	CP298	15 MCG					
					56		011	BLEED	1			631		< 5		
					56		021	INJ	2	CP298	15 MCG					
					111		021	BLEED	2			1289		5		
	M	CAUC		10M	0		001	PREBLEED				< 125		< 5		
					0		011	INJ	1	CP298	15 MCG					
					57		011	BLEED	1			158		< 5		
					57		021	INJ	2	CP298	15 MCG					
					92		021	BLEED	2			709		5		
	F	CAUC		10M	0		001	PREBLEED				< 125		< 5		
					0		011	INJ	1	CP298	15 MCG					
					56		011	BLEED	1			4819		5		
					56		021	INJ	2	CP298	15 MCG					
					91		021	BLEED	2			9596		5		
	F	OTHE		9M	0		001	PREBLEED				< 125				
					0		011	INJ	1	CP298	15 MCG					
					63		011	BLEED	1			1323				
					63		021	INJ	2	CP298	15 MCG					
					91		021	BLEED	2			9343				
	M	CAUC		8M	0		001	PREBLEED				< 125				
					0		011	INJ	1	CP298	15 MCG					
					96		011	BLEED	1			1130	05/			
					96		021	INJ	2	CP298	15 MCG					
					125		021	BLEED	2			25996	05/			
	M	OTHE		6M	0		001	PREBLEED				207				
					0		011	INJ	1	CP298	15 MCG					
					68		011	BLEED	1			4718				
					68		021	INJ	2	CP298	15 MCG					
					119		021	BLEED	2			14117				
	M	CAUC		2M	0		001	PREBLEED				319				
					0		011	INJ	1	CP29B	15 MCG					
					64		011	BLEED	1			2149				
					64		021	INJ	2	CP298	15 MCG					
	M	CAUC		3M	0		001	PREBLEED				< 125				

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	CAUC	(b) (6)	3M	0	(b) (6)	011	INJ 1	CP298	15 MCG						
					79		011	BLEED 1			05/	1129				
					79		021	INJ 2	CP298	15 MCG						
					107		021	BLEED 2			05/	854				
	M	CAUC		6M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP298	15 MCG						
					64		011	BLEED 1				4621				
					84		021	INJ 2	CP298	15 MCG						
					115		021	BLEED 2			05/	4586				
	F	CAUC		5M	0		001	PREBLEED				183				
					0		011	INJ 1	CP298	15 MCG						
					63		021	INJ 2	CP298	15 MCG						
					99		021	BLEED 1				25193				
	F	CAUC		6M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP298	15 MCG						
					69		011	BLEED 1				3499				
					69		021	INJ 2	CP298	15 MCG						
					104		021	BLEED 2				7051				
	M	CAUC		6M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP298	15 MCG						
					62		021	INJ 2	CP298	15 MCG						
					98		021	BLEED 1				43048				
	F	CAUC		5M	0		001	PREBLEED				125				
					0		011	INJ 1	CP298	15 MCG						
					58		021	INJ 2	CP298	15 MCG						
					92		021	BLEED 1				15032				
	F	CAUC		3M	0		011	INJ 1	CP298	15 MCG						
					77		021	INJ 2	CP298	15 MCG						
	F	CAUC		3M	0		011	INJ 1	CP298	15 MCG						
					77		021	INJ 2	CP298	15 MCG						
	M	CAUC		8M	0		011	INJ 1	CR132	15 MCG						
					63		021	INJ 2	CR132	15 MCG						

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	F	CAUC	(b) (6)	3M	0	(b) (6)	011	INJ 1	CP298	15 MCG						
					61		021	INJ 2	CP298	15 MCG						
	F	CAUC		5M	0		011	INJ 1	CP298	15 MCG						
					63		021	INJ 2	CP298	15 MCG						
	F	CAUC		6M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP749	15 MCG						
					77		011	BLEED 1			05/	645				
					77		021	INJ 2	CP749	15 MCG						
					104		021	BLEED 2			05/	1922				
	M	CAUC		4M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CR132	15 MCG						
					90		011	BLEED 1			05/	4997				
					90		021	INJ 2	CR132	15 MCG						
					125		021	BLEED 2			05/	4878				
	M	OTHE		6M	0		001	PREBLEED				161				
					0		011	INJ 1	CP298	15 MCG						
					63		011	BLEED 1				1963				
					63		021	INJ 2	CP298	15 MCG						
					97		021	BLEED 2				2040				
	M	CAUC		10M	0		011	INJ 1	CP298	15 MCG						
					80		021	INJ 2	CP298	15 MCG						
	F	CAUC		9M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP749	15 MCG						
					57		021	INJ 2	CP749	15 MCG						
					85		021	BLEED 1				3200				
	F	BLAC		9M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CR132	15 MCG						
					57		011	BLEED 1				13240				
					57		021	INJ 2	CR132	15 MCG						
	M	HISP		8M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP298	15 MCG						
					63		011	BLEED 1				9663				

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ RIA	CODE/ SBA	CODE/ OPSO
(b) (6)	M	HISP	(b) (6)	8M	63	(b) (6)	021	INJ 2	CP298	15 MCG			
					93		021	BLEED 2			9921		
	F	OTHE		7M	0		011	INJ 1	CP749	15 MCG			
					56		021	INJ 2	CP749	15 MCG			
	M	BLAC		7M	0		011	INJ 1	CR132	15 MCG			
					70		021	INJ 2	CR132	15 MCG			
	F	CAUC		2M	0		001	PREBLEED			181		
					0		011	INJ 1	CR132	15 MCG			
					64		011	BLEED 1			11886		
					64		021	INJ 2	CR132	15 MCG			
	F	CAUC		2M	0		011	INJ 1	CP298	15 MCG			
					63		021	INJ 2	CP298	15 MCG			
	M	BLAC		6M	0		001	PREBLEED			< 125		
					0		011	INJ 1	CP298	15 MCG			
					69		011	BLEED 1			4035		
	F	BLAC		6M	0		001	PREBLEED			< 125		
					0		011	INJ 1	CR132	15 MCG			
					69		011	BLEED 1			707		
	M	CAUC		5M	0		001	PREBLEED			367		
					0		011	INJ 1	CP298	15 MCG			
					62		011	BLEED 1			8510		
	F	CAUC		9M	0		001	PREBLEED			291		
					0		011	INJ 1	CP749	15 MCG			
					66		011	BLEED 1			3573		
	M	CAUC		8M	0		011	INJ 1	CR132	15 MCG			
	F	BLAC		9M	0		011	INJ 1	CP749	15 MCG			
	F	OTHE		11M	0		011	INJ 1	CP298	15 MCG			
	F	BLAC		4M	0		011	INJ 1	CP298	15 MCG			

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	F	CAUC	(b) (6)	2M	0	(b) (6)		011 INJ	1	CP298.	15 MCG					
	M	CAUC		3M	0			011 INJ	1	CP749.	15 MCG					
	F	CAUC		9M	0			011 INJ	1	CR132.	15 MCG					
	F	BLAC		9M	0			011 INJ	1	CP749.	15 MCG					
	F	CAUC		1M	0			011 INJ	1	CP749.	15 MCG					
	F	CAUC		4M	0			011 INJ	1	CP298.	15 MCG					
	F	BLAC		10M	0			011 INJ	1	CP749.	15 MCG					
	F	CAUC		11M	0			011 INJ	1	CR132.	15 MCG					
	M	CAUC		6M	0			011 INJ	1	CP298.	15 MCG					
	F	CAUC		4M	0			011 INJ	1	CR132.	15 MCG					
	M	BLAC		5M	0			011 INJ	1	CP298.	15 MCG					

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	CAUC	(b) (6)	13M	0	(b) (6)	001	PREBLEED				< 125		< 2		
					0		011	INJ 1	CP241	15 MCG						
					33		011	BLEED 1				295		< 2		
	M	BLAC		19M	0		001	PREBLEED				< 125		< 5		
					0		011	INJ 1	CP241	15 MCG						
					44		011	BLEED 1				3912		20		
	F	OTHE		15M	0		001	PREBLEED				< 125		< 5		
					0		011	INJ 1	CP241	15 MCG						
					41		011	BLEED 1				3321		20		
	M	BLAC		17M	0		011	INJ 1	CP241	15 MCG						
	M	BLAC		2Y	0		011	INJ 1	CP241	15 MCG						
	M	BLAC		2Y	0		001	PREBLEED				< 125		< 5		
					0		011	INJ 1	CP241	15 MCG						
					31		011	BLEED 1				1895		80		
	F	OTHE		12M	0		001	PREBLEED				< 125		< 5		
					0		011	INJ 1	CP241	15 MCG						
					31		011	BLEED 1				14617		20		
	M	CAUC		13M	0		001	PREBLEED				243		5		
					0		011	INJ 1	CP241	15 MCG						
					29		011	BLEED 1				1953		80		
	M	HISP		24M	0		001	PREBLEED				< 125		< 2		
					0		011	INJ 1	CP241	15 MCG						
					29		011	BLEED 1				3300		2		
	M	HISP		15M	0		011	INJ 1	CP241	15 MCG						
	M	HISP		15M	0		011	INJ 1	CP241	15 MCG						
	M	BLAC		20M	0		001	PREBLEED				< 125		< 5		
					0		011	INJ 1	CP241	15 MCG						
					32		011	BLEED 1				1746		20		
	F	BLAC		15M	0		001	PREBLEED				< 125		< 5		

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	F	BLAC	(b) (6)	15M	0	(b) (6)	011	INJ	1	CP241 15 MCG						
					30		011	BLEED	1			844		20		
	F	HISP		14M	0		011	INJ	1	CP241 15 MCG						
	M	BLAC		12M	0		011	INJ	1	CP241 15 MCG						
	M	CAUC		24M	0		001	PREBLEED				< 125		< 5		
					0		011	INJ	1	CP241 15 MCG						
					33		011	BLEED	1			3287		20		
	M	BLAC		20M	0		001	PREBLEED				< 125		< 5		
					0		011	INJ	1	CP241 15 MCG						
					31		011	BLEED	1			13608		20		
	F	BLAC		2Y	0		011	INJ	1	CP241 15 MCG						
	F	CAUC		2Y	-7		001	PREBLEED				159		< 5		
					0		011	INJ	1	CP241 15 MCG						
					29		011	BLEED	1			7525		>= 80		
	F	BLAC		12M	0		011	INJ	1	CP241 15 MCG						
	M	BLAC		22M	0		011	INJ	1	CP241 15 MCG						
	F	OTHE		13M	0		011	INJ	1	CP241 15 MCG						
	F	OTHE		3Y	0		001	PREBLEED			04/	668	04/	5		
					0		011	INJ	1	CP241 15 MCG						
					27		011	BLEED	1		04/	10350	04/	80		
	F	CAUC		4M	0		011	INJ	1	CP241 15 MCG						
	M	BLAC		8M	0		011	INJ	1	CP241 15 MCG						
	F	CAUC		2M	0		001	PREBLEED				153		< 5		
					0		011	INJ	1	CP241 15 MCG						
					63		011	BLEED	1			11740		20		
	M	CAUC		2M	0		001	PREBLEED				143		< 5		

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	CAUC	(b) (6)	22M	0	(b) (6)	011	INJ	1	CP241	15 MCG					
					63		011	BLEED	1			6748		20		
	F	CAUC		18M	0		001	PREBLEED				127		< 5		
					0		011	INJ	1	CP241	15 MCG					
					35		011	BLEED	1			18785		20		
	M	BLAC		15M	0		001	PREBLEED				238		5		
					0		011	INJ	1	CP241	15 MCG					
					35		011	BLEED	1			6415		> 80		
	F	BLAC		2Y	0		001	PREBLEED				175				
					0		011	INJ	1	CP298	15 MCG					
					28		011	BLEED	1			36019				
	F	CAUC		24M	0		001	PREBLEED				173		< 5		
					0		011	INJ	1	CP298	15 MCG					
					28		011	BLEED	1			67376		20		
	M	OTHE		12M	0		001	PREBLEED				< 125				
					0		011	INJ	1	CP298	15 MCG					
					28		011	BLEED	1			1602				
	F	OTHE		15M	0		001	PREBLEED				293		< 5		
					0		011	INJ	1	CP298	15 MCG					
					94		011	BLEED	1			5218		20		
	F	OTHE		18M	0		001	PREBLEED				< 125		< 5		
					0		011	INJ	1	CP298	15 MCG					
					42		011	BLEED	1			28503		20		
	M	OTHE		17M	0		001	PREBLEED				< 125		< 5		
					0		011	INJ	1	CP298	15 MCG					
					22		011	BLEED	1			338		5		
	F	CAUC		20M	0		011	INJ	1	CP298	15 MCG					
	M	CAUC		23M	0		001	PREBLEED				< 125		< 5		
					0		011	INJ	1	CP298	15 MCG					
					38		011	BLEED	1			2323		>= 80		

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	BLAC	(b) (6)	23M	0	(b) (6)	001	PREBLEED				283		< 5		
					0		011	INJ 1	CP298	15 MCG						
					35		011	BLEED 1				1373		5		
	M	CAUC		13M	0		001	PREBLEED				241		< 5		
					0		011	INJ 1	CP298	15 MCG						
					35		011	BLEED 1				9485		>= 80		
	F	BLAC		13M	0		001	PREBLEED				223		< 5		
					0		011	INJ 1	CP298	15 MCG						
					34		011	BLEED 1				2076		20		
	F	BLAC		24M	0		011	INJ 1	CP298	15 MCG						
	F	HISP		12M	0		001	PREBLEED				< 125		< 5		
					0		011	INJ 1	CP298	15 MCG						
					24		011	BLEED 1				1501		20		
	F	BLAC		13M	0		011	INJ 1	CP298	15 MCG						
	M	BLAC		20M	0		001	PREBLEED				182				
					0		011	INJ 1	CP298	15 MCG						
					49		011	BLEED 1				3111				
	F	CAUC		16M	0		001	PREBLEED				222				
					0		011	INJ 1	CP298	15 MCG						
					56		011	BLEED 1				27028				
	M	OTHE		18M	-7		001	PREBLEED				699		< 5		
					0		011	INJ 1	CP298	15 MCG						
					28		011	BLEED 1				16748		80		
	M	CAUC		2Y	0		001	PREBLEED				131		< 5		
					0		011	INJ 1	CP298	15 MCG						
					43		011	BLEED 1				19106		>= 80		
	F	HISP		23M	0		001	PREBLEED				< 125		< 5		42
					0		011	INJ 1	CP749	15 MCG						
					43		011	BLEED 1				2641		20		97
	M	CAUC		2Y	0		011	INJ 1	CR132	15 MCG						

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	F	BLAC	(b) (6)	2Y	0	(b) (6)	011	INJ 1	CP749	15 MCG						
	F	CAUC		2Y	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP298	15 MCG						
					35		011	BLEED 1				10491				
	M	BLAC		21M	0		001	PREBLEED				314		< 5		43
					0		011	INJ 1	CR132	15 MCG						
					29		011	BLEED 1				31363		>= 80		100
	F	BLAC		23M	0		011	INJ 1	CP298	15 MCG						
	M	CAUC		24M	0		011	INJ 1	CP298	15 MCG						
	F	BLAC		18M	0		011	INJ 1	CR132	15 MCG						
	F	BLAC		21M	0		011	INJ 1	CP749	15 MCG						
	M	BLAC		2Y	0		011	INJ 1	CP749	15 MCG						
	M	BLAC		2Y	0		011	INJ 1	CP749	15 MCG						
	M	CAUC		20M	0		011	INJ 1	CR132	15 MCG						
	F	BLAC		2Y	0		011	INJ 1	CP298	15 MCG						
	M	BLAC		12M	0		011	INJ 1	CR132	15 MCG						
	F	BLAC		12M	0		011	INJ 1	CP298	15 MCG						
	F	CAUC		19M	0		001	PREBLEED				270		< 5		
					0		011	INJ 1	CP749	15 MCG						
					29		011	BLEED 1				7022		>= 80		
	F	OTHE		12M	0		011	INJ 1	CP749	15 MCG						
	M	CAUC		14M	0		011	INJ 1	CP749	15 MCG						
	M	CAUC		2Y	0		001	PREBLEED				< 125		< 5		
					0		011	INJ 1	CP749	15 MCG						

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	CAUC	(b) (6)	2Y	36	(b) (6)	011	BLEED	1			32948		20		
	M	BLAC		2Y	0		011	INJ	1	CR132	15 MCG					
	F	BLAC		16M	0		001	PREBLEED				< 125		< 5		
					0		011	INJ	1	CR132	15 MCG					
					35		011	BLEED	1			13215		>= 80		
	F	CAUC		13M	0		001	PREBLEED				444				
					0		011	INJ	1	CP298	15 MCG					
					28		011	BLEED	1			1863				
	M	CAUC		2Y	0		011	INJ	1	CP298	15 MCG					
	F	BLAC		23M	0		001	PREBLEED				< 125				
					0		011	INJ	1	CP298	15 MCG					
					36		011	BLEED	1			4845				
	M	BLAC		22M	0		011	INJ	1	CP749	15 MCG					
	F	HISP		21M	0		011	INJ	1	CP749	15 MCG					
	F	BLAC		24M	0		011	INJ	1	CP298	15 MCG					
	M	CAUC		2Y	0		011	INJ	1	CR132	15 MCG					
	F	BLAC		2Y	0		011	INJ	1	CR132	15 MCG					
	M	HISP		12M	0		011	INJ	1	CP298	15 MCG					
	M	OTHE		14M	0		011	INJ	1	CR132	15 MCG					
	M	BLAC		17M	0		011	INJ	1	CR132	15 MCG					
	M	CAUC		15M	0		001	PREBLEED				< 125				
					0		011	INJ	1	CP749	15 MCG					
					41		011	BLEED	1			4543				
	M	BLAC		23M	0		011	INJ	1	CP749	15 MCG					
	M	BLAC		15M	0		011	INJ	1	CP749	15 MCG					

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	CAUC	(b) (6)	23M	0	(b) (6)	011	INJ	1	CP298	15	MCG				
	F	OTHE		24M	0		011	INJ	1	CR132	15	MCG				
	F	OTHE		4Y	0		011	INJ	1	CR132	15	MCG				

TABLE 2

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	IGG1	CODE/	IGG2	CODE/	IGGM	CODE/	IGG TOTAL
(b) (6)	M	HISP	(b) (6)	7M	0	(b) (6)	011	INJ	1 CP241	15 MCG								
					63		021	INJ	2 CP241	15 MCG								
	F	BLAC		9M	0		001	PREBLEED				< 600				< 100		< 100
					0		011	INJ	1 CP241	15 MCG								
					61		011	BLEED	1			7830				177		1427
					61		021	INJ	2 CP241	15 MCG								
	M	BLAC		9M	-15		001	PREBLEED				< 600				< 100		< 100
					0		011	INJ	1 CP241	15 MCG								
					122		011	BLEED	1		05/	2599			05/	< 100	05/	461
					122		021	INJ	2 CP241	15 MCG								
	M	OTHE		3M	0		001	PREBLEED				< 600				< 100		< 100
					0		011	INJ	1 CP241	15 MCG								
					119		011	BLEED	1		05/	9976			05/	< 100	05/	943
					119		021	INJ	2 CP241	15 MCG								
	F	BLAC		2M	0		011	INJ	1 CP241	15 MCG								
					100		021	INJ	2 CP241	15 MCG								
	M	BLAC		2M	0		011	INJ	1 CP241	15 MCG								
					100		021	INJ	2 CP241	15 MCG								
	F	BLAC		4M	0		011	INJ	1 CP241	15 MCG								
					78		021	INJ	2 CP241	15 MCG								
	F	CAUC		1M	0		001	PREBLEED				< 600		< 250		< 100		187
					0		011	INJ	1 CP241	15 MCG								
					63		011	BLEED	1			4916		< 250		< 100		1023
					63		021	INJ	2 CP241	15 MCG								
					98		021	BLEED	2			11916		< 250		< 100		1600
	M	BLAC		8M	0		011	INJ	1 CP241	15 MCG								
					83		021	INJ	2 CP241	15 MCG								
	F	OTHE		6M	0		001	PREBLEED				< 600		< 250		< 100		< 100
					0		011	INJ	1 CP241	15 MCG								
					71		011	BLEED	1		05/	9157	05/	< 250	05/	< 100	05/	1223
					71		021	INJ	2 CP241	15 MCG								

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	IGG1	CODE/	IGG2	CODE/	IGGM	CODE/	IGG TOTAL
(b) (6)	F	OTHE	(b) (6)	6M	105	(b) (6)	021	BLEED 2			05/	15364	05/	< 250	05/	< 100	05/	1632
	F	OTHE		6M	0		001	PREBLEED				< 600		< 250		< 100		< 100
					0		011	INJ 1	CP241	15 MCG								
					71		011	BLEED 1			05/	30124	05/	< 250	05/	< 100	05/	1865
					71		021	INJ 2	CP241	15 MCG								
					105		021	BLEED 2			05/	9314	05/	< 250	05/	< 100	05/	833
	F	BLAC		7M	0		011	INJ 1	CP241	15 MCG								
	F	OTHE		6M	0		011	INJ 1	CP241	15 MCG								
					105		021	INJ 2	CP241	15 MCG								
	F	BLAC		8M	0		001	PREBLEED				< 600		< 250		< 100		< 100
					0		011	INJ 1	CP241	15 MCG								
					41		011	BLEED 1			05/	< 600	05/	< 250	05/	< 100	05/	244
					41		021	INJ 2	CP241	15 MCG								
					83		021	BLEED 2			05/	2353	05/	< 250	05/	1108	05/	530
	M	CAUC		4M	0		001	PREBLEED				< 600				< 100		< 100
					0		011	INJ 1	CP241	15 MCG								
					63		011	BLEED 1				2108				< 100		269
					63		021	INJ 2	CP241	15 MCG								
					106		021	BLEED 2				5775				181		1013
	F	BLAC		9M	0		011	INJ 1	CP298	15 MCG								
	M	OTHE		3M	0		001	PREBLEED				< 600		< 250		< 100		< 100
					0		011	INJ 1	CP298	15 MCG								
					56		011	BLEED 1				8500		< 250		< 100		513
					56		021	INJ 2	CP298	15 MCG								
					111		021	BLEED 2				10980		< 250		< 100		969
	M	CAUC		10M	0		001	PREBLEED				< 600		< 250		< 100		< 100
					0		011	INJ 1	CP298	15 MCG								
					57		011	BLEED 1				< 600		< 250		< 100		115
					57		021	INJ 2	CP298	15 MCG								
					92		021	BLEED 2				1572		< 250		< 100		192
	F	CAUC		10M	0		001	PREBLEED				< 600		< 250		< 100		< 100

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ IGG1	CODE/ IGG2	CODE/ IGGM	CODE/IGG TOTAL
(b) (6)	F	CAUC	(b) (6)	10M	0	(b) (6)	011	INJ 1	CP298	15 MCG				
					56		011	BLEED 1			27159	< 250	276	2757
					56		021	INJ 2	CP298	15 MCG				
					91		021	BLEED 2			52652	< 250	177	7707
	F	OTHE		9M	0		001	PREBLEED			< 600	< 250	< 100	< 100
					0		011	INJ 1	CP298	15 MCG				
					63		011	BLEED 1			1897	< 250	< 100	396
					63		021	INJ 2	CP298	15 MCG				
					91		021	BLEED 2				< 250	298	1713
	M	CAUC		8M	0		011	INJ 1	CP298	15 MCG				
					96		021	INJ 2	CP298	15 MCG				
	M	OTHE		6M	0		001	PREBLEED			< 600		< 100	< 100
					0		011	INJ 1	CP298	15 MCG				
					68		011	BLEED 1			10718		< 100	348
					68		021	INJ 2	CP298	15 MCG				
					119		021	BLEED 2				< 250	< 100	2391
	M	CAUC		2M	0		001	PREBLEED			< 600		< 100	< 100
					0		011	INJ 1	CP298	15 MCG				
					64		011	BLEED 1			28178		< 100	3055
					64		021	INJ 2	CP298	15 MCG				
	M	CAUC		3M	0		011	INJ 1	CP298	15 MCG				
					79		021	INJ 2	CP298	15 MCG				
	M	CAUC		6M	0		011	INJ 1	CP298	15 MCG				
					84		021	INJ 2	CP298	15 MCG				
	F	CAUC		5M	0		011	INJ 1	CP298	15 MCG				
					63		021	INJ 2	CP298	15 MCG				
	F	CAUC		6M	0		011	INJ 1	CP298	15 MCG				
					69		021	INJ 2	CP298	15 MCG				
	M	CAUC		6M	0		011	INJ 1	CP298	15 MCG				
					62		021	INJ 2	CP298	15 MCG				
	F	CAUC		5M	0		011	INJ 1	CP298	15 MCG				

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT		LOT	DOSE	CODE/	IGG1	CODE/	IGG2	CODE/	IGGM	CODE/IGG TOTAL
(b) (6)	F	CAUC	(b) (6)	5M	58	(b) (6)	021	INJ	2	CP298	15 MCG							
	F	CAUC		3M	0		011	INJ	1	CP298	15 MCG							
					77		021	INJ	2	CP298	15 MCG							
	F	CAUC		3M	0		011	INJ	1	CP298	15 MCG							
					77		021	INJ	2	CP298	15 MCG							
	M	CAUC		8M	0		011	INJ	1	CR132	15 MCG							
					63		021	INJ	2	CR132	15 MCG							
	F	CAUC		3M	0		011	INJ	1	CP298	15 MCG							
					61		021	INJ	2	CP298	15 MCG							
	F	CAUC		5M	0		011	INJ	1	CP298	15 MCG							
					63		021	INJ	2	CP298	15 MCG							
	F	CAUC		6M	0		001	PREBLEED					< 600				< 100	< 100
					0		011	INJ	1	CP749	15 MCG							
					77		011	BLEED	1			05/	1195			05/	< 100	05/ 237
					77		021	INJ	2	CP749	15 MCG							
					104		021	BLEED	2			05/	5561			05/	< 100	05/ 446
	M	CAUC		4M	0		001	PREBLEED					< 600		< 250		< 100	< 100
					0		011	INJ	1	CR132	15 MCG							
					90		011	BLEED	1			05/	1914	05/	460	05/	< 100	05/ 1049
					90		021	INJ	2	CR132	15 MCG							
	M	OTHE		6M	0		011	INJ	1	CP298	15 MCG							
					63		021	INJ	2	CP298	15 MCG							
	M	CAUC		10M	0		011	INJ	1	CP298	15 MCG							
					80		021	INJ	2	CP298	15 MCG							
	F	CAUC		9M	0		001	PREBLEED					< 600				< 100	< 100
					0		011	INJ	1	CP749	15 MCG							
					57		021	INJ	2	CP749	15 MCG							
					85		021	BLEED	1				2587				513	799
	F	BLAC		9M	0		001	PREBLEED					< 600		< 250		< 100	< 100

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ IGG1	CODE/ IGG2	CODE/ IGGM	CODE/IGG TOTAL
(b) (6)	F	BLAC	(b) (6)	9M	0	(b) (6)	011	INJ	1	CR132	15 MCG			
					57		011	BLEED	1		17193	275	732	2357
					57		021	INJ	2	CR132	15 MCG			
	M	HISP		8M	0		011	INJ	1	CP298	15 MCG			
					63		021	INJ	2	CP298	15 MCG			
	F	OTHE		7M	0		011	INJ	1	CP749	15 MCG			
					56		021	INJ	2	CP749	15 MCG			
	M	BLAC		7M	0		011	INJ	1	CR132	15 MCG			
					70		021	INJ	2	CR132	15 MCG			
	F	CAUC		2M	0		011	INJ	1	CR132	15 MCG			
					64		021	INJ	2	CR132	15 MCG			
	F	CAUC		2M	0		011	INJ	1	CP298	15 MCG			
					63		021	INJ	2	CP298	15 MCG			
	M	BLAC		6M	0		011	INJ	1	CP298	15 MCG			
	F	BLAC		6M	0		011	INJ	1	CR132	15 MCG			
	M	CAUC		5M	0		011	INJ	1	CP298	15 MCG			
	F	CAUC		9M	0		011	INJ	1	CP749	15 MCG			
	M	CAUC		8M	0		011	INJ	1	CR132	15 MCG			
	F	BLAC		9M	0		011	INJ	1	CP749	15 MCG			
	F	OTHE		11M	0		011	INJ	1	CP298	15 MCG			
	F	BLAC		4M	0		011	INJ	1	CP298	15 MCG			
	F	CAUC		2M	0		011	INJ	1	CP298	15 MCG			
	M	CAUC		3M	0		011	INJ	1	CP749	15 MCG			
	F	CAUC		9M	0		011	INJ	1	CR132	15 MCG			

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ IGG1	CODE/ IGG2	CODE/ IGGM	CODE/IGG TOTAL
(b) (6)	F	BLAC	(b) (6)	9M	0	(b) (6)	011	INJ 1	CP749	15 MCG				
	F	CAUC		1M	0		011	INJ 1	CP749	15 MCG				
	F	CAUC		4M	0		011	INJ 1	CP298	15 MCG				
	F	BLAC		10M	0		011	INJ 1	CP749	15 MCG				
	F	CAUC		11M	0		011	INJ 1	CR132	15 MCG				
	M	CAUC		6M	0		011	INJ 1	CP298	15 MCG				
	F	CAUC		4M	0		011	INJ 1	CR132	15 MCG				
	M	BLAC		5M	0		011	INJ 1	CP298	15 MCG				

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ IGG1	CODE/ IGG2	CODE/ IGGM	CODE/IGG TOTAL
(b) (6)	M	CAUC	(b) (6)	13M	0	(b) (6)	001	PREBLEED			< 600	< 250	269	< 100
					0		011	INJ 1	CP241	15 MCG				
					33		011	BLEED 1			< 600	< 250	449	< 100
	M	BLAC		19M	0		001	PREBLEED				< 250		
					0		011	INJ 1	CP241	15 MCG				
					44		011	BLEED 1				< 250		
	F	OTHE		15M	0		001	PREBLEED			< 600	< 250	< 100	< 100
					0		011	INJ 1	CP241	15 MCG				
					41		011	BLEED 1			11260	< 250	1104	1275
	M	BLAC		17M	0		011	INJ 1	CP241	15 MCG				
	M	BLAC		2Y	0		011	INJ 1	CP241	15 MCG				
	M	BLAC		2Y	0		001	PREBLEED				< 250		
					0		011	INJ 1	CP241	15 MCG				
					31		011	BLEED 1				< 250		
	F	OTHE		12M	0		001	PREBLEED			< 600	< 250	< 100	< 100
					0		011	INJ 1	CP241	15 MCG				
					31		011	BLEED 1			37877	< 250	163	3389
	M	CAUC		13M	0		001	PREBLEED			< 600	< 250	< 100	< 100
					0		011	INJ 1	CP241	15 MCG				
					29		011	BLEED 1			4199	287	550	821
	M	HISP		24M	0		001	PREBLEED				< 250		
					0		011	INJ 1	CP241	15 MCG				
					29		011	BLEED 1				468		
	M	HISP		15M	0		011	INJ 1	CP241	15 MCG				
	M	HISP		15M	0		011	INJ 1	CP241	15 MCG				
	M	BLAC		20M	0		011	INJ 1	CP241	15 MCG				
	F	BLAC		15M	0		001	PREBLEED			< 600		< 100	< 100
					0		011	INJ 1	CP241	15 MCG				

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ IGG1	CODE/ IGG2	CODE/ IGGM	CODE/IGG TOTAL
(b) (6)	F	BLAC	(b) (6)	15M	30	(b) (6)	011	BLEED	1		< 600		< 100	< 100
	F	HISP		14M	0		011	INJ	1	CP241 15 MCG				
	M	BLAC		12M	0		011	INJ	1	CP241 15 MCG				
	M	CAUC		24M	0		011	INJ	1	CP241 15 MCG				
	M	BLAC		20M	0		011	INJ	1	CP241 15 MCG				
	F	BLAC		2Y	0		011	INJ	1	CP241 15 MCG				
	F	CAUC		2Y	0		011	INJ	1	CP241 15 MCG				
	F	BLAC		12M	0		011	INJ	1	CP241 15 MCG				
	M	BLAC		22M	0		011	INJ	1	CP241 15 MCG				
	F	OTHE		13M	0		011	INJ	1	CP241 15 MCG				
	F	OTHE		3Y	0		011	INJ	1	CP241 15 MCG				
	F	CAUC		14M	0		011	INJ	1	CP241 15 MCG				
	M	BLAC		18M	0		011	INJ	1	CP241 15 MCG				
	F	CAUC		22M	0		011	INJ	1	CP241 15 MCG				
	M	CAUC		22M	0		011	INJ	1	CP241 15 MCG				
	F	CAUC		18M	0		001	PREBLEED					< 100	220
					0		011	INJ	1	CP241 15 MCG				
					35		011	BLEED	1				399	6802
	M	BLAC		15M	0		001	PREBLEED			< 600			
					0		011	INJ	1	CP241 15 MCG				
					35		011	BLEED	1		7827			
	F	BLAC		2Y	0		001	PREBLEED			< 600	< 250	< 100	< 100
					0		011	INJ	1	CP298 15 MCG				

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ IGG1	CODE/ IGG2	CODE/ IGGM	CODE/IGG TOTAL
(b) (6)	F	BLAC	(b) (6)	2Y	28	(b) (6)	011	BLEED 1			30140	337	1226	9487
	F	CAUC		24M	0		001	PREBLEED			< 600	< 250		
					0		011	INJ 1	CP298	15 MCG				
					28		011	BLEED 1			64555	468		
	M	OTHE		12M	0		011	INJ 1	CP298	15 MCG				
	F	OTHE		15M	0		011	INJ 1	CP298	15 MCG				
	F	OTHE		18M	0		001	PREBLEED			< 600	< 250		
					0		011	INJ 1	CP298	15 MCG				
					42		011	BLEED 1			20061	617		
	M	OTHE		17M	0		011	INJ 1	CP298	15 MCG				
	F	CAUC		20M	0		011	INJ 1	CP298	15 MCG				
	M	CAUC		23M	0		001	PREBLEED			< 600	< 250		
					0		011	INJ 1	CP298	15 MCG				
					38		011	BLEED 1			4275	< 250		
	M	BLAC		23M	0		001	PREBLEED			< 600			
					0		011	INJ 1	CP298	15 MCG				
					35		011	BLEED 1			7937			
	M	CAUC		13M	0		011	INJ 1	CP298	15 MCG				
	F	BLAC		13M	0		011	INJ 1	CP298	15 MCG				
	F	BLAC		24M	0		011	INJ 1	CP298	15 MCG				
	F	HISP		12M	0		011	INJ 1	CP298	15 MCG				
	F	BLAC		13M	0		011	INJ 1	CP298	15 MCG				
	M	BLAC		20M	0		011	INJ 1	CP298	15 MCG				
	F	CAUC		16M	0		011	INJ 1	CP298	15 MCG				
	M	OTHE		18M	0		011	INJ 1	CP298	15 MCG				

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ IGG1	CODE/ IGG2	CODE/ IGGM	CODE/IGG TOTAL
(b) (6)	M	CAUC	(b) (6)	2Y	0	(b) (6)	001	PREBLEED			< 600			
					0		011	INJ 1	CP298	15 MCG				
					43		011	BLEED 1			11285			
	F	HISP		23M	0		001	PREBLEED			< 600	< 250	726	< 100
					0		011	INJ 1	CP749	15 MCG				
					43		011	BLEED 1			7414	333	2271	941
	M	CAUC		2Y	0		011	INJ 1	CR132	15 MCG				
	F	BLAC		2Y	0		011	INJ 1	CP749	15 MCG				
	F	CAUC		2Y	0		011	INJ 1	CP298	15 MCG				
	M	BLAC		21M	0		001	PREBLEED			< 600	< 250		
					0		011	INJ 1	CR132	15 MCG				
					29		011	BLEED 1			6201	< 250		
	F	BLAC		23M	0		011	INJ 1	CP298	15 MCG				
	M	CAUC		24M	0		011	INJ 1	CP298	15 MCG				
	F	BLAC		18M	0		011	INJ 1	CR132	15 MCG				
	F	BLAC		21M	0		011	INJ 1	CP749	15 MCG				
	M	BLAC		2Y	0		011	INJ 1	CP749	15 MCG				
	M	BLAC		2Y	0		011	INJ 1	CP749	15 MCG				
	M	CAUC		20M	0		011	INJ 1	CR132	15 MCG				
	F	BLAC		2Y	0		011	INJ 1	CP298	15 MCG				
	M	BLAC		12M	0		011	INJ 1	CR132	15 MCG				
	F	BLAC		12M	0		011	INJ 1	CP298	15 MCG				
	F	CAUC		19M	0		001	PREBLEED			< 600		< 100	< 100
					0		011	INJ 1	CP749	15 MCG				

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	IGG1	CODE/	IGG2	CODE/	IGGM	CODE/IGG TOTAL
(b) (6)	F	CAUC	(b) (6)	19M	29	(b) (6)	011	BLEED 1				2715				3331	987
	F	OTHE		12M	0		011	INJ 1	CP749	15 MCG							
	M	CAUC		14M	0		011	INJ 1	CP749	15 MCG							
	M	CAUC		2Y	0		001	PREBLEED				< 600				110	< 100
					0		011	INJ 1	CP749	15 MCG							
					36		011	BLEED 1				10031				1142	9671
	M	BLAC		2Y	0		011	INJ 1	CR132	15 MCG							
	F	BLAC		16M	0		001	PREBLEED				< 600		< 250		215	< 100
					0		011	INJ 1	CR132	15 MCG							
					35		011	BLEED 1				2727		758		4568	989
	F	CAUC		13M	0		011	INJ 1	CP298	15 MCG							
	M	CAUC		2Y	0		011	INJ 1	CP298	15 MCG							
	F	BLAC		23M	0		011	INJ 1	CP298	15 MCG							
	M	BLAC		22M	0		011	INJ 1	CP749	15 MCG							
	F	HISP		21M	0		011	INJ 1	CP749	15 MCG							
	F	BLAC		24M	0		011	INJ 1	CP298	15 MCG							
	M	CAUC		2Y	0		011	INJ 1	CR132	15 MCG							
	F	BLAC		2Y	0		011	INJ 1	CR132	15 MCG							
	M	HISP		12M	0		011	INJ 1	CP298	15 MCG							
	M	OTHE		14M	0		011	INJ 1	CR132	15 MCG							
	M	BLAC		17M	0		011	INJ 1	CR132	15 MCG							
	M	CAUC		15M	0		011	INJ 1	CP749	15 MCG							
	M	BLAC		23M	0		011	INJ 1	CP749	15 MCG							

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ IGG1	CODE/ IGG2	CODE/ IGGM	CODE/IGG TOTAL
(b) (6)	M	BLAC	(b) (6)	15M	0	(b) (6)	011	INJ 1	CP749	15 MCG				
	M	CAUC		23M	0		011	INJ 1	CP298	15 MCG				
	F	OTHE		24M	0		011	INJ 1	CR132	15 MCG				
	F	OTHE		4Y	0		011	INJ 1	CR132	15 MCG				

TABLE 3
ANTIBODY RESPONSES

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
ASSAY : RIA
LOT NUMBER : CP241
DOSE : 15 MCG
POPULATION : HEALTHY CHILDREN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
1- 6 MOS.	PRE INJ	50 (1/ 2)	0 (0/ 2)			0.203 (2)
	MONTH 2	100 (2/ 2)	50 (1/ 2)	100 (2/ 2)	4.9	1.424 (2)
	MONTH 3	100 (2/ 2)	100 (2/ 2)	100 (2/ 2)	10.8	3.113 (2)
7-11 MOS.	PRE INJ	0 (0/ 2)	0 (0/ 2)			0.063 (2)
	MONTH 2	100 (1/ 1)	100 (1/ 1)	100 (1/ 1)	102.7	12.832 (1)
	MONTH 7-10	100 (2/ 2)	100 (2/ 2)	100 (2/ 2)	17.8	2.219 (2)
12-71 MOS.	PRE INJ	21 (3/ 14)	0 (0/ 14)			0.085 (14)
	MONTH 1	100 (14/ 14)	86 (12/ 14)	100 (14/ 14)	25.0	3.497 (14)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 4

ANTIBODY RESPONSES

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
ASSAY : RIA
LOT NUMBER : CP298
DOSE : 15 MCG
POPULATION : HEALTHY CHILDREN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
1- 6 MOS.	PRE INJ	50 (4/ 8)	0 (0/ 8)			0.125 (8)
	MONTH 2	100 (5/ 5)	80 (4/ 5)	100 (5/ 5)	12.1	2.131 (5)
	MONTH 3	100 (5/ 5)	100 (5/ 5)	100 (5/ 5)	83.6	11.858 (5)
7-11 MOS.	PRE INJ	0 (0/ 4)	0 (0/ 4)			0.062 (4)
	MONTH 2	100 (4/ 4)	75 (3/ 4)	75 (3/ 4)	14.1	1.766 (4)
	MONTH 3	100 (4/ 4)	75 (3/ 4)	100 (4/ 4)	40.1	5.011 (4)
12-71 MOS.	PRE INJ	50 (8/ 16)	0 (0/ 16)			0.135 (16)
	MONTH 1	100 (16/ 16)	94 (15/ 16)	100 (16/ 16)	28.6	5.250 (16)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 5

ANTIBODY RESPONSES

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
ASSAY : RIA
LOT NUMBER : CP749
DOSE : 15 MCG
POPULATION : HEALTHY CHILDREN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
7-11 MOS.	PRE INJ	0 (0/ 1)	0 (0/ 1)			0.063 (1)
	MONTH 3	100 (1/ 1)	100 (1/ 1)	100 (1/ 1)	25.6	3.200 (1)
12-71 MOS.	PRE INJ	25 (1/ 4)	0 (0/ 4)			0.090 (4)
	MONTH 1	100 (4/ 4)	100 (4/ 4)	100 (4/ 4)	47.9	7.259 (4)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 6
ANTIBODY RESPONSES

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
ASSAY : RIA
LOT NUMBER : CR132
DOSE : 15 MCG
POPULATION : HEALTHY CHILDREN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
1- 6 MOS.	PRE INJ	100 (1/ 1)	0 (0/ 1)			0.181 (1)
	MONTH 2	100 (1/ 1)	100 (1/ 1)	100 (1/ 1)	65.7	11.886 (1)
7-11 MOS.	PRE INJ	0 (0/ 1)	0 (0/ 1)			0.063 (1)
	MONTH 2	100 (1/ 1)	100 (1/ 1)	100 (1/ 1)	105.9	13.240 (1)
12-71 MOS.	PRE INJ	50 (1/ 2)	0 (0/ 2)			0.140 (2)
	MONTH 1	100 (2/ 2)	100 (2/ 2)	100 (2/ 2)	102.8	20.358 (2)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 7

ANTIBODY RESPONSES
CHILDREN RANDOMIZED TO CONSISTENCY LOTS - ALL

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
ASSAY : RIA
LOT NUMBER : CP298
DOSE : 15 MCG
POPULATION : HEALTHY CHILDREN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
1- 6 MOS.	PRE INJ	100 (1/ 1)	0 (0/ 1)			0.161 (1)
	MONTH 2	100 (1/ 1)	100 (1/ 1)	100 (1/ 1)	12.2	1.963 (1)
	MONTH 3	100 (1/ 1)	100 (1/ 1)	100 (1/ 1)	12.7	2.040 (1)
7-11 MOS.	PRE INJ	0 (0/ 1)	0 (0/ 1)			0.063 (1)
	MONTH 2	100 (1/ 1)	100 (1/ 1)	100 (1/ 1)	77.3	9.663 (1)
	MONTH 3	100 (1/ 1)	100 (1/ 1)	100 (1/ 1)	79.4	9.921 (1)
12-71 MOS.	PRE INJ	25 (1/ 4)	0 (0/ 4)			0.123 (4)
	MONTH 1	100 (4/ 4)	100 (4/ 4)	100 (4/ 4)	37.6	6.522 (4)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 8

ANTIBODY RESPONSES
CHILDREN RANDOMIZED TO CONSISTENCY LOTS - ALL

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
ASSAY : RIA
LOT NUMBER : CP749
DOSE : 15 MCG
POPULATION : HEALTHY CHILDREN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
1-11 MOS.	PRE INJ	0 (0/ 1)	0 (0/ 1)			0.063 (1)
	MONTH 3	100 (1/ 1)	100 (1/ 1)	100 (1/ 1)	25.6	3.200 (1)
12-71 MOS.	PRE INJ	25 (1/ 4)	0 (0/ 4)			0.090 (4)
	MONTH 1	100 (4/ 4)	100 (4/ 4)	100 (4/ 4)	47.9	7.259 (4)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 9

ANTIBODY RESPONSES
CHILDREN RANDOMIZED TO CONSISTENCY LOTS - ALL

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
ASSAY : RIA
LOT NUMBER : CR132
DOSE : 15 MCG
POPULATION : HEALTHY CHILDREN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
1- 6 MOS.	PRE INJ	100 (1/ 1)	0 (0/ 1)			0.181 (1)
	MONTH 2	100 (1/ 1)	100 (1/ 1)	100 (1/ 1)	65.7	11.886 (1)
7-11 MOS.	PRE INJ	0 (0/ 1)	0 (0/ 1)			0.063 (1)
	MONTH 2	100 (1/ 1)	100 (1/ 1)	100 (1/ 1)	105.9	13.240 (1)
12-71 MOS.	PRE INJ	50 (1/ 2)	0 (0/ 2)			0.140 (2)
	MONTH 1	100 (2/ 2)	100 (2/ 2)	100 (2/ 2)	102.8	20.358 (2)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 10

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	15	
VACCINEES WITH NO COMPLAINTS :	8	(72.7 %)
VACCINEES WITH COMPLAINTS :	3	(27.3 %)
VACCINEES WITH NO DATA :	4	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 11 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	2	18.2
PAIN/SORENESS, INJ. SITE	2	18.2
SWELLING, INJ. SITE (<=1 IN.)	1	9.1
SYSTEMIC REACTIONS	3	27.3
IRRITABILITY	3	27.3
FATIGUE	1	9.1
PROLONGED CRYING, >1/2 HR	1	9.1
TEETHING	1	9.1
WARM TO TOUCH	1	9.1

TABLE 10 (cont.)

C L I N I C A L C O M P L A I N T S B Y F R E Q U E N C Y

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 2	
TOTAL VACCINEES :	14	
VACCINEES WITH NO COMPLAINTS :	5	(62.5 %)
VACCINEES WITH COMPLAINTS :	3	(37.5 %)
VACCINEES WITH NO DATA :	6	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 8 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	3	37.5
PAIN/SORENESS, INJ. SITE	3	37.5
ERYTHEMA, INJ. SITE (<=1 IN.)	1	12.5
SWELLING, INJ. SITE (<=1 IN.)	1	12.5
SYSTEMIC REACTIONS	3	37.5
IRRITABILITY	3	37.5
FATIGUE	1	12.5

TABLE 10 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
POPULATION : HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	29	
VACCINEES WITH NO COMPLAINTS :	13	(52.0 %)
VACCINEES WITH COMPLAINTS :	12	(48.0 %)
VACCINEES WITH NO DATA :	4	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 25 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	7	28.0
PAIN/SORENESS, INJ. SITE	5	20.0
ERYTHEMA, INJ. SITE (<=1 IN.)	3	12.0
SWELLING, INJ. SITE (<=1 IN.)	3	12.0
SYSTEMIC REACTIONS	10	40.0
IRRITABILITY	7	28.0
WARM TO TOUCH	7	28.0
FATIGUE	5	20.0
DIARRHEA	3	12.0
WHEEZING	2	8.0
COUGH	1	4.0
CRYING	1	4.0
GAIT ABNORMALITIES	1	4.0
MYALGIA	1	4.0
NAUSEA	1	4.0
OTITIS MEDIA	1	4.0
PROLONGED CRYING, >1/2 HR	1	4.0
RASH	1	4.0
TEETHING	1	4.0
VOMITING	1	4.0

TABLE 10 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	30	
VACCINEES WITH NO COMPLAINTS :	9	(33.3 %)
VACCINEES WITH COMPLAINTS :	18	(66.7 %)
VACCINEES WITH NO DATA :	3	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 27 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	15	55.6
ERYTHEMA, INJ. SITE (<=1 IN.)	12	44.4
SWELLING, INJ. SITE (<=1 IN.)	5	18.5
PAIN/SORENESS, INJ. SITE	3	11.1
ERYTHEMA, INJ. SITE (>1 INCH)	2	7.4
INDURATION, INJECTION SITE	1	3.7
SWELLING, INJ. SITE (>1 INCH)	1	3.7
SYSTEMIC REACTIONS	14	51.9
IRRITABILITY	7	25.9
FATIGUE	5	18.5
WARM TO TOUCH	4	14.8
TEETHING	2	7.4
UPPER RESPIRATORY INFECTION, NOS	2	7.4
ATOPIC DERMATITIS	1	3.7
DIARRHEA	1	3.7
LARYNGEAL SPASM	1	3.7
RASH	1	3.7
SINUSITIS	1	3.7
WHEEZING	1	3.7

TABLE 10 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 2	
TOTAL VACCINEES :	21	
VACCINEES WITH NO COMPLAINTS :	7	(41.2 %)
VACCINEES WITH COMPLAINTS :	10	(58.8 %)
VACCINEES WITH NO DATA :	4	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 17 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	10	58.8
ERYTHEMA, INJ. SITE (<=1 IN.)	8	47.1
SWELLING, INJ. SITE (<=1 IN.)	4	23.5
PAIN/SORENESS, INJ. SITE	3	17.6
SYSTEMIC REACTIONS	6	35.3
IRRITABILITY	6	35.3
FATIGUE	5	29.4
WARM TO TOUCH	2	11.8
APPETITE INCREASE	1	5.9
RASH	1	5.9
TEETHING	1	5.9

TABLE 10 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
POPULATION : HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	29	
VACCINEES WITH NO COMPLAINTS :	9	(40.9 %)
VACCINEES WITH COMPLAINTS :	13	(59.1 %)
VACCINEES WITH NO DATA :	7	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 22 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	7	31.8
PAIN/SORENESS, INJ. SITE	5	22.7
ERYTHEMA, INJ. SITE (<=1 IN.)	4	18.2
SWELLING, INJ. SITE (<=1 IN.)	3	13.6
SYSTEMIC REACTIONS	12	54.5
IRRITABILITY	6	27.3
FATIGUE	5	22.7
WARM TO TOUCH	5	22.7
COUGH	2	9.1
RASH	2	9.1
ATOPIC DERMATITIS	1	4.5
DIARRHEA	1	4.5
HORDEOLUM	1	4.5
OTITIS MEDIA	1	4.5
PAIN	1	4.5
PROLONGED CRYING, >1/2 HR	1	4.5
TEETHING	1	4.5
URTICARIA	1	4.5
VOMITING	1	4.5
WHEEZING	1	4.5

TABLE 10 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	9	
VACCINEES WITH NO COMPLAINTS :	2	(40.0 %)
VACCINEES WITH COMPLAINTS :	3	(60.0 %)
VACCINEES WITH NO DATA :	4	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 5 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	2	40.0
ERYTHEMA, INJ. SITE (<=1 IN.)	2	40.0
SWELLING, INJ. SITE (<=1 IN.)	1	20.0
SYSTEMIC REACTIONS	1	20.0
IRRITABILITY	1	20.0

TABLE 10 (cont.)

C L I N I C A L C O M P L A I N T S B Y F R E Q U E N C Y

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 2	
TOTAL VACCINEES :	3	
VACCINEES WITH NO COMPLAINTS :	2	(66.7 %)
VACCINEES WITH COMPLAINTS :	1	(33.3 %)
VACCINEES WITH NO DATA :	0	

CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 3 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	1	33.3
ERYTHEMA, INJ. SITE (<=1 IN.)	1	33.3
SYSTEMIC REACTIONS	1	33.3
FATIGUE	1	33.3
IRRITABILITY	1	33.3
WARM TO TOUCH	1	33.3

TABLE 10 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
POPULATION : HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	14	
VACCINEES WITH NO COMPLAINTS :	4	(44.4 %)
VACCINEES WITH COMPLAINTS :	5	(55.6 %)
VACCINEES WITH NO DATA :	5	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 9 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	2	22.2
ERYTHEMA, INJ. SITE (<=1 IN.)	2	22.2
SWELLING, INJ. SITE (<=1 IN.)	2	22.2
INDURATION, INJECTION SITE	1	11.1
SYSTEMIC REACTIONS	5	55.6
IRRITABILITY	2	22.2
ATOPIC DERMATITIS	1	11.1
COUGH	1	11.1
FATIGUE	1	11.1
NASAL DISCHARGE	1	11.1
PROLONGED CRYING, >1/2 HR	1	11.1
RASH	1	11.1
TEETHING	1	11.1
TINEA CORPORIS	1	11.1
UPPER RESPIRATORY INFECTION, NOS	1	11.1
WARM TO TOUCH	1	11.1

TABLE 10 (cont.)

C L I N I C A L C O M P L A I N T S B Y F R E Q U E N C Y

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
LOT NUMBER : CR132
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	10	
VACCINEES WITH NO COMPLAINTS :	3	(37.5 %)
VACCINEES WITH COMPLAINTS :	5	(62.5 %)
VACCINEES WITH NO DATA :	2	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 8 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	4	50.0
ERYTHEMA, INJ. SITE (<=1 IN.)	4	50.0
PAIN/SORENESS, INJ. SITE	1	12.5
SWELLING, INJ. SITE (<=1 IN.)	1	12.5
SYSTEMIC REACTIONS	4	50.0
IRRITABILITY	3	37.5
WARM TO TOUCH	2	25.0
FATIGUE	1	12.5
OTITIS MEDIA	1	12.5
RASH	1	12.5

TABLE 10 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
LOT NUMBER : CR132
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 2	
TOTAL VACCINEES :	5	
VACCINEES WITH NO COMPLAINTS :	0	(0.0 %)
VACCINEES WITH COMPLAINTS :	3	(100.0 %)
VACCINEES WITH NO DATA :	2	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 3 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	0	0.0
SYSTEMIC REACTIONS	3	100.0
DIARRHEA	1	33.3
IRRITABILITY	1	33.3
OTITIS MEDIA	1	33.3
RASH	1	33.3
TEETHING	1	33.3
VOMITING	1	33.3
WARM TO TOUCH	1	33.3

TABLE 10 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
LOT NUMBER : CR132
POPULATION : HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	13	
VACCINEES WITH NO COMPLAINTS :	2	(40.0 %)
VACCINEES WITH COMPLAINTS :	3	(60.0 %)
VACCINEES WITH NO DATA :	8	

CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 5 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	3	60.0
SWELLING, INJ. SITE (<=1 IN.)	2	40.0
ERYTHEMA, INJ. SITE (<=1 IN.)	1	20.0
INDURATION, INJECTION SITE	1	20.0
PAIN/SORENESS, INJ. SITE	1	20.0
SWELLING, INJ. SITE (>1 INCH)	1	20.0
SYSTEMIC REACTIONS	3	60.0
IRRITABILITY	2	40.0
DIARRHEA	1	20.0
GAIT ABNORMALITIES	1	20.0
TEETHING	1	20.0
WARM TO TOUCH	1	20.0

TABLE 11

CLINICAL COMPLAINTS

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (15 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
LOCAL REACTIONS	1 (9.1%)	2 (18.2%)	2 (28.6%)	2 (28.6%)	1 (14.3%)	1 (14.3%)		2 (18.2%)
PAIN/SORENESS, INJ. SITE	1 (9.1%)	2 (18.2%)	1 (14.3%)	1 (14.3%)	0 (0.0%)	0 (0.0%)		2 (18.2%)
SWELLING, INJ. SITE (<=1 IN.)	1 (9.1%)	1 (9.1%)	1 (14.3%)	1 (14.3%)	1 (14.3%)	1 (14.3%)		1 (9.1%)
SYSTEMIC	3 (27.3%)	2 (18.2%)	1 (14.3%)	1 (14.3%)	1 (14.3%)	1 (14.3%)		3 (27.3%)
BODY AS A WHOLE/SITE UNSPEC.	2 (18.2%)	1 (9.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (18.2%)
FATIGUE	1 (9.1%)	1 (9.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (9.1%)
WARM TO TOUCH	1 (9.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (9.1%)
DIGESTIVE SYSTEM	1 (9.1%)	1 (9.1%)	1 (14.3%)	1 (14.3%)	1 (14.3%)	1 (14.3%)		1 (9.1%)
TEETHING	1 (9.1%)	1 (9.1%)	1 (14.3%)	1 (14.3%)	1 (14.3%)	1 (14.3%)		1 (9.1%)
NERVOUS SYSTEM & PSYCHIATRIC	3 (27.3%)	2 (18.2%)	0 (0.0%)	0 (0.0%)	1 (14.3%)	0 (0.0%)		3 (27.3%)
IRRITABILITY	3 (27.3%)	2 (18.2%)	0 (0.0%)	0 (0.0%)	1 (14.3%)	0 (0.0%)		3 (27.3%)

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (15 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
PROLONGED CRYING, >1/2 HR	1 (9.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (9.1%)
VACCINEES WITH COMPLAINTS	3 (27.3%)	3 (27.3%)	2 (28.6%)	2 (28.6%)	2 (28.6%)	2 (28.6%)		3 (27.3%)
VACCINEES WITH NO COMPLAINTS	8 (72.7%)	8 (72.7%)	5 (71.4%)	5 (71.4%)	5 (71.4%)	5 (71.4%)		8 (72.7%)
TOTAL VACCINEES REPORTING	11	11	7	7	7	7		11
VACCINEES WITH NO DATA	4	4	8	8	8	8		4

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (14 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
LOCAL REACTIONS	1 (12.5%)	2 (25.0%)	1 (20.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)		3 (37.5%)
ERYTHEMA, INJ. SITE (<=1 IN.)	1 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (12.5%)
PAIN/SORENESS, INJ. SITE	1 (12.5%)	2 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		3 (37.5%)
SWELLING, INJ. SITE (<=1 IN.)	0 (0.0%)	1 (12.5%)	1 (20.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)		1 (12.5%)
SYSTEMIC	2 (25.0%)	2 (25.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		3 (37.5%)
BODY AS A WHOLE/SITE UNSPEC.	1 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (12.5%)
FATIGUE	1 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (12.5%)
NERVOUS SYSTEM & PSYCHIATRIC	2 (25.0%)	2 (25.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		3 (37.5%)
IRRITABILITY	2 (25.0%)	2 (25.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		3 (37.5%)
VACCINEES WITH COMPLAINTS	2 (25.0%)	3 (37.5%)	2 (40.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)		3 (37.5%)
VACCINEES WITH NO COMPLAINTS	6 (75.0%)	5 (62.5%)	3 (60.0%)	3 (75.0%)	3 (75.0%)	3 (75.0%)		5 (62.5%)

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (14 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
TOTAL VACCINEES REPORTING	8	8	5	4	4	4		8
VACCINEES WITH NO DATA	6	6	9	10	10	10		6

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (29 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
LOCAL REACTIONS	6 (25.0%)	6 (24.0%)	1 (4.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		7 (28.0%)
ERYTHEMA, INJ. SITE (<=1 IN.)	2 (8.3%)	2 (8.0%)	1 (4.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		3 (12.0%)
PAIN/SORENESS, INJ. SITE	4 (16.7%)	4 (16.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		5 (20.0%)
SWELLING, INJ. SITE (<=1 IN.)	1 (4.2%)	3 (12.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		3 (12.0%)
SYSTEMIC	6 (25.0%)	8 (32.0%)	5 (23.8%)	3 (15.8%)	5 (26.3%)	4 (22.2%)		10 (40.0%)
BODY AS A WHOLE/SITE UNSPEC.	4 (16.7%)	4 (16.0%)	4 (19.0%)	2 (10.5%)	3 (15.8%)	0 (0.0%)		7 (28.0%)
FATIGUE	4 (16.7%)	1 (4.0%)	2 (9.5%)	2 (10.5%)	2 (10.5%)	0 (0.0%)		5 (20.0%)
WARM TO TOUCH	3 (12.5%)	3 (12.0%)	4 (19.0%)	1 (5.3%)	1 (5.3%)	0 (0.0%)		7 (28.0%)
DIGESTIVE SYSTEM	2 (8.3%)	3 (12.0%)	1 (4.8%)	1 (5.3%)	2 (10.5%)	2 (11.1%)		4 (16.0%)
DIARRHEA	1 (4.2%)	2 (8.0%)	1 (4.8%)	1 (5.3%)	2 (10.5%)	2 (11.1%)		3 (12.0%)
NAUSEA	0 (0.0%)	1 (4.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (4.0%)

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (29 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5	COMPLAINTS
TEETHING	1 (4.2%)	1 (4.0%)	1 (4.8%)	1 (5.3%)	1 (5.3%)	1 (5.6%)	1 (4.0%)
VOMITING	1 (4.2%)	1 (4.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (4.0%)
MUSCULOSKELETAL SYSTEM	1 (4.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (4.0%)
MYALGIA	1 (4.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (4.0%)
NERVOUS SYSTEM & PSYCHIATRIC	5 (20.8%)	5 (20.0%)	2 (9.5%)	2 (10.5%)	3 (15.8%)	2 (11.1%)	8 (32.0%)
CRYING	1 (4.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (4.0%)
GAIT ABNORMALITIES	1 (4.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (4.0%)
IRRITABILITY	4 (16.7%)	5 (20.0%)	2 (9.5%)	2 (10.5%)	3 (15.8%)	2 (11.1%)	7 (28.0%)
PROLONGED CRYING, >1/2 HR	1 (4.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (4.0%)
RESPIRATORY SYSTEM	0 (0.0%)	1 (4.0%)	2 (9.5%)	2 (10.5%)	1 (5.3%)	2 (11.1%)	3 (12.0%)
COUGH	0 (0.0%)	1 (4.0%)	1 (4.8%)	1 (5.3%)	0 (0.0%)	0 (0.0%)	1 (4.0%)
WHEEZING	0 (0.0%)	0 (0.0%)	1 (4.8%)	1 (5.3%)	1 (5.3%)	2 (11.1%)	2 (8.0%)

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (29 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
SKIN & SKIN APPENDAGE	0 (0.0%)	0 (0.0%)	1 (4.8%)	1 (5.3%)	0 (0.0%)	0 (0.0%)		1 (4.0%)
RASH	0 (0.0%)	0 (0.0%)	1 (4.8%)	1 (5.3%)	0 (0.0%)	0 (0.0%)		1 (4.0%)
SPECIAL SENSES	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (5.6%)		1 (4.0%)
OTITIS MEDIA	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (5.6%)		1 (4.0%)
VACCINEES WITH COMPLAINTS	8 (33.3%)	10 (40.0%)	5 (23.8%)	3 (15.8%)	5 (26.3%)	4 (22.2%)		12 (48.0%)
VACCINEES WITH NO COMPLAINTS	16 (66.7%)	15 (60.0%)	16 (76.2%)	16 (84.2%)	14 (73.7%)	14 (77.8%)		13 (52.0%)
TOTAL VACCINEES REPORTING	24	25	21	19	19	18		25
VACCINEES WITH NO DATA	5	4	8	10	10	11		4

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (30 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5	COMPLAINTS
LOCAL REACTIONS	10 (37.0%)	12 (44.4%)	5 (19.2%)	2 (7.7%)	1 (4.0%)	1 (4.0%)	15 (55.6%)
ERYTHEMA, INJ. SITE (>1 INCH)	0 (0.0%)	1 (3.7%)	1 (3.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (7.4%)
ERYTHEMA, INJ. SITE (<=1 IN.)	9 (33.3%)	8 (29.6%)	2 (7.7%)	1 (3.8%)	0 (0.0%)	0 (0.0%)	12 (44.4%)
INDURATION, INJECTION SITE	0 (0.0%)	0 (0.0%)	1 (3.8%)	1 (3.8%)	1 (4.0%)	1 (4.0%)	1 (3.7%)
PAIN/SORENESS, INJ. SITE	2 (7.4%)	3 (11.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (11.1%)
SWELLING, INJ. SITE (>1 INCH)	1 (3.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.7%)
SWELLING, INJ. SITE (<=1 IN.)	2 (7.4%)	3 (11.1%)	2 (7.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	5 (18.5%)
SYSTEMIC	10 (37.0%)	10 (37.0%)	6 (23.1%)	5 (19.2%)	4 (16.0%)	3 (12.0%)	14 (51.9%)
BODY AS A WHOLE/SITE UNSPEC.	4 (14.8%)	6 (22.2%)	3 (11.5%)	0 (0.0%)	1 (4.0%)	1 (4.0%)	8 (29.6%)
FATIGUE	4 (14.8%)	3 (11.1%)	2 (7.7%)	0 (0.0%)	1 (4.0%)	1 (4.0%)	5 (18.5%)
WARM TO TOUCH	0 (0.0%)	3 (11.1%)	1 (3.8%)	0 (0.0%)	1 (4.0%)	1 (4.0%)	4 (14.8%)

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (30 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
DIGESTIVE SYSTEM	2 (7.4%)	2 (7.4%)	2 (7.7%)	1 (3.8%)	1 (4.0%)	2 (8.0%)		3 (11.1%)
DIARRHEA	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (4.0%)		1 (3.7%)
TEETHING	2 (7.4%)	2 (7.4%)	2 (7.7%)	1 (3.8%)	1 (4.0%)	1 (4.0%)		2 (7.4%)
NERVOUS SYSTEM & PSYCHIATRIC	5 (18.5%)	4 (14.8%)	4 (15.4%)	1 (3.8%)	1 (4.0%)	1 (4.0%)		7 (25.9%)
IRRITABILITY	5 (18.5%)	4 (14.8%)	4 (15.4%)	1 (3.8%)	1 (4.0%)	1 (4.0%)		7 (25.9%)
RESPIRATORY SYSTEM	1 (3.7%)	2 (7.4%)	2 (7.7%)	2 (7.7%)	2 (8.0%)	2 (8.0%)		3 (11.1%)
LARYNGEAL SPASM	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.8%)	1 (4.0%)	1 (4.0%)		1 (3.7%)
SINUSITIS	1 (3.7%)	1 (3.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (3.7%)
UPPER RESPIRATORY INFECTION, NOS	1 (3.7%)	2 (7.4%)	1 (3.8%)	1 (3.8%)	1 (4.0%)	1 (4.0%)		2 (7.4%)
WHEEZING	0 (0.0%)	0 (0.0%)	1 (3.8%)	1 (3.8%)	1 (4.0%)	1 (4.0%)		1 (3.7%)
SKIN & SKIN APPENDAGE	0 (0.0%)	1 (3.7%)	1 (3.8%)	2 (7.7%)	1 (4.0%)	0 (0.0%)		2 (7.4%)
ATOPIC DERMATITIS	0 (0.0%)	1 (3.7%)	1 (3.8%)	1 (3.8%)	0 (0.0%)	0 (0.0%)		1 (3.7%)

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (30 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
RASH	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.8%)	1 (4.0%)	0 (0.0%)		1 (3.7%)
VACCINEES WITH COMPLAINTS	14 (51.9%)	16 (59.3%)	9 (34.6%)	7 (26.9%)	5 (20.0%)	4 (16.0%)		18 (66.7%)
VACCINEES WITH NO COMPLAINTS	13 (48.1%)	11 (40.7%)	17 (65.4%)	19 (73.1%)	20 (80.0%)	21 (84.0%)		9 (33.3%)
TOTAL VACCINEES REPORTING	27	27	26	26	25	25		27
VACCINEES WITH NO DATA	3	3	4	4	5	5		3

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (21 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
LOCAL REACTIONS	7 (41.2%)	9 (52.9%)	4 (26.7%)	3 (20.0%)	2 (13.3%)	0 (0.0%)		10 (58.8%)
ERYTHEMA, INJ. SITE (<=1 IN.)	6 (35.3%)	7 (41.2%)	4 (26.7%)	3 (20.0%)	2 (13.3%)	0 (0.0%)		8 (47.1%)
PAIN/SORENESS, INJ. SITE	3 (17.6%)	3 (17.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		3 (17.6%)
SWELLING, INJ. SITE (<=1 IN.)	2 (11.8%)	3 (17.6%)	1 (6.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		4 (23.5%)
SYSTEMIC	5 (29.4%)	6 (35.3%)	3 (20.0%)	4 (26.7%)	2 (13.3%)	3 (20.0%)		6 (35.3%)
BODY AS A WHOLE/SITE UNSPEC.	5 (29.4%)	2 (11.8%)	3 (20.0%)	1 (6.7%)	0 (0.0%)	1 (6.7%)		5 (29.4%)
FATIGUE	5 (29.4%)	1 (5.9%)	3 (20.0%)	1 (6.7%)	0 (0.0%)	0 (0.0%)		5 (29.4%)
WARM TO TOUCH	0 (0.0%)	1 (5.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (6.7%)		2 (11.8%)
DIGESTIVE SYSTEM	1 (5.9%)	1 (5.9%)	1 (6.7%)	1 (6.7%)	1 (6.7%)	1 (6.7%)		1 (5.9%)
APPETITE INCREASE	1 (5.9%)	1 (5.9%)	1 (6.7%)	1 (6.7%)	1 (6.7%)	1 (6.7%)		1 (5.9%)
TEETHING	1 (5.9%)	1 (5.9%)	1 (6.7%)	1 (6.7%)	1 (6.7%)	1 (6.7%)		1 (5.9%)

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (21 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
NERVOUS SYSTEM & PSYCHIATRIC	4 (23.5%)	6 (35.3%)	3 (20.0%)	2 (13.3%)	1 (6.7%)	1 (6.7%)		6 (35.3%)
IRRITABILITY	4 (23.5%)	6 (35.3%)	3 (20.0%)	2 (13.3%)	1 (6.7%)	1 (6.7%)		6 (35.3%)
SKIN & SKIN APPENDAGE	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (6.7%)	0 (0.0%)	0 (0.0%)		1 (5.9%)
RASH	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (6.7%)	0 (0.0%)	0 (0.0%)		1 (5.9%)
VACCINEES WITH COMPLAINTS	9 (52.9%)	9 (52.9%)	5 (33.3%)	5 (33.3%)	3 (20.0%)	3 (20.0%)		10 (58.8%)
VACCINEES WITH NO COMPLAINTS	8 (47.1%)	8 (47.1%)	10 (66.7%)	10 (66.7%)	12 (80.0%)	12 (80.0%)		7 (41.2%)
TOTAL VACCINEES REPORTING	17	17	15	15	15	15		17
VACCINEES WITH NO DATA	4	4	6	6	6	6		4

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (29 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5	COMPLAINTS
LOCAL REACTIONS	6 (27.3%)	5 (22.7%)	2 (11.1%)	1 (5.6%)	0 (0.0%)	0 (0.0%)	7 (31.8%)
ERYTHEMA, INJ. SITE (<=1 IN.)	3 (13.6%)	1 (4.5%)	2 (11.1%)	1 (5.6%)	0 (0.0%)	0 (0.0%)	4 (18.2%)
PAIN/SORENESS, INJ. SITE	4 (18.2%)	4 (18.2%)	1 (5.6%)	1 (5.6%)	0 (0.0%)	0 (0.0%)	5 (22.7%)
SWELLING, INJ. SITE (<=1 IN.)	2 (9.1%)	1 (4.5%)	1 (5.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (13.6%)
SYSTEMIC	4 (18.2%)	6 (27.3%)	6 (33.3%)	5 (27.8%)	1 (5.6%)	3 (17.6%)	12 (54.5%)
BODY AS A WHOLE/SITE UNSPEC.	3 (13.6%)	3 (13.6%)	4 (22.2%)	2 (11.1%)	0 (0.0%)	1 (5.9%)	7 (31.8%)
FATIGUE	2 (9.1%)	2 (9.1%)	2 (11.1%)	1 (5.6%)	0 (0.0%)	1 (5.9%)	5 (22.7%)
PAIN	1 (4.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (4.5%)
WARM TO TOUCH	2 (9.1%)	3 (13.6%)	2 (11.1%)	1 (5.6%)	0 (0.0%)	0 (0.0%)	5 (22.7%)
DIGESTIVE SYSTEM	0 (0.0%)	1 (4.5%)	1 (5.6%)	1 (5.6%)	0 (0.0%)	1 (5.9%)	3 (13.6%)
DIARRHEA	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (5.9%)	1 (4.5%)

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (29 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5	
TEETHING	0 (0.0%)	0 (0.0%)	1 (5.6%)	1 (5.6%)	0 (0.0%)	0 (0.0%)	1 (4.5%)
VOMITING	0 (0.0%)	1 (4.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (4.5%)
NERVOUS SYSTEM & PSYCHIATRIC	2 (9.1%)	5 (22.7%)	2 (11.1%)	2 (11.1%)	1 (5.6%)	1 (5.9%)	7 (31.8%)
IRRITABILITY	2 (9.1%)	4 (18.2%)	2 (11.1%)	2 (11.1%)	1 (5.6%)	1 (5.9%)	6 (27.3%)
PROLONGED CRYING, >1/2 HR	0 (0.0%)	1 (4.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (4.5%)
RESPIRATORY SYSTEM	1 (4.5%)	1 (4.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (5.9%)	2 (9.1%)
COUGH	1 (4.5%)	1 (4.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (5.9%)	2 (9.1%)
WHEEZING	1 (4.5%)	1 (4.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (4.5%)
SKIN & SKIN APPENDAGE	0 (0.0%)	0 (0.0%)	3 (16.7%)	2 (11.1%)	1 (5.6%)	1 (5.9%)	3 (13.6%)
ATOPIC DERMATITIS	0 (0.0%)	0 (0.0%)	1 (5.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (4.5%)
RASH	0 (0.0%)	0 (0.0%)	2 (11.1%)	2 (11.1%)	1 (5.6%)	1 (5.9%)	2 (9.1%)
URTICARIA	0 (0.0%)	0 (0.0%)	1 (5.6%)	1 (5.6%)	1 (5.6%)	1 (5.9%)	1 (4.5%)

TABLE 11 (cont.)
CLINICAL COMPLAINTS

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (29 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
SPECIAL SENSES	1 (4.5%)	1 (4.5%)	1 (5.6%)	1 (5.6%)	0 (0.0%)	0 (0.0%)		2 (9.1%)
HORDEOLUM	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (5.6%)	0 (0.0%)	0 (0.0%)		1 (4.5%)
OTITIS MEDIA	1 (4.5%)	1 (4.5%)	1 (5.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (4.5%)
VACCINEES WITH COMPLAINTS	8 (36.4%)	9 (40.9%)	6 (33.3%)	5 (27.8%)	1 (5.6%)	3 (17.6%)		13 (59.1%)
VACCINEES WITH NO COMPLAINTS	14 (63.6%)	13 (59.1%)	12 (66.7%)	13 (72.2%)	17 (94.4%)	14 (82.4%)		9 (40.9%)
TOTAL VACCINEES REPORTING	22	22	18	18	18	17		22
VACCINEES WITH NO DATA	7	7	11	11	11	12		7

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (9 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
LOCAL REACTIONS	1 (20.0%)	2 (40.0%)	1 (25.0%)	1 (25.0%)	0 (0.0%)	0 (0.0%)		2 (40.0%)
ERYTHEMA, INJ. SITE (<=1 IN.)	1 (20.0%)	2 (40.0%)	1 (25.0%)	1 (25.0%)	0 (0.0%)	0 (0.0%)		2 (40.0%)
SWELLING, INJ. SITE (<=1 IN.)	1 (20.0%)	1 (20.0%)	1 (25.0%)	1 (25.0%)	0 (0.0%)	0 (0.0%)		1 (20.0%)
SYSTEMIC	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (20.0%)
NERVOUS SYSTEM & PSYCHIATRIC	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (20.0%)
IRRITABILITY	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (20.0%)
VACCINEES WITH COMPLAINTS	2 (40.0%)	2 (40.0%)	1 (25.0%)	1 (25.0%)	0 (0.0%)	0 (0.0%)		3 (60.0%)
VACCINEES WITH NO COMPLAINTS	3 (60.0%)	3 (60.0%)	3 (75.0%)	3 (75.0%)	4 (100.0%)	4 (100.0%)		2 (40.0%)
TOTAL VACCINEES REPORTING	5	5	4	4	4	4		5
VACCINEES WITH NO DATA	4	4	5	5	5	5		4

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (3 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
LOCAL REACTIONS	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (33.3%)
ERYTHEMA, INJ. SITE (<=1 IN.)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (33.3%)
SYSTEMIC	1 (33.3%)	1 (33.3%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (33.3%)
BODY AS A WHOLE/SITE UNSPEC.	1 (33.3%)	1 (33.3%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (33.3%)
FATIGUE	0 (0.0%)	1 (33.3%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (33.3%)
WARM TO TOUCH	1 (33.3%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (33.3%)
NERVOUS SYSTEM & PSYCHIATRIC	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (33.3%)
IRRITABILITY	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (33.3%)
VACCINEES WITH COMPLAINTS	1 (33.3%)	1 (33.3%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (33.3%)
VACCINEES WITH NO COMPLAINTS	2 (66.7%)	2 (66.7%)	2 (66.7%)	3 (100.0%)	3 (100.0%)	3 (100.0%)		2 (66.7%)
TOTAL VACCINEES REPORTING	3	3	3	3	3	3		3

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (3 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
VACCINEES WITH NO DATA	0	0	0	0	0	0		0

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (14 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5	COMPLAINTS
LOCAL REACTIONS	2 (22.2%)	2 (22.2%)	1 (11.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (22.2%)
ERYTHEMA, INJ. SITE (<=1 IN.)	2 (22.2%)	2 (22.2%)	1 (11.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (22.2%)
INDURATION, INJECTION SITE	1 (11.1%)	1 (11.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (11.1%)
SWELLING, INJ. SITE (<=1 IN.)	2 (22.2%)	2 (22.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (22.2%)
SYSTEMIC	3 (33.3%)	3 (33.3%)	3 (33.3%)	4 (44.4%)	3 (33.3%)	3 (33.3%)	5 (55.6%)
BODY AS A WHOLE/SITE UNSPEC.	1 (11.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (11.1%)	0 (0.0%)	2 (22.2%)
FATIGUE	1 (11.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (11.1%)
WARM TO TOUCH	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (11.1%)	0 (0.0%)	1 (11.1%)
DIGESTIVE SYSTEM	0 (0.0%)	0 (0.0%)	1 (11.1%)	1 (11.1%)	1 (11.1%)	1 (11.1%)	1 (11.1%)
TEETHING	0 (0.0%)	0 (0.0%)	1 (11.1%)	1 (11.1%)	1 (11.1%)	1 (11.1%)	1 (11.1%)
NERVOUS SYSTEM & PSYCHIATRIC	1 (11.1%)	2 (22.2%)	0 (0.0%)	1 (11.1%)	0 (0.0%)	0 (0.0%)	3 (33.3%)

TABLE 11 (cont.)
CLINICAL COMPLAINTS

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (14 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		
IRRITABILITY	0 (0.0%)	1 (11.1%)	0 (0.0%)	1 (11.1%)	0 (0.0%)	0 (0.0%)		2 (22.2%)
PROLONGED CRYING, >1/2 HR	1 (11.1%)	1 (11.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (11.1%)
RESPIRATORY SYSTEM	0 (0.0%)	0 (0.0%)	1 (11.1%)	2 (22.2%)	2 (22.2%)	2 (22.2%)		2 (22.2%)
COUGH	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (11.1%)	1 (11.1%)		1 (11.1%)
NASAL DISCHARGE	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (11.1%)	1 (11.1%)	1 (11.1%)		1 (11.1%)
UPPER RESPIRATORY INFECTION, NOS	0 (0.0%)	0 (0.0%)	1 (11.1%)	1 (11.1%)	1 (11.1%)	1 (11.1%)		1 (11.1%)
SKIN & SKIN APPENDAGE	1 (11.1%)	2 (22.2%)	2 (22.2%)	2 (22.2%)	1 (11.1%)	1 (11.1%)		2 (22.2%)
ATOPIC DERMATITIS	0 (0.0%)	1 (11.1%)	1 (11.1%)	1 (11.1%)	1 (11.1%)	1 (11.1%)		1 (11.1%)
RASH	0 (0.0%)	1 (11.1%)	1 (11.1%)	1 (11.1%)	1 (11.1%)	1 (11.1%)		1 (11.1%)
TINEA CORPORIS	1 (11.1%)	1 (11.1%)	1 (11.1%)	1 (11.1%)	0 (0.0%)	0 (0.0%)		1 (11.1%)
VACCINEES WITH COMPLAINTS	4 (44.4%)	4 (44.4%)	3 (33.3%)	4 (44.4%)	3 (33.3%)	3 (33.3%)		5 (55.6%)
VACCINEES WITH NO COMPLAINTS	5 (55.6%)	5 (55.6%)	6 (66.7%)	5 (55.6%)	6 (66.7%)	6 (66.7%)		4 (44.4%)

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (14 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
								**********
TOTAL VACCINEES REPORTING	9	9	9	9	9	9		9
VACCINEES WITH NO DATA	5	5	5	5	5	5		5

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
LOT NUMBER : CR132
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (10 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
LOCAL REACTIONS	2 (25.0%)	3 (37.5%)	1 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		4 (50.0%)
ERYTHEMA, INJ. SITE (<=1 IN.)	2 (25.0%)	3 (37.5%)	1 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		4 (50.0%)
PAIN/SORENESS, INJ. SITE	1 (12.5%)	1 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (12.5%)
SWELLING, INJ. SITE (<=1 IN.)	1 (12.5%)	1 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (12.5%)
SYSTEMIC	3 (37.5%)	2 (25.0%)	1 (12.5%)	1 (12.5%)	2 (25.0%)	1 (12.5%)		4 (50.0%)
BODY AS A WHOLE/SITE UNSPEC.	2 (25.0%)	2 (25.0%)	1 (12.5%)	1 (12.5%)	0 (0.0%)	0 (0.0%)		3 (37.5%)
FATIGUE	1 (12.5%)	1 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (12.5%)
HARM TO TOUCH	1 (12.5%)	1 (12.5%)	1 (12.5%)	1 (12.5%)	0 (0.0%)	0 (0.0%)		2 (25.0%)
NERVOUS SYSTEM & PSYCHIATRIC	2 (25.0%)	1 (12.5%)	1 (12.5%)	1 (12.5%)	0 (0.0%)	0 (0.0%)		3 (37.5%)
IRRITABILITY	2 (25.0%)	1 (12.5%)	1 (12.5%)	1 (12.5%)	0 (0.0%)	0 (0.0%)		3 (37.5%)
SKIN & SKIN APPENDAGE	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (12.5%)	0 (0.0%)		1 (12.5%)

TABLE 11 (cont.)
CLINICAL COMPLAINTS

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
LOT NUMBER : CR132
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (10 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
RASH	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (12.5%)	0 (0.0%)		1 (12.5%)
SPECIAL SENSES	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (12.5%)	1 (12.5%)	1 (12.5%)		1 (12.5%)
OTITIS MEDIA	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (12.5%)	1 (12.5%)	1 (12.5%)		1 (12.5%)
VACCINEES WITH COMPLAINTS	4 (50.0%)	4 (50.0%)	2 (25.0%)	1 (12.5%)	2 (25.0%)	1 (12.5%)		5 (62.5%)
VACCINEES WITH NO COMPLAINTS	4 (50.0%)	4 (50.0%)	6 (75.0%)	7 (87.5%)	6 (75.0%)	7 (87.5%)		3 (37.5%)
TOTAL VACCINEES REPORTING	8	8	8	8	8	8		8
VACCINEES WITH NO DATA	2	2	2	2	2	2		2

TABLE 11 (cont.)
CLINICAL COMPLAINTS

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
LOT NUMBER : CR132
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (5 VACCINEES) - INJECTION: 2						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5	COMPLAINTS
SYSTEMIC	3 (100.0%)	2 (66.7%)	1 (33.3%)	1 (33.3%)	2 (66.7%)	3 (100.0%)	3 (100.0%)
BODY AS A WHOLE/SITE UNSPEC.	1 (33.3%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
WARM TO TOUCH	1 (33.3%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
DIGESTIVE SYSTEM	1 (33.3%)	1 (33.3%)	1 (33.3%)	1 (33.3%)	1 (33.3%)	2 (66.7%)	2 (66.7%)
DIARRHEA	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)	1 (33.3%)
TEETHING	1 (33.3%)	1 (33.3%)	1 (33.3%)	1 (33.3%)	1 (33.3%)	1 (33.3%)	1 (33.3%)
VOMITING	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)	1 (33.3%)
NERVOUS SYSTEM & PSYCHIATRIC	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
IRRITABILITY	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)
SKIN & SKIN APPENDAGE	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)	1 (33.3%)	1 (33.3%)
RASH	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)	1 (33.3%)	1 (33.3%)

TABLE 11 (cont.)
CLINICAL COMPLAINTS

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
LOT NUMBER : CR132
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (5 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
SPECIAL SENSES	0 (0.0%)	1 (33.3%)	1 (33.3%)	1 (33.3%)	1 (33.3%)	1 (33.3%)		1 (33.3%)
OTITIS MEDIA	0 (0.0%)	1 (33.3%)	1 (33.3%)	1 (33.3%)	1 (33.3%)	1 (33.3%)		1 (33.3%)
VACCINEES WITH COMPLAINTS	3 (100.0%)	2 (66.7%)	1 (33.3%)	1 (33.3%)	2 (66.7%)	3 (100.0%)		3 (100.0%)
VACCINEES WITH NO COMPLAINTS	0 (0.0%)	1 (33.3%)	2 (66.7%)	2 (66.7%)	1 (33.3%)	0 (0.0%)		0 (0.0%)
TOTAL VACCINEES REPORTING	3	3	3	3	3	3		3
VACCINEES WITH NO DATA	2	2	2	2	2	2		2

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
LOT NUMBER : CR132
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (13 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5	COMPLAINTS
LOCAL REACTIONS	3 (60.0%)	2 (40.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (60.0%)
ERYTHEMA, INJ. SITE (<=1 IN.)	1 (20.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)
INDURATION, INJECTION SITE	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)
PAIN/SORENESS, INJ. SITE	1 (20.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)
SWELLING, INJ. SITE (>1 INCH)	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)
SWELLING, INJ. SITE (<=1 IN.)	1 (20.0%)	2 (40.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (40.0%)
SYSTEMIC	3 (60.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (60.0%)
BODY AS A WHOLE/SITE UNSPEC.	1 (20.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)
WARM TO TOUCH	1 (20.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)
DIGESTIVE SYSTEM	2 (40.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (40.0%)
DIARRHEA	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
LOT NUMBER : CR132
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (13 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
TEETHING	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (20.0%)
NERVOUS SYSTEM & PSYCHIATRIC	2 (40.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (40.0%)
GAIT ABNORMALITIES	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (20.0%)
IRRITABILITY	2 (40.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (40.0%)
VACCINEES WITH COMPLAINTS	3 (60.0%)	2 (40.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		3 (60.0%)
VACCINEES WITH NO COMPLAINTS	2 (40.0%)	3 (60.0%)	5 (100.0%)	5 (100.0%)	5 (100.0%)	5 (100.0%)		2 (40.0%)
TOTAL VACCINEES REPORTING	5	5	5	5	5	5		5
VACCINEES WITH NO DATA	8	8	8	8	8	8		8

TABLE 12

MAXIMUM TEMPERATURES

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (15 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		MAX TEMP
NORMAL	1 (20.0%)	1 (16.7%)	1 (16.7%)	1 (16.7%)	1 (16.7%)	1 (16.7%)		1 (16.7%)
< 99	3 (60.0%)	4 (66.7%)	4 (66.7%)	5 (83.3%)	5 (83.3%)	5 (83.3%)		2 (33.3%)
99 - 99.9	1 (20.0%)	1 (16.7%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		3 (50.0%)
TEMPERATURE TAKEN	5 (33.3%)	6 (40.0%)	6 (40.0%)	6 (40.0%)	6 (40.0%)	6 (40.0%)		6 (40.0%)
TEMPERATURE NOT TAKEN	10 (66.7%)	9 (60.0%)	9 (60.0%)	9 (60.0%)	9 (60.0%)	9 (60.0%)		9 (60.0%)

TABLE 12 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (14 VACCINEES) - INJECTION 2							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
< 99	2 (66.7%)	3 (75.0%)	4 (100.0%)	4 (100.0%)	4 (100.0%)	4 (100.0%)		3 (75.0%)
99 - 99.9	1 (33.3%)	1 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (25.0%)
TEMPERATURE TAKEN	3 (21.4%)	4 (28.6%)	4 (28.6%)	4 (28.6%)	4 (28.6%)	4 (28.6%)		4 (28.6%)
TEMPERATURE NOT TAKEN	11 (78.6%)	10 (71.4%)	10 (71.4%)	10 (71.4%)	10 (71.4%)	10 (71.4%)		10 (71.4%)

TABLE 12 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE

MAX TEMPERATURE (DEG F, ORAL)	NUMBER OF VACCINEES (29 VACCINEES) - INJECTION 1 — DAYS POST VACCINATION 0	1	2	3	4	5		NUMBER WITH MAX TEMP
< 99	5 (38.5%)	9 (56.3%)	11 (68.8%)	13 (81.3%)	10 (62.5%)	9 (60.0%)		3 (18.8%)
99 - 99.9	6 (46.2%)	6 (37.5%)	5 (31.3%)	2 (12.5%)	4 (25.0%)	6 (40.0%)		10 (62.5%)
100 - 100.9	1 (7.7%)	1 (6.3%)	0 (0.0%)	1 (6.3%)	2 (12.5%)	0 (0.0%)		2 (12.5%)
101 - 101.9	1 (7.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (6.3%)
TEMPERATURE TAKEN	13 (44.8%)	16 (55.2%)	16 (55.2%)	16 (55.2%)	16 (55.2%)	15 (51.7%)		16 (55.2%)
TEMPERATURE NOT TAKEN	16 (55.2%)	13 (44.8%)	13 (44.8%)	13 (44.8%)	13 (44.8%)	14 (48.3%)		13 (44.8%)

TABLE 12 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (30 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
NORMAL	1 (4.2%)	1 (4.0%)	1 (4.3%)	1 (4.5%)	1 (4.3%)	1 (4.2%)		1 (4.0%)
< 99	14 (58.3%)	10 (40.0%)	11 (47.8%)	11 (50.0%)	14 (60.9%)	13 (54.2%)		7 (28.0%)
99 - 99.9	6 (25.0%)	11 (44.0%)	8 (34.8%)	8 (36.4%)	6 (26.1%)	8 (33.3%)		11 (44.0%)
100 - 100.9	3 (12.5%)	3 (12.0%)	3 (13.0%)	2 (9.1%)	2 (8.7%)	1 (4.2%)		5 (20.0%)
101 - 101.9	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (4.2%)		1 (4.0%)
TEMPERATURE TAKEN	24 (80.0%)	25 (83.3%)	23 (76.7%)	22 (73.3%)	23 (76.7%)	24 (80.0%)		25 (83.3%)
TEMPERATURE NOT TAKEN	6 (20.0%)	5 (16.7%)	7 (23.3%)	8 (26.7%)	7 (23.3%)	6 (20.0%)		5 (16.7%)

TABLE 12 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (21 VACCINEES) - INJECTION 2							
	DAYS POST VACCINATION							NUMBER
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		WITH MAX TEMP
< 99	11 (91.7%)	8 (66.7%)	8 (66.7%)	10 (83.3%)	6 (66.7%)	8 (66.7%)		4 (33.3%)
99 - 99.9	1 (8.3%)	4 (33.3%)	4 (33.3%)	2 (16.7%)	3 (33.3%)	4 (33.3%)		8 (66.7%)
TEMPERATURE TAKEN	12 (57.1%)	12 (57.1%)	12 (57.1%)	12 (57.1%)	9 (42.9%)	12 (57.1%)		12 (57.1%)
TEMPERATURE NOT TAKEN	9 (42.9%)	9 (42.9%)	9 (42.9%)	9 (42.9%)	12 (57.1%)	9 (42.9%)		9 (42.9%)

TABLE 12 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (29 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
NORMAL	5 (27.8%)	4 (25.0%)	4 (23.5%)	4 (23.5%)	4 (26.7%)	3 (21.4%)		5 (27.8%)
< 99	9 (50.0%)	8 (50.0%)	9 (52.9%)	9 (52.9%)	10 (66.7%)	9 (64.3%)		6 (33.3%)
99 - 99.9	2 (11.1%)	3 (18.8%)	3 (17.6%)	4 (23.5%)	1 (6.7%)	2 (14.3%)		5 (27.8%)
103 - 103.9	1 (5.6%)	1 (6.3%)	1 (5.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (5.6%)
FEVER	1 (5.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (5.6%)
TEMPERATURE TAKEN	18 (62.1%)	16 (55.2%)	17 (58.6%)	17 (58.6%)	15 (51.7%)	14 (48.3%)		18 (62.1%)
TEMPERATURE NOT TAKEN	11 (37.9%)	13 (44.8%)	12 (41.4%)	12 (41.4%)	14 (48.3%)	15 (51.7%)		11 (37.9%)

TABLE 12 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (9 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
< 99	3 (75.0%)	2 (50.0%)	3 (75.0%)	3 (75.0%)	3 (75.0%)	3 (75.0%)		2 (50.0%)
99 - 99.9	0 (0.0%)	2 (50.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)		1 (25.0%)
100 - 100.9	1 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (25.0%)
TEMPERATURE TAKEN	4 (44.4%)	4 (44.4%)	4 (44.4%)	4 (44.4%)	4 (44.4%)	4 (44.4%)		4 (44.4%)
TEMPERATURE NOT TAKEN	5 (55.6%)	5 (55.6%)	5 (55.6%)	5 (55.6%)	5 (55.6%)	5 (55.6%)		5 (55.6%)

TABLE 12 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (3 VACCINEES) - INJECTION 2							
	DAYS POST VACCINATION							NUMBER WITH
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		MAX TEMP
< 99	1 (50.0%)	1 (50.0%)	1 (50.0%)	1 (50.0%)	1 (50.0%)	1 (50.0%)		1 (50.0%)
99 - 99.9	0 (0.0%)	1 (50.0%)	1 (50.0%)	1 (50.0%)	1 (50.0%)	1 (50.0%)		0 (0.0%)
100 - 100.9	1 (50.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (50.0%)
TEMPERATURE TAKEN	2 (66.7%)	2 (66.7%)	2 (66.7%)	2 (66.7%)	2 (66.7%)	2 (66.7%)		2 (66.7%)
TEMPERATURE NOT TAKEN	1 (33.3%)	1 (33.3%)	1 (33.3%)	1 (33.3%)	1 (33.3%)	1 (33.3%)		1 (33.3%)

TABLE 12 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (14 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
NORMAL	1 (20.0%)	1 (20.0%)	2 (40.0%)	2 (40.0%)	2 (50.0%)	2 (40.0%)		1 (20.0%)
< 99	4 (80.0%)	4 (80.0%)	3 (60.0%)	3 (60.0%)	2 (50.0%)	3 (60.0%)		4 (80.0%)
TEMPERATURE TAKEN	5 (35.7%)	5 (35.7%)	5 (35.7%)	5 (35.7%)	4 (28.6%)	5 (35.7%)		5 (35.7%)
TEMPERATURE NOT TAKEN	9 (64.3%)	9 (64.3%)	9 (64.3%)	9 (64.3%)	10 (71.4%)	9 (64.3%)		9 (64.3%)

TABLE 12 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
LOT NUMBER : CR132
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (10 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
NORMAL	0 (0.0%)	1 (14.3%)	0 (0.0%)	1 (14.3%)	1 (16.7%)	0 (0.0%)		0 (0.0%)
< 99	3 (50.0%)	4 (57.1%)	4 (57.1%)	4 (57.1%)	3 (50.0%)	4 (66.7%)		4 (57.1%)
99 - 99.9	2 (33.3%)	1 (14.3%)	3 (42.9%)	2 (28.6%)	1 (16.7%)	2 (33.3%)		1 (14.3%)
100 - 100.9	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)	0 (0.0%)		1 (14.3%)
101 - 101.9	0 (0.0%)	1 (14.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (14.3%)
TEMPERATURE TAKEN	6 (60.0%)	7 (70.0%)	7 (70.0%)	7 (70.0%)	6 (60.0%)	6 (60.0%)		7 (70.0%)
TEMPERATURE NOT TAKEN	4 (40.0%)	3 (30.0%)	3 (30.0%)	3 (30.0%)	4 (40.0%)	4 (40.0%)		3 (30.0%)

TABLE 12 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
LOT NUMBER : CR132
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (5 VACCINEES) - INJECTION 2							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
< 99	2 (66.7%)	2 (66.7%)	2 (66.7%)	1 (50.0%)	2 (66.7%)	2 (66.7%)		2 (66.7%)
99 - 99.9	1 (33.3%)	1 (33.3%)	1 (33.3%)	1 (50.0%)	1 (33.3%)	1 (33.3%)		1 (33.3%)
TEMPERATURE TAKEN	3 (60.0%)	3 (60.0%)	3 (60.0%)	2 (40.0%)	3 (60.0%)	3 (60.0%)		3 (60.0%)
TEMPERATURE NOT TAKEN	2 (40.0%)	2 (40.0%)	2 (40.0%)	3 (60.0%)	2 (40.0%)	2 (40.0%)		2 (40.0%)

TABLE 12 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : AZIMI, PARVIN H.
STUDY : 000407
VACCINE : HIB CONJUGATE
LOT NUMBER : CR132
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (13 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		MAX TEMP
< 99	2 (50.0%)	3 (75.0%)	4 (100.0%)	4 (100.0%)	4 (100.0%)	4 (100.0%)		2 (50.0%)
99 - 99.9	2 (50.0%)	1 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (50.0%)
TEMPERATURE TAKEN	4 (30.8%)	4 (30.8%)	4 (30.8%)	4 (30.8%)	4 (30.8%)	4 (30.8%)		4 (30.8%)
TEMPERATURE NOT TAKEN	9 (69.2%)	9 (69.2%)	9 (69.2%)	9 (69.2%)	9 (69.2%)	9 (69.2%)		9 (69.2%)

STUDY 004-08

PROGRAM: Haemophilus b Conjugate Vaccine (Neisseria meningitidis Outer Membrane Protein Complex), Study #0004-08.

PURPOSE: To evaluate the safety and immunogenicity of Haemophilus b Conjugate Vaccine (Neisseria meningitidis Outer Membrane Protein Complex) in healthy infants and children 2 months to 5 years of age.

VACCINE: Haemophilus b Conjugate Vaccine (Neisseria meningitidis Outer Membrane Protein Complex).

Lot 1069/C-P241 - (b) (4) mcg polysaccharide/ml
(b) (4) mcg meningococcal protein/ml
Lot 1072/C-P298 - (b) (4) mcg polysaccaride/ml
(b) (4) mcg meningococcal protein/ml
Lot 1080/C-P749 - (b) (4) mcg polysaccharide/ml
(b) (4) mcg meningococcal protein/ml
Lot 1085/C-R132 - (b) (4) mcg polysaccharide/ml
(b) (4) mcg meningococcal protein/ml

Diluent
Aluminum hydroxide diluent
Lot (b) (4)

INVESTIGATOR: Jeffrey Blumer, M.D.
Rainbow Babies and Children's Hospital
2101 Adelbert Road
Cleveland, Ohio 44106

STUDY LOCATION: Rainbow Babies and Children's Hospital
2101 Adelbert Road
Cleveland, Ohio 44106

DATE INITIATED: May 28, 1987

DATE COMPLETED: In progress.

STUDY POPULATION: Healthy infants and children 2 to 71 months of age are included in the study. A subset of infants and children were randomized to receive the three clinical lots of vaccine (1072/C-P298, 1080/C-P749, 1085/C-R132).

STUDY PROCEDURE: Infants 2 to 11 months of age receive 2 injections of the vaccine given 2 months apart, while children 12 months of age and older receive a single injection. Vaccine is reconstituted in aluminum hydroxide and administered by intramuscular route. The dose for each injection is 15 mcg polysaccharide in the appropriate volume - 0.75 ml for Lot 1069/C-P241 and 0.5 ml for Lots 1072/C-P298, 1080/C-P749, and 1085/C-R132.

Parents or guardians are required to record the vaccinee's temperature and any systemic or injection site reactions for 5 days after each injection. Unexpected or serious reactions are to be reported immediately to the study physician.

A blood sample is obtained immediately before each injection and one month after the last (or only) injection. Additional samples are obtained 7 to 10 months after the last injection for infants 2 to 11 months of age and at 15 to 18 months postvaccination for children 12 to 71 months of age.

All serum samples are assayed by Merck Sharp & Dohme Research Laboratories for antibody to H. influenzae type b capsular polysaccharide by radioimmunoassay (RIA). Selected samples are also tested for serum bactericidal activity, quantitation of IgG_1 and IgG_2 subclass, and IgM and total IgG antibodies. Testing for opsonophagocytic activity was done at the University of Alabama.

RESULTS: Demographic information and individual pre and postvaccination antibody data for each vaccinee enrolled in the study is reported in Tables 1 and 2.

1. Number Vaccinated:

Lot	Age	Injection No. 1	Injection No. 2
1069/C-P241	2-11 mo.	7	7
	12-71 mo.	25	--
1072/C-P298	2-11 mo.	13	11
	12-71 mo.	47	--
1080/C-P749	2-11 mo.	5	4
	12-71 mo.	10	--
1085/C-R132	2-11 mo.	5	5
	12-71 mo.	10	--

Children randomized to receive the clinical lots were assigned case numbers (b) (6) .

2. Serologic Results

Antibody responses (RIA) prior to and after vaccination are as follows:

Age	Time	% With Anti-PRP >0.15 mcg Ab/ml	% With Anti-PRP >1.0 mcg Ab/ml	GMT (mcg Ab/ml) All Vaccinees
2-11 mo.	Pre	32 (6/19)	0 (0/19)	0.10
	2 mo.	100 (19/19)	84 (16/19)	3.34
	3 mo.	100 (17/17)	100 (17/17)	6.18
12-71 mo.	Pre	46 (34/74)	9 (7/74)	0.17
	1 mo.	100 (74/74)	96 (71/74)	12.09

Antibody responses (by lot per age group) prior to vaccination through 10 months postvaccination are included in Tables 3-6. Responses for children randomized to receive the clinical lots are shown in Tables 7-9.

RESULTS: (CONT.)

3. Clinical Results:

The frequencies of selected injection site and systemic reactions during the 48 hours after vaccination are as follows:

	% Vaccinees with Reactions		
	2 - 11 Months of Age		12 - 71 Months of Age
Type of Reaction	Injection 1	Injection 2	Injection 1
Injection Site			
Erythema >1 inch	3.8 (1/26)	8.3 (2/24)	0.0 (0/87
Swelling >1 inch	3.8 (1/26)	0.0 (0/24)	1.1 (1/87)
Pain/Soreness	7.7 (2/26)	8.3 (2/24)	18.4 (16/87)
Systemic			
Irritability	26.9 (7/26)	12.5 (3/24)	13.8 (12/87)
Sleepiness/ Lethargy/Fatigue	34.6 (9/26)	20.8 (5/24)	8.0 (7/87)

Reaction frequencies and maximum temperatures recorded during the five days following each injection of vaccine are reported in Tables 10-12.

No serious or alarming reactions attributable to the vaccine were reported.

TABLE 1

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	CAUC	(b) (6)	10M	0	(b) (6)	001	PREBLEED				< 125		< 5		
					0		011	INJ 1	CP241	15 MCG						
					64		011	BLEED 1				11741		40		
					64		021	INJ 2	CP241	15 MCG						
					92		021	BLEED 2				24754		40		
					273		071	BLEED 3				8703				
	M	CAUC		8M	0		001	PREBLEED				165		< 5		
					0		011	INJ 1	CP241	15 MCG						
					62		011	BLEED 1				248		< 5		
					62		021	INJ 2	CP241	15 MCG						
					102		021	BLEED 2				3070		20		
	M	CAUC		9M	0		001	PREBLEED				< 125		< 5		
					0		011	INJ 1	CP241	15 MCG						
					62		011	BLEED 1				12983		10		
					62		021	INJ 2	CP241	15 MCG						
					94		021	BLEED 2				38523		20		
	M	CAUC		7M	0		001	PREBLEED				< 125		< 5		
					0		011	INJ 1	CP241	15 MCG						
					63		011	BLEED 1				4632		20		
					63		021	INJ 2	CP241	15 MCG						
					92		021	BLEED 2				5734		40		
	F	OTHE		5M	0		001	PREBLEED				144				
					0		011	INJ 1	CP241	15 MCG						
					54		011	BLEED 1				12081				
					54		021	INJ 2	CP241	15 MCG						
					84		021	BLEED 2				13585				
	M	BLAC		5M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP241	15 MCG						
					59		011	BLEED 1				6086				
					59		021	INJ 2	CP241	15 MCG						
	F	CAUC		3M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP241	15 MCG						
					61		011	BLEED 1				2099				
					61		021	INJ 2	CP241	15 MCG						

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	F	CAUC	(b) (6)	3M	91	(b) (6)	021	BLEED 2				4057				
	M	BLAC		9M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP298	15 MCG						
					70		011	BLEED 1				2907				
					70		021	INJ 2	CP298	15 MCG						
					91		021	BLEED 2				4096				
	F	BLAC		10M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP298	15 MCG						
					69		011	BLEED 1				2577				
					69		021	INJ 2	CP298	15 MCG						
					102		021	BLEED 2				1743				
	F	CAUC		11M	0		001	PREBLEED				< 125				0
					0		011	INJ 1	CP298	15 MCG						
					43		011	BLEED 1				3386				100
	F	CAUC		7M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP298	15 MCG						
					67		011	BLEED 1				896				
					67		021	INJ 2	CP298	15 MCG						
					94		021	BLEED 2				1120				
	M	BLAC		2M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP298	15 MCG						
					65		011	BLEED 1				3607				
					65		021	INJ 2	CP298	15 MCG						
					100		021	BLEED 2				7507				
	F	CAUC		6M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP298	15 MCG						
					85		011	BLEED 1			05/	3230				
					85		021	INJ 2	CP298	15 MCG						
					120		021	BLEED 2			05/	3153				
	F	CAUC		2M	0		001	PREBLEED				236				
					0		011	INJ 1	CP298	15 MCG						
					67		011	BLEED 1				2860				
					67		021	INJ 2	CP298	15 MCG						

005500

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	F	CAUC	(b) (6)	2M	102	(b) (6)	021	BLEED	2			2512				
	M	BLAC		11M	0		011	INJ	1 CP298	15 MCG						
	M	BLAC		9M	0		011	INJ	1 CP749	15 MCG						
	F	BLAC		8M	0		011	INJ	1 CP298	15 MCG						
					63		021	INJ	2 CP298	15 MCG						
	M	BLAC		9M	0		011	INJ	1 CR132	15 MCG						
					62		021	INJ	2 CR132	15 MCG						
	M	BLAC		9M	0		011	INJ	1 CP298	15 MCG						
					59		021	INJ	2 CP298	15 MCG						
	F	BLAC		5M	0		011	INJ	1 CP749	15 MCG						
					61		021	INJ	2 CP749	15 MCG						
	F	BLAC		9M	0		011	INJ	1 CR132	15 MCG						
					65		021	INJ	2 CR132	15 MCG						
	M	BLAC		9M	0		001	PREBLEED				125				
					0		011	INJ	1 CR132	15 MCG						
					56		011	BLEED	1			4266				
					56		021	INJ	2 CR132	15 MCG						
	F	BLAC		4M	0		001	PREBLEED				< 125				
					0		011	INJ	1 CP749	15 MCG						
					62		011	BLEED	1			603				
					62		021	INJ	2 CP749	15 MCG						
					91		021	BLEED	2			1868				
	F	BLAC		9M	0		001	PREBLEED				< 125				
					0		011	INJ	1 CP298	15 MCG						
					56		011	BLEED	1			5240				
					56		021	INJ	2 CP298	15 MCG						
					92		021	BLEED	2			12430				
	M	BLAC		9M	0		001	PREBLEED				167				
					0		011	INJ	1 CP298	15 MCG						

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	BLAC	(b) (6)	9M	62	(b) (6)	011	BLEED 1				2914				
					62		021	INJ 2	CP298	15 MCG						
					92		021	BLEED 2				8961				
	M	BLAC		11M	0		001	PREBLEED				273				
					0		011	INJ 1	CP298	15 MCG						
					74		011	BLEED 1			05/	11325				
					74		021	INJ 2	CP298	15 MCG						
	F	BLAC		8M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP749	15 MCG						
					73		011	BLEED 1			05/	2300				
					73		021	INJ 2	CP749	15 MCG						
					109		021	BLEED 2			05/	29767				
	M	BLAC		2M	0		001	PREBLEED				170		< 2		
					0		011	INJ 1	CR132	15 MCG						
					68		011	BLEED 1				1008		< 2		
					68		021	INJ 2	CR132	15 MCG						
					101		021	BLEED 2				4449		< 8		
	M	CAUC		2M	0		001	PREBLEED				251		< 2		
					0		011	INJ 1	CR132	15 MCG						
					70		011	BLEED 1				19885		8		
					70		021	INJ 2	CR132	15 MCG						
					98		021	BLEED 2				22158		>= 32		
	M	BLAC		11M	0		001	PREBLEED				259				
					0		011	INJ 1	CP749	15 MCG						
					61		011	BLEED 1				6155				
					61		021	INJ 2	CP749	15 MCG						
					98		021	BLEED 2				9638				

29500

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	F	CAUC	(b) (6)	12M	0	(b) (6)	001	PREBLEED				< 125		< 2		
					0		011	INJ 1	CP241	15 MCG						
					28		011	BLEED 1				1210		< 2		
	M	CAUC		4Y	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP241	15 MCG						
					30		011	BLEED 1				130105				
	M	CAUC		16M	0		001	PREBLEED				< 125		< 5		
					0		011	INJ 1	CP241	15 MCG						
					30		011	BLEED 1				1678		20		
	F	CAUC		2Y	0		001	PREBLEED				365				
					0		011	INJ 1	CP241	15 MCG						
					31		011	BLEED 1				237041				
	F	CAUC		17M	0		001	PREBLEED				< 125		< 5		
					0		011	INJ 1	CP241	15 MCG						
					30		011	BLEED 1				3649		>= 80		
	M	CAUC		12M	0		001	PREBLEED				< 125		< 5		
					0		011	INJ 1	CP241	15 MCG						
					32		011	BLEED 1				5339		20		
	F	CAUC		23M	0		001	PREBLEED				158				
					0		011	INJ 1	CP241	15 MCG						
					30		011	BLEED 1				20657				
	F	BLAC		2Y	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP241	15 MCG						
					29		011	BLEED 1				32086				
	F	BLAC		2Y	0		001	PREBLEED				137				
					0		011	INJ 1	CP241	15 MCG						
					29		011	BLEED 1				19985				
	F	BLAC		2Y	0		001	PREBLEED				781				
					0		011	INJ 1	CP241	15 MCG						
					29		011	BLEED 1				12951				
	M	BLAC		13M	0		001	PREBLEED				< 125		< 5		

00563

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	BLAC	(b) (6)	13M	0	(b) (6)	011	INJ	1	CP241	15 MCG					
					29		011	BLEED	1			322		< 5		
	M	BLAC		14M	0		001	PREBLEED				6536		< 5		
					0		011	INJ	1	CP241	15 MCG					
					29		011	BLEED	1			22214		20		
	M	CAUC		15M	0		001	PREBLEED				188		< 5		
					0		011	INJ	1	CP241	15 MCG					
					31		011	BLEED	1			46557		160		
	F	BLAC		24M	0		001	PREBLEED				< 125		< 5		
					0		011	INJ	1	CP241	15 MCG					
					28		011	BLEED	1			8991		40		
	M	BLAC		2Y	0		001	PREBLEED				< 125		< 5		
					0		011	INJ	1	CP241	15 MCG					
					29		011	BLEED	1			52345		320		
	F	BLAC		24M	0		001	PREBLEED				281		5		
					0		011	INJ	1	CP241	15 MCG					
					28		011	BLEED	1			63684		320		
	M	BLAC		2Y	0		001	PREBLEED				< 125		< 5		
					0		011	INJ	1	CP241	15 MCG					
					30		011	BLEED	1			144907		320		
	M	BLAC		5Y	0		001	PREBLEED				237				
					0		011	INJ	1	CP241	15 MCG					
					35		011	BLEED	1			26537				
	F	BLAC		15M	0		001	PREBLEED				< 125		< 5		
					0		011	INJ	1	CP241	15 MCG					
					31		011	BLEED	1			23180		80		
	F	BLAC		3Y	0		001	PREBLEED				2020		10		
					0		011	INJ	1	CP241	15 MCG					
					44		011	BLEED	1			171502		320		
	F	BLAC		2Y	0		001	PREBLEED				< 125		< 5		

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ RIA	CODE/ SBA	CODE/ OPSO
(b) (6)	F	BLAC	(b) (6)	2Y	0	(b) (6)	011	INJ	1	CP241	15 MCG		
					29		D11	BLEED	1		42010	160	
	F	BLAC		4Y	0		001	PREBLEED			6117		
					0		011	INJ	1	CP241	15 MCG		
					31		011	BLEED	1		18104		
	M	CAUC		2Y	0		001	PREBLEED			< 125	< 5	
					0		011	INJ	1	CP241	15 MCG		
					28		011	BLEED	1		5142	20	
	M	BLAC		2Y	0		001	PREBLEED			< 125	< 5	
					0		011	INJ	1	CP241	15 MCG		
					30		011	BLEED	1		93940	320	
	F	BLAC		2Y	0		001	PREBLEED			< 125		
					0		011	INJ	1	CP241	15 MCG		
					29		011	BLEED	1		89267		
	F	CAUC		15M	0		001	PREBLEED			< 125	< 5	
					0		011	INJ	1	CP298	15 MCG		
					28		011	BLEED	1		5114	5	
	F	BLAC		2Y	0		001	PREBLEED			< 125	5	
					0		011	INJ	1	CP298	15 MCG		
					29		011	BLEED	1		421	80	
	F	CAUC		5Y	0		001	PREBLEED			10791		
					0		011	INJ	1	CP298	15 MCG		
					32		011	BLEED	1		516560		
	M	BLAC		22M	0		001	PREBLEED			< 125	< 5	
					0		011	INJ	1	CP298	15 MCG		
					34		011	BLEED	1		1720	>= 80	
	M	BLAC		13M	0		001	PREBLEED			163	< 5	
					0		011	INJ	1	CP298	15 MCG		
					28		D11	BLEED	1		4336	20	
	F	CAUC		13M	0		001	PREBLEED			< 125	< 5	

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ RIA	CODE/ SBA	CODE/ OPSO
(b) (6)	F	CAUC	(b) (6)	13M	0	(b) (6)	011	INJ 1	CP298	15 MCG			
					31		011	BLEED 1			25045	20	
	F	BLAC		2Y	0		001	PREBLEED			386	< 5	
					0		011	INJ 1	CP298	15 MCG			
					30		011	BLEED 1			2025	5	
	F	CAUC		4Y	0		001	PREBLEED			1367		
					0		011	INJ 1	CP298	15 MCG			
					29		011	BLEED 1			91990		
	F	CAUC		24M	0		001	PREBLEED			< 125		
					0		011	INJ 1	CP298	15 MCG			
					29		011	BLEED 1			24975		
	F	BLAC		2Y	0		001	PREBLEED			613		24
					0		011	INJ 1	CP298	15 MCG			
					35		011	BLEED 1			13900		89
	F	BLAC		12M	0		001	PREBLEED			< 125	< 5	14
					0		011	INJ 1	CP298	15 MCG			
					39		011	BLEED 1			3695	20	100
	F	BLAC		2Y	0		001	PREBLEED			425		39
					0		011	INJ 1	CP298	15 MCG			
					30		011	BLEED 1			22400		93
	M	BLAC		15M	0		001	PREBLEED			227	< 5	0
					0		011	INJ 1	CP298	15 MCG			
					30		011	BLEED 1			49640	>= 80	95
	M	BLAC		24M	0		001	PREBLEED			< 125		20
					0		011	INJ 1	CP298	15 MCG			
					36		011	BLEED 1			19816		92
	M	BLAC		2Y	0		001	PREBLEED			301		5
					0		011	INJ 1	CP298	15 MCG			
					35		011	BLEED 1			945		100
					168		071	BLEED 2			587		
	M	BLAC		4Y	0		011	INJ 1	CP298	15 MCG			

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	BLAC	(b) (6)	21M	0	(b) (6)	001	PREBLEED				< 125				13
					0		011	INJ 1	CP298	15 MCG						
					28		011	BLEED 1				87474				100
	M	BLAC		14M	0		001	PREBLEED				354		< 5		19
					0		011	INJ 1	CP298	15 MCG						
					27		011	BLEED 1				1821		20		81
	M	BLAC		20M	0		001	PREBLEED				818				26
					0		011	INJ 1	CP298	15 MCG						
					28		011	BLEED 1				5904				66
	F	BLAC		20M	0		001	PREBLEED				152				25
					0		011	INJ 1	CP298	15 MCG						
					28		011	BLEED 1				58881				96
	M	BLAC		14M	0		001	PREBLEED				160				
					0		011	INJ 1	CP298	15 MCG						
					38		011	BLEED 1				11160				
	F	BLAC		24M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP298	15 MCG						
					30		011	BLEED 1				2588				
	F	BLAC		24M	0		001	PREBLEED				146				15
					0		011	INJ 1	CP298	15 MCG						
					29		011	BLEED 1				8158				98
	M	BLAC		15M	0		001	PREBLEED				< 125		< 5		34
					0		011	INJ 1	CP298	15 MCG						
					31		011	BLEED 1				3994		>= 80		92
	M	BLAC		24M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP298	15 MCG						
					33		011	BLEED 1				1480				
	F	BLAC		15M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP298	15 MCG						
					31		011	BLEED 1				4984				
	M	CAUC		24M	0		011	INJ 1	CP298	15 MCG						

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	BLAC	(b) (6)	20M	0	(b) (6)	001	PREBLEED				477				
					0		011	INJ 1	CP298	15 MCG						
					39		011	BLEED 1				4784				
	F	BLAC		2Y	0		001	PREBLEED				129				
					0		011	INJ 1	CP298	15 MCG						
					31		011	BLEED 1				2822				
	F	BLAC		2Y	0		001	PREBLEED				320				
					0		011	INJ 1	CP298	15 MCG						
					31		011	BLEED 1				14443				
	F	BLAC		19M	0		011	INJ 1	CP298	15 MCG						
	F	BLAC		19M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP298	15 MCG						
					31		011	BLEED 1				13669				
	F	BLAC		12M	0		001	PREBLEED				132				
					0		011	INJ 1	CP298	15 MCG						
					27		011	BLEED 1				10729				
	M	BLAC		2Y	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP298	15 MCG						
					31		011	BLEED 1				13909				
	M	BLAC		24M	0		001	PREBLEED				225				
					0		011	INJ 1	CP298	15 MCG						
					38		011	BLEED 1				27152				
	F	BLAC		3Y	0		001	PREBLEED				2944				
					0		011	INJ 1	CP298	15 MCG						
					34		011	BLEED 1				9261				
	M	BLAC		18M	0		001	PREBLEED				349		< 5		0
					0		011	INJ 1	CP749	15 MCG						
					31		011	BLEED 1				17744		20		100
	M	BLAC		23M	0		011	INJ 1	CP298	15 MCG						
	M	BLAC		16M	0		001	PREBLEED				193		< 5		

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ RIA	CODE/ SBA	CODE/ OPSO
(b) (6)	M	BLAC	(b) (6)	16M	0	(b) (6)	011	INJ 1	CP749	15 MCG			
					31		011	BLEED 1			2266	20	
	F	BLAC		22M	0		001	PREBLEED			320	< 5	21
					0		011	INJ 1	CR132	15 MCG			
					31		011	BLEED 1			78166	>= 80	100
	F	BLAC		22M	0		011	INJ 1	CR132	15 MCG			
	M	BLAC		24M	0		001	PREBLEED			1288	20	
					0		011	INJ 1	CP298	15 MCG			
					34		011	BLEED 1			2564	>= 80	
	M	BLAC		13M	0		001	PREBLEED			372		
					0		011	INJ 1	CP298	15 MCG			
					44		011	BLEED 1			3824		
	F	BLAC		16M	0		001	PREBLEED			< 125	< 5	
					0		011	INJ 1	CP749	15 MCG			
					36		011	BLEED 1			7751	>= 80	
	M	BLAC		4Y	0		001	PREBLEED			459	< 5	28
					0		011	INJ 1	CR132	15 MCG			
					31		011	BLEED 1			88250	>= 80	88
	F	BLAC		20M	0		011	INJ 1	CR132	15 MCG			
	F	BLAC		22M	0		001	PREBLEED			< 125	< 5	
					0		011	INJ 1	CP749	15 MCG			
					28		011	BLEED 1			1337	>= 80	
	F	BLAC		13M	0		001	PREBLEED			149		
					0		011	INJ 1	CP298	15 MCG			
					30		011	BLEED 1			7054		
	F	BLAC		12M	0		001	PREBLEED			239		
					0		011	INJ 1	CP298	15 MCG			
					33		011	BLEED 1			4263		
	F	BLAC		2Y	0		011	INJ 1	CR132	15 MCG			

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	BLAC	(b) (6)	2Y	0	(b) (6)	001	PREBLEED				< 125		< 5		35
					0		011	INJ 1	CP749	15 MCG						
					39		011	BLEED 1				5380		20		94
	F	BLAC		12M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP298	15 MCG						
					38		011	BLEED 1				14719				
	M	BLAC		2Y	0		001	PREBLEED				175		< 5		
					0		011	INJ 1	CP749	15 MCG						
					45		011	BLEED 1				31950		>= 80		
	M	BLAC		13M	0		001	PREBLEED				< 125		< 5		
					0		011	INJ 1	CR132	15 MCG						
					33		011	BLEED 1				1233		20		
	F	BLAC		2Y	0		001	PREBLEED				< 125		< 5		
					0		011	INJ 1	CR132	15 MCG						
					23		011	BLEED 1				31181				
	F	BLAC		3Y	0		011	INJ 1	CR132	15 MCG						
	M	BLAC		21M	0		001	PREBLEED				464		< 5		
					0		011	INJ 1	CP749	15 MCG						
					28		011	BLEED 1				36922		>= 80		
	M	BLAC		12M	0		011	INJ 1	CP749	15 MCG						
	M	BLAC		2Y	0		011	INJ 1	CP298	15 MCG						
	M	CAUC		24M	0		011	INJ 1	CP298	15 MCG						
	F	BLAC		5Y	0		011	INJ 1	CR132	15 MCG						
	F	CAUC		24M	0		011	INJ 1	CP749	15 MCG						
	F	BLAC		12M	0		011	INJ 1	CP749	15 MCG						
	F	BLAC		2Y	0		011	INJ 1	CP298	15 MCG						
	M	BLAC		2Y	0		011	INJ 1	CP298	15 MCG						

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	F	BLAC	(b) (6)	2Y	0	(b) (6)	011	INJ	1	CR132	15 MCG					
	F	BLAC		12M	0		011	INJ	1	CP298	15 MCG					

TABLE 2

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ IGG1	CODE/ IGG2	CODE/ IGGM	CODE/IGG TOTAL
(b) (6)	M	CAUC	(b) (6)	10M	0	(b) (6)	011	INJ 1	CP241	15 MCG				
					64		021	INJ 2	CP241	15 MCG				
	M	CAUC		8M	0		011	INJ 1	CP241	15 MCG				
					62		021	INJ 2	CP241	15 MCG				
	M	CAUC		9M	0		011	INJ 1	CP241	15 MCG				
					62		021	INJ 2	CP241	15 MCG				
	M	CAUC		7M	0		011	INJ 1	CP241	15 MCG				
					63		021	INJ 2	CP241	15 MCG				
	F	OTHE		5M	0		011	INJ 1	CP241	15 MCG				
					54		021	INJ 2	CP241	15 MCG				
	M	BLAC		5M	0		011	INJ 1	CP241	15 MCG				
					59		021	INJ 2	CP241	15 MCG				
	F	CAUC		3M	0		011	INJ 1	CP241	15 MCG				
					61		021	INJ 2	CP241	15 MCG				
	M	BLAC		9M	0		011	INJ 1	CP298	15 MCG				
					70		021	INJ 2	CP298	15 MCG				
	F	BLAC		10M	0		011	INJ 1	CP298	15 MCG				
					69		021	INJ 2	CP298	15 MCG				
	F	CAUC		11M	0		001	PREBLEED			< 600		< 100	< 100
					0		011	INJ 1	CP298	15 MCG				
					43		011	BLEED 1			2113		496	511
	F	CAUC		7M	0		011	INJ 1	CP298	15 MCG				
					67		021	INJ 2	CP298	15 MCG				
	M	BLAC		2M	0		011	INJ 1	CP298	15 MCG				
					65		021	INJ 2	CP298	15 MCG				
	F	CAUC		6M	0		011	INJ 1	CP298	15 MCG				
					85		021	INJ 2	CP298	15 MCG				
	F	CAUC		2M	0		011	INJ 1	CP298	15 MCG				

27500 00572

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT		LOT	DOSE	CODE/ IGG1	CODE/ IGG2	CODE/ IGGM	CODE/IGG TOTAL
(b) (6)	F	CAUC	(b) (6)	2M	67	(b) (6)	021	INJ	2	CP298	15 MCG				
	M	BLAC		11M	0		011	INJ	1	CP298	15 MCG				
	M	BLAC		9M	0		011	INJ	1	CP749	15 MCG				
	F	BLAC		8M	0		011	INJ	1	CP298	15 MCG				
					63		021	INJ	2	CP298	15 MCG				
	M	BLAC		9M	0		011	INJ	1	CR132	15 MCG				
					62		021	INJ	2	CR132	15 MCG				
	M	BLAC		9M	0		011	INJ	1	CP298	15 MCG				
					59		021	INJ	2	CP298	15 MCG				
	F	BLAC		5M	0		011	INJ	1	CP749	15 MCG				
					61		021	INJ	2	CP749	15 MCG				
	F	BLAC		9M	0		011	INJ	1	CR132	15 MCG				
					65		021	INJ	2	CR132	15 MCG				
	M	BLAC		9M	0		001	PREBLEED				< 100		< 100	
					0		011	INJ	1	CR132	15 MCG				
					56		011	BLEED	1			244		< 100	
					56		021	INJ	2	CR132	15 MCG				
	F	BLAC		4M	0		011	INJ	1	CP749	15 MCG				
					62		021	INJ	2	CP749	15 MCG				
	F	BLAC		9M	0		011	INJ	1	CP298	15 MCG				
					56		021	INJ	2	CP298	15 MCG				
	M	BLAC		9M	0		011	INJ	1	CP298	15 MCG				
					62		021	INJ	2	CP298	15 MCG				
	M	BLAC		11M	0		011	INJ	1	CP298	15 MCG				
					74		021	INJ	2	CP298	15 MCG				
	F	BLAC		8M	0		011	INJ	1	CP749	15 MCG				
					73		021	INJ	2	CP749	15 MCG				

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	IGG1	CODE/	IGG2	CODE/	IGGM	CODE/	IGG TOTAL
(b) (6)	M	BLAC	(b) (6)	2M	0	(b) (6)	001	PREBLEED								< 100		< 100
					0		011	INJ 1	CR132	15 MCG								
					68		011	BLEED 1								< 100		109
					68		021	INJ 2	CR132	15 MCG								
					101		021	BLEED 2								< 100	01/	QNS
	M	CAUC		2M	0		001	PREBLEED				< 600		< 250		< 100		< 100
					0		011	INJ 1	CR132	15 MCG								
					70		011	BLEED 1				28304		< 250		366		1432
					70		021	INJ 2	CR132	15 MCG								
					98		021	BLEED 2				27149		< 250		733		6326
	M	BLAC		11M	0		001	PREBLEED				< 600				< 100		< 100
					0		011	INJ 1	CP749	15 MCG								
					61		011	BLEED 1				5768				443		839
					61		021	INJ 2	CP749	15 MCG								
					98		021	BLEED 2				16033				< 100		2061

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ IGG1	CODE/ IGG2	CODE/ IGGM	CODE/IGG TOTAL
(b) (6)	F	CAUC	(b) (6)	12M	0	(b) (6)	011	INJ 1	CP241	15 MCG				
	M	CAUC		4Y	0		001	PREBLEED			< 600		< 100	< 100
					0		011	INJ 1	CP241	15 MCG				
					30		011	BLEED 1			98693		4930	27827
	M	CAUC		16M	0		001	PREBLEED			< 600		< 100	< 100
					0		011	INJ 1	CP241	15 MCG				
					30		011	BLEED 1			1544		121	182
	F	CAUC		2Y	0		001	PREBLEED			< 600		< 100	< 100
					0		011	INJ 1	CP241	15 MCG				
					31		011	BLEED 1			461316		1798	64019
	F	CAUC		17M	0		011	INJ 1	CP241	15 MCG				
	M	CAUC		12M	0		011	INJ 1	CP241	15 MCG				
	F	CAUC		23M	0		001	PREBLEED			< 600		300	< 100
					0		011	INJ 1	CP241	15 MCG				
					30		011	BLEED 1			19580		1037	3047
	F	BLAC		2Y	0		001	PREBLEED			< 600		114	< 100
					0		011	INJ 1	CP241	15 MCG				
					29		011	BLEED 1			38341		1022	16984
	F	BLAC		2Y	0		001	PREBLEED			< 600		110	< 100
					0		011	INJ 1	CP241	15 MCG				
					29		011	BLEED 1			45389		1774	11379
	F	BLAC		2Y	0		001	PREBLEED			< 600		280	< 100
					0		011	INJ 1	CP241	15 MCG				
					29		011	BLEED 1			26052		9711	8132
	M	BLAC		13M	0		011	INJ 1	CP241	15 MCG				
	M	BLAC		14M	0		011	INJ 1	CP241	15 MCG				
	M	CAUC		15M	0		011	INJ 1	CP241	15 MCG				
	F	BLAC		24M	0		001	PREBLEED			< 600		500	< 100

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	IGG1	CODE/	IGG2	CODE/	IGGM	CODE/IGG TOTAL
(b) (6)	F	BLAC	(b) (6)	24M	0	(b) (6)	011	INJ 1	CP241	15 MCG							
					28		011	BLEED 1				15630				1139	1824
	M	BLAC		2Y	0		001	PREBLEED								1280	< 100
					0		011	INJ 1	CP241	15 MCG							
					29		011	BLEED 1								3021	14452
	F	BLAC		24M	0		011	INJ 1	CP241	15 MCG							
	M	BLAC		2Y	0		011	INJ 1	CP241	15 MCG							
	M	BLAC		5Y	0		011	INJ 1	CP241	15 MCG							
	F	BLAC		15M	0		011	INJ 1	CP241	15 MCG							
	F	BLAC		3Y	0		011	INJ 1	CP241	15 MCG							
	F	BLAC		2Y	0		011	INJ 1	CP241	15 MCG							
	F	BLAC		4Y	0		001	PREBLEED				< 600		< 250			
					0		011	INJ 1	CP241	15 MCG							
					31		011	BLEED 1				5840		593			
	M	CAUC		2Y	0		011	INJ 1	CP241	15 MCG							
	M	BLAC		2Y	0		011	INJ 1	CP241	15 MCG							
	F	BLAC		2Y	0		011	INJ 1	CP241	15 MCG							
	F	CAUC		15M	0		001	PREBLEED				< 600				< 100	< 100
					0		011	INJ 1	CP298	15 MCG							
					28		011	BLEED 1				7676				556	833
	F	BLAC		2Y	0		001	PREBLEED								1039	178
					0		011	INJ 1	CP298	15 MCG							
					29		011	BLEED 1								1759	1241
	F	CAUC		5Y	0		001	PREBLEED				1902		379		101	191
					0		011	INJ 1	CP298	15 MCG							
					32		011	BLEED 1				573576		24305		8569	70955

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ IGG1	CODE/ IGG2	CODE/ IGGM	CODE/IGG TOTAL
(b) (6)	M	BLAC	(b) (6)	22M	0	(b) (6)	001	PREBLEED					< 100	< 100
					0		011	INJ 1	CP298	15 MCG				
					34		011	BLEED 1					1465	292
	M	BLAC		13M	0		001	PREBLEED			< 600		< 100	< 100
					0		011	INJ 1	CP298	15 MCG				
					28		011	BLEED 1			5395		500	308
	F	CAUC		13M	0		001	PREBLEED			< 600		137	< 100
					0		011	INJ 1	CP298	15 MCG				
					31		011	BLEED 1			23364		1418	1719
	F	BLAC		2Y	0		001	PREBLEED					136	< 100
					0		011	INJ 1	CP298	15 MCG				
					30		011	BLEED 1					367	176
	F	CAUC		4Y	0		001	PREBLEED			< 600	< 250	225	< 100
					0		011	INJ 1	CP298	15 MCG				
					29		011	BLEED 1			45967	481	9982	4430
	F	CAUC		24M	0		001	PREBLEED					278	< 100
					0		011	INJ 1	CP298	15 MCG				
					29		011	BLEED 1					14364	12491
	F	BLAC		2Y	0		001	PREBLEED					200	< 100
					0		011	INJ 1	CP298	15 MCG				
					35		011	BLEED 1					999	1168
	F	BLAC		12M	0		001	PREBLEED			< 600		< 100	< 100
					0		011	INJ 1	CP298	15 MCG				
					39		011	BLEED 1			12220		1250	2043
	F	BLAC		2Y	0		001	PREBLEED			< 600	< 250	200	< 100
					0		011	INJ 1	CP298	15 MCG				
					30		011	BLEED 1			5915	430	3773	873
	M	BLAC		15M	0		001	PREBLEED			< 600		< 100	< 100
					0		011	INJ 1	CP298	15 MCG				
					30		011	BLEED 1			93721		4212	24494
	M	BLAC		24M	0		011	INJ 1	CP298	15 MCG				

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ IGG1	CODE/ IGG2	CODE/ IGGM	CODE/IGG TOTAL
(b) (6)	M	BLAC	(b) (6)	2Y	0	(b) (6)	001	PREBLEED					< 100	< 100
					0		011	INJ 1	CP298	15 MCG				
					35		011	BLEED 1					219	279
	M	BLAC		4Y	0		011	INJ 1	CP298	15 MCG				
	M	BLAC		21M	0		001	PREBLEED					< 100	< 100
					0		011	INJ 1	CP298	15 MCG				
					28		011	BLEED 1					500	11189
	M	BLAC		14M	0		001	PREBLEED			< 600		< 100	< 100
					0		011	INJ 1	CP298	15 MCG				
					27		011	BLEED 1			1387		126	479
	M	BLAC		20M	0		001	PREBLEED					< 100	< 100
					0		011	INJ 1	CP298	15 MCG				
					28		011	BLEED 1					993	4029
	F	BLAC		20M	0		001	PREBLEED					< 100	< 100
					0		011	INJ 1	CP298	15 MCG				
					28		011	BLEED 1					648	28766
	M	BLAC		14M	0		011	INJ 1	CP298	15 MCG				
	F	BLAC		24M	0		001	PREBLEED					< 100	160
					0		011	INJ 1	CP298	15 MCG				
					30		011	BLEED 1					4099	2286
	F	BLAC		24M	0		001	PREBLEED					< 100	< 100
					0		011	INJ 1	CP298	15 MCG				
					29		011	BLEED 1					1054	3418
	M	BLAC		15M	0		001	PREBLEED			< 600		< 100	< 100
					0		011	INJ 1	CP298	15 MCG				
					31		011	BLEED 1			5393		< 100	889
	M	BLAC		24M	0		011	INJ 1	CP298	15 MCG				
	F	BLAC		15M	0		011	INJ 1	CP298	15 MCG				
	M	CAUC		24M	0		011	INJ 1	CP298	15 MCG				

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	IGG1	CODE/	IGG2	CODE/	IGGM	CODE/IGG TOTAL
(b) (6)	M	BLAC	(b) (6)	20M	0	(b) (6)	011	INJ 1	CP298	15 MCG							
	F	BLAC		2Y	0		011	INJ 1	CP298	15 MCG							
	F	BLAC		2Y	0		011	INJ 1	CP298	15 MCG							
	F	BLAC		19M	0		011	INJ 1	CP298	15 MCG							
	F	BLAC		19M	0		011	INJ 1	CP298	15 MCG							
	F	BLAC		12M	0		011	INJ 1	CP298	15 MCG							
	M	BLAC		2Y	0		011	INJ 1	CP298	15 MCG							
	M	BLAC		24M	0		011	INJ 1	CP298	15 MCG							
	F	BLAC		3Y	0		011	INJ 1	CP298	15 MCG							
	M	BLAC		18M	0		001	PREBLEED				< 600				< 100	< 100
					0		011	INJ 1	CP749	15 MCG							
					31		011	BLEED 1				26493				391	4059
	M	BLAC		23M	0		011	INJ 1	CP298	15 MCG							
	M	BLAC		16M	0		001	PREBLEED				< 600				< 100	117
					0		011	INJ 1	CP749	15 MCG							
					31		011	BLEED 1				3581				2475	645
	F	BLAC		22M	0		001	PREBLEED				< 600		< 250		< 100	< 100
					0		011	INJ 1	CR132	15 MCG							
					31		011	BLEED 1				70285		431		5341	8726
	F	BLAC		22M	0		011	INJ 1	CR132	15 MCG							
	M	BLAC		24M	0		011	INJ 1	CP298	15 MCG							
	M	BLAC		13M	0		011	INJ 1	CP298	15 MCG							
	F	BLAC		16M	0		001	PREBLEED				< 600				178	< 100
					0		011	INJ 1	CP749	15 MCG							

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	IGG1	CODE/	IGG2	CODE/	IGGM	CODE/IGG TOTAL
(b) (6)	F	BLAC	(b) (6)	16M	36	(b) (6)	011	BLEED 1				17720				2929	5533
	M	BLAC		4Y	0		001	PREBLEED				< 600		< 250		611	< 100
					0		011	INJ 1	CR132	15 MCG							
					31		011	BLEED 1				26014		854		4890	2157
	F	BLAC		20M	0		011	INJ 1	CR132	15 MCG							
	F	BLAC		22M	0		001	PREBLEED				< 600				159	< 100
					0		011	INJ 1	CP749	15 MCG							
					28		011	BLEED 1				< 600				400	< 100
	F	BLAC		13M	0		011	INJ 1	CP298	15 MCG							
	F	BLAC		12M	0		011	INJ 1	CP298	15 MCG							
	F	BLAC		2Y	0		011	INJ 1	CR132	15 MCG							
	M	BLAC		2Y	0		001	PREBLEED				< 600				134	117
					0		011	INJ 1	CP749	15 MCG							
					39		011	BLEED 1				10507				240	1752
	F	BLAC		12M	0		011	INJ 1	CP298	15 MCG							
	M	BLAC		2Y	0		001	PREBLEED								< 100	< 100
					0		011	INJ 1	CP749	15 MCG							
					45		011	BLEED 1								349	8385
	M	BLAC		13M	0		011	INJ 1	CR132	15 MCG							
	F	BLAC		2Y	0		011	INJ 1	CR132	15 MCG							
	F	BLAC		3Y	0		011	INJ 1	CR132	15 MCG							
	M	BLAC		21M	0		011	INJ 1	CP749	15 MCG							
	M	BLAC		12M	0		011	INJ 1	CP749	15 MCG							
	M	BLAC		2Y	0		011	INJ 1	CP298	15 MCG							
	M	CAUC		24M	0		011	INJ 1	CP298	15 MCG							

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS EVENT		LOT	DOSE	CODE/ IGG1	CODE/ IGG2	CODE/ IGGM	CODE/IGG TOTAL
(b) (6)	F	BLAC	(b) (6)	5Y	0	(b) (6)	011	INJ	1	CR132	15 MCG			
	F	CAUC		24M	0		011	INJ	1	CP749	15 MCG			
	F	BLAC		12M	0		011	INJ	1	CP749	15 MCG			
	F	BLAC		2Y	0		011	INJ	1	CP298	15 MCG			
	M	BLAC		2Y	0		011	INJ	1	CP298	15 MCG			
	F	BLAC		2Y	0		011	INJ	1	CR132	15 MCG			
	F	BLAC		12M	0		011	INJ	1	CP298	15 MCG			

TABLE 3
ANTIBODY RESPONSES

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
ASSAY : RIA
LOT NUMBER : CP241
DOSE : 15 MCG
POPULATION : HEALTHY CHILDREN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
1- 6 MOS.	PRE INJ	0 (0/ 3)	0 (0/ 3)			0.083 (3)
	MONTH 2	100 (3/ 3)	100 (3/ 3)	100 (3/ 3)	40.9	5.364 (3)
	MONTH 3	100 (2/ 2)	100 (2/ 2)	100 (2/ 2)	55.3	7.424 (2)
7-11 MOS.	PRE INJ	25 (1/ 4)	0 (0/ 4)			0.080 (4)
	MONTH 2	100 (4/ 4)	75 (3/ 4)	75 (3/ 4)	27.2	3.638 (4)
	MONTH 3	100 (4/ 4)	100 (4/ 4)	100 (4/ 4)	85.0	11.383 (4)
	MONTH 7-10	100 (1/ 1)	100 (1/ 1)	100 (1/ 1)	69.6	8.703 (1)
12-71 MOS.	PRE INJ	36 (9/ 25)	12 (3/ 25)			0.155 (25)
	MONTH 1	100 (25/ 25)	96 (24/ 25)	100 (25/ 25)	89.3	20.932 (25)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 4
ANTIBODY RESPONSES

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
ASSAY : RIA
LOT NUMBER : CP298
DOSE : 15 MCG
POPULATION : HEALTHY CHILDREN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
1- 6 MOS.	PRE INJ	50 (1/ 2)	0 (0/ 2)			0.121 (2)
	MONTH 2	100 (2/ 2)	100 (2/ 2)	100 (2/ 2)	18.7	3.212 (2)
	MONTH 3	100 (2/ 2)	100 (2/ 2)	100 (2/ 2)	25.3	4.343 (2)
7-11 MOS.	PRE INJ	20 (1/ 5)	0 (0/ 5)			0.076 (5)
	MONTH 2	100 (5/ 5)	80 (4/ 5)	100 (5/ 5)	19.1	2.524 (5)
	MONTH 3	100 (5/ 5)	100 (5/ 5)	100 (5/ 5)	29.4	3.890 (5)
12-71 MOS.	PRE INJ	50 (19/ 38)	11 (4/ 38)			0.191 (38)
	MONTH 1	100 (38/ 38)	95 (36/ 38)	97 (37/ 38)	33.8	8.458 (38)
	MONTH 6-9	100 (1/ 1)	0 (0/ 1)	0 (0/ 1)	2.0	0.587 (1)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 5

ANTIBODY RESPONSES

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
ASSAY : RIA
LOT NUMBER : CP749
DOSE : 15 MCG
POPULATION : HEALTHY CHILDREN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
1- 6 MOS.	PRE INJ	0 (0/ 1)	0 (0/ 1)			0.063 (1)
	MONTH 2	100 (1/ 1)	0 (0/ 1)	100 (1/ 1)	4.8	0.603 (1)
	MONTH 3	100 (1/ 1)	100 (1/ 1)	100 (1/ 1)	14.9	1.868 (1)
7-11 MOS.	PRE INJ	100 (1/ 1)	0 (0/ 1)			0.259 (1)
	MONTH 2	100 (1/ 1)	100 (1/ 1)	100 (1/ 1)	23.8	6.155 (1)
	MONTH 3	100 (1/ 1)	100 (1/ 1)	100 (1/ 1)	37.2	9.638 (1)
12-71 MOS.	PRE INJ	57 (4/ 7)	0 (0/ 7)			0.145 (7)
	MONTH 1	100 (7/ 7)	100 (7/ 7)	100 (7/ 7)	42.4	8.269 (7)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE,
AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 6

ANTIBODY RESPONSES

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
ASSAY : RIA
LOT NUMBER : CR132
DOSE : 15 MCG
POPULATION : HEALTHY CHILDREN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
1- 6 MOS.	PRE INJ	100 (2/ 2)	0 (0/ 2)			0.207 (2)
	MONTH 2	100 (2/ 2)	100 (2/ 2)	100 (2/ 2)	21.7	4.477 (2)
	MONTH 3	100 (2/ 2)	100 (2/ 2)	100 (2/ 2)	48.1	9.929 (2)
7-11 MOS.	PRE INJ	0 (0/ 1)	0 (0/ 1)			0.125 (1)
	MONTH 2	100 (1/ 1)	100 (1/ 1)	100 (1/ 1)	34.1	4.266 (1)
12-71 MOS.	PRE INJ	50 (2/ 4)	0 (0/ 4)			0.155 (4)
	MONTH 1	100 (4/ 4)	100 (4/ 4)	100 (4/ 4)	103.7	22.693 (4)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE,
AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 7

A N T I B O D Y R E S P O N S E S
CHILDREN RANDOMIZED TO CONSISTENCY LOTS - ALL

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
ASSAY : RIA
LOT NUMBER : CP298
DOSE : 15 MCG
POPULATION : HEALTHY CHILDREN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
7-11 MOS.	PRE INJ	50 (1/ 2)	0 (0/ 2)			0.102 (2)
	MONTH 2	100 (2/ 2)	100 (2/ 2)	100 (2/ 2)	27.0	3.908 (2)
	MONTH 3	100 (2/ 2)	100 (2/ 2)	100 (2/ 2)	73.0	10.554 (2)
12-71 MOS.	PRE INJ	60 (3/ 5)	20 (1/ 5)			0.254 (5)
	MONTH 1	100 (5/ 5)	100 (5/ 5)	80 (4/ 5)	18.3	5.339 (5)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 8

ANTIBODY RESPONSES
CHILDREN RANDOMIZED TO CONSISTENCY LOTS - ALL

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
ASSAY : RIA
LOT NUMBER : CP749
DOSE : 15 MCG
POPULATION : HEALTHY CHILDREN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
1- 6 MOS.	PRE INJ	0 (0/ 1)	0 (0/ 1)			0.063 (1)
	MONTH 2	100 (1/ 1)	0 (0/ 1)	100 (1/ 1)	4.8	0.603 (1)
	MONTH 3	100 (1/ 1)	100 (1/ 1)	100 (1/ 1)	14.9	1.868 (1)
7-11 MOS.	PRE INJ	100 (1/ 1)	0 (0/ 1)			0.259 (1)
	MONTH 2	100 (1/ 1)	100 (1/ 1)	100 (1/ 1)	23.8	6.155 (1)
	MONTH 3	100 (1/ 1)	100 (1/ 1)	100 (1/ 1)	37.2	9.638 (1)
12-71 MOS.	PRE INJ	57 (4/ 7)	0 (0/ 7)			0.145 (7)
	MONTH 1	100 (7/ 7)	100 (7/ 7)	100 (7/ 7)	42.4	8.269 (7)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 9

ANTIBODY RESPONSES
CHILDREN RANDOMIZED TO CONSISTENCY LOTS - ALL

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
ASSAY : RIA
LOT NUMBER : CR132
DOSE : 15 MCG
POPULATION : HEALTHY CHILDREN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
1- 6 MOS.	PRE INJ	100 (2/ 2)	0 (0/ 2)			0.207 (2)
	MONTH 2	100 (2/ 2)	100 (2/ 2)	100 (2/ 2)	21.7	4.477 (2)
	MONTH 3	100 (2/ 2)	100 (2/ 2)	100 (2/ 2)	48.1	9.929 (2)
7-11 MOS.	PRE INJ	0 (0/ 1)	0 (0/ 1)			0.125 (1)
	MONTH 2	100 (1/ 1)	100 (1/ 1)	100 (1/ 1)	34.1	4.266 (1)
12-71 MOS.	PRE INJ	50 (2/ 4)	0 (0/ 4)			0.155 (4)
	MONTH 1	100 (4/ 4)	100 (4/ 4)	100 (4/ 4)	103.7	22.693 (4)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE,
AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 10

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	7	
VACCINEES WITH NO COMPLAINTS :	1	(14.3 %)
VACCINEES WITH COMPLAINTS :	6	(85.7 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 7 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	3	42.9
ERYTHEMA, INJ. SITE (<=1 IN.)	2	28.6
PAIN/SORENESS, INJ. SITE	2	28.6
SWELLING, INJ. SITE (<=1 IN.)	2	28.6
INDURATION, INJECTION SITE	1	14.3
SWELLING, INJ. SITE (>1 INCH)	1	14.3
SYSTEMIC REACTIONS	5	71.4
FATIGUE	5	71.4
IRRITABILITY	4	57.1
TEETHING	4	57.1
PROLONGED CRYING, >1/2 HR	1	14.3
WARM TO TOUCH	1	14.3

005580

TABLE 10 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE	HIB CONJUGATE INJECTION: 2	
TOTAL VACCINEES	7	
VACCINEES WITH NO COMPLAINTS	2	(28.6 %)
VACCINEES WITH COMPLAINTS	5	(71.4 %)
VACCINEES WITH NO DATA	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 7 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	2	28.6
ERYTHEMA, INJ. SITE (<=1 IN.)	2	28.6
SWELLING, INJ. SITE (<=1 IN.)	2	28.6
ERYTHEMA, INJ. SITE (>1 INCH)	1	14.3
PAIN/SORENESS, INJ. SITE	1	14.3
SYSTEMIC REACTIONS	5	71.4
FATIGUE	2	28.6
IRRITABILITY	2	28.6
TEETHING	2	28.6
WARM TO TOUCH	2	28.6
PROLONGED CRYING, >1/2 HR	1	14.3
RASH	1	14.3

TABLE 10 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
POPULATION : HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES	25	
VACCINEES WITH NO COMPLAINTS	14	(56.0 %)
VACCINEES WITH COMPLAINTS	11	(44.0 %)
VACCINEES WITH NO DATA	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 25 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	7	28.0
PAIN/SORENESS, INJ. SITE	6	24.0
ERYTHEMA, INJ. SITE (<=1 IN.)	1	4.0
SWELLING, INJ. SITE (<=1 IN.)	1	4.0
SWELLING, INJ. SITE (>1 INCH)	1	4.0
SYSTEMIC REACTIONS	7	28.0
FATIGUE	4	16.0
WARM TO TOUCH	3	12.0
IRRITABILITY	2	8.0
TEETHING	2	8.0
ANOREXIA	1	4.0
COMMON COLD	1	4.0
DIARRHEA	1	4.0
OTITIS MEDIA	1	4.0
PALLOR	1	4.0
PHARYNGEAL PAIN	1	4.0
POLYDIPSIA	1	4.0
PROLONGED CRYING, >1/2 HR	1	4.0

TABLE 10 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES	13	
VACCINEES WITH NO COMPLAINTS	5	(45.5 %)
VACCINEES WITH COMPLAINTS	6	(54.5 %)
VACCINEES WITH NO DATA	2	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 11 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	2	18.2
ERYTHEMA, INJ. SITE (>1 INCH)	1	9.1
SWELLING, INJ. SITE (<=1 IN.)	1	9.1
SYSTEMIC REACTIONS	5	45.5
FATIGUE	4	36.4
IRRITABILITY	4	36.4
DIARRHEA	2	18.2
TEETHING	1	9.1
VOMITING	1	9.1

TABLE 10 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 2	
TOTAL VACCINEES :	11	
VACCINEES WITH NO COMPLAINTS :	5	(55.6 %)
VACCINEES WITH COMPLAINTS :	4	(44.4 %)
VACCINEES WITH NO DATA :	2	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 9 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	4	44.4
ERYTHEMA, INJ. SITE (<=1 IN.)	2	22.2
ERYTHEMA, INJ. SITE (>1 INCH)	2	22.2
SWELLING, INJ. SITE (<=1 IN.)	1	11.1
SYSTEMIC REACTIONS	4	44.4
FATIGUE	2	22.2
TEETHING	2	22.2
DIARRHEA	1	11.1
FACIAL EDEMA	1	11.1
IRRITABILITY	1	11.1
WARM TO TOUCH	1	11.1

TABLE 10 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
POPULATION : HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES	47	
VACCINEES WITH NO COMPLAINTS	23	(52.3 %)
VACCINEES WITH COMPLAINTS	21	(47.7 %)
VACCINEES WITH NO DATA	3	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 44 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	10	22.7
PAIN/SORENESS, INJ. SITE	8	18.2
SWELLING, INJ. SITE (<=1 IN.)	4	9.1
ERYTHEMA, INJ. SITE (<=1 IN.)	1	2.3
INDURATION, INJECTION SITE	1	2.3
SWELLING, INJ. SITE (>1 INCH)	1	2.3
SYSTEMIC REACTIONS	17	38.6
IRRITABILITY	9	20.5
DIARRHEA	5	11.4
FATIGUE	3	6.8
HARM TO TOUCH	3	6.8
COMMON COLD	2	4.5
TEETHING	2	4.5
ASTHMA	1	2.3
RASH	1	2.3
SINUSITIS	1	2.3
WHEEZING	1	2.3

TABLE 10 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	5	
VACCINEES WITH NO COMPLAINTS :	1	(25.0 %)
VACCINEES WITH COMPLAINTS :	3	(75.0 %)
VACCINEES WITH NO DATA :	1	

CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 4 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	1	25.0
SWELLING, INJ. SITE (<=1 IN.)	1	25.0
SYSTEMIC REACTIONS	3	75.0
ATOPIC DERMATITIS	1	25.0
DIARRHEA	1	25.0
IRRITABILITY	1	25.0
OTITIS MEDIA	1	25.0
VOMITING	1	25.0

TABLE 10 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 2	
TOTAL VACCINEES :	4	
VACCINEES WITH NO COMPLAINTS :	4	(100.0 %)
VACCINEES WITH COMPLAINTS :	0	(0.0 %)
VACCINEES WITH NO DATA :	0	

CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 4 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	0	0.0

TABLE 10 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
POPULATION : HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	10	
VACCINEES WITH NO COMPLAINTS :	7	(77.8 %)
VACCINEES WITH COMPLAINTS :	2	(22.2 %)
VACCINEES WITH NO DATA :	1	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 9 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	2	22.2
PAIN/SORENESS, INJ. SITE	2	22.2
ERYTHEMA, INJ. SITE (<=1 IN.)	1	11.1
SWELLING, INJ. SITE (<=1 IN.)	1	11.1
SYSTEMIC REACTIONS	1	11.1
WARM TO TOUCH	1	11.1

TABLE 10 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
LOT NUMBER : CR132
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES	5	
VACCINEES WITH NO COMPLAINTS	3	(75.0 %)
VACCINEES WITH COMPLAINTS	1	(25.0 %)
VACCINEES WITH NO DATA	1	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 4 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	0	0.0
SYSTEMIC REACTIONS	1	25.0
IRRITABILITY	1	25.0

TABLE 10 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
LOT NUMBER : CR132
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 2	
TOTAL VACCINEES :	5	
VACCINEES WITH NO COMPLAINTS :	3	(75.0 %)
VACCINEES WITH COMPLAINTS :	1	(25.0 %)
VACCINEES WITH NO DATA :	1	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 4 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	1	25.0
PAIN/SORENESS, INJ. SITE	1	25.0
SWELLING, INJ. SITE (<=1 IN.)	1	25.0
SYSTEMIC REACTIONS	1	25.0
FATIGUE	1	25.0

TABLE 10 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
LOT NUMBER : CR132
POPULATION : HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	10	
VACCINEES WITH NO COMPLAINTS :	7	(77.8 %)
VACCINEES WITH COMPLAINTS :	2	(22.2 %)
VACCINEES WITH NO DATA :	1	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 9 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	1	11.1
PAIN/SORENESS, INJ. SITE	1	11.1
SYSTEMIC REACTIONS	2	22.2
FEVER	1	11.1
IRRITABILITY	1	11.1

TABLE 11

CLINICAL COMPLAINTS

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (7 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5	
LOCAL REACTIONS	2 (28.6%)	3 (42.9%)	3 (42.9%)	2 (28.6%)	2 (28.6%)	2 (28.6%)	3 (42.9%)
ERYTHEMA, INJ. SITE (<=1 IN.)	1 (14.3%)	2 (28.6%)	1 (14.3%)	1 (14.3%)	0 (0.0%)	0 (0.0%)	2 (28.6%)
INDURATION, INJECTION SITE	1 (14.3%)	1 (14.3%)	1 (14.3%)	1 (14.3%)	1 (14.3%)	1 (14.3%)	1 (14.3%)
PAIN/SORENESS, INJ. SITE	1 (14.3%)	2 (28.6%)	2 (28.6%)	1 (14.3%)	1 (14.3%)	1 (14.3%)	2 (28.6%)
SWELLING, INJ. SITE (>1 INCH)	1 (14.3%)	1 (14.3%)	1 (14.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (14.3%)
SWELLING, INJ. SITE (<=1 IN.)	1 (14.3%)	1 (14.3%)	1 (14.3%)	2 (28.6%)	2 (28.6%)	2 (28.6%)	2 (28.6%)
SYSTEMIC	4 (57.1%)	3 (42.9%)	3 (42.9%)	3 (42.9%)	1 (14.3%)	1 (14.3%)	5 (71.4%)
BODY AS A WHOLE/SITE UNSPEC.	3 (42.9%)	2 (28.6%)	2 (28.6%)	2 (28.6%)	0 (0.0%)	0 (0.0%)	5 (71.4%)
FATIGUE	3 (42.9%)	2 (28.6%)	2 (28.6%)	2 (28.6%)	0 (0.0%)	0 (0.0%)	5 (71.4%)
HARM TO TOUCH	1 (14.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (14.3%)
DIGESTIVE SYSTEM	3 (42.9%)	2 (28.6%)	2 (28.6%)	2 (28.6%)	1 (14.3%)	1 (14.3%)	4 (57.1%)

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (7 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
TEETHING	3 (42.9%)	2 (28.6%)	2 (28.6%)	2 (28.6%)	1 (14.3%)	1 (14.3%)		4 (57.1%)
NERVOUS SYSTEM & PSYCHIATRIC	3 (42.9%)	2 (28.6%)	2 (28.6%)	1 (14.3%)	0 (0.0%)	1 (14.3%)		4 (57.1%)
IRRITABILITY	2 (28.6%)	2 (28.6%)	2 (28.6%)	1 (14.3%)	0 (0.0%)	1 (14.3%)		4 (57.1%)
PROLONGED CRYING, >1/2 HR	1 (14.3%)	0 (0.0%)	1 (14.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (14.3%)
VACCINEES WITH COMPLAINTS	5 (71.4%)	4 (57.1%)	4 (57.1%)	4 (57.1%)	3 (42.9%)	3 (42.9%)		6 (85.7%)
VACCINEES WITH NO COMPLAINTS	2 (28.6%)	3 (42.9%)	3 (42.9%)	3 (42.9%)	4 (57.1%)	4 (57.1%)		1 (14.3%)
TOTAL VACCINEES REPORTING	7	7	7	7	7	7		7
VACCINEES WITH NO DATA	0	0	0	0	0	0		0

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (7 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
LOCAL REACTIONS	2 (28.6%)	2 (28.6%)	1 (14.3%)	1 (14.3%)	1 (14.3%)	0 (0.0%)		2 (28.6%)
ERYTHEMA, INJ. SITE (>1 INCH)	1 (14.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (14.3%)
ERYTHEMA, INJ. SITE (<=1 IN.)	0 (0.0%)	2 (28.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (28.6%)
PAIN/SORENESS, INJ. SITE	1 (14.3%)	1 (14.3%)	1 (14.3%)	1 (14.3%)	1 (14.3%)	0 (0.0%)		1 (14.3%)
SWELLING, INJ. SITE (<=1 IN.)	2 (28.6%)	2 (28.6%)	1 (14.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (28.6%)
SYSTEMIC	3 (42.9%)	3 (42.9%)	3 (42.9%)	3 (42.9%)	3 (42.9%)	2 (28.6%)		5 (71.4%)
BODY AS A WHOLE/SITE UNSPEC.	2 (28.6%)	2 (28.6%)	1 (14.3%)	1 (14.3%)	1 (14.3%)	0 (0.0%)		3 (42.9%)
FATIGUE	2 (28.6%)	1 (14.3%)	1 (14.3%)	1 (14.3%)	1 (14.3%)	0 (0.0%)		2 (28.6%)
HARM TO TOUCH	1 (14.3%)	1 (14.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (28.6%)
DIGESTIVE SYSTEM	1 (14.3%)	1 (14.3%)	1 (14.3%)	1 (14.3%)	1 (14.3%)	2 (28.6%)		2 (28.6%)
TEETHING	1 (14.3%)	1 (14.3%)	1 (14.3%)	1 (14.3%)	1 (14.3%)	2 (28.6%)		2 (28.6%)

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (7 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
NERVOUS SYSTEM & PSYCHIATRIC	1 (14.3%)	2 (28.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (28.6%)
IRRITABILITY	1 (14.3%)	2 (28.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (28.6%)
PROLONGED CRYING, >1/2 HR	1 (14.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (14.3%)
SKIN & SKIN APPENDAGE	0 (0.0%)	1 (14.3%)	1 (14.3%)	1 (14.3%)	1 (14.3%)	0 (0.0%)		1 (14.3%)
RASH	0 (0.0%)	1 (14.3%)	1 (14.3%)	1 (14.3%)	1 (14.3%)	0 (0.0%)		1 (14.3%)
VACCINEES WITH COMPLAINTS	4 (57.1%)	3 (42.9%)	3 (42.9%)	3 (42.9%)	3 (42.9%)	2 (28.6%)		5 (71.4%)
VACCINEES WITH NO COMPLAINTS	3 (42.9%)	4 (57.1%)	4 (57.1%)	4 (57.1%)	4 (57.1%)	5 (71.4%)		2 (28.6%)
TOTAL VACCINEES REPORTING	7	7	7	7	7	7		7
VACCINEES WITH NO DATA	0	0	0	0	0	0		0

110900

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (25 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5	COMPLAINTS
LOCAL REACTIONS	4 (16.0%)	5 (20.0%)	2 (8.0%)	2 (8.0%)	0 (0.0%)	0 (0.0%)	7 (28.0%)
ERYTHEMA, INJ. SITE (<=1 IN.)	0 (0.0%)	1 (4.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (4.0%)
PAIN/SORENESS, INJ. SITE	4 (16.0%)	4 (16.0%)	2 (8.0%)	1 (4.0%)	0 (0.0%)	0 (0.0%)	6 (24.0%)
SWELLING, INJ. SITE (>1 INCH)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (4.0%)	0 (0.0%)	0 (0.0%)	1 (4.0%)
SWELLING, INJ. SITE (<=1 IN.)	0 (0.0%)	1 (4.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (4.0%)
SYSTEMIC	2 (8.0%)	6 (24.0%)	5 (20.0%)	2 (8.0%)	2 (8.0%)	2 (8.0%)	7 (28.0%)
BODY AS A WHOLE/SITE UNSPEC.	1 (4.0%)	4 (16.0%)	2 (8.0%)	1 (4.0%)	1 (4.0%)	0 (0.0%)	5 (20.0%)
FATIGUE	1 (4.0%)	3 (12.0%)	1 (4.0%)	1 (4.0%)	1 (4.0%)	0 (0.0%)	4 (16.0%)
HARM TO TOUCH	1 (4.0%)	2 (8.0%)	1 (4.0%)	1 (4.0%)	1 (4.0%)	0 (0.0%)	3 (12.0%)
DIGESTIVE SYSTEM	1 (4.0%)	3 (12.0%)	4 (16.0%)	2 (8.0%)	2 (8.0%)	2 (8.0%)	4 (16.0%)
ANOREXIA	0 (0.0%)	1 (4.0%)	1 (4.0%)	1 (4.0%)	1 (4.0%)	1 (4.0%)	1 (4.0%)

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE

	NUMBER OF VACCINEES (25 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5	COMPLAINTS
DIARRHEA	0 (0.0%)	0 (0.0%)	1 (4.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (4.0%)
POLYDIPSIA	0 (0.0%)	1 (4.0%)	1 (4.0%)	1 (4.0%)	1 (4.0%)	1 (4.0%)	1 (4.0%)
TEETHING	1 (4.0%)	2 (8.0%)	2 (8.0%)	1 (4.0%)	1 (4.0%)	1 (4.0%)	2 (8.0%)
NERVOUS SYSTEM & PSYCHIATRIC	1 (4.0%)	2 (8.0%)	1 (4.0%)	1 (4.0%)	1 (4.0%)	0 (0.0%)	2 (8.0%)
IRRITABILITY	1 (4.0%)	2 (8.0%)	1 (4.0%)	1 (4.0%)	1 (4.0%)	0 (0.0%)	2 (8.0%)
PROLONGED CRYING, >1/2 HR	0 (0.0%)	1 (4.0%)	0 (0.0%)	1 (4.0%)	1 (4.0%)	0 (0.0%)	1 (4.0%)
RESPIRATORY SYSTEM	0 (0.0%)	1 (4.0%)	1 (4.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (8.0%)
COMMON COLD	0 (0.0%)	0 (0.0%)	1 (4.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (4.0%)
PHARYNGEAL PAIN	0 (0.0%)	1 (4.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (4.0%)
SKIN & SKIN APPENDAGE	1 (4.0%)	1 (4.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (4.0%)
PALLOR	1 (4.0%)	1 (4.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (4.0%)
SPECIAL SENSES	0 (0.0%)	0 (0.0%)	1 (4.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (4.0%)

90900

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (25 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
OTITIS MEDIA	0 (0.0%)	0 (0.0%)	1 (4.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (4.0%)
VACCINEES WITH COMPLAINTS	5 (20.0%)	9 (36.0%)	7 (28.0%)	4 (16.0%)	2 (8.0%)	2 (8.0%)		11 (44.0%)
VACCINEES WITH NO COMPLAINTS	20 (80.0%)	16 (64.0%)	18 (72.0%)	21 (84.0%)	23 (92.0%)	23 (92.0%)		14 (56.0%)
TOTAL VACCINEES REPORTING	25	25	25	25	25	25		25
VACCINEES WITH NO DATA	0	0	0	0	0	0		0

70900

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (13 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5	COMPLAINTS
LOCAL REACTIONS	0 (0.0%)	2 (18.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (18.2%)
ERYTHEMA, INJ. SITE (>1 INCH)	0 (0.0%)	1 (9.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (9.1%)
SWELLING, INJ. SITE (<=1 IN.)	0 (0.0%)	1 (9.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (9.1%)
SYSTEMIC	3 (27.3%)	2 (18.2%)	1 (10.0%)	2 (20.0%)	2 (20.0%)	3 (30.0%)	5 (45.5%)
BODY AS A WHOLE/SITE UNSPEC.	3 (27.3%)	1 (9.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (10.0%)	4 (36.4%)
FATIGUE	3 (27.3%)	1 (9.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (10.0%)	4 (36.4%)
DIGESTIVE SYSTEM	1 (9.1%)	1 (9.1%)	1 (10.0%)	2 (20.0%)	2 (20.0%)	2 (20.0%)	4 (36.4%)
DIARRHEA	1 (9.1%)	0 (0.0%)	0 (0.0%)	1 (10.0%)	1 (10.0%)	0 (0.0%)	2 (18.2%)
TEETHING	0 (0.0%)	1 (9.1%)	1 (10.0%)	1 (10.0%)	1 (10.0%)	1 (10.0%)	1 (9.1%)
VOMITING	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (10.0%)	1 (9.1%)
NERVOUS SYSTEM & PSYCHIATRIC	1 (9.1%)	2 (18.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (20.0%)	4 (36.4%)

0060A

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (13 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
IRRITABILITY	1 (9.1%)	2 (18.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (20.0%)		4 (36.4%)
VACCINEES WITH COMPLAINTS	3 (27.3%)	3 (27.3%)	1 (10.0%)	2 (20.0%)	2 (20.0%)	3 (30.0%)		6 (54.5%)
VACCINEES WITH NO COMPLAINTS	8 (72.7%)	8 (72.7%)	9 (90.0%)	8 (80.0%)	8 (80.0%)	7 (70.0%)		5 (45.5%)
TOTAL VACCINEES REPORTING	11	11	10	10	10	10		11
VACCINEES WITH NO DATA	2	2	3	3	3	3		2

60900

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (11 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
LOCAL REACTIONS	1 (11.1%)	2 (22.2%)	2 (22.2%)	1 (11.1%)	2 (22.2%)	1 (11.1%)		4 (44.4%)
ERYTHEMA, INJ. SITE (>1 INCH)	0 (0.0%)	1 (11.1%)	1 (11.1%)	0 (0.0%)	1 (11.1%)	0 (0.0%)		2 (22.2%)
ERYTHEMA, INJ. SITE (<=1 IN.)	1 (11.1%)	1 (11.1%)	1 (11.1%)	1 (11.1%)	1 (11.1%)	0 (0.0%)		2 (22.2%)
SWELLING, INJ. SITE (<=1 IN.)	0 (0.0%)	1 (11.1%)	1 (11.1%)	1 (11.1%)	1 (11.1%)	1 (11.1%)		1 (11.1%)
SYSTEMIC	4 (44.4%)	3 (33.3%)	3 (33.3%)	2 (22.2%)	2 (22.2%)	2 (22.2%)		4 (44.4%)
BODY AS A WHOLE/SITE UNSPEC.	3 (33.3%)	1 (11.1%)	1 (11.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		3 (33.3%)
FACIAL EDEMA	0 (0.0%)	1 (11.1%)	1 (11.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (11.1%)
FATIGUE	2 (22.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (22.2%)
HARM TO TOUCH	1 (11.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (11.1%)
DIGESTIVE SYSTEM	2 (22.2%)	2 (22.2%)	2 (22.2%)	2 (22.2%)	2 (22.2%)	2 (22.2%)		2 (22.2%)
DIARRHEA	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (11.1%)	1 (11.1%)	0 (0.0%)		1 (11.1%)

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (11 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
TEETHING	2 (22.2%)	2 (22.2%)	2 (22.2%)	2 (22.2%)	2 (22.2%)	2 (22.2%)		2 (22.2%)
NERVOUS SYSTEM & PSYCHIATRIC	1 (11.1%)	1 (11.1%)	1 (11.1%)	0 (0.0%)	1 (11.1%)	1 (11.1%)		1 (11.1%)
IRRITABILITY	1 (11.1%)	1 (11.1%)	1 (11.1%)	0 (0.0%)	1 (11.1%)	1 (11.1%)		1 (11.1%)
VACCINEES WITH COMPLAINTS	4 (44.4%)	4 (44.4%)	4 (44.4%)	2 (22.2%)	2 (22.2%)	2 (22.2%)		4 (44.4%)
VACCINEES WITH NO COMPLAINTS	5 (55.6%)	5 (55.6%)	5 (55.6%)	7 (77.8%)	7 (77.8%)	7 (77.8%)		5 (55.6%)
TOTAL VACCINEES REPORTING	9	9	9	9	9	9		9
VACCINEES WITH NO DATA	2	2	2	2	2	2		2

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (47 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5	
LOCAL REACTIONS	7 (15.9%)	5 (11.4%)	4 (9.1%)	3 (6.8%)	2 (4.5%)	2 (4.5%)	10 (22.7%)
ERYTHEMA, INJ. SITE (<=1 IN.)	0 (0.0%)	1 (2.3%)	1 (2.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.3%)
INDURATION, INJECTION SITE	1 (2.3%)	1 (2.3%)	1 (2.3%)	1 (2.3%)	1 (2.3%)	1 (2.3%)	1 (2.3%)
PAIN/SORENESS, INJ. SITE	5 (11.4%)	3 (6.8%)	3 (6.8%)	2 (4.5%)	1 (2.3%)	1 (2.3%)	8 (18.2%)
SWELLING, INJ. SITE (>1 INCH)	0 (0.0%)	1 (2.3%)	1 (2.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.3%)
SWELLING, INJ. SITE (<=1 IN.)	2 (4.5%)	1 (2.3%)	2 (4.5%)	2 (4.5%)	1 (2.3%)	1 (2.3%)	4 (9.1%)
SYSTEMIC	9 (20.5%)	12 (27.3%)	10 (22.7%)	4 (9.1%)	2 (4.5%)	1 (2.3%)	17 (38.6%)
BODY AS A WHOLE/SITE UNSPEC.	3 (6.8%)	4 (9.1%)	1 (2.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	5 (11.4%)
FATIGUE	2 (4.5%)	3 (6.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (6.8%)
WARM TO TOUCH	2 (4.5%)	2 (4.5%)	1 (2.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (6.8%)
DIGESTIVE SYSTEM	2 (4.5%)	4 (9.1%)	4 (9.1%)	1 (2.3%)	0 (0.0%)	0 (0.0%)	7 (15.9%)

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (47 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5	
DIARRHEA	0 (0.0%)	2 (4.5%)	4 (9.1%)	1 (2.3%)	0 (0.0%)	0 (0.0%)	5 (11.4%)
TEETHING	2 (4.5%)	2 (4.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (4.5%)
NERVOUS SYSTEM & PSYCHIATRIC	3 (6.8%)	6 (13.6%)	5 (11.4%)	2 (4.5%)	0 (0.0%)	0 (0.0%)	9 (20.5%)
IRRITABILITY	3 (6.8%)	6 (13.6%)	5 (11.4%)	2 (4.5%)	0 (0.0%)	0 (0.0%)	9 (20.5%)
RESPIRATORY SYSTEM	2 (4.5%)	2 (4.5%)	2 (4.5%)	1 (2.3%)	1 (2.3%)	1 (2.3%)	3 (6.8%)
ASTHMA	1 (2.3%)	1 (2.3%)	1 (2.3%)	1 (2.3%)	1 (2.3%)	1 (2.3%)	1 (2.3%)
COMMON COLD	1 (2.3%)	1 (2.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (4.5%)
SINUSITIS	0 (0.0%)	0 (0.0%)	1 (2.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.3%)
WHEEZING	1 (2.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.3%)
SKIN & SKIN APPENDAGE	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.3%)	0 (0.0%)	1 (2.3%)
RASH	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.3%)	0 (0.0%)	1 (2.3%)
VACCINEES WITH COMPLAINTS	13 (29.5%)	14 (31.8%)	14 (31.8%)	7 (15.9%)	4 (9.1%)	3 (6.8%)	21 (47.7%)

00613

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (47 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
VACCINEES WITH NO COMPLAINTS	31 (70.5%)	30 (68.2%)	30 (68.2%)	37 (84.1%)	40 (90.9%)	41 (93.2%)		23 (52.3%)
TOTAL VACCINEES REPORTING	44	44	44	44	44	44		44
VACCINEES WITH NO DATA	3	3	3	3	3	3		3

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (5 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5	COMPLAINTS
LOCAL REACTIONS	0 (0.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)	0 (0.0%)	1 (25.0%)
SWELLING, INJ. SITE (<=1 IN.)	0 (0.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)	0 (0.0%)	1 (25.0%)
SYSTEMIC	2 (50.0%)	2 (50.0%)	2 (50.0%)	2 (50.0%)	1 (25.0%)	0 (0.0%)	3 (75.0%)
DIGESTIVE SYSTEM	0 (0.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)	0 (0.0%)	1 (25.0%)
DIARRHEA	0 (0.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)	0 (0.0%)	1 (25.0%)
VOMITING	0 (0.0%)	1 (25.0%)	1 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (25.0%)
NERVOUS SYSTEM & PSYCHIATRIC	1 (25.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)	0 (0.0%)	0 (0.0%)	1 (25.0%)
IRRITABILITY	1 (25.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)	0 (0.0%)	0 (0.0%)	1 (25.0%)
SKIN & SKIN APPENDAGE	1 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (25.0%)
ATOPIC DERMATITIS	1 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (25.0%)
SPECIAL SENSES	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (25.0%)	0 (0.0%)	1 (25.0%)

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (5 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		
OTITIS MEDIA	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (25.0%)	0 (0.0%)		1 (25.0%)
VACCINEES WITH COMPLAINTS	2 (50.0%)	2 (50.0%)	2 (50.0%)	2 (50.0%)	1 (25.0%)	0 (0.0%)		3 (75.0%)
VACCINEES WITH NO COMPLAINTS	2 (50.0%)	2 (50.0%)	2 (50.0%)	2 (50.0%)	3 (75.0%)	4 (100.0%)		1 (25.0%)
TOTAL VACCINEES REPORTING	4	4	4	4	4	4		4
VACCINEES WITH NO DATA	1	1	1	1	1	1		1

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (4 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		**********
VACCINEES WITH COMPLAINTS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)
VACCINEES WITH NO COMPLAINTS	4 (100.0%)	4 (100.0%)	4 (100.0%)	4 (100.0%)	4 (100.0%)	4 (100.0%)		4 (100.0%)
TOTAL VACCINEES REPORTING	4	4	4	4	4	4		4
VACCINEES WITH NO DATA	0	0	0	0	0	0		0

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (10 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
LOCAL REACTIONS	1 (11.1%)	2 (22.2%)	2 (25.0%)	1 (12.5%)	1 (12.5%)	1 (12.5%)		2 (22.2%)
ERYTHEMA, INJ. SITE (<=1 IN.)	0 (0.0%)	1 (11.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (11.1%)
PAIN/SORENESS, INJ. SITE	1 (11.1%)	2 (22.2%)	2 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (22.2%)
SWELLING, INJ. SITE (<=1 IN.)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (12.5%)	1 (12.5%)	1 (12.5%)		1 (11.1%)
SYSTEMIC	0 (0.0%)	1 (11.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (11.1%)
BODY AS A WHOLE/SITE UNSPEC.	0 (0.0%)	1 (11.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (11.1%)
HARM TO TOUCH	0 (0.0%)	1 (11.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (11.1%)
VACCINEES WITH COMPLAINTS	1 (11.1%)	2 (22.2%)	2 (25.0%)	1 (12.5%)	1 (12.5%)	1 (12.5%)		2 (22.2%)
VACCINEES WITH NO COMPLAINTS	8 (88.9%)	7 (77.8%)	6 (75.0%)	7 (87.5%)	7 (87.5%)	7 (87.5%)		7 (77.8%)
TOTAL VACCINEES REPORTING	9	9	8	8	8	8		9

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (10 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5	COMPLAINTS
VACCINEES WITH NO DATA	1	1	2	2	2	2	1

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
LOT NUMBER : CR132
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (5 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
								**********
SYSTEMIC	1 (25.0%)	1 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (25.0%)
NERVOUS SYSTEM & PSYCHIATRIC	1 (25.0%)	1 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (25.0%)
IRRITABILITY	1 (25.0%)	1 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (25.0%)
VACCINEES WITH COMPLAINTS	1 (25.0%)	1 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (25.0%)
VACCINEES WITH NO COMPLAINTS	3 (75.0%)	3 (75.0%)	4 (100.0%)	4 (100.0%)	4 (100.0%)	4 (100.0%)		3 (75.0%)
TOTAL VACCINEES REPORTING	4	4	4	4	4	4		4
VACCINEES WITH NO DATA	1	1	1	1	1	1		1

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
LOT NUMBER : CR132
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (5 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
LOCAL REACTIONS	1 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (25.0%)
PAIN/SORENESS, INJ. SITE	1 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (25.0%)
SWELLING, INJ. SITE (<=1 IN.)	1 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (25.0%)
SYSTEMIC	1 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (25.0%)
BODY AS A WHOLE/SITE UNSPEC.	1 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (25.0%)
FATIGUE	1 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (25.0%)
VACCINEES WITH COMPLAINTS	1 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (25.0%)
VACCINEES WITH NO COMPLAINTS	3 (75.0%)	4 (100.0%)	3 (100.0%)	3 (100.0%)	3 (100.0%)	3 (100.0%)		3 (75.0%)
TOTAL VACCINEES REPORTING	4	4	3	3	3	3		4
VACCINEES WITH NO DATA	1	1	2	2	2	2		1

TABLE 11 (cont,)

CLINICAL COMPLAINTS

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
LOT NUMBER : CR132
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (10 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
LOCAL REACTIONS	0 (0.0%)	0 (0.0%)	1 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (11.1%)
PAIN/SORENESS, INJ. SITE	0 (0.0%)	0 (0.0%)	1 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (11.1%)
SYSTEMIC	1 (11.1%)	0 (0.0%)	1 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (22.2%)
BODY AS A WHOLE/SITE UNSPEC.	0 (0.0%)	0 (0.0%)	1 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (11.1%)
FEVER	0 (0.0%)	0 (0.0%)	1 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (11.1%)
NERVOUS SYSTEM & PSYCHIATRIC	1 (11.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (11.1%)
IRRITABILITY	1 (11.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (11.1%)
VACCINEES WITH COMPLAINTS	1 (11.1%)	0 (0.0%)	1 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (22.2%)
VACCINEES WITH NO COMPLAINTS	8 (88.9%)	9 (100.0%)	7 (87.5%)	8 (100.0%)	8 (100.0%)	8 (100.0%)		7 (77.8%)
TOTAL VACCINEES REPORTING	9	9	8	8	8	8		9

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
LOT NUMBER : CR132
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (10 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5	COMPLAINTS
VACCINEES WITH NO DATA	1	1	2	2	2	2	1

TABLE 12

MAXIMUM TEMPERATURES

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (7 VACCINEES) - INJECTION 1						
	DAYS POST VACCINATION						NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5	
< 99	4 (57.1%)	5 (71.4%)	4 (57.1%)	4 (57.1%)	5 (71.4%)	5 (71.4%)	3 (42.9%)
99 - 99.9	2 (28.6%)	1 (14.3%)	2 (28.6%)	2 (28.6%)	2 (28.6%)	2 (28.6%)	3 (42.9%)
100 - 100.9	1 (14.3%)	1 (14.3%)	1 (14.3%)	1 (14.3%)	0 (0.0%)	0 (0.0%)	1 (14.3%)
TEMPERATURE TAKEN	7 (100.0%)	7 (100.0%)	7 (100.0%)	7 (100.0%)	7 (100.0%)	7 (100.0%)	7 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

TABLE 12 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (7 VACCINEES) - INJECTION 2							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
< 99	5 (83.3%)	2 (33.3%)	5 (83.3%)	4 (66.7%)	5 (83.3%)	5 (83.3%)		2 (33.3%)
99 - 99.9	0 (0.0%)	3 (50.0%)	1 (16.7%)	2 (33.3%)	1 (16.7%)	0 (0.0%)		1 (16.7%)
100 - 100.9	1 (16.7%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (33.3%)
101 - 101.9	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)		1 (16.7%)
TEMPERATURE TAKEN	6 (85.7%)	6 (85.7%)	6 (85.7%)	6 (85.7%)	6 (85.7%)	6 (85.7%)		6 (85.7%)
TEMPERATURE NOT TAKEN	1 (14.3%)	1 (14.3%)	1 (14.3%)	1 (14.3%)	1 (14.3%)	1 (14.3%)		1 (14.3%)

TABLE 12 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (25 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
< 99	18 (72.0%)	15 (60.0%)	20 (80.0%)	20 (80.0%)	17 (73.9%)	21 (87.5%)		12 (48.0%)
99 - 99.9	6 (24.0%)	9 (36.0%)	4 (16.0%)	4 (16.0%)	5 (21.7%)	2 (8.3%)		10 (40.0%)
100 - 100.9	1 (4.0%)	1 (4.0%)	0 (0.0%)	1 (4.0%)	0 (0.0%)	1 (4.2%)		1 (4.0%)
101 - 101.9	0 (0.0%)	0 (0.0%)	1 (4.0%)	0 (0.0%)	1 (4.3%)	0 (0.0%)		2 (8.0%)
TEMPERATURE TAKEN	25 (100.0%)	25 (100.0%)	25 (100.0%)	25 (100.0%)	23 (92.0%)	24 (96.0%)		25 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (8.0%)	1 (4.0%)		0 (0.0%)

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TABLE 12 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (13 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
NORMAL	1 (9.1%)	1 (10.0%)	2 (20.0%)	2 (20.0%)	2 (22.2%)	2 (22.2%)		1 (9.1%)
< 99	9 (81.8%)	5 (50.0%)	7 (70.0%)	6 (60.0%)	2 (22.2%)	3 (33.3%)		2 (18.2%)
99 - 99.9	1 (9.1%)	4 (40.0%)	1 (10.0%)	2 (20.0%)	5 (55.6%)	4 (44.4%)		8 (72.7%)
TEMPERATURE TAKEN	11 (84.6%)	10 (76.9%)	10 (76.9%)	10 (76.9%)	9 (69.2%)	9 (69.2%)		11 (84.6%)
TEMPERATURE NOT TAKEN	2 (15.4%)	3 (23.1%)	3 (23.1%)	3 (23.1%)	4 (30.8%)	4 (30.8%)		2 (15.4%)

TABLE 12 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (11 VACCINEES) - INJECTION 2							
	DAYS POST VACCINATION							NUMBER
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		WITH MAX TEMP
NORMAL	1 (11.1%)	1 (11.1%)	1 (12.5%)	1 (12.5%)	1 (12.5%)	1 (14.3%)		1 (11.1%)
< 99	8 (88.9%)	6 (66.7%)	7 (87.5%)	5 (62.5%)	6 (75.0%)	5 (71.4%)		4 (44.4%)
99 - 99.9	0 (0.0%)	2 (22.2%)	0 (0.0%)	1 (12.5%)	0 (0.0%)	0 (0.0%)		3 (33.3%)
100 - 100.9	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (12.5%)	1 (12.5%)	1 (14.3%)		1 (11.1%)
TEMPERATURE TAKEN	9 (81.8%)	9 (81.8%)	8 (72.7%)	8 (72.7%)	8 (72.7%)	7 (63.6%)		9 (81.8%)
TEMPERATURE NOT TAKEN	2 (18.2%)	2 (18.2%)	3 (27.3%)	3 (27.3%)	3 (27.3%)	4 (36.4%)		2 (18.2%)

TABLE 12 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (47 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
NORMAL	1 (2.4%)	3 (7.1%)	3 (7.1%)	3 (7.1%)	3 (7.3%)	3 (7.3%)		1 (2.4%)
< 99	28 (66.7%)	27 (64.3%)	24 (57.1%)	25 (59.5%)	30 (73.2%)	28 (68.3%)		16 (38.1%)
99 - 99.9	8 (19.0%)	9 (21.4%)	12 (28.6%)	12 (28.6%)	5 (12.2%)	10 (24.4%)		15 (35.7%)
100 - 100.9	4 (9.5%)	2 (4.8%)	2 (4.8%)	1 (2.4%)	2 (4.9%)	0 (0.0%)		7 (16.7%)
101 - 101.9	1 (2.4%)	0 (0.0%)	1 (2.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (2.4%)
102 - 102.9	0 (0.0%)	1 (2.4%)	0 (0.0%)	1 (2.4%)	1 (2.4%)	0 (0.0%)		2 (4.8%)
TEMPERATURE TAKEN	42 (89.4%)	42 (89.4%)	42 (89.4%)	42 (89.4%)	41 (87.2%)	41 (87.2%)		42 (89.4%)
TEMPERATURE NOT TAKEN	5 (10.6%)	5 (10.6%)	5 (10.6%)	5 (10.6%)	6 (12.8%)	6 (12.8%)		5 (10.6%)

TABLE 12 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (5 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
NORMAL	1 (25.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)		1 (25.0%)
< 99	2 (50.0%)	2 (50.0%)	2 (50.0%)	2 (50.0%)	2 (50.0%)	1 (25.0%)		1 (25.0%)
99 - 99.9	1 (25.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)	2 (50.0%)		2 (50.0%)
TEMPERATURE TAKEN	4 (80.0%)	4 (80.0%)	4 (80.0%)	4 (80.0%)	4 (80.0%)	4 (80.0%)		4 (80.0%)
TEMPERATURE NOT TAKEN	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)		1 (20.0%)

TABLE 12 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (4 VACCINEES) - INJECTION 2							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
< 99	2 (50.0%)	2 (50.0%)	3 (75.0%)	3 (75.0%)	3 (75.0%)	3 (75.0%)		1 (25.0%)
99 - 99.9	2 (50.0%)	2 (50.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)		3 (75.0%)
TEMPERATURE TAKEN	4 (100.0%)	4 (100.0%)	4 (100.0%)	4 (100.0%)	4 (100.0%)	4 (100.0%)		4 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)

TABLE 12 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (10 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
NORMAL	1 (11.1%)	0 (0.0%)	1 (12.5%)	2 (28.6%)	2 (25.0%)	2 (25.0%)		0 (0.0%)
< 99	4 (44.4%)	4 (44.4%)	3 (37.5%)	1 (14.3%)	3 (37.5%)	3 (37.5%)		3 (33.3%)
99 - 99.9	3 (33.3%)	3 (33.3%)	2 (25.0%)	3 (42.9%)	2 (25.0%)	2 (25.0%)		3 (33.3%)
100 - 100.9	1 (11.1%)	2 (22.2%)	2 (25.0%)	1 (14.3%)	1 (12.5%)	1 (12.5%)		3 (33.3%)
TEMPERATURE TAKEN	9 (90.0%)	9 (90.0%)	8 (80.0%)	7 (70.0%)	8 (80.0%)	8 (80.0%)		9 (90.0%)
TEMPERATURE NOT TAKEN	1 (10.0%)	1 (10.0%)	2 (20.0%)	3 (30.0%)	2 (20.0%)	2 (20.0%)		1 (10.0%)

TABLE 12 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
LOT NUMBER : CR132
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (5 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
NORMAL	1 (25.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)		1 (25.0%)
< 99	1 (25.0%)	2 (50.0%)	2 (50.0%)	2 (50.0%)	2 (50.0%)	1 (25.0%)		1 (25.0%)
99 - 99.9	2 (50.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)	2 (50.0%)		2 (50.0%)
TEMPERATURE TAKEN	4 (80.0%)	4 (80.0%)	4 (80.0%)	4 (80.0%)	4 (80.0%)	4 (80.0%)		4 (80.0%)
TEMPERATURE NOT TAKEN	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)		1 (20.0%)

TABLE 12 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
LOT NUMBER : CR132
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (5 VACCINEES) - INJECTION 2							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
< 99	2 (50.0%)	3 (75.0%)	3 (75.0%)	2 (50.0%)	3 (75.0%)	3 (75.0%)		2 (50.0%)
99 - 99.9	2 (50.0%)	1 (25.0%)	1 (25.0%)	2 (50.0%)	1 (25.0%)	1 (25.0%)		2 (50.0%)
TEMPERATURE TAKEN	4 (80.0%)	4 (80.0%)	4 (80.0%)	4 (80.0%)	4 (80.0%)	4 (80.0%)		4 (80.0%)
TEMPERATURE NOT TAKEN	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)		1 (20.0%)

TABLE 12 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : BLUMER,JEFFREY L.
STUDY : 000408
VACCINE : HIB CONJUGATE
LOT NUMBER : CR132
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (10 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
NORMAL	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (14.3%)	1 (14.3%)	1 (14.3%)		0 (0.0%)
< 99	7 (77.8%)	7 (87.5%)	4 (57.1%)	3 (42.9%)	5 (71.4%)	3 (42.9%)		5 (55.6%)
99 - 99.9	1 (11.1%)	1 (12.5%)	2 (28.6%)	2 (28.6%)	1 (14.3%)	3 (42.9%)		2 (22.2%)
100 - 100.9	1 (11.1%)	0 (0.0%)	0 (0.0%)	1 (14.3%)	0 (0.0%)	0 (0.0%)		1 (11.1%)
101 - 101.9	0 (0.0%)	0 (0.0%)	1 (14.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (11.1%)
TEMPERATURE TAKEN	9 (90.0%)	8 (80.0%)	7 (70.0%)	7 (70.0%)	7 (70.0%)	7 (70.0%)		9 (90.0%)
TEMPERATURE NOT TAKEN	1 (10.0%)	2 (20.0%)	3 (30.0%)	3 (30.0%)	3 (30.0%)	3 (30.0%)		1 (10.0%)

STUDY 004-09

PROGRAM: Haemophilus b Conjugate Vaccine (Neisseria meningitidis Outer Membrane Protein Complex), Study #0004-09.

PURPOSE: To evaluate the safety and immunogenicity of Haemophilus b Conjugate Vaccine (Neisseria meningitidis Outer Membrane Protein Complex) in healthy infants and children 2 months to 5 years of age.

VACCINE: Haemophilus b Conjugate Vaccine (Neisseria meningitidis Outer Membrane Protein Complex).

Lot 1069/C-P241 - (b) (4) mcg polysaccharide/ml
(b) (4) mcg meningococcal protein/ml
Lot 1080/C-P749 - (b) (4) mcg polysaccharide/ml
(b) (4) mcg meningococcal protein/ml
Lot 1085/C-R132 - (b) (4) mcg polysaccharide/ml
(b) (4) mcg meningococcal protein/ml

Diluent
Aluminum hydroxide diluent
Lot (b) (4)

INVESTIGATOR: Elia Ayoub, M.D.
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SUB-INVESTIGATOR: Munir Rizkallah, M.D.
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Rose Fortunado, M.D.
Douglas Barrett, M.D.

STUDY LOCATION: Department of Pediatrics
Box J296, JHMC
University of Florida
Gainesville, Florida 32610

DATE INITIATED: September 1, 1987

DATE COMPLETED: In progress.

STUDY POPULATION: Healthy infants and children 2 to 71 months of age are included in the study.

STUDY PROCEDURE: Infants 2 to 11 months of age receive 2 injections of the vaccine given 2 months apart, while children 12 months of age and older receive a single injection. Vaccine is reconstituted in aluminum hydroxide and administered by intramuscular route. The dose for each injection is 15 mcg polysaccharide in the appropriate volume - 0.75 ml for Lot 1069/C-P241 and 0.5 ml for Lots 1080/C-P749, and 1085/C-R132.

Parents or guardians are required to record the vaccinee's temperature and any systemic or injection site reactions for 5 days after each injection. Unexpected or serious reactions are to be reported immediately to the study physician.

A blood sample is obtained immediately before each injection and one month after the last (or only) injection. Additional samples are obtained 7 to 10 months after the last injection for infants 2 to 11 months of age and at 15 to 18 months postvaccination for children 12 to 71 months of age.

All serum samples are assayed by Merck Sharp & Dohme Research Laboratories for antibody to H. influenzae type b capsular polysaccharide by radioimmunoassay (RIA).

RESULTS: Demographic information and individual pre and postvaccination antibody data for each vaccinee enrolled in the study is reported in Table 1.

1. Number Vaccinated:

Lot	Age	Injection No. 1	2
1069/C-P241	2-11 mo.	15	11
	12-71 mo.	13	--
1080/C-P749	2-11 mo.	17	9
	12-71 mo.	34	--
1085/C-R132	2-11 mo.	3	0
	12-71 mo.	2	--

Three children (case no. (b) (6) received mixed lots - Lot 1069/C-P241 as injection 1 and Lot 1080/C-P749 as injection 2.

2. Serologic Results

Antibody responses (RIA) prior to and after vaccination are as follows:

Age	Time	% With Anti-PRP >0.15 mcg Ab/ml	% With Anti-PRP >1.0 mcg Ab/ml	GMT (mcg Ab/ml) All Vaccinees
2-11 mo.	Pre	8 (1/12)	0 (0/12)	0.07
	2 mo.	100 (11/11)	100 (11/11)	2.392
	3 mo.	100 (9/9)	89 (8/9)	5.91
12-71 mo.	Pre	41 (9/22)	5 (1/22)	0.12
	1 mo.	100 (22/22)	100 (22/22)	8.87

Antibody responses (by lot per age group) prior to vaccination through 3 months postvaccination are included in Tables 2-3. If vaccine recipients received mixed lots, they were excluded from summaries by lot.

RESULTS: (CONT.)

3. Clinical Results:

The frequencies of selected injection site and systemic reactions during the 48 hours after vaccination are as follows:

	% Vaccinees with Reactions		
	2 - 11 Months of Age		12 - 71 Months of Age
Type of Reaction	Injection 1	Injection 2	Injection 1
Injection Site			
Erythema >1 inch	0.0 (0/29)	0.0 (0/19)	0.0 (0/38)
Swelling >1 inch	0.0 (0/29)	0.0 (0/19)	5.3 (2/38)
Pain/Soreness	13.8 (4/29)	15.8 (3/19)	39.5 (15/38)
Systemic			
Irritability	55.2 (16/29)	42.1 (8/19)	44.7 (17/38)
Sleepiness/ Lethargy/Fatigue	48.3 (14/29)	36.8 (7/19)	26.3 (10/38)

Reaction frequencies and maximum temperatures recorded during the five days following each injection of vaccine are reported in Tables 4-6.

No serious or alarming reactions attributable to the vaccine were reported.

TABLE 1

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : AYOUB, ELIA
STUDY : 000409
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA
(b) (6)	F	CAUC	(b) (6)	11M	0	(b) (6)	011	INJ 1	CR132	15 MCG		
	M	CAUC		11M	0		001	PREBLEED				< 125
					0		011	INJ 1	CP241	15 MCG		
					56		011	BLEED 1				3376
					56		021	INJ 2	CP241	15 MCG		
					84		021	BLEED 2				18601
	M	CAUC		10M	0		001	PREBLEED				133
					0		011	INJ 1	CP241	15 MCG		
					84		011	BLEED 1			05/	4198
					84		021	INJ 2	CP749	15 MCG		
					112		021	BLEED 2			05/	18200
	F	CAUC		7M	0		001	PREBLEED				< 125
					0		011	INJ 1	CP241	15 MCG		
					154		071	BLEED 1			05/	2461
					203		071	BLEED 2			05/	29382
	F	CAUC		10M	0		001	PREBLEED				< 125
					0		011	INJ 1	CP241	15 MCG		
					56		011	BLEED 1				8588
					56		021	INJ 2	CP241	15 MCG		
					140		021	BLEED 2				3604
	M	CAUC		11M	0		001	PREBLEED				< 125
					0		011	INJ 1	CP241	15 MCG		
					71		011	BLEED 1			05/	5667
					71		021	INJ 2	CP241	15 MCG		
					98		021	BLEED 2			05/	29142
	F	CAUC		10M	0		001	PREBLEED				< 125
					0		011	INJ 1	CP241	15 MCG		
					63		011	BLEED 1				5034
					63		021	INJ 2	CP241	15 MCG		
					105		021	BLEED 2				11170
	F	CAUC		9M	0		001	PREBLEED				< 125
					0		011	INJ 1	CP241	15 MCG		
					55		011	BLEED 1				1761

006900

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : AYOUB, ELIA
STUDY : 000409
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA
(b) (6)	F	CAUC	(b) (6)	9M	55	(b) (6)	021	INJ 2	CP241	15 MCG		
					83		021	BLEED 2				971
	M	CAUC		6M	0		001	PREBLEED				< 125
					0		011	INJ 1	CP241	15 MCG		
					91		011	BLEED 1			05/	420
					91		021	INJ 2	CP241	15 MCG		
	F	CAUC		10M	0		011	INJ 1	CP749	15 MCG		
	M	CAUC		9M	0		001	PREBLEED				< 125
					0		011	INJ 1	CP749	15 MCG		
					56		011	BLEED 1				2716
					56		021	INJ 2	CP749	15 MCG		
	M	CAUC		9M	0		001	PREBLEED				< 125
					0		011	INJ 1	CP749	15 MCG		
					56		D11	BLEED 1				944
	M	CAUC		9M	0		011	INJ 1	CP749	15 MCG		
	M	CAUC		7M	0		011	INJ 1	CP749	15 MCG		
	F	CAUC		6M	0		011	INJ 1	CP749	15 MCG		
	F	CAUC		9M	0		011	INJ 1	CP749	15 MCG		
	M	CAUC		6M	0		011	INJ 1	CP749	15 MCG		
	M	OTHE		9M	0		011	INJ 1	CP749	15 MCG		
	F	CAUC		10M	0		011	INJ 1	CR132	15 MCG		
	F	CAUC		2M	0		001	PREBLEED				180
					0		011	INJ 1	CP241	15 MCG		
					147		011	BLEED 1			05/	1697
					147		021	INJ 2	CP241	15 MCG		
	F	CAUC		4M	0		001	PREBLEED				< 125
					0		011	INJ 1	CP241	15 MCG		

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : AYOUB, ELIA
STUDY : 000409
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA
(b) (6)	F	CAUC	(b) (6)	4M	56	(b) (6)	011	BLEED 1				3990
					56		021	INJ 2	CP241	15 MCG		
					90		021	BLEED 2				10902
	M	CAUC		5M	0		001	PREBLEED				150
					0		011	INJ 1	CP241	15 MCG		
					56		011	BLEED 1				1212
					56		021	INJ 2	CP241	15 MCG		
					84		021	BLEED 2				5317
	M	CAUC		3M	0		001	PREBLEED				< 125
					0		011	INJ 1	CP241	15 MCG		
					56		011	BLEED 1				4278
					56		021	INJ 2	CP241	15 MCG		
					91		021	BLEED 2				5385
	F	CAUC		3M	0		001	PREBLEED				< 125
					0		011	INJ 1	CP241	15 MCG		
					56		011	BLEED 1				1743
					56		021	INJ 2	CP749	15 MCG		
					91		021	BLEED 2				1633
	M	CAUC		4M	0		001	PREBLEED				< 125
					0		011	INJ 1	CP241	15 MCG		
					71		011	BLEED 1			05/	503
					71		021	INJ 2	CP749	15 MCG		
	F	CAUC		3M	0		001	PREBLEED				< 125
					0		011	INJ 1	CP241	15 MCG		
					55		011	BLEED 1				1334
					55		021	INJ 2	CP241	15 MCG		
					90		021	BLEED 2				9085
	M	CAUC		2M	0		011	INJ 1	CP749	15 MCG		
					83		021	INJ 2	CP749	15 MCG		
	M	CAUC		2M	0		011	INJ 1	CP749	15 MCG		
					63		021	INJ 2	CP749	15 MCG		
	M	CAUC		2M	0		001	PREBLEED				209

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : AYOUB, ELIA
STUDY : 000409
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA
(b) (6)	M	CAUC	(b) (6)	2M	0	(b) (6)	011	INJ 1	CP749	15 MCG		
					57		011	BLEED 1				4524
					70		021	INJ 2	CP749	15 MCG		
					98		021	BLEED 2				9417
	F	CAUC		3M	0		001	PREBLEED				< 125
					0		011	INJ 1	CP749	15 MCG		
					63		011	BLEED 1				3886
					63		021	INJ 2	CP749	15 MCG		
	M	BLAC		2M	0		001	PREBLEED				435
					0		011	INJ 1	CP749	15 MCG		
					56		011	BLEED 1				1385
	M	CAUC		2M	0		011	INJ 1	CP749	15 MCG		
					63		021	INJ 2	CP749	15 MCG		
	M	CAUC		3M	0		011	INJ 1	CP749	15 MCG		
	F	CAUC		2M	0		011	INJ 1	CP749	15 MCG		
	F	CAUC		5M	0		011	INJ 1	CR132	15 MCG		

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : AYOUB, ELIA
STUDY : 000409
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA
(b) (6)	M	CAUC	(b) (6)	2Y	0	(b) (6)	001	PREBLEED				< 125
					0		011	INJ 1	CP241	15 MCG		
					122		011	BLEED 1				13097
	F	CAUC		2Y	0		001	PREBLEED				708
					0		011	INJ 1	CP241	15 MCG		
	M	CAUC		4Y	0		001	PREBLEED				249
					0		011	INJ 1	CP241	15 MCG		
					29		011	BLEED 1				80851
	F	CAUC		2Y	0		011	INJ 1	CP749	15 MCG		
	M	CAUC		3Y	0		011	INJ 1	CP749	15 MCG		
	F	CAUC		2Y	0		001	PREBLEED				< 125
					0		011	INJ 1	CP749	15 MCG		
					48		011	BLEED 1				23413
	F	CAUC		2Y	0		011	INJ 1	CP749	15 MCG		
	M	CAUC		2Y	0		001	PREBLEED				< 125
					0		011	INJ 1	CP749	15 MCG		
					28		011	BLEED 1				51000
	M	CAUC		2Y	0		001	PREBLEED				1623
					0		011	INJ 1	CP749	15 MCG		
					49		011	BLEED 1				52266
	M	CAUC		2Y	0		001	PREBLEED				< 125
					0		011	INJ 1	CP749	15 MCG		
					28		011	BLEED 1				9916
	F	CAUC		2Y	0		011	INJ 1	CP749	15 MCG		
	F	CAUC		2Y	0		011	INJ 1	CP749	15 MCG		
	F	CAUC		2Y	0		011	INJ 1	CP749	15 MCG		
	M	CAUC		2Y	0		011	INJ 1	CP749	15 MCG		

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : AYOUB, ELIA
STUDY : 000409
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA
(b) (6)	M	CAUC	(b) (6)	3Y	0	(b) (6)	011	INJ	1	CP749	15 MCG	
	M	CAUC		2Y	0		011	INJ	1	CP749	15 MCG	
	M	HISP		2Y	0		011	INJ	1	CP749	15 MCG	
	F	CAUC		13M	0		001	PREBLEED				< 125
					0		011	INJ	1	CP241	15 MCG	
					28		011	BLEED	1			27889
	F	CAUC		17M	0		001	PREBLEED				494
					0		011	INJ	1	CP241	15 MCG	
					29		011	BLEED	1			11070
	M	CAUC		23M	0		001	PREBLEED				< 125
					0		011	INJ	1	CP241	15 MCG	
					28		011	BLEED	1			35934
	M	CAUC		19M	0		001	PREBLEED				196
					0		011	INJ	1	CP241	15 MCG	
					28		011	BLEED	1			1659
	M	CAUC		19M	0		001	PREBLEED				389
					0		011	INJ	1	CP241	15 MCG	
					28		011	BLEED	1			42928
	M	CAUC		12M	0		011	INJ	1	CP241	15 MCG	
	M	BLAC		24M	0		001	PREBLEED				160
					0		011	INJ	1	CP241	15 MCG	
					27		011	BLEED	1			2733
	M	CAUC		18M	0		001	PREBLEED				< 125
					0		011	INJ	1	CP241	15 MCG	
					28		011	BLEED	1			12530
	F	CAUC		18M	0		011	INJ	1	CP241	15 MCG	
	F	CAUC		22M	0		001	PREBLEED				< 125
					0		011	INJ	1	CP241	15 MCG	

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : AYOUB, ELIA
STUDY : 000409
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA
(b) (6)	F	CAUC	(b) (6)	22M	71	(b) (6)	011	BLEED	1			6621
	M	CAUC		12M	0		011	INJ	1	CP749 15 MCG		
	F	CAUC		19M	0		011	INJ	1	CP749 15 MCG		
	M	CAUC		12M	0		011	INJ	1	CP749 15 MCG		
	M	CAUC		18M	0		011	INJ	1	CP749 15 MCG		
	M	CAUC		18M	0		001	PREBLEED				< 125
					0		011	INJ	1	CP749 15 MCG		
					28		011	BLEED	1			4969
	F	BLAC		20M	0		001	PREBLEED				< 125
					0		011	INJ	1	CP749 15 MCG		
					35		011	BLEED	1			38527
	M	CAUC		12M	0		011	INJ	1	CP749 15 MCG		
	F	CAUC		18M	0		001	PREBLEED				< 125
					0		011	INJ	1	CP749 15 MCG		
					28		011	BLEED	1			5599
	M	CAUC		20M	0		001	PREBLEED				133
					0		011	INJ	1	CP749 15 MCG		
					27		011	BLEED	1			1204
	F	CAUC		23M	0		001	PREBLEED				< 125
					0		011	INJ	1	CP749 15 MCG		
					36		011	BLEED	1			3093
	M	CAUC		19M	0		001	PREBLEED				< 125
					0		011	INJ	1	CP749 15 MCG		
					28		011	BLEED	1			1641
	M	CAUC		18M	0		001	PREBLEED				192
					0		011	INJ	1	CP749 15 MCG		
					28		011	BLEED	1			4355
	M	CAUC		15M	0		001	PREBLEED				< 125

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : AYOUB, ELIA
STUDY : 000409
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT		LOT	DOSE	CODE/	RIA
(b) (6)	M	CAUC	(b) (6)	15M	0	(b) (6)	011	INJ	1	CP749	15 MCG		
					28		011	BLEED	1				2121
	M	CAUC		15M	0		001	PREBLEED					259
					0		011	INJ	1	CP749	15 MCG		
					28		011	BLEED	1				3433
	F	CAUC		16M	0		001	PREBLEED					247
					0		011	INJ	1	CP749	15 MCG		
					28		011	BLEED	1				2523
	F	CAUC		22M	0		011	INJ	1	CP749	15 MCG		
	M	CAUC		23M	0		011	INJ	1	CP749	15 MCG		
	F	CAUC		17M	0		011	INJ	1	CP749	15 MCG		
	M	CAUC		18M	0		011	INJ	1	CP749	15 MCG		
	F	CAUC		18M	0		011	INJ	1	CP749	15 MCG		
	F	CAUC		15M	0		011	INJ	1	CR132	15 MCG		
	M	CAUC		12M	0		011	INJ	1	CR132	15 MCG		

TABLE 2

ANTIBODY RESPONSES

INVESTIGATOR : AYOUB, ELIA
STUDY : 000409
VACCINE : HIB CONJUGATE
ASSAY : RIA
LOT NUMBER : CP241
DOSE : 15 MCG
POPULATION : HEALTHY CHILDREN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
1- 6 MOS.	PRE INJ	0 (0/ 4)	0 (0/ 4)			0.078 (4)
	MONTH 2	100 (4/ 4)	100 (4/ 4)	100 (4/ 4)	17.5	2.292 (4)
	MONTH 3	100 (4/ 4)	100 (4/ 4)	100 (4/ 4)	55.8	7.297 (4)
7-11 MOS.	PRE INJ	0 (0/ 4)	0 (0/ 4)			0.062 (4)
	MONTH 2	100 (4/ 4)	100 (4/ 4)	100 (4/ 4)	32.0	4.004 (4)
	MONTH 3	100 (3/ 3)	67 (2/ 3)	100 (3/ 3)	46.9	5.865 (3)
12-71 MOS.	PRE INJ	63 (5/ 8)	0 (0/ 8)			0.157 (8)
	MONTH 1	100 (8/ 8)	100 (8/ 8)	100 (8/ 8)	72.3	14.706 (8)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 3

A N T I B O D Y R E S P O N S E S

INVESTIGATOR : AYOUB, ELIA
STUDY : 000409
VACCINE : HIB CONJUGATE
ASSAY : RIA
LOT NUMBER : CP749
DOSE : 15 MCG
POPULATION : HEALTHY CHILDREN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
1- 6 MOS.	PRE INJ	50 (1/ 2)	0 (0/ 2)			0.114 (2)
	MONTH 2	100 (1/ 1)	100 (1/ 1)	100 (1/ 1)	31.1	3.886 (1)
	MONTH 3	100 (1/ 1)	100 (1/ 1)	100 (1/ 1)	45.1	9.417 (1)
7-11 MOS.	PRE INJ	0 (0/ 1)	0 (0/ 1)			0.063 (1)
	MONTH 2	100 (1/ 1)	100 (1/ 1)	100 (1/ 1)	21.7	2.716 (1)
12-71 MOS.	PRE INJ	29 (4/ 14)	7 (1/ 14)			0.110 (14)
	MONTH 1	100 (14/ 14)	100 (14/ 14)	100 (14/ 14)	38.6	6.641 (14)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 4

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : AYOUB, ELIA
STUDY : 000409
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	15	
VACCINEES WITH NO COMPLAINTS :	1	(6.7 %)
VACCINEES WITH COMPLAINTS :	14	(93.3 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 15 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	5	33.3
ERYTHEMA, INJ. SITE (<=1 IN.)	3	20.0
PAIN/SORENESS, INJ. SITE	2	13.3
SWELLING, INJ. SITE (<=1 IN.)	1	6.7
SYSTEMIC REACTIONS	13	86.7
IRRITABILITY	10	66.7
FATIGUE	9	60.0
HARM TO TOUCH	7	46.7
TEETHING	6	40.0
RASH	3	20.0
ANOREXIA	2	13.3
OTITIS MEDIA	2	13.3
PROLONGED CRYING, >1/2 HR	2	13.3
VOMITING	2	13.3
ALLERGIC RHINITIS	1	6.7
CANDIDIASIS	1	6.7
DIARRHEA	1	6.7
NASAL CONGESTION	1	6.7
WHEEZING	1	6.7

TABLE 4 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : AYOUB, ELIA
STUDY : 000409
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 2	
TOTAL VACCINEES :	11	
VACCINEES WITH NO COMPLAINTS :	2	(18.2 %)
VACCINEES WITH COMPLAINTS :	9	(81.8 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 11 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	4	36.4
SWELLING, INJ. SITE (<=1 IN.)	4	36.4
PAIN/SORENESS, INJ. SITE	2	18.2
ERYTHEMA, INJ. SITE (<=1 IN.)	1	9.1
SYSTEMIC REACTIONS	8	72.7
FATIGUE	6	54.5
IRRITABILITY	6	54.5
TEETHING	4	36.4
WARM TO TOUCH	3	27.3
RASH	2	18.2
DIARRHEA	1	9.1
OTITIS MEDIA	1	9.1
PROLONGED CRYING, >1/2 HR	1	9.1

TABLE 4 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : AYOUB, ELIA
STUDY : 000409
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
POPULATION : HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES	13	
VACCINEES WITH NO COMPLAINTS	2	(18.2 %)
VACCINEES WITH COMPLAINTS	9	(81.8 %)
VACCINEES WITH NO DATA	2	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 11 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	3	27.3
PAIN/SORENESS, INJ. SITE	3	27.3
ERYTHEMA, INJ. SITE (<=1 IN.)	1	9.1
SWELLING, INJ. SITE (<=1 IN.)	1	9.1
SYSTEMIC REACTIONS	7	63.6
IRRITABILITY	7	63.6
FATIGUE	3	27.3
HARM TO TOUCH	3	27.3
DIARRHEA	2	18.2
PROLONGED CRYING, >1/2 HR	2	18.2
TEETHING	2	18.2
FEVER	1	9.1
VOMITING	1	9.1

TABLE 4 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : AYOUB, ELIA
STUDY : 000409
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES	17	
VACCINEES WITH NO COMPLAINTS	2	(14.3 %)
VACCINEES WITH COMPLAINTS	12	(85.7 %)
VACCINEES WITH NO DATA	3	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 14 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	2	14.3
PAIN/SORENESS, INJ. SITE	2	14.3
SWELLING, INJ. SITE (<=1 IN.)	1	7.1
SYSTEMIC REACTIONS	11	78.6
IRRITABILITY	7	50.0
FATIGUE	5	35.7
WARM TO TOUCH	5	35.7
DERMATOMYCOSES	1	7.1
DIARRHEA	1	7.1
EYE SWELLING	1	7.1
HYPERHYDROSIS	1	7.1
OTITIS EXTERNA	1	7.1
SCLERAL DISORDERS	1	7.1
TEETHING	1	7.1

TABLE 4 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : AYOUB, ELIA
STUDY : 000409
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE	HIB CONJUGATE INJECTION: 2	
TOTAL VACCINEES	9	
VACCINEES WITH NO COMPLAINTS	4	(50.0 %)
VACCINEES WITH COMPLAINTS	4	(50.0 %)
VACCINEES WITH NO DATA	1	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 8 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	2	25.0
SWELLING, INJ. SITE (<=1 IN.)	2	25.0
ERYTHEMA, INJ. SITE (<=1 IN.)	1	12.5
PAIN/SORENESS, INJ. SITE	1	12.5
SYSTEMIC REACTIONS	4	50.0
IRRITABILITY	2	25.0
TEETHING	2	25.0
COMMON COLD	1	12.5
COUGH	1	12.5
FATIGUE	1	12.5
NASAL DISCHARGE	1	12.5
WHEEZING	1	12.5

TABLE 4 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : AYOUB, ELIA
STUDY : 000409
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
POPULATION : HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	34	
VACCINEES WITH NO COMPLAINTS :	3	(11.1 %)
VACCINEES WITH COMPLAINTS :	24	(88.9 %)
VACCINEES WITH NO DATA :	7	

CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 27 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	14	51.9
PAIN/SORENESS, INJ. SITE	12	44.4
ERYTHEMA, INJ. SITE (<=1 IN.)	6	22.2
SWELLING, INJ. SITE (<=1 IN.)	4	14.8
SWELLING, INJ. SITE (>1 INCH)	2	7.4
INDURATION, INJECTION SITE	1	3.7
SYSTEMIC REACTIONS	21	77.8
IRRITABILITY	10	37.0
FATIGUE	8	29.6
HARM TO TOUCH	7	25.9
DIARRHEA	4	14.8
COMMON COLD	2	7.4
FEVER	2	7.4
RIGHT AXIS DEVIATION	2	7.4
TEETHING	2	7.4
ALLERGIC RHINITIS	1	3.7
ANOREXIA	1	3.7
HEADACHE	1	3.7
INFECTIOUS GASTROENTERITIS	1	3.7
NASAL DISCHARGE	1	3.7
PROLONGED CRYING, >1/2 HR	1	3.7
RASH	1	3.7
VOMITING	1	3.7

TABLE 5

CLINICAL COMPLAINTS

INVESTIGATOR : AYOUB, ELIA
STUDY : 000409
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (15 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
LOCAL REACTIONS	3 (20.0%)	4 (26.7%)	1 (6.7%)	1 (6.7%)	1 (7.1%)	0 (0.0%)		5 (33.3%)
ERYTHEMA, INJ. SITE (<=1 IN.)	2 (13.3%)	2 (13.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		3 (20.0%)
PAIN/SORENESS, INJ. SITE	1 (6.7%)	1 (6.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (13.3%)
SWELLING, INJ. SITE (<=1 IN.)	1 (6.7%)	1 (6.7%)	1 (6.7%)	1 (6.7%)	1 (7.1%)	0 (0.0%)		1 (6.7%)
SYSTEMIC	12 (80.0%)	12 (80.0%)	10 (66.7%)	9 (60.0%)	9 (64.3%)	8 (61.5%)		13 (86.7%)
BODY AS A WHOLE/SITE UNSPEC.	8 (53.3%)	8 (53.3%)	1 (6.7%)	1 (6.7%)	1 (7.1%)	0 (0.0%)		11 (73.3%)
FATIGUE	6 (40.0%)	6 (40.0%)	1 (6.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		9 (60.0%)
HARM TO TOUCH	4 (26.7%)	4 (26.7%)	0 (0.0%)	1 (6.7%)	1 (7.1%)	0 (0.0%)		7 (46.7%)
DIGESTIVE SYSTEM	4 (26.7%)	6 (40.0%)	4 (26.7%)	5 (33.3%)	4 (28.6%)	3 (23.1%)		8 (53.3%)
ANOREXIA	1 (6.7%)	2 (13.3%)	1 (6.7%)	1 (6.7%)	1 (7.1%)	1 (7.7%)		2 (13.3%)
DIARRHEA	1 (6.7%)	1 (6.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (6.7%)

TABLE 5 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : AYOUB, ELIA
STUDY : 000409
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (15 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		
TEETHING	4 (26.7%)	5 (33.3%)	4 (26.7%)	4 (26.7%)	4 (28.6%)	3 (23.1%)		6 (40.0%)
VOMITING	0 (0.0%)	1 (6.7%)	1 (6.7%)	1 (6.7%)	0 (0.0%)	0 (0.0%)		2 (13.3%)
NERVOUS SYSTEM & PSYCHIATRIC	7 (46.7%)	7 (46.7%)	4 (26.7%)	1 (6.7%)	3 (21.4%)	1 (7.7%)		10 (66.7%)
IRRITABILITY	7 (46.7%)	7 (46.7%)	4 (26.7%)	1 (6.7%)	3 (21.4%)	1 (7.7%)		10 (66.7%)
PROLONGED CRYING, >1/2 HR	1 (6.7%)	2 (13.3%)	1 (6.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (13.3%)
RESPIRATORY SYSTEM	1 (6.7%)	2 (13.3%)	2 (13.3%)	1 (6.7%)	2 (14.3%)	2 (15.4%)		2 (13.3%)
ALLERGIC RHINITIS	1 (6.7%)	1 (6.7%)	1 (6.7%)	1 (6.7%)	1 (7.1%)	1 (7.7%)		1 (6.7%)
NASAL CONGESTION	0 (0.0%)	0 (0.0%)	1 (6.7%)	1 (6.7%)	1 (7.1%)	1 (7.7%)		1 (6.7%)
WHEEZING	0 (0.0%)	1 (6.7%)	1 (6.7%)	0 (0.0%)	1 (7.1%)	1 (7.7%)		1 (6.7%)
SKIN & SKIN APPENDAGE	1 (6.7%)	3 (20.0%)	3 (20.0%)	3 (20.0%)	3 (21.4%)	4 (30.8%)		4 (26.7%)
CANDIDIASIS	1 (6.7%)	1 (6.7%)	1 (6.7%)	1 (6.7%)	1 (7.1%)	1 (7.7%)		1 (6.7%)
RASH	0 (0.0%)	2 (13.3%)	2 (13.3%)	2 (13.3%)	2 (14.3%)	3 (23.1%)		3 (20.0%)

TABLE 5 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : AYOUB, ELIA
STUDY : 000409
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (15 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
SPECIAL SENSES	2 (13.3%)	2 (13.3%)	2 (13.3%)	2 (13.3%)	2 (14.3%)	2 (15.4%)		2 (13.3%)
OTITIS MEDIA	2 (13.3%)	2 (13.3%)	2 (13.3%)	2 (13.3%)	2 (14.3%)	2 (15.4%)		2 (13.3%)
VACCINEES WITH COMPLAINTS	13 (86.7%)	13 (86.7%)	11 (73.3%)	10 (66.7%)	10 (71.4%)	8 (61.5%)		14 (93.3%)
VACCINEES WITH NO COMPLAINTS	2 (13.3%)	2 (13.3%)	4 (26.7%)	5 (33.3%)	4 (28.6%)	5 (38.5%)		1 (6.7%)
TOTAL VACCINEES REPORTING	15	15	15	15	14	13		15
VACCINEES WITH NO DATA	0	0	0	0	1	2		0

TABLE 5 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : AYOUB, ELIA
STUDY : 000409
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE — NUMBER OF VACCINEES (11 VACCINEES) - INJECTION: 2

CLINICAL COMPLAINTS	DAYS POST VACCINATION 0	1	2	3	4	5		NUMBER WITH COMPLAINTS
LOCAL REACTIONS	4 (36.4%)	2 (18.2%)	2 (18.2%)	1 (9.1%)	1 (9.1%)	1 (9.1%)		4 (36.4%)
ERYTHEMA, INJ. SITE (<=1 IN.)	1 (9.1%)	1 (9.1%)	1 (9.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (9.1%)
PAIN/SORENESS, INJ. SITE	2 (18.2%)	1 (9.1%)	1 (9.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (18.2%)
SWELLING, INJ. SITE (<=1 IN.)	4 (36.4%)	1 (9.1%)	1 (9.1%)	1 (9.1%)	1 (9.1%)	1 (9.1%)		4 (36.4%)
SYSTEMIC	7 (63.6%)	5 (45.5%)	5 (45.5%)	5 (45.5%)	5 (45.5%)	5 (45.5%)		8 (72.7%)
BODY AS A WHOLE/SITE UNSPEC.	6 (54.5%)	3 (27.3%)	2 (18.2%)	1 (9.1%)	1 (9.1%)	0 (0.0%)		7 (63.6%)
FATIGUE	6 (54.5%)	3 (27.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		6 (54.5%)
HARM TO TOUCH	1 (9.1%)	1 (9.1%)	2 (18.2%)	1 (9.1%)	1 (9.1%)	0 (0.0%)		3 (27.3%)
DIGESTIVE SYSTEM	3 (27.3%)	2 (18.2%)	3 (27.3%)	3 (27.3%)	3 (27.3%)	3 (27.3%)		4 (36.4%)
DIARRHEA	0 (0.0%)	0 (0.0%)	1 (9.1%)	1 (9.1%)	1 (9.1%)	1 (9.1%)		1 (9.1%)
TEETHING	3 (27.3%)	2 (18.2%)	3 (27.3%)	3 (27.3%)	3 (27.3%)	3 (27.3%)		4 (36.4%)

TABLE 5 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : AYOUB, ELIA
STUDY : 000409
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (11 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
NERVOUS SYSTEM & PSYCHIATRIC	6 (54.5%)	3 (27.3%)	2 (18.2%)	1 (9.1%)	1 (9.1%)	1 (9.1%)		6 (54.5%)
IRRITABILITY	6 (54.5%)	3 (27.3%)	2 (18.2%)	1 (9.1%)	1 (9.1%)	1 (9.1%)		6 (54.5%)
PROLONGED CRYING, >1/2 HR	0 (0.0%)	1 (9.1%)	1 (9.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (9.1%)
SKIN & SKIN APPENDAGE	0 (0.0%)	1 (9.1%)	1 (9.1%)	1 (9.1%)	2 (18.2%)	0 (0.0%)		2 (18.2%)
RASH	0 (0.0%)	1 (9.1%)	1 (9.1%)	1 (9.1%)	2 (18.2%)	0 (0.0%)		2 (18.2%)
SPECIAL SENSES	1 (9.1%)	1 (9.1%)	1 (9.1%)	1 (9.1%)	1 (9.1%)	1 (9.1%)		1 (9.1%)
OTITIS MEDIA	1 (9.1%)	1 (9.1%)	1 (9.1%)	1 (9.1%)	1 (9.1%)	1 (9.1%)		1 (9.1%)
VACCINEES WITH COMPLAINTS	8 (72.7%)	7 (63.6%)	7 (63.6%)	6 (54.5%)	6 (54.5%)	6 (54.5%)		9 (81.8%)
VACCINEES WITH NO COMPLAINTS	3 (27.3%)	4 (36.4%)	4 (36.4%)	5 (45.5%)	5 (45.5%)	5 (45.5%)		2 (18.2%)
TOTAL VACCINEES REPORTING	11	11	11	11	11	11		11
VACCINEES WITH NO DATA	0	0	0	0	0	0		0

TABLE 5 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : AYOUB, ELIA
STUDY : 000409
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (13 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5	
LOCAL REACTIONS	2 (18.2%)	2 (18.2%)	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (27.3%)
ERYTHEMA, INJ. SITE (<=1 IN.)	0 (0.0%)	1 (9.1%)	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (9.1%)
PAIN/SORENESS, INJ. SITE	2 (18.2%)	2 (18.2%)	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (27.3%)
SWELLING, INJ. SITE (<=1 IN.)	0 (0.0%)	1 (9.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (9.1%)
SYSTEMIC	7 (63.6%)	3 (27.3%)	4 (40.0%)	4 (40.0%)	4 (40.0%)	4 (40.0%)	7 (63.6%)
BODY AS A WHOLE/SITE UNSPEC.	5 (45.5%)	1 (9.1%)	1 (10.0%)	3 (30.0%)	1 (10.0%)	1 (10.0%)	5 (45.5%)
FATIGUE	3 (27.3%)	1 (9.1%)	1 (10.0%)	2 (20.0%)	1 (10.0%)	1 (10.0%)	3 (27.3%)
FEVER	1 (9.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (9.1%)
WARM TO TOUCH	1 (9.1%)	1 (9.1%)	1 (10.0%)	3 (30.0%)	0 (0.0%)	0 (0.0%)	3 (27.3%)
DIGESTIVE SYSTEM	1 (9.1%)	2 (18.2%)	3 (30.0%)	2 (20.0%)	2 (20.0%)	2 (20.0%)	4 (36.4%)
DIARRHEA	0 (0.0%)	1 (9.1%)	2 (20.0%)	0 (0.0%)	1 (10.0%)	1 (10.0%)	2 (18.2%)

TABLE 5 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : AYOUB, ELIA
STUDY : 000409
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (13 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
TEETHING	1 (9.1%)	1 (9.1%)	2 (20.0%)	2 (20.0%)	2 (20.0%)	2 (20.0%)		2 (18.2%)
VOMITING	0 (0.0%)	1 (9.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (9.1%)
NERVOUS SYSTEM & PSYCHIATRIC	7 (63.6%)	2 (18.2%)	3 (30.0%)	2 (20.0%)	2 (20.0%)	2 (20.0%)		7 (63.6%)
IRRITABILITY	7 (63.6%)	2 (18.2%)	3 (30.0%)	2 (20.0%)	2 (20.0%)	2 (20.0%)		7 (63.6%)
PROLONGED CRYING, >1/2 HR	1 (9.1%)	1 (9.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (18.2%)
VACCINEES WITH COMPLAINTS	8 (72.7%)	4 (36.4%)	5 (50.0%)	4 (40.0%)	4 (40.0%)	4 (40.0%)		9 (81.8%)
VACCINEES WITH NO COMPLAINTS	3 (27.3%)	7 (63.6%)	5 (50.0%)	6 (60.0%)	6 (60.0%)	6 (60.0%)		2 (18.2%)
TOTAL VACCINEES REPORTING	11	11	10	10	10	10		11
VACCINEES WITH NO DATA	2	2	3	3	3	3		2

TABLE 5 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : AYOUB, ELIA
STUDY : 000409
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (17 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5	COMPLAINTS
LOCAL REACTIONS	2 (14.3%)	1 (7.1%)	1 (7.1%)	1 (7.1%)	1 (7.1%)	1 (7.1%)	2 (14.3%)
PAIN/SORENESS, INJ. SITE	2 (14.3%)	1 (7.1%)	1 (7.1%)	1 (7.1%)	1 (7.1%)	1 (7.1%)	2 (14.3%)
SWELLING, INJ. SITE (<=1 IN.)	1 (7.1%)	1 (7.1%)	1 (7.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.1%)
SYSTEMIC	8 (57.1%)	6 (42.9%)	5 (35.7%)	4 (28.6%)	4 (28.6%)	3 (21.4%)	11 (78.6%)
BODY AS A WHOLE/SITE UNSPEC.	4 (28.6%)	3 (21.4%)	3 (21.4%)	2 (14.3%)	2 (14.3%)	1 (7.1%)	8 (57.1%)
FATIGUE	3 (21.4%)	2 (14.3%)	2 (14.3%)	1 (7.1%)	1 (7.1%)	1 (7.1%)	5 (35.7%)
HARM TO TOUCH	2 (14.3%)	3 (21.4%)	2 (14.3%)	2 (14.3%)	2 (14.3%)	1 (7.1%)	5 (35.7%)
DIGESTIVE SYSTEM	1 (7.1%)	1 (7.1%)	1 (7.1%)	1 (7.1%)	1 (7.1%)	1 (7.1%)	1 (7.1%)
DIARRHEA	1 (7.1%)	1 (7.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.1%)
TEETHING	1 (7.1%)	1 (7.1%)	1 (7.1%)	1 (7.1%)	1 (7.1%)	1 (7.1%)	1 (7.1%)
NERVOUS SYSTEM & PSYCHIATRIC	4 (28.6%)	4 (28.6%)	2 (14.3%)	0 (0.0%)	2 (14.3%)	1 (7.1%)	7 (50.0%)

00663

TABLE 5 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : AYOUB, ELIA
STUDY : 000409
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (17 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		
IRRITABILITY	4 (28.6%)	4 (28.6%)	2 (14.3%)	0 (0.0%)	2 (14.3%)	1 (7.1%)		7 (50.0%)
SKIN & SKIN APPENDAGE	1 (7.1%)	2 (14.3%)	2 (14.3%)	2 (14.3%)	2 (14.3%)	2 (14.3%)		2 (14.3%)
DERMATOMYCOSES	0 (0.0%)	1 (7.1%)	1 (7.1%)	1 (7.1%)	1 (7.1%)	1 (7.1%)		1 (7.1%)
HYPERHYDROSIS	1 (7.1%)	1 (7.1%)	1 (7.1%)	1 (7.1%)	1 (7.1%)	1 (7.1%)		1 (7.1%)
SPECIAL SENSES	2 (14.3%)	2 (14.3%)	1 (7.1%)	1 (7.1%)	1 (7.1%)	1 (7.1%)		3 (21.4%)
EYE SWELLING	0 (0.0%)	1 (7.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (7.1%)
OTITIS EXTERNA	1 (7.1%)	1 (7.1%)	1 (7.1%)	1 (7.1%)	1 (7.1%)	1 (7.1%)		1 (7.1%)
SCLERAL DISORDERS	1 (7.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (7.1%)
VACCINEES WITH COMPLAINTS	9 (64.3%)	6 (42.9%)	5 (35.7%)	4 (28.6%)	4 (28.6%)	3 (21.4%)		12 (85.7%)
VACCINEES WITH NO COMPLAINTS	5 (35.7%)	8 (57.1%)	9 (64.3%)	10 (71.4%)	10 (71.4%)	11 (78.6%)		2 (14.3%)
TOTAL VACCINEES REPORTING	14	14	14	14	14	14		14

00664

TABLE 5 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : AYOUB, ELIA
STUDY : 000409
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (17 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5	COMPLAINTS
VACCINEES WITH NO DATA	3	3	3	3	3	3	3

59900

TABLE 5 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : AYOUB, ELIA
STUDY : 000409
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (9 VACCINEES) - INJECTION: 2						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5	COMPLAINTS
LOCAL REACTIONS	1 (12.5%)	2 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (25.0%)
ERYTHEMA, INJ. SITE (<=1 IN.)	0 (0.0%)	1 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (12.5%)
PAIN/SORENESS, INJ. SITE	1 (12.5%)	1 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (12.5%)
SWELLING, INJ. SITE (<=1 IN.)	1 (12.5%)	1 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (25.0%)
SYSTEMIC	3 (37.5%)	1 (12.5%)	1 (12.5%)	1 (12.5%)	1 (12.5%)	1 (12.5%)	4 (50.0%)
BODY AS A WHOLE/SITE UNSPEC.	1 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (12.5%)
FATIGUE	1 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (12.5%)
DIGESTIVE SYSTEM	1 (12.5%)	0 (0.0%)	0 (0.0%)	1 (12.5%)	0 (0.0%)	0 (0.0%)	2 (25.0%)
TEETHING	1 (12.5%)	0 (0.0%)	0 (0.0%)	1 (12.5%)	0 (0.0%)	0 (0.0%)	2 (25.0%)
NERVOUS SYSTEM & PSYCHIATRIC	1 (12.5%)	1 (12.5%)	0 (0.0%)	1 (12.5%)	0 (0.0%)	0 (0.0%)	2 (25.0%)
IRRITABILITY	1 (12.5%)	1 (12.5%)	0 (0.0%)	1 (12.5%)	0 (0.0%)	0 (0.0%)	2 (25.0%)

TABLE 5 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : AYOUB, ELIA
STUDY : 000409
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (9 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		
RESPIRATORY SYSTEM	0 (0.0%)	1 (12.5%)	1 (12.5%)	1 (12.5%)	1 (12.5%)	1 (12.5%)		1 (12.5%)
COMMON COLD	0 (0.0%)	0 (0.0%)	1 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (12.5%)
COUGH	0 (0.0%)	1 (12.5%)	0 (0.0%)	1 (12.5%)	1 (12.5%)	1 (12.5%)		1 (12.5%)
NASAL DISCHARGE	0 (0.0%)	1 (12.5%)	0 (0.0%)	1 (12.5%)	1 (12.5%)	1 (12.5%)		1 (12.5%)
WHEEZING	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (12.5%)	0 (0.0%)	0 (0.0%)		1 (12.5%)
VACCINEES WITH COMPLAINTS	3 (37.5%)	2 (25.0%)	1 (12.5%)	1 (12.5%)	1 (12.5%)	1 (12.5%)		4 (50.0%)
VACCINEES WITH NO COMPLAINTS	5 (62.5%)	6 (75.0%)	7 (87.5%)	7 (87.5%)	7 (87.5%)	7 (87.5%)		4 (50.0%)
TOTAL VACCINEES REPORTING	8	8	8	8	8	8		8
VACCINEES WITH NO DATA	1	1	1	1	1	1		1

00667

TABLE 5 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : AYOUB, ELIA
STUDY : 000409
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (34 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
LOCAL REACTIONS	10 (37.0%)	12 (44.4%)	5 (18.5%)	5 (18.5%)	3 (11.1%)	3 (11.1%)		14 (51.9%)
ERYTHEMA, INJ. SITE (<=1 IN.)	1 (3.7%)	6 (22.2%)	1 (3.7%)	1 (3.7%)	1 (3.7%)	1 (3.7%)		6 (22.2%)
INDURATION, INJECTION SITE	0 (0.0%)	1 (3.7%)	1 (3.7%)	1 (3.7%)	1 (3.7%)	1 (3.7%)		1 (3.7%)
PAIN/SORENESS, INJ. SITE	9 (33.3%)	10 (37.0%)	4 (14.8%)	4 (14.8%)	2 (7.4%)	2 (7.4%)		12 (44.4%)
SWELLING, INJ. SITE (>1 INCH)	1 (3.7%)	2 (7.4%)	1 (3.7%)	1 (3.7%)	0 (0.0%)	0 (0.0%)		2 (7.4%)
SWELLING, INJ. SITE (<=1 IN.)	0 (0.0%)	1 (3.7%)	3 (11.1%)	3 (11.1%)	3 (11.1%)	3 (11.1%)		4 (14.8%)
SYSTEMIC	16 (59.3%)	15 (55.6%)	9 (33.3%)	8 (29.6%)	7 (25.9%)	6 (22.2%)		21 (77.8%)
BODY AS A WHOLE/SITE UNSPEC.	8 (29.6%)	6 (22.2%)	2 (7.4%)	2 (7.4%)	2 (7.4%)	3 (11.1%)		13 (48.1%)
FATIGUE	4 (14.8%)	3 (11.1%)	1 (3.7%)	0 (0.0%)	1 (3.7%)	1 (3.7%)		8 (29.6%)
FEVER	1 (3.7%)	1 (3.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.7%)		2 (7.4%)
HARM TO TOUCH	4 (14.8%)	2 (7.4%)	2 (7.4%)	2 (7.4%)	2 (7.4%)	3 (11.1%)		7 (25.9%)

TABLE 5 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : AYOUB, ELIA
STUDY : 000409
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (34 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5	
CARDIOVASCULAR SYSTEM	2 (7.4%)	2 (7.4%)	2 (7.4%)	2 (7.4%)	2 (7.4%)	2 (7.4%)	2 (7.4%)
RIGHT AXIS DEVIATION	2 (7.4%)	2 (7.4%)	2 (7.4%)	2 (7.4%)	2 (7.4%)	2 (7.4%)	2 (7.4%)
DIGESTIVE SYSTEM	2 (7.4%)	4 (14.8%)	4 (14.8%)	3 (11.1%)	2 (7.4%)	3 (11.1%)	7 (25.9%)
ANOREXIA	1 (3.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.7%)
DIARRHEA	0 (0.0%)	3 (11.1%)	3 (11.1%)	2 (7.4%)	1 (3.7%)	1 (3.7%)	4 (14.8%)
INFECTIOUS GASTROENTERITIS	0 (0.0%)	0 (0.0%)	1 (3.7%)	1 (3.7%)	1 (3.7%)	1 (3.7%)	1 (3.7%)
TEETHING	1 (3.7%)	1 (3.7%)	1 (3.7%)	1 (3.7%)	1 (3.7%)	2 (7.4%)	2 (7.4%)
VOMITING	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.7%)	1 (3.7%)	1 (3.7%)
NERVOUS SYSTEM & PSYCHIATRIC	7 (25.9%)	6 (22.2%)	3 (11.1%)	3 (11.1%)	1 (3.7%)	1 (3.7%)	10 (37.0%)
HEADACHE	1 (3.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.7%)
IRRITABILITY	7 (25.9%)	6 (22.2%)	3 (11.1%)	3 (11.1%)	1 (3.7%)	1 (3.7%)	10 (37.0%)
PROLONGED CRYING, >1/2 HR	0 (0.0%)	0 (0.0%)	1 (3.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.7%)

0990

TABLE 5 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : AYOUB, ELIA
STUDY : 000409
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (34 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		
RESPIRATORY SYSTEM	3 (11.1%)	3 (11.1%)	3 (11.1%)	3 (11.1%)	2 (7.4%)	1 (3.7%)		3 (11.1%)
ALLERGIC RHINITIS	1 (3.7%)	1 (3.7%)	1 (3.7%)	1 (3.7%)	1 (3.7%)	1 (3.7%)		1 (3.7%)
COMMON COLD	2 (7.4%)	2 (7.4%)	2 (7.4%)	2 (7.4%)	1 (3.7%)	0 (0.0%)		2 (7.4%)
NASAL DISCHARGE	0 (0.0%)	1 (3.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (3.7%)
SKIN & SKIN APPENDAGE	0 (0.0%)	1 (3.7%)	1 (3.7%)	1 (3.7%)	1 (3.7%)	0 (0.0%)		1 (3.7%)
RASH	0 (0.0%)	1 (3.7%)	1 (3.7%)	1 (3.7%)	1 (3.7%)	0 (0.0%)		1 (3.7%)
VACCINEES WITH COMPLAINTS	19 (70.4%)	20 (74.1%)	12 (44.4%)	10 (37.0%)	9 (33.3%)	9 (33.3%)		24 (88.9%)
VACCINEES WITH NO COMPLAINTS	8 (29.6%)	7 (25.9%)	15 (55.6%)	17 (63.0%)	18 (66.7%)	18 (66.7%)		3 (11.1%)
TOTAL VACCINEES REPORTING	27	27	27	27	27	27		27
VACCINEES WITH NO DATA	7	7	7	7	7	7		7

TABLE 6

MAXIMUM TEMPERATURES

INVESTIGATOR : AYOUB, ELIA
STUDY : 000409
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE — NUMBER OF VACCINEES (15 VACCINEES) - INJECTION 1

MAX TEMPERATURE (DEG F, ORAL)	DAYS POST VACCINATION 0	1	2	3	4	5		NUMBER WITH MAX TEMP
< 99	7 (46.7%)	5 (33.3%)	9 (64.3%)	8 (61.5%)	6 (54.5%)	6 (54.5%)		3 (20.0%)
99 - 99.9	7 (46.7%)	6 (40.0%)	4 (28.6%)	5 (38.5%)	4 (36.4%)	5 (45.5%)		8 (53.3%)
100 - 100.9	1 (6.7%)	3 (20.0%)	0 (0.0%)	0 (0.0%)	1 (9.1%)	0 (0.0%)		3 (20.0%)
101 - 101.9	0 (0.0%)	0 (0.0%)	1 (7.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)
103 - 103.9	0 (0.0%)	1 (6.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (6.7%)
TEMPERATURE TAKEN	15 (100.0%)	15 (100.0%)	14 (93.3%)	13 (86.7%)	11 (73.3%)	11 (73.3%)		15 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	0 (0.0%)	1 (6.7%)	2 (13.3%)	4 (26.7%)	4 (26.7%)		0 (0.0%)

TABLE 6 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : AYOUB, ELIA
STUDY : 000409
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (11 VACCINEES) - INJECTION 2							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
< 99	7 (63.6%)	6 (54.5%)	7 (63.6%)	7 (70.0%)	8 (80.0%)	9 (90.0%)		5 (45.5%)
99 - 99.9	4 (36.4%)	4 (36.4%)	4 (36.4%)	3 (30.0%)	2 (20.0%)	1 (10.0%)		5 (45.5%)
100 - 100.9	0 (0.0%)	1 (9.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (9.1%)
TEMPERATURE TAKEN	11 (100.0%)	11 (100.0%)	11 (100.0%)	10 (90.9%)	10 (90.9%)	10 (90.9%)		11 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (9.1%)	1 (9.1%)	1 (9.1%)		0 (0.0%)

TABLE 6 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : AYOUB, ELIA
STUDY : 000409
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (13 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
NORMAL	1 (9.1%)	2 (18.2%)	1 (12.5%)	1 (11.1%)	1 (10.0%)	1 (11.1%)		1 (9.1%)
< 99	7 (63.6%)	6 (54.5%)	4 (50.0%)	5 (55.6%)	8 (80.0%)	7 (77.8%)		6 (54.5%)
99 - 99.9	1 (9.1%)	3 (27.3%)	3 (37.5%)	3 (33.3%)	1 (10.0%)	1 (11.1%)		2 (18.2%)
100 - 100.9	1 (9.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (9.1%)
FEVER	1 (9.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (9.1%)
TEMPERATURE TAKEN	11 (84.6%)	11 (84.6%)	8 (61.5%)	9 (69.2%)	10 (76.9%)	9 (69.2%)		11 (84.6%)
TEMPERATURE NOT TAKEN	2 (15.4%)	2 (15.4%)	5 (38.5%)	4 (30.8%)	3 (23.1%)	4 (30.8%)		2 (15.4%)

TABLE 6 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : AYOUB, ELIA
STUDY : 000409
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (17 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
NORMAL	2 (14.3%)	2 (14.3%)	3 (23.1%)	3 (21.4%)	2 (16.7%)	2 (15.4%)		2 (14.3%)
< 99	3 (21.4%)	6 (42.9%)	5 (38.5%)	3 (21.4%)	4 (33.3%)	6 (46.2%)		0 (0.0%)
99 - 99.9	6 (42.9%)	5 (35.7%)	4 (30.8%)	7 (50.0%)	4 (33.3%)	4 (30.8%)		6 (42.9%)
100 - 100.9	2 (14.3%)	0 (0.0%)	1 (7.7%)	1 (7.1%)	2 (16.7%)	1 (7.7%)		5 (35.7%)
FEVER	1 (7.1%)	1 (7.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (7.1%)
TEMPERATURE TAKEN	14 (82.4%)	14 (82.4%)	13 (76.5%)	14 (82.4%)	12 (70.6%)	13 (76.5%)		14 (82.4%)
TEMPERATURE NOT TAKEN	3 (17.6%)	3 (17.6%)	4 (23.5%)	3 (17.6%)	5 (29.4%)	4 (23.5%)		3 (17.6%)

TABLE 6 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : AYOUB, ELIA
STUDY : 000409
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (9 VACCINEES) - INJECTION 2							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
< 99	4 (50.0%)	6 (85.7%)	5 (71.4%)	3 (42.9%)	5 (71.4%)	6 (85.7%)		2 (25.0%)
99 - 99.9	3 (37.5%)	1 (14.3%)	2 (28.6%)	3 (42.9%)	2 (28.6%)	1 (14.3%)		4 (50.0%)
100 - 100.9	1 (12.5%)	0 (0.0%)	0 (0.0%)	1 (14.3%)	0 (0.0%)	0 (0.0%)		2 (25.0%)
TEMPERATURE TAKEN	8 (88.9%)	7 (77.8%)	7 (77.8%)	7 (77.8%)	7 (77.8%)	7 (77.8%)		8 (88.9%)
TEMPERATURE NOT TAKEN	1 (11.1%)	2 (22.2%)	2 (22.2%)	2 (22.2%)	2 (22.2%)	2 (22.2%)		1 (11.1%)

TABLE 6 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : AYOUB, ELIA
STUDY : 000409
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (34 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
NORMAL	0 (0.0%)	1 (4.2%)	1 (4.3%)	1 (4.5%)	1 (4.3%)	1 (4.5%)		0 (0.0%)
< 99	11 (47.8%)	11 (45.8%)	12 (52.2%)	10 (45.5%)	13 (56.5%)	12 (54.5%)		9 (36.0%)
99 - 99.9	5 (21.7%)	8 (33.3%)	7 (30.4%)	10 (45.5%)	9 (39.1%)	7 (31.8%)		6 (24.0%)
100 - 100.9	4 (17.4%)	2 (8.3%)	1 (4.3%)	1 (4.5%)	0 (0.0%)	1 (4.5%)		4 (16.0%)
101 - 101.9	2 (8.7%)	0 (0.0%)	1 (4.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (8.0%)
102 - 102.9	1 (4.3%)	2 (8.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (4.5%)		3 (12.0%)
103 - 103.9	0 (0.0%)	0 (0.0%)	1 (4.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (4.0%)
TEMPERATURE TAKEN	23 (67.6%)	24 (70.6%)	23 (67.6%)	22 (64.7%)	23 (67.6%)	22 (64.7%)		25 (73.5%)
TEMPERATURE NOT TAKEN	11 (32.4%)	10 (29.4%)	11 (32.4%)	12 (35.3%)	11 (32.4%)	12 (35.3%)		9 (26.5%)

00576

PROGRAM: Haemophilus b Conjugate Vaccine (Neisseria meningitidis Outer Membrane Protein Complex), Study #0004-10.

PURPOSE: To evaluate the safety and immunogenicity of Haemophilus b Conjugate Vaccine (Neisseria meningitidis Outer Membrane Protein Complex) in healthy infants and children 2 months to 5 years of age.

VACCINE: Haemophilus b Conjugate Vaccine (Neisseria meningitidis Outer Membrane Protein Complex).

Lot 1069/C-P241 - (b) (4) mcg polysaccharide/ml
(b) (4) mcg meningococcal protein/ml
Lot 1072/C-P298 - (b) (4) mcg polysaccaride/ml
(b) (4) mcg meningococcal protein/ml
Lot 1080/C-P749 - (b) (4) mcg polysaccharide/ml
(b) (4) mcg meningococcal protein/ml
Lot 1085/C-R132 - (b) (4) mcg polysaccharide/ml
(b) (4) mcg meningococcal protein/ml

Diluent
Aluminum hydroxide diluent
Lot (b) (4)

INVESTIGATOR: Ziad Shehab, M.D.
University of Arizona Medical Center
Dept. of Pediatrics
1501 N. Campbell Ave.
Tucson, Arizona 85724

SUB-INVESTIGATOR: C. George Ray, M.D.

STUDY LOCATION: Pediatric Outpatient Clinic
College of Medicine
University of Arizona
Tucson, Arizona 85724

DATE INITIATED: April 29, 1987

DATE COMPLETED: In progress.

STUDY POPULATION: Healthy infants and children 2 to 71 months of age are included in the study. A subset of infants and children were randomized to receive the three clinical lots of vaccine (1072/C-P298, 1080/C-P749, 1085/C-R132).

STUDY PROCEDURE: Infants 2 to 11 months of age receive 2 injections of the vaccine given 2 months apart, while children 12 months of age and older receive a single injection. Vaccine is reconstituted in aluminum hydroxide and administered by intramuscular route. The dose for each injection is 15 mcg polysaccharide in the appropriate volume - 0.75 ml for Lot 1069/C-P241 and 0.5 ml for Lots 1072/C-P298, 1080/C-P749, and 1085/C-R132.

Parents or guardians are required to record the vaccinee's temperature and any systemic or injection site reactions for 5 days after each injection. Unexpected or serious reactions are to be reported immediately to the study physician.

A blood sample is obtained immediately before each injection and one month after the last (or only) injection. Additional samples are obtained 7 to 10 months after the last injection for infants 2 to 11 months of age and at 15 to 18 months postvaccination for children 12 to 71 months of age.

All serum samples are assayed by Merck Sharp & Dohme Research Laboratories for antibody to H. influenzae type b capsular polysaccharide by radioimmunoassay (RIA). Selected samples are also tested for serum bactericidal activity, quantitation of IgG_1 and IgG_2 subclass, and IgM and total IgG antibodies. Testing for opsonophagocytic activity was done at the University of Alabama.

RESULTS: Demographic information and individual pre and postvaccination antibody data for each vaccinee enrolled in the study is reported in Tables 1 and 2.

1. Number Vaccinated:

Lot	Age	Injection No. 1	Injection No. 2
1069/C-P241	2-11 mo.	15	14
	12-71 mo.	15	--
1072/C-P298	2-11 mo.	38	31
	12-71 mo.	28	--
1080/C-P749	2-11 mo.	16	9
	12-71 mo.	11	--
1085/C-R132	2-11 mo.	16	10
	12-71 mo.	12	--

Children randomized to receive the clinical lots were assigned case numbers (b) (6).

One child (case no. (b) (6)) received mixed lots - Lot 1069/C-P241 as injection 1 and Lot 1080/C-P749 as injection 2.

2. Serologic Results

Antibody responses (RIA) prior to and after vaccination are as follows:

Age	Time	% With Anti-PRP >0.15 mcg Ab/ml	% With Anti-PRP >1.0 mcg Ab/ml	GMT (mcg Ab/ml) All Vaccinees
2-11 mo.	Pre	29 (16/55)	0 (0/55)	0.10
	2 mo.	100 (50/50)	72 (36/50)	2.07
	3 mo.	98 (48/49)	88 (43/49)	4.83
12-71 mo.	Pre	45 (24/53)	23 (12/53)	0.24
	1 mo.	100 (53/53)	89 (47/53)	8.19

RESULTS: (CONT.)

Antibody responses (by lot per age group) prior to vaccination through 10 months postvaccination are included in Tables 3-6. Responses for children randomized to receive the consistency lots are shown in Tables 7-9. If vaccine recipients received mixed lots, they were excluded from summaries by lot.

3. Clinical Results:

The frequencies of selected injection site and systemic reactions during the 48 hours after vaccination are as follows:

	% Vaccinees with Reactions		
	2 - 11 Months of Age		12 - 71 Months of Age
Type of Reaction	Injection 1	Injection 2	Injection 1
Injection Site			
Erythema >1 inch	1.5 (1/68)	3.2 (2/62)	0.0 (0/65)
Swelling >1 inch	0.0 (0/68)	4.8 (3/62)	0.0 (0/65)
Pain/Soreness	7.4 (5/68)	11.3 (7/62)	26.2 (17/65)
Systemic			
Irritability	29.4 (20/68)	29.0 (18/62)	21.5 (14/65)
Sleepiness/ Lethargy/Fatigue	27.9 (19/68)	21.0 (13/62)	16.9 (11/65)

Reaction frequencies and maximum temperatures recorded during the five days following each injection of vaccine are reported in Tables 10-12.

No serious vaccine-related reactions were reported.

One serious adverse reaction occurred which was unrelated to vaccination. A 6-month old infant was hospitalized with the diagnosis of cervical cellulitis. Blood and CSF cultures were negative. Urine antigen detection for Haemophilus influenzae were negative (probable staphylococcal cellulitis). The infant recovered without residual effects.

TABLE 1

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	CAUC	(b) (6)	4M	0	(b) (6)	001	PREBLEED				< 125				0
					0		011	INJ 1	CP241	15 MCG						
					63		011	BLEED 1				2745				89
					63		021	INJ 2	CP241	15 MCG						
					91		021	BLEED 2				12205				87
					407		071	BLEED 3				1551				
	M	CAUC		7M	0		001	PREBLEED				< 125				0
					0		011	INJ 1	CP241	15 MCG						
					56		011	BLEED 1				633				99
					56		021	INJ 2	CP241	15 MCG						
					98		021	BLEED 2				5453				
					372		071	BLEED 3				19863				
	M	CAUC		5M	0		001	PREBLEED				< 125				0
					0		011	INJ 1	CP241	15 MCG						
					56		011	BLEED 1				2174				0
					56		021	INJ 2	CP241	15 MCG						
					84		021	BLEED 2				2538				72
					337		071	BLEED 3				263				
	F	HISP		3M	0		001	PREBLEED				< 125				0
					0		011	INJ 1	CP241	15 MCG						
					63		011	BLEED 1				18972				97
					63		021	INJ 2	CP241	15 MCG						
					91		021	BLEED 2				13953				96
					379		071	BLEED 3				2607				
	M	HISP		7M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP241	15 MCG						
					70		011	BLEED 1				14325				
					70		021	INJ 2	CP241	15 MCG						
	F	CAUC		2M	0		001	PREBLEED				172				
					0		011	INJ 1	CP241	15 MCG						
					70		011	BLEED 1				5063				
					70		021	INJ 2	CP241	15 MCG						
					112		021	BLEED 2				5962				
	M	CAUC		9M	0		001	PREBLEED				< 125				0

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ RIA	CODE/ SBA	CODE/ OPSO
(b) (6)	M	CAUC	(b) (6)	9M	0	(b) (6)	011	INJ 1	CP241	15 MCG			
					56		011	BLEED 1			4919		0
					56		021	INJ 2	CP241	15 MCG			
					84		021	BLEED 2			7988		95
	M	HISP		3M	0		001	PREBLEED			< 125		0
					0		011	INJ 1	CP241	15 MCG			
					56		011	BLEED 1			2140		55
					56		021	INJ 2	CP241	15 MCG			
					84		021	BLEED 2			8095		89
	F	CAUC		8M	0		001	PREBLEED			< 125		
					0		011	INJ 1	CP241	15 MCG			
					56		011	BLEED 1			15662		
					56		021	INJ 2	CP241	15 MCG			
					84		021	BLEED 2			33254		
					302		071	BLEED 3			279		
	M	CAUC		8M	0		001	PREBLEED			< 250		
					0		011	INJ 1	CP241	15 MCG			
					56		011	BLEED 1			411		
					56		021	INJ 2	CP241	15 MCG			
					84		021	BLEED 2			7750		
	F	CAUC		3M	0		001	PREBLEED			< 125		
					0		011	INJ 1	CP241	15 MCG			
					56		011	BLEED 1			20900		
					56		021	INJ 2	CP241	15 MCG			
					86		021	BLEED 2			23378		
	F	CAUC		10M	0		001	PREBLEED			< 125		
					0		011	INJ 1	CP241	15 MCG			
					56		011	BLEED 1			4602		
					56		021	INJ 2	CP241	15 MCG			
	F	CAUC		10M	0		001	PREBLEED			< 125		
					0		011	INJ 1	CP241	15 MCG			
					56		011	BLEED 1			6026		
					56		021	INJ 2	CP241	15 MCG			
	M	CAUC		2M	0		001	PREBLEED			191		

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	CAUC	(b) (6)	2M	0	(b) (6)	011	INJ 1	CP241	15 MCG						
					77		011	BLEED 1			05/	2276				
					77		021	INJ 2	CP749	15 MCG						
					107		021	BLEED 2			05/	4316				
	M	CAUC		3M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP241	15 MCG						
					56		021	INJ 2	CP241	15 MCG						
					85		021	BLEED 1				4188				
	M	CAUC		4M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP298	15 MCG						
					56		011	BLEED 1				188				
					56		021	INJ 2	CP298	15 MCG						
					84		021	BLEED 2				339				
	F	CAUC		6M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP298	15 MCG						
					56		011	BLEED 1				10213				
					56		021	INJ 2	CP298	15 MCG						
					84		021	BLEED 2				14047				
	F	CAUC		4M	0		001	PREBLEED				210		< 2		
					0		011	INJ 1	CP298	15 MCG						
					56		011	BLEED 1				903		< 2		
					56		021	INJ 2	CP298	15 MCG						
					84		021	BLEED 2				1681		< 5		
	F	CAUC		4M	0		001	PREBLEED				669	01/	QNS		
					0		011	INJ 1	CP298	15 MCG						
					56		011	BLEED 1				2665		>= 80		
					56		021	INJ 2	CP298	15 MCG						
					84		021	BLEED 2				2012		>= 80		
	M	CAUC		5M	0		001	PREBLEED				200		< 5		
					0		011	INJ 1	CP298	15 MCG						
					56		011	BLEED 1						5		
					56		021	INJ 2	CP298	15 MCG						
					84		021	BLEED 2				7233		5		
	F	HISP		3M	0		001	PREBLEED				< 125		< 2		0

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	F	HISP	(b) (6)	3M	0	(b) (6)	011	INJ 1	CP298	15 MCG						
					64		011	BLEED 1				1782	01/	QNS	01/	
					64		021	INJ 2	CP298	15 MCG						
					112		021	BLEED 2				11271		< 2		99
	M	CAUC		10M	0		001	PREBLEED				< 125		< 5		
					0		011	INJ 1	CP298	15 MCG						
					64		011	BLEED 1				2231		5		
					64		021	INJ 2	CP298	15 MCG						
					91		021	BLEED 2				19784		>= 80		
	M	CAUC		4M	0		001	PREBLEED				< 125		< 2		
					0		011	INJ 1	CP298	15 MCG						
					77		011	BLEED 1			05/	2527	05/	< 2		
					77		021	INJ 2	CP298	15 MCG						
					105		021	BLEED 2			05/	1864	05/	< 2		
	F	CAUC		3M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP298	15 MCG						
					63		011	BLEED 1				598				
					63		021	INJ 2	CP298	15 MCG						
					112		021	BLEED 2				< 125				
					161		071	BLEED 3				517				
	F	CAUC		8M	0		011	INJ 1	CP298	15 MCG						
	M	CAUC		3M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP298	15 MCG						
					84		011	BLEED 1			05/	8666				
					84		021	INJ 2	CP298	15 MCG						
					112		021	BLEED 2			05/	7658				
	F	CAUC		11M	0		001	PREBLEED				< 125		< 2		
					0		011	INJ 1	CP298	15 MCG						
					63		011	BLEED 1				12076		>= 32		
					63		021	INJ 2	CP298	15 MCG						
					119		021	BLEED 2				44891		>= 32		
	M	CAUC		9M	0		001	PREBLEED				< 125		< 2		
					0		011	INJ 1	CP298	15 MCG						

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	CAUC	(b) (6)	9M	63	(b) (6)	011	BLEED 1				<= 953				
					63		021	INJ 2	CP298	15 MCG						
					112		021	BLEED 2				6354		>= 32		
					239		071	BLEED 3				2207				
	F	CAUC		4M	0		001	PREBLEED				< 125			01/	QNS
					0		011	INJ 1	CP298	15 MCG						
					56		011	BLEED 1				3359				100
					56		021	INJ 2	CP298	15 MCG						
					84		021	BLEED 2				6048				100
	F	CAUC		3M	0		001	PREBLEED				< 125		< 5		
					0		011	INJ 1	CP298	15 MCG						
					56		011	BLEED 1				1374		5		
					56		021	INJ 2	CP298	15 MCG						
					98		021	BLEED 2				2177		5		
	F	CAUC		3M	0		001	PREBLEED				504		< 5		
					0		011	INJ 1	CP298	15 MCG						
					56		011	BLEED 1				3920		5		
					56		021	INJ 2	CP298	15 MCG						
					84		021	BLEED 2				9759		20		
	F	CAUC		2M	0		001	PREBLEED				< 125		< 5		
					0		011	INJ 1	CP298	15 MCG						
					56		011	BLEED 1				310		< 5		
					56		021	INJ 2	CP298	15 MCG						
					84		021	BLEED 2				876		20		
	F	CAUC		6M	0		001	PREBLEED				< 125		< 2		
					0		011	INJ 1	CP298	15 MCG						
					56		011	BLEED 1				418		< 2		
					56		021	INJ 2	CP298	15 MCG						
					84		021	BLEED 2				3203		< 2		
	M	CAUC		4M	0		001	PREBLEED				< 125		< 2		
					0		011	INJ 1	CP298	15 MCG						
					56		011	BLEED 1				1567		< 2		
					56		021	INJ 2	CP298	15 MCG						
					91		021	BLEED 2				4012		2		

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	CAUC	(b) (6)	6M	0	(b) (6)	001	PREBLEED				< 125		< 2		
					0		011	INJ 1	CP298	15 MCG						
					63		021	INJ 2	CP298	15 MCG						
					98		021	BLEED 1				11991		>= 32		
	M	CAUC		5M	0		001	PREBLEED				< 125		< 5		
					0		011	INJ 1	CP298	15 MCG						
					56		011	BLEED 1				4654		>= 80		
					56		021	INJ 2	CP298	15 MCG						
					84		021	BLEED 2				11238		>= 80		
	M	CAUC		6M	0		001	PREBLEED				< 125		< 5		
					0		011	INJ 1	CP298	15 MCG						
					63		011	BLEED 1				883		< 5		
					63		021	INJ 2	CP298	15 MCG						
					98		021	BLEED 2				3481		20		
	M	CAUC		10M	0		001	PREBLEED				241				
					0		011	INJ 1	CP298	15 MCG						
					56		011	BLEED 1				3436				
					56		021	INJ 2	CP298	15 MCG						
					84		021	BLEED 2				9321				
	F	CAUC		4M	0		011	INJ 1	CR132	15 MCG						
	F	CAUC		4M	0		011	INJ 1	CP749	15 MCG						
	M	CAUC		2M	0		011	INJ 1	CP298	15 MCG						
	M	CAUC		2M	0		011	INJ 1	CP749	15 MCG						
	M	HISP		2M	0		011	INJ 1	CR132	15 MCG						
	M	CAUC		2M	0		011	INJ 1	CP298	15 MCG						
	M	CAUC		9M	0		011	INJ 1	CP298	15 MCG						
	M	CAUC		5M	0		011	INJ 1	CR132	15 MCG						
	F	HISP		5M	0		011	INJ 1	CP749	15 MCG						

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ RIA	CODE/ SBA	CODE/ OPSO
(b) (6)	F	CAUC	(b) (6)	11M	0	(b) (6)	001	PREBLEED			< 125		
					0		011	INJ 1	CP749	15 MCG			
					57		011	BLEED 1			514		
	M	HISP		3M	0		001	PREBLEED			148		
					0		011	INJ 1	CR132	15 MCG			
					57		011	BLEED 1			1010		
	M	CAUC		3M	0		001	PREBLEED			< 125		
					0		011	INJ 1	CP298	15 MCG			
					57		011	BLEED 1			3887		
	F	CAUC		5M	0		001	PREBLEED			< 125		
					0		011	INJ 1	CP749	15 MCG			
					57		011	BLEED 1			5264		
	M	CAUC		2M	0		001	PREBLEED			< 125		
					0		011	INJ 1	CP298	15 MCG			
					64		011	BLEED 1			882		
	M	CAUC		3M	0		001	PREBLEED			150		
					0		011	INJ 1	CR132	15 MCG			
					64		011	BLEED 1			5128		
	F	OTHE		6M	0		011	INJ 1	CR132	15 MCG			
					57		021	INJ 2	CR132	15 MCG			
	M	CAUC		6M	0		001	PREBLEED			129		
					0		011	INJ 1	CP749	15 MCG			
					57		011	BLEED 1			1212		
					57		021	INJ 2	CP749	15 MCG			
	F	CAUC		6M	0		001	PREBLEED			129		
					0		011	INJ 1	CP749	15 MCG			
					78		011	BLEED 1			386		
	M	CAUC		4M	0		001	PREBLEED			< 125		
					0		011	INJ 1	CP749	15 MCG			
					64		011	BLEED 1			3577		
					99		011	BLEED 2			10804		

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	CAUC	(b) (6)	2M	0	(b) (6)	001	PREBLEED				< 125				
					0		011	INJ 1	CR132	15 MCG						
					62		011	BLEED 1				11474				
					92		011	BLEED 2				22532				
	F	CAUC		2M	0		001	PREBLEED				410				
					0		011	INJ 1	CP298	15 MCG						
					64		011	BLEED 1				522				
					64		021	INJ 2	CP298	15 MCG						
	M	CAUC		2M	0		011	INJ 1	CR132	15 MCG						
					64		021	INJ 2	CR132	15 MCG						
	M	CAUC		3M	0		001	PREBLEED				250				
					0		011	INJ 1	CP298	15 MCG						
					57		011	BLEED 1				1801				
					57		021	INJ 2	CP298	15 MCG						
					92		021	BLEED 2				765				
	F	OTHE		3M	0		001	PREBLEED				235				
					0		011	INJ 1	CP749	15 MCG						
					78		011	BLEED 1				1580				
					113		011	BLEED 2				4270				
	M	CAUC		4M	0		001	PREBLEED				533		< 2		
					0		011	INJ 1	CR132	15 MCG						
					57		011	BLEED 1				153		< 2		
					57		021	INJ 2	CR132	15 MCG						
					92		011	BLEED 2				434		< 2		
	F	CAUC		4M	0		001	PREBLEED				163		< 2		
					0		011	INJ 1	CR132	15 MCG						
					56		011	BLEED 1				1389		8		
					56		021	INJ 2	CR132	15 MCG						
					85		021	BLEED 2				1349		8		
	F	CAUC		7M	0		001	PREBLEED				< 125		< 2		
					0		011	INJ 1	CP749	15 MCG						
					56		011	BLEED 1				8996		8		
					56		021	INJ 2	CP749	15 MCG						

00688

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	F	CAUC	(b) (6)	7M	85	(b) (6)	021	BLEED 2				28457		8		
	M	CAUC		3M	0		001	PREBLEED				323		< 2		
					0		011	INJ 1	CP298	15 MCG						
					56		011	BLEED 1				2315		8		
					56		021	INJ 2	CP298	15 MCG						
					85		021	BLEED 2				3714		8		
	F	CAUC		2M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP298	15 MCG						
					70		011	BLEED 1				2811				
					70		021	INJ 2	CP298	15 MCG						
					106		021	BLEED 2				3500				
	M	CAUC		9M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP298	15 MCG						
					63		011	BLEED 1				409				
					63		021	INJ 2	CP298	15 MCG						
					99		021	BLEED 2				978				
	F	CAUC		9M	0		001	PREBLEED				< 125		< 2		10
					0		011	INJ 1	CP749	15 MCG						
					63		011	BLEED 1				4099		8		100
					63		021	INJ 2	CP749	15 MCG						
					91		021	BLEED 2				6447		8		99
	F	CAUC		9M	0		001	PREBLEED				< 125		< 2		18
					0		011	INJ 1	CR132	15 MCG						
					63		011	BLEED 1				6910		8		100
					63		021	INJ 2	CR132	15 MCG						
					91		021	BLEED 2				10952		2		100
	F	HISP		2M	0		011	INJ 1	CP298	15 MCG						
	M	CAUC		3M	0		011	INJ 1	CR132	15 MCG						
					63		011	BLEED 1				952		< 2		77
					63		021	INJ 2	CR132	15 MCG						
					91		021	BLEED 2				23999		8		100
	F	CAUC		5M	0		001	PREBLEED				203		< 2		6

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	F	CAUC	(b) (6)	5M	0	(b) (6)	011	INJ 1	CP749	15 MCG						
					56		011	BLEED 1				3457		8		98
					56		021	INJ 2	CP749	15 MCG						
					84		021	BLEED 2				16337		8		90
	M	CAUC		4M	0		001	PREBLEED				232		< 2		25
					0		011	INJ 1	CR132	15 MCG						
					62		011	BLEED 1				2599		< 2		100
					62		021	INJ 2	CR132	15 MCG						
					90		021	BLEED 2				6660		2		100
	F	CAUC		6M	0		011	INJ 1	CR132	15 MCG						
					63		011	BLEED 1				4591		8		
					63		021	INJ 2	CR132	15 MCG						
					98		021	BLEED 2				20347		8		
	F	CAUC		3M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP749	15 MCG						
					56		021	INJ 2	CP749	15 MCG						
					84		021	BLEED 1				1526				
	M	CAUC		2M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP298	15 MCG						
					56		011	BLEED 1				302				
					56		021	INJ 2	CP298	15 MCG						
					84		021	BLEED 2				3732				
	F	CAUC		2M	0		001	PREBLEED				< 125		< 2		6
					0		011	INJ 1	CP749	15 MCG						
					56		011	BLEED 1				3375		< 2		94
					56		021	INJ 2	CP749	15 MCG						
					98		021	BLEED 2				3033		< 2		98
	M	CAUC		5M	0		001	PREBLEED				305				
					0		011	INJ 1	CP298	15 MCG						
					56		011	BLEED 1				1623				
					56		021	INJ 2	CP298	15 MCG						
					84		021	BLEED 2				8832				
	F	CAUC		11M	0		001	PREBLEED				307		< 2		

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	F	CAUC	(b) (6)	11M	0	(b) (6)	011	INJ 1	CR132	15 MCG						
					56		011	BLEED 1				442		< 2		
					56		021	INJ 2	CR132	15 MCG						
					98		021	BLEED 2				3797		8		
	M	CAUC		5M	0		001	PREBLEED				< 125		< 2		23
					0		011	INJ 1	CP749	15 MCG						
					52		011	BLEED 1				2660		8		98
					52		021	INJ 2	CP749	15 MCG						
					84		021	BLEED 2				4589		8		99
	M	CAUC		5M	0		001	PREBLEED				153		< 2	01/	QNS
					0		011	INJ 1	CP749	15 MCG						
					77		011	BLEED 1			05/	1524	05/	< 2	05/	100
					77		021	INJ 2	CP749	15 MCG						
					105		021	BLEED 2			05/	2526	05/	< 2	05/	100
	M	CAUC		10M	0		001	PREBLEED				< 125		< 5		
					0		011	INJ 1	CP298	15 MCG						
					63		011	BLEED 1				1745		< 5		
					63		021	INJ 2	CP298	15 MCG						
					91		021	BLEED 2				7648		5		
	M	CAUC		7M	0		001	PREBLEED				< 125		< 2		29
					0		011	INJ 1	CR132	15 MCG						
					77		011	BLEED 1			05/	5532	05/	8	05/	100
					77		021	INJ 2	CR132	15 MCG						
					119		021	BLEED 2			05/	8308	05/	>= 32	05/	100
	M	CAUC		3M	0		001	PREBLEED				< 125		< 5		
					0		011	INJ 1	CP298	15 MCG						
					63		021	INJ 2	CP298	15 MCG						
					91		021	BLEED 1				87006		>= 80		

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	CAUC	(b) (6)	15M	0	(b) (6)	001	PREBLEED				163				
					0		011	INJ 1	CP241	15 MCG						
					35		011	BLEED 1				56721				
	M	CAUC		4Y	0		001	PREBLEED				2199				
					0		011	INJ 1	CP241	15 MCG						
					35		011	BLEED 1				58561				
	M	CAUC		21M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP241	15 MCG						
					35		011	BLEED 1				37806				
					379		071	BLEED 2				193				
	F	CAUC		20M	0		001	PREBLEED				4175				
					0		011	INJ 1	CP241	15 MCG						
					35		011	BLEED 1				74464				
					372		071	BLEED 2				11725				
	F	CAUC		21M	0		001	PREBLEED				571				0
					0		011	INJ 1	CP241	15 MCG						
					35		011	BLEED 1				2402				4
					407		071	BLEED 2				798				
	M	CAUC		15M	0		001	PREBLEED				< 125				0
					0		011	INJ 1	CP241	15 MCG						
					34		011	BLEED 1				4882				96
	F	CAUC		12M	0		001	PREBLEED				< 125				0
					0		011	INJ 1	CP241	15 MCG						
					28		011	BLEED 1				5624				78
	M	CAUC		2Y	0		001	PREBLEED				147				
					0		011	INJ 1	CP241	15 MCG						
					28		011	BLEED 1				15228				
	M	CAUC		12M	0		001	PREBLEED				< 125				0
					0		011	INJ 1	CP241	15 MCG						
					29		011	BLEED 1				257				0
	M	CAUC		13M	0		001	PREBLEED				168				

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	CAUC	(b) (6)	13M	0	(b) (6)	011	INJ	1	CP241	15 MCG					
					29		011	BLEED	1			11615				
	F	CAUC		12M	0		001	PREBLEED				< 125				0
					0		011	INJ	1	CP241	15 MCG					
					28		011	BLEED	1			10954				99
	F	CAUC		4Y	0		001	PREBLEED				2931				0
					0		011	INJ	1	CP241	15 MCG					
					28		011	BLEED	1			66225				87
	F	CAUC		2Y	0		001	PREBLEED				3882				
					0		011	INJ	1	CP241	15 MCG					
					28		011	BLEED	1			102876				
	F	CAUC		4Y	0		001	PREBLEED				35220				
					0		011	INJ	1	CP241	15 MCG					
					28		011	BLEED	1			35838				
	F	CAUC		2Y	0		001	PREBLEED				503				
					0		011	INJ	1	CP241	15 MCG					
					35		011	BLEED	1			4245				
	F	CAUC		13M	0		001	PREBLEED				< 125		5		19
					0		011	INJ	1	CP298	15 MCG					
					28		011	BLEED	1			2425				98
	M	CAUC		14M	0		011	INJ	1	CP298	15 MCG					
					28		011	BLEED	1			504				
	F	HISP		16M	0		001	PREBLEED				< 125		< 5		6
					0		011	INJ	1	CP298	15 MCG					
					35		011	BLEED	1			2085		>= 80		95
	M	CAUC		21M	0		001	PREBLEED				302				
					0		011	INJ	1	CP298	15 MCG					
					28		011	BLEED	1			17998				
	M	CAUC		13M	0		001	PREBLEED				< 125		< 5		0
					0		011	INJ	1	CP298	15 MCG					

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	CAUC	(b) (6)	13M	28	(b) (6)	011	BLEED 1				1397		>= 80		99
	M	CAUC		17M	0		001	PREBLEED				< 125		< 5		0
					0		011	INJ 1	CP298	15 MCG						
					28		011	BLEED 1				3353		20		100
	F	CAUC		24M	0		001	PREBLEED				1193				
					0		011	INJ 1	CP298	15 MCG						
					28		011	BLEED 1				2560				
	M	CAUC		14M	0		001	PREBLEED				145		< 5		9
					0		011	INJ 1	CP298	15 MCG						
					35		011	BLEED 1				1118		20		50
	M	CAUC		12M	0		001	PREBLEED				< 125				0
					0		011	INJ 1	CP298	15 MCG						
					42		011	BLEED 1				493				14
	F	CAUC		16M	0		001	PREBLEED				< 125		< 5		6
					0		011	INJ 1	CP298	15 MCG						
					28		011	BLEED 1				658		< 5		9
	F	CAUC		2Y	0		001	PREBLEED				< 125		< 5		
					0		011	INJ 1	CP298	15 MCG						
					70		011	BLEED 1				6460		5		
	F	CAUC		16M	0		001	PREBLEED				< 125		< 5		
					0		011	INJ 1	CP298	15 MCG						
					50		011	BLEED 1				11368		>= 80		
	M	CAUC		2Y	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP298	15 MCG						
					28		011	BLEED 1				54586				
	M	CAUC		18M	0		001	PREBLEED				935		< 5		
					0		011	INJ 1	CP298	15 MCG						
					56		011	BLEED 1				1145		5		
	F	CAUC		22M	0		001	PREBLEED				240				< 5
					0		011	INJ 1	CP298	15 MCG						

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TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	F	CAUC	(b) (6)	22M	36	(b) (6)	011	BLEED 1				3459				20
	F	CAUC		22M	0		001	PREBLEED				< 125				< 5
					0		011	INJ 1	CP298	15 MCG						
					36		011	BLEED 1				21673				20
	F	CAUC		19M	0		001	PREBLEED				< 125				14
					0		011	INJ 1	CP298	15 MCG						
					29		011	BLEED 1				16097				89
	M	CAUC		12M	0		001	PREBLEED				< 125				0
					0		011	INJ 1	CP749	15 MCG						
					22		011	BLEED 1				1632				63
	M	CAUC		12M	0		001	PREBLEED				< 125				44
					0		011	INJ 1	CR132	15 MCG						
					29		011	BLEED 1				1949				91
	F	BLAC		22M	0		011	INJ 1	CP749	15 MCG						
	M	BLAC		14M	0		011	INJ 1	CP298	15 MCG						
	M	BLAC		3Y	0		011	INJ 1	CR132	15 MCG						
	M	CAUC		14M	0		001	PREBLEED				367		< 5		
					0		011	INJ 1	CP298	15 MCG						
					28		011	BLEED 1				8430		>= 80		
	F	CAUC		24M	0		011	INJ 1	CP749	15 MCG						
					29		011	BLEED 1				21656				
	M	CAUC		15M	0		001	PREBLEED				148				
					0		011	INJ 1	CP749	15 MCG						
					29		011	BLEED 1				737				
	F	CAUC		18M	0		001	PREBLEED				2681		20		
					0		011	INJ 1	CR132	15 MCG						
					28		011	BLEED 1				69159		320		
	F	CAUC		20M	0		001	PREBLEED				< 125				22

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	F	CAUC	(b) (6)	20M	0	(b) (6)	011	INJ 1	CR132	15 MCG						
					34		011	BLEED 1				38723				94
	M	CAUC		22M	0		001	PREBLEED				1539				
					0		011	INJ 1	CP298	15 MCG						
					48		011	BLEED 1				42328				
	F	CAUC		4Y	0		001	PREBLEED				< 125		< 5		44
					0		011	INJ 1	CP749	15 MCG						
					28		011	BLEED 1				1320		>= 80		95
	F	CAUC		17M	0		001	PREBLEED				301				
					0		011	INJ 1	CP749	15 MCG						
					56		011	BLEED 1				4812				
	F	CAUC		24M	0		001	PREBLEED				2514		20		
					0		011	INJ 1	CP298	15 MCG						
					42		011	BLEED 1				7858		20		
	M	OTHE		24M	0		001	PREBLEED				12061		20		
					0		011	INJ 1	CP298	15 MCG						
					42		011	BLEED 1				42877		20		
	M	CAUC		12M	0		001	PREBLEED				< 125		< 2		46
					0		011	INJ 1	CR132	15 MCG						
					28		011	BLEED 1				7981		>= 8		81
	F	CAUC		23M	0		011	INJ 1	CR132	15 MCG						
					28		011	BLEED 1				1395				
	F	CAUC		19M	0		001	PREBLEED				180		< 5		32
					0		011	INJ 1	CR132	15 MCG						
					42		011	BLEED 1				3368		20		100
	F	CAUC		13M	0		001	PREBLEED				226		< 5		
					0		011	INJ 1	CP298	15 MCG						
					28		011	BLEED 1				4022		>= 80		
	F	CAUC		20M	0		001	PREBLEED				< 125		< 5		
					0		011	INJ 1	CP749	15 MCG						

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	F	CAUC	(b) (6)	20M	28	(b) (6)	011	BLEED 1				1505		>= 80		
	F	CAUC		24M	0		001	PREBLEED				308		< 5		
					0		011	INJ 1	CP298	15 MCG						
					36		011	BLEED 1				8305		20		
	F	CAUC		4Y	0		001	PREBLEED				4423		< 5		
					0		011	INJ 1	CP749	15 MCG						
					35		011	BLEED 1				122284		20		
	M	HISP		2Y	0		001	PREBLEED				277		< 5		18
					0		011	INJ 1	CR132	15 MCG						
					35		011	BLEED 1				30907		>= 80		100
	F	CAUC		24M	0		001	PREBLEED				719				
					0		011	INJ 1	CP298	15 MCG						
					28		011	BLEED 1				52372				
	M	CAUC		19M	0		001	PREBLEED				< 125		< 5		29
					0		011	INJ 1	CP749	15 MCG						
					28		011	BLEED 1				14207		80		100
	M	HISP		17M	0		011	INJ 1	CP298	15 MCG						
	M	CAUC		3Y	0		001	PREBLEED				< 125		< 2		< 5
					0		011	INJ 1	CR132	15 MCG						
					36		011	BLEED 1				365		< 2		< 5
	M	HISP		4Y	0		011	INJ 1	CP749	15 MCG						
	M	HISP		23M	0		011	INJ 1	CR132	15 MCG						
	M	HISP		21M	0		001	PREBLEED				2106		< 2		
					0		011	INJ 1	CR132	15 MCG						
					29		011	BLEED 1				6934		8		
	M	CAUC		4Y	0		001	PREBLEED				< 125		< 5		
					0		011	INJ 1	CR132	15 MCG						
					42		011	BLEED 1				94330		>= 80		
	F	CAUC		12M	0		001	PREBLEED				< 125				

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	F	CAUC	(b) (6)	12M	0	(b) (6)	011	INJ	1	CP749	15 MCG					
					28		011	BLEED	1			969				
	M	CAUC		12M	0		001	PREBLEED				< 125				
					0		011	INJ	1	CP298	15 MCG					
					28		011	BLEED	1			12857				
	M	CAUC		2Y	0		001	PREBLEED				< 125				
					0		011	INJ	1	CP298	15 MCG					
					42		011	BLEED	1			27040				

TABLE 2

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ IGG1	CODE/ IGG2	CODE/ IGGM	CODE/IGG TOTAL
(b) (6)	M	CAUC	(b) (6)	4M	0	(b) (6)	011	INJ	1 CP241	15 MCG				
					63		021	INJ	2 CP241	15 MCG				
	M	CAUC		7M	0		011	INJ	1 CP241	15 MCG				
					56		021	INJ	2 CP241	15 MCG				
	M	CAUC		5M	0		011	INJ	1 CP241	15 MCG				
					56		021	INJ	2 CP241	15 MCG				
	F	HISP		3M	0		011	INJ	1 CP241	15 MCG				
					63		021	INJ	2 CP241	15 MCG				
	M	HISP		7M	0		011	INJ	1 CP241	15 MCG				
					70		021	INJ	2 CP241	15 MCG				
	F	CAUC		2M	0		011	INJ	1 CP241	15 MCG				
					70		021	INJ	2 CP241	15 MCG				
	M	CAUC		9M	0		011	INJ	1 CP241	15 MCG				
					56		021	INJ	2 CP241	15 MCG				
	M	HISP		3M	0		011	INJ	1 CP241	15 MCG				
					56		021	INJ	2 CP241	15 MCG				
	F	CAUC		8M	0		011	INJ	1 CP241	15 MCG				
					56		021	INJ	2 CP241	15 MCG				
	M	CAUC		8M	0		011	INJ	1 CP241	15 MCG				
					56		021	INJ	2 CP241	15 MCG				
	F	CAUC		3M	0		011	INJ	1 CP241	15 MCG				
					56		021	INJ	2 CP241	15 MCG				
	F	CAUC		10M	0		011	INJ	1 CP241	15 MCG				
					56		021	INJ	2 CP241	15 MCG				
	F	CAUC		10M	0		011	INJ	1 CP241	15 MCG				
					56		021	INJ	2 CP241	15 MCG				
	M	CAUC		2M	0		011	INJ	1 CP241	15 MCG				

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	IGG1	CODE/	IGG2	CODE/	IGGM	CODE/	IGG TOTAL
(b) (6)	M	CAUC	(b) (6)	2M	77	(b) (6)	021	INJ 2	CP749	15 MCG								
	M	CAUC		3M	0		011	INJ 1	CP241	15 MCG								
					56		021	INJ 2	CP241	15 MCG								
	M	CAUC		4M	0		011	INJ 1	CP298	15 MCG								
					56		021	INJ 2	CP298	15 MCG								
	F	CAUC		6M	0		001	PREBLEED				< 600						
					0		011	INJ 1	CP298	15 MCG								
					56		011	BLEED 1				15110						
					56		021	INJ 2	CP298	15 MCG								
					84		021	BLEED 2				23448						
	F	CAUC		4M	0		001	PREBLEED				< 600		< 250		< 100		< 100
					0		011	INJ 1	CP298	15 MCG								
					56		011	BLEED 1				1767		< 250		< 100		230
					56		021	INJ 2	CP298	15 MCG								
					84		021	BLEED 2			01/	QNS				< 100	01/	QNS
	F	CAUC		4M	0		011	INJ 1	CP298	15 MCG								
					56		021	INJ 2	CP298	15 MCG								
	M	CAUC		5M	0		001	PREBLEED				< 600		< 250		< 100		535
					0		011	INJ 1	CP298	15 MCG								
					56		011	BLEED 1			01/	QNS				177	01/	
					56		021	INJ 2	CP298	15 MCG								
					84		021	BLEED 2				23056		< 250		< 100		11077
	F	HISP		3M	0		001	PREBLEED				< 600				< 100		< 100
					0		011	INJ 1	CP298	15 MCG								
					64		011	BLEED 1				5864				< 100		1831
					64		021	INJ 2	CP298	15 MCG								
					112		021	BLEED 2				19630				189		13020
	M	CAUC		10M	0		001	PREBLEED				< 600				< 100		< 100
					0		011	INJ 1	CP298	15 MCG								
					64		011	BLEED 1				8688				2190	01/	QNS
					64		021	INJ 2	CP298	15 MCG								
					91		021	BLEED 2				72275				1050		20200

00700

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	IGG1	CODE/	IGG2	CODE/	IGGM	CODE/IGG TOTAL
(b) (6)	M	CAUC	(b) (6)	4M	0	(b) (6)	001	PREBLEED				< 600				< 100	< 100
					0		011	INJ 1	CP298	15 MCG							
					77		011	BLEED 1			01/	QNS			05/	QNS	05/ 372
					77		021	INJ 2	CP298	15 MCG							
					105		021	BLEED 2			05/	6023			05/	< 100	05/ 922
	F	CAUC		3M	0		011	INJ 1	CP298	15 MCG							
					63		021	INJ 2	CP298	15 MCG							
	F	CAUC		8M	0		011	INJ 1	CP298	15 MCG							
	M	CAUC		3M	0		011	INJ 1	CP298	15 MCG							
					84		021	INJ 2	CP298	15 MCG							
	F	CAUC		11M	0		011	INJ 1	CP298	15 MCG							
					63		021	INJ 2	CP298	15 MCG							
	M	CAUC		9M	0		011	INJ 1	CP298	15 MCG							
					63		021	INJ 2	CP298	15 MCG							
	F	CAUC		4M	0		011	INJ 1	CP298	15 MCG							
					56		021	INJ 2	CP298	15 MCG							
	F	CAUC		3M	0		011	INJ 1	CP298	15 MCG							
					56		021	INJ 2	CP298	15 MCG							
	F	CAUC		3M	0		001	PREBLEED				< 600				< 100	277
					0		011	INJ 1	CP298	15 MCG							
					56		011	BLEED 1				2999				106	2597
					56		021	INJ 2	CP298	15 MCG							
					84		021	BLEED 2				18164				163	2756
	F	CAUC		2M	0		001	PREBLEED				< 600				< 100	< 100
					0		011	INJ 1	CP298	15 MCG							
					56		011	BLEED 1				< 600				< 100	< 100
					56		021	INJ 2	CP298	15 MCG							
					84		021	BLEED 2				< 600			01/	QNS	154
	F	CAUC		6M	0		001	PREBLEED				< 600				< 100	< 100
					0		011	INJ 1	CP298	15 MCG							

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	IGG1	CODE/	IGG2	CODE/	IGGM	CODE/	IGG TOTAL
(b) (6)	F	CAUC	(b) (6)	6M	56	(b) (6)	011	BLEED 1				1485				< 100		372
					56		021	INJ 2	CP298	15 MCG								
					84		021	BLEED 2				2543			01/	QNS	01/	QNS
	M	CAUC		4M	0		011	INJ 1	CP298	15 MCG								
					56		021	INJ 2	CP298	15 MCG								
	M	CAUC		6M	0		011	INJ 1	CP298	15 MCG								
					63		021	INJ 2	CP298	15 MCG								
	M	CAUC		5M	0		001	PREBLEED				< 600				< 100		< 100
					0		011	INJ 1	CP298	15 MCG								
					56		011	BLEED 1				2934				575		591
					56		021	INJ 2	CP298	15 MCG								
					84		021	BLEED 2				5264				526		215
	M	CAUC		6M	0		001	PREBLEED								< 100		440
					0		011	INJ 1	CP298	15 MCG								
					63		011	BLEED 1								193		911
					63		021	INJ 2	CP298	15 MCG								
					98		021	BLEED 2								1697		1555
	M	CAUC		10M	0		011	INJ 1	CP298	15 MCG								
					56		021	INJ 2	CP298	15 MCG								
	F	CAUC		4M	0		011	INJ 1	CR132	15 MCG								
	F	CAUC		4M	0		011	INJ 1	CP749	15 MCG								
	M	CAUC		2M	0		011	INJ 1	CP298	15 MCG								
	M	CAUC		2M	0		011	INJ 1	CP749	15 MCG								
	M	HISP		2M	0		011	INJ 1	CR132	15 MCG								
	M	CAUC		2M	0		011	INJ 1	CP298	15 MCG								
	M	CAUC		9M	0		011	INJ 1	CP298	15 MCG								
	M	CAUC		5M	0		011	INJ 1	CR132	15 MCG								

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ IGG1	CODE/ IGG2	CODE/ IGGM	CODE/IGG TOTAL
(b) (6)	F	HISP	(b) (6)	5M	0	(b) (6)	011	INJ 1	CP749	15 MCG				
	F	CAUC		11M	0		011	INJ 1	CP749	15 MCG				
	M	HISP		3M	0		011	INJ 1	CR132	15 MCG				
	M	CAUC		3M	0		011	INJ 1	CP298	15 MCG				
	F	CAUC		5M	0		011	INJ 1	CP749	15 MCG				
	M	CAUC		2M	0		011	INJ 1	CP298	15 MCG				
	M	CAUC		3M	0		011	INJ 1	CR132	15 MCG				
	F	OTHE		6M	0		001	PREBLEED					< 100	< 100
					0		011	INJ 1	CR132	15 MCG				
					57		011	BLEED 1					< 100	1521
					57		021	INJ 2	CR132	15 MCG				
	M	CAUC		6M	0		001	PREBLEED					< 100	< 100
					0		011	INJ 1	CP749	15 MCG				
					57		011	BLEED 1					< 100	245
					57		021	INJ 2	CP749	15 MCG				
	F	CAUC		6M	0		011	INJ 1	CP749	15 MCG				
	M	CAUC		4M	0		001	PREBLEED					< 100	< 100
					0		011	INJ 1	CP749	15 MCG				
					64		011	BLEED 1					< 100	438
	M	CAUC		2M	0		011	INJ 1	CR132	15 MCG				
	F	CAUC		2M	0		011	INJ 1	CP298	15 MCG				
					64		021	INJ 2	CP298	15 MCG				
	M	CAUC		2M	0		001	PREBLEED					< 100	< 100
					0		011	INJ 1	CR132	15 MCG				
					64		011	BLEED 1					< 100	857
					64		021	INJ 2	CR132	15 MCG				
	M	CAUC		3M	0		011	INJ 1	CP298	15 MCG				

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ IGG1	CODE/ IGG2	CODE/ IGGM	CODE/IGG TOTAL
(b) (6)	M	CAUC	(b) (6)	3M	57	(b) (6)	021	INJ 2	CP298	15 MCG				
	F	OTHE		3M	0		011	INJ 1	CP749	15 MCG				
	M	CAUC		4M	0		001	PREBLEED					< 100	< 100
					0		011	INJ 1	CR132	15 MCG				
					57		011	BLEED 1					< 100	< 100
					57		021	INJ 2	CR132	15 MCG				
					92		011	BLEED 2					< 100	371
	F	CAUC		4M	0		001	PREBLEED			< 600		< 100	< 100
					0		011	INJ 1	CR132	15 MCG				
					56		011	BLEED 1			926		< 100	124
					56		021	INJ 2	CR132	15 MCG				
					85		021	BLEED 2			3998		< 100	659
	F	CAUC		7M	0		011	INJ 1	CP749	15 MCG				
					56		021	INJ 2	CP749	15 MCG				
	M	CAUC		3M	0		011	INJ 1	CP298	15 MCG				
					56		021	INJ 2	CP298	15 MCG				
	F	CAUC		2M	0		011	INJ 1	CP298	15 MCG				
					70		021	INJ 2	CP298	15 MCG				
	M	CAUC		9M	0		011	INJ 1	CP298	15 MCG				
					63		021	INJ 2	CP298	15 MCG				
	F	CAUC		9M	0		001	PREBLEED			< 600		< 100	< 100
					0		011	INJ 1	CP749	15 MCG				
					63		011	BLEED 1			7353		242	1546
					63		021	INJ 2	CP749	15 MCG				
					91		021	BLEED 2			15874		645	4226
	F	CAUC		9M	0		001	PREBLEED			< 600	< 250	< 100	< 100
					0		011	INJ 1	CR132	15 MCG				
					63		011	BLEED 1			18296	< 250	210	1647
					63		021	INJ 2	CR132	15 MCG				
					91		021	BLEED 2			32938	< 250	< 100	2977
	F	HISP		2M	0		011	INJ 1	CP298	15 MCG				

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ IGG1	CODE/ IGG2	CODE/ IGGM	CODE/IGG TOTAL
(b) (6)	M	CAUC	(b) (6)	3M	0	(b) (6)	011	INJ 1	CR132	15 MCG				
					63		021	INJ 2	CR132	15 MCG				
	F	CAUC		5M	0		011	INJ 1	CP749	15 MCG				
					56		021	INJ 2	CP749	15 MCG				
	M	CAUC		4M	0		001	PREBLEED				< 250	< 100	< 100
					0		011	INJ 1	CR132	15 MCG				
					62		011	BLEED 1				< 250	138	295
					62		021	INJ 2	CR132	15 MCG				
					90		021	BLEED 2				< 250	154	821
	F	CAUC		6M	0		011	INJ 1	CR132	15 MCG				
					63		021	INJ 2	CR132	15 MCG				
	F	CAUC		3M	0		001	PREBLEED			< 600			
					0		011	INJ 1	CP749	15 MCG				
					56		021	INJ 2	CP749	15 MCG				
					84		021	BLEED 1			5528			
	M	CAUC		2M	0		011	INJ 1	CP298	15 MCG				
					56		021	INJ 2	CP298	15 MCG				
	F	CAUC		2M	0		001	PREBLEED			< 600	< 250	< 100	< 100
					0		011	INJ 1	CP749	15 MCG				
					56		011	BLEED 1			11360	< 250	117	885
					56		021	INJ 2	CP749	15 MCG				
					98		021	BLEED 2			15101	< 250	208	1170
	M	CAUC		5M	0		011	INJ 1	CP298	15 MCG				
					56		021	INJ 2	CP298	15 MCG				
	F	CAUC		11M	0		001	PREBLEED			< 600	< 250	< 100	< 100
					0		011	INJ 1	CR132	15 MCG				
					56		011	BLEED 1			2692	< 250	503	398
					56		021	INJ 2	CR132	15 MCG				
					98		021	BLEED 2			10479	< 250	1040	1240
	M	CAUC		5M	0		001	PREBLEED			< 600	< 250	< 100	< 100
					0		011	INJ 1	CP749	15 MCG				

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	IGG1	CODE/	IGG2	CODE/	IGGM	CODE/	IGG TOTAL
(b) (6)	M	CAUC	(b) (6)	5M	52	(b) (6)	011	BLEED 1				6164		< 250		161		834
					52		021	INJ 2	CP749	15 MCG								
					84		021	BLEED 2				9597		< 250		111		2022
	M	CAUC		5M	0		001	PREBLEED				< 600		< 250		< 100		< 100
					0		011	INJ 1	CP749	15 MCG								
					77		011	BLEED 1			05/	4793	05/	< 250	05/	< 100	05/	508
					77		021	INJ 2	CP749	15 MCG								
					105		021	BLEED 2			05/	9081	05/	< 250	05/	< 100	05/	595
	M	CAUC		10M	0		011	INJ 1	CP298	15 MCG								
					63		021	INJ 2	CP298	15 MCG								
	M	CAUC		7M	0		001	PREBLEED				< 600		< 250		< 100		< 100
					0		011	INJ 1	CR132	15 MCG								
					77		011	BLEED 1			05/	5764	05/	< 250	05/	< 100	05/	1346
					77		021	INJ 2	CR132	15 MCG								
					119		021	BLEED 2			05/	19233	05/	528	05/	417	05/	3242
	M	CAUC		3M	0		011	INJ 1	CP298	15 MCG								
					63		021	INJ 2	CP298	15 MCG								

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ IGG1	CODE/ IGG2	CODE/ IGGM	CODE/IGG TOTAL
(b) (6)	M	CAUC	(b) (6)	15M	0	(b) (6)	011	INJ 1	CP241	15 MCG				
	M	CAUC		4Y	0		011	INJ 1	CP241	15 MCG				
	M	CAUC		21M	0		011	INJ 1	CP241	15 MCG				
	F	CAUC		20M	0		011	INJ 1	CP241	15 MCG				
	F	CAUC		21M	0		011	INJ 1	CP241	15 MCG				
	M	CAUC		15M	0		011	INJ 1	CP241	15 MCG				
	F	CAUC		12M	0		011	INJ 1	CP241	15 MCG				
	M	CAUC		2Y	0		011	INJ 1	CP241	15 MCG				
	M	CAUC		12M	0		011	INJ 1	CP241	15 MCG				
	M	CAUC		13M	0		011	INJ 1	CP241	15 MCG				
	F	CAUC		12M	0		011	INJ 1	CP241	15 MCG				
	F	CAUC		4Y	0		011	INJ 1	CP241	15 MCG				
	F	CAUC		2Y	0		011	INJ 1	CP241	15 MCG				
	F	CAUC		4Y	0		011	INJ 1	CP241	15 MCG				
	F	CAUC		2Y	0		011	INJ 1	CP241	15 MCG				
	F	CAUC		13M	0		001	PREBLEED			< 600	< 250	2569	< 100
					0		011	INJ 1	CP298	15 MCG				
					28		011	BLEED 1			5949	< 250	3466	2502
	M	CAUC		14M	0		011	INJ 1	CP298	15 MCG				
	F	HISP		16M	0		001	PREBLEED			< 600	< 250	< 100	< 100
					0		011	INJ 1	CP298	15 MCG				
					35		011	BLEED 1			< 600	< 250	1134	200
	M	CAUC		21M	0		001	PREBLEED			< 600	< 250	326	< 100

00707

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	IGG1	CODE/	IGG2	CODE/	IGGM	CODE/IGG TOTAL
(b) (6)	M	CAUC	(b) (6)	21M	0	(b) (6)	011	INJ 1	CP298	15 MCG							
					28		011	BLEED 1				17286		< 250		23934	6609
	M	CAUC		13M	0		001	PREBLEED				< 600		< 250		< 100	< 100
					0		011	INJ 1	CP298	15 MCG							
					28		011	BLEED 1				6166		< 250		7604	1306
	M	CAUC		17M	0		001	PREBLEED				< 600				< 100	< 100
					0		011	INJ 1	CP298	15 MCG							
					28		011	BLEED 1				4284				594	798
	F	CAUC		24M	0		001	PREBLEED				< 600					
					0		011	INJ 1	CP298	15 MCG							
					28		011	BLEED 1				2341					
	M	CAUC		14M	0		001	PREBLEED				< 600				< 100	< 100
					0		011	INJ 1	CP298	15 MCG							
					35		011	BLEED 1				1943				< 100	389
	M	CAUC		12M	0		001	PREBLEED				< 600					
					0		011	INJ 1	CP298	15 MCG							
					42		011	BLEED 1				1989					
	F	CAUC		16M	0		001	PREBLEED				< 600					
					0		011	INJ 1	CP298	15 MCG							
					28		011	BLEED 1				1164					
	F	CAUC		2Y	0		011	INJ 1	CP298	15 MCG							
	F	CAUC		16M	0		001	PREBLEED				< 600				< 100	< 100
					0		011	INJ 1	CP298	15 MCG							
					50		011	BLEED 1				18449				114	3792
	M	CAUC		2Y	0		001	PREBLEED								944	< 100
					0		011	INJ 1	CP298	15 MCG							
					28		011	BLEED 1								1598	01/ QNS
	M	CAUC		18M	0		001	PREBLEED				< 600				410	< 100
					0		011	INJ 1	CP298	15 MCG							
					56		011	BLEED 1				4285				846	542

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	IGG1	CODE/	IGG2	CODE/	IGGM	CODE/	IGG TOTAL
(b) (6)	F	CAUC	(b) (6)	22M	0	(b) (6)	001	PREBLEED				< 600				266		< 100
					0		011	INJ 1	CP298	15 MCG								
					36		011	BLEED 1				7294				1043		6485
	F	CAUC		22M	0		001	PREBLEED				< 600				< 100		< 100
					0		011	INJ 1	CP298	15 MCG								
					36		011	BLEED 1				19387				1006		7225
	F	CAUC		19M	0		001	PREBLEED				< 600				343		< 100
					0		011	INJ 1	CP298	15 MCG								
					29		011	BLEED 1				15839				2471		1990
	M	CAUC		12M	0		001	PREBLEED				< 600		< 250		< 100		< 100
					0		011	INJ 1	CP749	15 MCG								
					22		011	BLEED 1				1389		< 250		635		197
	M	CAUC		12M	0		001	PREBLEED						< 250		< 100	01/	QNS
					0		011	INJ 1	CR132	15 MCG								
					29		011	BLEED 1						< 250		1126	01/	QNS
	F	BLAC		22M	0		011	INJ 1	CP749	15 MCG								
	M	BLAC		14M	0		011	INJ 1	CP298	15 MCG								
	M	BLAC		3Y	0		011	INJ 1	CR132	15 MCG								
	M	CAUC		14M	0		011	INJ 1	CP298	15 MCG								
	F	CAUC		24M	0		011	INJ 1	CP749	15 MCG								
	M	CAUC		15M	0		001	PREBLEED				< 600		< 250		< 100		< 100
					0		011	INJ 1	CP749	15 MCG								
					29		011	BLEED 1				4996		269		1030		1234
	F	CAUC		18M	0		001	PREBLEED				1139		< 250				
					0		011	INJ 1	CR132	15 MCG								
					28		011	BLEED 1				78527		1484				
	F	CAUC		20M	0		001	PREBLEED				< 600		< 250				
					0		011	INJ 1	CR132	15 MCG								

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ IGG1	CODE/ IGG2	CODE/ IGGM	CODE/IGG TOTAL
(b) (6)	F	CAUC	(b) (6)	20M	34	(b) (6)	011	BLEED 1			18587	772		
	M	CAUC		22M	0		011	INJ 1	CP298	15 MCG				
	F	CAUC		4Y	0		001	PREBLEED			< 600			
					0		011	INJ 1	CP749	15 MCG				
					28		011	BLEED 1			5063			
	F	CAUC		17M	0		001	PREBLEED			< 600	< 250	< 100	< 100
					0		011	INJ 1	CP749	15 MCG				
					56		011	BLEED 1			7699	< 250	1981	2292
	F	CAUC		24M	0		011	INJ 1	CP298	15 MCG				
	M	OTHE		24M	0		011	INJ 1	CP298	15 MCG				
	M	CAUC		12M	0		001	PREBLEED			< 600	< 250	< 100	< 100
					0		011	INJ 1	CR132	15 MCG				
					28		011	BLEED 1			3046	< 250	546	793
	F	CAUC		23M	0		011	INJ 1	CR132	15 MCG				
	F	CAUC		19M	0		001	PREBLEED			< 600	< 250	161	< 100
					0		011	INJ 1	CR132	15 MCG				
					42		011	BLEED 1			8088	452	605	803
	F	CAUC		13M	0		011	INJ 1	CP298	15 MCG				
	F	CAUC		20M	0		001	PREBLEED			< 600		< 100	< 100
					0		011	INJ 1	CP749	15 MCG				
					28		011	BLEED 1			3088		1017	170
	F	CAUC		24M	0		011	INJ 1	CP298	15 MCG				
	F	CAUC		4Y	0		001	PREBLEED			< 600		< 100	181
					0		011	INJ 1	CP749	15 MCG				
					35		011	BLEED 1			< 600		489	10388
	M	HISP		2Y	0		001	PREBLEED			< 600	< 250	< 100	< 100
					0		011	INJ 1	CR132	15 MCG				

00710

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ IGG1	CODE/ IGG2	CODE/ IGGM	CODE/IGG TOTAL
(b) (6)	M	HISP	(b) (6)	2Y	35	(b) (6)	011	BLEED	1		46914	1672	1374	13874
	F	CAUC		24M	0		011	INJ	1	CP298 15 MCG				
	M	CAUC		19M	0		001	PREBLEED			< 600		240	< 100
					0		011	INJ	1	CP749 15 MCG				
					28		011	BLEED	1		37891		1323	4179
	M	HISP		17M	0		011	INJ	1	CP298 15 MCG				
	M	CAUC		3Y	0		001	PREBLEED			< 600		140	< 100
					0		011	INJ	1	CR132 15 MCG				
					36		011	BLEED	1		1769		338	310
	M	HISP		4Y	0		011	INJ	1	CP749 15 MCG				
	M	HISP		23M	0		011	INJ	1	CR132 15 MCG				
	M	HISP		21M	0		001	PREBLEED			3845		< 100	< 100
					0		011	INJ	1	CR132 15 MCG				
					29		011	BLEED	1		11280		< 100	978
	M	CAUC		4Y	0		001	PREBLEED			< 600		246	< 100
					0		011	INJ	1	CR132 15 MCG				
					42		011	BLEED	1		34733		1992	24057
	F	CAUC		12M	0		011	INJ	1	CP749 15 MCG				
	M	CAUC		12M	0		011	INJ	1	CP298 15 MCG				
	M	CAUC		2Y	0		011	INJ	1	CP298 15 MCG				

TABLE 3
ANTIBODY RESPONSES

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
ASSAY : RIA
LOT NUMBER : CP241
DOSE : 15 MCG
POPULATION : HEALTHY CHILDREN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
1- 6 MOS.	PRE INJ	14 (1/ 7)	0 (0/ 7)			0.072 (7)
	MONTH 2	100 (6/ 6)	100 (6/ 6)	100 (6/ 6)	41.2	5.430 (6)
	MONTH 3	100 (7/ 7)	100 (7/ 7)	100 (7/ 7)	60.9	7.970 (7)
7-11 MOS.	PRE INJ	14 (1/ 7)	0 (0/ 7)			0.069 (7)
	MONTH 2	100 (7/ 7)	71 (5/ 7)	86 (6/ 7)	26.1	3.608 (7)
	MONTH 3	100 (4/ 4)	100 (4/ 4)	100 (4/ 4)	69.2	10.293 (4)
	MONTH 7-10	100 (1/ 1)	0 (0/ 1)	100 (1/ 1)	2.2	0.279 (1)
12-71 MOS.	PRE INJ	60 (9/ 15)	33 (5/ 15)			0.437 (15)
	MONTH 1	100 (15/ 15)	93 (14/ 15)	93 (14/ 15)	26.7	14.684 (15)
	MONTH 12-13	100 (3/ 3)	33 (1/ 3)	33 (1/ 3)	1.8	1.218 (3)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 4

ANTIBODY RESPONSES

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
ASSAY : RIA
LOT NUMBER : CP298
DOSE : 15 MCG
POPULATION : HEALTHY CHILDREN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
1- 6 MOS.	PRE INJ	35 (8/ 23)	0 (0/ 23)			0.112 (23)
	MONTH 2	100 (20/ 20)	60 (12/ 20)	90 (18/ 20)	7.3	1.310 (20)
	MONTH 3	95 (21/ 22)	82 (18/ 22)	95 (21/ 22)	21.9	3.586 (22)
7-11 MOS.	PRE INJ	17 (1/ 6)	0 (0/ 6)			0.078 (6)
	MONTH 2	100 (6/ 6)	67 (4/ 6)	100 (6/ 6)	14.3	1.995 (6)
	MONTH 3	100 (5/ 5)	80 (4/ 5)	100 (5/ 5)	43.1	6.145 (5)
	MONTH 7-10	100 (1/ 1)	100 (1/ 1)	100 (1/ 1)	17.7	2.207 (1)
12-71 MOS.	PRE INJ	45 (10/ 22)	18 (4/ 22)			0.203 (22)
	MONTH 1	100 (22/ 22)	91 (20/ 22)	100 (22/ 22)	23.5	6.775 (22)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 5

ANTIBODY RESPONSES

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
ASSAY : RIA
LOT NUMBER : CP749
DOSE : 15 MCG
POPULATION : HEALTHY CHILDREN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
1- 6 MOS.	PRE INJ	20 (1/ 5)	0 (0/ 5)			0.091 (5)
	MONTH 2	100 (4/ 4)	100 (4/ 4)	100 (4/ 4)	17.4	2.477 (4)
	MONTH 3	100 (4/ 4)	100 (4/ 4)	100 (4/ 4)	30.6	4.316 (4)
7-11 MOS.	PRE INJ	0 (0/ 2)	0 (0/ 2)			0.063 (2)
	MONTH 2	100 (2/ 2)	100 (2/ 2)	100 (2/ 2)	48.6	6.072 (2)
	MONTH 3	100 (2/ 2)	100 (2/ 2)	100 (2/ 2)	108.4	13.545 (2)
12-71 MOS.	PRE INJ	14 (1/ 7)	14 (1/ 7)			0.130 (7)
	MONTH 1	100 (7/ 7)	71 (5/ 7)	100 (7/ 7)	15.4	3.273 (7)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 6
ANTIBODY RESPONSES

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
ASSAY : RIA
LOT NUMBER : CR132
DOSE : 15 MCG
POPULATION : HEALTHY CHILDREN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
1- 6 MOS.	PRE INJ	100 (3/ 3)	0 (0/ 3)			0.272 (3)
	MONTH 2	100 (3/ 3)	67 (2/ 3)	67 (2/ 3)	3.0	0.820 (3)
	MONTH 3	100 (3/ 3)	67 (2/ 3)	67 (2/ 3)	5.8	1.574 (3)
7-11 MOS.	PRE INJ	50 (1/ 2)	0 (0/ 2)			0.139 (2)
	MONTH 2	100 (2/ 2)	50 (1/ 2)	50 (1/ 2)	8.9	1.748 (2)
	MONTH 3	100 (2/ 2)	100 (2/ 2)	100 (2/ 2)	32.9	6.449 (2)
12-71 MOS.	PRE INJ	44 (4/ 9)	22 (2/ 9)			0.186 (9)
	MONTH 1	100 (9/ 9)	89 (8/ 9)	100 (9/ 9)	36.7	10.039 (9)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 7

A N T I B O D Y R E S P O N S E S
CHILDREN RANDOMIZED TO CONSISTENCY LOTS - ALL

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
ASSAY : RIA
LOT NUMBER : CP298
DOSE : 15 MCG
POPULATION : HEALTHY CHILDREN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
1- 6 MOS.	PRE INJ	57 (4/ 7)	0 (0/ 7)			0.158 (7)
	MONTH 2	100 (6/ 6)	67 (4/ 6)	83 (5/ 6)	5.2	1.201 (6)
	MONTH 3	100 (6/ 6)	83 (5/ 6)	100 (6/ 6)	29.0	5.527 (6)
7-11 MOS.	PRE INJ	0 (0/ 2)	0 (0/ 2)			0.063 (2)
	MONTH 2	100 (2/ 2)	50 (1/ 2)	100 (2/ 2)	6.8	0.845 (2)
	MONTH 3	100 (2/ 2)	50 (1/ 2)	100 (2/ 2)	21.9	2.735 (2)
12-71 MOS.	PRE INJ	70 (7/ 10)	30 (3/ 10)			0.429 (10)
	MONTH 1	100 (10/ 10)	100 (10/ 10)	100 (10/ 10)	30.5	16.109 (10)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE,
AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

STUDY 004-10

TABLE 8

A N T I B O D Y R E S P O N S E S
CHILDREN RANDOMIZED TO CONSISTENCY LOTS - ALL

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
ASSAY : RIA
LOT NUMBER : CP749
DOSE : 15 MCG
POPULATION : HEALTHY CHILDREN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
1- 6 MOS.	PRE INJ	20 (1/ 5)	0 (0/ 5)			0.091 (5)
	MONTH 2	100 (4/ 4)	100 (4/ 4)	100 (4/ 4)	17.4	2.477 (4)
	MONTH 3	100 (4/ 4)	100 (4/ 4)	100 (4/ 4)	30.6	4.316 (4)
7-11 MOS.	PRE INJ	0 (0/ 2)	0 (0/ 2)			0.063 (2)
	MONTH 2	100 (2/ 2)	100 (2/ 2)	100 (2/ 2)	48.6	6.072 (2)
	MONTH 3	100 (2/ 2)	100 (2/ 2)	100 (2/ 2)	108.4	13.545 (2)
12-71 MOS.	PRE INJ	14 (1/ 7)	14 (1/ 7)			0.130 (7)
	MONTH 1	100 (7/ 7)	71 (5/ 7)	100 (7/ 7)	15.4	3.273 (7)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE,
AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 9

ANTIBODY RESPONSES
CHILDREN RANDOMIZED TO CONSISTENCY LOTS - ALL

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
ASSAY : RIA
LOT NUMBER : CR132
DOSE : 15 MCG
POPULATION : HEALTHY CHILDREN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
1- 6 MOS.	PRE INJ	100 (3/ 3)	0 (0/ 3)			0.272 (3)
	MONTH 2	100 (3/ 3)	67 (2/ 3)	67 (2/ 3)	3.0	0.820 (3)
	MONTH 3	100 (3/ 3)	67 (2/ 3)	67 (2/ 3)	5.8	1.574 (3)
7-11 MOS.	PRE INJ	50 (1/ 2)	0 (0/ 2)			0.139 (2)
	MONTH 2	100 (2/ 2)	50 (1/ 2)	50 (1/ 2)	8.9	1.748 (2)
	MONTH 3	100 (2/ 2)	100 (2/ 2)	100 (2/ 2)	32.9	6.449 (2)
12-71 MOS.	PRE INJ	44 (4/ 9)	22 (2/ 9)			0.186 (9)
	MONTH 1	100 (9/ 9)	89 (8/ 9)	100 (9/ 9)	36.7	10.039 (9)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 10

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	15	
VACCINEES WITH NO COMPLAINTS :	4	(26.7 %)
VACCINEES WITH COMPLAINTS :	11	(73.3 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 15 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	3	20.0
ERYTHEMA, INJ. SITE (<=1 IN.)	3	20.0
SWELLING, INJ. SITE (<=1 IN.)	3	20.0
ERYTHEMA, INJ. SITE (>1 INCH)	1	6.7
SYSTEMIC REACTIONS	9	60.0
FATIGUE	5	33.3
IRRITABILITY	4	26.7
TEETHING	4	26.7
WARM TO TOUCH	2	13.3
COUGH	1	6.7
DIARRHEA	1	6.7
LARYNGEOTRACHEOBRONCHITIS	1	6.7
NASAL CONGESTION	1	6.7
PROLONGED CRYING, >1/2 HR	1	6.7
WHEEZING	1	6.7

TABLE 10 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE	HIB CONJUGATE INJECTION: 2	
TOTAL VACCINEES	14	
VACCINEES WITH NO COMPLAINTS	3	(23.1 %)
VACCINEES WITH COMPLAINTS	10	(76.9 %)
VACCINEES WITH NO DATA	1	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 13 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	6	46.2
ERYTHEMA, INJ. SITE (<=1 IN.)	3	23.1
SWELLING, INJ. SITE (<=1 IN.)	3	23.1
ERYTHEMA, INJ. SITE (>1 INCH)	2	15.4
INDURATION, INJECTION SITE	2	15.4
PAIN/SORENESS, INJ. SITE	2	15.4
ECCHYMOSIS, INJECTION SITE	1	7.7
SWELLING, INJ. SITE (>1 INCH)	1	7.7
SYSTEMIC REACTIONS	9	69.2
IRRITABILITY	6	46.2
DIARRHEA	3	23.1
FATIGUE	3	23.1
TEETHING	3	23.1
COMMON COLD	1	7.7
COUGH	1	7.7
EAR INFECTION, NOS	1	7.7
NASAL DISCHARGE	1	7.7
RASH	1	7.7
VOMITING	1	7.7
WARM TO TOUCH	1	7.7
WHEEZING	1	7.7

TABLE 10 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
POPULATION : HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	15	
VACCINEES WITH NO COMPLAINTS :	4	(26.7 %)
VACCINEES WITH COMPLAINTS :	11	(73.3 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 15 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	7	46.7
PAIN/SORENESS, INJ. SITE	6	40.0
ERYTHEMA, INJ. SITE (<=1 IN.)	1	6.7
STIFFNESS/TIGHTNESS, INJECTION SITE	1	6.7
SYSTEMIC REACTIONS	7	46.7
FATIGUE	4	26.7
IRRITABILITY	3	20.0
TEETHING	3	20.0
DIARRHEA	2	13.3
PROLONGED CRYING, >1/2 HR	2	13.3
WARM TO TOUCH	2	13.3
ANOREXIA	1	6.7
MEDIASTINAL ABSCESS	1	6.7
OTALGIA	1	6.7
SKIN INFLAMMATION	1	6.7

TABLE 10 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	38	
VACCINEES WITH NO COMPLAINTS :	7	(21.2 %)
VACCINEES WITH COMPLAINTS :	26	(78.8 %)
VACCINEES WITH NO DATA :	5	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 33 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	12	36.4
ERYTHEMA, INJ. SITE (<=1 IN.)	6	18.2
SWELLING, INJ. SITE (<=1 IN.)	5	15.2
PAIN/SORENESS, INJ. SITE	3	9.1
INDURATION, INJECTION SITE	2	6.1
SYSTEMIC REACTIONS	22	66.7
IRRITABILITY	12	36.4
FATIGUE	9	27.3
DIARRHEA	6	18.2
WARM TO TOUCH	6	18.2
TEETHING	4	12.1
BRONCHIOLITIS, ACUTE	2	6.1
COUGH	2	6.1
FEVER	2	6.1
COMMON COLD	1	3.0
CONJUNCTIVITIS	1	3.0
HYPERHYDROSIS	1	3.0
NASAL CONGESTION	1	3.0
NASAL DISCHARGE	1	3.0
OTITIS MEDIA	1	3.0
PHARYNGITIS	1	3.0
PROLONGED CRYING, >1/2 HR	1	3.0
SNEEZING	1	3.0
VOMITING	1	3.0
WHEEZING	1	3.0

TABLE 10 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 2	
TOTAL VACCINEES :	31	
VACCINEES WITH NO COMPLAINTS :	11	(35.5 %)
VACCINEES WITH COMPLAINTS :	20	(64.5 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 31 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	8	25.8
ERYTHEMA, INJ. SITE (<=1 IN.)	5	16.1
PAIN/SORENESS, INJ. SITE	3	9.7
SWELLING, INJ. SITE (<=1 IN.)	3	9.7
SWELLING, INJ. SITE (>1 INCH)	2	6.5
ERYTHEMA, INJ. SITE (>1 INCH)	1	3.2
INDURATION, INJECTION SITE	1	3.2
SYSTEMIC REACTIONS	19	61.3
IRRITABILITY	11	35.5
FATIGUE	8	25.8
WARM TO TOUCH	7	22.6
VOMITING	4	12.9
DIARRHEA	3	9.7
EAR INFECTION, NOS	2	6.5
NASAL DISCHARGE	2	6.5
UNUSUAL HIGH-PITCHED CRYING	2	6.5
ATOPIC DERMATITIS	1	3.2
CONJUNCTIVITIS	1	3.2
FLU-LIKE ILLNESS	1	3.2
GASTRITIS, ACUTE	1	3.2
INSOMNIA	1	3.2
NAUSEA	1	3.2
OTITIS MEDIA	1	3.2
PROLONGED CRYING, >1/2 HR	1	3.2
RASH	1	3.2
TEETHING	1	3.2
VIRUS INFECTION	1	3.2
WHEEZING	1	3.2

TABLE 10 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
POPULATION : HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	28	
VACCINEES WITH NO COMPLAINTS :	13	(48.1 %)
VACCINEES WITH COMPLAINTS :	14	(51.9 %)
VACCINEES WITH NO DATA :	1	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 27 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	7	25.9
PAIN/SORENESS, INJ. SITE	6	22.2
SWELLING, INJ. SITE (<=1 IN.)	3	11.1
ERYTHEMA, INJ. SITE (<=1 IN.)	2	7.4
INDURATION, INJECTION SITE	2	7.4
SYSTEMIC REACTIONS	9	33.3
IRRITABILITY	6	22.2
FATIGUE	4	14.8
WARM TO TOUCH	3	11.1
RASH	2	7.4
ANOREXIA	1	3.7
DIARRHEA	1	3.7
FUNGUS INFECTION	1	3.7
SALIVATION INCREASE	1	3.7
TEETHING	1	3.7

TABLE 10 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	16	
VACCINEES WITH NO COMPLAINTS :	4	(40.0 %)
VACCINEES WITH COMPLAINTS :	6	(60.0 %)
VACCINEES WITH NO DATA :	6	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 10 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	2	20.0
PAIN/SORENESS, INJ. SITE	2	20.0
SYSTEMIC REACTIONS	6	60.0
FATIGUE	4	40.0
IRRITABILITY	4	40.0
WARM TO TOUCH	3	30.0
RASH	2	20.0
ATOPIC DERMATITIS	1	10.0
BRONCHIOLITIS, ACUTE	1	10.0
CONSTIPATION	1	10.0
COUGH	1	10.0
HYPERKINESIA	1	10.0
NASAL CONGESTION	1	10.0
TEETHING	1	10.0
WHEEZING	1	10.0

TABLE 10 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 2	
TOTAL VACCINEES :	9	
VACCINEES WITH NO COMPLAINTS :	3	(33.3 %)
VACCINEES WITH COMPLAINTS :	6	(66.7 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 9 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	3	33.3
ERYTHEMA, INJ. SITE (<=1 IN.)	3	33.3
SWELLING, INJ. SITE (<=1 IN.)	2	22.2
PAIN/SORENESS, INJ. SITE	1	11.1
SYSTEMIC REACTIONS	4	44.4
FATIGUE	2	22.2
IRRITABILITY	2	22.2
WARM TO TOUCH	2	22.2
DIARRHEA	1	11.1
FEVER	1	11.1
INSOMNIA	1	11.1
TEETHING	1	11.1
VOMITING	1	11.1

TABLE 10 (cont.)

C L I N I C A L C O M P L A I N T S B Y F R E Q U E N C Y

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
POPULATION : HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	11	
VACCINEES WITH NO COMPLAINTS :	5	(45.5 %)
VACCINEES WITH COMPLAINTS :	6	(54.5 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 11 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	3	27.3
ERYTHEMA, INJ. SITE (<=1 IN.)	2	18.2
PAIN/SORENESS, INJ. SITE	1	9.1
SYSTEMIC REACTIONS	4	36.4
FATIGUE	2	18.2
IRRITABILITY	2	18.2
ATOPIC DERMATITIS	1	9.1
NERVOUSNESS	1	9.1
TEETHING	1	9.1

TABLE 10 (cont.)

C L I N I C A L C O M P L A I N T S B Y F R E Q U E N C Y

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
LOT NUMBER : CR132
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	16	
VACCINEES WITH NO COMPLAINTS :	3	(30.0 %)
VACCINEES WITH COMPLAINTS :	7	(70.0 %)
VACCINEES WITH NO DATA :	6	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 10 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	3	30.0
SWELLING, INJ. SITE (<=1 IN.)	2	20.0
ERYTHEMA, INJ. SITE (<=1 IN.)	1	10.0
SYSTEMIC REACTIONS	6	60.0
FATIGUE	4	40.0
IRRITABILITY	3	30.0
COUGH	1	10.0
DIARRHEA	1	10.0
PRURITUS	1	10.0
VOMITING	1	10.0

TABLE 10 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
LOT NUMBER : CR132
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 2	
TOTAL VACCINEES :	10	
VACCINEES WITH NO COMPLAINTS :	2	(20.0 %)
VACCINEES WITH COMPLAINTS :	8	(80.0 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 10 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	3	30.0
SWELLING, INJ. SITE (<=1 IN.)	3	30.0
ERYTHEMA, INJ. SITE (<=1 IN.)	2	20.0
PAIN/SORENESS, INJ. SITE	1	10.0
SWELLING, INJ. SITE (>1 INCH)	1	10.0
SYSTEMIC REACTIONS	6	60.0
FATIGUE	2	20.0
IRRITABILITY	2	20.0
NASAL DISCHARGE	2	20.0
NERVOUSNESS	2	20.0
COMMON COLD	1	10.0
CONSTIPATION	1	10.0
COUGH	1	10.0
PROLONGED CRYING, >1/2 HR	1	10.0
TEETHING	1	10.0
WARM TO TOUCH	1	10.0

TABLE 10 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
LOT NUMBER : CR132
POPULATION : HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	12	
VACCINEES WITH NO COMPLAINTS :	4	(33.3 %)
VACCINEES WITH COMPLAINTS :	8	(66.7 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 12 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	7	58.3
ERYTHEMA, INJ. SITE (<=1 IN.)	4	33.3
PAIN/SORENESS, INJ. SITE	4	33.3
SWELLING, INJ. SITE (<=1 IN.)	1	8.3
SYSTEMIC REACTIONS	6	50.0
IRRITABILITY	5	41.7
FATIGUE	4	33.3
ANOREXIA	1	8.3
CRYING	1	8.3
DIARRHEA	1	8.3
EAR INFECTION, NOS	1	8.3
INFLUENZA	1	8.3
NAUSEA	1	8.3
UNUSUAL HIGH-PITCHED CRYING	1	8.3
VOMITING	1	8.3
WARM TO TOUCH	1	8.3

TABLE 11

CLINICAL COMPLAINTS

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (15 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5	COMPLAINTS
LOCAL REACTIONS	1 (6.7%)	3 (20.0%)	2 (13.3%)	2 (13.3%)	1 (6.7%)	1 (6.7%)	3 (20.0%)
ERYTHEMA, INJ. SITE (>1 INCH)	0 (0.0%)	1 (6.7%)	1 (6.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (6.7%)
ERYTHEMA, INJ. SITE (<=1 IN.)	1 (6.7%)	2 (13.3%)	0 (0.0%)	1 (6.7%)	1 (6.7%)	1 (6.7%)	3 (20.0%)
SWELLING, INJ. SITE (<=1 IN.)	0 (0.0%)	2 (13.3%)	1 (6.7%)	1 (6.7%)	0 (0.0%)	0 (0.0%)	3 (20.0%)
SYSTEMIC	4 (26.7%)	7 (46.7%)	5 (33.3%)	3 (20.0%)	3 (20.0%)	4 (26.7%)	9 (60.0%)
BODY AS A WHOLE/SITE UNSPEC.	3 (20.0%)	5 (33.3%)	2 (13.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	6 (40.0%)
FATIGUE	2 (13.3%)	4 (26.7%)	1 (6.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	5 (33.3%)
HARM TO TOUCH	2 (13.3%)	1 (6.7%)	1 (6.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (13.3%)
DIGESTIVE SYSTEM	3 (20.0%)	2 (13.3%)	3 (20.0%)	3 (20.0%)	3 (20.0%)	4 (26.7%)	4 (26.7%)
DIARRHEA	1 (6.7%)	1 (6.7%)	1 (6.7%)	1 (6.7%)	1 (6.7%)	0 (0.0%)	1 (6.7%)
TEETHING	3 (20.0%)	2 (13.3%)	3 (20.0%)	3 (20.0%)	3 (20.0%)	4 (26.7%)	4 (26.7%)

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (15 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		
NERVOUS SYSTEM & PSYCHIATRIC	1 (6.7%)	4 (26.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		4 (26.7%)
IRRITABILITY	1 (6.7%)	4 (26.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		4 (26.7%)
PROLONGED CRYING, >1/2 HR	1 (6.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (6.7%)
RESPIRATORY SYSTEM	0 (0.0%)	1 (6.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (6.7%)
COUGH	0 (0.0%)	1 (6.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (6.7%)
LARYNGEOTRACHEOBRONCHITIS	0 (0.0%)	1 (6.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (6.7%)
NASAL CONGESTION	0 (0.0%)	1 (6.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (6.7%)
WHEEZING	0 (0.0%)	1 (6.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (6.7%)
VACCINEES WITH COMPLAINTS	5 (33.3%)	10 (66.7%)	7 (46.7%)	5 (33.3%)	4 (26.7%)	5 (33.3%)		11 (73.3%)
VACCINEES WITH NO COMPLAINTS	10 (66.7%)	5 (33.3%)	8 (53.3%)	10 (66.7%)	11 (73.3%)	10 (66.7%)		4 (26.7%)
TOTAL VACCINEES REPORTING	15	15	15	15	15	15		15

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (15 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
VACCINEES WITH NO DATA	0	0	0	0	0	0		0

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TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (14 VACCINEES) - INJECTION: 2						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5	COMPLAINTS
LOCAL REACTIONS	3 (23.1%)	4 (30.8%)	4 (30.8%)	4 (30.8%)	3 (23.1%)	2 (15.4%)	6 (46.2%)
ECCHYMOSIS, INJECTION SITE	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.7%)	1 (7.7%)
ERYTHEMA, INJ. SITE (>1 INCH)	0 (0.0%)	1 (7.7%)	1 (7.7%)	1 (7.7%)	0 (0.0%)	1 (7.7%)	2 (15.4%)
ERYTHEMA, INJ. SITE (<=1 IN.)	2 (15.4%)	2 (15.4%)	1 (7.7%)	1 (7.7%)	1 (7.7%)	1 (7.7%)	3 (23.1%)
INDURATION, INJECTION SITE	0 (0.0%)	1 (7.7%)	1 (7.7%)	2 (15.4%)	1 (7.7%)	1 (7.7%)	2 (15.4%)
PAIN/SORENESS, INJ. SITE	1 (7.7%)	1 (7.7%)	1 (7.7%)	1 (7.7%)	0 (0.0%)	0 (0.0%)	2 (15.4%)
SWELLING, INJ. SITE (>1 INCH)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.7%)	1 (7.7%)
SWELLING, INJ. SITE (<=1 IN.)	1 (7.7%)	2 (15.4%)	3 (23.1%)	3 (23.1%)	2 (15.4%)	0 (0.0%)	3 (23.1%)
SYSTEMIC	9 (69.2%)	9 (69.2%)	7 (53.8%)	6 (46.2%)	6 (46.2%)	6 (46.2%)	9 (69.2%)
BODY AS A WHOLE/SITE UNSPEC.	3 (23.1%)	3 (23.1%)	2 (15.4%)	2 (15.4%)	0 (0.0%)	0 (0.0%)	3 (23.1%)
FATIGUE	3 (23.1%)	2 (15.4%)	2 (15.4%)	2 (15.4%)	0 (0.0%)	0 (0.0%)	3 (23.1%)

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (14 VACCINEES) - INJECTION: 2						
	DAYS POST VACCINATION						NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5	
HARM TO TOUCH	0 (0.0%)	1 (7.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.7%)
DIGESTIVE SYSTEM	4 (30.8%)	4 (30.8%)	4 (30.8%)	4 (30.8%)	4 (30.8%)	4 (30.8%)	6 (46.2%)
DIARRHEA	0 (0.0%)	1 (7.7%)	2 (15.4%)	3 (23.1%)	3 (23.1%)	3 (23.1%)	3 (23.1%)
TEETHING	3 (23.1%)	3 (23.1%)	2 (15.4%)	2 (15.4%)	2 (15.4%)	2 (15.4%)	3 (23.1%)
VOMITING	1 (7.7%)	1 (7.7%)	1 (7.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.7%)
NERVOUS SYSTEM & PSYCHIATRIC	6 (46.2%)	4 (30.8%)	3 (23.1%)	3 (23.1%)	1 (7.7%)	1 (7.7%)	6 (46.2%)
IRRITABILITY	6 (46.2%)	4 (30.8%)	3 (23.1%)	3 (23.1%)	1 (7.7%)	1 (7.7%)	6 (46.2%)
RESPIRATORY SYSTEM	1 (7.7%)	2 (15.4%)	2 (15.4%)	1 (7.7%)	1 (7.7%)	1 (7.7%)	2 (15.4%)
COMMON COLD	1 (7.7%)	1 (7.7%)	1 (7.7%)	1 (7.7%)	1 (7.7%)	1 (7.7%)	1 (7.7%)
COUGH	1 (7.7%)	1 (7.7%)	1 (7.7%)	1 (7.7%)	1 (7.7%)	1 (7.7%)	1 (7.7%)
NASAL DISCHARGE	1 (7.7%)	1 (7.7%)	1 (7.7%)	1 (7.7%)	1 (7.7%)	1 (7.7%)	1 (7.7%)
WHEEZING	0 (0.0%)	1 (7.7%)	1 (7.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.7%)

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (14 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		
SKIN & SKIN APPENDAGE	1 (7.7%)	1 (7.7%)	1 (7.7%)	1 (7.7%)	1 (7.7%)	1 (7.7%)		1 (7.7%)
RASH	1 (7.7%)	1 (7.7%)	1 (7.7%)	1 (7.7%)	1 (7.7%)	1 (7.7%)		1 (7.7%)
SPECIAL SENSES	0 (0.0%)	0 (0.0%)	1 (7.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (7.7%)
EAR INFECTION, NOS	0 (0.0%)	0 (0.0%)	1 (7.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (7.7%)
VACCINEES WITH COMPLAINTS	9 (69.2%)	10 (76.9%)	8 (61.5%)	8 (61.5%)	8 (61.5%)	7 (53.8%)		10 (76.9%)
VACCINEES WITH NO COMPLAINTS	4 (30.8%)	3 (23.1%)	5 (38.5%)	5 (38.5%)	5 (38.5%)	6 (46.2%)		3 (23.1%)
TOTAL VACCINEES REPORTING	13	13	13	13	13	13		13
VACCINEES WITH NO DATA	1	1	1	1	1	1		1

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILOREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (15 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
LOCAL REACTIONS	6 (40.0%)	5 (33.3%)	2 (13.3%)	1 (6.7%)	0 (0.0%)	0 (0.0%)		7 (46.7%)
ERYTHEMA, INJ. SITE (<=1 IN.)	1 (6.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (6.7%)
PAIN/SORENESS, INJ. SITE	6 (40.0%)	4 (26.7%)	2 (13.3%)	1 (6.7%)	0 (0.0%)	0 (0.0%)		6 (40.0%)
STIFFNESS/TIGHTNESS, INJECTION SI	0 (0.0%)	1 (6.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (6.7%)
SYSTEMIC	3 (20.0%)	5 (33.3%)	4 (26.7%)	4 (26.7%)	2 (13.3%)	3 (20.0%)		7 (46.7%)
BODY AS A WHOLE/SITE UNSPEC.	2 (13.3%)	2 (13.3%)	2 (13.3%)	1 (6.7%)	1 (6.7%)	2 (13.3%)		4 (26.7%)
FATIGUE	2 (13.3%)	1 (6.7%)	1 (6.7%)	0 (0.0%)	0 (0.0%)	1 (6.7%)		4 (26.7%)
HARM TO TOUCH	0 (0.0%)	2 (13.3%)	2 (13.3%)	1 (6.7%)	1 (6.7%)	1 (6.7%)		2 (13.3%)
DIGESTIVE SYSTEM	1 (6.7%)	3 (20.0%)	2 (13.3%)	2 (13.3%)	1 (6.7%)	1 (6.7%)		4 (26.7%)
ANOREXIA	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (6.7%)		1 (6.7%)
DIARRHEA	0 (0.0%)	0 (0.0%)	1 (6.7%)	0 (0.0%)	0 (0.0%)	1 (6.7%)		2 (13.3%)

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (15 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
TEETHING	1 (6.7%)	3 (20.0%)	1 (6.7%)	2 (13.3%)	1 (6.7%)	1 (6.7%)		3 (20.0%)
NERVOUS SYSTEM & PSYCHIATRIC	2 (13.3%)	2 (13.3%)	2 (13.3%)	1 (6.7%)	0 (0.0%)	0 (0.0%)		4 (26.7%)
IRRITABILITY	2 (13.3%)	1 (6.7%)	2 (13.3%)	1 (6.7%)	0 (0.0%)	0 (0.0%)		3 (20.0%)
PROLONGED CRYING, >1/2 HR	1 (6.7%)	1 (6.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (13.3%)
RESPIRATORY SYSTEM	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (6.7%)	0 (0.0%)		1 (6.7%)
MEDIASTINAL ABSCESS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (6.7%)	0 (0.0%)		1 (6.7%)
SKIN & SKIN APPENDAGE	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (6.7%)	0 (0.0%)		1 (6.7%)
SKIN INFLAMMATION	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (6.7%)	0 (0.0%)		1 (6.7%)
SPECIAL SENSES	0 (0.0%)	1 (6.7%)	1 (6.7%)	1 (6.7%)	0 (0.0%)	0 (0.0%)		1 (6.7%)
OTALGIA	0 (0.0%)	1 (6.7%)	1 (6.7%)	1 (6.7%)	0 (0.0%)	0 (0.0%)		1 (6.7%)
VACCINEES WITH COMPLAINTS	7 (46.7%)	9 (60.0%)	5 (33.3%)	4 (26.7%)	2 (13.3%)	3 (20.0%)		11 (73.3%)
VACCINEES WITH NO COMPLAINTS	8 (53.3%)	6 (40.0%)	10 (66.7%)	11 (73.3%)	13 (86.7%)	12 (80.0%)		4 (26.7%)

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (15 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
TOTAL VACCINEES REPORTING	15	15	15	15	15	15		15
VACCINEES WITH NO DATA	0	0	0	0	0	0		0

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (38 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
LOCAL REACTIONS	7 (22.6%)	7 (21.2%)	3 (9.1%)	4 (12.1%)	4 (12.1%)	4 (12.1%)		12 (36.4%)
ERYTHEMA, INJ. SITE (<=1 IN.)	3 (9.7%)	5 (15.2%)	2 (6.1%)	2 (6.1%)	2 (6.1%)	1 (3.0%)		6 (18.2%)
INDURATION, INJECTION SITE	0 (0.0%)	1 (3.0%)	1 (3.0%)	2 (6.1%)	2 (6.1%)	2 (6.1%)		2 (6.1%)
PAIN/SORENESS, INJ. SITE	2 (6.5%)	2 (6.1%)	1 (3.0%)	1 (3.0%)	1 (3.0%)	1 (3.0%)		3 (9.1%)
SWELLING, INJ. SITE (<=1 IN.)	3 (9.7%)	3 (9.1%)	2 (6.1%)	2 (6.1%)	2 (6.1%)	2 (6.1%)		5 (15.2%)
SYSTEMIC	9 (29.0%)	15 (45.5%)	12 (36.4%)	11 (33.3%)	11 (33.3%)	12 (36.4%)		22 (66.7%)
BODY AS A WHOLE/SITE UNSPEC.	5 (16.1%)	8 (24.2%)	3 (9.1%)	2 (6.1%)	3 (9.1%)	1 (3.0%)		13 (39.4%)
FATIGUE	5 (16.1%)	4 (12.1%)	3 (9.1%)	2 (6.1%)	2 (6.1%)	0 (0.0%)		9 (27.3%)
FEVER	0 (0.0%)	2 (6.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (6.1%)
HARM TO TOUCH	0 (0.0%)	4 (12.1%)	0 (0.0%)	1 (3.0%)	1 (3.0%)	1 (3.0%)		6 (18.2%)
DIGESTIVE SYSTEM	3 (9.7%)	6 (18.2%)	4 (12.1%)	5 (15.2%)	5 (15.2%)	6 (18.2%)		9 (27.3%)

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (38 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
DIARRHEA	1 (3.2%)	2 (6.1%)	2 (6.1%)	2 (6.1%)	2 (6.1%)	3 (9.1%)		6 (18.2%)
TEETHING	2 (6.5%)	3 (9.1%)	3 (9.1%)	4 (12.1%)	4 (12.1%)	4 (12.1%)		4 (12.1%)
VOMITING	0 (0.0%)	1 (3.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (3.0%)
NERVOUS SYSTEM & PSYCHIATRIC	4 (12.9%)	7 (21.2%)	5 (15.2%)	3 (9.1%)	2 (6.1%)	3 (9.1%)		13 (39.4%)
IRRITABILITY	4 (12.9%)	7 (21.2%)	4 (12.1%)	3 (9.1%)	2 (6.1%)	3 (9.1%)		12 (36.4%)
PROLONGED CRYING, >1/2 HR	0 (0.0%)	0 (0.0%)	1 (3.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (3.0%)
RESPIRATORY SYSTEM	1 (3.2%)	2 (6.1%)	2 (6.1%)	4 (12.1%)	4 (12.1%)	4 (12.1%)		4 (12.1%)
BRONCHIOLITIS, ACUTE	1 (3.2%)	1 (3.0%)	1 (3.0%)	2 (6.1%)	2 (6.1%)	2 (6.1%)		2 (6.1%)
COMMON COLD	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.0%)	1 (3.0%)	1 (3.0%)		1 (3.0%)
COUGH	0 (0.0%)	1 (3.0%)	0 (0.0%)	2 (6.1%)	2 (6.1%)	1 (3.0%)		2 (6.1%)
NASAL CONGESTION	0 (0.0%)	1 (3.0%)	1 (3.0%)	1 (3.0%)	1 (3.0%)	1 (3.0%)		1 (3.0%)
NASAL DISCHARGE	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.0%)	1 (3.0%)	1 (3.0%)		1 (3.0%)

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (38 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
PHARYNGITIS	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.0%)	1 (3.0%)	1 (3.0%)		1 (3.0%)
SNEEZING	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.0%)	1 (3.0%)	1 (3.0%)		1 (3.0%)
WHEEZING	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.0%)	1 (3.0%)	0 (0.0%)		1 (3.0%)
SKIN & SKIN APPENDAGE	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.0%)		1 (3.0%)
HYPERHYDROSIS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.0%)		1 (3.0%)
SPECIAL SENSES	1 (3.2%)	2 (6.1%)	2 (6.1%)	2 (6.1%)	2 (6.1%)	2 (6.1%)		2 (6.1%)
CONJUNCTIVITIS	0 (0.0%)	1 (3.0%)	1 (3.0%)	1 (3.0%)	1 (3.0%)	1 (3.0%)		1 (3.0%)
OTITIS MEDIA	1 (3.2%)	1 (3.0%)	1 (3.0%)	1 (3.0%)	1 (3.0%)	1 (3.0%)		1 (3.0%)
VACCINEES WITH COMPLAINTS	12 (38.7%)	19 (57.6%)	13 (39.4%)	12 (36.4%)	13 (39.4%)	14 (42.4%)		26 (78.8%)
VACCINEES WITH NO COMPLAINTS	19 (61.3%)	14 (42.4%)	20 (60.6%)	21 (63.6%)	20 (60.6%)	19 (57.6%)		7 (21.2%)
TOTAL VACCINEES REPORTING	31	33	33	33	33	33		33

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TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (38 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
VACCINEES WITH NO DATA	7	5	5	5	5	5		5

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (31 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		
LOCAL REACTIONS	5 (16.7%)	7 (23.3%)	4 (13.3%)	3 (9.7%)	3 (9.7%)	2 (6.5%)		8 (25.8%)
ERYTHEMA, INJ. SITE (>1 INCH)	0 (0.0%)	1 (3.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (3.2%)
ERYTHEMA, INJ. SITE (<=1 IN.)	2 (6.7%)	3 (10.0%)	3 (10.0%)	2 (6.5%)	2 (6.5%)	0 (0.0%)		5 (16.1%)
INDURATION, INJECTION SITE	0 (0.0%)	1 (3.3%)	1 (3.3%)	1 (3.2%)	1 (3.2%)	1 (3.2%)		1 (3.2%)
PAIN/SORENESS, INJ. SITE	3 (10.0%)	2 (6.7%)	1 (3.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		3 (9.7%)
SWELLING, INJ. SITE (>1 INCH)	1 (3.3%)	2 (6.7%)	1 (3.3%)	1 (3.2%)	0 (0.0%)	0 (0.0%)		2 (6.5%)
SWELLING, INJ. SITE (<=1 IN.)	2 (6.7%)	2 (6.7%)	1 (3.3%)	1 (3.2%)	2 (6.5%)	2 (6.5%)		3 (9.7%)
SYSTEMIC	8 (26.7%)	13 (43.3%)	10 (33.3%)	5 (16.1%)	6 (19.4%)	6 (19.4%)		19 (61.3%)
BODY AS A WHOLE/SITE UNSPEC.	6 (20.0%)	3 (10.0%)	2 (6.7%)	2 (6.5%)	3 (9.7%)	3 (9.7%)		10 (32.3%)
FATIGUE	5 (16.7%)	2 (6.7%)	2 (6.7%)	1 (3.2%)	1 (3.2%)	2 (6.5%)		8 (25.8%)
FLU-LIKE ILLNESS	0 (0.0%)	0 (0.0%)	1 (3.3%)	1 (3.2%)	1 (3.2%)	1 (3.2%)		1 (3.2%)

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE — NUMBER OF VACCINEES (31 VACCINEES) - INJECTION: 2

CLINICAL COMPLAINTS	DAYS POST VACCINATION 0	1	2	3	4	5	NUMBER WITH COMPLAINTS
VIRUS INFECTION	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.2%)	1 (3.2%)
HARM TO TOUCH	2 (6.7%)	2 (6.7%)	1 (3.3%)	0 (0.0%)	3 (9.7%)	3 (9.7%)	7 (22.6%)
DIGESTIVE SYSTEM	1 (3.3%)	3 (10.0%)	3 (10.0%)	2 (6.5%)	2 (6.5%)	2 (6.5%)	5 (16.1%)
DIARRHEA	0 (0.0%)	1 (3.3%)	2 (6.7%)	0 (0.0%)	0 (0.0%)	1 (3.2%)	3 (9.7%)
GASTRITIS, ACUTE	0 (0.0%)	0 (0.0%)	1 (3.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.2%)
NAUSEA	0 (0.0%)	0 (0.0%)	1 (3.3%)	1 (3.2%)	0 (0.0%)	0 (0.0%)	1 (3.2%)
TEETHING	1 (3.3%)	1 (3.3%)	1 (3.3%)	1 (3.2%)	1 (3.2%)	1 (3.2%)	1 (3.2%)
VOMITING	0 (0.0%)	2 (6.7%)	1 (3.3%)	1 (3.2%)	1 (3.2%)	0 (0.0%)	4 (12.9%)
NERVOUS SYSTEM & PSYCHIATRIC	5 (16.7%)	6 (20.0%)	4 (13.3%)	3 (9.7%)	3 (9.7%)	3 (9.7%)	13 (41.9%)
INSOMNIA	1 (3.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.2%)
IRRITABILITY	4 (13.3%)	5 (16.7%)	3 (10.0%)	3 (9.7%)	3 (9.7%)	3 (9.7%)	11 (35.5%)
PROLONGED CRYING, >1/2 HR	0 (0.0%)	0 (0.0%)	1 (3.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.2%)

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (31 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
UNUSUAL HIGH-PITCHED CRYING	0 (0.0%)	1 (3.3%)	2 (6.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (6.5%)
RESPIRATORY SYSTEM	0 (0.0%)	2 (6.7%)	3 (10.0%)	2 (6.5%)	1 (3.2%)	1 (3.2%)		3 (9.7%)
NASAL DISCHARGE	0 (0.0%)	1 (3.3%)	2 (6.7%)	1 (3.2%)	0 (0.0%)	0 (0.0%)		2 (6.5%)
WHEEZING	0 (0.0%)	1 (3.3%)	1 (3.3%)	1 (3.2%)	1 (3.2%)	1 (3.2%)		1 (3.2%)
SKIN & SKIN APPENDAGE	0 (0.0%)	1 (3.3%)	2 (6.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (6.5%)
ATOPIC DERMATITIS	0 (0.0%)	0 (0.0%)	1 (3.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (3.2%)
RASH	0 (0.0%)	1 (3.3%)	1 (3.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (3.2%)
SPECIAL SENSES	2 (6.7%)	2 (6.7%)	0 (0.0%)	0 (0.0%)	1 (3.2%)	0 (0.0%)		4 (12.9%)
CONJUNCTIVITIS	1 (3.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (3.2%)
EAR INFECTION, NOS	0 (0.0%)	1 (3.3%)	0 (0.0%)	0 (0.0%)	1 (3.2%)	0 (0.0%)		2 (6.5%)
OTITIS MEDIA	1 (3.3%)	1 (3.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (3.2%)
VACCINEES WITH COMPLAINTS	10 (33.3%)	15 (50.0%)	11 (36.7%)	6 (19.4%)	8 (25.8%)	7 (22.6%)		20 (64.5%)

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (31 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
VACCINEES WITH NO COMPLAINTS	20 (66.7%)	15 (50.0%)	19 (63.3%)	25 (80.6%)	23 (74.2%)	24 (77.4%)		11 (35.5%)
TOTAL VACCINEES REPORTING	30	30	30	31	31	31		31
VACCINEES WITH NO DATA	1	1	1	0	0	0		0

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (28 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
LOCAL REACTIONS	3 (11.1%)	6 (22.2%)	1 (3.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		7 (25.9%)
ERYTHEMA, INJ. SITE (<=1 IN.)	2 (7.4%)	1 (3.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (7.4%)
INDURATION, INJECTION SITE	0 (0.0%)	2 (7.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (7.4%)
PAIN/SORENESS, INJ. SITE	3 (11.1%)	5 (18.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		6 (22.2%)
SWELLING, INJ. SITE (<=1 IN.)	2 (7.4%)	2 (7.4%)	1 (3.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		3 (11.1%)
SYSTEMIC	5 (18.5%)	6 (22.2%)	3 (11.1%)	4 (14.8%)	2 (7.4%)	1 (3.7%)		9 (33.3%)
BODY AS A WHOLE/SITE UNSPEC.	4 (14.8%)	2 (7.4%)	1 (3.7%)	2 (7.4%)	1 (3.7%)	1 (3.7%)		6 (22.2%)
FATIGUE	3 (11.1%)	1 (3.7%)	0 (0.0%)	1 (3.7%)	0 (0.0%)	0 (0.0%)		4 (14.8%)
FUNGUS INFECTION	0 (0.0%)	1 (3.7%)	1 (3.7%)	1 (3.7%)	1 (3.7%)	1 (3.7%)		1 (3.7%)
HARM TO TOUCH	1 (3.7%)	1 (3.7%)	0 (0.0%)	1 (3.7%)	1 (3.7%)	1 (3.7%)		3 (11.1%)
DIGESTIVE SYSTEM	0 (0.0%)	1 (3.7%)	1 (3.7%)	2 (7.4%)	2 (7.4%)	1 (3.7%)		2 (7.4%)

0078

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (28 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		
ANOREXIA	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.7%)	0 (0.0%)		1 (3.7%)
DIARRHEA	0 (0.0%)	1 (3.7%)	1 (3.7%)	1 (3.7%)	1 (3.7%)	1 (3.7%)		1 (3.7%)
SALIVATION INCREASE	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.7%)	1 (3.7%)	0 (0.0%)		1 (3.7%)
TEETHING	0 (0.0%)	1 (3.7%)	1 (3.7%)	1 (3.7%)	1 (3.7%)	1 (3.7%)		1 (3.7%)
NERVOUS SYSTEM & PSYCHIATRIC	2 (7.4%)	5 (18.5%)	3 (11.1%)	2 (7.4%)	0 (0.0%)	0 (0.0%)		6 (22.2%)
IRRITABILITY	2 (7.4%)	5 (18.5%)	3 (11.1%)	2 (7.4%)	0 (0.0%)	0 (0.0%)		6 (22.2%)
SKIN & SKIN APPENDAGE	0 (0.0%)	1 (3.7%)	1 (3.7%)	2 (7.4%)	1 (3.7%)	0 (0.0%)		2 (7.4%)
RASH	0 (0.0%)	1 (3.7%)	1 (3.7%)	2 (7.4%)	1 (3.7%)	0 (0.0%)		2 (7.4%)
VACCINEES WITH COMPLAINTS	8 (29.6%)	11 (40.7%)	4 (14.8%)	4 (14.8%)	2 (7.4%)	1 (3.7%)		14 (51.9%)
VACCINEES WITH NO COMPLAINTS	19 (70.4%)	16 (59.3%)	23 (85.2%)	23 (85.2%)	25 (92.6%)	26 (96.3%)		13 (48.1%)
TOTAL VACCINEES REPORTING	27	27	27	27	27	27		27

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (28 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
VACCINEES WITH NO DATA	1	1	1	1	1	1		1

05700

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (16 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5	COMPLAINTS
LOCAL REACTIONS	2 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (20.0%)
PAIN/SORENESS, INJ. SITE	2 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (20.0%)
SYSTEMIC	3 (30.0%)	4 (40.0%)	5 (50.0%)	4 (40.0%)	3 (30.0%)	4 (40.0%)	6 (60.0%)
BODY AS A WHOLE/SITE UNSPEC.	2 (20.0%)	3 (30.0%)	3 (30.0%)	1 (10.0%)	1 (10.0%)	1 (10.0%)	5 (50.0%)
FATIGUE	1 (10.0%)	2 (20.0%)	0 (0.0%)	0 (0.0%)	1 (10.0%)	1 (10.0%)	4 (40.0%)
HARM TO TOUCH	1 (10.0%)	2 (20.0%)	3 (30.0%)	1 (10.0%)	0 (0.0%)	0 (0.0%)	3 (30.0%)
DIGESTIVE SYSTEM	1 (10.0%)	2 (20.0%)	2 (20.0%)	1 (10.0%)	1 (10.0%)	1 (10.0%)	2 (20.0%)
CONSTIPATION	0 (0.0%)	1 (10.0%)	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (10.0%)
TEETHING	1 (10.0%)	1 (10.0%)	1 (10.0%)	1 (10.0%)	1 (10.0%)	1 (10.0%)	1 (10.0%)
NERVOUS SYSTEM & PSYCHIATRIC	1 (10.0%)	1 (10.0%)	2 (20.0%)	1 (10.0%)	1 (10.0%)	2 (20.0%)	4 (40.0%)
HYPERKINESIA	0 (0.0%)	0 (0.0%)	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (10.0%)

15700

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (16 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
IRRITABILITY	1 (10.0%)	1 (10.0%)	2 (20.0%)	1 (10.0%)	1 (10.0%)	2 (20.0%)		4 (40.0%)
RESPIRATORY SYSTEM	1 (10.0%)	1 (10.0%)	1 (10.0%)	1 (10.0%)	2 (20.0%)	2 (20.0%)		2 (20.0%)
BRONCHIOLITIS, ACUTE	0 (0.0%)	0 (0.0%)	1 (10.0%)	1 (10.0%)	0 (0.0%)	1 (10.0%)		1 (10.0%)
COUGH	0 (0.0%)	0 (0.0%)	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (10.0%)
NASAL CONGESTION	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (10.0%)	1 (10.0%)		1 (10.0%)
WHEEZING	1 (10.0%)	1 (10.0%)	1 (10.0%)	1 (10.0%)	1 (10.0%)	1 (10.0%)		1 (10.0%)
SKIN & SKIN APPENDAGE	0 (0.0%)	0 (0.0%)	2 (20.0%)	2 (20.0%)	1 (10.0%)	1 (10.0%)		3 (30.0%)
ATOPIC DERMATITIS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (10.0%)	1 (10.0%)		1 (10.0%)
RASH	0 (0.0%)	0 (0.0%)	2 (20.0%)	2 (20.0%)	0 (0.0%)	0 (0.0%)		2 (20.0%)
VACCINEES WITH COMPLAINTS	4 (40.0%)	4 (40.0%)	5 (50.0%)	4 (40.0%)	3 (30.0%)	4 (40.0%)		6 (60.0%)
VACCINEES WITH NO COMPLAINTS	6 (60.0%)	6 (60.0%)	5 (50.0%)	6 (60.0%)	7 (70.0%)	6 (60.0%)		4 (40.0%)
TOTAL VACCINEES REPORTING	10	10	10	10	10	10		10

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (16 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
VACCINEES WITH NO DATA	6	6	6	6	6	6		6

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (9 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
LOCAL REACTIONS	1 (11.1%)	3 (33.3%)	1 (11.1%)	1 (11.1%)	1 (11.1%)	1 (11.1%)		3 (33.3%)
ERYTHEMA, INJ. SITE (<=1 IN.)	1 (11.1%)	3 (33.3%)	1 (11.1%)	1 (11.1%)	1 (11.1%)	1 (11.1%)		3 (33.3%)
PAIN/SORENESS, INJ. SITE	0 (0.0%)	1 (11.1%)	1 (11.1%)	1 (11.1%)	1 (11.1%)	1 (11.1%)		1 (11.1%)
SWELLING, INJ. SITE (<=1 IN.)	1 (11.1%)	2 (22.2%)	1 (11.1%)	1 (11.1%)	1 (11.1%)	1 (11.1%)		2 (22.2%)
SYSTEMIC	1 (11.1%)	2 (22.2%)	2 (22.2%)	2 (22.2%)	2 (22.2%)	2 (22.2%)		4 (44.4%)
BODY AS A WHOLE/SITE UNSPEC.	0 (0.0%)	2 (22.2%)	2 (22.2%)	0 (0.0%)	1 (11.1%)	1 (11.1%)		4 (44.4%)
FATIGUE	0 (0.0%)	0 (0.0%)	1 (11.1%)	0 (0.0%)	1 (11.1%)	1 (11.1%)		2 (22.2%)
FEVER	0 (0.0%)	1 (11.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (11.1%)
HARM TO TOUCH	0 (0.0%)	1 (11.1%)	1 (11.1%)	0 (0.0%)	1 (11.1%)	1 (11.1%)		2 (22.2%)
DIGESTIVE SYSTEM	1 (11.1%)	1 (11.1%)	1 (11.1%)	1 (11.1%)	2 (22.2%)	2 (22.2%)		2 (22.2%)
DIARRHEA	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (11.1%)	1 (11.1%)		1 (11.1%)

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (9 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		
TEETHING	1 (11.1%)	1 (11.1%)	1 (11.1%)	1 (11.1%)	1 (11.1%)	1 (11.1%)		1 (11.1%)
VOMITING	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (11.1%)	1 (11.1%)		1 (11.1%)
NERVOUS SYSTEM & PSYCHIATRIC	0 (0.0%)	1 (11.1%)	2 (22.2%)	2 (22.2%)	0 (0.0%)	0 (0.0%)		2 (22.2%)
INSOMNIA	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (11.1%)	0 (0.0%)	0 (0.0%)		1 (11.1%)
IRRITABILITY	0 (0.0%)	1 (11.1%)	2 (22.2%)	2 (22.2%)	0 (0.0%)	0 (0.0%)		2 (22.2%)
VACCINEES WITH COMPLAINTS	2 (22.2%)	4 (44.4%)	2 (22.2%)	2 (22.2%)	2 (22.2%)	2 (22.2%)		6 (66.7%)
VACCINEES WITH NO COMPLAINTS	7 (77.8%)	5 (55.6%)	7 (77.8%)	7 (77.8%)	7 (77.8%)	7 (77.8%)		3 (33.3%)
TOTAL VACCINEES REPORTING	9	9	9	9	9	9		9
VACCINEES WITH NO DATA	0	0	0	0	0	0		0

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (11 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5	COMPLAINTS
LOCAL REACTIONS	2 (18.2%)	3 (27.3%)	1 (9.1%)	1 (9.1%)	1 (9.1%)	0 (0.0%)	3 (27.3%)
ERYTHEMA, INJ. SITE (<=1 IN.)	1 (9.1%)	2 (18.2%)	1 (9.1%)	1 (9.1%)	1 (9.1%)	0 (0.0%)	2 (18.2%)
PAIN/SORENESS, INJ. SITE	1 (9.1%)	1 (9.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (9.1%)
SYSTEMIC	2 (18.2%)	3 (27.3%)	1 (9.1%)	1 (9.1%)	1 (9.1%)	3 (27.3%)	4 (36.4%)
BODY AS A WHOLE/SITE UNSPEC.	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (18.2%)	2 (18.2%)
FATIGUE	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (18.2%)	2 (18.2%)
DIGESTIVE SYSTEM	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (9.1%)	1 (9.1%)
TEETHING	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (9.1%)	1 (9.1%)
NERVOUS SYSTEM & PSYCHIATRIC	2 (18.2%)	2 (18.2%)	1 (9.1%)	1 (9.1%)	1 (9.1%)	2 (18.2%)	3 (27.3%)
IRRITABILITY	1 (9.1%)	1 (9.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (9.1%)	2 (18.2%)
NERVOUSNESS	1 (9.1%)	1 (9.1%)	1 (9.1%)	1 (9.1%)	1 (9.1%)	1 (9.1%)	1 (9.1%)

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (11 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
SKIN & SKIN APPENDAGE	0 (0.0%)	1 (9.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (9.1%)
ATOPIC DERMATITIS	0 (0.0%)	1 (9.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (9.1%)
VACCINEES WITH COMPLAINTS	4 (36.4%)	6 (54.5%)	2 (18.2%)	2 (18.2%)	2 (18.2%)	3 (27.3%)		6 (54.5%)
VACCINEES WITH NO COMPLAINTS	7 (63.6%)	5 (45.5%)	9 (81.8%)	9 (81.8%)	9 (81.8%)	8 (72.7%)		5 (45.5%)
TOTAL VACCINEES REPORTING	11	11	11	11	11	11		11
VACCINEES WITH NO DATA	0	0	0	0	0	0		0

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
LOT NUMBER : CR132
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (16 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		
LOCAL REACTIONS	1 (10.0%)	3 (30.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		3 (30.0%)
ERYTHEMA, INJ. SITE (<=1 IN.)	0 (0.0%)	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (10.0%)
SWELLING, INJ. SITE (<=1 IN.)	1 (10.0%)	2 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (20.0%)
SYSTEMIC	3 (30.0%)	3 (30.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (10.0%)		6 (60.0%)
BODY AS A WHOLE/SITE UNSPEC.	1 (10.0%)	2 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (10.0%)		4 (40.0%)
FATIGUE	1 (10.0%)	2 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (10.0%)		4 (40.0%)
DIGESTIVE SYSTEM	2 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (20.0%)
DIARRHEA	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (10.0%)
VOMITING	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (10.0%)
NERVOUS SYSTEM & PSYCHIATRIC	1 (10.0%)	2 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		3 (30.0%)
IRRITABILITY	1 (10.0%)	2 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		3 (30.0%)

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
LOT NUMBER : CR132
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (16 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		
RESPIRATORY SYSTEM	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (10.0%)		1 (10.0%)
COUGH	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (10.0%)		1 (10.0%)
SKIN & SKIN APPENDAGE	0 (0.0%)	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (10.0%)
PRURITUS	0 (0.0%)	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (10.0%)
VACCINEES WITH COMPLAINTS	4 (40.0%)	6 (60.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (10.0%)		7 (70.0%)
VACCINEES WITH NO COMPLAINTS	6 (60.0%)	4 (40.0%)	10 (100.0%)	10 (100.0%)	10 (100.0%)	9 (90.0%)		3 (30.0%)
TOTAL VACCINEES REPORTING	10	10	10	10	10	10		10
VACCINEES WITH NO DATA	6	6	6	6	6	6		6

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
LOT NUMBER : CR132
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (10 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
LOCAL REACTIONS	2 (20.0%)	3 (30.0%)	2 (20.0%)	2 (20.0%)	2 (20.0%)	2 (20.0%)		3 (30.0%)
ERYTHEMA, INJ. SITE (<=1 IN.)	1 (10.0%)	2 (20.0%)	2 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (20.0%)
PAIN/SORENESS, INJ. SITE	1 (10.0%)	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (10.0%)
SWELLING, INJ. SITE (>1 INCH)	0 (0.0%)	1 (10.0%)	1 (10.0%)	1 (10.0%)	0 (0.0%)	0 (0.0%)		1 (10.0%)
SWELLING, INJ. SITE (<=1 IN.)	2 (20.0%)	2 (20.0%)	1 (10.0%)	1 (10.0%)	2 (20.0%)	2 (20.0%)		3 (30.0%)
SYSTEMIC	2 (20.0%)	4 (40.0%)	4 (40.0%)	4 (40.0%)	3 (30.0%)	3 (30.0%)		6 (60.0%)
BODY AS A WHOLE/SITE UNSPEC.	1 (10.0%)	1 (10.0%)	1 (10.0%)	2 (20.0%)	0 (0.0%)	0 (0.0%)		3 (30.0%)
FATIGUE	1 (10.0%)	1 (10.0%)	1 (10.0%)	1 (10.0%)	0 (0.0%)	0 (0.0%)		2 (20.0%)
HARM TO TOUCH	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (10.0%)	0 (0.0%)	0 (0.0%)		1 (10.0%)
DIGESTIVE SYSTEM	1 (10.0%)	2 (20.0%)	1 (10.0%)	1 (10.0%)	1 (10.0%)	1 (10.0%)		2 (20.0%)
CONSTIPATION	0 (0.0%)	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (10.0%)

00760

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
LOT NUMBER : CR132
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (10 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
TEETHING	1 (10.0%)	1 (10.0%)	1 (10.0%)	1 (10.0%)	1 (10.0%)	1 (10.0%)		1 (10.0%)
NERVOUS SYSTEM & PSYCHIATRIC	2 (20.0%)	2 (20.0%)	1 (10.0%)	1 (10.0%)	1 (10.0%)	1 (10.0%)		3 (30.0%)
IRRITABILITY	1 (10.0%)	2 (20.0%)	1 (10.0%)	1 (10.0%)	1 (10.0%)	1 (10.0%)		2 (20.0%)
NERVOUSNESS	1 (10.0%)	1 (10.0%)	1 (10.0%)	1 (10.0%)	1 (10.0%)	1 (10.0%)		2 (20.0%)
PROLONGED CRYING, >1/2 HR	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (10.0%)
RESPIRATORY SYSTEM	0 (0.0%)	1 (10.0%)	2 (20.0%)	2 (20.0%)	2 (20.0%)	2 (20.0%)		2 (20.0%)
COMMON COLD	0 (0.0%)	0 (0.0%)	1 (10.0%)	1 (10.0%)	1 (10.0%)	1 (10.0%)		1 (10.0%)
COUGH	0 (0.0%)	0 (0.0%)	1 (10.0%)	1 (10.0%)	1 (10.0%)	1 (10.0%)		1 (10.0%)
NASAL DISCHARGE	0 (0.0%)	1 (10.0%)	2 (20.0%)	2 (20.0%)	2 (20.0%)	2 (20.0%)		2 (20.0%)
VACCINEES WITH COMPLAINTS	4 (40.0%)	6 (60.0%)	6 (60.0%)	6 (60.0%)	5 (50.0%)	5 (50.0%)		8 (80.0%)
VACCINEES WITH NO COMPLAINTS	6 (60.0%)	4 (40.0%)	4 (40.0%)	4 (40.0%)	5 (50.0%)	5 (50.0%)		2 (20.0%)
TOTAL VACCINEES REPORTING	10	10	10	10	10	10		10

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
LOT NUMBER : CR132
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (10 VACCINEES) - INJECTION: 2						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5	COMPLAINTS
VACCINEES WITH NO DATA	0	0	0	0	0	0	0

00762

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
LOT NUMBER : CR132
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (12 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
LOCAL REACTIONS	5 (50.0%)	6 (50.0%)	4 (33.3%)	1 (8.3%)	0 (0.0%)	0 (0.0%)		7 (58.3%)
ERYTHEMA, INJ. SITE (<=1 IN.)	2 (20.0%)	4 (33.3%)	3 (25.0%)	1 (8.3%)	0 (0.0%)	0 (0.0%)		4 (33.3%)
PAIN/SORENESS, INJ. SITE	4 (40.0%)	3 (25.0%)	2 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		4 (33.3%)
SWELLING, INJ. SITE (<=1 IN.)	0 (0.0%)	1 (8.3%)	1 (8.3%)	1 (8.3%)	0 (0.0%)	0 (0.0%)		1 (8.3%)
SYSTEMIC	4 (40.0%)	5 (41.7%)	2 (16.7%)	2 (16.7%)	1 (8.3%)	2 (16.7%)		6 (50.0%)
BODY AS A WHOLE/SITE UNSPEC.	1 (10.0%)	3 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (8.3%)		5 (41.7%)
FATIGUE	1 (10.0%)	3 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		4 (33.3%)
HARM TO TOUCH	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (8.3%)		1 (8.3%)
DIGESTIVE SYSTEM	1 (10.0%)	1 (8.3%)	1 (8.3%)	1 (8.3%)	1 (8.3%)	2 (16.7%)		2 (16.7%)
ANOREXIA	1 (10.0%)	1 (8.3%)	1 (8.3%)	1 (8.3%)	1 (8.3%)	1 (8.3%)		1 (8.3%)
DIARRHEA	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (8.3%)		1 (8.3%)

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
LOT NUMBER : CR132
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (12 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
NAUSEA	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (8.3%)		1 (8.3%)
VOMITING	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (8.3%)		1 (8.3%)
NERVOUS SYSTEM & PSYCHIATRIC	2 (20.0%)	4 (33.3%)	1 (8.3%)	0 (0.0%)	0 (0.0%)	1 (8.3%)		5 (41.7%)
CRYING	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (8.3%)
IRRITABILITY	2 (20.0%)	4 (33.3%)	1 (8.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		5 (41.7%)
UNUSUAL HIGH-PITCHED CRYING	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (8.3%)		1 (8.3%)
RESPIRATORY SYSTEM	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (8.3%)		1 (8.3%)
INFLUENZA	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (8.3%)		1 (8.3%)
SPECIAL SENSES	1 (10.0%)	1 (8.3%)	1 (8.3%)	1 (8.3%)	0 (0.0%)	0 (0.0%)		1 (8.3%)
EAR INFECTION, NOS	1 (10.0%)	1 (8.3%)	1 (8.3%)	1 (8.3%)	0 (0.0%)	0 (0.0%)		1 (8.3%)
VACCINEES WITH COMPLAINTS	5 (50.0%)	8 (66.7%)	5 (41.7%)	3 (25.0%)	1 (8.3%)	2 (16.7%)		8 (66.7%)
VACCINEES WITH NO COMPLAINTS	5 (50.0%)	4 (33.3%)	7 (58.3%)	9 (75.0%)	11 (91.7%)	10 (83.3%)		4 (33.3%)

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
LOT NUMBER : CR132
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (12 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5	**********
TOTAL VACCINEES REPORTING	10	12	12	12	12	12	12
VACCINEES WITH NO DATA	2	0	0	0	0	0	0

TABLE 12

MAXIMUM TEMPERATURES

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (15 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
NORMAL	0 (0.0%)	1 (6.7%)	1 (6.7%)	1 (6.7%)	1 (6.7%)	1 (7.1%)		0 (0.0%)
< 99	10 (71.4%)	9 (60.0%)	12 (80.0%)	12 (80.0%)	12 (80.0%)	10 (71.4%)		7 (46.7%)
99 - 99.9	4 (28.6%)	4 (26.7%)	2 (13.3%)	2 (13.3%)	2 (13.3%)	2 (14.3%)		7 (46.7%)
100 - 100.9	0 (0.0%)	1 (6.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.1%)		1 (6.7%)
TEMPERATURE TAKEN	14 (93.3%)	15 (100.0%)	15 (100.0%)	15 (100.0%)	15 (100.0%)	14 (93.3%)		15 (100.0%)
TEMPERATURE NOT TAKEN	1 (6.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (6.7%)		0 (0.0%)

TABLE 12 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (14 VACCINEES) - INJECTION 2							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
NORMAL	1 (7.7%)	1 (7.7%)	1 (7.7%)	1 (7.7%)	1 (8.3%)	1 (7.7%)		1 (7.7%)
< 99	8 (61.5%)	8 (61.5%)	10 (76.9%)	11 (84.6%)	10 (83.3%)	10 (76.9%)		7 (53.8%)
99 - 99.9	4 (30.8%)	3 (23.1%)	2 (15.4%)	1 (7.7%)	1 (8.3%)	2 (15.4%)		4 (30.8%)
101 - 101.9	0 (0.0%)	1 (7.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (7.7%)
TEMPERATURE TAKEN	13 (92.9%)	13 (92.9%)	13 (92.9%)	13 (92.9%)	12 (85.7%)	13 (92.9%)		13 (92.9%)
TEMPERATURE NOT TAKEN	1 (7.1%)	1 (7.1%)	1 (7.1%)	1 (7.1%)	2 (14.3%)	1 (7.1%)		1 (7.1%)

TABLE 12 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (15 VACCINEES) - INJECTION 1						
	DAYS POST VACCINATION						NUMBER WITH
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5	MAX TEMP
NORMAL	0 (0.0%)	0 (0.0%)	1 (7.7%)	1 (7.7%)	1 (7.7%)	1 (7.7%)	0 (0.0%)
< 99	11 (78.6%)	7 (53.8%)	10 (76.9%)	9 (69.2%)	10 (76.9%)	11 (84.6%)	5 (35.7%)
99 - 99.9	3 (21.4%)	6 (46.2%)	2 (15.4%)	3 (23.1%)	2 (15.4%)	1 (7.7%)	9 (64.3%)
TEMPERATURE TAKEN	14 (93.3%)	13 (86.7%)	13 (86.7%)	13 (86.7%)	13 (86.7%)	13 (86.7%)	14 (93.3%)
TEMPERATURE NOT TAKEN	1 (6.7%)	2 (13.3%)	2 (13.3%)	2 (13.3%)	2 (13.3%)	2 (13.3%)	1 (6.7%)

TABLE 12 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (38 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
NORMAL	1 (3.4%)	1 (3.0%)	1 (3.0%)	1 (3.0%)	1 (3.0%)	1 (3.0%)		1 (3.0%)
< 99	16 (55.2%)	14 (42.4%)	14 (42.4%)	17 (51.5%)	19 (57.6%)	16 (48.5%)		8 (24.2%)
99 - 99.9	12 (41.4%)	15 (45.5%)	17 (51.5%)	14 (42.4%)	11 (33.3%)	15 (45.5%)		19 (57.6%)
100 - 100.9	0 (0.0%)	2 (6.1%)	1 (3.0%)	1 (3.0%)	2 (6.1%)	1 (3.0%)		4 (12.1%)
101 - 101.9	0 (0.0%)	1 (3.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (3.0%)
TEMPERATURE TAKEN	29 (76.3%)	33 (86.8%)	33 (86.8%)	33 (86.8%)	33 (86.8%)	33 (86.8%)		33 (86.8%)
TEMPERATURE NOT TAKEN	9 (23.7%)	5 (13.2%)	5 (13.2%)	5 (13.2%)	5 (13.2%)	5 (13.2%)		5 (13.2%)

TABLE 12 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (31 VACCINEES) - INJECTION 2							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
NORMAL	3 (10.7%)	2 (7.1%)	2 (7.1%)	2 (6.7%)	2 (6.7%)	2 (6.5%)		2 (6.5%)
< 99	9 (32.1%)	12 (42.9%)	13 (46.4%)	13 (43.3%)	14 (46.7%)	15 (48.4%)		9 (29.0%)
99 - 99.9	14 (50.0%)	9 (32.1%)	10 (35.7%)	14 (46.7%)	10 (33.3%)	12 (38.7%)		13 (41.9%)
100 - 100.9	1 (3.6%)	4 (14.3%)	2 (7.1%)	1 (3.3%)	2 (6.7%)	0 (0.0%)		3 (9.7%)
101 - 101.9	1 (3.6%)	1 (3.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.2%)		2 (6.5%)
102 - 102.9	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (6.7%)	0 (0.0%)		1 (3.2%)
103 - 103.9	0 (0.0%)	0 (0.0%)	1 (3.6%)	0 (0.0%)	0 (0.0%)	1 (3.2%)		1 (3.2%)
TEMPERATURE TAKEN	28 (90.3%)	28 (90.3%)	28 (90.3%)	30 (96.8%)	30 (96.8%)	31 (100.0%)		31 (100.0%)
TEMPERATURE NOT TAKEN	3 (9.7%)	3 (9.7%)	3 (9.7%)	1 (3.2%)	1 (3.2%)	0 (0.0%)		0 (0.0%)

TABLE 12 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (28 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
NORMAL	1 (4.0%)	2 (7.7%)	2 (8.0%)	2 (8.0%)	2 (8.0%)	2 (8.3%)		2 (7.7%)
< 99	15 (60.0%)	12 (46.2%)	13 (52.0%)	11 (44.0%)	14 (56.0%)	13 (54.2%)		10 (38.5%)
99 - 99.9	8 (32.0%)	11 (42.3%)	9 (36.0%)	10 (40.0%)	8 (32.0%)	8 (33.3%)		12 (46.2%)
100 - 100.9	1 (4.0%)	1 (3.8%)	1 (4.0%)	2 (8.0%)	1 (4.0%)	1 (4.2%)		2 (7.7%)
TEMPERATURE TAKEN	25 (89.3%)	26 (92.9%)	25 (89.3%)	25 (89.3%)	25 (89.3%)	24 (85.7%)		26 (92.9%)
TEMPERATURE NOT TAKEN	3 (10.7%)	2 (7.1%)	3 (10.7%)	3 (10.7%)	3 (10.7%)	4 (14.3%)		2 (7.1%)

TABLE 12 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (16 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
< 99	4 (44.4%)	4 (40.0%)	5 (50.0%)	4 (50.0%)	6 (66.7%)	6 (60.0%)		2 (20.0%)
99 - 99.9	4 (44.4%)	4 (40.0%)	4 (40.0%)	3 (37.5%)	2 (22.2%)	3 (30.0%)		6 (60.0%)
100 - 100.9	1 (11.1%)	1 (10.0%)	1 (10.0%)	1 (12.5%)	1 (11.1%)	1 (10.0%)		1 (10.0%)
101 - 101.9	0 (0.0%)	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (10.0%)
TEMPERATURE TAKEN	9 (56.3%)	10 (62.5%)	10 (62.5%)	8 (50.0%)	9 (56.3%)	10 (62.5%)		10 (62.5%)
TEMPERATURE NOT TAKEN	7 (43.8%)	6 (37.5%)	6 (37.5%)	8 (50.0%)	7 (43.8%)	6 (37.5%)		6 (37.5%)

TABLE 12 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (9 VACCINEES) - INJECTION 2							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
NORMAL	0 (0.0%)	1 (11.1%)	1 (11.1%)	1 (12.5%)	1 (12.5%)	1 (12.5%)		0 (0.0%)
< 99	2 (28.6%)	4 (44.4%)	4 (44.4%)	4 (50.0%)	2 (25.0%)	2 (25.0%)		0 (0.0%)
99 - 99.9	5 (71.4%)	3 (33.3%)	2 (22.2%)	3 (37.5%)	4 (50.0%)	4 (50.0%)		6 (66.7%)
100 - 100.9	0 (0.0%)	1 (11.1%)	1 (11.1%)	0 (0.0%)	1 (12.5%)	1 (12.5%)		2 (22.2%)
102 - 102.9	0 (0.0%)	0 (0.0%)	1 (11.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (11.1%)
TEMPERATURE TAKEN	7 (77.8%)	9 (100.0%)	9 (100.0%)	8 (88.9%)	8 (88.9%)	8 (88.9%)		9 (100.0%)
TEMPERATURE NOT TAKEN	2 (22.2%)	0 (0.0%)	0 (0.0%)	1 (11.1%)	1 (11.1%)	1 (11.1%)		0 (0.0%)

TABLE 12 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (11 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
NORMAL	0 (0.0%)	1 (9.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (9.1%)
< 99	5 (62.5%)	7 (63.6%)	6 (60.0%)	5 (55.6%)	5 (50.0%)	6 (60.0%)		3 (27.3%)
99 - 99.9	2 (25.0%)	2 (18.2%)	3 (30.0%)	4 (44.4%)	4 (40.0%)	2 (20.0%)		4 (36.4%)
100 - 100.9	0 (0.0%)	1 (9.1%)	1 (10.0%)	0 (0.0%)	1 (10.0%)	1 (10.0%)		2 (18.2%)
101 - 101.9	1 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)
102 - 102.9	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (10.0%)		1 (9.1%)
TEMPERATURE TAKEN	8 (72.7%)	11 (100.0%)	10 (90.9%)	9 (81.8%)	10 (90.9%)	10 (90.9%)		11 (100.0%)
TEMPERATURE NOT TAKEN	3 (27.3%)	0 (0.0%)	1 (9.1%)	2 (18.2%)	1 (9.1%)	1 (9.1%)		0 (0.0%)

TABLE 12 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
LOT NUMBER : CR132
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (16 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
NORMAL	0 (0.0%)	0 (0.0%)	1 (10.0%)	1 (10.0%)	1 (10.0%)	1 (10.0%)		0 (0.0%)
< 99	4 (57.1%)	5 (50.0%)	7 (70.0%)	6 (60.0%)	5 (50.0%)	6 (60.0%)		4 (40.0%)
99 - 99.9	3 (42.9%)	3 (30.0%)	1 (10.0%)	3 (30.0%)	4 (40.0%)	3 (30.0%)		3 (30.0%)
100 - 100.9	0 (0.0%)	1 (10.0%)	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (20.0%)
101 - 101.9	0 (0.0%)	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (10.0%)
TEMPERATURE TAKEN	7 (43.8%)	10 (62.5%)	10 (62.5%)	10 (62.5%)	10 (62.5%)	10 (62.5%)		10 (62.5%)
TEMPERATURE NOT TAKEN	9 (56.3%)	6 (37.5%)	6 (37.5%)	6 (37.5%)	6 (37.5%)	6 (37.5%)		6 (37.5%)

TABLE 12 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
LOT NUMBER : CR132
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (10 VACCINEES) - INJECTION 2							
	DAYS POST VACCINATION							NUMBER WITH
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		MAX TEMP
NORMAL	1 (12.5%)	1 (10.0%)	1 (10.0%)	1 (10.0%)	1 (10.0%)	1 (10.0%)		1 (10.0%)
< 99	3 (37.5%)	3 (30.0%)	4 (40.0%)	3 (30.0%)	5 (50.0%)	5 (50.0%)		3 (30.0%)
99 - 99.9	4 (50.0%)	5 (50.0%)	4 (40.0%)	6 (60.0%)	4 (40.0%)	4 (40.0%)		5 (50.0%)
100 - 100.9	0 (0.0%)	1 (10.0%)	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (10.0%)
TEMPERATURE TAKEN	8 (80.0%)	10 (100.0%)	10 (100.0%)	10 (100.0%)	10 (100.0%)	10 (100.0%)		10 (100.0%)
TEMPERATURE NOT TAKEN	2 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)

TABLE 12 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : SHEHAB, ZIAD M.
STUDY : 000410
VACCINE : HIB CONJUGATE
LOT NUMBER : CR132
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (12 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
NORMAL	0 (0.0%)	1 (8.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (8.3%)
< 99	4 (66.7%)	5 (41.7%)	8 (72.7%)	7 (63.6%)	8 (72.7%)	8 (72.7%)		4 (33.3%)
99 - 99.9	2 (33.3%)	6 (50.0%)	3 (27.3%)	3 (27.3%)	2 (18.2%)	2 (18.2%)		6 (50.0%)
100 - 100.9	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (9.1%)	1 (9.1%)	0 (0.0%)		0 (0.0%)
104 - 104.9	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (9.1%)		1 (8.3%)
TEMPERATURE TAKEN	6 (50.0%)	12 (100.0%)	11 (91.7%)	11 (91.7%)	11 (91.7%)	11 (91.7%)		12 (100.0%)
TEMPERATURE NOT TAKEN	6 (50.0%)	0 (0.0%)	1 (8.3%)	1 (8.3%)	1 (8.3%)	1 (8.3%)		0 (0.0%)

STUDY 004-11

PROGRAM: Haemophilus b Conjugate Vaccine (Neisseria meningitidis Outer Membrane Protein Complex), Study #0004-11.

PURPOSE: To evaluate the safety and immunogenicity of Haemophilus b Conjugate Vaccine (Neisseria meningitidis Outer Membrane Protein Complex) in healthy infants 2 months to 5 years of age.

VACCINE: Haemophilus b Conjugate Vaccine (Neisseria meningitidis Outer Membrane Protein Complex).

Lot 1069/C-P241 - (b) (4) mcg polysaccharide/ml
(b) (4) mcg meningococcal protein/ml

Diluent
Aluminum hydroxide diluent
Lot (b) (4)

INVESTIGATOR: Trudy Murphy, M.D.
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Department of Pediatrics
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Dallas, Texas 75235-9063

SUB-INVESTIGATOR: Mark Clanton, M.D.

STUDY LOCATION: University of Texas Health Science Center
Carver Clinic
Dallas, Texas 75235-9063

DATE INITIATED: May 21, 1987

DATE COMPLETED: In progress.

STUDY POPULATION: Healthy infants 2 to 5 months of age are included in the study.

STUDY PROCEDURE: Infants 2 to 5 months of age received two 0.75 ml (15 mcg polysaccharide) intramuscular injections of vaccine reconstituted in aluminum hydroxide, two months apart.

Parents or guardians are required to record the vaccinee's temperature and any systemic or injection site reactions for 5 days after each injection. Unexpected or serious reactions are to be reported immediately to the study physician.

A blood sample is obtained immediately before each injection and at 1 month and 7-10 months after the last injection.

All serum samples are assayed by Merck Sharp & Dohme Research Laboratories for antibody to H. influenzae type b capsular polysaccharide by radioimmunoassay (RIA).

RESULTS: Demographic information and individual pre and postvaccination antibody data for each vaccinee enrolled in the study is reported in Table 1.

1. Number Vaccinated:

Lot	Injection No. 1	2
1069/C-P241	26	25

2. Serologic Results

Antibody responses (RIA) prior to vaccination and at 2, 3 months are as follows:

Time	% With Anti-PRP >0.15 mcg Ab/ml	>1.0 mcg Ab/ml	GMT (mcg Ab/ml) All Vaccinees
Pre	33 (5/15)	0 (0/15)	0.11
2 mo.	100 (15/15)	93 (14/15)	4.56
3 mo.	100 (13/13)	92 (12/13)	7.02

Antibody responses prior to vaccination through 12 months are included in Table 2.

RESULTS: (CONT.)

3. Clinical Results:

The frequencies of selected injection site and systemic reactions during the 48 hours after vaccination are as follows:

Type of Reaction	% Vaccinees with Reactions Injection 1	Injection
Injection Site		
Erythema >1 inch	0.0 (0/26)	0.0 (0/25)
Swelling >1 inch	0.0 (0/26)	0.0 (0/25)
Pain/Soreness	15.4 (4/26)	12.0 (3/25)
Systemic		
Irritability	26.9 (7/26)	4.0 (1/25)
Sleepiness/ Lethargy/Fatigue	23.1 (6/26)	4.0 (1/25)

Reaction frequencies and maximum temperatures recorded during the five days following each injection of vaccine are reported in Tables 3-5.

No serious or alarming reactions attributable to the vaccine were reported.

TABLE 1

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : MURPHY, TRUDY
STUDY : 000411
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	F	BLAC	(b) (6)	3M	0	(b) (6)	001	PREBLEED				< 125				
					0		011	INJ 1	CP241	15 MCG						
					67		011	BLEED 1				5838				
					67		021	INJ 2	CP241	15 MCG						
					103		021	BLEED 2				9974				
					236		071	BLEED 3				5755				
					277		071	BLEED 4				3422				
	F	BLAC		4M	0		001	PREBLEED				401				
					0		011	INJ 1	CP241	15 MCG						
					75		011	BLEED 1			05/	3181				
					75		021	INJ 2	CP241	15 MCG						
	F	BLAC		4M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP241	15 MCG						
					61		011	BLEED 1				9690				
					61		021	INJ 2	CP241	15 MCG						
					92		021	BLEED 2				9896				
					277		071	BLEED 3				1089				
	M	BLAC		3M	0		001	PREBLEED				155				
					0		011	INJ 1	CP241	15 MCG						
					64		011	BLEED 1				8204				
					64		021	INJ 2	CP241	15 MCG						
					95		021	BLEED 2				12744				
					274		071	BLEED 3				818				
	F	BLAC		5M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP241	15 MCG						
					61		011	BLEED 1				2016				
					61		021	INJ 2	CP241	15 MCG						
					112		021	BLEED 2				31730				
					180		071	BLEED 3				18177				
					279		071	BLEED 4				3906				
	M	BLAC		2M	0		001	PREBLEED				196				
					0		011	INJ 1	CP241	15 MCG						
					99		011	BLEED 1			05/	1352				
					99		021	INJ 2	CP241	15 MCG						
					129		021	BLEED 2			05/	4881				

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : MURPHY, TRUDY
STUDY : 000411
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	BLAC	(b) (6)	2M	274	(b) (6)	071	BLEED 3			05/	252				
	F	BLAC		4M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP241	15 MCG						
					62		011	BLEED 1				3624				
					62		021	INJ 2	CP241	15 MCG						
					93		021	BLEED 2				15779				
					216		071	BLEED 3				2665				
					274		071	BLEED 4				1660				
	F	BLAC		2M	0		001	PREBLEED				202				
					0		011	INJ 1	CP241	15 MCG						
					99		011	BLEED 1			05/	5026				
					99		021	INJ 2	CP241	15 MCG						
					155		021	BLEED 2			05/	7165				
	F	BLAC		2M	0		011	INJ 1	CP241	15 MCG						
	F	BLAC		3M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP241	15 MCG						
					61		011	BLEED 1				45408				
					61		021	INJ 2	CP241	15 MCG						
					96		021	BLEED 2				74951				
					208		071	BLEED 3				9562				
	M	BLAC		2M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP241	15 MCG						
					80		011	BLEED 1			05/	26113				
					80		021	INJ 2	CP241	15 MCG						
					119		021	BLEED 2			05/	33765				
	F	BLAC		2M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP241	15 MCG						
					92		011	BLEED 1			05/	2242				
					92		021	INJ 2	CP241	15 MCG						
					148		021	BLEED 2			05/	3237				
	F	BLAC		3M	0		001	PREBLEED				534				
					0		011	INJ 1	CP241	15 MCG						
					100		011	BLEED 1			05/	2328				

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : MURPHY, TRUDY
STUDY : 000411
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	F	BLAC	(b) (6)	3M	100	(b) (6)	021	INJ 2	CP241	15 MCG						
					136		021	BLEED 2			05/	5073				
	M	BLAC		3M	0		001	PREBLEED				327				
					0		011	INJ 1	CP241	15 MCG						
					62		011	BLEED 1				49945				
					62		021	INJ 2	CP241	15 MCG						
					119		021	BLEED 2				99453				
	F	BLAC		2M	0		001	PREBLEED				180				
					0		011	INJ 1	CP241	15 MCG						
					87		011	BLEED 1			05/	1791				
					87		021	INJ 2	CP241	15 MCG						
					119		021	BLEED 2			05/	4966				
	M	BLAC		2M	0		001	PREBLEED				290				
					0		011	INJ 1	CP241	15 MCG						
					84		011	BLEED 1			05/	1499				
					84		021	INJ 2	CP241	15 MCG						
					119		021	BLEED 2			05/	18427				
	M	CAUC		2M	0		001	PREBLEED				844				
					0		011	INJ 1	CP241	15 MCG						
					62		011	BLEED 1				2255				
					62		021	INJ 2	CP241	15 MCG						
					92		021	BLEED 2				1165				
	M	BLAC		3M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP241	15 MCG						
					62		011	BLEED 1				1484				
					62		021	INJ 2	CP241	15 MCG						
					95		021	BLEED 2				3831				
	F	BLAC		3M	0		001	PREBLEED				290				
					0		011	INJ 1	CP241	15 MCG						
					61		011	BLEED 1				1836				
					61		021	INJ 2	CP241	15 MCG						
					96		021	BLEED 2				10208				
	M	BLAC		2M	0		001	PREBLEED				< 125				

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : MURPHY, TRUDY
STUDY : 000411
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	BLAC	(b) (6)	2M	0	(b) (6)	011	INJ 1	CP241	15 MCG						
					62		011	BLEED 1				2652				
					62		021	INJ 2	CP241	15 MCG						
					95		021	BLEED 2				6232				
	M	BLAC		2M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP241	15 MCG						
					61		011	BLEED 1				194				
					61		021	INJ 2	CP241	15 MCG						
					96		021	BLEED 2				443				
	F	BLAC		2M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP241	15 MCG						
					62		011	BLEED 1				2651				
					62		021	INJ 2	CP241	15 MCG						
					92		021	BLEED 2				1587				
	M	BLAC		2M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP241	15 MCG						
					64		011	BLEED 1				4272				
					64		021	INJ 2	CP241	15 MCG						
					93		021	BLEED 2				15147				
	F	BLAC		3M	0		001	PREBLEED				330				
					0		011	INJ 1	CP241	15 MCG						
					61		011	BLEED 1				27522				
					61		021	INJ 2	CP241	15 MCG						
					96		021	BLEED 2				22222				
	F	BLAC		2M	0		001	PREBLEED				136				
					0		011	INJ 1	CP241	15 MCG						
					88		011	BLEED 1			05/	959				
					88		021	INJ 2	CP241	15 MCG						
					141		021	BLEED 2			05/	7358				
	M	BLAC		2M	0		001	PREBLEED				166				
					0		011	INJ 1	CP241	15 MCG						
					88		011	BLEED 1			05/	783				
					88		021	INJ 2	CP241	15 MCG						
					141		021	BLEED 2			05/	4357				

TABLE 2
ANTIBODY RESPONSES

INVESTIGATOR : MURPHY, TRUDY
STUDY : 000411
VACCINE : HIB CONJUGATE
ASSAY : RIA
LOT NUMBER : CP241
DOSE : 15 MCG
POPULATION : HEALTHY CHILDREN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
1- 6 MOS.	PRE INJ	33 (5/ 15)	0 (0/ 15)			0.109 (15)
	MONTH 2	100 (15/ 15)	93 (14/ 15)	93 (14/ 15)	26.3	4.556 (15)
	MONTH 3	100 (13/ 13)	92 (12/ 13)	92 (12/ 13)	41.5	7.017 (13)
	MONTH 7-10	100 (6/ 6)	83 (5/ 6)	100 (6/ 6)	18.5	2.396 (6)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 3

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : MURPHY, TRUDY
STUDY : 000411
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	26	
VACCINEES WITH NO COMPLAINTS :	11	(42.3 %)
VACCINEES WITH COMPLAINTS :	15	(57.7 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 26 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	7	26.9
PAIN/SORENESS, INJ. SITE	4	15.4
SWELLING, INJ. SITE (<=1 IN.)	3	11.5
ERYTHEMA, INJ. SITE (<=1 IN.)	1	3.8
SYSTEMIC REACTIONS	13	50.0
IRRITABILITY	7	26.9
FATIGUE	6	23.1
VOMITING	5	19.2
HARM TO TOUCH	4	15.4
PROLONGED CRYING, >1/2 HR	3	11.5
ANOREXIA	2	7.7
DIARRHEA	2	7.7
TEETHING	2	7.7
GASTROENTERITIS, NONINFECTIOUS	1	3.8
NAUSEA	1	3.8
RASH	1	3.8

TABLE 3 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : MURPHY, TRUDY
STUDY : 000411
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 2	
TOTAL VACCINEES :	25	
VACCINEES WITH NO COMPLAINTS :	18	(72.0 %)
VACCINEES WITH COMPLAINTS :	7	(28.0 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 25 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	5	20.0
PAIN/SORENESS, INJ. SITE	3	12.0
SWELLING, INJ. SITE (<=1 IN.)	3	12.0
ERYTHEMA, INJ. SITE (>1 INCH)	1	4.0
SYSTEMIC REACTIONS	6	24.0
WARM TO TOUCH	4	16.0
DIARRHEA	2	8.0
TEETHING	2	8.0
FATIGUE	1	4.0
FEVER	1	4.0
IRRITABILITY	1	4.0
RASH	1	4.0

TABLE 4

PATIENT COUNT CLINICAL COMPLAINTS

INVESTIGATOR : MURPHY, TRUDY
STUDY : 000411
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (26 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5	
LOCAL REACTIONS	6 (23.1%)	1 (3.8%)	1 (3.8%)	1 (3.8%)	0 (0.0%)	0 (0.0%)	7 (26.9%)
ERYTHEMA, INJ. SITE (<=1 IN.)	0 (0.0%)	1 (3.8%)	1 (3.8%)	1 (3.8%)	0 (0.0%)	0 (0.0%)	1 (3.8%)
PAIN/SORENESS, INJ. SITE	4 (15.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (15.4%)
SWELLING, INJ. SITE (<=1 IN.)	3 (11.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (11.5%)
SYSTEMIC	10 (38.5%)	10 (38.5%)	6 (23.1%)	2 (7.7%)	1 (3.8%)	1 (3.8%)	13 (50.0%)
BODY AS A WHOLE/SITE UNSPEC.	7 (26.9%)	4 (15.4%)	1 (3.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	8 (30.8%)
FATIGUE	6 (23.1%)	2 (7.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	6 (23.1%)
HARM TO TOUCH	3 (11.5%)	2 (7.7%)	1 (3.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (15.4%)
DIGESTIVE SYSTEM	5 (19.2%)	6 (23.1%)	5 (19.2%)	2 (7.7%)	1 (3.8%)	1 (3.8%)	8 (30.8%)
ANOREXIA	0 (0.0%)	2 (7.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (7.7%)
DIARRHEA	2 (7.7%)	2 (7.7%)	2 (7.7%)	1 (3.8%)	0 (0.0%)	0 (0.0%)	2 (7.7%)

TABLE 4 (cont.)

PATIENT COUNT CLINICAL COMPLAINTS

INVESTIGATOR : MURPHY, TRUDY
STUDY : 000411
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (26 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		
GASTROENTERITIS, NONINFECTIOUS	1 (3.8%)	1 (3.8%)	1 (3.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (3.8%)
NAUSEA	1 (3.8%)	1 (3.8%)	1 (3.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (3.8%)
TEETHING	2 (7.7%)	2 (7.7%)	2 (7.7%)	1 (3.8%)	1 (3.8%)	1 (3.8%)		2 (7.7%)
VOMITING	3 (11.5%)	2 (7.7%)	3 (11.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		5 (19.2%)
NERVOUS SYSTEM & PSYCHIATRIC	5 (19.2%)	3 (11.5%)	2 (7.7%)	1 (3.8%)	0 (0.0%)	0 (0.0%)		7 (26.9%)
IRRITABILITY	5 (19.2%)	3 (11.5%)	2 (7.7%)	1 (3.8%)	0 (0.0%)	0 (0.0%)		7 (26.9%)
PROLONGED CRYING, >1/2 HR	2 (7.7%)	2 (7.7%)	1 (3.8%)	1 (3.8%)	0 (0.0%)	0 (0.0%)		3 (11.5%)
SKIN & SKIN APPENDAGE	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.8%)	0 (0.0%)	0 (0.0%)		1 (3.8%)
RASH	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.8%)	0 (0.0%)	0 (0.0%)		1 (3.8%)
VACCINEES WITH COMPLAINTS	12 (46.2%)	10 (38.5%)	6 (23.1%)	3 (11.5%)	1 (3.8%)	1 (3.8%)		15 (57.7%)
VACCINEES WITH NO COMPLAINTS	14 (53.8%)	16 (61.5%)	20 (76.9%)	23 (88.5%)	25 (96.2%)	25 (96.2%)		11 (42.3%)
TOTAL VACCINEES REPORTING	26	26	26	26	26	26		26

TABLE 4 (cont.)

PATIENT COUNT CLINICAL COMPLAINTS

INVESTIGATOR : MURPHY, TRUDY
STUDY : 000411
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (26 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
VACCINEES WITH NO DATA	0	0	0	0	0	0		0

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TABLE 4 (cont.)

PATIENT COUNT CLINICAL COMPLAINTS

INVESTIGATOR : MURPHY, TRUDY
STUDY : 000411
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (25 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
LOCAL REACTIONS	5 (20.0%)	2 (8.0%)	2 (8.0%)	2 (8.0%)	2 (8.3%)	1 (4.2%)		5 (20.0%)
ERYTHEMA, INJ. SITE (>1 INCH)	1 (4.0%)	1 (4.0%)	1 (4.0%)	1 (4.0%)	1 (4.2%)	1 (4.2%)		1 (4.0%)
PAIN/SORENESS, INJ. SITE	3 (12.0%)	1 (4.0%)	1 (4.0%)	1 (4.0%)	1 (4.2%)	0 (0.0%)		3 (12.0%)
SWELLING, INJ. SITE (<=1 IN.)	3 (12.0%)	1 (4.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		3 (12.0%)
SYSTEMIC	5 (20.0%)	6 (24.0%)	4 (16.0%)	3 (12.0%)	2 (8.3%)	2 (8.3%)		6 (24.0%)
BODY AS A WHOLE/SITE UNSPEC.	3 (12.0%)	3 (12.0%)	2 (8.0%)	0 (0.0%)	1 (4.2%)	1 (4.2%)		5 (20.0%)
FATIGUE	1 (4.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (4.0%)
FEVER	1 (4.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (4.0%)
HARM TO TOUCH	2 (8.0%)	3 (12.0%)	2 (8.0%)	0 (0.0%)	1 (4.2%)	1 (4.2%)		4 (16.0%)
DIGESTIVE SYSTEM	2 (8.0%)	4 (16.0%)	2 (8.0%)	3 (12.0%)	1 (4.2%)	1 (4.2%)		4 (16.0%)
DIARRHEA	0 (0.0%)	2 (8.0%)	1 (4.0%)	1 (4.0%)	0 (0.0%)	0 (0.0%)		2 (8.0%)

TABLE 4 (cont.)

PATIENT COUNT CLINICAL COMPLAINTS

INVESTIGATOR : MURPHY, TRUDY
STUDY : 000411
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (25 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
TEETHING	2 (8.0%)	2 (8.0%)	1 (4.0%)	2 (8.0%)	1 (4.2%)	1 (4.2%)		2 (8.0%)
NERVOUS SYSTEM & PSYCHIATRIC	1 (4.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (4.0%)
IRRITABILITY	1 (4.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (4.0%)
SKIN & SKIN APPENDAGE	1 (4.0%)	1 (4.0%)	1 (4.0%)	1 (4.0%)	1 (4.2%)	1 (4.2%)		1 (4.0%)
RASH	1 (4.0%)	1 (4.0%)	1 (4.0%)	1 (4.0%)	1 (4.2%)	1 (4.2%)		1 (4.0%)
VACCINEES WITH COMPLAINTS	6 (24.0%)	6 (24.0%)	4 (16.0%)	3 (12.0%)	3 (12.5%)	2 (8.3%)		7 (28.0%)
VACCINEES WITH NO COMPLAINTS	19 (76.0%)	19 (76.0%)	21 (84.0%)	22 (88.0%)	21 (87.5%)	22 (91.7%)		18 (72.0%)
TOTAL VACCINEES REPORTING	25	25	25	25	24	24		25
VACCINEES WITH NO DATA	0	0	0	0	1	1		0

TABLE 5

PATIENT COUNT MAXIMUM TEMPERATURES

INVESTIGATOR : MURPHY, TRUDY
STUDY : 000411
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (26 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
NORMAL	0 (0.0%)	1 (3.8%)	1 (4.0%)	0 (0.0%)	1 (4.0%)	1 (4.0%)		0 (0.0%)
< 99	23 (88.5%)	18 (69.2%)	24 (96.0%)	25 (96.2%)	23 (92.0%)	23 (92.0%)		17 (65.4%)
99 - 99.9	2 (7.7%)	6 (23.1%)	0 (0.0%)	1 (3.8%)	0 (0.0%)	1 (4.0%)		6 (23.1%)
100 - 100.9	1 (3.8%)	1 (3.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (7.7%)
101 - 101.9	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (4.0%)	0 (0.0%)		1 (3.8%)
TEMPERATURE TAKEN	26 (100.0%)	26 (100.0%)	25 (96.2%)	26 (100.0%)	25 (96.2%)	25 (96.2%)		26 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	0 (0.0%)	1 (3.8%)	0 (0.0%)	1 (3.8%)	1 (3.8%)		0 (0.0%)

TABLE 5 (cont.)

PATIENT COUNT MAXIMUM TEMPERATURES

INVESTIGATOR : MURPHY, TRUDY
STUDY : 000411
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (25 VACCINEES) - INJECTION 2							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
< 99	23 (92.0%)	21 (84.0%)	25 (100.0%)	25 (100.0%)	24 (100.0%)	23 (100.0%)		20 (80.0%)
99 - 99.9	1 (4.0%)	3 (12.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		3 (12.0%)
100 - 100.9	0 (0.0%)	1 (4.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (4.0%)
101 - 101.9	1 (4.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (4.0%)
TEMPERATURE TAKEN	25 (100.0%)	25 (100.0%)	25 (100.0%)	25 (100.0%)	24 (96.0%)	23 (92.0%)		25 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (4.0%)	2 (8.0%)		0 (0.0%)

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Twenty-eighth Interscience Conference
Antimicrobial Agents and Chemotherapy
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Abstracts of the 1988 ICAAC
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BLACK INFANTS WHO LACK KM(1) IG ALLOTYPE SHOW HIGH ANTICAPSULAR ANTIBODY RESPONSES TO H. INFLUENZAE B - N. MENINGITIDIS OUTER MEMBRANE PROTEIN CONJUGATE VACCINE (Hib PS-OMP).

MS Clanton, DM Granoff, B Pilot, JP Pandey, TV Murphy. U. Tx Southwestern Med. Ctr., Dallas, TX, Med. Univ. of S.C., Charleston, SC, Wash. U., St. Louis, Mo.

Blacks lacking Km(1) have a higher relative risk of meningitis and lower conc. of antibody following vaccination with plain Hib-PS vaccine than blacks with the Km(1). However, 7-17 mo. old blacks lacking Km(1) had a good antibody response to a single injection of Hib PS-OMP conjugate vaccine (Study #1, J Infect Dis, in press). The purpose of study #2 was to compare the responses of 2-5 mo old black infants given 2 doses of Hib PS-OMP, given 2 mo. apart. In study #2, black infants lacking Km(1) had higher total antibody responses. IgG responses were not significantly different (5.8 vs 3.0 ug/ml, p=0.24).

				Total anti-PS antibody (Geo. mean, ug/ml)				
Study	Km(1)	No.	Mean Age(mo)	Pre	Post-dose #1		Post-dose#2	
1	Pos.	22	11.5	ND	5.0	p>.5	ND	
	Neg.	27	11.9	ND	4.1		ND	
2	Pos.	10	2.9	0.10	2.0	p=.09	5.1	p=.03
	Neg.	13	2.4	0.12	4.8		14.8	

Lack of the Km(1) allotype does not correlate with lower total or IgG responses to conjugate vaccine. Infants lacking Km(1), a phenotype associated with increased risk of meningitis, have comparable or higher antibody responses to 2 doses of conjugate than infants with Km(1).

STUDY 004-12

PROGRAM: Haemophilus b Conjugate Vaccine (Neisseria meningitidis Outer Membrane Protein Complex), Study #0004-12.

PURPOSE: To evaluate the safety and immunogenicity of Haemophilus b Conjugate Vaccine (Neisseria meningitidis Outer Membrane Protein Complex) in healthy infants and children 2 months to 5 years of age.

VACCINE: Haemophilus b Conjugate Vaccine (Neisseria meningitidis Outer Membrane Protein Complex).

Lot 1069/C-P241 - (b) (4) mcg polysaccharide/ml
(b) (4) mcg meningococcal protein/ml
Lot 1072/C-P298 - (b) (4) mcg polysaccaride/ml
(b) (4) mcg meningococcal protein/ml
Lot 1080/C-P749 - (b) (4) mcg polysaccharide/ml
(b) (4) mcg meningococcal protein/ml
Lot 1085/C-R132 - (b) (4) mcg polysaccharide/ml
(b) (4) mcg meningococcal protein/ml

Diluent
Aluminum hydroxide diluent
Lot (b) (4)

INVESTIGATOR: Harry L. Keyserling, M.D.
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SUB-INVESTIGATOR: A. Russell Gerber, M.D.
Hervey W. Froehlich, Jr., M.D.

STUDY LOCATION: Emory University Clinic
2032 Ridgewood Dr.
Atlanta, Georgia 30322

Grady Hospital Clinic
80 Butler St., S.E.
Atlanta, Georgia 30303

DATE INITIATED: July 11, 1987

DATE COMPLETED: In progress.

STUDY POPULATION: Healthy infants and children 2 to 71 months of age are included in the study.

STUDY PROCEDURE: Infants 2 to 11 months of age receive 2 injections of the vaccine given 2 months apart, while children 12 months of age and older receive a single injection. Vaccine is reconstituted in aluminum hydroxide and administered by intramuscular route. The dose for each injection is 15 mcg polysaccharide in the appropriate volume - 0.75 ml for Lot 1069/C-P241 and 0.5 ml for Lots 1072/C-P298, 1080/C-P749, and 1085/C-R132.

Parents or guardians are required to record the vaccinee's temperature and any systemic or injection site reactions for 5 days after each injection. Unexpected or serious reactions are to be reported immediately to the study physician.

A blood sample is obtained immediately before each injection and one month after the last (or only) injection. Additional samples are obtained 7 to 10 months after the last injection for infants 2 to 11 months of age and at 15 to 18 months postvaccination for children 12 to 71 months of age.

All serum samples are assayed by Merck Sharp & Dohme Research Laboratories for antibody to H. influenzae type b capsular polysaccharide by radioimmunoassay (RIA). Selected samples are also tested for serum bactericidal activity, and quantitation of IgG_1 subclass.

RESULTS: Demographic information and individual pre and postvaccination antibody data for each vaccinee enrolled in the study is reported in Table 1.

1. Number Vaccinated:

Lot	Age	Injection No. 1	Injection No. 2
1069/C-P241	2-11 mo.	9	9
	12-71 mo.	16	--
1072/C-P298	2-11 mo.	21	21
	12-71 mo.	13	--
1080/C-P749	2-11 mo.	69	31
	12-71 mo.	75	--
1085/C-R132	2-11 mo.	3	0
	12-71 mo.	6	--

2. Serologic Results

Antibody responses (RIA) prior to and after vaccination are as follows:

Age	Time	% With Anti-PRP >0.15 mcg Ab/ml	% With Anti-PRP >1.0 mcg Ab/ml	GMT (mcg Ab/ml) All Vaccinees
2-11 mo.	Pre	25 (13/53)	2 (1/53)	0.10
	2 mo.	98 (52/53)	83 (44/53)	2.83
	3 mo.	100 (42/42)	90 (38/42)	5.93

No serology was done for children 12 months of age and older.

Antibody responses (by lot per age group) prior to vaccination through 10 months postvaccination are included in Tables 2-4.

RESULTS: (CONT.)

3. Clinical Results:

The frequencies of selected injection site and systemic reactions during the 48 hours after vaccination are as follows:

	% Vaccinees with Reactions		
	2 - 11 Months of Age		12 - 71 Months of Age
Type of Reaction	Injection 1	Injection 2	Injection 1
Injection Site			
Erythema >1 inch	2.0 (2/102)	0.0 (0/61)	1.8 (2/109)
Swelling >1 inch	2.0 (2/102)	0.0 (0/61)	0.9 (1/109)
Pain/Soreness	8.8 (9/102)	9.8 (6/61)	24.8 (27/109)
Systemic			
Irritability	43.1 (44/102)	32.8 (20/61)	31.2 (34/109)
Sleepiness/ Lethargy/Fatigue	25.5 (26/102)	16.4 (10/61)	19.3 (21/109)

Reaction frequencies and maximum temperatures recorded during the five days following each injection of vaccine are reported in Tables 5-7.

No serious or alarming reactions attributable to the vaccine were reported.

TABLE 1

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : KEYSERLING, HARRY
STUDY : 000412
VACCINE : HIB CONJUGATE
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	IGG1
(b) (6)	M	CAUC	(b) (6)	16M	0	(b) (6)	011	INJ 1	CP241	15 MCG						
	M	CAUC		8M	0		001	PREBLEED				< 125		< 5		
					0		011	INJ 1	CP241	15 MCG						
					70		011	BLEED 1				16415		>= 80		
					70		021	INJ 2	CP241	15 MCG						
					105		021	BLEED 2				14196		>= 80		
	F	CAUC		5M	0		001	PREBLEED				< 125		< 2		
					0		011	INJ 1	CP241	15 MCG						
					70		011	BLEED 1				6330		8		
					70		021	INJ 2	CP241	15 MCG						
					105		021	BLEED 2				9989		8		
					294		071	BLEED 3				2178				
	F	CAUC		10M	0		011	INJ 1	CP241	15 MCG						
					70		011	BLEED 1				1597				
					70		021	INJ 2	CP241	15 MCG						
					105		021	BLEED 2				6406				
					294		071	BLEED 3				1492				
	M	CAUC		12M	0		011	INJ 1	CP241	15 MCG						
	M	CAUC		5M	0		001	PREBLEED				264		< 2		
					0		011	INJ 1	CP241	15 MCG						
					63		011	BLEED 1				4500		< 2		
					63		021	INJ 2	CP241	15 MCG						
					105		021	BLEED 2				15383		2		
	M	CAUC		4M	0		001	PREBLEED				345		< 2		
					0		011	INJ 1	CP241	15 MCG						
					63		011	BLEED 1				1579		< 2		
					63		021	INJ 2	CP241	15 MCG						
					105		021	BLEED 2				4622		< 2		
	M	CAUC		12M	0		011	INJ 1	CP241	15 MCG						
	F	CAUC		12M	0		011	INJ 1	CP241	15 MCG						
	F	CAUC		21M	0		011	INJ 1	CP241	15 MCG						
	F	CAUC		19M	0		011	INJ 1	CP241	15 MCG						

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : KEYSERLING, HARRY
STUDY : 000412
VACCINE : HIB CONJUGATE
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	IGG1
(b) (6)	M	CAUC	(b) (6)	14M	0	(b) (6)	011	INJ 1	CP241	15 MCG						
	F	OTHE		6M	0		001	PREBLEED				< 125		< 5		
					0		011	INJ 1	CP241	15 MCG						
					63		011	BLEED 1				43387		20		
					63		021	INJ 2	CP241	15 MCG						
					112		021	BLEED 2				25038		5		
	M	CAUC		12M	0		011	INJ 1	CP241	15 MCG						
	F	HISP		13M	0		011	INJ 1	CP241	15 MCG						
	M	CAUC		15M	0		011	INJ 1	CP241	15 MCG						
	F	CAUC		15M	0		011	INJ 1	CP241	15 MCG						
	M	CAUC		18M	0		011	INJ 1	CP241	15 MCG						
	F	CAUC		3M	0		001	PREBLEED				135				
					0		011	INJ 1	CP241	15 MCG						
					63		011	BLEED 1				1871				
					63		021	INJ 2	CP241	15 MCG						
					112		021	BLEED 2				11305				
	M	CAUC		12M	0		011	INJ 1	CP241	15 MCG						
	F	CAUC		18M	0		011	INJ 1	CP241	15 MCG						
	M	CAUC		3M	0		001	PREBLEED				303				
					0		011	INJ 1	CP241	15 MCG						
					77		011	BLEED 1			05/	56570				
					77		021	INJ 2	CP241	15 MCG						
					112		021	BLEED 2			05/	34749				
	F	CAUC		17M	0		011	INJ 1	CP241	15 MCG						
	F	CAUC		16M	0		011	INJ 1	CP241	15 MCG						
	M	CAUC		2M	0		001	PREBLEED				150				
					0		011	INJ 1	CP241	15 MCG						
					70		011	BLEED 1				1484				

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : KEYSERLING, HARRY
STUDY : 000412
VACCINE : HIB CONJUGATE
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	IGG1
(b) (6)	M	CAUC	(b) (6)	2M	70	(b) (6)	021	INJ 2	CP241	15 MCG						
					105		021	BLEED 2				1387				
	M	CAUC		20M	0		011	INJ 1	CP298	15 MCG						
	F	CAUC		5M	-10		001	PREBLEED				214				< 600
					0		011	INJ 1	CP298	15 MCG						
					63		011	BLEED 1				1804				1804
					63		021	INJ 2	CP298	15 MCG						
					102		021	BLEED 2				3099				4630
	F	CAUC		3M	0		001	PREBLEED				259				< 600
					0		011	INJ 1	CP298	15 MCG						
					63		011	BLEED 1				2681				1829
					63		021	INJ 2	CP298	15 MCG						
					98		021	BLEED 2				7272				9413
	F	OTHE		12M	0		011	INJ 1	CP298	15 MCG						
	F	CAUC		2Y	0		011	INJ 1	CP298	15 MCG						
	M	CAUC		13M	0		011	INJ 1	CP298	15 MCG						
	M	CAUC		2M	0		001	PREBLEED				284				< 600
					0		011	INJ 1	CP298	15 MCG						
					77		011	BLEED 1			05/	463		05/		< 600
					77		021	INJ 2	CP298	15 MCG						
					119		021	BLEED 2			05/	4911		05/		5627
	M	CAUC		3M	0		001	PREBLEED				160				< 600
					0		011	INJ 1	CP298	15 MCG						
					63		011	BLEED 1				1600				902
					63		021	INJ 2	CP298	15 MCG						
					91		021	BLEED 2				3099				6460
	M	CAUC		21M	0		011	INJ 1	CP298	15 MCG						
	M	CAUC		21M	0		011	INJ 1	CP298	15 MCG						
	M	CAUC		6M	0		001	PREBLEED				584				
					0		011	INJ 1	CP298	15 MCG						

20800

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : KEYSERLING, HARRY
STUDY : 000412
VACCINE : HIB CONJUGATE
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	IGG1
(b) (6)	M	CAUC	(b) (6)	6M	63	(b) (6)	011	BLEED 1				999				
					63		021	INJ 2	CP298	15 MCG						
	F	CAUC		20M	0		011	INJ 1	CP298	15 MCG						
	F	CAUC		13M	0		011	INJ 1	CP298	15 MCG						
	M	CAUC		2M	0		001	PREBLEED				134				< 600
					0		011	INJ 1	CP298	15 MCG						
					56		011	BLEED 1				1979				1375
					56		021	INJ 2	CP298	15 MCG						
					84		021	BLEED 2				1125				2865
	M	CAUC		3M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP298	15 MCG						
					77		011	BLEED 1			05/	468				
					77		021	INJ 2	CP298	15 MCG						
					112		021	BLEED 2			05/	610				
	F	CAUC		6M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP298	15 MCG						
					70		011	BLEED 1				1584				
					70		021	INJ 2	CP298	15 MCG						
					112		021	BLEED 2				3795				
	F	CAUC		13M	0		011	INJ 1	CP298	15 MCG						
	F	CAUC		4M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP298	15 MCG						
					70		011	BLEED 1				16018				
					70		021	INJ 2	CP298	15 MCG						
					112		021	BLEED 2				11733				
	M	BLAC		3Y	0		011	INJ 1	CP298	15 MCG						
	F	CAUC		6M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP298	15 MCG						
					63		011	BLEED 1				4472				
					63		021	INJ 2	CP298	15 MCG						
					105		021	BLEED 2				14858				
	M	CAUC		2M	0		001	PREBLEED				< 125				

00803

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : KEYSERLING, HARRY
STUDY : 000412
VACCINE : HIB CONJUGATE
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ RIA	CODE/ SBA	CODE/ IGG1
(b) (6)	M	CAUC	(b) (6)	2M	0	(b) (6)	011	INJ 1	CP298	15 MCG			
					56		011	BLEED 1			2987		
					56		021	INJ 2	CP298	15 MCG			
					98		021	BLEED 2			10495		
	F	CAUC		6M	0		001	PREBLEED			< 125		
					0		011	INJ 1	CP298	15 MCG			
					63		011	BLEED 1			18571		
					63		021	INJ 2	CP298	15 MCG			
					98		021	BLEED 2			44397		
	M	CAUC		3M	0		001	PREBLEED			252		
					0		011	INJ 1	CP298	15 MCG			
					63		011	BLEED 1			39499		
					63		021	INJ 2	CP298	15 MCG			
					105		021	BLEED 2			63559		
	F	BLAC		10M	0		001	PREBLEED			< 125		
					0		011	INJ 1	CP298	15 MCG			
					63		011	BLEED 1			11584		
					63		021	INJ 2	CP298	15 MCG			
					105		021	BLEED 2			15529		
	F	CAUC		5M	0		001	PREBLEED			255		
					0		011	INJ 1	CP298	15 MCG			
					63		011	BLEED 1			< 125		
					63		021	INJ 2	CP298	15 MCG			
					98		021	BLEED 2			1378		
	M	CAUC		10M	0		001	PREBLEED			138		
					0		011	INJ 1	CP298	15 MCG			
					70		011	BLEED 1			3573		
					70		021	INJ 2	CP298	15 MCG			
					105		021	BLEED 2			4774		
	F	CAUC		9M	0		001	PREBLEED			1796		
					0		011	INJ 1	CP298	15 MCG			
					63		011	BLEED 1			2685		
					63		021	INJ 2	CP298	15 MCG			
					98		021	BLEED 2			8898		
	M	CAUC		13M	0		011	INJ 1	CP298	15 MCG			

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : KEYSERLING, HARRY
STUDY : 000412
VACCINE : HIB CONJUGATE
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	IGG1
(b) (6)	F	CAUC	(b) (6)	5M	0	(b) (6)	001	PREBLEED				< 125				
					0		011	INJ 1	CP298	15 MCG						
					63		011	BLEED 1				5100				
					63		021	INJ 2	CP298	15 MCG						
	M	CAUC		5M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP298	15 MCG						
					67		011	BLEED 1				37598				
					67		021	INJ 2	CP298	15 MCG						
					98		021	BLEED 2				75009				
	M	CAUC		21M	0		011	INJ 1	CP298	15 MCG						
	F	BLAC		2Y	0		011	INJ 1	CP298	15 MCG						
	M	CAUC		11M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP298	15 MCG						
					56		011	BLEED 1				3899				
					56		021	INJ 2	CP298	15 MCG						
					98		021	BLEED 2				2874				
	F	CAUC		4M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP298	15 MCG						
					56		011	BLEED 1				284				
					56		021	INJ 2	CP298	15 MCG						
					91		021	BLEED 2				230				
	F	CAUC		2M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP749	15 MCG						
					70		011	BLEED 1				1497				
					70		021	INJ 2	CP749	15 MCG						
					112		021	BLEED 2				2661				
	F	CAUC		12M	0		011	INJ 1	CP749	15 MCG						
	F	CAUC		10M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP749	15 MCG						
					70		011	BLEED 1				10484				
					70		021	INJ 2	CP749	15 MCG						
					119		021	BLEED 2				7524				
	F	CAUC		2M	0		001	PREBLEED				< 125				

50800

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : KEYSERLING, HARRY
STUDY : 000412
VACCINE : HIB CONJUGATE
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	IGG1
(b) (6)	F	CAUC	(b) (6)	2M	0	(b) (6)	011	INJ 1	CP749	15 MCG						
					77		011	BLEED 1			05/	7164				
					77		021	INJ 2	CP749	15 MCG						
					126		021	BLEED 2			05/	10047				
	F	CAUC		2Y	0		011	INJ 1	CP749	15 MCG						
	M	CAUC		16M	0		011	INJ 1	CP749	15 MCG						
	M	CAUC		15M	0		011	INJ 1	CP749	15 MCG						
	F	CAUC		3Y	0		011	INJ 1	CP749	15 MCG						
	F	CAUC		6M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP749	15 MCG						
					70		011	BLEED 1				2753				
					70		021	INJ 2	CP749	15 MCG						
					105		021	BLEED 2				4013				
	M	CAUC		2Y	0		011	INJ 1	CP749	15 MCG						
	M	CAUC		14M	0		011	INJ 1	CP749	15 MCG						
	M	CAUC		4M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP749	15 MCG						
					70		011	BLEED 1				205				
					70		021	INJ 2	CP749	15 MCG						
					105		021	BLEED 2				2061				
	M	CAUC		13M	0		011	INJ 1	CP749	15 MCG						
	F	CAUC		18M	0		011	INJ 1	CP749	15 MCG						
	M	CAUC		10M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP749	15 MCG						
					63		011	BLEED 1				1597				
					63		021	INJ 2	CP749	15 MCG						
					98		021	BLEED 2				5491				
	M	CAUC		2Y	0		011	INJ 1	CP749	15 MCG						
	M	CAUC		2M	0		001	PREBLEED				< 125				

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : KEYSERLING, HARRY
STUDY : 000412
VACCINE : HIB CONJUGATE
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ RIA	CODE/ SBA	CODE/ IGG1
(b) (6)	M	CAUC	(b) (6)	2M	0	(b) (6)	011	INJ 1	CP749	15 MCG			
					63		011	BLEED 1			32014		
					63		021	INJ 2	CP749	15 MCG			
					98		021	BLEED 2			48326		
	M	CAUC		13M	0		011	INJ 1	CP749	15 MCG			
	M	CAUC		7M	0		001	PREBLEED			< 125		
					0		011	INJ 1	CP749	15 MCG			
					58		011	BLEED 1			1328		
					58		021	INJ 2	CP749	15 MCG			
					119		021	BLEED 2			1726		
	M	CAUC		3M	0		001	PREBLEED			< 125		
					0		011	INJ 1	CP749	15 MCG			
					70		011	BLEED 1			2299		
					70		021	INJ 2	CP749	15 MCG			
					95		021	BLEED 2			2624		
	F	CAUC		23M	0		011	INJ 1	CP749	15 MCG			
	M	CAUC		2M	0		001	PREBLEED			< 125		
					0		011	INJ 1	CP749	15 MCG			
					63		011	BLEED 1			727		
					63		021	INJ 2	CP749	15 MCG			
					105		021	BLEED 2			3273		
	M	CAUC		6M	0		001	PREBLEED			< 125		
					0		011	INJ 1	CP749	15 MCG			
					63		011	BLEED 1			1002		
					63		021	INJ 2	CP749	15 MCG			
					98		021	BLEED 2			989		
	M	CAUC		7M	0		001	PREBLEED			159		
					0		011	INJ 1	CP749	15 MCG			
					70		011	BLEED 1			4152		
					70		021	INJ 2	CP749	15 MCG			
					105		021	BLEED 2			7046		
	M	BLAC		8M	0		001	PREBLEED			< 125		
					0		011	INJ 1	CP749	15 MCG			

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : KEYSERLING, HARRY
STUDY : 000412
VACCINE : HIB CONJUGATE
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	IGG1
(b) (6)	M	BLAC	(b) (6)	8M	63	(b) (6)	011	BLEED 1				4949				
					63		021	INJ 2	CP749	15 MCG						
					105		021	BLEED 2				40078				
	F	CAUC		3M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP749	15 MCG						
					63		011	BLEED 1				3956				
					63		021	INJ 2	CP749	15 MCG						
					98		021	BLEED 2				4176				
	M	CAUC		12M	0		011	INJ 1	CP749	15 MCG						
	M	CAUC		7M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP749	15 MCG						
					63		011	BLEED 1				3650				
					63		021	INJ 2	CP749	15 MCG						
					91		021	BLEED 2				10488				
	F	CAUC		2M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP749	15 MCG						
					63		011	BLEED 1				523				
					63		021	INJ 2	CP749	15 MCG						
					91		021	BLEED 2				993				
	F	CAUC		13M	0		011	INJ 1	CP749	15 MCG						
	F	CAUC		18M	0		011	INJ 1	CP749	15 MCG						
	F	OTHE		2M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP749	15 MCG						
					70		011	BLEED 1				13283				
					70		021	INJ 2	CP749	15 MCG						
					98		021	BLEED 2				8388				
	F	CAUC		24M	0		011	INJ 1	CP749	15 MCG						
	F	CAUC		5M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP749	15 MCG						
					63		011	BLEED 1				2318				
					63		021	INJ 2	CP749	15 MCG						
					105		021	BLEED 2				2548				

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : KEYSERLING, HARRY
STUDY : 000412
VACCINE : HIB CONJUGATE
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT		LOT	DOSE	CODE/ RIA	CODE/ SBA	CODE/ IGG1
(b) (6)	F	CAUC	(b) (6)	15M	0	(b) (6)	011	INJ	1	CP749	15 MCG			
	M	CAUC		14M	0		011	INJ	1	CP749	15 MCG			
	F	CAUC		2M	0		001	PREBLEED				< 125		
					0		011	INJ	1	CP749	15 MCG			
					70		011	BLEED	1			596		
					77		021	INJ	2	CP749	15 MCG			
	M	BLAC		2Y	0		011	INJ	1	CP749	15 MCG			
	M	CAUC		5M	0		001	PREBLEED				< 125		
					0		011	INJ	1	CP749	15 MCG			
					63		011	BLEED	1			307		
					63		021	INJ	2	CP749	15 MCG			
					98		021	BLEED	2			479		
	F	CAUC		3M	0		001	PREBLEED				168		
					0		011	INJ	1	CP749	15 MCG			
					63		011	BLEED	1			9410		
					63		021	INJ	2	CP749	15 MCG			
					98		021	BLEED	2			22477		
	F	CAUC		16M	0		011	INJ	1	CP749	15 MCG			
	F	CAUC		23M	0		011	INJ	1	CP749	15 MCG			
	F	CAUC		2Y	0		011	INJ	1	CP749	15 MCG			
	F	CAUC		24M	0		011	INJ	1	CP749	15 MCG			
	M	BLAC		3Y	0		011	INJ	1	CP749	15 MCG			
	M	CAUC		2M	0		001	PREBLEED				146		
					0		011	INJ	1	CP749	15 MCG			
					70		011	BLEED	1			1365		
					70		021	INJ	2	CP749	15 MCG			
	F	CAUC		18M	0		011	INJ	1	CP749	15 MCG			
	F	CAUC		18M	0		011	INJ	1	CP749	15 MCG			

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : KEYSERLING, HARRY
STUDY : 000412
VACCINE : HIB CONJUGATE
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT		LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	IGG1
(b) (6)	F	CAUC	(b) (6)	15M	0	(b) (6)	011	INJ	1	CP749	15 MCG						
	M	CAUC		18M	0		011	INJ	1	CP749	15 MCG						
	F	CAUC		3M	0		011	INJ	1	CP749	15 MCG						
					70		021	INJ	2	CP749	15 MCG						
	F	CAUC		23M	0		011	INJ	1	CP749	15 MCG						
	F	CAUC		6M	0		001	PREBLEED					226				
					0		011	INJ	1	CP749	15 MCG						
					62		011	BLEED	1				1079				
					63		021	INJ	2	CP749	15 MCG						
	M	CAUC		4Y	0		011	INJ	1	CP749	15 MCG						
	F	CAUC		19M	0		011	INJ	1	CP749	15 MCG						
	F	CAUC		17M	0		011	INJ	1	CP749	15 MCG						
	M	CAUC		4M	0		001	PREBLEED					252				
					0		011	INJ	1	CP749	15 MCG						
					63		011	BLEED	1				3827				
					63		021	INJ	2	CP749	15 MCG						
	F	CAUC		3Y	0		011	INJ	1	CP749	15 MCG						
	M	CAUC		4M	0		001	PREBLEED					< 125				
					0		011	INJ	1	CP749	15 MCG						
					63		011	BLEED	1				4375				
					63		021	INJ	2	CP749	15 MCG						
	M	BLAC		2Y	0		011	INJ	1	CP749	15 MCG						
	M	BLAC		13M	0		011	INJ	1	CP749	15 MCG						
	F	BLAC		17M	0		011	INJ	1	CP749	15 MCG						
	M	BLAC		3Y	0		011	INJ	1	CP749	15 MCG						
	M	BLAC		3Y	0		011	INJ	1	CP749	15 MCG						

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : KEYSERLING, HARRY
STUDY : 000412
VACCINE : HIB CONJUGATE
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	IGG1
(b) (6)	M	BLAC	(b) (6)	21M	0	(b) (6)	011	INJ	1 CP749	15 MCG						
	F	BLAC		15M	0		011	INJ	1 CP749	15 MCG						
	F	BLAC		14M	0		011	INJ	1 CP749	15 MCG						
	M	CAUC		7M	0		011	INJ	1 CP749	15 MCG						
					63		021	INJ	2 CP749	15 MCG						
	F	CAUC		4M	0		001	PREBLEED				< 125				
					0		011	INJ	1 CP749	15 MCG						
					70		011	BLEED	1			3741				
					70		021	INJ	2 CP749	15 MCG						
	F	CAUC		2Y	0		011	INJ	1 CP749	15 MCG						
	M	BLAC		18M	0		011	INJ	1 CP749	15 MCG						
	M	CAUC		16M	0		011	INJ	1 CP749	15 MCG						
	F	CAUC		24M	0		011	INJ	1 CP749	15 MCG						
	M	CAUC		24M	0		011	INJ	1 CP749	15 MCG						
	F	CAUC		5M	0		011	INJ	1 CP749	15 MCG						
	F	BLAC		18M	0		011	INJ	1 CP749	15 MCG						
	M	BLAC		15M	0		011	INJ	1 CP749	15 MCG						
	F	BLAC		4M	0		011	INJ	1 CP749	15 MCG						
	M	BLAC		2Y	0		011	INJ	1 CP749	15 MCG						
	M	CAUC		2Y	0		011	INJ	1 CP749	15 MCG						
	M	CAUC		10M	0		001	PREBLEED				135				
					0		011	INJ	1 CP749	15 MCG						
					63		011	BLEED	1			19023				
	M	CAUC		2M	0		001	PREBLEED				< 125				

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : KEYSERLING, HARRY
STUDY : 000412
VACCINE : HIB CONJUGATE
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	IGG1
(b) (6)	M	CAUC	(b) (6)	2M	0	(b) (6)	011	INJ	1	CP749	15 MCG					
					63		011	BLEED	1			3795				
					63		021	INJ	2	CP749	15 MCG					
	M	CAUC		4M	0		011	INJ	1	CP749	15 MCG					
	F	CAUC		12M	0		011	INJ	1	CP749	15 MCG					
	M	CAUC		5M	0		001	PREBLEED				< 125				
					0		011	INJ	1	CP749	15 MCG					
					63		011	BLEED	1			661				
					63		021	INJ	2	CP749	15 MCG					
	M	CAUC		3M	0		001	PREBLEED				< 125				
					0		011	INJ	1	CP749	15 MCG					
					63		011	BLEED	1			12268				
	M	CAUC		3M	0		011	INJ	1	CP749	15 MCG					
	M	CAUC		6M	0		011	INJ	1	CP749	15 MCG					
	F	CAUC		3Y	0		011	INJ	1	CP749	15 MCG					
	M	CAUC		2Y	0		011	INJ	1	CP749	15 MCG					
	F	CAUC		4M	0		011	INJ	1	CP749	15 MCG					
					63		021	INJ	2	CP749	15 MCG					
	M	CAUC		18M	0		011	INJ	1	CP749	15 MCG					
	M	CAUC		2M	0		011	INJ	1	CP749	15 MCG					
	F	CAUC		12M	0		011	INJ	1	CP749	15 MCG					
	F	CAUC		3M	0		011	INJ	1	CP749	15 MCG					
	F	BLAC		2Y	0		011	INJ	1	CP749	15 MCG					
	F	BLAC		2Y	0		011	INJ	1	CP749	15 MCG					
	F	CAUC		2M	0		011	INJ	1	CP749	15 MCG					

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : KEYSERLING, HARRY
STUDY : 000412
VACCINE : HIB CONJUGATE
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT		LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	IGG1
(b) (6)	M	OTHE	(b) (6)	18M	0	(b) (6)	011	INJ	1	CP749	15 MCG						
	F	CAUC		18M	0		011	INJ	1	CP749	15 MCG						
	F	CAUC		19M	0		011	INJ	1	CP749	15 MCG						
	F	CAUC		20M	0		011	INJ	1	CP749	15 MCG						
	F	CAUC		7M	0		011	INJ	1	CP749	15 MCG						
	F	CAUC		6M	0		011	INJ	1	CP749	15 MCG						
	M	CAUC		6M	0		011	INJ	1	CP749	15 MCG						
	M	CAUC		12M	0		011	INJ	1	CP749	15 MCG						
	M	CAUC		3M	0		011	INJ	1	CP749	15 MCG						
	M	CAUC		5M	0		011	INJ	1	CP749	15 MCG						
	M	CAUC		15M	0		011	INJ	1	CP749	15 MCG						
	F	CAUC		5M	0		011	INJ	1	CP749	15 MCG						
	M	CAUC		2M	0		011	INJ	1	CP749	15 MCG						
	M	BLAC		2Y	0		011	INJ	1	CP749	15 MCG						
	F	CAUC		3M	0		011	INJ	1	CP749	15 MCG						
	F	CAUC		3Y	0		011	INJ	1	CP749	15 MCG						
	M	CAUC		2Y	0		011	INJ	1	CP749	15 MCG						
	F	CAUC		4M	0		011	INJ	1	CP749	15 MCG						
	M	CAUC		3M	0		011	INJ	1	CP749	15 MCG						
	M	CAUC		2M	0		011	INJ	1	CP749	15 MCG						
	M	CAUC		9M	0		011	INJ	1	CP749	15 MCG						

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : KEYSERLING, HARRY
STUDY : 000412
VACCINE : HIB CONJUGATE
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT		LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	IGG1
(b) (6)	F	BLAC	(b) (6)	24M	0	(b) (6)	011	INJ	1	CP749	15 MCG						
	M	CAUC		4M	0		011	INJ	1	CP749	15 MCG						
	M	CAUC		18M	0		011	INJ	1	CP749	15 MCG						
	F	CAUC		2Y	0		011	INJ	1	CP749	15 MCG						
	F	CAUC		4M	0		011	INJ	1	CP749	15 MCG						
	F	CAUC		2M	0		011	INJ	1	CP749	15 MCG						
	F	CAUC		9M	0		011	INJ	1	CP749	15 MCG						
	M	CAUC		24M	0		011	INJ	1	CP749	15 MCG						
	F	CAUC		12M	0		011	INJ	1	CP749	15 MCG						
	F	CAUC		23M	0		011	INJ	1	CP749	15 MCG						
	F	CAUC		2Y	0		011	INJ	1	CP749	15 MCG						
	M	CAUC		6M	0		011	INJ	1	CP749	15 MCG						
	M	CAUC		3M	0		011	INJ	1	CP749	15 MCG						
	F	BLAC		7M	0		011	INJ	1	CP749	15 MCG						
	F	CAUC		6M	0		011	INJ	1	CP749	15 MCG						
	M	CAUC		2Y	0		011	INJ	1	CP749	15 MCG						
	F	CAUC		1M	0		011	INJ	1	CP749	15 MCG						
	F	CAUC		9M	0		011	INJ	1	CP749	15 MCG						
	F	CAUC		9M	0		011	INJ	1	CP749	15 MCG						
	F	CAUC		1M	0		011	INJ	1	CP749	15 MCG						
	F	CAUC		6M	0		011	INJ	1	CP749	15 MCG						

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : KEYSERLING, HARRY
STUDY : 000412
VACCINE : HIB CONJUGATE
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT		LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	IGG1
(b) (6)	M	CAUC	(b) (6)	3M	0	(b) (6)	011	INJ	1	CP749	15 MCG						
	F	CAUC		5M	0		011	INJ	1	CP749	15 MCG						
	F	CAUC		5M	0		011	INJ	1	CP749	15 MCG						
	F	OTHE		2M	0		011	INJ	1	CR132	15 MCG						
	F	CAUC		2M	0		011	INJ	1	CR132	15 MCG						
	M	CAUC		1M	0		011	INJ	1	CR132	15 MCG						
	F	CAUC		15M	0		011	INJ	1	CR132	15 MCG						
	M	CAUC		12M	0		011	INJ	1	CR132	15 MCG						
	M	CAUC		12M	0		011	INJ	1	CR132	15 MCG						
	F	CAUC		2Y	0		011	INJ	1	CR132	15 MCG						
	M	CAUC		12M	0		011	INJ	1	CR132	15 MCG						
	M	CAUC		12M	0		011	INJ	1	CP749	15 MCG						
	M	CAUC		2Y	0		011	INJ	1	CR132	15 MCG						

TABLE 2

ANTIBODY RESPONSES

INVESTIGATOR : KEYSERLING, HARRY
STUDY : 000412
VACCINE : HIB CONJUGATE
ASSAY : RIA
LOT NUMBER : CP241
DOSE : 15 MCG
POPULATION : HEALTHY CHILDREN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
1- 6 MOS.	PRE INJ	33 (2/ 6)	0 (0/ 6)			0.139 (6)
	MONTH 2	100 (6/ 6)	100 (6/ 6)	100 (6/ 6)	23.9	4.191 (6)
	MONTH 3	100 (6/ 6)	100 (6/ 6)	100 (6/ 6)	46.2	8.083 (6)
	MONTH 7-10	100 (1/ 1)	100 (1/ 1)	100 (1/ 1)	17.4	2.178 (1)
7-11 MOS.	PRE INJ	0 (0/ 1)	0 (0/ 1)			0.063 (1)
	MONTH 2	100 (1/ 1)	100 (1/ 1)	100 (1/ 1)	131.3	16.415 (1)
	MONTH 3	100 (1/ 1)	100 (1/ 1)	100 (1/ 1)	113.6	14.196 (1)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

NO SEROLOGY WAS OBTAINED FOR CHILDREN !@ MONTHS OF AGE OR OLDER.

TABLE 3

ANTIBODY RESPONSES

INVESTIGATOR : KEYSERLING, HARRY
STUDY : 000412
VACCINE : HIB CONJUGATE
ASSAY : RIA
LOT NUMBER : CP298
DOSE : 15 MCG
POPULATION : HEALTHY CHILDREN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
1- 6 MOS.	PRE INJ	40 (6/ 15)	0 (0/ 15)			0.117 (15)
	MONTH 2	93 (14/ 15)	80 (12/ 15)	87 (13/ 15)	18.4	2.979 (15)
	MONTH 3	100 (13/ 13)	92 (12/ 13)	92 (12/ 13)	41.3	6.495 (13)
7-11 MOS.	PRE INJ	25 (1/ 4)	25 (1/ 4)			0.176 (4)
	MONTH 2	100 (4/ 4)	100 (4/ 4)	75 (3/ 4)	18.3	4.562 (4)
	MONTH 3	100 (4/ 4)	100 (4/ 4)	100 (4/ 4)	26.5	6.599 (4)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

NO SEROLOGY WAS OBTAINED FOR CHILDREN I@ MONTHS OF AGE OR OLDER.

TABLE 4

ANTIBODY RESPONSES

INVESTIGATOR : KEYSERLING, HARRY
STUDY : 000412
VACCINE : HIB CONJUGATE
ASSAY : RIA
LOT NUMBER : CP749
DOSE : 15 MCG
POPULATION : HEALTHY CHILDREN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
1- 6 MOS.	PRE INJ	14 (3/ 21)	0 (0/ 21)			0.077 (21)
	MONTH 2	100 (21/ 21)	71 (15/ 21)	95 (20/ 21)	14.3	1.944 (21)
	MONTH 3	100 (13/ 13)	77 (10/ 13)	100 (13/ 13)	26.7	3.416 (13)
7-11 MOS.	PRE INJ	17 (1/ 6)	0 (0/ 6)			0.073 (6)
	MONTH 2	100 (6/ 6)	100 (6/ 6)	100 (6/ 6)	26.5	3.444 (6)
	MONTH 3	100 (5/ 5)	100 (5/ 5)	100 (5/ 5)	79.4	10.412 (5)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

NO SEROLOGY WAS OBTAINED FOR CHILDREN 1@ MONTHS OF AGE OR OLDER.

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : KEYSERLING, HARRY
STUDY : 000412
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	9	
VACCINEES WITH NO COMPLAINTS :	4	(44.4 %)
VACCINEES WITH COMPLAINTS :	5	(55.6 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 9 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	3	33.3
ERYTHEMA, INJ. SITE (<=1 IN.)	2	22.2
PAIN/SORENESS, INJ. SITE	2	22.2
ERYTHEMA, INJ. SITE (>1 INCH)	1	11.1
SWELLING, INJ. SITE (<=1 IN.)	1	11.1
SYSTEMIC REACTIONS	4	44.4
FATIGUE	3	33.3
IRRITABILITY	2	22.2
EAR INFECTION, NOS	1	11.1
PHARYNGITIS	1	11.1
TEETHING	1	11.1
WARM TO TOUCH	1	11.1

TABLE 5 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : KEYSERLING, HARRY
STUDY : 000412
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 2	
TOTAL VACCINEES :	9	
VACCINEES WITH NO COMPLAINTS :	5	(55.6 %)
VACCINEES WITH COMPLAINTS :	4	(44.4 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 9 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	1	11.1
ERYTHEMA, INJ. SITE (<=1 IN.)	1	11.1
SYSTEMIC REACTIONS	4	44.4
BRONCHIOLITIS, ACUTE	1	11.1
COMMON COLD	1	11.1
FATIGUE	1	11.1
IRRITABILITY	1	11.1
TEETHING	1	11.1
TONSILLITIS	1	11.1

TABLE 5 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : KEYSERLING, HARRY
STUDY : 000412
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
POPULATION : HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	16	
VACCINEES WITH NO COMPLAINTS :	4	(25.0 %)
VACCINEES WITH COMPLAINTS :	12	(75.0 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 16 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	5	31.3
PAIN/SORENESS, INJ. SITE	4	25.0
ERYTHEMA, INJ. SITE (<=1 IN.)	2	12.5
SWELLING, INJ. SITE (<=1 IN.)	1	6.3
SYSTEMIC REACTIONS	10	62.5
IRRITABILITY	7	43.8
TEETHING	4	25.0
FATIGUE	3	18.8
WARM TO TOUCH	2	12.5
COMMON COLD	1	6.3
DIARRHEA	1	6.3
SUTURES	1	6.3
WHEEZING	1	6.3

TABLE 5 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : KEYSERLING, HARRY
STUDY : 000412
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	21	
VACCINEES WITH NO COMPLAINTS :	6	(28.6 %)
VACCINEES WITH COMPLAINTS :	15	(71.4 %)
VACCINEES WITH NO DATA :	0	

CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 21 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	7	33.3
ERYTHEMA, INJ. SITE (<=1 IN.)	5	23.8
ERYTHEMA, INJ. SITE (>1 INCH)	1	4.8
SWELLING, INJ. SITE (<=1 IN.)	1	4.8
SWELLING, INJ. SITE (>1 INCH)	1	4.8
SYSTEMIC REACTIONS	13	61.9
IRRITABILITY	9	42.9
FATIGUE	4	19.0
TEETHING	4	19.0
WARM TO TOUCH	3	14.3
COMMON COLD	1	4.8
NASAL CONGESTION	1	4.8
NERVOUSNESS	1	4.8
VOMITING	1	4.8
WHEEZING	1	4.8
WOLFF-PARKINSON-WHITE SYNDROME	1	4.8

TABLE 5 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : KEYSERLING, HARRY
STUDY : 000412
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 2	
TOTAL VACCINEES :	21	
VACCINEES WITH NO COMPLAINTS :	7	(33.3 %)
VACCINEES WITH COMPLAINTS :	14	(66.7 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 21 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	8	38.1
ERYTHEMA, INJ. SITE (<=1 IN.)	5	23.8
PAIN/SORENESS, INJ. SITE	2	9.5
SWELLING, INJ. SITE (<=1 IN.)	1	4.8
SYSTEMIC REACTIONS	12	57.1
IRRITABILITY	8	38.1
TEETHING	7	33.3
COMMON COLD	4	19.0
FATIGUE	3	14.3
BRONCHIOLITIS, ACUTE	1	4.8
DIARRHEA	1	4.8
ENDOPHTHALMITIS	1	4.8
NASAL CONGESTION	1	4.8
OTITIS MEDIA	1	4.8
PROLONGED CRYING, >1/2 HR	1	4.8
UNUSUAL HIGH-PITCHED CRYING	1	4.8
WARM TO TOUCH	1	4.8
WHEEZING	1	4.8
WOLFF-PARKINSON-WHITE SYNDROME	1	4.8

TABLE 5 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : KEYSERLING, HARRY
STUDY : 000412
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
POPULATION : HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	13	
VACCINEES WITH NO COMPLAINTS :	3	(23.1 %)
VACCINEES WITH COMPLAINTS :	10	(76.9 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 13 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	5	38.5
PAIN/SORENESS, INJ. SITE	3	23.1
ERYTHEMA, INJ. SITE (<=1 IN.)	2	15.4
SWELLING, INJ. SITE (>1 INCH)	1	7.7
SYSTEMIC REACTIONS	8	61.5
IRRITABILITY	6	46.2
FATIGUE	4	30.8
COMMON COLD	3	23.1
DIARRHEA	2	15.4
NASAL DISCHARGE	2	15.4
TEETHING	2	15.4
VOMITING	2	15.4
BRONCHITIS, ACUTE	1	7.7
COUGH	1	7.7
OTITIS MEDIA	1	7.7
PROLONGED CRYING, >1/2 HR	1	7.7
RASH	1	7.7
WARM TO TOUCH	1	7.7

TABLE 5 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : KEYSERLING, HARRY
STUDY : 000412
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES	69	
VACCINEES WITH NO COMPLAINTS	12	(17.4 %)
VACCINEES WITH COMPLAINTS	57	(82.6 %)
VACCINEES WITH NO DATA	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 69 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	29	42.0
ERYTHEMA, INJ. SITE (<=1 IN.)	24	34.8
PAIN/SORENESS, INJ. SITE	7	10.1
SWELLING, INJ. SITE (<=1 IN.)	6	8.7
SWELLING, INJ. SITE (>1 INCH)	1	1.4
SYSTEMIC REACTIONS	51	73.9
IRRITABILITY	34	49.3
FATIGUE	22	31.9
WARM TO TOUCH	20	29.0
DIARRHEA	9	13.0
VOMITING	8	11.6
COMMON COLD	5	7.2
PROLONGED CRYING, >1/2 HR	5	7.2
EAR INFECTION, NOS	4	5.8
TEETHING	4	5.8
COUGH	3	4.3
FEVER	3	4.3
NASAL DISCHARGE	2	2.9
WHEEZING	2	2.9
ATOPIC DERMATITIS	1	1.4
BRONCHIOLITIS, ACUTE	1	1.4
GASTROENTERITIS, NONINFECTIOUS	1	1.4
NASAL CONGESTION	1	1.4
POLYDIPSIA	1	1.4
RASH	1	1.4
UNUSUAL HIGH-PITCHED CRYING	1	1.4

TABLE 5 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : KEYSERLING, HARRY
STUDY : 000412
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE	HIB CONJUGATE INJECTION: 2	
TOTAL VACCINEES	31	
VACCINEES WITH NO COMPLAINTS	7	(22.6 %)
VACCINEES WITH COMPLAINTS	24	(77.4 %)
VACCINEES WITH NO DATA	0	

CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 31 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	13	41.9
ERYTHEMA, INJ. SITE (<=1 IN.)	10	32.3
PAIN/SORENESS, INJ. SITE	4	12.9
SWELLING, INJ. SITE (<=1 IN.)	2	6.5
SYSTEMIC REACTIONS	22	71.0
IRRITABILITY	13	41.9
HARM TO TOUCH	10	32.3
FATIGUE	6	19.4
DIARRHEA	5	16.1
RASH	3	9.7
COMMON COLD	2	6.5
EAR INFECTION, NOS	2	6.5
VOMITING	2	6.5
ASTHMA	1	3.2
INFECTIOUS GASTROENTERITIS	1	3.2
INFLUENZA	1	3.2
NASAL CONGESTION	1	3.2
ORAL CANDIDIASIS	1	3.2
PROLONGED CRYING, >1/2 HR	1	3.2
TEETHING	1	3.2
UNUSUAL HIGH-PITCHED CRYING	1	3.2
WHEEZING	1	3.2

TABLE 5 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : KEYSERLING, HARRY
STUDY : 000412
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
POPULATION : HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	75	
VACCINEES WITH NO COMPLAINTS :	28	(37.8 %)
VACCINEES WITH COMPLAINTS :	46	(62.2 %)
VACCINEES WITH NO DATA :	1	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 74 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	31	41.9
PAIN/SORENESS, INJ. SITE	19	25.7
ERYTHEMA, INJ. SITE (<=1 IN.)	11	14.9
SWELLING, INJ. SITE (<=1 IN.)	5	6.8
ERYTHEMA, INJ. SITE (>1 INCH)	2	2.7
SYSTEMIC REACTIONS	33	44.6
IRRITABILITY	26	35.1
FATIGUE	16	21.6
DIARRHEA	8	10.8
HARM TO TOUCH	7	9.5
NASAL DISCHARGE	3	4.1
PROLONGED CRYING, >1/2 HR	3	4.1
VOMITING	3	4.1
ANOREXIA	2	2.7
PHARYNGITIS	2	2.7
TEETHING	2	2.7
ASTHMA	1	1.4
COMMON COLD	1	1.4
CONJUNCTIVITIS	1	1.4
COUGH	1	1.4
FEVER	1	1.4
HYPERSENSITIVITY	1	1.4
NASAL CONGESTION	1	1.4
NAUSEA	1	1.4
OTITIS MEDIA	1	1.4
SLEEP DISORDERS	1	1.4
UPPER RESPIRATORY INFECTION, NOS	1	1.4
WHEEZING	1	1.4

TABLE 5 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : KEYSERLING, HARRY
STUDY : 000412
VACCINE : HIB CONJUGATE
LOT NUMBER : CR132
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES	3	
VACCINEES WITH NO COMPLAINTS	3	(100.0 %)
VACCINEES WITH COMPLAINTS	0	(0.0 %)
VACCINEES WITH NO DATA	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 3 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	0	0.0

TABLE 5 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : KEYSERLING, HARRY
STUDY : 000412
VACCINE : HIB CONJUGATE
LOT NUMBER : CR132
POPULATION : HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	6	
VACCINEES WITH NO COMPLAINTS :	0	(0.0 %)
VACCINEES WITH COMPLAINTS :	6	(100.0 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 6 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	3	50.0
ERYTHEMA, INJ. SITE (<=1 IN.)	2	33.3
PAIN/SORENESS, INJ. SITE	2	33.3
SWELLING, INJ. SITE (<=1 IN.)	1	16.7
SYSTEMIC REACTIONS	4	66.7
DIARRHEA	2	33.3
FATIGUE	2	33.3
IRRITABILITY	2	33.3
VOMITING	2	33.3
CONJUNCTIVITIS	1	16.7
COUGH	1	16.7
EAR INFECTION, NOS	1	16.7
NASAL DISCHARGE	1	16.7
NAUSEA	1	16.7
PAIN	1	16.7
WARM TO TOUCH	1	16.7

TABLE 6
CLINICAL COMPLAINTS

INVESTIGATOR : KEYSERLING, HARRY
STUDY : 000412
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE — NUMBER OF VACCINEES (9 VACCINEES) - INJECTION: 1

CLINICAL COMPLAINTS	DAYS POST VACCINATION 0	1	2	3	4	5		NUMBER WITH COMPLAINTS
LOCAL REACTIONS	1 (11.1%)	2 (22.2%)	1 (11.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		3 (33.3%)
ERYTHEMA, INJ. SITE (>1 INCH)	0 (0.0%)	1 (11.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (11.1%)
ERYTHEMA, INJ. SITE (<=1 IN.)	0 (0.0%)	1 (11.1%)	1 (11.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (22.2%)
PAIN/SORENESS, INJ. SITE	1 (11.1%)	1 (11.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (22.2%)
SWELLING, INJ. SITE (<=1 IN.)	0 (0.0%)	1 (11.1%)	1 (11.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (11.1%)
SYSTEMIC	2 (22.2%)	3 (33.3%)	0 (0.0%)	1 (11.1%)	1 (11.1%)	1 (11.1%)		4 (44.4%)
BODY AS A WHOLE/SITE UNSPEC.	1 (11.1%)	2 (22.2%)	0 (0.0%)	1 (11.1%)	1 (11.1%)	1 (11.1%)		4 (44.4%)
FATIGUE	1 (11.1%)	2 (22.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		3 (33.3%)
HARM TO TOUCH	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (11.1%)	1 (11.1%)	1 (11.1%)		1 (11.1%)
DIGESTIVE SYSTEM	1 (11.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (11.1%)
TEETHING	1 (11.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (11.1%)

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : KEYSERLING, HARRY
STUDY : 000412
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (9 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
NERVOUS SYSTEM & PSYCHIATRIC	1 (11.1%)	2 (22.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (22.2%)
IRRITABILITY	1 (11.1%)	2 (22.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (22.2%)
RESPIRATORY SYSTEM	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (11.1%)		1 (11.1%)
PHARYNGITIS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (11.1%)		1 (11.1%)
SPECIAL SENSES	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (11.1%)		1 (11.1%)
EAR INFECTION, NOS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (11.1%)		1 (11.1%)
VACCINEES WITH COMPLAINTS	2 (22.2%)	4 (44.4%)	1 (11.1%)	1 (11.1%)	1 (11.1%)	1 (11.1%)		5 (55.6%)
VACCINEES WITH NO COMPLAINTS	7 (77.8%)	5 (55.6%)	8 (88.9%)	8 (88.9%)	8 (88.9%)	8 (88.9%)		4 (44.4%)
TOTAL VACCINEES REPORTING	9	9	9	9	9	9		9
VACCINEES WITH NO DATA	0	0	0	0	0	0		0

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : KEYSERLING, HARRY
STUDY : 000412
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (9 VACCINEES) - INJECTION: 2						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5	COMPLAINTS
LOCAL REACTIONS	1 (11.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (11.1%)
ERYTHEMA, INJ. SITE (<=1 IN.)	1 (11.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (11.1%)
SYSTEMIC	1 (11.1%)	2 (22.2%)	2 (22.2%)	2 (22.2%)	3 (33.3%)	2 (22.2%)	4 (44.4%)
BODY AS A WHOLE/SITE UNSPEC.	0 (0.0%)	1 (11.1%)	1 (11.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (11.1%)
FATIGUE	0 (0.0%)	1 (11.1%)	1 (11.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (11.1%)
DIGESTIVE SYSTEM	0 (0.0%)	1 (11.1%)	1 (11.1%)	1 (11.1%)	1 (11.1%)	1 (11.1%)	1 (11.1%)
TEETHING	0 (0.0%)	1 (11.1%)	1 (11.1%)	1 (11.1%)	1 (11.1%)	1 (11.1%)	1 (11.1%)
NERVOUS SYSTEM & PSYCHIATRIC	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (11.1%)	0 (0.0%)	1 (11.1%)
IRRITABILITY	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (11.1%)	0 (0.0%)	1 (11.1%)
RESPIRATORY SYSTEM	1 (11.1%)	1 (11.1%)	1 (11.1%)	1 (11.1%)	1 (11.1%)	1 (11.1%)	2 (22.2%)
BRONCHIOLITIS, ACUTE	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (11.1%)	1 (11.1%)	1 (11.1%)	1 (11.1%)

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : KEYSERLING, HARRY
STUDY : 000412
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (9 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
COMMON COLD	1 (11.1%)	1 (11.1%)	1 (11.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (11.1%)
TONSILLITIS	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (11.1%)	1 (11.1%)	1 (11.1%)		1 (11.1%)
VACCINEES WITH COMPLAINTS	1 (11.1%)	2 (22.2%)	2 (22.2%)	2 (22.2%)	3 (33.3%)	2 (22.2%)		4 (44.4%)
VACCINEES WITH NO COMPLAINTS	8 (88.9%)	7 (77.8%)	7 (77.8%)	7 (77.8%)	6 (66.7%)	7 (77.8%)		5 (55.6%)
TOTAL VACCINEES REPORTING	9	9	9	9	9	9		9
VACCINEES WITH NO DATA	0	0	0	0	0	0		0

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : KEYSERLING, HARRY
STUDY : 000412
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (16 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5	COMPLAINTS
LOCAL REACTIONS	4 (25.0%)	2 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	5 (31.3%)
ERYTHEMA, INJ. SITE (<=1 IN.)	1 (6.3%)	2 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (12.5%)
PAIN/SORENESS, INJ. SITE	3 (18.8%)	1 (6.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (25.0%)
SWELLING, INJ. SITE (<=1 IN.)	1 (6.3%)	1 (6.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (6.3%)
SYSTEMIC	5 (31.3%)	4 (25.0%)	4 (25.0%)	5 (31.3%)	4 (25.0%)	5 (31.3%)	10 (62.5%)
BODY AS A WHOLE/SITE UNSPEC.	2 (12.5%)	2 (12.5%)	1 (6.3%)	0 (0.0%)	1 (6.3%)	2 (12.5%)	6 (37.5%)
FATIGUE	2 (12.5%)	1 (6.3%)	1 (6.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (18.8%)
SUTURES	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (6.3%)	1 (6.3%)
HARM TO TOUCH	0 (0.0%)	1 (6.3%)	0 (0.0%)	0 (0.0%)	1 (6.3%)	1 (6.3%)	2 (12.5%)
DIGESTIVE SYSTEM	3 (18.8%)	3 (18.8%)	4 (25.0%)	2 (12.5%)	3 (18.8%)	2 (12.5%)	5 (31.3%)
DIARRHEA	0 (0.0%)	0 (0.0%)	1 (6.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (6.3%)

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : KEYSERLING, HARRY
STUDY : 000412
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (16 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
TEETHING	3 (18.8%)	3 (18.8%)	3 (18.8%)	2 (12.5%)	3 (18.8%)	2 (12.5%)		4 (25.0%)
NERVOUS SYSTEM & PSYCHIATRIC	3 (18.8%)	3 (18.8%)	1 (6.3%)	2 (12.5%)	1 (6.3%)	1 (6.3%)		7 (43.8%)
IRRITABILITY	3 (18.8%)	3 (18.8%)	1 (6.3%)	2 (12.5%)	1 (6.3%)	1 (6.3%)		7 (43.8%)
RESPIRATORY SYSTEM	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (6.3%)	1 (6.3%)	1 (6.3%)		1 (6.3%)
COMMON COLD	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (6.3%)	0 (0.0%)	0 (0.0%)		1 (6.3%)
WHEEZING	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (6.3%)	1 (6.3%)	1 (6.3%)		1 (6.3%)
VACCINEES WITH COMPLAINTS	7 (43.8%)	5 (31.3%)	4 (25.0%)	5 (31.3%)	4 (25.0%)	5 (31.3%)		12 (75.0%)
VACCINEES WITH NO COMPLAINTS	9 (56.3%)	11 (68.8%)	12 (75.0%)	11 (68.8%)	12 (75.0%)	11 (68.8%)		4 (25.0%)
TOTAL VACCINEES REPORTING	16	16	16	16	16	16		16
VACCINEES WITH NO DATA	0	0	0	0	0	0		0

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : KEYSERLING, HARRY
STUDY : 000412
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (21 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5	COMPLAINTS
LOCAL REACTIONS	2 (9.5%)	6 (28.6%)	2 (9.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	7 (33.3%)
ERYTHEMA, INJ. SITE (>1 INCH)	0 (0.0%)	1 (4.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (4.8%)
ERYTHEMA, INJ. SITE (<=1 IN.)	2 (9.5%)	4 (19.0%)	1 (4.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	5 (23.8%)
SWELLING, INJ. SITE (>1 INCH)	0 (0.0%)	0 (0.0%)	1 (4.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (4.8%)
SWELLING, INJ. SITE (<=1 IN.)	0 (0.0%)	1 (4.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (4.8%)
SYSTEMIC	9 (42.9%)	10 (47.6%)	8 (38.1%)	8 (38.1%)	8 (38.1%)	7 (33.3%)	13 (61.9%)
BODY AS A WHOLE/SITE UNSPEC.	2 (9.5%)	5 (23.8%)	1 (4.8%)	2 (9.5%)	0 (0.0%)	0 (0.0%)	6 (28.6%)
FATIGUE	1 (4.8%)	4 (19.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (19.0%)
HARM TO TOUCH	1 (4.8%)	1 (4.8%)	1 (4.8%)	2 (9.5%)	0 (0.0%)	0 (0.0%)	3 (14.3%)
CARDIOVASCULAR SYSTEM	1 (4.8%)	1 (4.8%)	1 (4.8%)	1 (4.8%)	1 (4.8%)	1 (4.8%)	1 (4.8%)
WOLFF-PARKINSON-WHITE SYNDROME	1 (4.8%)	1 (4.8%)	1 (4.8%)	1 (4.8%)	1 (4.8%)	1 (4.8%)	1 (4.8%)

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : KEYSERLING, HARRY
STUDY : 000412
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (21 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		
DIGESTIVE SYSTEM	2 (9.5%)	5 (23.8%)	5 (23.8%)	4 (19.0%)	4 (19.0%)	4 (19.0%)		5 (23.8%)
TEETHING	2 (9.5%)	4 (19.0%)	4 (19.0%)	4 (19.0%)	4 (19.0%)	4 (19.0%)		4 (19.0%)
VOMITING	0 (0.0%)	1 (4.8%)	1 (4.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (4.8%)
NERVOUS SYSTEM & PSYCHIATRIC	5 (23.8%)	4 (19.0%)	2 (9.5%)	3 (14.3%)	3 (14.3%)	1 (4.8%)		9 (42.9%)
IRRITABILITY	5 (23.8%)	4 (19.0%)	2 (9.5%)	2 (9.5%)	2 (9.5%)	0 (0.0%)		9 (42.9%)
NERVOUSNESS	0 (0.0%)	1 (4.8%)	1 (4.8%)	1 (4.8%)	1 (4.8%)	1 (4.8%)		1 (4.8%)
RESPIRATORY SYSTEM	0 (0.0%)	1 (4.8%)	2 (9.5%)	2 (9.5%)	2 (9.5%)	2 (9.5%)		2 (9.5%)
COMMON COLD	0 (0.0%)	1 (4.8%)	1 (4.8%)	1 (4.8%)	1 (4.8%)	1 (4.8%)		1 (4.8%)
NASAL CONGESTION	0 (0.0%)	0 (0.0%)	1 (4.8%)	1 (4.8%)	1 (4.8%)	1 (4.8%)		1 (4.8%)
WHEEZING	0 (0.0%)	1 (4.8%)	1 (4.8%)	1 (4.8%)	1 (4.8%)	1 (4.8%)		1 (4.8%)
VACCINEES WITH COMPLAINTS	10 (47.6%)	13 (61.9%)	8 (38.1%)	8 (38.1%)	8 (38.1%)	7 (33.3%)		15 (71.4%)
VACCINEES WITH NO COMPLAINTS	11 (52.4%)	8 (38.1%)	13 (61.9%)	13 (61.9%)	13 (61.9%)	14 (66.7%)		6 (28.6%)

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : KEYSERLING, HARRY
STUDY : 000412
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (21 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
TOTAL VACCINEES REPORTING	21	21	21	21	21	21		21
VACCINEES WITH NO DATA	0	0	0	0	0	0		0

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : KEYSERLING, HARRY
STUDY : 000412
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (21 VACCINEES) - INJECTION: 2						
	DAYS POST VACCINATION						NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5	
LOCAL REACTIONS	7 (33.3%)	3 (14.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	8 (38.1%)
ERYTHEMA, INJ. SITE (<=1 IN.)	4 (19.0%)	3 (14.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	5 (23.8%)
PAIN/SORENESS, INJ. SITE	2 (9.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (9.5%)
SWELLING, INJ. SITE (<=1 IN.)	1 (4.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (4.8%)
SYSTEMIC	11 (52.4%)	10 (47.6%)	9 (42.9%)	9 (42.9%)	8 (38.1%)	8 (38.1%)	12 (57.1%)
BODY AS A WHOLE/SITE UNSPEC.	2 (9.5%)	0 (0.0%)	1 (4.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (14.3%)
FATIGUE	2 (9.5%)	0 (0.0%)	1 (4.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (14.3%)
WARM TO TOUCH	0 (0.0%)	0 (0.0%)	1 (4.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (4.8%)
CARDIOVASCULAR SYSTEM	1 (4.8%)	1 (4.8%)	1 (4.8%)	1 (4.8%)	1 (4.8%)	1 (4.8%)	1 (4.8%)
WOLFF-PARKINSON-WHITE SYNDROME	1 (4.8%)	1 (4.8%)	1 (4.8%)	1 (4.8%)	1 (4.8%)	1 (4.8%)	1 (4.8%)
DIGESTIVE SYSTEM	5 (23.8%)	6 (28.6%)	6 (28.6%)	5 (23.8%)	5 (23.8%)	5 (23.8%)	7 (33.3%)

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TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : KEYSERLING, HARRY
STUDY : 000412
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (21 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
DIARRHEA	1 (4.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (4.8%)
TEETHING	5 (23.8%)	6 (28.6%)	6 (28.6%)	5 (23.8%)	5 (23.8%)	5 (23.8%)		7 (33.3%)
NERVOUS SYSTEM & PSYCHIATRIC	4 (19.0%)	5 (23.8%)	3 (14.3%)	3 (14.3%)	2 (9.5%)	1 (4.8%)		9 (42.9%)
IRRITABILITY	3 (14.3%)	4 (19.0%)	3 (14.3%)	3 (14.3%)	2 (9.5%)	1 (4.8%)		8 (38.1%)
PROLONGED CRYING, >1/2 HR	1 (4.8%)	1 (4.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (4.8%)
UNUSUAL HIGH-PITCHED CRYING	1 (4.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (4.8%)
RESPIRATORY SYSTEM	3 (14.3%)	3 (14.3%)	3 (14.3%)	4 (19.0%)	4 (19.0%)	3 (14.3%)		6 (28.6%)
BRONCHIOLITIS, ACUTE	1 (4.8%)	1 (4.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (4.8%)
COMMON COLD	2 (9.5%)	2 (9.5%)	3 (14.3%)	4 (19.0%)	3 (14.3%)	2 (9.5%)		4 (19.0%)
NASAL CONGESTION	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (4.8%)	1 (4.8%)		1 (4.8%)
WHEEZING	1 (4.8%)	1 (4.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (4.8%)
SPECIAL SENSES	0 (0.0%)	0 (0.0%)	1 (4.8%)	1 (4.8%)	1 (4.8%)	1 (4.8%)		2 (9.5%)

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : KEYSERLING, HARRY
STUDY : 000412
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (21 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		
ENDOPHTHALMITIS	0 (0.0%)	0 (0.0%)	1 (4.8%)	1 (4.8%)	1 (4.8%)	0 (0.0%)		1 (4.8%)
OTITIS MEDIA	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (4.8%)		1 (4.8%)
VACCINEES WITH COMPLAINTS	13 (61.9%)	11 (52.4%)	9 (42.9%)	9 (42.9%)	8 (38.1%)	8 (38.1%)		14 (66.7%)
VACCINEES WITH NO COMPLAINTS	8 (38.1%)	10 (47.6%)	12 (57.1%)	12 (57.1%)	13 (61.9%)	13 (61.9%)		7 (33.3%)
TOTAL VACCINEES REPORTING	21	21	21	21	21	21		21
VACCINEES WITH NO DATA	0	0	0	0	0	0		0

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : KEYSERLING, HARRY
STUDY : 000412
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (13 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
LOCAL REACTIONS	2 (15.4%)	3 (23.1%)	1 (7.7%)	1 (7.7%)	1 (7.7%)	0 (0.0%)		5 (38.5%)
ERYTHEMA, INJ. SITE (<=1 IN.)	0 (0.0%)	2 (15.4%)	1 (7.7%)	1 (7.7%)	1 (7.7%)	0 (0.0%)		2 (15.4%)
PAIN/SORENESS, INJ. SITE	2 (15.4%)	1 (7.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		3 (23.1%)
SWELLING, INJ. SITE (>1 INCH)	0 (0.0%)	1 (7.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (7.7%)
SYSTEMIC	5 (38.5%)	6 (46.2%)	5 (38.5%)	7 (53.8%)	6 (46.2%)	5 (38.5%)		8 (61.5%)
BODY AS A WHOLE/SITE UNSPEC.	2 (15.4%)	0 (0.0%)	3 (23.1%)	1 (7.7%)	2 (15.4%)	2 (15.4%)		4 (30.8%)
FATIGUE	2 (15.4%)	0 (0.0%)	3 (23.1%)	1 (7.7%)	2 (15.4%)	2 (15.4%)		4 (30.8%)
HARM TO TOUCH	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.7%)	0 (0.0%)		1 (7.7%)
DIGESTIVE SYSTEM	2 (15.4%)	3 (23.1%)	2 (15.4%)	3 (23.1%)	3 (23.1%)	2 (15.4%)		4 (30.8%)
DIARRHEA	0 (0.0%)	1 (7.7%)	0 (0.0%)	1 (7.7%)	1 (7.7%)	0 (0.0%)		2 (15.4%)
TEETHING	2 (15.4%)	2 (15.4%)	2 (15.4%)	2 (15.4%)	2 (15.4%)	2 (15.4%)		2 (15.4%)

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : KEYSERLING, HARRY
STUDY : 000412
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (13 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5	COMPLAINTS
VOMITING	1 (7.7%)	1 (7.7%)	0 (0.0%)	0 (0.0%)	1 (7.7%)	0 (0.0%)	2 (15.4%)
NERVOUS SYSTEM & PSYCHIATRIC	4 (30.8%)	3 (23.1%)	3 (23.1%)	2 (15.4%)	1 (7.7%)	3 (23.1%)	6 (46.2%)
IRRITABILITY	4 (30.8%)	3 (23.1%)	3 (23.1%)	2 (15.4%)	1 (7.7%)	2 (15.4%)	6 (46.2%)
PROLONGED CRYING, >1/2 HR	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.7%)	1 (7.7%)	1 (7.7%)
RESPIRATORY SYSTEM	0 (0.0%)	2 (15.4%)	3 (23.1%)	4 (30.8%)	3 (23.1%)	3 (23.1%)	6 (46.2%)
BRONCHITIS, ACUTE	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.7%)	1 (7.7%)	1 (7.7%)
COMMON COLD	0 (0.0%)	1 (7.7%)	3 (23.1%)	2 (15.4%)	2 (15.4%)	2 (15.4%)	3 (23.1%)
COUGH	0 (0.0%)	1 (7.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.7%)
NASAL DISCHARGE	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (15.4%)	0 (0.0%)	0 (0.0%)	2 (15.4%)
SKIN & SKIN APPENDAGE	1 (7.7%)	0 (0.0%)	1 (7.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.7%)
RASH	1 (7.7%)	0 (0.0%)	1 (7.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.7%)
SPECIAL SENSES	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.7%)	1 (7.7%)	1 (7.7%)	1 (7.7%)

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : KEYSERLING, HARRY
STUDY : 000412
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (13 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
OTITIS MEDIA	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.7%)	1 (7.7%)	1 (7.7%)		1 (7.7%)
VACCINEES WITH COMPLAINTS	5 (38.5%)	8 (61.5%)	6 (46.2%)	8 (61.5%)	7 (53.8%)	5 (38.5%)		10 (76.9%)
VACCINEES WITH NO COMPLAINTS	8 (61.5%)	5 (38.5%)	7 (53.8%)	5 (38.5%)	6 (46.2%)	8 (61.5%)		3 (23.1%)
TOTAL VACCINEES REPORTING	13	13	13	13	13	13		13
VACCINEES WITH NO DATA	0	0	0	0	0	0		0

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : KEYSERLING, HARRY
STUDY : 000412
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE — NUMBER OF VACCINEES (69 VACCINEES) - INJECTION: 1

CLINICAL COMPLAINTS	DAYS POST VACCINATION 0	1	2	3	4	5		NUMBER WITH COMPLAINTS
LOCAL REACTIONS	20 (29.0%)	16 (23.2%)	5 (7.2%)	1 (1.4%)	0 (0.0%)	0 (0.0%)		29 (42.0%)
ERYTHEMA, INJ. SITE (<=1 IN.)	16 (23.2%)	15 (21.7%)	5 (7.2%)	1 (1.4%)	0 (0.0%)	0 (0.0%)		24 (34.8%)
PAIN/SORENESS, INJ. SITE	5 (7.2%)	2 (2.9%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		7 (10.1%)
SWELLING, INJ. SITE (>1 INCH)	1 (1.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (1.4%)
SWELLING, INJ. SITE (<=1 IN.)	3 (4.3%)	3 (4.3%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		6 (8.7%)
SYSTEMIC	40 (58.0%)	27 (39.1%)	18 (26.1%)	17 (24.6%)	20 (29.0%)	16 (23.2%)		51 (73.9%)
BODY AS A WHOLE/SITE UNSPEC.	25 (36.2%)	18 (26.1%)	8 (11.6%)	7 (10.1%)	4 (5.8%)	4 (5.8%)		34 (49.3%)
FATIGUE	17 (24.6%)	11 (15.9%)	5 (7.2%)	4 (5.8%)	3 (4.3%)	3 (4.3%)		22 (31.9%)
FEVER	0 (0.0%)	2 (2.9%)	1 (1.4%)	0 (0.0%)	1 (1.4%)	1 (1.4%)		3 (4.3%)
HARM TO TOUCH	11 (15.9%)	9 (13.0%)	5 (7.2%)	3 (4.3%)	1 (1.4%)	0 (0.0%)		20 (29.0%)
DIGESTIVE SYSTEM	5 (7.2%)	6 (8.7%)	8 (11.6%)	8 (11.6%)	10 (14.5%)	8 (11.6%)		18 (26.1%)

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : KEYSERLING, HARRY
STUDY : 000412
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (69 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5	COMPLAINTS
DIARRHEA	0 (0.0%)	3 (4.3%)	5 (7.2%)	5 (7.2%)	4 (5.8%)	4 (5.8%)	9 (13.0%)
GASTROENTERITIS, NONINFECTIOUS	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.4%)	1 (1.4%)	1 (1.4%)	1 (1.4%)
POLYDIPSIA	0 (0.0%)	1 (1.4%)	1 (1.4%)	1 (1.4%)	1 (1.4%)	1 (1.4%)	1 (1.4%)
TEETHING	4 (5.8%)	3 (4.3%)	2 (2.9%)	2 (2.9%)	2 (2.9%)	2 (2.9%)	4 (5.8%)
VOMITING	2 (2.9%)	1 (1.4%)	1 (1.4%)	2 (2.9%)	4 (5.8%)	3 (4.3%)	8 (11.6%)
NERVOUS SYSTEM & PSYCHIATRIC	24 (34.8%)	14 (20.3%)	10 (14.5%)	4 (5.8%)	6 (8.7%)	3 (4.3%)	36 (52.2%)
IRRITABILITY	23 (33.3%)	14 (20.3%)	10 (14.5%)	3 (4.3%)	5 (7.2%)	2 (2.9%)	34 (49.3%)
PROLONGED CRYING, >1/2 HR	3 (4.3%)	1 (1.4%)	1 (1.4%)	1 (1.4%)	1 (1.4%)	1 (1.4%)	5 (7.2%)
UNUSUAL HIGH-PITCHED CRYING	0 (0.0%)	0 (0.0%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.4%)
RESPIRATORY SYSTEM	5 (7.2%)	6 (8.7%)	6 (8.7%)	6 (8.7%)	5 (7.2%)	5 (7.2%)	9 (13.0%)
BRONCHIOLITIS, ACUTE	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.4%)	1 (1.4%)	1 (1.4%)	1 (1.4%)
COMMON COLD	3 (4.3%)	4 (5.8%)	3 (4.3%)	3 (4.3%)	2 (2.9%)	2 (2.9%)	5 (7.2%)

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : KEYSERLING, HARRY
STUDY : 000412
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (69 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
COUGH	0 (0.0%)	1 (1.4%)	2 (2.9%)	2 (2.9%)	2 (2.9%)	2 (2.9%)		3 (4.3%)
NASAL CONGESTION	0 (0.0%)	1 (1.4%)	1 (1.4%)	1 (1.4%)	1 (1.4%)	1 (1.4%)		1 (1.4%)
NASAL DISCHARGE	1 (1.4%)	1 (1.4%)	1 (1.4%)	1 (1.4%)	1 (1.4%)	1 (1.4%)		2 (2.9%)
WHEEZING	2 (2.9%)	2 (2.9%)	2 (2.9%)	1 (1.4%)	1 (1.4%)	1 (1.4%)		2 (2.9%)
SKIN & SKIN APPENDAGE	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (2.9%)	2 (2.9%)	1 (1.4%)		2 (2.9%)
ATOPIC DERMATITIS	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.4%)	1 (1.4%)	1 (1.4%)		1 (1.4%)
RASH	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.4%)	1 (1.4%)	0 (0.0%)		1 (1.4%)
SPECIAL SENSES	0 (0.0%)	0 (0.0%)	1 (1.4%)	4 (5.8%)	4 (5.8%)	4 (5.8%)		4 (5.8%)
EAR INFECTION, NOS	0 (0.0%)	0 (0.0%)	1 (1.4%)	4 (5.8%)	4 (5.8%)	4 (5.8%)		4 (5.8%)
VACCINEES WITH COMPLAINTS	45 (65.2%)	36 (52.2%)	21 (30.4%)	18 (26.1%)	20 (29.0%)	16 (23.2%)		57 (82.6%)
VACCINEES WITH NO COMPLAINTS	24 (34.8%)	33 (47.8%)	48 (69.6%)	51 (73.9%)	49 (71.0%)	53 (76.8%)		12 (17.4%)
TOTAL VACCINEES REPORTING	69	69	69	69	69	69		69

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : KEYSERLING, HARRY
STUDY : 000412
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (69 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5	**********
VACCINEES WITH NO DATA	0	0	0	0	0	0	0

0048A

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : KEYSERLING, HARRY
STUDY : 000412
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (31 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
LOCAL REACTIONS	9 (30.0%)	9 (29.0%)	2 (6.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		13 (41.9%)
ERYTHEMA, INJ. SITE (<=1 IN.)	6 (20.0%)	8 (25.8%)	2 (6.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		10 (32.3%)
PAIN/SORENESS, INJ. SITE	3 (10.0%)	2 (6.5%)	1 (3.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		4 (12.9%)
SWELLING, INJ. SITE (<=1 IN.)	1 (3.3%)	2 (6.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (6.5%)
SYSTEMIC	17 (56.7%)	16 (51.6%)	9 (29.0%)	10 (32.3%)	8 (25.8%)	8 (26.7%)		22 (71.0%)
BODY AS A WHOLE/SITE UNSPEC.	9 (30.0%)	3 (9.7%)	3 (9.7%)	4 (12.9%)	2 (6.5%)	2 (6.7%)		12 (38.7%)
FATIGUE	6 (20.0%)	3 (9.7%)	2 (6.5%)	2 (6.5%)	1 (3.2%)	1 (3.3%)		6 (19.4%)
HARM TO TOUCH	5 (16.7%)	2 (6.5%)	2 (6.5%)	3 (9.7%)	2 (6.5%)	1 (3.3%)		10 (32.3%)
DIGESTIVE SYSTEM	3 (10.0%)	4 (12.9%)	4 (12.9%)	4 (12.9%)	4 (12.9%)	3 (10.0%)		6 (19.4%)
DIARRHEA	2 (6.7%)	2 (6.5%)	3 (9.7%)	3 (9.7%)	3 (9.7%)	2 (6.7%)		5 (16.1%)
INFECTIOUS GASTROENTERITIS	1 (3.3%)	1 (3.2%)	1 (3.2%)	1 (3.2%)	1 (3.2%)	0 (0.0%)		1 (3.2%)

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : KEYSERLING, HARRY
STUDY : 000412
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE — NUMBER OF VACCINEES (31 VACCINEES) - INJECTION: 2

CLINICAL COMPLAINTS	DAYS POST VACCINATION 0	1	2	3	4	5		NUMBER WITH COMPLAINTS
ORAL CANDIDIASIS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.2%)	1 (3.3%)		1 (3.2%)
TEETHING	0 (0.0%)	1 (3.2%)	1 (3.2%)	1 (3.2%)	1 (3.2%)	1 (3.3%)		1 (3.2%)
VOMITING	1 (3.3%)	1 (3.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (6.5%)
NERVOUS SYSTEM & PSYCHIATRIC	9 (30.0%)	11 (35.5%)	4 (12.9%)	5 (16.1%)	3 (9.7%)	1 (3.3%)		13 (41.9%)
IRRITABILITY	9 (30.0%)	10 (32.3%)	4 (12.9%)	5 (16.1%)	3 (9.7%)	1 (3.3%)		13 (41.9%)
PROLONGED CRYING, >1/2 HR	0 (0.0%)	1 (3.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (3.2%)
UNUSUAL HIGH-PITCHED CRYING	0 (0.0%)	1 (3.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (3.2%)
RESPIRATORY SYSTEM	1 (3.3%)	2 (6.5%)	2 (6.5%)	2 (6.5%)	4 (12.9%)	4 (13.3%)		5 (16.1%)
ASTHMA	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.2%)	1 (3.3%)		1 (3.2%)
COMMON COLD	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.2%)	2 (6.7%)		2 (6.5%)
INFLUENZA	1 (3.3%)	1 (3.2%)	1 (3.2%)	1 (3.2%)	1 (3.2%)	1 (3.3%)		1 (3.2%)
NASAL CONGESTION	0 (0.0%)	1 (3.2%)	1 (3.2%)	1 (3.2%)	1 (3.2%)	0 (0.0%)		1 (3.2%)

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : KEYSERLING, HARRY
STUDY : 000412
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (31 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
WHEEZING	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.2%)	1 (3.3%)		1 (3.2%)
SKIN & SKIN APPENDAGE	3 (10.0%)	1 (3.2%)	1 (3.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		3 (9.7%)
RASH	3 (10.0%)	1 (3.2%)	1 (3.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		3 (9.7%)
SPECIAL SENSES	1 (3.3%)	1 (3.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.3%)		2 (6.5%)
EAR INFECTION, NOS	1 (3.3%)	1 (3.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.3%)		2 (6.5%)
VACCINEES WITH COMPLAINTS	17 (56.7%)	19 (61.3%)	10 (32.3%)	10 (32.3%)	8 (25.8%)	8 (26.7%)		24 (77.4%)
VACCINEES WITH NO COMPLAINTS	13 (43.3%)	12 (38.7%)	21 (67.7%)	21 (67.7%)	23 (74.2%)	22 (73.3%)		7 (22.6%)
TOTAL VACCINEES REPORTING	30	31	31	31	31	30		31
VACCINEES WITH NO DATA	1	0	0	0	0	1		0

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : KEYSERLING, HARRY
STUDY : 000412
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (75 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5	COMPLAINTS
LOCAL REACTIONS	19 (25.7%)	16 (21.6%)	5 (6.8%)	2 (2.7%)	0 (0.0%)	0 (0.0%)	31 (41.9%)
ERYTHEMA, INJ. SITE (>1 INCH)	0 (0.0%)	2 (2.7%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (2.7%)
ERYTHEMA, INJ. SITE (<=1 IN.)	3 (4.1%)	9 (12.2%)	3 (4.1%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	11 (14.9%)
PAIN/SORENESS, INJ. SITE	15 (20.3%)	5 (6.8%)	1 (1.4%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	19 (25.7%)
SWELLING, INJ. SITE (<=1 IN.)	4 (5.4%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	5 (6.8%)
SYSTEMIC	19 (25.7%)	22 (29.7%)	15 (20.3%)	12 (16.2%)	14 (18.9%)	13 (17.6%)	33 (44.6%)
BODY AS A WHOLE/SITE UNSPEC.	11 (14.9%)	7 (9.5%)	3 (4.1%)	2 (2.7%)	2 (2.7%)	4 (5.4%)	19 (25.7%)
FATIGUE	10 (13.5%)	4 (5.4%)	3 (4.1%)	2 (2.7%)	1 (1.4%)	2 (2.7%)	16 (21.6%)
FEVER	0 (0.0%)	1 (1.4%)	1 (1.4%)	1 (1.4%)	1 (1.4%)	1 (1.4%)	1 (1.4%)
WARM TO TOUCH	3 (4.1%)	4 (5.4%)	1 (1.4%)	1 (1.4%)	1 (1.4%)	1 (1.4%)	7 (9.5%)
DIGESTIVE SYSTEM	1 (1.4%)	7 (9.5%)	5 (6.8%)	5 (6.8%)	4 (5.4%)	3 (4.1%)	12 (16.2%)

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : KEYSERLING, HARRY
STUDY : 000412
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (75 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5	
ANOREXIA	0 (0.0%)	2 (2.7%)	1 (1.4%)	1 (1.4%)	1 (1.4%)	1 (1.4%)	2 (2.7%)
DIARRHEA	1 (1.4%)	4 (5.4%)	4 (5.4%)	3 (4.1%)	2 (2.7%)	1 (1.4%)	8 (10.8%)
NAUSEA	0 (0.0%)	1 (1.4%)	1 (1.4%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	1 (1.4%)
TEETHING	0 (0.0%)	0 (0.0%)	1 (1.4%)	1 (1.4%)	0 (0.0%)	1 (1.4%)	2 (2.7%)
VOMITING	0 (0.0%)	2 (2.7%)	0 (0.0%)	2 (2.7%)	1 (1.4%)	0 (0.0%)	3 (4.1%)
METABOLIC/NUTRITIONAL/IMMUNE	1 (1.4%)	1 (1.4%)	1 (1.4%)	1 (1.4%)	1 (1.4%)	1 (1.4%)	1 (1.4%)
HYPERSENSITIVITY	1 (1.4%)	1 (1.4%)	1 (1.4%)	1 (1.4%)	1 (1.4%)	1 (1.4%)	1 (1.4%)
NERVOUS SYSTEM & PSYCHIATRIC	14 (18.9%)	13 (17.6%)	4 (5.4%)	3 (4.1%)	4 (5.4%)	4 (5.4%)	27 (36.5%)
IRRITABILITY	14 (18.9%)	13 (17.6%)	4 (5.4%)	3 (4.1%)	3 (4.1%)	3 (4.1%)	26 (35.1%)
PROLONGED CRYING, >1/2 HR	1 (1.4%)	0 (0.0%)	0 (0.0%)	1 (1.4%)	1 (1.4%)	1 (1.4%)	3 (4.1%)
SLEEP DISORDERS	0 (0.0%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.4%)
RESPIRATORY SYSTEM	2 (2.7%)	5 (6.8%)	5 (6.8%)	5 (6.8%)	7 (9.5%)	6 (8.1%)	8 (10.8%)

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : KEYSERLING, HARRY
STUDY : 000412
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (75 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		
ASTHMA	1 (1.4%)	1 (1.4%)	1 (1.4%)	1 (1.4%)	1 (1.4%)	1 (1.4%)		1 (1.4%)
COMMON COLD	0 (0.0%)	1 (1.4%)	1 (1.4%)	1 (1.4%)	1 (1.4%)	1 (1.4%)		1 (1.4%)
COUGH	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.4%)	0 (0.0%)	1 (1.4%)		1 (1.4%)
NASAL CONGESTION	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.4%)	1 (1.4%)	1 (1.4%)		1 (1.4%)
NASAL DISCHARGE	1 (1.4%)	2 (2.7%)	2 (2.7%)	2 (2.7%)	2 (2.7%)	1 (1.4%)		3 (4.1%)
PHARYNGITIS	0 (0.0%)	0 (0.0%)	1 (1.4%)	1 (1.4%)	2 (2.7%)	2 (2.7%)		2 (2.7%)
UPPER RESPIRATORY INFECTION, NOS	0 (0.0%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (1.4%)
WHEEZING	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.4%)	1 (1.4%)		1 (1.4%)
SPECIAL SENSES	0 (0.0%)	0 (0.0%)	1 (1.4%)	1 (1.4%)	2 (2.7%)	2 (2.7%)		2 (2.7%)
CONJUNCTIVITIS	0 (0.0%)	0 (0.0%)	1 (1.4%)	1 (1.4%)	1 (1.4%)	1 (1.4%)		1 (1.4%)
OTITIS MEDIA	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.4%)	1 (1.4%)		1 (1.4%)
VACCINEES WITH COMPLAINTS	29 (39.2%)	33 (44.6%)	19 (25.7%)	13 (17.6%)	14 (18.9%)	13 (17.6%)		46 (62.2%)

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : KEYSERLING, HARRY
STUDY : 000412
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (75 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		**********
VACCINEES WITH NO COMPLAINTS	45 (60.8%)	41 (55.4%)	55 (74.3%)	61 (82.4%)	60 (81.1%)	61 (82.4%)		28 (37.8%)
TOTAL VACCINEES REPORTING	74	74	74	74	74	74		74
VACCINEES WITH NO DATA	1	1	1	1	1	1		1

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : KEYSERLING, HARRY
STUDY : 000412
VACCINE : HIB CONJUGATE
LOT NUMBER : CR132
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (3 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5	**********
VACCINEES WITH COMPLAINTS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
VACCINEES WITH NO COMPLAINTS	3 (100.0%)	3 (100.0%)	3 (100.0%)	3 (100.0%)	3 (100.0%)	3 (100.0%)	3 (100.0%)
TOTAL VACCINEES REPORTING	3	3	3	3	3	3	3
VACCINEES WITH NO DATA	0	0	0	0	0	0	0

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : KEYSERLING, HARRY
STUDY : 000412
VACCINE : HIB CONJUGATE
LOT NUMBER : CR132
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (6 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
LOCAL REACTIONS	2 (33.3%)	2 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		3 (50.0%)
ERYTHEMA, INJ. SITE (<=1 IN.)	1 (16.7%)	2 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (33.3%)
PAIN/SORENESS, INJ. SITE	1 (16.7%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (33.3%)
SWELLING, INJ. SITE (<=1 IN.)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (16.7%)
SYSTEMIC	2 (33.3%)	2 (33.3%)	2 (33.3%)	2 (33.3%)	2 (33.3%)	1 (16.7%)		4 (66.7%)
BODY AS A WHOLE/SITE UNSPEC.	2 (33.3%)	2 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		3 (50.0%)
FATIGUE	1 (16.7%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (33.3%)
PAIN	1 (16.7%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (16.7%)
WARM TO TOUCH	1 (16.7%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (16.7%)
DIGESTIVE SYSTEM	0 (0.0%)	1 (16.7%)	2 (33.3%)	1 (16.7%)	1 (16.7%)	0 (0.0%)		2 (33.3%)
DIARRHEA	0 (0.0%)	1 (16.7%)	2 (33.3%)	1 (16.7%)	1 (16.7%)	0 (0.0%)		2 (33.3%)

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : KEYSERLING, HARRY
STUDY : 000412
VACCINE : HIB CONJUGATE
LOT NUMBER : CR132
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (6 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5	
NAUSEA	0 (0.0%)	1 (16.7%)	1 (16.7%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
VOMITING	0 (0.0%)	1 (16.7%)	1 (16.7%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	2 (33.3%)
NERVOUS SYSTEM & PSYCHIATRIC	0 (0.0%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	1 (16.7%)	0 (0.0%)	2 (33.3%)
IRRITABILITY	0 (0.0%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	1 (16.7%)	0 (0.0%)	2 (33.3%)
RESPIRATORY SYSTEM	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)	1 (16.7%)	1 (16.7%)	1 (16.7%)
COUGH	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)	1 (16.7%)	1 (16.7%)	1 (16.7%)
NASAL DISCHARGE	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
SPECIAL SENSES	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)	1 (16.7%)	1 (16.7%)
CONJUNCTIVITIS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)	1 (16.7%)	1 (16.7%)
EAR INFECTION, NOS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)	1 (16.7%)	1 (16.7%)
VACCINEES WITH COMPLAINTS	4 (66.7%)	3 (50.0%)	2 (33.3%)	2 (33.3%)	2 (33.3%)	1 (16.7%)	6 (100.0%)
VACCINEES WITH NO COMPLAINTS	2 (33.3%)	3 (50.0%)	4 (66.7%)	4 (66.7%)	4 (66.7%)	5 (83.3%)	0 (0.0%)

00858

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : KEYSERLING, HARRY
STUDY : 000412
VACCINE : HIB CONJUGATE
LOT NUMBER : CR132
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (6 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5	COMPLAINTS
TOTAL VACCINEES REPORTING	6	6	6	6	6	6	6
VACCINEES WITH NO DATA	0	0	0	0	0	0	0

TABLE 7

MAXIMUM TEMPERATURES

INVESTIGATOR : KEYSERLING, HARRY
STUDY : 000412
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (9 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
< 99	4 (44.4%)	2 (22.2%)	4 (44.4%)	1 (11.1%)	2 (22.2%)	2 (22.2%)		1 (11.1%)
99 - 99.9	5 (55.6%)	6 (66.7%)	5 (55.6%)	7 (77.8%)	5 (55.6%)	6 (66.7%)		5 (55.6%)
100 - 100.9	0 (0.0%)	1 (11.1%)	0 (0.0%)	0 (0.0%)	1 (11.1%)	0 (0.0%)		2 (22.2%)
101 - 101.9	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (11.1%)	1 (11.1%)	0 (0.0%)		0 (0.0%)
102 - 102.9	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (11.1%)		1 (11.1%)
TEMPERATURE TAKEN	9 (100.0%)	9 (100.0%)	9 (100.0%)	9 (100.0%)	9 (100.0%)	9 (100.0%)		9 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)

00800

TABLE 7 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : KEYSERLING, HARRY
STUDY : 000412
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (9 VACCINEES) - INJECTION 2							
	DAYS POST VACCINATION							NUMBER WITH
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		MAX TEMP
< 99	4 (44.4%)	6 (66.7%)	4 (44.4%)	4 (44.4%)	5 (55.6%)	4 (44.4%)		2 (22.2%)
99 - 99.9	4 (44.4%)	3 (33.3%)	5 (55.6%)	5 (55.6%)	4 (44.4%)	5 (55.6%)		6 (66.7%)
100 - 100.9	1 (11.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (11.1%)
TEMPERATURE TAKEN	9 (100.0%)	9 (100.0%)	9 (100.0%)	9 (100.0%)	9 (100.0%)	9 (100.0%)		9 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)

TABLE 7 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : KEYSERLING, HARRY
STUDY : 000412
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (16 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
< 99	10 (62.5%)	8 (50.0%)	10 (62.5%)	10 (62.5%)	10 (62.5%)	10 (62.5%)		7 (43.8%)
99 - 99.9	5 (31.3%)	6 (37.5%)	6 (37.5%)	5 (31.3%)	4 (25.0%)	5 (31.3%)		6 (37.5%)
100 - 100.9	0 (0.0%)	1 (6.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (6.3%)
101 - 101.9	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (6.3%)	2 (12.5%)	1 (6.3%)		1 (6.3%)
102 - 102.9	1 (6.3%)	1 (6.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (6.3%)
TEMPERATURE TAKEN	16 (100.0%)	16 (100.0%)	16 (100.0%)	16 (100.0%)	16 (100.0%)	16 (100.0%)		16 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)

TABLE 7 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : KEYSERLING, HARRY
STUDY : 000412
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (21 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
< 99	9 (42.9%)	11 (52.4%)	11 (57.9%)	10 (47.6%)	11 (52.4%)	10 (47.6%)		5 (23.8%)
99 - 99.9	11 (52.4%)	8 (38.1%)	7 (36.8%)	10 (47.6%)	9 (42.9%)	10 (47.6%)		14 (66.7%)
100 - 100.9	1 (4.8%)	2 (9.5%)	1 (5.3%)	1 (4.8%)	1 (4.8%)	0 (0.0%)		1 (4.8%)
101 - 101.9	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (4.8%)		1 (4.8%)
TEMPERATURE TAKEN	21 (100.0%)	21 (100.0%)	19 (90.5%)	21 (100.0%)	21 (100.0%)	21 (100.0%)		21 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	0 (0.0%)	2 (9.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)

TABLE 7 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : KEYSERLING, HARRY
STUDY : 000412
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (21 VACCINEES) - INJECTION 2							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
< 99	16 (76.2%)	15 (71.4%)	13 (61.9%)	17 (85.0%)	12 (57.1%)	13 (65.0%)		8 (38.1%)
99 - 99.9	5 (23.8%)	6 (28.6%)	8 (38.1%)	3 (15.0%)	8 (38.1%)	7 (35.0%)		12 (57.1%)
100 - 100.9	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (4.8%)	0 (0.0%)		1 (4.8%)
TEMPERATURE TAKEN	21 (100.0%)	21 (100.0%)	21 (100.0%)	20 (95.2%)	21 (100.0%)	20 (95.2%)		21 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (4.8%)	0 (0.0%)	1 (4.8%)		0 (0.0%)

TABLE 7 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : KEYSERLING, HARRY
STUDY : 000412
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (13 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
NORMAL	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.7%)	1 (7.7%)		0 (0.0%)
< 99	8 (61.5%)	5 (38.5%)	6 (46.2%)	8 (61.5%)	7 (53.8%)	7 (53.8%)		2 (15.4%)
99 - 99.9	3 (23.1%)	8 (61.5%)	7 (53.8%)	4 (30.8%)	4 (30.8%)	4 (30.8%)		9 (69.2%)
100 - 100.9	2 (15.4%)	0 (0.0%)	0 (0.0%)	1 (7.7%)	1 (7.7%)	1 (7.7%)		2 (15.4%)
TEMPERATURE TAKEN	13 (100.0%)	13 (100.0%)	13 (100.0%)	13 (100.0%)	13 (100.0%)	13 (100.0%)		13 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)

TABLE 7 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : KEYSERLING, HARRY
STUDY : 000412
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (69 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
< 99	41 (61.2%)	28 (41.8%)	38 (55.9%)	34 (50.7%)	36 (52.9%)	39 (58.2%)		16 (23.2%)
99 - 99.9	20 (29.9%)	31 (46.3%)	25 (36.8%)	28 (41.8%)	29 (42.6%)	24 (35.8%)		37 (53.6%)
100 - 100.9	1 (1.5%)	5 (7.5%)	4 (5.9%)	3 (4.5%)	2 (2.9%)	3 (4.5%)		6 (8.7%)
101 - 101.9	3 (4.5%)	2 (3.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.5%)		4 (5.8%)
102 - 102.9	2 (3.0%)	0 (0.0%)	0 (0.0%)	1 (1.5%)	1 (1.5%)	0 (0.0%)		3 (4.3%)
103 - 103.9	0 (0.0%)	1 (1.5%)	1 (1.5%)	1 (1.5%)	0 (0.0%)	0 (0.0%)		3 (4.3%)
TEMPERATURE TAKEN	67 (97.1%)	67 (97.1%)	68 (98.6%)	67 (97.1%)	68 (98.6%)	67 (97.1%)		69 (100.0%)
TEMPERATURE NOT TAKEN	2 (2.9%)	2 (2.9%)	1 (1.4%)	2 (2.9%)	1 (1.4%)	2 (2.9%)		0 (0.0%)

99866

TABLE 7 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : KEYSERLING, HARRY
STUDY : 000412
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE — NUMBER OF VACCINEES (31 VACCINEES) - INJECTION 2

MAX TEMPERATURE (DEG F, ORAL)	DAYS POST VACCINATION 0	1	2	3	4	5		NUMBER WITH MAX TEMP
< 99	16 (51.6%)	15 (50.0%)	17 (58.6%)	14 (46.7%)	14 (46.7%)	17 (60.7%)		7 (22.6%)
99 - 99.9	11 (35.5%)	11 (36.7%)	8 (27.6%)	15 (50.0%)	14 (46.7%)	9 (32.1%)		15 (48.4%)
100 - 100.9	0 (0.0%)	2 (6.7%)	3 (10.3%)	0 (0.0%)	1 (3.3%)	1 (3.6%)		3 (9.7%)
101 - 101.9	3 (9.7%)	2 (6.7%)	1 (3.4%)	1 (3.3%)	1 (3.3%)	0 (0.0%)		4 (12.9%)
102 - 102.9	1 (3.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (3.2%)
103 - 103.9	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.6%)		1 (3.2%)
TEMPERATURE TAKEN	31 (100.0%)	30 (96.8%)	29 (93.5%)	30 (96.8%)	30 (96.8%)	28 (90.3%)		31 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	1 (3.2%)	2 (6.5%)	1 (3.2%)	1 (3.2%)	3 (9.7%)		0 (0.0%)

TABLE 7 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : KEYSERLING, HARRY
STUDY : 000412
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (75 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
NORMAL	2 (2.7%)	3 (4.1%)	3 (4.1%)	3 (4.1%)	3 (4.1%)	3 (4.1%)		2 (2.7%)
< 99	42 (56.8%)	43 (58.9%)	49 (66.2%)	47 (64.4%)	51 (69.9%)	51 (69.9%)		20 (27.0%)
99 - 99.9	24 (32.4%)	22 (30.1%)	20 (27.0%)	22 (30.1%)	16 (21.9%)	17 (23.3%)		39 (52.7%)
100 - 100.9	4 (5.4%)	3 (4.1%)	2 (2.7%)	1 (1.4%)	2 (2.7%)	1 (1.4%)		8 (10.8%)
101 - 101.9	1 (1.4%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.4%)		2 (2.7%)
102 - 102.9	1 (1.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.4%)	0 (0.0%)		2 (2.7%)
103 - 103.9	0 (0.0%)	1 (1.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (1.4%)
TEMPERATURE TAKEN	74 (98.7%)	73 (97.3%)	74 (98.7%)	73 (97.3%)	73 (97.3%)	73 (97.3%)		74 (98.7%)
TEMPERATURE NOT TAKEN	1 (1.3%)	2 (2.7%)	1 (1.3%)	2 (2.7%)	2 (2.7%)	2 (2.7%)		1 (1.3%)

TABLE 7 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : KEYSERLING, HARRY
STUDY : 000412
VACCINE : HIB CONJUGATE
LOT NUMBER : CR132
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (3 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		MAX TEMP
< 99	2 (66.7%)	2 (66.7%)	2 (66.7%)	2 (66.7%)	2 (66.7%)	2 (66.7%)		2 (66.7%)
99 - 99.9	1 (33.3%)	1 (33.3%)	1 (33.3%)	0 (0.0%)	1 (33.3%)	1 (33.3%)		0 (0.0%)
100 - 100.9	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)		1 (33.3%)
TEMPERATURE TAKEN	3 (100.0%)	3 (100.0%)	3 (100.0%)	3 (100.0%)	3 (100.0%)	3 (100.0%)		3 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)

TABLE 7 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : KEYSERLING, HARRY
STUDY : 000412
VACCINE : HIB CONJUGATE
LOT NUMBER : CR132
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (6 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
< 99	4 (66.7%)	4 (66.7%)	4 (66.7%)	3 (60.0%)	4 (66.7%)	4 (66.7%)		3 (50.0%)
99 - 99.9	2 (33.3%)	1 (16.7%)	2 (33.3%)	1 (20.0%)	1 (16.7%)	2 (33.3%)		1 (16.7%)
100 - 100.9	0 (0.0%)	1 (16.7%)	0 (0.0%)	1 (20.0%)	1 (16.7%)	0 (0.0%)		2 (33.3%)
TEMPERATURE TAKEN	6 (100.0%)	6 (100.0%)	6 (100.0%)	5 (83.3%)	6 (100.0%)	6 (100.0%)		6 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)	0 (0.0%)	0 (0.0%)		0 (0.0%)

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PRODUCT LICENSE APPLICATION

PLA-0002-XXX-HC48 vol. 4

Merck and Co., Inc.
Haemophilus b Conjugate Vaccine
(Meningococcal Protein Conjugate)

8-6-1



DCC Volume Sequence No. 000196

87-C54 continued

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August 31, 1988

Clinical Report
in Support of a Product License Application
for
PEDVAX-HIB ™
Haemophilus b Conjugate Vaccine
(*Neisseria meningitidis* Outer Membrane Protein Complex)
Volume 3 of 4
Merck Sharp & Dohme Research Laboratories

PROGRAM: Haemophilus b Conjugate Vaccine (Neisseria meningitidis Outer Membrane Protein Complex), Study #0004-13.

PURPOSE: To evaluate the safety and immunogenicity of Haemophilus b Conjugate Vaccine (Neisseria meningitidis Outer Membrane Protein Complex) in healthy infants and children 2 months to 5 years of age.

VACCINE: Haemophilus b Conjugate Vaccine (Neisseria meningitidis Outer Membrane Protein Complex).

Lot 1069/C-P241 - (b) (4) mcg polysaccharide/ml
(b) (4) mcg meningococcal protein/ml
Lot 1080/C-P749 - (b) (4) polysaccharide/ml
(b) (4) mcg meningococcal protein/ml

Diluent
Aluminum hydroxide diluent
Lot (b) (4)

INVESTIGATOR: Georges Peter, M.D.
Division of Pediatric Infectious Diseases
Rhode Island Hospital
593 Eddy Street
Providence, Rhode Island 02902

SUB-INVESTIGATOR: Fernando J. Indacochea, M.D.

STUDY LOCATION: Rhode Island Hospital
593 Eddy Street
Providence, Rhode Island 02902

DATE INITIATED: June 9, 1987

DATE COMPLETED: In progress.

STUDY POPULATION: Healthy infants and children 2 to 71 months of age are included in the study.

STUDY PROCEDURE: Infants 2 to 11 months of age receive 2 injections of the vaccine given 2 months apart, while children 12 months of age and older receive a single injection. Vaccine is reconstituted in aluminum hydroxide and administered by intramuscular route. The dose for each injection is 15 mcg polysaccharide in the appropriate volume - 0.75 ml for Lot 1069/C-P241 and 0.5 ml for Lot 1080/C-P749.

Parents or guardians are required to record the vaccinee's temperature and any systemic or injection site reactions for 5 days after each injection. Unexpected or serious reactions are to be reported immediately to the study physician.

A blood sample is obtained immediately before each injection and one month after the last (or only) injection. Additional samples are obtained 7 to 10 months after the last injection for infants 2 to 11 months of age and at 15 to 18 months postvaccination for children 12 to 71 months of age.

All serum samples are assayed by Merck Sharp & Dohme Research Laboratories for antibody to H. influenzae type b capsular polysaccharide by radioimmunoassay (RIA). Selected samples are also tested for serum bactericidal activity, quantitation of IgG_1 and IgG_2 subclass, and IgM and total IgG antibodies. Testing for opsonophagocytic activity was done at the University of Alabama.

RESULTS: Demographic information and individual pre and postvaccination antibody data for each vaccinee enrolled in the study is reported in Table 1 and 2.

1. Number Vaccinated:

Lot	Age	Injection No. 1	Injection No. 2
1069/C-P241	2-11 mo.	5	4
	12-71 mo.	17	--
1080/C-P749	2-11 mo.	10	7
	12-71 mo.	15	--

2. Serologic Results

Antibody responses (RIA) prior to and after vaccination are as follows:

Age	Time	% With Anti-PRP >0.15 mcg Ab/ml	% With Anti-PRP >1.0 mcg Ab/ml	GMT (mcg Ab/ml) All Vaccinees
2-11 mo.	Pre	20 (1/5)	0 (0/5)	0.09
	2 mo.	100 (5/5)	80 (4/5)	2.04
	3 mo.	100 (4/4)	100 (4/4)	9.11
12-71 mo.	Pre	17 (4/23)	4 (1/23)	0.10
	1 mo.	100 (23/23)	96 (22/23)	7.06

Antibody responses (by lot per age group) prior to vaccination through 3 months postvaccination are included in Tables 3 and 4.

RESULTS: (CONT.)

4. Clinical Results:

The frequencies of selected injection site and systemic reactions during the 48 hours after vaccination are as follows:

	% Vaccinees with Reactions		
	2 - 11 Months of Age		12 - 71 Months of Age
Type of Reaction	Injection 1	Injection 2	Injection 1
Injection Site			
Erythema >1 inch	0.0 (0/15)	0.0 (0/11)	0.0 (0/30)
Swelling >1 inch	0.0 (0/15)	0.0 (0/11)	0.0 (0/30)
Pain/Soreness	0.0 (0/15)	0.0 (0/11)	6.7 (2/30)
Systemic			
Irritability	26.7 (4/15)	18.2 (2/11)	30.0 (9/30)
Sleepiness/ Lethargy/Fatigue	33.3 (5/15)	18.2 (2/11)	13.3 (4/30)

Reaction frequencies and maximum temperatures recorded during the five days following each injection of vaccine are reported in Tables 5-7.

No serious or alarming reactions attributable to the vaccine were reported.

TABLE 1

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : GEORGES PETER
STUDY : 000413
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	F	CAUC	(b) (6)	11M	0	(b) (6)	001	PREBLEED				< 125				0
					0		011	INJ 1	CP241	15 MCG						
					28		011	BLEED 1				1573				76
	F	CAUC		10M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP241	15 MCG						
					61		011	BLEED 1				41561				
					81		021	INJ 2	CP241	15 MCG						
					134		021	BLEED 2			05/	29293				
	M	CAUC		11M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP241	15 MCG						
					61		011	BLEED 1				1789				
					74		021	INJ 2	CP241	15 MCG						
					116		021	BLEED 2			05/	7140				
	F	CAUC		9M	0		001	PREBLEED				317				
					0		011	INJ 1	CP241	15 MCG						
					61		011	BLEED 1				3581				
					61		021	INJ 2	CP241	15 MCG						
					89		021	BLEED 2				4946				
	F	HISP		10M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP241	15 MCG						
					82		011	BLEED 1			05/	7214				
					82		021	INJ 2	CP241	15 MCG						
					124		021	BLEED 2			05/	59631				
	F	CAUC		6M	0		001	PREBLEED				< 125		< 2		
					0		011	INJ 1	CP749	15 MCG						
					59		011	BLEED 1				1067		< 2		
					59		021	INJ 2	CP749	15 MCG						
					92		021	BLEED 2				9302		>= 32		
	F	CAUC		10M	0		001	PREBLEED				< 125		< 2		
					0		011	INJ 1	CP749	15 MCG						
					69		011	BLEED 1				11584		>= 32		
					69		021	INJ 2	CP749	15 MCG						
					98		021	BLEED 2				65723		>= 32		
	F	CAUC		7M	0		001	PREBLEED				< 125		< 2		

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : GEORGES PETER
STUDY : 000413
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	F	CAUC	(b) (6)	7M	0	(b) (6)	011	INJ	1	CP749	15 MCG					
					65		011	BLEED	1			2163		8		
					65		021	INJ	2	CP749	15 MCG					
					99		021	BLEED	2			2281		>= 32		
	F	CAUC		10M	0		001	PREBLEED				< 125		< 2		
					0		011	INJ	1	CP749	15 MCG					
					55		011	BLEED	1			230		8		
					71		021	INJ	2	CP749	15 MCG					
					104		021	BLEED	2			694	05/	B		
	F	CAUC		8M	0		001	PREBLEED				< 125				
					0		011	INJ	1	CP749	15 MCG					
					63		011	BLEED	1			373				
					63		021	INJ	2	CP749	15 MCG					
	M	CAUC		2M	0		011	INJ	1	CP749	15 MCG					
					98		021	INJ	2	CP749	15 MCG					
	M	CAUC		4M	0		011	INJ	1	CP749	15 MCG					
	F	CAUC		4M	0		001	PREBLEED				< 125				
					0		011	INJ	1	CP749	15 MCG					
					73		011	BLEED	1			1511	05/			
					73		021	INJ	2	CP749	15 MCG					
	F	CAUC		7M	0		011	INJ	1	CP749	15 MCG					
	M	CAUC		5M	0		011	INJ	1	CP749	15 MCG					

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : GEORGES PETER
STUDY : 000413
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	F	CAUC	(b) (6)	14M	0	(b) (6)	001	PREBLEED				< 125				0
					0		011	INJ 1	CP241	15 MCG						
					23		011	BLEED 1				3474				78
	F	CAUC		14M	0		001	PREBLEED				169				0
					0		011	INJ 1	CP241	15 MCG						
					28		011	BLEED 1				144790				97
	F	CAUC		12M	0		001	PREBLEED				128				0
					0		011	INJ 1	CP241	15 MCG						
					30		011	BLEED 1				7925				94
	F	CAUC		13M	0		001	PREBLEED				183				0
					0		011	INJ 1	CP241	15 MCG						
					36		011	BLEED 1				7346				97
	M	CAUC		15M	0		011	INJ 1	CP241	15 MCG						
	F	CAUC		12M	0		001	PREBLEED				150				3
					0		011	INJ 1	CP241	15 MCG						
					36		011	BLEED 1				2708				97
	M	CAUC		12M	0		001	PREBLEED				< 125				0
					0		011	INJ 1	CP241	15 MCG						
					36		011	BLEED 1				4089				92
	M	CAUC		12M	0		001	PREBLEED				353				
					0		011	INJ 1	CP241	15 MCG						
					28		011	BLEED 1				9436				
	M	CAUC		12M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP241	15 MCG						
					43		011	BLEED 1				565				
	F	CAUC		16M	-1		001	PREBLEED				< 125				
					0		011	INJ 1	CP241	15 MCG						
					34		011	BLEED 1				23025				
	F	CAUC		23M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP241	15 MCG						

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : GEORGES PETER
STUDY : 000413
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ RIA	CODE/ SBA	CODE/ OPSO
(b) (6)	F	CAUC	(b) (6)	23M	32	(b) (6)	011	BLEED 1			31351		
	M	CAUC		23M	0		001	PREBLEED			< 125		
					0		011	INJ 1	CP241	15 MCG			
					32		011	BLEED 1			8832		
	F	CAUC		13M	0		001	PREBLEED			< 125		
					0		011	INJ 1	CP241	15 MCG			
					32		011	BLEED 1			11248		
	F	CAUC		13M	0		001	PREBLEED			< 125		
					0		011	INJ 1	CP241	15 MCG			
					29		011	BLEED 1			8268		
	F	CAUC		13M	0		001	PREBLEED			< 125		
					0		011	INJ 1	CP241	15 MCG			
					35		011	BLEED 1			60797		
	M	CAUC		14M	0		001	PREBLEED			< 125		
					0		011	INJ 1	CP241	15 MCG			
					40		011	BLEED 1			7909		
	M	CAUC		21M	0		001	PREBLEED			< 125		
					0		011	INJ 1	CP241	15 MCG			
					42		011	BLEED 1			4078		
	F	CAUC		24M	0		001	PREBLEED			< 125	< 5	49
					0		011	INJ 1	CP749	15 MCG			
					48		011	BLEED 1			22142	>= 80	100
	M	CAUC		12M	0		001	PREBLEED			< 125	< 5	0
					0		011	INJ 1	CP749	15 MCG			
					28		011	BLEED 1			1646	>= 80	96
	M	CAUC		13M	0		001	PREBLEED			< 125	< 5	
					0		011	INJ 1	CP749	15 MCG			
					35		011	BLEED 1			1816	20	
	M	CAUC		12M	0		001	PREBLEED			< 125	< 5	
					0		011	INJ 1	CP749	15 MCG			

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : GEORGES PETER
STUDY : 000413
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	CAUC	(b) (6)	12M	35	(b) (6)	011	BLEED	1			2487		5		
	F	CAUC		12M	0		001	PREBLEED				4916		< 5		
					0		011	INJ	1	CP749	15 MCG					
					35		011	BLEED	1			5942		5		
	M	HISP		12M	0		001	PREBLEED				< 125		< 5		
					0		011	INJ	1	CP749	15 MCG					
					33		011	BLEED	1			1827		5		
	M	CAUC		12M	0		001	PREBLEED				142		< 5		
					0		011	INJ	1	CP749	15 MCG					
					29		011	BLEED	1			9339		>= 80		
	F	CAUC		12M	0		011	INJ	1	CP749	15 MCG					
					32		011	BLEED	1			890				
	M	CAUC		13M	0		011	INJ	1	CP749	15 MCG					
	F	CAUC		12M	0		011	INJ	1	CP749	15 MCG					
	F	CAUC		13M	0		011	INJ	1	CP749	15 MCG					
	M	CAUC		14M	0		011	INJ	1	CP749	15 MCG					
	F	CAUC		14M	0		011	INJ	1	CP749	15 MCG					
	M	CAUC		13M	0		011	INJ	1	CP749	15 MCG					
	M	CAUC		15M	0		011	INJ	1	CP749	15 MCG					

TABLE 2

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : GEORGES PETER
STUDY : 000413
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT		LOT	DOSE	CODE/ IGG1	CODE/ IGG2	CODE/ IGGM	CODE/IGG TOTAL
(b) (6)	F	CAUC	(b) (6)	11M	0	(b) (6)	011	INJ	1	CP241	15 MCG				
	F	CAUC		10M	0		011	INJ	1	CP241	15 MCG				
					81		021	INJ	2	CP241	15 MCG				
	M	CAUC		11M	0		011	INJ	1	CP241	15 MCG				
					74		021	INJ	2	CP241	15 MCG				
	F	CAUC		9M	0		011	INJ	1	CP241	15 MCG				
					61		021	INJ	2	CP241	15 MCG				
	F	HISP		10M	0		011	INJ	1	CP241	15 MCG				
					82		021	INJ	2	CP241	15 MCG				
	F	CAUC		6M	0		011	INJ	1	CP749	15 MCG				
					59		021	INJ	2	CP749	15 MCG				
	F	CAUC		10M	0		011	INJ	1	CP749	15 MCG				
					69		021	INJ	2	CP749	15 MCG				
	F	CAUC		7M	0		011	INJ	1	CP749	15 MCG				
					65		021	INJ	2	CP749	15 MCG				
	F	CAUC		10M	0		011	INJ	1	CP749	15 MCG				
					71		021	INJ	2	CP749	15 MCG				
	F	CAUC		8M	0		011	INJ	1	CP749	15 MCG				
					63		021	INJ	2	CP749	15 MCG				
	M	CAUC		2M	0		011	INJ	1	CP749	15 MCG				
					98		021	INJ	2	CP749	15 MCG				
	M	CAUC		4M	0		011	INJ	1	CP749	15 MCG				
	F	CAUC		4M	0		011	INJ	1	CP749	15 MCG				
					73		021	INJ	2	CP749	15 MCG				
	F	CAUC		7M	0		011	INJ	1	CP749	15 MCG				
	M	CAUC		5M	0		011	INJ	1	CP749	15 MCG				

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : GEORGES PETER
STUDY : 000413
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ IGG1	CODE/ IGG2	CODE/ IGGM	CODE/IGG TOTAL
(b) (6)	F	CAUC	(b) (6)	14M	0	(b) (6)	011	INJ 1	CP241	15 MCG				
	F	CAUC		14M	0		011	INJ 1	CP241	15 MCG				
	F	CAUC		12M	0		011	INJ 1	CP241	15 MCG				
	F	CAUC		13M	0		011	INJ 1	CP241	15 MCG				
	M	CAUC		15M	0		011	INJ 1	CP241	15 MCG				
	F	CAUC		12M	0		011	INJ 1	CP241	15 MCG				
	M	CAUC		12M	0		011	INJ 1	CP241	15 MCG				
	M	CAUC		12M	0		011	INJ 1	CP241	15 MCG				
	M	CAUC		12M	0		011	INJ 1	CP241	15 MCG				
	F	CAUC		16M	0		011	INJ 1	CP241	15 MCG				
	F	CAUC		23M	0		001	PREBLEED			< 600			
					0		011	INJ 1	CP241	15 MCG				
					32		011	BLEED 1			23300			
	M	CAUC		23M	0		001	PREBLEED			< 600			
					0		011	INJ 1	CP241	15 MCG				
					32		011	BLEED 1			14193			
	F	CAUC		13M	0		011	INJ 1	CP241	15 MCG				
	F	CAUC		13M	0		011	INJ 1	CP241	15 MCG				
	F	CAUC		13M	0		001	PREBLEED					< 100	< 100
					0		011	INJ 1	CP241	15 MCG				
					35		011	BLEED 1					386	1537
	M	CAUC		14M	0		011	INJ 1	CP241	15 MCG				
	M	CAUC		21M	0		001	PREBLEED			< 600			
					0		011	INJ 1	CP241	15 MCG				

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : GEORGES PETER
STUDY : 000413
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ IGG1	CODE/ IGG2	CODE/ IGGM	CODE/IGG TOTAL
(b) (6)	M	CAUC	(b) (6)	21M	42	(b) (6)	011	BLEED 1			7171			
	F	CAUC		24M	0		001	PREBLEED			< 600	< 250	336	< 100
					0		011	INJ 1	CP749	15 MCG				
					48		011	BLEED 1			52672	756	1663	4262
	M	CAUC		12M	0		001	PREBLEED			< 600		< 100	< 100
					0		011	INJ 1	CP749	15 MCG				
					28		011	BLEED 1			1199		1069	104
	M	CAUC		13M	0		011	INJ 1	CP749	15 MCG				
	M	CAUC		12M	0		011	INJ 1	CP749	15 MCG				
	F	CAUC		12M	0		011	INJ 1	CP749	15 MCG				
	M	HISP		12M	0		011	INJ 1	CP749	15 MCG				
	M	CAUC		12M	0		011	INJ 1	CP749	15 MCG				
	F	CAUC		12M	0		011	INJ 1	CP749	15 MCG				
	M	CAUC		13M	0		011	INJ 1	CP749	15 MCG				
	F	CAUC		12M	0		011	INJ 1	CP749	15 MCG				
	F	CAUC		13M	0		011	INJ 1	CP749	15 MCG				
	M	CAUC		14M	0		011	INJ 1	CP749	15 MCG				
	F	CAUC		14M	0		011	INJ 1	CP749	15 MCG				
	M	CAUC		13M	0		011	INJ 1	CP749	15 MCG				
	M	CAUC		15M	0		011	INJ 1	CP749	15 MCG				

TABLE 3

ANTIBODY RESPONSES

INVESTIGATOR : GEORGES PETER
STUDY : 000413
VACCINE : HIB CONJUGATE
ASSAY : RIA
LOT NUMBER : CP241
DOSE : 15 MCG
POPULATION : HEALTHY CHILDREN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
7-11 MOS.	PRE INJ	100 (1/ 1)	0 (0/ 1)			0.317 (1)
	MONTH 2	100 (1/ 1)	100 (1/ 1)	100 (1/ 1)	11.3	3.581 (1)
	MONTH 3	100 (1/ 1)	100 (1/ 1)	100 (1/ 1)	15.6	4.946 (1)
12-71 MOS.	PRE INJ	19 (3/ 16)	0 (0/ 16)			0.088 (16)
	MONTH 1	100 (16/ 16)	94 (15/ 16)	100 (16/ 16)	64.2	9.046 (16)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 4

A N T I B O D Y R E S P O N S E S

INVESTIGATOR : GEORGES PETER
STUDY : 000413
VACCINE : HIB CONJUGATE
ASSAY : RIA
LOT NUMBER : CP749
DOSE : 15 MCG
POPULATION : HEALTHY CHILDREN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
1- 6 MOS.	PRE INJ	0 (0/ 1)	0 (0/ 1)			0.063 (1)
	MONTH 2	100 (1/ 1)	100 (1/ 1)	100 (1/ 1)	8.5	1.067 (1)
	MONTH 3	100 (1/ 1)	100 (1/ 1)	100 (1/ 1)	74.4	9.302 (1)
7-11 MOS.	PRE INJ	0 (0/ 3)	0 (0/ 3)			0.063 (3)
	MONTH 2	100 (3/ 3)	67 (2/ 3)	100 (3/ 3)	16.9	2.106 (3)
	MONTH 3	100 (2/ 2)	100 (2/ 2)	100 (2/ 2)	98.0	12.244 (2)
12-71 MOS.	PRE INJ	14 (1/ 7)	14 (1/ 7)			0.131 (7)
	MONTH 1	100 (7/ 7)	100 (7/ 7)	86 (6/ 7)	18.6	4.011 (7)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 5

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : GEORGES PETER
STUDY : 000413
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES	5	
VACCINEES WITH NO COMPLAINTS	2	(40.0 %)
VACCINEES WITH COMPLAINTS	3	(60.0 %)
VACCINEES WITH NO DATA	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 5 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	0	0.0
SYSTEMIC REACTIONS	3	60.0
DIARRHEA	2	40.0
TEETHING	2	40.0
ATOPIC DERMATITIS	1	20.0
COMMON COLD	1	20.0
COUGH	1	20.0
FATIGUE	1	20.0
FEVER	1	20.0
FLUSHING	1	20.0
IRRITABILITY	1	20.0
OTALGIA	1	20.0
WARM TO TOUCH	1	20.0

TABLE 5 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : GEORGES PETER
STUDY : 000413
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 2	
TOTAL VACCINEES :	4	
VACCINEES WITH NO COMPLAINTS :	1	(25.0 %)
VACCINEES WITH COMPLAINTS :	3	(75.0 %)
VACCINEES WITH NO DATA :	0	

CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 4 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	0	0.0
SYSTEMIC REACTIONS	3	75.0
FATIGUE	1	25.0
IRRITABILITY	1	25.0
TEETHING	1	25.0
URTICARIA	1	25.0
WARM TO TOUCH	1	25.0

TABLE 5 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : GEORGES PETER
STUDY : 000413
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
POPULATION : HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	17	
VACCINEES WITH NO COMPLAINTS :	5	(29.4 %)
VACCINEES WITH COMPLAINTS :	12	(70.6 %)
VACCINEES WITH NO DATA :	0	

CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 17 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	3	17.6
ERYTHEMA, INJ. SITE (<=1 IN.)	2	11.8
PAIN/SORENESS, INJ. SITE	1	5.9
SYSTEMIC REACTIONS	12	70.6
IRRITABILITY	6	35.3
TEETHING	6	35.3
DIARRHEA	4	23.5
FATIGUE	3	17.6
SLEEP DISORDERS	2	11.8
VOMITING	2	11.8
COUGH	1	5.9
IMPETIGO	1	5.9
NASAL CONGESTION	1	5.9
NAUSEA	1	5.9
OTITIS MEDIA	1	5.9
PROLONGED CRYING, >1/2 HR	1	5.9
RHINITIS	1	5.9
UPPER RESPIRATORY INFECTION, NOS	1	5.9
URTICARIA	1	5.9
WARM TO TOUCH	1	5.9

TABLE 5 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : GEORGES PETER
STUDY : 000413
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

	HIB CONJUGATE INJECTION: 1	
VACCINE :		
TOTAL VACCINEES :	10	
VACCINEES WITH NO COMPLAINTS :	1	(10.0 %)
VACCINEES WITH COMPLAINTS :	9	(90.0 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 10 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	1	10.0
ERYTHEMA, INJ. SITE (<=1 IN.)	1	10.0
SYSTEMIC REACTIONS	8	80.0
FATIGUE	5	50.0
IRRITABILITY	4	40.0
TEETHING	4	40.0
DIARRHEA	2	20.0
PROLONGED CRYING, >1/2 HR	2	20.0
UPPER RESPIRATORY INFECTION, NOS	2	20.0
CONSTIPATION	1	10.0
FLATULENCE	1	10.0
GASTROENTERITIS, NONINFECTIOUS	1	10.0
RASH	1	10.0
RHINITIS	1	10.0
VOMITING	1	10.0
WARM TO TOUCH	1	10.0
WHEEZING	1	10.0

TABLE 5 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : GEORGES PETER
STUDY : 000413
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 2	
TOTAL VACCINEES :	7	
VACCINEES WITH NO COMPLAINTS :	2	(28.6 %)
VACCINEES WITH COMPLAINTS :	5	(71.4 %)
VACCINEES WITH NO DATA :	0	

CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 7 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	2	28.6
ERYTHEMA, INJ. SITE (<=1 IN.)	2	28.6
SYSTEMIC REACTIONS	4	57.1
OTITIS MEDIA	3	42.9
IRRITABILITY	2	28.6
WARM TO TOUCH	2	28.6
FATIGUE	1	14.3
RHINITIS	1	14.3
SEROUS OTITIS MEDIA	1	14.3
TEETHING	1	14.3
UPPER RESPIRATORY INFECTION, NOS	1	14.3

TABLE 5 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : GEORGES PETER
STUDY : 000413
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
POPULATION : HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	15	
VACCINEES WITH NO COMPLAINTS :	7	(53.8 %)
VACCINEES WITH COMPLAINTS :	6	(46.2 %)
VACCINEES WITH NO DATA :	2	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 13 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	4	30.8
ERYTHEMA, INJ. SITE (<=1 IN.)	3	23.1
PAIN/SORENESS, INJ. SITE	1	7.7
SWELLING, INJ. SITE (<=1 IN.)	1	7.7
SYSTEMIC REACTIONS	6	46.2
IRRITABILITY	5	38.5
FATIGUE	3	23.1
TEETHING	3	23.1
INSOMNIA	1	7.7
HARM TO TOUCH	1	7.7

TABLE 6

CLINICAL COMPLAINTS

INVESTIGATOR : GEORGES PETER
STUDY : 000413
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (5 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5	COMPLAINTS
SYSTEMIC	3 (60.0%)	3 (60.0%)	3 (60.0%)	3 (60.0%)	3 (60.0%)	3 (60.0%)	3 (60.0%)
BODY AS A WHOLE/SITE UNSPEC.	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)	1 (20.0%)	2 (40.0%)
FATIGUE	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)
FEVER	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)
HARM TO TOUCH	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)
DIGESTIVE SYSTEM	3 (60.0%)	3 (60.0%)	3 (60.0%)	3 (60.0%)	3 (60.0%)	3 (60.0%)	3 (60.0%)
DIARRHEA	1 (20.0%)	1 (20.0%)	2 (40.0%)	2 (40.0%)	1 (20.0%)	1 (20.0%)	2 (40.0%)
TEETHING	2 (40.0%)	2 (40.0%)	2 (40.0%)	2 (40.0%)	2 (40.0%)	2 (40.0%)	2 (40.0%)
NERVOUS SYSTEM & PSYCHIATRIC	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)
IRRITABILITY	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)
RESPIRATORY SYSTEM	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : GEORGES PETER
STUDY : 000413
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (5 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
COMMON COLD	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)	1 (20.0%)		1 (20.0%)
COUGH	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)	1 (20.0%)		1 (20.0%)
SKIN & SKIN APPENDAGE	1 (20.0%)	1 (20.0%)	2 (40.0%)	2 (40.0%)	1 (20.0%)	1 (20.0%)		2 (40.0%)
ATOPIC DERMATITIS	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)		1 (20.0%)
FLUSHING	0 (0.0%)	0 (0.0%)	1 (20.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)		1 (20.0%)
SPECIAL SENSES	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)		1 (20.0%)
OTALGIA	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)		1 (20.0%)
VACCINEES WITH COMPLAINTS	3 (60.0%)	3 (60.0%)	3 (60.0%)	3 (60.0%)	3 (60.0%)	3 (60.0%)		3 (60.0%)
VACCINEES WITH NO COMPLAINTS	2 (40.0%)	2 (40.0%)	2 (40.0%)	2 (40.0%)	2 (40.0%)	2 (40.0%)		2 (40.0%)
TOTAL VACCINEES REPORTING	5	5	5	5	5	5		5
VACCINEES WITH NO DATA	0	0	0	0	0	0		0

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : GEORGES PETER
STUDY : 000413
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (4 VACCINEES) - INJECTION: 2						
	DAYS POST VACCINATION						NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5	**********
SYSTEMIC	1 (25.0%)	3 (75.0%)	3 (75.0%)	2 (50.0%)	3 (75.0%)	2 (50.0%)	3 (75.0%)
BODY AS A WHOLE/SITE UNSPEC.	0 (0.0%)	1 (25.0%)	1 (25.0%)	0 (0.0%)	1 (25.0%)	0 (0.0%)	1 (25.0%)
FATIGUE	0 (0.0%)	1 (25.0%)	1 (25.0%)	0 (0.0%)	1 (25.0%)	0 (0.0%)	1 (25.0%)
HARM TO TOUCH	0 (0.0%)	1 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (25.0%)
DIGESTIVE SYSTEM	1 (25.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)
TEETHING	1 (25.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)
NERVOUS SYSTEM & PSYCHIATRIC	0 (0.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)
IRRITABILITY	0 (0.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)
SKIN & SKIN APPENDAGE	0 (0.0%)	1 (25.0%)	1 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (25.0%)
URTICARIA	0 (0.0%)	1 (25.0%)	1 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (25.0%)
VACCINEES WITH COMPLAINTS	1 (25.0%)	3 (75.0%)	3 (75.0%)	2 (50.0%)	3 (75.0%)	2 (50.0%)	3 (75.0%)

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : GEORGES PETER
STUDY : 000413
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (4 VACCINEES) - INJECTION: 2						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5	COMPLAINTS
							**********
VACCINEES WITH NO COMPLAINTS	3 (75.0%)	1 (25.0%)	1 (25.0%)	2 (50.0%)	1 (25.0%)	2 (50.0%)	1 (25.0%)
TOTAL VACCINEES REPORTING	4	4	4	4	4	4	4
VACCINEES WITH NO DATA	0	0	0	0	0	0	0

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : GEORGES PETER
STUDY : 000413
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (17 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5	COMPLAINTS
LOCAL REACTIONS	3 (17.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (17.6%)
ERYTHEMA, INJ. SITE (<=1 IN.)	2 (11.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (11.8%)
PAIN/SORENESS, INJ. SITE	1 (5.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (5.9%)
SYSTEMIC	10 (58.8%)	9 (52.9%)	9 (52.9%)	7 (41.2%)	7 (41.2%)	7 (41.2%)	12 (70.6%)
BODY AS A WHOLE/SITE UNSPEC.	3 (17.6%)	1 (5.9%)	1 (5.9%)	1 (5.9%)	1 (5.9%)	1 (5.9%)	4 (23.5%)
FATIGUE	3 (17.6%)	1 (5.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (17.6%)
HARM TO TOUCH	0 (0.0%)	0 (0.0%)	1 (5.9%)	1 (5.9%)	1 (5.9%)	1 (5.9%)	1 (5.9%)
DIGESTIVE SYSTEM	8 (47.1%)	6 (35.3%)	7 (41.2%)	5 (29.4%)	6 (35.3%)	6 (35.3%)	10 (58.8%)
DIARRHEA	3 (17.6%)	0 (0.0%)	1 (5.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (23.5%)
NAUSEA	1 (5.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (5.9%)
TEETHING	6 (35.3%)	6 (35.3%)	6 (35.3%)	5 (29.4%)	5 (29.4%)	5 (29.4%)	6 (35.3%)

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : GEORGES PETER
STUDY : 000413
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (17 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5	
VOMITING	1 (5.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (5.9%)	1 (5.9%)	2 (11.8%)
NERVOUS SYSTEM & PSYCHIATRIC	2 (11.8%)	4 (23.5%)	4 (23.5%)	1 (5.9%)	0 (0.0%)	0 (0.0%)	7 (41.2%)
IRRITABILITY	2 (11.8%)	3 (17.6%)	3 (17.6%)	1 (5.9%)	0 (0.0%)	0 (0.0%)	6 (35.3%)
PROLONGED CRYING, >1/2 HR	0 (0.0%)	0 (0.0%)	1 (5.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (5.9%)
SLEEP DISORDERS	0 (0.0%)	1 (5.9%)	2 (11.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (11.8%)
RESPIRATORY SYSTEM	0 (0.0%)	1 (5.9%)	1 (5.9%)	1 (5.9%)	2 (11.8%)	2 (11.8%)	2 (11.8%)
COUGH	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (5.9%)	1 (5.9%)	1 (5.9%)
NASAL CONGESTION	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (5.9%)	0 (0.0%)	1 (5.9%)
RHINITIS	0 (0.0%)	1 (5.9%)	1 (5.9%)	1 (5.9%)	1 (5.9%)	1 (5.9%)	1 (5.9%)
UPPER RESPIRATORY INFECTION, NOS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (5.9%)	1 (5.9%)
SKIN & SKIN APPENDAGE	1 (5.9%)	2 (11.8%)	2 (11.8%)	2 (11.8%)	2 (11.8%)	1 (5.9%)	2 (11.8%)
IMPETIGO	1 (5.9%)	1 (5.9%)	1 (5.9%)	1 (5.9%)	1 (5.9%)	1 (5.9%)	1 (5.9%)

00896

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : GEORGES PETER
STUDY : 000413
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (17 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		
URTICARIA	0 (0.0%)	1 (5.9%)	1 (5.9%)	1 (5.9%)	1 (5.9%)	0 (0.0%)		1 (5.9%)
SPECIAL SENSES	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (5.9%)	1 (5.9%)	1 (5.9%)		1 (5.9%)
OTITIS MEDIA	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (5.9%)	1 (5.9%)	1 (5.9%)		1 (5.9%)
VACCINEES WITH COMPLAINTS	10 (58.8%)	9 (52.9%)	9 (52.9%)	7 (41.2%)	7 (41.2%)	7 (41.2%)		12 (70.6%)
VACCINEES WITH NO COMPLAINTS	7 (41.2%)	8 (47.1%)	8 (47.1%)	10 (58.8%)	10 (58.8%)	10 (58.8%)		5 (29.4%)
TOTAL VACCINEES REPORTING	17	17	17	17	17	17		17
VACCINEES WITH NO DATA	0	0	0	0	0	0		0

00897

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : GEORGES PETER
STUDY : 000413
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (10 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
LOCAL REACTIONS	1 (10.0%)	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (10.0%)
ERYTHEMA, INJ. SITE (<=1 IN.)	1 (10.0%)	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (10.0%)
SYSTEMIC	7 (70.0%)	6 (60.0%)	6 (60.0%)	6 (60.0%)	6 (60.0%)	6 (60.0%)		8 (80.0%)
BODY AS A WHOLE/SITE UNSPEC.	4 (40.0%)	2 (20.0%)	1 (10.0%)	1 (10.0%)	0 (0.0%)	1 (10.0%)		5 (50.0%)
FATIGUE	4 (40.0%)	2 (20.0%)	1 (10.0%)	1 (10.0%)	0 (0.0%)	1 (10.0%)		5 (50.0%)
WARM TO TOUCH	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (10.0%)
DIGESTIVE SYSTEM	6 (60.0%)	6 (60.0%)	6 (60.0%)	5 (50.0%)	5 (50.0%)	5 (50.0%)		6 (60.0%)
CONSTIPATION	1 (10.0%)	1 (10.0%)	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (10.0%)
DIARRHEA	0 (0.0%)	1 (10.0%)	2 (20.0%)	1 (10.0%)	1 (10.0%)	1 (10.0%)		2 (20.0%)
FLATULENCE	0 (0.0%)	0 (0.0%)	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (10.0%)
GASTROENTERITIS, NONINFECTIOUS	1 (10.0%)	1 (10.0%)	1 (10.0%)	1 (10.0%)	1 (10.0%)	1 (10.0%)		1 (10.0%)

00898

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : GEORGES PETER
STUDY : 000413
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (10 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		
TEETHING	4 (40.0%)	4 (40.0%)	4 (40.0%)	4 (40.0%)	4 (40.0%)	4 (40.0%)		4 (40.0%)
VOMITING	1 (10.0%)	1 (10.0%)	0 (0.0%)	1 (10.0%)	1 (10.0%)	1 (10.0%)		1 (10.0%)
NERVOUS SYSTEM & PSYCHIATRIC	2 (20.0%)	0 (0.0%)	2 (20.0%)	3 (30.0%)	2 (20.0%)	2 (20.0%)		4 (40.0%)
IRRITABILITY	2 (20.0%)	0 (0.0%)	2 (20.0%)	3 (30.0%)	2 (20.0%)	2 (20.0%)		4 (40.0%)
PROLONGED CRYING, >1/2 HR	1 (10.0%)	0 (0.0%)	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (20.0%)
RESPIRATORY SYSTEM	0 (0.0%)	0 (0.0%)	1 (10.0%)	2 (20.0%)	2 (20.0%)	2 (20.0%)		2 (20.0%)
RHINITIS	0 (0.0%)	0 (0.0%)	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (10.0%)
UPPER RESPIRATORY INFECTION, NOS	0 (0.0%)	0 (0.0%)	1 (10.0%)	2 (20.0%)	2 (20.0%)	2 (20.0%)		2 (20.0%)
WHEEZING	0 (0.0%)	0 (0.0%)	1 (10.0%)	1 (10.0%)	1 (10.0%)	1 (10.0%)		1 (10.0%)
SKIN & SKIN APPENDAGE	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (10.0%)	0 (0.0%)		1 (10.0%)
RASH	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (10.0%)	0 (0.0%)		1 (10.0%)
VACCINEES WITH COMPLAINTS	8 (80.0%)	7 (70.0%)	6 (60.0%)	6 (60.0%)	6 (60.0%)	6 (60.0%)		9 (90.0%)

00899

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : GEORGES PETER
STUDY : 000413
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (10 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
								**********
VACCINEES WITH NO COMPLAINTS	2 (20.0%)	3 (30.0%)	4 (40.0%)	4 (40.0%)	4 (40.0%)	4 (40.0%)		1 (10.0%)
TOTAL VACCINEES REPORTING	10	10	10	10	10	10		10
VACCINEES WITH NO DATA	0	0	0	0	0	0		0

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : GEORGES PETER
STUDY : 000413
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (7 VACCINEES) - INJECTION: 2						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5	COMPLAINTS
LOCAL REACTIONS	2 (28.6%)	2 (28.6%)	1 (14.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (28.6%)
ERYTHEMA, INJ. SITE (<=1 IN.)	2 (28.6%)	2 (28.6%)	1 (14.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (28.6%)
SYSTEMIC	3 (42.9%)	3 (42.9%)	3 (42.9%)	3 (42.9%)	3 (42.9%)	3 (42.9%)	4 (57.1%)
BODY AS A WHOLE/SITE UNSPEC.	0 (0.0%)	0 (0.0%)	1 (14.3%)	1 (14.3%)	1 (14.3%)	1 (14.3%)	2 (28.6%)
FATIGUE	0 (0.0%)	0 (0.0%)	1 (14.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (14.3%)
HARM TO TOUCH	0 (0.0%)	0 (0.0%)	1 (14.3%)	1 (14.3%)	1 (14.3%)	1 (14.3%)	2 (28.6%)
DIGESTIVE SYSTEM	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (14.3%)	1 (14.3%)	1 (14.3%)
TEETHING	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (14.3%)	1 (14.3%)	1 (14.3%)
NERVOUS SYSTEM & PSYCHIATRIC	0 (0.0%)	0 (0.0%)	1 (14.3%)	1 (14.3%)	1 (14.3%)	1 (14.3%)	2 (28.6%)
IRRITABILITY	0 (0.0%)	0 (0.0%)	1 (14.3%)	1 (14.3%)	1 (14.3%)	1 (14.3%)	2 (28.6%)
RESPIRATORY SYSTEM	0 (0.0%)	0 (0.0%)	1 (14.3%)	1 (14.3%)	1 (14.3%)	1 (14.3%)	2 (28.6%)

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : GEORGES PETER
STUDY : 000413
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (7 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
RHINITIS	0 (0.0%)	0 (0.0%)	1 (14.3%)	1 (14.3%)	0 (0.0%)	0 (0.0%)		1 (14.3%)
UPPER RESPIRATORY INFECTION, NOS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (14.3%)	1 (14.3%)		1 (14.3%)
SPECIAL SENSES	3 (42.9%)	3 (42.9%)	3 (42.9%)	3 (42.9%)	2 (28.6%)	3 (42.9%)		4 (57.1%)
OTITIS MEDIA	2 (28.6%)	2 (28.6%)	2 (28.6%)	2 (28.6%)	2 (28.6%)	3 (42.9%)		3 (42.9%)
SEROUS OTITIS MEDIA	1 (14.3%)	1 (14.3%)	1 (14.3%)	1 (14.3%)	0 (0.0%)	0 (0.0%)		1 (14.3%)
VACCINEES WITH COMPLAINTS	5 (71.4%)	5 (71.4%)	4 (57.1%)	3 (42.9%)	3 (42.9%)	3 (42.9%)		5 (71.4%)
VACCINEES WITH NO COMPLAINTS	2 (28.6%)	2 (28.6%)	3 (42.9%)	4 (57.1%)	4 (57.1%)	4 (57.1%)		2 (28.6%)
TOTAL VACCINEES REPORTING	7	7	7	7	7	7		7
VACCINEES WITH NO DATA	0	0	0	0	0	0		0

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : GEORGES PETER
STUDY : 000413
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (15 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		
LOCAL REACTIONS	2 (15.4%)	4 (30.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		4 (30.8%)
ERYTHEMA, INJ. SITE (<=1 IN.)	1 (7.7%)	3 (23.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		3 (23.1%)
PAIN/SORENESS, INJ. SITE	1 (7.7%)	1 (7.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (7.7%)
SHELLING, INJ. SITE (<=1 IN.)	0 (0.0%)	1 (7.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (7.7%)
SYSTEMIC	4 (30.8%)	3 (23.1%)	2 (15.4%)	4 (30.8%)	3 (23.1%)	3 (23.1%)		6 (46.2%)
BODY AS A WHOLE/SITE UNSPEC.	2 (15.4%)	0 (0.0%)	0 (0.0%)	1 (7.7%)	0 (0.0%)	1 (7.7%)		4 (30.8%)
FATIGUE	1 (7.7%)	0 (0.0%)	0 (0.0%)	1 (7.7%)	0 (0.0%)	1 (7.7%)		3 (23.1%)
WARM TO TOUCH	1 (7.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (7.7%)
DIGESTIVE SYSTEM	1 (7.7%)	2 (15.4%)	2 (15.4%)	3 (23.1%)	3 (23.1%)	3 (23.1%)		3 (23.1%)
TEETHING	1 (7.7%)	2 (15.4%)	2 (15.4%)	3 (23.1%)	3 (23.1%)	3 (23.1%)		3 (23.1%)
NERVOUS SYSTEM & PSYCHIATRIC	3 (23.1%)	2 (15.4%)	1 (7.7%)	1 (7.7%)	1 (7.7%)	2 (15.4%)		5 (38.5%)

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : GEORGES PETER
STUDY : 000413
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (15 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
INSOMNIA	1 (7.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (7.7%)
IRRITABILITY	3 (23.1%)	2 (15.4%)	1 (7.7%)	1 (7.7%)	1 (7.7%)	2 (15.4%)		5 (38.5%)
VACCINEES WITH COMPLAINTS	4 (30.8%)	6 (46.2%)	2 (15.4%)	4 (30.8%)	3 (23.1%)	3 (23.1%)		6 (46.2%)
VACCINEES WITH NO COMPLAINTS	9 (69.2%)	7 (53.8%)	11 (84.6%)	9 (69.2%)	10 (76.9%)	10 (76.9%)		7 (53.8%)
TOTAL VACCINEES REPORTING	13	13	13	13	13	13		13
VACCINEES WITH NO DATA	2	2	2	2	2	2		2

TABLE 7

MAXIMUM TEMPERATURES

INVESTIGATOR : GEORGES PETER
STUDY : 000413
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (5 VACCINEES) - INJECTION 1						
	DAYS POST VACCINATION						NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5	
< 99	3 (100.0%)	3 (100.0%)	3 (100.0%)	3 (100.0%)	3 (75.0%)	3 (75.0%)	3 (75.0%)
101 - 101.9	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (25.0%)	0 (0.0%)	0 (0.0%)
102 - 102.9	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (25.0%)	1 (25.0%)
TEMPERATURE TAKEN	3 (60.0%)	3 (60.0%)	3 (60.0%)	3 (60.0%)	4 (80.0%)	4 (80.0%)	4 (80.0%)
TEMPERATURE NOT TAKEN	2 (40.0%)	2 (40.0%)	2 (40.0%)	2 (40.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)

TABLE 7 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : GEORGES PETER
STUDY : 000413
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (4 VACCINEES) - INJECTION 2						
	DAYS POST VACCINATION						NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5	
NORMAL	0 (0.0%)	1 (33.3%)	1 (33.3%)	1 (33.3%)	1 (33.3%)	1 (33.3%)	0 (0.0%)
< 99	2 (66.7%)	1 (33.3%)	2 (66.7%)	2 (66.7%)	2 (66.7%)	2 (66.7%)	1 (33.3%)
99 - 99.9	1 (33.3%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (66.7%)
TEMPERATURE TAKEN	3 (75.0%)	3 (75.0%)	3 (75.0%)	3 (75.0%)	3 (75.0%)	3 (75.0%)	3 (75.0%)
TEMPERATURE NOT TAKEN	1 (25.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)

TABLE 7 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : GEORGES PETER
STUDY : 000413
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (17 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
NORMAL	0 (0.0%)	2 (11.8%)	2 (11.8%)	2 (11.8%)	2 (11.8%)	2 (11.8%)		0 (0.0%)
< 99	11 (64.7%)	13 (76.5%)	13 (76.5%)	14 (82.4%)	15 (88.2%)	15 (88.2%)		8 (47.1%)
99 - 99.9	5 (29.4%)	2 (11.8%)	2 (11.8%)	1 (5.9%)	0 (0.0%)	0 (0.0%)		8 (47.1%)
100 - 100.9	1 (5.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (5.9%)
TEMPERATURE TAKEN	17 (100.0%)	17 (100.0%)	17 (100.0%)	17 (100.0%)	17 (100.0%)	17 (100.0%)		17 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)

00907

TABLE 7 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : GEORGES PETER
STUDY : 000413
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (10 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
NORMAL	1 (10.0%)	1 (11.1%)	1 (11.1%)	1 (11.1%)	1 (11.1%)	0 (0.0%)		0 (0.0%)
< 99	8 (80.0%)	7 (77.8%)	6 (66.7%)	8 (88.9%)	7 (77.8%)	6 (66.7%)		5 (50.0%)
99 - 99.9	1 (10.0%)	0 (0.0%)	1 (11.1%)	0 (0.0%)	1 (11.1%)	2 (22.2%)		3 (30.0%)
101 - 101.9	0 (0.0%)	0 (0.0%)	1 (11.1%)	0 (0.0%)	0 (0.0%)	1 (11.1%)		1 (10.0%)
103 - 103.9	0 (0.0%)	1 (11.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (10.0%)
TEMPERATURE TAKEN	10 (100.0%)	9 (90.0%)	9 (90.0%)	9 (90.0%)	9 (90.0%)	9 (90.0%)		10 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	1 (10.0%)	1 (10.0%)	1 (10.0%)	1 (10.0%)	1 (10.0%)		0 (0.0%)

TABLE 7 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : GEORGES PETER
STUDY : 000413
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (7 VACCINEES) - INJECTION 2							
	DAYS POST VACCINATION							NUMBER WITH
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		MAX TEMP
NORMAL	1 (16.7%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)
< 99	4 (66.7%)	3 (60.0%)	3 (60.0%)	3 (60.0%)	3 (60.0%)	3 (60.0%)		3 (50.0%)
99 - 99.9	0 (0.0%)	1 (20.0%)	0 (0.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)		0 (0.0%)
100 - 100.9	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (16.7%)
102 - 102.9	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)	1 (20.0%)		1 (16.7%)
103 - 103.9	0 (0.0%)	0 (0.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (16.7%)
TEMPERATURE TAKEN	6 (85.7%)	5 (71.4%)	5 (71.4%)	5 (71.4%)	5 (71.4%)	5 (71.4%)		6 (85.7%)
TEMPERATURE NOT TAKEN	1 (14.3%)	2 (28.6%)	2 (28.6%)	2 (28.6%)	2 (28.6%)	2 (28.6%)		1 (14.3%)

TABLE 7 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : GEORGES PETER
STUDY : 000413
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (15 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
< 99	7 (63.6%)	7 (63.6%)	8 (80.0%)	8 (72.7%)	6 (54.5%)	8 (72.7%)		5 (45.5%)
99 - 99.9	3 (27.3%)	3 (27.3%)	2 (20.0%)	3 (27.3%)	5 (45.5%)	3 (27.3%)		4 (36.4%)
100 - 100.9	1 (9.1%)	1 (9.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (18.2%)
TEMPERATURE TAKEN	11 (73.3%)	11 (73.3%)	10 (66.7%)	11 (73.3%)	11 (73.3%)	11 (73.3%)		11 (73.3%)
TEMPERATURE NOT TAKEN	4 (26.7%)	4 (26.7%)	5 (33.3%)	4 (26.7%)	4 (26.7%)	4 (26.7%)		4 (26.7%)

PROGRAM: Haemophilus b Conjugate Vaccine (Neisseria meningitidis Outer Membrane Protein Complex), Study 004-14

PURPOSE: To evaluate the safety and immunogenicity of Haemophilus b conjugate vaccine (Neisseria meningitidis outer membrane protein complex) in healthy American Indian infants 2 to 71 months of age.

VACCINE: Haemophilus b Conjugate Vaccine (Neisseria meningitidis Outer Membrane Protein Complex) (PRP-OMPC)

Lot 1069/C-P241 - (b) (4) mcg polysaccharide/ml
mcg meningococcal protein/ml

Lot 1072/C-P298 - mcg polysaccharide/ml
mcg meningococcal protein/ml

Lot 1080/C-P749 - mcg polysaccharide/ml
mcg meningococcal protein/ml

Aluminum hydroxide diluent
Lot (b) (4)

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SUB-INVESTIGATOR: Raymond Reid, M.D.
Janne Ameido-Hill
U.S. Public Health Service
Indian Health Service Hospitals
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Route 73
White River, Arizona 85941

STUDY LOCATION: U.S. Public Health Service
Indian Health Service Hospitals
on the Navajo and Apache Reservation

DATE STUDY INITIATED: May 29, 1987

DATE STUDY COMPLETED: In progress.

STUDY POPULATION: Healthy infants and children 2 to 71 months of age are included in the study.

STUDY PROCEDURE: Infants 2 to 11 months of age receive two injections of PRP-OMPC vaccine given 2 months apart while children 12 months of age and older receive a single injection. Vaccine is reconstituted in aluminum hydroxide and administered by intramuscular route. The dose for each injection is 15 mcg of polysaccharide in the appropriate volume. Lot 1069/C-P241 is reconstituted to contain 15 mcg polysaccharide in 0.75 ml, while Lots 1072/C-P298 and 1080/C-P749 are reconstituted to contain 15 mcg polysaccharide in 0.5 ml.

The parent or guardian is required to record the vaccine recipient's temperature and any reactions at the injection site or systemic complaints for 5 days after each injection of vaccine. Unexpected or serious reactions are to be reported immediately to the study physician. Serious adverse experiences in the 14 days following each injection of vaccine are required to be reported by the investigator.

A blood sample is obtained prior to each injection of vaccine and 1 and 7 to 10 months after the last or a single injection of vaccine. Additional follow-up blood samples are obtained 7 to 10 months after the last injection of vaccine from infants 2 to 11 months of age and at 15 to 18 months postvaccination from children $\geq$12 months of age.

All serum samples are assayed for antibody to the capsular polysaccharide of Haemophilus influenzae type b by radioimmunoassay. Selected samples may be tested for bactericidal and opsonophagocytic activity, immunoglobulin isotype and subclass IgG. Opsonophagocytic assays are performed at the University of Alabama. All other assays are performed at Merck Sharp & Dohme Research Laboratories.

RESULTS: Demographic information and individual pre and postimmunization antibody data for each vaccine recipient are presented in Tables 1 and 2.

1. Current status:

Lot	Age	No. Vaccinated Injection 1	No. Vaccinated Injection 2
1069/C-P241	2-11 mos	14	11
	12-71 mos	49	--
1072/C-P298	2-11 mos	69	54
	12-71 mos	28	--
1080/C-P749	2-11 mos	17	0
	12-71 mos	36	--

One infant (Case No. (b) (6)) received Lot 1069/C-P241 as injection 1 and Lot 1072/C-P298 as injection 2. Thirteen subjects (Case Nos. (b) (6) (b) (6)) received a 10.5 mcg dose of polysaccharide as injection 1.

2. Serologic results:

Anti-PRP responses prior to each injection of vaccine and 1 month after the last or a single injection of vaccine are as follows:

Age	Time	% With Anti-PRP >0.15 mcg/ml	% With Anti-PRP >1.0 mcg/ml	GMT (mcg/ml) All Vaccinees
2-11 mos	Pre	48 (13/27)	7 (2/27)	0.18
	Post 1	100 (27/27)	81 (22/27)	2.76
	Post 2	100 (13/13)	77 (10/13)	4.10
12-71 mos	Pre	65 (30/46)	11 (5/46)	0.26
	Post	100 (43/43)	95 (41/43)	11.52

Antibody responses are presented in Tables 3 and 4 by lot. If vaccine recipients received mixed lots or doses, they are excluded from all summaries by lot.

RESULTS: (CONT.)

3. Clinical results:

The incidence of selected injection site and systemic reactions occurring within 2 days after vaccination are as follows:

	% of Vaccinees with Reaction		
	2-11 Mos		12-71 Mos
Type of Reaction	Injection 1	Injection 2	
Injection Site:			
Pain/Soreness	5 (5/99)	10 (6/63)	17 (19/109)
Erythema >1 inch	0 (0/99)	0 (0/63)	0 (0/109)
Swelling >1 inch	0 (0/99)	5 (3/63)	0 (0/109
Induration	4 (4/99)	16 (10/63)	10 (11/109)
Systemic:			
Irritability	17 (17/99)	16 (10/63)	13 (14/109)
Sleepiness/Lethargy/ Fatigue	9 (9/99)	0 (0/63)	7 (8/109)

The frequencies of all clinical reactions and maximum temperatures occurring during the 5 days following each injection of vaccine are presented in Tables 5 to 7 by lot.

No serious or alarming reactions attributable to vaccine have been reported. Five serious adverse experiences unrelated to vaccination were reported:

1) Case No. (b) (6), a 5 month old female developed gastroenteritis and was hospitalized with moderate dehydration 2 days after receiving an initial injection of Lot 1069/C-P241. She was treated with oral rehydration and Tylenol and discharged 2 days later. The infant was readmitted 2 days after discharge with the same symptoms and remained hospitalized for an additional 3 days. No bacterial pathogens were isolated; viral studies were not done.

RESULTS:
(CONT.)

2) Case No. (b) (6), a 3 month old female, developed acute watery diarrhea with minimal dehydration, conjunctivitis and an upper respiratory infection 3 days after receiving an initial injection of Lot 1072/C-P298. She was hospitalized 1 week later and an x-ray revealed middle lobe pneumonia and bronchiolitis. The child subsequently recovered and was discharged.

3) Case No. (b) (6), a 5 month old female, experienced mild bronchiolitis, conjunctivitis, and temperature of 100.1°F rectal on the day she received a second injection of Lot 1069/C-P241. Five days later the infant was hospitalized with a temperature of 102°F rectal and diagnosed as having asceptic meningitis. Blood and CSF cultures were negative. The WBC was 36,500 (59 poly, 30 lymph). She subsequently recovered and was discharged in 3 days.

4) Case No. (b) (6), a 2 month old female, was hospitalized with an upper respiratory infection 5 days after receiving an initial injection of Lot 1072/C-P298. She recovered and was discharged 3 days later.

5) Case No. (b) (6), a 4 month old female, was hospitalized with an upper respiratory infection 14 days after receiving an initial injection of Lot 1072/C-P298. She recovered and was discharged within 4 days.

TABLE 1

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	AM I	(b) (6)	3M	0	(b) (6)	011	INJ 1	CP241	15 MCG						
	M	AM I		3M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP241	15 MCG						
					64		011	BLEED 1				3918				
					64		021	INJ 2	CP241	15 MCG						
					98		021	BLEED 2				10595				
	F	AM I		2M	0		011	INJ 1	CP298	15 MCG						
					63		021	INJ 2	CP298	15 MCG						
	F	AM I		3M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP298	15 MCG						
					67		011	BLEED 1				1442				
					67		021	INJ 2	CP298	15 MCG						
	M	AM I		2M	0		001	PREBLEED				274				
					0		011	INJ 1	CP241	15 MCG						
					64		011	BLEED 1				4565				
					64		021	INJ 2	CP298	15 MCG						
					92		021	BLEED 2				3367				
	F	AM I		2M	0		001	PREBLEED				206				
					0		011	INJ 1	CP241	15 MCG						
					61		011	BLEED 1				1186				
					61		021	INJ 2	CP241	15 MCG						
					89		021	BLEED 2				31431				
	F	AM I		1M	0		001	PREBLEED				139				
					0		011	INJ 1	CP241	15 MCG						
					56		011	BLEED 1				1024				
					56		021	INJ 2	CP241	15 MCG						
					86		021	BLEED 2				2216				
	F	AM I		3M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP241	15 MCG						
					56		011	BLEED 1				547				
					56		021	INJ 2	CP241	15 MCG						
					104		021	BLEED 2				724				
	M	AM I		2M	0		001	PREBLEED				< 125				

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	AM I	(b) (6)	2M	0	(b) (6)	011	INJ 1	CP241	15 MCG						
					61		011	BLEED 1				3137				
					61		021	INJ 2	CP241	15 MCG						
	F	AM I		3M	0		001	PREBLEED				1148				
					0		011	INJ 1	CP298	15 MCG						
					62		011	BLEED 1				2029				
					62		021	INJ 2	CP298	15 MCG						
	M	AM I		1M	0		001	PREBLEED				883				
					0		011	INJ 1	CP241	15 MCG						
					70		011	BLEED 1				748				
					70		021	INJ 2	CP241	15 MCG						
	F	AM I		2M	0		001	PREBLEED				143		< 2		
					0		011	INJ 1	CP241	15 MCG						
					61		011	BLEED 1				17558		2		
					61		021	INJ 2	CP241	15 MCG						
					89		021	BLEED 2				2058		< 2		
	F	AM I		2M	0		001	PREBLEED				432				
					0		011	INJ 1	CP298	15 MCG						
					61		011	BLEED 1				247				
					61		021	INJ 2	CP298	15 MCG						
	F	AM I		2M	0		001	PREBLEED				143				
					0		011	INJ 1	CP241	15 MCG						
					98		011	BLEED 1			05/	1032				
					98		021	INJ 2	CP241	15 MCG						
	F	AM I		1M	0		011	INJ 1	CP241	15 MCG						
	M	AM I		1M	0		001	PREBLEED				128				
					0		011	INJ 1	CP241	15 MCG						
					57		011	BLEED 1				490				
					57		021	INJ 2	CP241	15 MCG						
					91		021	BLEED 2				775				
	F	AM I		2M	0		011	INJ 1	CP298	15 MCG						
					83		021	INJ 2	CP298	15 MCG						

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	AM I	(b) (6)	1M	0	(b) (6)	001	PREBLEED				163		< 2		
					0		011	INJ 1	CP241	15 MCG						
					78		011	BLEED 1			05/	1972	05/	8		
					78		021	INJ 2	CP241	15 MCG						
					105		021	BLEED 2			05/	9137	05/	8		
	M	AM I		1M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP241	15 MCG						
					70		011	BLEED 1				1391				
					70		021	INJ 2	CP241	15 MCG						
	M	AM I		1M	0		011	INJ 1	CP298	15 MCG						
					91		021	INJ 2	CP298	15 MCG						
	M	AM I		2M	0		001	PREBLEED				3087				
					0		011	INJ 1	CP298	15 MCG						
					60		011	BLEED 1				1402				
					60		021	INJ 2	CP298	15 MCG						
	F	AM I		2M	0		011	INJ 1	CP298	15 MCG						
					86		021	INJ 2	CP298	15 MCG						
	M	AM I		2M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP298	15 MCG						
					64		011	BLEED 1				978				
					65		021	INJ 2	CP298	15 MCG						
	M	AM I		1M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP298	15 MCG						
					62		011	BLEED 1				5216				
					62		021	INJ 2	CP298	15 MCG						
	F	AM I		1M	0		001	PREBLEED				250				
					0		011	INJ 1	CP298	15 MCG						
					79		011	BLEED 1			05/	1854				
					79		021	INJ 2	CP298	15 MCG						
	F	AM I		3M	0		011	INJ 1	CP298	15 MCG						
					51		021	INJ 2	CP298	15 MCG						
	F	AM I		2M	0		011	INJ 1	CP298	15 MCG						

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	F	AM I	(b) (6)	2M	91	(b) (6)	021	INJ 2	CP298	15 MCG						
	F	AM I		4M	0		011	INJ 1	CP298	15 MCG						
					60		021	INJ 2	CP298	15 MCG						
	M	AM I		2M	0		011	INJ 1	CP298	15 MCG						
					47		021	INJ 2	CP298	15 MCG						
	F	AM I		3M	0		011	INJ 1	CP749	15 MCG						
	M	AM I		2M	0		011	INJ 1	CP749	15 MCG						
	F	AM I		2M	0		011	INJ 1	CP749	15 MCG						
	F	AM I		2M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP298	15 MCG						
					61		011	BLEED 1				6278				
					61		021	INJ 2	CP298	15 MCG						
					101		021	BLEED 2				11607				
	F	AM I		2M	0		011	INJ 1	CP298	15 MCG						
					58		021	INJ 2	CP298	15 MCG						
	M	AM I		1M	0		001	PREBLEED				< 125		< 2		
					0		011	INJ 1	CP298	15 MCG						
					61		011	BLEED 1				1201		8		
					61		021	INJ 2	CP298	15 MCG						
					93		021	BLEED 2				909		2		
	M	AM I		1M	0		001	PREBLEED				565				
					0		011	INJ 1	CP298	15 MCG						
					61		011	BLEED 1				30574				
					61		021	INJ 2	CP298	15 MCG						
					89		021	BLEED 2				14327				
	F	AM I		2M	0		001	PREBLEED				< 125		< 2		
					0		011	INJ 1	CP298	15 MCG						
					72		011	BLEED 1			05/	6869	05/	>= 32		
					72		021	INJ 2	CP298	15 MCG						
					107		021	BLEED 2			05/	2512	05/	>= 32		

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	F	AM I	(b) (6)	1M	0	(b) (6)	001	PREBLEED				199		< 2		
					0		011	INJ 1	CP298	15 MCG						
					64		011	BLEED 1				31151		>= 32		
					64		021	INJ 2	CP298	15 MCG						
					101		021	BLEED 2				10686		>= 32		
	F	AM I		2M	0		001	PREBLEED				2073				
					0		011	INJ 1	CP298	15 MCG						
					80		011	BLEED 1			05/	8606				
					80		021	INJ 2	CP298	15 MCG						
	F	AM I		2M	0		011	INJ 1	CP298	15 MCG						
	F	AM I		3M	0		001	PREBLEED				988		< 2		
					0		011	INJ 1	CP298	15 MCG						
					63		011	BLEED 1				7238		>= 32		
					63		021	INJ 2	CP298	15 MCG						
					99		021	BLEED 2				7226		>= 32		
	M	AM I		2M	0		011	INJ 1	CP298	15 MCG						
	M	AM I		4M	0		011	INJ 1	CP298	15 MCG						
	M	AM I		3M	0		011	INJ 1	CP298	15 MCG						
	F	AM I		3M	0		011	INJ 1	CP298	15 MCG						
					84		021	INJ 2	CP298	15 MCG						
	M	AM I		2M	0		001	PREBLEED				169		< 2		
					0		011	INJ 1	CP298	15 MCG						
					63		011	BLEED 1				4308		>= 32		
					63		021	INJ 2	CP298	15 MCG						
					89		021	BLEED 2				2763		8		
	M	AM I		2M	0		001	PREBLEED				< 250				
					0		011	INJ 1	CP298	15 MCG						
					72		011	BLEED 1			05/	489				
					72		021	INJ 2	CP298	15 MCG						
	M	AM I		3M	0		001	PREBLEED				204				

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ RIA	CODE/ SBA	CODE/ OPSO
(b) (6)	M	AM I	(b) (6)	3M	0	(b) (6)	011	INJ 1	CP298	15 MCG			
					60		011	BLEED 1			9338		
					60		021	INJ 2	CP298	15 MCG			
	M	AM I		3M	0		011	INJ 1	CP298	15 MCG			
					63		021	INJ 2	CP298	15 MCG			
	M	AM I		2M	0		011	INJ 1	CP298	15 MCG			
	F	AM I		2M	0		001	PREBLEED			142		
					0		011	INJ 1	CP298	15 MCG			
					64		011	BLEED 1			5172		
					64		021	INJ 2	CP298	15 MCG			
	F	AM I		2M	0		011	INJ 1	CP298	15 MCG			
	F	AM I		3M	0		001	PREBLEED			< 125		
					0		011	INJ 1	CP298	15 MCG			
					56		011	BLEED 1			6368		
					56		021	INJ 2	CP298	15 MCG			
	M	AM I		2M	0		001	PREBLEED			217		
					0		011	INJ 1	CP298	15 MCG			
					56		011	BLEED 1			2106		
					56		021	INJ 2	CP298	15 MCG			
	F	AM I		2M	0		011	INJ 1	CP298	15 MCG			
					67		021	INJ 2	CP298	15 MCG			
	M	AM I		2M	0		001	PREBLEED			445		
					0		011	INJ 1	CP298	15 MCG			
					56		011	BLEED 1			3298		
					56		021	INJ 2	CP298	15 MCG			
	M	AM I		1M	0		011	INJ 1	CP298	15 MCG			
					61		021	INJ 2	CP298	15 MCG			
	M	AM I		3M	0		011	INJ 1	CP298	15 MCG			
					62		021	INJ 2	CP298	15 MCG			
	F	AM I		2M	0		011	INJ 1	CP298	15 MCG			

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	F	AM I	(b) (6)	2M	69	(b) (6)	021	INJ	2	CP298	15 MCG					
	F	AM I		2M	0		011	INJ	1	CP298	15 MCG					
					78		021	INJ	2	CP298	15 MCG					
	F	AM I		2M	0		011	INJ	1	CP298	15 MCG					
					69		021	INJ	2	CP298	15 MCG					
	M	AM I		2M	0		011	INJ	1	CP298	15 MCG					
	F	AM I		2M	0		011	INJ	1	CP298	15 MCG					
					67		021	INJ	2	CP298	15 MCG					
	F	AM I		1M	0		011	INJ	1	CP298	15 MCG					
					82		021	INJ	2	CP298	15 MCG					
	M	AM I		2M	0		011	INJ	1	CP298	15 MCG					
	M	AM I		2M	0		011	INJ	1	CP298	15 MCG					
	M	AM I		2M	0		011	INJ	1	CP298	15 MCG					
					69		021	INJ	2	CP298	15 MCG					
	M	AM I		2M	0		011	INJ	1	CP298	15 MCG					
					57		021	INJ	2	CP298	15 MCG					
	M	AM I		2M	0		011	INJ	1	CP298	10.5 MCG					
					66		021	INJ	2	CP298	15 MCG					
	F	AM I		2M	0		011	INJ	1	CP298	10.5 MCG					
					61		021	INJ	2	CP298	15 MCG					
	F	AM I		1M	0		011	INJ	1	CP298	10.5 MCG					
					77		021	INJ	2	CP298	15 MCG					
	M	AM I		2M	0		011	INJ	1	CP298	10.5 MCG					
					56		021	INJ	2	CP298	15 MCG					
	F	AM I		1M	0		011	INJ	1	CP298	10.5 MCG					
					63		021	INJ	2	CP298	15 MCG					

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	AM I	(b) (6)	2M	0	(b) (6)		011 INJ	1	CP298	10.5 MCG					
					53			021 INJ	2	CP298	15 MCG					
	F	AM I		2M	0			011 INJ	1	CP298	10.5 MCG					
					61			021 INJ	2	CP298	15 MCG					
	M	AM I		1M	0			011 INJ	1	CP298	10.5 MCG					
					81			021 INJ	2	CP298	15 MCG					
	F	AM I		1M	0			011 INJ	1	CP298	10.5 MCG					
					80			021 INJ	2	CP298	15 MCG					
	F	AM I		2M	0			011 INJ	1	CP298	10.5 MCG					
					54			021 INJ	2	CP298	15 MCG					
	M	AM I		3M	0			011 INJ	1	CP298	10.5 MCG					
					63			021 INJ	2	CP298	15 MCG					
	M	AM I		1M	0			011 INJ	1	CP298	10.5 MCG					
	F	AM I		1M	0			011 INJ	1	CP298	15 MCG					
	F	AM I		2M	0			011 INJ	1	CP298	15 MCG					
	F	AM I		1M	0			011 INJ	1	CP298	15 MCG					
	M	AM I		1M	0			011 INJ	1	CP298	15 MCG					
	F	AM I		1M	0			011 INJ	1	CP298	15 MCG					
	F	AM I		1M	0			011 INJ	1	CP298	15 MCG					
	F	OTHE		1M	0			011 INJ	1	CP749	15 MCG					
	M	AM I		3M	0			011 INJ	1	CP749	15 MCG					
	M	AM I		1M	0			011 INJ	1	CP749	15 MCG					
	M	AM I		3M	0			011 INJ	1	CP749	15 MCG					
	M	AM I		1M	0			011 INJ	1	CP749	15 MCG					

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	AM I	(b) (6)	1M	0	(b) (6)	011	INJ	1	CP749	15 MCG					
	F	AM I		2M	0		011	INJ	1	CP749	15 MCG					
	M	AM I		2M	0		011	INJ	1	CP749	15 MCG					
	M	AM I		1M	0		011	INJ	1	CP749	15 MCG					
	F	AM I		2M	0		011	INJ	1	CP749	15 MCG					
	F	AM I		1M	0		011	INJ	1	CP749	15 MCG					
	M	AM I		1M	0		011	INJ	1	CP749	15 MCG					
	F	AM I		2M	0		011	INJ	1	CP749	15 MCG					
	F	AM I		1M	0		011	INJ	1	CP749	15 MCG					

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	AM I	(b) (6)	4Y	0	(b) (6)	001	PREBLEED				240		< 5		
					0		011	INJ 1	CP241	15 MCG						
					28		011	BLEED 1				17639		160		
					206		071	BLEED 2				1203				
	F	AM I		3Y	0		001	PREBLEED				684		< 5		
					0		011	INJ 1	CP241	15 MCG						
					47		011	BLEED 1				23922		40		
					210		071	BLEED 2				2065				
	M	AM I		23M	0		001	PREBLEED				< 125		< 5		
					0		011	INJ 1	CP241	15 MCG						
					47		011	BLEED 1				18748		80		
					210		071	BLEED 2				2323				
	F	AM I		3Y	0		001	PREBLEED				353		< 5		
					0		011	INJ 1	CP241	15 MCG						
					32		011	BLEED 1				17765		160		
					206		071	BLEED 2				3429				
	F	AM I		21M	0		001	PREBLEED				254				
					0		011	INJ 1	CP241	15 MCG						
					83		011	BLEED 1				15486				
					182		071	BLEED 2				3043				
	M	AM I		3Y	0		001	PREBLEED				873		40		
					0		011	INJ 1	CP241	15 MCG						
					27		011	BLEED 1				12944		160		
					190		071	BLEED 2				2296				
	M	AM I		4Y	0		001	PREBLEED				< 125				22
					0		011	INJ 1	CP241	15 MCG						
					84		011	BLEED 1				14360				93
					182		071	BLEED 2				1103				
	F	AM I		4Y	0		001	PREBLEED				207		< 5		
					0		011	INJ 1	CP241	15 MCG						
					33		011	BLEED 1				25950		320		
					196		071	BLEED 2				5925				
	F	AM I		2Y	0		001	PREBLEED				< 125		< 5		

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ RIA	CODE/ SBA	CODE/ OPSO
(b) (6)	F	AM I	(b) (6)	2Y	0	(b) (6)	011	INJ 1	CP241	15 MCG			
					27		011	BLEED 1			2331	40	
					196		071	BLEED 2			776		
	M	AM I		3Y	0		001	PREBLEED			< 125	< 5	
					0		011	INJ 1	CP241	15 MCG			
					27		011	BLEED 1			25948	320	
					196		071	BLEED 2			11273		
	F	AM I		3Y	0		001	PREBLEED			202	< 5	
					0		011	INJ 1	CP241	15 MCG			
					27		011	BLEED 1			92550	640	
	F	AM I		3Y	0		001	PREBLEED			306	40	
					0		011	INJ 1	CP241	15 MCG			
					27		011	BLEED 1			7470	640	
					189		071	BLEED 2			1480		
	M	AM I		2Y	0		001	PREBLEED			< 125	< 5	
					0		011	INJ 1	CP241	15 MCG			
					27		011	BLEED 1			24509	160	
					189		071	BLEED 2			936		
	F	AM I		3Y	0		001	PREBLEED			< 125	< 5	
					0		011	INJ 1	CP241	15 MCG			
					34		011	BLEED 1			4008	40	
					200		071	BLEED 2			506		
	M	AM I		23M	0		001	PREBLEED			< 125	< 5	
					0		011	INJ 1	CP241	15 MCG			
					34		011	BLEED 1			3257	40	
					200		071	BLEED 2			785		
	M	AM I		17M	0		001	PREBLEED			< 125	< 5	
					0		011	INJ 1	CP241	15 MCG			
					37		011	BLEED 1			961	10	
	M	AM I		3Y	0		001	PREBLEED			< 125	< 5	
					0		011	INJ 1	CP241	15 MCG			
					28		011	BLEED 1			62536	320	

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ RIA	RIA	CODE/ SBA	SBA	CODE/ OPSO	OPSO
(b) (6)	M	AM I	(b) (6)	3Y	210	(b) (6)	071	BLEED 2				2029				
	F	AM I		3Y	0		001	PREBLEED				< 125		< 5		
					0		011	INJ 1	CP241	15 MCG						
					30		011	BLEED 1				11694		320		
					188		071	BLEED 2				2534				
	F	AM I		2Y	0		001	PREBLEED				< 125		< 5		
					0		011	INJ 1	CP241	15 MCG						
					30		011	BLEED 1				4360		80		
					188		071	BLEED 2				785				
	M	AM I		23M	0		001	PREBLEED				< 125		< 5		
					0		011	INJ 1	CP241	15 MCG						
					28		011	BLEED 1				2212		20		
	F	AM I		3Y	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP241	15 MCG						
					73		011	BLEED 1				31866				
	M	AM I		3Y	0		001	PREBLEED				484				14
					0		011	INJ 1	CP241	15 MCG						
					28		011	BLEED 1				59476				81
					182		071	BLEED 2				2118				
	F	AM I		3Y	0		001	PREBLEED				336				
					0		011	INJ 1	CP241	15 MCG						
					28		011	BLEED 1				22085				
					182		071	BLEED 2				1673				
	M	AM I		3Y	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP241	15 MCG						
					35		011	BLEED 1				3440				
					188		071	BLEED 2				234				
	M	AM I		3Y	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP241	15 MCG						
					73		011	BLEED 1				49113				
	F	AM I		3Y	0		001	PREBLEED				< 125				

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ RIA	CODE/ SBA	CODE/ OPSO
(b) (6)	F	AM I	(b) (6)	3Y	0	(b) (6)	011	INJ 1	CP241	15 MCG			
					35		011	BLEED 1			5453		
					175		071	BLEED 2			1288		
	M	AM I		3Y	0		001	PREBLEED			364		31
					0		011	INJ 1	CP241	15 MCG			
					46		011	BLEED 1			31830		98
					183		071	BLEED 2			3147		
	F	AM I		20M	0		001	PREBLEED			466		
					0		011	INJ 1	CP241	15 MCG			
					30		011	BLEED 1			3005		
	F	AM I		18M	0		001	PREBLEED			< 125		
					0		011	INJ 1	CP241	15 MCG			
					34		011	BLEED 1			13345		
					190		071	BLEED 2			1409		
	F	AM I		2Y	0		001	PREBLEED			522		
					0		011	INJ 1	CP241	15 MCG			
					33		011	BLEED 1			21949		
					186		071	BLEED 2			3657		
	F	AM I		23M	0		001	PREBLEED			< 125		
					0		011	INJ 1	CP241	15 MCG			
					28		011	BLEED 1			1258		
					183		071	BLEED 2			450		
	F	AM I		24M	0		001	PREBLEED			592		
					0		011	INJ 1	CP241	15 MCG			
					29		011	BLEED 1			2287		
					190		071	BLEED 2			683		
	M	AM I		4Y	0		001	PREBLEED			550		
					0		011	INJ 1	CP298	15 MCG			
					29		011	BLEED 1			33387		
	M	AM I		22M	0		001	PREBLEED			246		21
					0		011	INJ 1	CP241	15 MCG			
					50		011	BLEED 1			10130		87

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	F	AM I	(b) (6)	3Y	0	(b) (6)	001	PREBLEED				272				
					0		011	INJ 1	CP241	15 MCG						
					113		011	BLEED 1				2307				
	M	AM I		5Y	0		001	PREBLEED				1285				
					0		011	INJ 1	CP241	15 MCG						
					30		011	BLEED 1				40248				
	F	AM I		3Y	0		001	PREBLEED				2281				
					0		011	INJ 1	CP241	15 MCG						
					30		011	BLEED 1				19701				
	F	AM I		3Y	0		001	PREBLEED				165				
					0		011	INJ 1	CP241	15 MCG						
					31		011	BLEED 1				2923				
					182		071	BLEED 2				195				
	M	AM I		3Y	0		001	PREBLEED				253				
					0		011	INJ 1	CP241	15 MCG						
					35		011	BLEED 1				36558				
					180		071	BLEED 2				1126				
	M	AM I		3Y	0		001	PREBLEED				490				
					0		011	INJ 1	CP241	15 MCG						
					57		011	BLEED 1				28836				
					176		071	BLEED 2				3353				
	M	AM I		3Y	0		001	PREBLEED				577				44
					0		011	INJ 1	CP241	15 MCG						
					31		011	BLEED 1				28620				98
					182		071	BLEED 2				22168				
	F	AM I		4Y	0		001	PREBLEED				6243				
					0		011	INJ 1	CP241	15 MCG						
					31		011	BLEED 1				140789				
	M	AM I		4Y	0		001	PREBLEED				381				
					0		011	INJ 1	CP241	15 MCG						
					31		011	BLEED 1				2090				
					182		071	BLEED 2				473				

02600

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	F	AM I	(b) (6)	2Y	0	(b) (6)	001	PREBLEED				516				
					0		011	INJ 1	CP241	15 MCG						
					68		011	BLEED 1				5218				
	F	AM I		3Y	0		001	PREBLEED				650				19
					0		011	INJ 1	CP241	15 MCG						
					31		011	BLEED 1				25101				99
	M	AM I		3Y	0		001	PREBLEED				3541				
					0		011	INJ 1	CP241	15 MCG						
					31		011	BLEED 1				85908				
					182		071	BLEED 2				19012				
	F	AM I		13M	0		001	PREBLEED				155		< 5		
					0		011	INJ 1	CP241	15 MCG						
					29		011	BLEED 1				398		>= 80		
					180		071	BLEED 2				976				
	M	AM I		3Y	0		001	PREBLEED				640				6
					0		011	INJ 1	CP241	15 MCG						
					76		011	BLEED 1				61288				96
	F	AM I		19M	0		001	PREBLEED				263				
					0		011	INJ 1	CP241	15 MCG						
					48		011	BLEED 1				23967				
	F	AM I		3Y	0		001	PREBLEED				7665				31
					0		011	INJ 1	CP241	15 MCG						
					28		011	BLEED 1				28636				78
	M	AM I		3Y	0		001	PREBLEED				2984		20		
					0		011	INJ 1	CP298	15 MCG						
					62		011	BLEED 1				32120		20		
	M	AM I		18M	0		001	PREBLEED				560				
					0		011	INJ 1	CP298	15 MCG						
					47		011	BLEED 1				1954				
	M	AM I		19M	0		001	PREBLEED				728		20		
					0		011	INJ 1	CP298	15 MCG						

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	AM I	(b) (6)	19M	30	(b) (6)	011	BLEED	1			18921		80		
	F	AM I		14M	0		011	INJ	1	CP749	15 MCG					
	F	AM I		16M	0		011	INJ	1	CP749	15 MCG					
	M	AM I		12M	0		011	INJ	1	CP749	15 MCG					
	M	AM I		13M	0		011	INJ	1	CP749	15 MCG					
	M	AM I		15M	0		011	INJ	1	CP749	15 MCG					
	M	AM I		13M	0		011	INJ	1	CP749	15 MCG					
	M	AM I		15M	0		011	INJ	1	CP749	15 MCG					
	M	AM I		14M	0		011	INJ	1	CP749	15 MCG					
	F	AM I		12M	0		011	INJ	1	CP749	15 MCG					
	M	AM I		16M	0		011	INJ	1	CP749	15 MCG					
	F	AM I		12M	0		011	INJ	1	CP298	15 MCG					
	M	AM I		14M	0		011	INJ	1	CP298	15 MCG					
	F	AM I		12M	0		011	INJ	1	CP298	15 MCG					
	M	AM I		13M	0		011	INJ	1	CP298	15 MCG					
	F	AM I		14M	0		011	INJ	1	CP298	15 MCG					
	M	AM I		15M	0		011	INJ	1	CP298	15 MCG					
	F	AM I		12M	0		011	INJ	1	CP298	15 MCG					
	M	AM I		15M	0		011	INJ	1	CP298	15 MCG					
	M	AM I		15M	0		011	INJ	1	CP298	15 MCG					
	M	AM I		13M	0		011	INJ	1	CP298	15 MCG					

17600

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT		LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	AM I	(b) (6)	14M	0	(b) (6)	011	INJ	1	CP749	15 MCG						
	F	AM I		14M	0		011	INJ	1	CP298	15 MCG						
	F	AM I		15M	0		011	INJ	1	CP298	15 MCG						
	M	AM I		14M	0		011	INJ	1	CP298	15 MCG						
	M	AM I		13M	0		011	INJ	1	CP298	10.5 MCG						
	F	AM I		17M	0		011	INJ	1	CP298	15 MCG						
	F	AM I		14M	0		011	INJ	1	CP749	15 MCG						
	F	AM I		16M	0		011	INJ	1	CP749	15 MCG						
	M	AM I		13M	0		011	INJ	1	CP298	15 MCG						
	M	AM I		18M	0		011	INJ	1	CP298	15 MCG						
	F	AM I		17M	0		011	INJ	1	CP749	15 MCG						
	M	AM I		17M	0		011	INJ	1	CP749	15 MCG						
	F	AM I		14M	0		011	INJ	1	CP749	15 MCG						
	F	AM I		18M	0		011	INJ	1	CP749	15 MCG						
	F	AM I		12M	0		011	INJ	1	CP749	15 MCG						
	F	AM I		14M	0		011	INJ	1	CP749	15 MCG						
	F	AM I		17M	0		011	INJ	1	CP749	15 MCG						
	F	AM I		17M	0		011	INJ	1	CP749	15 MCG						
	F	AM I		17M	0		011	INJ	1	CP749	15 MCG						
	F	AM I		16M	0		011	INJ	1	CP749	15 MCG						
	F	AM I		13M	0		011	INJ	1	CP749	15 MCG						

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	AM I	(b) (6)	18M	0	(b) (6)		011 INJ	1	CP749	15 MCG					
	F	AM I		16M	0			011 INJ	1	CP749	15 MCG					
	M	AM I		13M	0			011 INJ	1	CP749	15 MCG					
	M	AM I		18M	0			011 INJ	1	CP749	15 MCG					
	M	AM I		14M	0			011 INJ	1	CP749	15 MCG					
	M	AM I		15M	0			011 INJ	1	CP749	15 MCG					
	F	AM I		18M	0			011 INJ	1	CP749	15 MCG					
	M	AM I		12M	0			011 INJ	1	CP749	15 MCG					
	F	AM I		13M	0			011 INJ	1	CP749	15 MCG					
	M	AM I		14M	0			011 INJ	1	CP749	15 MCG					
	F	AM I		12M	0			011 INJ	1	CP749	15 MCG					
	F	AM I		15M	0			011 INJ	1	CP749	15 MCG					
	M	AM I		16M	0			011 INJ	1	CP298	15 MCG					
	F	AM I		17M	0			011 INJ	1	CP298	15 MCG					
	M	AM I		13M	0			011 INJ	1	CP298	15 MCG					
	F	AM I		12M	0			011 INJ	1	CP298	15 MCG					
	F	AM I		17M	0			011 INJ	1	CP298	15 MCG					
	F	AM I		12M	0			011 INJ	1	CP298	15 MCG					
	M	AM I		16M	0			011 INJ	1	CP298	15 MCG					

TABLE 2

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ IGG1	CODE/ IGG2	CODE/ IGGM	CODE/IGG TOTAL
(b) (6)	M	AM I	(b) (6)	3M	0	(b) (6)	011	INJ	1	CP241	15 MCG			
	M	AM I		3M	0		011	INJ	1	CP241	15 MCG			
					64		021	INJ	2	CP241	15 MCG			
	F	AM I		2M	0		011	INJ	1	CP298	15 MCG			
					63		021	INJ	2	CP298	15 MCG			
	F	AM I		3M	0		011	INJ	1	CP298	15 MCG			
					67		021	INJ	2	CP298	15 MCG			
	M	AM I		2M	0		011	INJ	1	CP241	15 MCG			
					64		021	INJ	2	CP298	15 MCG			
	F	AM I		2M	0		011	INJ	1	CP241	15 MCG			
					61		021	INJ	2	CP241	15 MCG			
	F	AM I		1M	0		011	INJ	1	CP241	15 MCG			
					56		021	INJ	2	CP241	15 MCG			
	F	AM I		3M	0		011	INJ	1	CP241	15 MCG			
					56		021	INJ	2	CP241	15 MCG			
	M	AM I		2M	0		011	INJ	1	CP241	15 MCG			
					61		021	INJ	2	CP241	15 MCG			
	F	AM I		3M	0		011	INJ	1	CP298	15 MCG			
					62		021	INJ	2	CP298	15 MCG			
	M	AM I		1M	0		011	INJ	1	CP241	15 MCG			
					70		021	INJ	2	CP241	15 MCG			
	F	AM I		2M	0		011	INJ	1	CP241	15 MCG			
					61		021	INJ	2	CP241	15 MCG			
	F	AM I		2M	0		011	INJ	1	CP298	15 MCG			
					61		021	INJ	2	CP298	15 MCG			
	F	AM I		2M	0		011	INJ	1	CP241	15 MCG			
					98		021	INJ	2	CP241	15 MCG			

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ IGG1	CODE/ IGG2	CODE/ IGGM	CODE/IGG TOTAL
(b) (6)	F	AM I	(b) (6)	1M	0	(b) (6)		011 INJ	1	CP241	15 MCG			
	M	AM I		1M	0			011 INJ	1	CP241	15 MCG			
					57			021 INJ	2	CP241	15 MCG			
	F	AM I		2M	0			011 INJ	1	CP298	15 MCG			
					83			021 INJ	2	CP298	15 MCG			
	M	AM I		1M	0			011 INJ	1	CP241	15 MCG			
					78			021 INJ	2	CP241	15 MCG			
	M	AM I		1M	0			011 INJ	1	CP241	15 MCG			
					70			021 INJ	2	CP241	15 MCG			
	M	AM I		1M	0			011 INJ	1	CP298	15 MCG			
					91			021 INJ	2	CP298	15 MCG			
	M	AM I		2M	0			011 INJ	1	CP298	15 MCG			
					60			021 INJ	2	CP298	15 MCG			
	F	AM I		2M	0			011 INJ	1	CP298	15 MCG			
					86			021 INJ	2	CP298	15 MCG			
	M	AM I		2M	0			011 INJ	1	CP298	15 MCG			
					65			021 INJ	2	CP298	15 MCG			
	M	AM I		1M	0			011 INJ	1	CP298	15 MCG			
					62			021 INJ	2	CP298	15 MCG			
	F	AM I		1M	0			011 INJ	1	CP298	15 MCG			
					79			021 INJ	2	CP298	15 MCG			
	F	AM I		3M	0			011 INJ	1	CP298	15 MCG			
					51			021 INJ	2	CP298	15 MCG			
	F	AM I		2M	0			011 INJ	1	CP298	15 MCG			
					91			021 INJ	2	CP298	15 MCG			
	F	AM I		4M	0			011 INJ	1	CP298	15 MCG			
					60			021 INJ	2	CP298	15 MCG			

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS EVENT	LOT	DOSE	CODE/ IGG1	CODE/ IGG2	CODE/ IGGM	CODE/IGG TOTAL
(b) (6)	M	AM I	(b) (6)	2M	0	(b) (6)	011 INJ	1	CP298	15 MCG			
					47		021 INJ	2	CP298	15 MCG			
	F	AM I		3M	0		011 INJ	1	CP749	15 MCG			
	M	AM I		2M	0		011 INJ	1	CP749	15 MCG			
	F	AM I		2M	0		011 INJ	1	CP749	15 MCG			
	F	AM I		2M	0		011 INJ	1	CP298	15 MCG			
					61		021 INJ	2	CP298	15 MCG			
	F	AM I		2M	0		011 INJ	1	CP298	15 MCG			
					58		021 INJ	2	CP298	15 MCG			
	M	AM I		1M	0		011 INJ	1	CP298	15 MCG			
					61		021 INJ	2	CP298	15 MCG			
	M	AM I		1M	0		011 INJ	1	CP298	15 MCG			
					61		021 INJ	2	CP298	15 MCG			
	F	AM I		2M	0		011 INJ	1	CP298	15 MCG			
					72		021 INJ	2	CP298	15 MCG			
	F	AM I		1M	0		011 INJ	1	CP298	15 MCG			
					64		021 INJ	2	CP298	15 MCG			
	F	AM I		2M	0		011 INJ	1	CP298	15 MCG			
					80		021 INJ	2	CP298	15 MCG			
	F	AM I		2M	0		011 INJ	1	CP298	15 MCG			
	F	AM I		3M	0		011 INJ	1	CP298	15 MCG			
					63		021 INJ	2	CP298	15 MCG			
	M	AM I		2M	0		011 INJ	1	CP298	15 MCG			
	M	AM I		4M	0		011 INJ	1	CP298	15 MCG			
	M	AM I		3M	0		011 INJ	1	CP298	15 MCG			

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ IGG1	CODE/ IGG2	CODE/ IGGM	CODE/IGG TOTAL
(b) (6)	F	AM I	(b) (6)	3M	0	(b) (6)		011 INJ	1	CP298 15 MCG				
					84			021 INJ	2	CP298 15 MCG				
	M	AM I		2M	0			011 INJ	1	CP298 15 MCG				
					63			021 INJ	2	CP298 15 MCG				
	M	AM I		2M	0			011 INJ	1	CP298 15 MCG				
					72			021 INJ	2	CP298 15 MCG				
	M	AM I		3M	0			011 INJ	1	CP298 15 MCG				
					60			021 INJ	2	CP298 15 MCG				
	M	AM I		3M	0			011 INJ	1	CP298 15 MCG				
					63			021 INJ	2	CP298 15 MCG				
	M	AM I		2M	0			011 INJ	1	CP298 15 MCG				
	F	AM I		2M	0			011 INJ	1	CP298 15 MCG				
					64			021 INJ	2	CP298 15 MCG				
	F	AM I		2M	0			011 INJ	1	CP298 15 MCG				
	F	AM I		3M	0			011 INJ	1	CP298 15 MCG				
					56			021 INJ	2	CP298 15 MCG				
	M	AM I		2M	0			011 INJ	1	CP298 15 MCG				
					56			021 INJ	2	CP298 15 MCG				
	F	AM I		2M	0			011 INJ	1	CP298 15 MCG				
					67			021 INJ	2	CP298 15 MCG				
	M	AM I		2M	0			011 INJ	1	CP298 15 MCG				
					56			021 INJ	2	CP298 15 MCG				
	M	AM I		1M	0			011 INJ	1	CP298 15 MCG				
					61			021 INJ	2	CP298 15 MCG				
	M	AM I		3M	0			011 INJ	1	CP298 15 MCG				
					62			021 INJ	2	CP298 15 MCG				
	F	AM I		2M	0			011 INJ	1	CP298 15 MCG				

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ IGG1	CODE/ IGG2	CODE/ IGGM	CODE/IGG TOTAL
(b) (6)	F	AM I	(b) (6)	2M	69	(b) (6)	021	INJ	2 CP298	15 MCG				
	F	AM I		2M	0		011	INJ	1 CP298	15 MCG				
					78		021	INJ	2 CP298	15 MCG				
	F	AM I		2M	0		011	INJ	1 CP298	15 MCG				
					69		021	INJ	2 CP298	15 MCG				
	M	AM I		2M	0		011	INJ	1 CP298	15 MCG				
	F	AM I		2M	0		011	INJ	1 CP298	15 MCG				
					67		021	INJ	2 CP298	15 MCG				
	F	AM I		1M	0		011	INJ	1 CP298	15 MCG				
					82		021	INJ	2 CP298	15 MCG				
	M	AM I		2M	0		011	INJ	1 CP298	15 MCG				
	M	AM I		2M	0		011	INJ	1 CP298	15 MCG				
	M	AM I		2M	0		011	INJ	1 CP298	15 MCG				
					69		021	INJ	2 CP298	15 MCG				
	M	AM I		2M	0		011	INJ	1 CP298	15 MCG				
					57		021	INJ	2 CP298	15 MCG				
	M	AM I		2M	0		011	INJ	1 CP298	10.5 MCG				
					66		021	INJ	2 CP298	15 MCG				
	F	AM I		2M	0		011	INJ	1 CP298	10.5 MCG				
					61		021	INJ	2 CP298	15 MCG				
	F	AM I		1M	0		011	INJ	1 CP298	10.5 MCG				
					77		021	INJ	2 CP298	15 MCG				
	M	AM I		2M	0		011	INJ	1 CP298	10.5 MCG				
					56		021	INJ	2 CP298	15 MCG				
	F	AM I		1M	0		011	INJ	1 CP298	10.5 MCG				
					63		021	INJ	2 CP298	15 MCG				

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ IGG1	CODE/ IGG2	CODE/ IGGM	CODE/IGG TOTAL
(b) (6)	M	AM I	(b) (6)	2M	0	(b) (6)		011 INJ	1 CP298	10.5 MCG				
					53			021 INJ	2 CP298	15 MCG				
	F	AM I		2M	0			011 INJ	1 CP298	10.5 MCG				
					61			021 INJ	2 CP298	15 MCG				
	M	AM I		1M	0			011 INJ	1 CP298	10.5 MCG				
					81			021 INJ	2 CP298	15 MCG				
	F	AM I		1M	0			011 INJ	1 CP298	10.5 MCG				
					80			021 INJ	2 CP298	15 MCG				
	F	AM I		2M	0			011 INJ	1 CP298	10.5 MCG				
					54			021 INJ	2 CP298	15 MCG				
	M	AM I		3M	0			011 INJ	1 CP298	10.5 MCG				
					63			021 INJ	2 CP298	15 MCG				
	M	AM I		1M	0			011 INJ	1 CP298	10.5 MCG				
	F	AM I		1M	0			011 INJ	1 CP298	15 MCG				
	F	AM I		2M	0			011 INJ	1 CP298	15 MCG				
	F	AM I		1M	0			011 INJ	1 CP298	15 MCG				
	M	AM I		1M	0			011 INJ	1 CP298	15 MCG				
	F	AM I		1M	0			011 INJ	1 CP298	15 MCG				
	F	AM I		1M	0			011 INJ	1 CP298	15 MCG				
	F	OTHE		1M	0			011 INJ	1 CP749	15 MCG				
	M	AM I		3M	0			011 INJ	1 CP749	15 MCG				
	M	AM I		1M	0			011 INJ	1 CP749	15 MCG				
	M	AM I		3M	0			011 INJ	1 CP749	15 MCG				
	M	AM I		1M	0			011 INJ	1 CP749	15 MCG				

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ IGG1	CODE/ IGG2	CODE/ IGGM	CODE/IGG TOTAL
(b) (6)	M	AM I	(b) (6)	1M	0	(b) (6)	011	INJ 1	CP749	15 MCG				
	F	AM I		2M	0		011	INJ 1	CP749	15 MCG				
	M	AM I		2M	0		011	INJ 1	CP749	15 MCG				
	M	AM I		1M	0		011	INJ 1	CP749	15 MCG				
	F	AM I		2M	0		011	INJ 1	CP749	15 MCG				
	F	AM I		1M	0		011	INJ 1	CP749	15 MCG				
	M	AM I		1M	0		011	INJ 1	CP749	15 MCG				
	F	AM I		2M	0		011	INJ 1	CP749	15 MCG				
	F	AM I		1M	0		011	INJ 1	CP749	15 MCG				

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ IGG1	CODE/ IGG2	CODE/ IGGM	CODE/IGG TOTAL
(b) (6)	M	AM I	(b) (6)	4Y	0	(b) (6)	001	PREBLEED			< 600	< 250	670	< 100
					0		011	INJ 1	CP241	15 MCG				
					28		011	BLEED 1			10881	578	2544	2763
					206		071	BLEED 2				< 250		
	F	AM I		3Y	0		001	PREBLEED			< 600	< 250	721	< 100
					0		011	INJ 1	CP241	15 MCG				
					47		011	BLEED 1			15288	1616	586	6829
					210		071	BLEED 2				< 250		
	M	AM I		23M	0		001	PREBLEED			< 600	< 250	< 100	< 100
					0		011	INJ 1	CP241	15 MCG				
					47		011	BLEED 1			10105	814	243	3390
					210		071	BLEED 2				< 250		
	F	AM I		3Y	0		001	PREBLEED			< 600	< 250	337	< 100
					0		011	INJ 1	CP241	15 MCG				
					32		011	BLEED 1			16127	< 250	1243	2160
					206		071	BLEED 2				< 250		
	F	AM I		21M	0		001	PREBLEED			< 600		161	< 100
					0		011	INJ 1	CP241	15 MCG				
					83		011	BLEED 1			14698		375	975
	M	AM I		3Y	0		001	PREBLEED			< 600		3066	< 100
					0		011	INJ 1	CP241	15 MCG				
					27		011	BLEED 1			16953		1834	380
	M	AM I		4Y	0		001	PREBLEED			< 600		106	< 100
					0		011	INJ 1	CP241	15 MCG				
					84		011	BLEED 1			10025		444	6191
	F	AM I		4Y	0		001	PREBLEED			< 600		625	< 100
					0		011	INJ 1	CP241	15 MCG				
					33		011	BLEED 1			14972		8557	3021
	F	AM I		2Y	0		001	PREBLEED			< 600		1138	< 100
					0		011	INJ 1	CP241	15 MCG				
					27		011	BLEED 1			4144		2947	2420
	M	AM I		3Y	0		001	PREBLEED			< 600		818	< 100

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ IGG1	CODE/ IGG2	CODE/ IGGM	CODE/IGG TOTAL
(b) (6)	M	AM I	(b) (6)	3Y	0	(b) (6)	011	INJ 1	CP241	15 MCG				
					27		011	BLEED 1			30423		2739	3191
	F	AM I		3Y	0		001	PREBLEED			< 600		531	< 100
					0		011	INJ 1	CP241	15 MCG				
					27		011	BLEED 1			13085		22686	6867
	F	AM I		3Y	0		001	PREBLEED			< 600		1434	< 100
					0		011	INJ 1	CP241	15 MCG				
					27		011	BLEED 1			11012		2222	2846
	M	AM I		2Y	0		001	PREBLEED			< 600		< 100	< 100
					0		011	INJ 1	CP241	15 MCG				
					27		011	BLEED 1			64607		877	10495
	F	AM I		3Y	0		001	PREBLEED			< 600		252	< 100
					0		011	INJ 1	CP241	15 MCG				
					34		011	BLEED 1			13565		1032	1155
	M	AM I		23M	0		001	PREBLEED			< 600		< 100	328
					0		011	INJ 1	CP241	15 MCG				
					34		011	BLEED 1			1369		158	< 100
	M	AM I		17M	0		001	PREBLEED			< 600		< 100	< 100
					0		011	INJ 1	CP241	15 MCG				
					37		011	BLEED 1			2763		1273	207
	M	AM I		3Y	0		001	PREBLEED			< 600		442	< 100
					0		011	INJ 1	CP241	15 MCG				
					28		011	BLEED 1			80115		2972	27627
	F	AM I		3Y	0		001	PREBLEED			< 600		891	< 100
					0		011	INJ 1	CP241	15 MCG				
					30		011	BLEED 1			16395		3113	1313
	F	AM I		2Y	0		001	PREBLEED			< 600		186	< 100
					0		011	INJ 1	CP241	15 MCG				
					30		011	BLEED 1			10615		2319	644
	M	AM I		23M	0		001	PREBLEED			< 600		207	< 100

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ IGG1	CODE/ IGG2	CODE/ IGGM	CODE/IGG TOTAL
(b) (6)	M	AM I	(b) (6)	23M	0	(b) (6)	011	INJ 1	CP241	15 MCG				
					28		011	BLEED 1			6183		737	314
	F	AM I		3Y	0		001	PREBLEED			< 600		119	< 100
					0		011	INJ 1	CP241	15 MCG				
					73		011	BLEED 1			92680		478	2203
	M	AM I		3Y	0		001	PREBLEED			< 600		< 100	< 100
					0		011	INJ 1	CP241	15 MCG				
					28		011	BLEED 1			94626		341	8401
	F	AM I		3Y	0		001	PREBLEED			< 600			
					0		011	INJ 1	CP241	15 MCG				
					28		011	BLEED 1			39600			
	M	AM I		3Y	0		001	PREBLEED			< 600			
					0		011	INJ 1	CP241	15 MCG				
					35		011	BLEED 1			11680			
	M	AM I		3Y	0		001	PREBLEED			< 600			
					0		011	INJ 1	CP241	15 MCG				
					73		011	BLEED 1			31050			
	F	AM I		3Y	0		001	PREBLEED			< 600			
					0		011	INJ 1	CP241	15 MCG				
					35		011	BLEED 1			4736			
	M	AM I		3Y	0		011	INJ 1	CP241	15 MCG				
	F	AM I		20M	0		011	INJ 1	CP241	15 MCG				
	F	AM I		18M	0		011	INJ 1	CP241	15 MCG				
	F	AM I		2Y	0		011	INJ 1	CP241	15 MCG				
	F	AM I		23M	0		011	INJ 1	CP241	15 MCG				
	F	AM I		24M	0		001	PREBLEED			< 600	< 250		
					0		011	INJ 1	CP241	15 MCG				
					29		011	BLEED 1			940	< 250		

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ IGG1	CODE/ IGG2	CODE/ IGGM	CODE/IGG TOTAL
(b) (6)	F	AM I	(b) (6)	24M	190	(b) (6)	071	BLEED	2		< 600	< 250		
	M	AM I		4Y	0		011	INJ	1	CP298 15 MCG				
	M	AM I		22M	0		011	INJ	1	CP241 15 MCG				
	F	AM I		3Y	0		011	INJ	1	CP241 15 MCG				
	M	AM I		5Y	0		011	INJ	1	CP241 15 MCG				
	F	AM I		3Y	0		011	INJ	1	CP241 15 MCG				
	F	AM I		3Y	0		011	INJ	1	CP241 15 MCG				
	M	AM I		3Y	0		011	INJ	1	CP241 15 MCG				
	M	AM I		3Y	0		011	INJ	1	CP241 15 MCG				
	M	AM I		3Y	0		011	INJ	1	CP241 15 MCG				
	F	AM I		4Y	0		011	INJ	1	CP241 15 MCG				
	M	AM I		4Y	0		011	INJ	1	CP241 15 MCG				
	F	AM I		2Y	0		011	INJ	1	CP241 15 MCG				
	F	AM I		3Y	0		011	INJ	1	CP241 15 MCG				
	M	AM I		3Y	0		011	INJ	1	CP241 15 MCG				
	F	AM I		13M	0		011	INJ	1	CP241 15 MCG				
	M	AM I		3Y	0		011	INJ	1	CP241 15 MCG				
	F	AM I		19M	0		011	INJ	1	CP241 15 MCG				
	F	AM I		3Y	0		011	INJ	1	CP241 15 MCG				
	M	AM I		3Y	0		011	INJ	1	CP298 15 MCG				
	M	AM I		18M	0		011	INJ	1	CP298 15 MCG				

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ IGG1	CODE/ IGG2	CODE/ IGGM	CODE/IGG TOTAL
(b) (6)	M	AM I	(b) (6)	19M	0	(b) (6)		011 INJ	1 CP298	15 MCG				
	F	AM I		14M	0			011 INJ	1 CP749	15 MCG				
	F	AM I		16M	0			011 INJ	1 CP749	15 MCG				
	M	AM I		12M	0			011 INJ	1 CP749	15 MCG				
	M	AM I		13M	0			011 INJ	1 CP749	15 MCG				
	M	AM I		15M	0			011 INJ	1 CP749	15 MCG				
	M	AM I		13M	0			011 INJ	1 CP749	15 MCG				
	M	AM I		15M	0			011 INJ	1 CP749	15 MCG				
	M	AM I		14M	0			011 INJ	1 CP749	15 MCG				
	F	AM I		12M	0			011 INJ	1 CP749	15 MCG				
	M	AM I		16M	0			011 INJ	1 CP749	15 MCG				
	F	AM I		12M	0			011 INJ	1 CP298	15 MCG				
	M	AM I		14M	0			011 INJ	1 CP298	15 MCG				
	F	AM I		12M	0			011 INJ	1 CP298	15 MCG				
	M	AM I		13M	0			011 INJ	1 CP298	15 MCG				
	F	AM I		14M	0			011 INJ	1 CP298	15 MCG				
	M	AM I		15M	0			011 INJ	1 CP298	15 MCG				
	F	AM I		12M	0			011 INJ	1 CP298	15 MCG				
	M	AM I		15M	0			011 INJ	1 CP298	15 MCG				
	M	AM I		15M	0			011 INJ	1 CP298	15 MCG				
	M	AM I		13M	0			011 INJ	1 CP298	15 MCG				

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ IGG1	CODE/ IGG2	CODE/ IGGM	CODE/IGG TOTAL
(b) (6)	M	AM I	(b) (6)	14M	0	(b) (6)		011 INJ	1 CP749	15 MCG				
	F	AM I		14M	0			011 INJ	1 CP298	15 MCG				
	F	AM I		15M	0			011 INJ	1 CP298	15 MCG				
	M	AM I		14M	0			011 INJ	1 CP298	15 MCG				
	M	AM I		13M	0			011 INJ	1 CP298	10.5 MCG				
	F	AM I		17M	0			011 INJ	1 CP298	15 MCG				
	F	AM I		14M	0			011 INJ	1 CP749	15 MCG				
	F	AM I		16M	0			011 INJ	1 CP749	15 MCG				
	M	AM I		13M	0			011 INJ	1 CP298	15 MCG				
	M	AM I		18M	0			011 INJ	1 CP298	15 MCG				
	F	AM I		17M	0			011 INJ	1 CP749	15 MCG				
	M	AM I		17M	0			011 INJ	1 CP749	15 MCG				
	F	AM I		14M	0			011 INJ	1 CP749	15 MCG				
	F	AM I		18M	0			011 INJ	1 CP749	15 MCG				
	F	AM I		12M	0			011 INJ	1 CP749	15 MCG				
	F	AM I		14M	0			011 INJ	1 CP749	15 MCG				
	F	AM I		17M	0			011 INJ	1 CP749	15 MCG				
	F	AM I		17M	0			011 INJ	1 CP749	15 MCG				
	F	AM I		17M	0			011 INJ	1 CP749	15 MCG				
	F	AM I		16M	0			011 INJ	1 CP749	15 MCG				
	F	AM I		13M	0			011 INJ	1 CP749	15 MCG				

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	IGG1	CODE/	IGG2	CODE/	IGGM	CODE/IGG	TOTAL
(b) (6)	M	AM I	(b) (6)	18M	0	(b) (6)		011 INJ	1	CP749	15 MCG							
	F	AM I		16M	0			011 INJ	1	CP749	15 MCG							
	M	AM I		13M	0			011 INJ	1	CP749	15 MCG							
	M	AM I		18M	0			011 INJ	1	CP749	15 MCG							
	M	AM I		14M	0			011 INJ	1	CP749	15 MCG							
	M	AM I		15M	0			011 INJ	1	CP749	15 MCG							
	F	AM I		18M	0			011 INJ	1	CP749	15 MCG							
	M	AM I		12M	0			011 INJ	1	CP749	15 MCG							
	F	AM I		13M	0			011 INJ	1	CP749	15 MCG							
	M	AM I		14M	0			011 INJ	1	CP749	15 MCG							
	F	AM I		12M	0			011 INJ	1	CP749	15 MCG							
	F	AM I		15M	0			011 INJ	1	CP749	15 MCG							
	M	AM I		16M	0			011 INJ	1	CP298	15 MCG							
	F	AM I		17M	0			011 INJ	1	CP298	15 MCG							
	M	AM I		13M	0			011 INJ	1	CP298	15 MCG							
	F	AM I		12M	0			011 INJ	1	CP298	15 MCG							
	F	AM I		17M	0			011 INJ	1	CP298	15 MCG							
	F	AM I		12M	0			011 INJ	1	CP298	15 MCG							
	M	AM I		16M	0			011 INJ	1	CP298	15 MCG							

TABLE 3

ANTIBODY RESPONSES

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
ASSAY : RIA
LOT NUMBER : CP241
DOSE : 15 MCG
POPULATION : HEALTHY CHILDREN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
1- 6 MOS.	PRE INJ	22 (2/ 9)	0 (0/ 9)			0.124 (9)
	MONTH 2	100 (9/ 9)	67 (6/ 9)	89 (8/ 9)	9.5	1.611 (9)
	MONTH 3	100 (6/ 6)	67 (4/ 6)	100 (6/ 6)	21.7	3.079 (6)
12-71 MOS.	PRE INJ	63 (27/ 43)	12 (5/ 43)			0.244 (43)
	MONTH 1	100 (40/ 40)	95 (38/ 40)	100 (40/ 40)	36.0	11.583 (40)
	MONTH 6-9	100 (33/ 33)	67 (22/ 33)	88 (29/ 33)	6.7	1.644 (33)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 4

ANTIBODY RESPONSES

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
ASSAY : RIA
LOT NUMBER : CP298
DOSE : 15 MCG
POPULATION : HEALTHY CHILDREN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
1- 6 MOS.	PRE INJ	59 (10/ 17)	12 (2/ 17)			0.216 (17)
	MONTH 2	100 (17/ 17)	88 (15/ 17)	82 (14/ 17)	12.9	3.569 (17)
	MONTH 3	100 (6/ 6)	83 (5/ 6)	100 (6/ 6)	21.9	5.642 (6)
12-71 MOS.	PRE INJ	100 (3/ 3)	0 (0/ 3)			0.608 (3)
	MONTH 1	100 (3/ 3)	100 (3/ 3)	100 (3/ 3)	17.7	10.727 (3)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 5

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	14	
VACCINEES WITH NO COMPLAINTS :	4	(28.6 %)
VACCINEES WITH COMPLAINTS :	10	(71.4 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 14 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	5	35.7
SWELLING, INJ. SITE (<=1 IN.)	4	28.6
PAIN/SORENESS, INJ. SITE	2	14.3
ERYTHEMA, INJ. SITE (<=1 IN.)	1	7.1
SYSTEMIC REACTIONS	9	64.3
DIARRHEA	4	28.6
IRRITABILITY	4	28.6
PROLONGED CRYING, >1/2 HR	4	28.6
VOMITING	3	21.4
COUGH	1	7.1
DEHYDRATION	1	7.1
FATIGUE	1	7.1
GASTROENTERITIS, NONINFECTIOUS	1	7.1
NAUSEA	1	7.1
TEETHING	1	7.1
UPPER RESPIRATORY INFECTION, NOS	1	7.1
WARM TO TOUCH	1	7.1

TABLE 5 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 2	
TOTAL VACCINEES :	11	
VACCINEES WITH NO COMPLAINTS :	1	(9.1 %)
VACCINEES WITH COMPLAINTS :	10	(90.9 %)
VACCINEES WITH NO DATA :	0	

CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 11 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	8	72.7
SWELLING, INJ. SITE (<=1 IN.)	8	72.7
ERYTHEMA, INJ. SITE (<=1 IN.)	2	18.2
INDURATION, INJECTION SITE	2	18.2
PAIN/SORENESS, INJ. SITE	1	9.1
SYSTEMIC REACTIONS	7	63.6
IRRITABILITY	3	27.3
CONJUNCTIVITIS	2	18.2
ASEPTIC MENINGITIS	1	9.1
ATOPIC DERMATITIS	1	9.1
BRONCHIOLITIS, ACUTE	1	9.1
DIARRHEA	1	9.1
GASTROENTERITIS, NONINFECTIOUS	1	9.1

TABLE 5 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
POPULATION : HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	49	
VACCINEES WITH NO COMPLAINTS :	11	(22.9 %)
VACCINEES WITH COMPLAINTS :	37	(77.1 %)
VACCINEES WITH NO DATA :	1	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 48 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	24	50.0
PAIN/SORENESS, INJ. SITE	14	29.2
ERYTHEMA, INJ. SITE (<=1 IN.)	8	16.7
SWELLING, INJ. SITE (<=1 IN.)	7	14.6
INDURATION, INJECTION SITE	6	12.5
ECCHYMOSIS, INJECTION SITE	2	4.2
SWELLING, INJ. SITE (>1 INCH)	1	2.1
SYSTEMIC REACTIONS	27	56.3
IRRITABILITY	11	22.9
FATIGUE	8	16.7
DIARRHEA	7	14.6
PROLONGED CRYING, >1/2 HR	6	12.5
NASAL DISCHARGE	4	8.3
WARM TO TOUCH	3	6.3
FEVER	2	4.2
OTITIS MEDIA	2	4.2
ATOPIC DERMATITIS	1	2.1
BREATH HOLDING	1	2.1
CHICKENPOX	1	2.1
CONJUNCTIVITIS	1	2.1
COUGH	1	2.1
GASTROINTESTINAL PAIN	1	2.1
NAUSEA	1	2.1
PRURITUS	1	2.1
SHIGELLOSIS	1	2.1
SLEEP DISORDERS	1	2.1
TEETHING	1	2.1
VOMITING	1	2.1

TABLE 5 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	69	
VACCINEES WITH NO COMPLAINTS :	26	(37.7 %)
VACCINEES WITH COMPLAINTS :	43	(62.3 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 69 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	7	10.1
SWELLING, INJ. SITE (<=1 IN.)	5	7.2
INDURATION, INJECTION SITE	4	5.8
ERYTHEMA, INJ. SITE (<=1 IN.)	2	2.9
PAIN/SORENESS, INJ. SITE	1	1.4
SYSTEMIC REACTIONS	40	58.0
DIARRHEA	9	13.0
IRRITABILITY	8	11.6
UPPER RESPIRATORY INFECTION, NOS	7	10.1
ATOPIC DERMATITIS	6	8.7
FATIGUE	6	8.7
OTITIS MEDIA	6	8.7
PROLONGED CRYING, >1/2 HR	6	8.7
VOMITING	6	8.7
RASH	5	7.2
COUGH	3	4.3
BRONCHIAL CONGESTION	1	1.4
COMMON COLD	1	1.4
CONJUNCTIVITIS	1	1.4
CONSTIPATION	1	1.4
LUNG DISORDERS	1	1.4
MILIARIA RUBRA	1	1.4
NASAL CONGESTION	1	1.4
NASAL DISCHARGE	1	1.4
ORAL CANDIDIASIS	1	1.4
OTALGIA	1	1.4
SKIN TEXTURE CHANGES	1	1.4
TEETHING	1	1.4
HARM TO TOUCH	1	1.4

TABLE 5 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 2	
TOTAL VACCINEES :	54	
VACCINEES WITH NO COMPLAINTS :	10	(19.2 %)
VACCINEES WITH COMPLAINTS :	42	(80.8 %)
VACCINEES WITH NO DATA :	2	

CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 52 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	27	51.9
INDURATION, INJECTION SITE	15	28.8
SWELLING, INJ. SITE (<=1 IN.)	11	21.2
ERYTHEMA, INJ. SITE (<=1 IN.)	10	19.2
PAIN/SORENESS, INJ. SITE	5	9.6
SWELLING, INJ. SITE (>1 INCH)	3	5.8
INFECTION, INJECTION SITE	1	1.9
KNOT, DPT INJECTION SITE	1	1.9
SYSTEMIC REACTIONS	30	57.7
IRRITABILITY	11	21.2
COUGH	8	15.4
RASH	7	13.5
ATOPIC DERMATITIS	6	11.5
DIARRHEA	6	11.5
NASAL DISCHARGE	6	11.5
HARM TO TOUCH	5	9.6
OTITIS MEDIA	3	5.8
UPPER RESPIRATORY INFECTION, NOS	2	3.8
CANDIDIASIS	1	1.9
COMMON COLD	1	1.9
CONJUNCTIVITIS	1	1.9
INJECTION SITE PAIN	1	1.9
LUNG DISORDERS	1	1.9
NASAL CONGESTION	1	1.9
OTALGIA	1	1.9
PNEUMONIA	1	1.9
PROLONGED CRYING, >1/2 HR	1	1.9
RIGHT AXIS DEVIATION	1	1.9
SKIN TEXTURE CHANGES	1	1.9
URTICARIA	1	1.9
WHEEZING	1	1.9

TABLE 5 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
POPULATION : HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	28	
VACCINEES WITH NO COMPLAINTS :	10	(38.5 %)
VACCINEES WITH COMPLAINTS :	16	(61.5 %)
VACCINEES WITH NO DATA :	2	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 26 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	10	38.5
ERYTHEMA, INJ. SITE (<=1 IN.)	6	23.1
INDURATION, INJECTION SITE	6	23.1
SWELLING, INJ. SITE (<=1 IN.)	6	23.1
PAIN/SORENESS, INJ. SITE	3	11.5
INFLAMMATION, INJ. SITE	1	3.8
SYSTEMIC REACTIONS	11	42.3
DIARRHEA	4	15.4
IRRITABILITY	3	11.5
OTITIS MEDIA	3	11.5
FATIGUE	2	7.7
UPPER RESPIRATORY INFECTION, NOS	2	7.7
VOMITING	2	7.7
WARM TO TOUCH	2	7.7
ATOPIC DERMATITIS	1	3.8
CONJUNCTIVITIS	1	3.8
COUGH	1	3.8
EAR FLUID	1	3.8
MUSCLE CRAMPS	1	3.8
RASH	1	3.8
SCABIES	1	3.8

TABLE 5 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	17	
VACCINEES WITH NO COMPLAINTS :	2	(12.5 %)
VACCINEES WITH COMPLAINTS :	14	(87.5 %)
VACCINEES WITH NO DATA :	1	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 16 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	5	31.3
SWELLING, INJ. SITE (<=1 IN.)	3	18.8
ERYTHEMA, INJ. SITE (<=1 IN.)	2	12.5
PAIN/SORENESS, INJ. SITE	2	12.5
SYSTEMIC REACTIONS	14	87.5
IRRITABILITY	6	37.5
DIARRHEA	5	31.3
EYE DISCHARGE	2	12.5
FATIGUE	2	12.5
WARM TO TOUCH	2	12.5
ATOPIC DERMATITIS	1	6.3
CRYING	1	6.3
NASAL CONGESTION	1	6.3
NASAL DISCHARGE	1	6.3
PROLONGED CRYING, >1/2 HR	1	6.3
RASH	1	6.3
VOMITING	1	6.3

TABLE 5 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
POPULATION : HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	36	
VACCINEES WITH NO COMPLAINTS :	4	(11.4 %)
VACCINEES WITH COMPLAINTS :	31	(88.6 %)
VACCINEES WITH NO DATA :	1	

CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 35 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	16	45.7
ERYTHEMA, INJ. SITE (<=1 IN.)	9	25.7
INDURATION, INJECTION SITE	5	14.3
PAIN/SORENESS, INJ. SITE	4	11.4
SWELLING, INJ. SITE (<=1 IN.)	4	11.4
SYSTEMIC REACTIONS	29	82.9
NASAL DISCHARGE	9	25.7
ATOPIC DERMATITIS	7	20.0
COUGH	7	20.0
IRRITABILITY	6	17.1
DIARRHEA	5	14.3
RASH	3	8.6
OTITIS MEDIA	2	5.7
PROLONGED CRYING, >1/2 HR	2	5.7
TEETHING	2	5.7
UPPER RESPIRATORY INFECTION, NOS	2	5.7
VOMITING	2	5.7
WHEEZING	2	5.7
CHICKENPOX	1	2.9
COMMON COLD	1	2.9
CONJUNCTIVITIS	1	2.9
DRY SKIN	1	2.9
ERYTHEMATOUS CONDITIONS	1	2.9
EYE DISCHARGE	1	2.9
FATIGUE	1	2.9
FEVER	1	2.9
INFECTIOUS GASTROENTERITIS	1	2.9
LUNG DISORDERS	1	2.9
NAUSEA	1	2.9
RIGHT AXIS DEVIATION	1	2.9
SINUSITIS	1	2.9

TABLE 5 (cont.)

C L I N I C A L C O M P L A I N T S B Y F R E Q U E N C Y

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
POPULATION : HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	36	
VACCINEES WITH NO COMPLAINTS :	4	(11.4 %)
VACCINEES WITH COMPLAINTS :	31	(88.6 %)
VACCINEES WITH NO DATA :	1	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 35 VACCINEES
(CONT.)		
WARM TO TOUCH	1	2.9

TABLE 6

CLINICAL COMPLAINTS

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (14 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
LOCAL REACTIONS	1 (7.1%)	4 (28.6%)	1 (7.7%)	0 (0.0%)	1 (9.1%)	2 (15.4%)		5 (35.7%)
ERYTHEMA, INJ. SITE (<=1 IN.)	0 (0.0%)	1 (7.1%)	1 (7.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (7.1%)
PAIN/SORENESS, INJ. SITE	1 (7.1%)	2 (14.3%)	1 (7.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (14.3%)
SWELLING, INJ. SITE (<=1 IN.)	0 (0.0%)	3 (21.4%)	1 (7.7%)	0 (0.0%)	1 (9.1%)	2 (15.4%)		4 (28.6%)
SYSTEMIC	4 (28.6%)	3 (21.4%)	4 (30.8%)	2 (15.4%)	4 (36.4%)	3 (23.1%)		9 (64.3%)
BODY AS A WHOLE/SITE UNSPEC.	0 (0.0%)	0 (0.0%)	1 (7.7%)	0 (0.0%)	2 (18.2%)	0 (0.0%)		2 (14.3%)
FATIGUE	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (9.1%)	0 (0.0%)		1 (7.1%)
HARM TO TOUCH	0 (0.0%)	0 (0.0%)	1 (7.7%)	0 (0.0%)	1 (9.1%)	0 (0.0%)		1 (7.1%)
DIGESTIVE SYSTEM	1 (7.1%)	0 (0.0%)	3 (23.1%)	2 (15.4%)	4 (36.4%)	2 (15.4%)		6 (42.9%)
DIARRHEA	1 (7.1%)	0 (0.0%)	1 (7.7%)	2 (15.4%)	3 (27.3%)	2 (15.4%)		4 (28.6%)
GASTROENTERITIS, NONINFECTIOUS	0 (0.0%)	0 (0.0%)	1 (7.7%)	1 (7.7%)	1 (9.1%)	1 (7.7%)		1 (7.1%)

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (14 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		
NAUSEA	0 (0.0%)	0 (0.0%)	1 (7.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (7.1%)
TEETHING	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (9.1%)	0 (0.0%)		1 (7.1%)
VOMITING	0 (0.0%)	0 (0.0%)	2 (15.4%)	0 (0.0%)	1 (9.1%)	0 (0.0%)		3 (21.4%)
METABOLIC/NUTRITIONAL/IMMUNE	0 (0.0%)	0 (0.0%)	1 (7.7%)	1 (7.7%)	1 (9.1%)	1 (7.7%)		1 (7.1%)
DEHYDRATION	0 (0.0%)	0 (0.0%)	1 (7.7%)	1 (7.7%)	1 (9.1%)	1 (7.7%)		1 (7.1%)
NERVOUS SYSTEM & PSYCHIATRIC	2 (14.3%)	2 (14.3%)	2 (15.4%)	0 (0.0%)	2 (18.2%)	0 (0.0%)		7 (50.0%)
IRRITABILITY	2 (14.3%)	0 (0.0%)	2 (15.4%)	0 (0.0%)	1 (9.1%)	0 (0.0%)		4 (28.6%)
PROLONGED CRYING, >1/2 HR	0 (0.0%)	2 (14.3%)	1 (7.7%)	0 (0.0%)	1 (9.1%)	0 (0.0%)		4 (28.6%)
RESPIRATORY SYSTEM	1 (7.1%)	1 (7.1%)	1 (7.7%)	0 (0.0%)	1 (9.1%)	1 (7.7%)		1 (7.1%)
COUGH	0 (0.0%)	0 (0.0%)	1 (7.7%)	0 (0.0%)	1 (9.1%)	1 (7.7%)		1 (7.1%)
UPPER RESPIRATORY INFECTION, NOS	1 (7.1%)	1 (7.1%)	1 (7.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (7.1%)
VACCINEES WITH COMPLAINTS	5 (35.7%)	5 (35.7%)	4 (30.8%)	2 (15.4%)	4 (36.4%)	5 (38.5%)		10 (71.4%)

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (14 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		**********
VACCINEES WITH NO COMPLAINTS	9 (64.3%)	9 (64.3%)	9 (69.2%)	11 (84.6%)	7 (63.6%)	8 (61.5%)		4 (28.6%)
TOTAL VACCINEES REPORTING	14	14	13	13	11	13		14
VACCINEES WITH NO DATA	0	0	1	1	3	1		0

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (11 VACCINEES) - INJECTION: 2						
	DAYS POST VACCINATION						NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5	
LOCAL REACTIONS	1 (10.0%)	3 (30.0%)	6 (60.0%)	6 (60.0%)	6 (60.0%)	5 (55.6%)	8 (72.7%)
ERYTHEMA, INJ. SITE (<=1 IN.)	0 (0.0%)	2 (20.0%)	2 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (18.2%)
INDURATION, INJECTION SITE	0 (0.0%)	1 (10.0%)	2 (20.0%)	1 (10.0%)	1 (10.0%)	1 (11.1%)	2 (18.2%)
PAIN/SORENESS, INJ. SITE	1 (10.0%)	0 (0.0%)	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (9.1%)
SWELLING, INJ. SITE (<=1 IN.)	0 (0.0%)	2 (20.0%)	6 (60.0%)	5 (50.0%)	5 (50.0%)	4 (44.4%)	8 (72.7%)
SYSTEMIC	5 (50.0%)	3 (30.0%)	3 (30.0%)	1 (10.0%)	1 (10.0%)	2 (22.2%)	7 (63.6%)
DIGESTIVE SYSTEM	2 (20.0%)	2 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (18.2%)
DIARRHEA	1 (10.0%)	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (9.1%)
GASTROENTERITIS, NONINFECTIOUS	1 (10.0%)	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (9.1%)
NERVOUS SYSTEM & PSYCHIATRIC	1 (10.0%)	0 (0.0%)	2 (20.0%)	0 (0.0%)	0 (0.0%)	2 (22.2%)	4 (36.4%)
ASEPTIC MENINGITIS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (11.1%)	1 (9.1%)

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (11 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		
IRRITABILITY	1 (10.0%)	0 (0.0%)	2 (20.0%)	0 (0.0%)	0 (0.0%)	1 (11.1%)		3 (27.3%)
RESPIRATORY SYSTEM	1 (10.0%)	1 (10.0%)	1 (10.0%)	1 (10.0%)	1 (10.0%)	1 (11.1%)		1 (9.1%)
BRONCHIOLITIS, ACUTE	1 (10.0%)	1 (10.0%)	1 (10.0%)	1 (10.0%)	1 (10.0%)	1 (11.1%)		1 (9.1%)
SKIN & SKIN APPENDAGE	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (9.1%)
ATOPIC DERMATITIS	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (9.1%)
SPECIAL SENSES	2 (20.0%)	1 (10.0%)	1 (10.0%)	1 (10.0%)	1 (10.0%)	1 (11.1%)		2 (18.2%)
CONJUNCTIVITIS	2 (20.0%)	1 (10.0%)	1 (10.0%)	1 (10.0%)	1 (10.0%)	1 (11.1%)		2 (18.2%)
VACCINEES WITH COMPLAINTS	5 (50.0%)	5 (50.0%)	8 (80.0%)	7 (70.0%)	7 (70.0%)	7 (77.8%)		10 (90.9%)
VACCINEES WITH NO COMPLAINTS	5 (50.0%)	5 (50.0%)	2 (20.0%)	3 (30.0%)	3 (30.0%)	2 (22.2%)		1 (9.1%)
TOTAL VACCINEES REPORTING	10	10	10	10	10	9		11
VACCINEES WITH NO DATA	1	1	1	1	1	2		0

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (49 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5	COMPLAINTS
LOCAL REACTIONS	6 (13.3%)	17 (35.4%)	7 (14.9%)	5 (10.6%)	5 (10.9%)	4 (8.5%)	24 (50.0%)
ECCHYMOSIS, INJECTION SITE	0 (0.0%)	0 (0.0%)	1 (2.1%)	2 (4.3%)	1 (2.2%)	1 (2.1%)	2 (4.2%)
ERYTHEMA, INJ. SITE (<=1 IN.)	2 (4.4%)	6 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	8 (16.7%)
INDURATION, INJECTION SITE	0 (0.0%)	1 (2.1%)	2 (4.3%)	4 (8.5%)	4 (8.7%)	3 (6.4%)	6 (12.5%)
PAIN/SORENESS, INJ. SITE	6 (13.3%)	10 (20.8%)	4 (8.5%)	2 (4.3%)	0 (0.0%)	2 (4.3%)	14 (29.2%)
SWELLING, INJ. SITE (>1 INCH)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.2%)	1 (2.1%)	1 (2.1%)
SWELLING, INJ. SITE (<=1 IN.)	0 (0.0%)	5 (10.4%)	2 (4.3%)	1 (2.1%)	3 (6.5%)	1 (2.1%)	7 (14.6%)
SYSTEMIC	12 (26.7%)	12 (25.0%)	13 (27.7%)	9 (19.1%)	9 (19.6%)	13 (27.7%)	27 (56.3%)
BODY AS A WHOLE/SITE UNSPEC.	2 (4.4%)	4 (8.3%)	4 (8.5%)	2 (4.3%)	1 (2.2%)	3 (6.4%)	10 (20.8%)
FATIGUE	2 (4.4%)	2 (4.2%)	2 (4.3%)	1 (2.1%)	0 (0.0%)	2 (4.3%)	8 (16.7%)
FEVER	0 (0.0%)	1 (2.1%)	1 (2.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (4.2%)

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (49 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5	
HARM TO TOUCH	1 (2.2%)	2 (4.2%)	1 (2.1%)	1 (2.1%)	1 (2.2%)	1 (2.1%)	3 (6.3%)
DIGESTIVE SYSTEM	3 (6.7%)	5 (10.4%)	6 (12.8%)	3 (6.4%)	4 (8.7%)	6 (12.8%)	10 (20.8%)
DIARRHEA	3 (6.7%)	5 (10.4%)	6 (12.8%)	3 (6.4%)	3 (6.5%)	4 (8.5%)	7 (14.6%)
GASTROINTESTINAL PAIN	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.2%)	0 (0.0%)	1 (2.1%)
NAUSEA	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.1%)	1 (2.1%)
SHIGELLOSIS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.2%)	1 (2.1%)	1 (2.1%)
TEETHING	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.1%)	1 (2.1%)
VOMITING	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.1%)	1 (2.1%)
NERVOUS SYSTEM & PSYCHIATRIC	4 (8.9%)	4 (8.3%)	4 (8.5%)	4 (8.5%)	1 (2.2%)	2 (4.3%)	13 (27.1%)
IRRITABILITY	2 (4.4%)	3 (6.3%)	4 (8.5%)	4 (8.5%)	1 (2.2%)	2 (4.3%)	11 (22.9%)
PROLONGED CRYING, >1/2 HR	3 (6.7%)	3 (6.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.1%)	6 (12.5%)
SLEEP DISORDERS	1 (2.2%)	1 (2.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.1%)

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (49 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
RESPIRATORY SYSTEM	1 (2.2%)	0 (0.0%)	1 (2.1%)	1 (2.1%)	0 (0.0%)	2 (4.3%)		5 (10.4%)
BREATH HOLDING	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.1%)	0 (0.0%)	0 (0.0%)		1 (2.1%)
COUGH	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.1%)		1 (2.1%)
NASAL DISCHARGE	1 (2.2%)	0 (0.0%)	1 (2.1%)	0 (0.0%)	0 (0.0%)	2 (4.3%)		4 (8.3%)
SKIN & SKIN APPENDAGE	1 (2.2%)	0 (0.0%)	0 (0.0%)	1 (2.1%)	2 (4.3%)	2 (4.3%)		3 (6.3%)
ATOPIC DERMATITIS	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.1%)	1 (2.2%)	1 (2.1%)		1 (2.1%)
CHICKENPOX	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.2%)	1 (2.1%)		1 (2.1%)
PRURITUS	1 (2.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (2.1%)
SPECIAL SENSES	2 (4.4%)	2 (4.2%)	2 (4.3%)	2 (4.3%)	2 (4.3%)	3 (6.4%)		3 (6.3%)
CONJUNCTIVITIS	1 (2.2%)	1 (2.1%)	1 (2.1%)	1 (2.1%)	1 (2.2%)	1 (2.1%)		1 (2.1%)
OTITIS MEDIA	1 (2.2%)	1 (2.1%)	1 (2.1%)	1 (2.1%)	1 (2.2%)	2 (4.3%)		2 (4.2%)
VACCINEES WITH COMPLAINTS	14 (31.1%)	24 (50.0%)	16 (34.0%)	13 (27.7%)	13 (28.3%)	14 (29.8%)		37 (77.1%)

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (49 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5	COMPLAINTS
VACCINEES WITH NO COMPLAINTS	31 (68.9%)	24 (50.0%)	31 (66.0%)	34 (72.3%)	33 (71.7%)	33 (70.2%)	********** 11 (22.9%)
TOTAL VACCINEES REPORTING	45	48	47	47	46	47	48
VACCINEES WITH NO DATA	4	1	2	2	3	2	1

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (57 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		
LOCAL REACTIONS	0 (0.0%)	5 (9.3%)	4 (7.5%)	5 (9.1%)	4 (7.3%)	4 (7.5%)		6 (10.5%)
ERYTHEMA, INJ. SITE (<=1 IN.)	0 (0.0%)	1 (1.9%)	1 (1.9%)	1 (1.8%)	0 (0.0%)	0 (0.0%)		1 (1.8%)
INDURATION, INJECTION SITE	0 (0.0%)	4 (7.4%)	3 (5.7%)	3 (5.5%)	3 (5.5%)	3 (5.7%)		4 (7.0%)
SWELLING, INJ. SITE (<=1 IN.)	0 (0.0%)	3 (5.6%)	3 (5.7%)	4 (7.3%)	2 (3.6%)	3 (5.7%)		4 (7.0%)
SYSTEMIC	19 (33.3%)	16 (29.6%)	12 (22.6%)	11 (20.0%)	13 (23.6%)	9 (17.0%)		32 (56.1%)
BODY AS A WHOLE/SITE UNSPEC.	3 (5.3%)	2 (3.7%)	1 (1.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		5 (8.8%)
FATIGUE	3 (5.3%)	2 (3.7%)	1 (1.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		5 (8.8%)
DIGESTIVE SYSTEM	2 (3.5%)	5 (9.3%)	4 (7.5%)	5 (9.1%)	4 (7.3%)	1 (1.9%)		11 (19.3%)
CONSTIPATION	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.8%)	0 (0.0%)	0 (0.0%)		1 (1.8%)
DIARRHEA	1 (1.8%)	3 (5.6%)	4 (7.5%)	2 (3.6%)	2 (3.6%)	1 (1.9%)		6 (10.5%)
ORAL CANDIDIASIS	1 (1.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (1.8%)

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (57 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5	
TEETHING	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.8%)	1 (1.8%)	0 (0.0%)	1 (1.8%)
VOMITING	0 (0.0%)	2 (3.7%)	1 (1.9%)	1 (1.8%)	1 (1.8%)	0 (0.0%)	5 (8.8%)
NERVOUS SYSTEM & PSYCHIATRIC	3 (5.3%)	4 (7.4%)	1 (1.9%)	2 (3.6%)	2 (3.6%)	1 (1.9%)	8 (14.0%)
IRRITABILITY	2 (3.5%)	3 (5.6%)	1 (1.9%)	2 (3.6%)	2 (3.6%)	1 (1.9%)	6 (10.5%)
PROLONGED CRYING, >1/2 HR	1 (1.8%)	2 (3.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (5.3%)
RESPIRATORY SYSTEM	6 (10.5%)	6 (11.1%)	6 (11.3%)	5 (9.1%)	6 (10.9%)	4 (7.5%)	12 (21.1%)
BRONCHIAL CONGESTION	1 (1.8%)	1 (1.9%)	1 (1.9%)	1 (1.8%)	0 (0.0%)	0 (0.0%)	1 (1.8%)
COMMON COLD	0 (0.0%)	0 (0.0%)	1 (1.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.8%)
COUGH	0 (0.0%)	1 (1.9%)	0 (0.0%)	1 (1.8%)	0 (0.0%)	0 (0.0%)	2 (3.5%)
LUNG DISORDERS	1 (1.8%)	1 (1.9%)	1 (1.9%)	1 (1.8%)	1 (1.8%)	0 (0.0%)	1 (1.8%)
NASAL CONGESTION	1 (1.8%)	1 (1.9%)	1 (1.9%)	1 (1.8%)	0 (0.0%)	0 (0.0%)	1 (1.8%)
NASAL DISCHARGE	1 (1.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.8%)

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (57 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		
UPPER RESPIRATORY INFECTION, NOS	2 (3.5%)	2 (3.7%)	2 (3.8%)	2 (3.6%)	5 (9.1%)	4 (7.5%)		7 (12.3%)
SKIN & SKIN APPENDAGE	6 (10.5%)	2 (3.7%)	2 (3.8%)	1 (1.8%)	2 (3.6%)	2 (3.8%)		7 (12.3%)
ATOPIC DERMATITIS	5 (8.8%)	2 (3.7%)	1 (1.9%)	1 (1.8%)	1 (1.8%)	1 (1.9%)		5 (8.8%)
MILIARIA RUBRA	0 (0.0%)	0 (0.0%)	1 (1.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (1.8%)
RASH	1 (1.8%)	0 (0.0%)	2 (3.8%)	1 (1.8%)	2 (3.6%)	2 (3.8%)		4 (7.0%)
SKIN TEXTURE CHANGES	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.8%)	0 (0.0%)	0 (0.0%)		1 (1.8%)
SPECIAL SENSES	2 (3.5%)	2 (3.7%)	3 (5.7%)	4 (7.3%)	4 (7.3%)	3 (5.7%)		7 (12.3%)
OTALGIA	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (1.8%)	0 (0.0%)		1 (1.8%)
OTITIS MEDIA	2 (3.5%)	2 (3.7%)	3 (5.7%)	4 (7.3%)	3 (5.5%)	3 (5.7%)		6 (10.5%)
VACCINEES WITH COMPLAINTS	19 (33.3%)	19 (35.2%)	14 (26.4%)	14 (25.5%)	16 (29.1%)	12 (22.6%)		34 (59.6%)
VACCINEES WITH NO COMPLAINTS	38 (66.7%)	35 (64.8%)	39 (73.6%)	41 (74.5%)	39 (70.9%)	41 (77.4%)		23 (40.4%)
TOTAL VACCINEES REPORTING	57	54	53	55	55	53		57

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (57 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
VACCINEES WITH NO DATA	0	3	4	2	2	4		0

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (43 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		
LOCAL REACTIONS	2 (4.8%)	11 (28.9%)	10 (25.6%)	11 (27.5%)	11 (27.5%)	10 (28.6%)		20 (47.6%)
ERYTHEMA, INJ. SITE (<=1 IN.)	1 (2.4%)	6 (15.8%)	4 (10.3%)	2 (5.0%)	0 (0.0%)	0 (0.0%)		7 (16.7%)
INDURATION, INJECTION SITE	0 (0.0%)	4 (10.5%)	7 (17.9%)	10 (25.0%)	10 (25.0%)	10 (28.6%)		15 (35.7%)
INFECTION, INJECTION SITE	0 (0.0%)	1 (2.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (2.4%)
KNOT, DPT INJECTION SITE	1 (2.4%)	1 (2.6%)	1 (2.6%)	1 (2.5%)	1 (2.5%)	1 (2.9%)		1 (2.4%)
PAIN/SORENESS, INJ. SITE	0 (0.0%)	4 (10.5%)	1 (2.6%)	1 (2.5%)	1 (2.5%)	0 (0.0%)		4 (9.5%)
SWELLING, INJ. SITE (>1 INCH)	0 (0.0%)	0 (0.0%)	1 (2.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (2.4%)
SWELLING, INJ. SITE (<=1 IN.)	1 (2.4%)	5 (13.2%)	5 (12.8%)	3 (7.5%)	3 (7.5%)	1 (2.9%)		6 (14.3%)
SYSTEMIC	16 (38.1%)	13 (34.2%)	13 (33.3%)	9 (22.5%)	9 (22.5%)	6 (17.1%)		25 (59.5%)
BODY AS A WHOLE/SITE UNSPEC.	2 (4.8%)	4 (10.5%)	1 (2.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		4 (9.5%)
INJECTION SITE PAIN	0 (0.0%)	1 (2.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (2.4%)

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (43 VACCINEES) - INJECTION: 2						
	DAYS POST VACCINATION						NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5	
WARM TO TOUCH	2 (4.8%)	4 (10.5%)	1 (2.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (9.5%)
CARDIOVASCULAR SYSTEM	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.5%)	1 (2.9%)	1 (2.4%)
RIGHT AXIS DEVIATION	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.5%)	1 (2.9%)	1 (2.4%)
DIGESTIVE SYSTEM	1 (2.4%)	4 (10.5%)	2 (5.1%)	3 (7.5%)	2 (5.0%)	2 (5.7%)	5 (11.9%)
DIARRHEA	1 (2.4%)	4 (10.5%)	2 (5.1%)	3 (7.5%)	2 (5.0%)	2 (5.7%)	5 (11.9%)
NERVOUS SYSTEM & PSYCHIATRIC	5 (11.9%)	5 (13.2%)	4 (10.3%)	2 (5.0%)	1 (2.5%)	0 (0.0%)	10 (23.8%)
IRRITABILITY	5 (11.9%)	5 (13.2%)	4 (10.3%)	2 (5.0%)	1 (2.5%)	0 (0.0%)	10 (23.8%)
RESPIRATORY SYSTEM	5 (11.9%)	3 (7.9%)	2 (5.1%)	4 (10.0%)	5 (12.5%)	4 (11.4%)	9 (21.4%)
COUGH	4 (9.5%)	1 (2.6%)	1 (2.6%)	2 (5.0%)	3 (7.5%)	2 (5.7%)	6 (14.3%)
LUNG DISORDERS	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.5%)	0 (0.0%)	0 (0.0%)	1 (2.4%)
NASAL CONGESTION	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.5%)	1 (2.5%)	1 (2.9%)	1 (2.4%)
NASAL DISCHARGE	3 (7.1%)	1 (2.6%)	0 (0.0%)	0 (0.0%)	1 (2.5%)	0 (0.0%)	4 (9.5%)

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (43 VACCINEES) - INJECTION: 2						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5	COMPLAINTS
PNEUMONIA	0 (0.0%)	1 (2.6%)	1 (2.6%)	1 (2.5%)	0 (0.0%)	0 (0.0%)	1 (2.4%)
UPPER RESPIRATORY INFECTION, NOS	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.5%)	1 (2.5%)	2 (5.7%)	2 (4.8%)
WHEEZING	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.5%)	1 (2.5%)	0 (0.0%)	1 (2.4%)
SKIN & SKIN APPENDAGE	8 (19.0%)	5 (13.2%)	5 (12.8%)	4 (10.0%)	3 (7.5%)	2 (5.7%)	9 (21.4%)
ATOPIC DERMATITIS	5 (11.9%)	4 (10.5%)	2 (5.1%)	1 (2.5%)	0 (0.0%)	0 (0.0%)	5 (11.9%)
CANDIDIASIS	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.5%)	1 (2.5%)	1 (2.9%)	1 (2.4%)
RASH	4 (9.5%)	3 (7.9%)	3 (7.7%)	1 (2.5%)	1 (2.5%)	1 (2.9%)	5 (11.9%)
SKIN TEXTURE CHANGES	0 (0.0%)	0 (0.0%)	1 (2.6%)	1 (2.5%)	1 (2.5%)	0 (0.0%)	1 (2.4%)
URTICARIA	0 (0.0%)	1 (2.6%)	1 (2.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.4%)
SPECIAL SENSES	1 (2.4%)	2 (5.3%)	3 (7.7%)	2 (5.0%)	2 (5.0%)	1 (2.9%)	4 (9.5%)
OTALGIA	0 (0.0%)	0 (0.0%)	1 (2.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.4%)
OTITIS MEDIA	1 (2.4%)	2 (5.3%)	2 (5.1%)	2 (5.0%)	2 (5.0%)	1 (2.9%)	3 (7.1%)

09974

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (43 VACCINEES) - INJECTION: 2						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5	COMPLAINTS
VACCINEES WITH COMPLAINTS	17 (40.5%)	19 (50.0%)	21 (53.8%)	19 (47.5%)	19 (47.5%)	15 (42.9%)	34 (81.0%)
VACCINEES WITH NO COMPLAINTS	25 (59.5%)	19 (50.0%)	18 (46.2%)	21 (52.5%)	21 (52.5%)	20 (57.1%)	8 (19.0%)
TOTAL VACCINEES REPORTING	42	38	39	40	40	35	42
VACCINEES WITH NO DATA	1	5	4	3	3	8	1

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (27 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		
LOCAL REACTIONS	2 (8.0%)	4 (16.0%)	6 (27.3%)	7 (33.3%)	3 (13.6%)	2 (9.5%)		9 (36.0%)
ERYTHEMA, INJ. SITE (<=1 IN.)	1 (4.0%)	3 (12.0%)	3 (13.6%)	1 (4.8%)	0 (0.0%)	0 (0.0%)		5 (20.0%)
INDURATION, INJECTION SITE	0 (0.0%)	1 (4.0%)	3 (13.6%)	5 (23.8%)	3 (13.6%)	2 (9.5%)		5 (20.0%)
INFLAMMATION, INJ. SITE	0 (0.0%)	0 (0.0%)	1 (4.5%)	1 (4.8%)	1 (4.5%)	0 (0.0%)		1 (4.0%)
PAIN/SORENESS, INJ. SITE	2 (8.0%)	0 (0.0%)	1 (4.5%)	1 (4.8%)	0 (0.0%)	0 (0.0%)		3 (12.0%)
SWELLING, INJ. SITE (<=1 IN.)	1 (4.0%)	2 (8.0%)	4 (18.2%)	5 (23.8%)	0 (0.0%)	1 (4.8%)		6 (24.0%)
SYSTEMIC	6 (24.0%)	7 (28.0%)	6 (27.3%)	7 (33.3%)	5 (22.7%)	6 (28.6%)		11 (44.0%)
BODY AS A WHOLE/SITE UNSPEC.	1 (4.0%)	1 (4.0%)	2 (9.1%)	1 (4.8%)	1 (4.5%)	1 (4.8%)		3 (12.0%)
FATIGUE	1 (4.0%)	0 (0.0%)	0 (0.0%)	1 (4.8%)	0 (0.0%)	0 (0.0%)		2 (8.0%)
HARM TO TOUCH	0 (0.0%)	1 (4.0%)	2 (9.1%)	1 (4.8%)	1 (4.5%)	1 (4.8%)		2 (8.0%)
DIGESTIVE SYSTEM	2 (8.0%)	1 (4.0%)	1 (4.5%)	3 (14.3%)	1 (4.5%)	1 (4.8%)		4 (16.0%)

000676

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (27 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5	
DIARRHEA	2 (8.0%)	1 (4.0%)	0 (0.0%)	3 (14.3%)	1 (4.5%)	1 (4.8%)	4 (16.0%)
VOMITING	0 (0.0%)	1 (4.0%)	1 (4.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (8.0%)
MUSCULOSKELETAL SYSTEM	0 (0.0%)	1 (4.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (4.0%)
MUSCLE CRAMPS	0 (0.0%)	1 (4.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (4.0%)
NERVOUS SYSTEM & PSYCHIATRIC	0 (0.0%)	1 (4.0%)	3 (13.6%)	1 (4.8%)	2 (9.1%)	2 (9.5%)	3 (12.0%)
IRRITABILITY	0 (0.0%)	1 (4.0%)	3 (13.6%)	1 (4.8%)	2 (9.1%)	2 (9.5%)	3 (12.0%)
RESPIRATORY SYSTEM	3 (12.0%)	1 (4.0%)	1 (4.5%)	1 (4.8%)	1 (4.5%)	1 (4.8%)	3 (12.0%)
COUGH	1 (4.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (4.0%)
UPPER RESPIRATORY INFECTION, NOS	2 (8.0%)	1 (4.0%)	1 (4.5%)	1 (4.8%)	1 (4.5%)	1 (4.8%)	2 (8.0%)
SKIN & SKIN APPENDAGE	2 (8.0%)	2 (8.0%)	2 (9.1%)	2 (9.5%)	1 (4.5%)	2 (9.5%)	3 (12.0%)
ATOPIC DERMATITIS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (4.8%)	1 (4.0%)
RASH	1 (4.0%)	1 (4.0%)	1 (4.5%)	1 (4.8%)	0 (0.0%)	0 (0.0%)	1 (4.0%)

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (27 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		
SCABIES	1 (4.0%)	1 (4.0%)	1 (4.5%)	1 (4.8%)	1 (4.5%)	1 (4.8%)		1 (4.0%)
SPECIAL SENSES	3 (12.0%)	2 (8.0%)	2 (9.1%)	2 (9.5%)	2 (9.1%)	3 (14.3%)		5 (20.0%)
CONJUNCTIVITIS	1 (4.0%)	1 (4.0%)	0 (0.0%)	0 (0.0%)	1 (4.5%)	1 (4.8%)		1 (4.0%)
EAR FLUID	0 (0.0%)	0 (0.0%)	1 (4.5%)	1 (4.8%)	0 (0.0%)	0 (0.0%)		1 (4.0%)
OTITIS MEDIA	2 (8.0%)	1 (4.0%)	1 (4.5%)	1 (4.8%)	1 (4.5%)	2 (9.5%)		3 (12.0%)
VACCINEES WITH COMPLAINTS	6 (24.0%)	10 (40.0%)	10 (45.5%)	11 (52.4%)	8 (36.4%)	7 (33.3%)		15 (60.0%)
VACCINEES WITH NO COMPLAINTS	19 (76.0%)	15 (60.0%)	12 (54.5%)	10 (47.6%)	14 (63.6%)	14 (66.7%)		10 (40.0%)
TOTAL VACCINEES REPORTING	25	25	22	21	22	21		25
VACCINEES WITH NO DATA	2	2	5	6	5	6		2

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (17 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
LOCAL REACTIONS	3 (18.8%)	1 (6.7%)	3 (18.8%)	1 (6.3%)	0 (0.0%)	0 (0.0%)		5 (31.3%)
ERYTHEMA, INJ. SITE (<=1 IN.)	1 (6.3%)	1 (6.7%)	1 (6.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (12.5%)
PAIN/SORENESS, INJ. SITE	2 (12.5%)	0 (0.0%)	1 (6.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (12.5%)
SWELLING, INJ. SITE (<=1 IN.)	0 (0.0%)	1 (6.7%)	1 (6.3%)	1 (6.3%)	0 (0.0%)	0 (0.0%)		3 (18.8%)
SYSTEMIC	13 (81.3%)	9 (60.0%)	6 (37.5%)	2 (12.5%)	5 (31.3%)	2 (12.5%)		14 (87.5%)
BODY AS A WHOLE/SITE UNSPEC.	3 (18.8%)	1 (6.7%)	1 (6.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		3 (18.8%)
FATIGUE	2 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (12.5%)
HARM TO TOUCH	1 (6.3%)	1 (6.7%)	1 (6.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (12.5%)
DIGESTIVE SYSTEM	5 (31.3%)	3 (20.0%)	2 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		6 (37.5%)
DIARRHEA	4 (25.0%)	3 (20.0%)	2 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		5 (31.3%)
VOMITING	1 (6.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (6.3%)

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (17 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5	COMPLAINTS
NERVOUS SYSTEM & PSYCHIATRIC	5 (31.3%)	2 (13.3%)	2 (12.5%)	0 (0.0%)	1 (6.3%)	0 (0.0%)	7 (43.8%)
CRYING	0 (0.0%)	0 (0.0%)	1 (6.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (6.3%)
IRRITABILITY	5 (31.3%)	2 (13.3%)	1 (6.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	6 (37.5%)
PROLONGED CRYING, >1/2 HR	0 (0.0%)	0 (0.0%)	1 (6.3%)	0 (0.0%)	1 (6.3%)	0 (0.0%)	1 (6.3%)
RESPIRATORY SYSTEM	1 (6.3%)	1 (6.7%)	0 (0.0%)	0 (0.0%)	1 (6.3%)	0 (0.0%)	2 (12.5%)
NASAL CONGESTION	1 (6.3%)	1 (6.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (6.3%)
NASAL DISCHARGE	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (6.3%)	0 (0.0%)	1 (6.3%)
SKIN & SKIN APPENDAGE	1 (6.3%)	2 (13.3%)	1 (6.3%)	1 (6.3%)	2 (12.5%)	1 (6.3%)	2 (12.5%)
ATOPIC DERMATITIS	0 (0.0%)	1 (6.7%)	0 (0.0%)	0 (0.0%)	1 (6.3%)	0 (0.0%)	1 (6.3%)
RASH	1 (6.3%)	1 (6.7%)	1 (6.3%)	1 (6.3%)	1 (6.3%)	1 (6.3%)	1 (6.3%)
SPECIAL SENSES	2 (12.5%)	2 (13.3%)	1 (6.3%)	1 (6.3%)	1 (6.3%)	1 (6.3%)	2 (12.5%)
EYE DISCHARGE	2 (12.5%)	2 (13.3%)	1 (6.3%)	1 (6.3%)	1 (6.3%)	1 (6.3%)	2 (12.5%)

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (17 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		**********
VACCINEES WITH COMPLAINTS	13 (81.3%)	9 (60.0%)	6 (37.5%)	3 (18.8%)	5 (31.3%)	2 (12.5%)		14 (87.5%)
VACCINEES WITH NO COMPLAINTS	3 (18.8%)	6 (40.0%)	10 (62.5%)	13 (81.3%)	11 (68.8%)	14 (87.5%)		2 (12.5%)
TOTAL VACCINEES REPORTING	16	15	16	16	16	16		16
VACCINEES WITH NO DATA	1	2	1	1	1	1		1

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (36 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5	COMPLAINTS
LOCAL REACTIONS	3 (8.6%)	11 (31.4%)	4 (12.1%)	3 (8.8%)	3 (9.1%)	4 (12.1%)	16 (45.7%)
ERYTHEMA, INJ. SITE (<=1 IN.)	0 (0.0%)	8 (22.9%)	2 (6.1%)	1 (2.9%)	1 (3.0%)	1 (3.0%)	9 (25.7%)
INDURATION, INJECTION SITE	0 (0.0%)	4 (11.4%)	3 (9.1%)	3 (8.8%)	3 (9.1%)	3 (9.1%)	5 (14.3%)
PAIN/SORENESS, INJ. SITE	3 (8.6%)	1 (2.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (11.4%)
SWELLING, INJ. SITE (<=1 IN.)	0 (0.0%)	2 (5.7%)	2 (6.1%)	1 (2.9%)	1 (3.0%)	1 (3.0%)	4 (11.4%)
SYSTEMIC	18 (51.4%)	17 (48.6%)	15 (45.5%)	16 (47.1%)	16 (48.5%)	11 (33.3%)	29 (82.9%)
BODY AS A WHOLE/SITE UNSPEC.	1 (2.9%)	0 (0.0%)	1 (3.0%)	0 (0.0%)	1 (3.0%)	0 (0.0%)	3 (8.6%)
FATIGUE	1 (2.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.9%)
FEVER	0 (0.0%)	0 (0.0%)	1 (3.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.9%)
HARM TO TOUCH	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.0%)	0 (0.0%)	1 (2.9%)
CARDIOVASCULAR SYSTEM	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.0%)	1 (3.0%)	1 (2.9%)

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (36 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5	
RIGHT AXIS DEVIATION	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.0%)	1 (3.0%)	1 (2.9%)
DIGESTIVE SYSTEM	2 (5.7%)	2 (5.7%)	3 (9.1%)	2 (5.9%)	3 (9.1%)	1 (3.0%)	9 (25.7%)
DIARRHEA	0 (0.0%)	1 (2.9%)	1 (3.0%)	2 (5.9%)	2 (6.1%)	1 (3.0%)	5 (14.3%)
INFECTIOUS GASTROENTERITIS	0 (0.0%)	0 (0.0%)	1 (3.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.9%)
NAUSEA	1 (2.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.9%)
TEETHING	1 (2.9%)	1 (2.9%)	1 (3.0%)	0 (0.0%)	1 (3.0%)	0 (0.0%)	2 (5.7%)
VOMITING	0 (0.0%)	0 (0.0%)	2 (6.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (5.7%)
NERVOUS SYSTEM & PSYCHIATRIC	3 (8.6%)	2 (5.7%)	1 (3.0%)	0 (0.0%)	3 (9.1%)	0 (0.0%)	7 (20.0%)
IRRITABILITY	2 (5.7%)	2 (5.7%)	1 (3.0%)	0 (0.0%)	3 (9.1%)	0 (0.0%)	6 (17.1%)
PROLONGED CRYING, >1/2 HR	2 (5.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (5.7%)
RESPIRATORY SYSTEM	12 (34.3%)	10 (28.6%)	9 (27.3%)	9 (26.5%)	7 (21.2%)	6 (18.2%)	15 (42.9%)
COMMON COLD	1 (2.9%)	1 (2.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.9%)

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (36 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5	
COUGH	4 (11.4%)	4 (11.4%)	4 (12.1%)	5 (14.7%)	5 (15.2%)	3 (9.1%)	7 (20.0%)
LUNG DISORDERS	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.9%)	0 (0.0%)	0 (0.0%)	1 (2.9%)
NASAL DISCHARGE	7 (20.0%)	6 (17.1%)	6 (18.2%)	4 (11.8%)	3 (9.1%)	3 (9.1%)	9 (25.7%)
SINUSITIS	1 (2.9%)	1 (2.9%)	1 (3.0%)	1 (2.9%)	1 (3.0%)	0 (0.0%)	1 (2.9%)
UPPER RESPIRATORY INFECTION, NOS	2 (5.7%)	1 (2.9%)	1 (3.0%)	0 (0.0%)	0 (0.0%)	1 (3.0%)	2 (5.7%)
WHEEZING	1 (2.9%)	0 (0.0%)	0 (0.0%)	1 (2.9%)	0 (0.0%)	0 (0.0%)	2 (5.7%)
SKIN & SKIN APPENDAGE	6 (17.1%)	8 (22.9%)	6 (18.2%)	6 (17.6%)	4 (12.1%)	4 (12.1%)	10 (28.6%)
ATOPIC DERMATITIS	5 (14.3%)	6 (17.1%)	4 (12.1%)	4 (11.8%)	3 (9.1%)	3 (9.1%)	7 (20.0%)
CHICKENPOX	1 (2.9%)	1 (2.9%)	1 (3.0%)	1 (2.9%)	1 (3.0%)	0 (0.0%)	1 (2.9%)
DRY SKIN	1 (2.9%)	1 (2.9%)	1 (3.0%)	1 (2.9%)	1 (3.0%)	1 (3.0%)	1 (2.9%)
ERYTHEMATOUS CONDITIONS	0 (0.0%)	1 (2.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.9%)
RASH	1 (2.9%)	2 (5.7%)	2 (6.1%)	2 (5.9%)	1 (3.0%)	2 (6.1%)	3 (8.6%)

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (36 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
SPECIAL SENSES	0 (0.0%)	2 (5.7%)	2 (6.1%)	1 (2.9%)	0 (0.0%)	1 (3.0%)		4 (11.4%)
CONJUNCTIVITIS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.0%)		1 (2.9%)
EYE DISCHARGE	0 (0.0%)	1 (2.9%)	1 (3.0%)	1 (2.9%)	0 (0.0%)	0 (0.0%)		1 (2.9%)
OTITIS MEDIA	0 (0.0%)	1 (2.9%)	1 (3.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (5.7%)
VACCINEES WITH COMPLAINTS	18 (51.4%)	24 (68.6%)	19 (57.6%)	19 (55.9%)	17 (51.5%)	14 (42.4%)		31 (88.6%)
VACCINEES WITH NO COMPLAINTS	17 (48.6%)	11 (31.4%)	14 (42.4%)	15 (44.1%)	16 (48.5%)	19 (57.6%)		4 (11.4%)
TOTAL VACCINEES REPORTING	35	35	33	34	33	33		35
VACCINEES WITH NO DATA	1	1	3	2	3	3		1

TABLE 7

MAXIMUM TEMPERATURES

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (14 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		MAX TEMP
< 99	14 (100.0%)	12 (100.0%)	10 (90.9%)	10 (90.9%)	8 (72.7%)	11 (91.7%)		10 (71.4%)
99 - 99.9	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (18.2%)	1 (8.3%)		2 (14.3%)
100 - 100.9	0 (0.0%)	0 (0.0%)	1 (9.1%)	1 (9.1%)	1 (9.1%)	0 (0.0%)		2 (14.3%)
TEMPERATURE TAKEN	14 (100.0%)	12 (85.7%)	11 (78.6%)	11 (78.6%)	11 (78.6%)	12 (85.7%)		14 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	2 (14.3%)	3 (21.4%)	3 (21.4%)	3 (21.4%)	2 (14.3%)		0 (0.0%)

TABLE 7 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (11 VACCINEES) - INJECTION 2							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
< 99	7 (63.6%)	3 (33.3%)	2 (25.0%)	3 (33.3%)	5 (62.5%)	6 (66.7%)		1 (9.1%)
99 - 99.9	4 (36.4%)	6 (66.7%)	6 (75.0%)	6 (66.7%)	2 (25.0%)	2 (22.2%)		9 (81.8%)
101 - 101.9	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (12.5%)	0 (0.0%)		0 (0.0%)
103 - 103.9	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (11.1%)		1 (9.1%)
TEMPERATURE TAKEN	11 (100.0%)	9 (81.8%)	8 (72.7%)	9 (81.8%)	8 (72.7%)	9 (81.8%)		11 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	2 (18.2%)	3 (27.3%)	2 (18.2%)	3 (27.3%)	2 (18.2%)		0 (0.0%)

TABLE 7 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (49 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
NORMAL	0 (0.0%)	1 (2.3%)	1 (2.3%)	0 (0.0%)	1 (2.3%)	1 (2.4%)		0 (0.0%)
< 99	26 (54.2%)	24 (55.8%)	34 (79.1%)	38 (82.6%)	35 (81.4%)	29 (69.0%)		10 (20.8%)
99 - 99.9	20 (41.7%)	17 (39.5%)	7 (16.3%)	7 (15.2%)	7 (16.3%)	12 (28.6%)		33 (68.8%)
100 - 100.9	1 (2.1%)	1 (2.3%)	1 (2.3%)	1 (2.2%)	0 (0.0%)	0 (0.0%)		4 (8.3%)
102 - 102.9	1 (2.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (2.1%)
TEMPERATURE TAKEN	48 (98.0%)	43 (87.8%)	43 (87.8%)	46 (93.9%)	43 (87.8%)	42 (85.7%)		48 (98.0%)
TEMPERATURE NOT TAKEN	1 (2.0%)	6 (12.2%)	6 (12.2%)	3 (6.1%)	6 (12.2%)	7 (14.3%)		1 (2.0%)

TABLE 7 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (57 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
< 99	52 (91.2%)	42 (82.4%)	48 (96.0%)	42 (84.0%)	45 (84.9%)	45 (86.5%)		33 (57.9%)
99 - 99.9	5 (8.8%)	9 (17.6%)	1 (2.0%)	5 (10.0%)	6 (11.3%)	7 (13.5%)		19 (33.3%)
100 - 100.9	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (6.0%)	2 (3.8%)	0 (0.0%)		4 (7.0%)
101 - 101.9	0 (0.0%)	0 (0.0%)	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (1.8%)
TEMPERATURE TAKEN	57 (100.0%)	51 (89.5%)	50 (87.7%)	50 (87.7%)	53 (93.0%)	52 (91.2%)		57 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	6 (10.5%)	7 (12.3%)	7 (12.3%)	4 (7.0%)	5 (8.8%)		0 (0.0%)

TABLE 7 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (43 VACCINEES) - INJECTION 2							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
NORMAL	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.7%)	1 (2.6%)	1 (3.0%)		0 (0.0%)
< 99	35 (83.3%)	28 (73.7%)	26 (72.2%)	28 (75.7%)	29 (76.3%)	27 (81.8%)		18 (42.9%)
99 - 99.9	6 (14.3%)	7 (18.4%)	9 (25.0%)	7 (18.9%)	8 (21.1%)	4 (12.1%)		19 (45.2%)
100 - 100.9	1 (2.4%)	2 (5.3%)	1 (2.8%)	1 (2.7%)	0 (0.0%)	1 (3.0%)		4 (9.5%)
101 - 101.9	0 (0.0%)	1 (2.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (2.4%)
TEMPERATURE TAKEN	42 (97.7%)	38 (88.4%)	36 (83.7%)	37 (86.0%)	38 (88.4%)	33 (76.7%)		42 (97.7%)
TEMPERATURE NOT TAKEN	1 (2.3%)	5 (11.6%)	7 (16.3%)	6 (14.0%)	5 (11.6%)	10 (23.3%)		1 (2.3%)

TABLE 7 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (27 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
NORMAL	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (4.8%)		0 (0.0%)
< 99	22 (84.6%)	20 (83.3%)	16 (76.2%)	17 (81.0%)	15 (75.0%)	15 (71.4%)		16 (61.5%)
99 - 99.9	4 (15.4%)	3 (12.5%)	4 (19.0%)	4 (19.0%)	4 (20.0%)	4 (19.0%)		7 (26.9%)
100 - 100.9	0 (0.0%)	0 (0.0%)	1 (4.8%)	0 (0.0%)	1 (5.0%)	0 (0.0%)		1 (3.8%)
101 - 101.9	0 (0.0%)	1 (4.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (3.8%)
102 - 102.9	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (4.8%)		1 (3.8%)
TEMPERATURE TAKEN	26 (96.3%)	24 (88.9%)	21 (77.8%)	21 (77.8%)	20 (74.1%)	21 (77.8%)		26 (96.3%)
TEMPERATURE NOT TAKEN	1 (3.7%)	3 (11.1%)	6 (22.2%)	6 (22.2%)	7 (25.9%)	6 (22.2%)		1 (3.7%)

TABLE 7 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (17 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
NORMAL	0 (0.0%)	0 (0.0%)	1 (7.1%)	1 (7.7%)	1 (7.1%)	0 (0.0%)		0 (0.0%)
< 99	14 (87.5%)	9 (69.2%)	13 (92.9%)	12 (92.3%)	13 (92.9%)	13 (92.9%)		10 (62.5%)
99 - 99.9	2 (12.5%)	4 (30.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.1%)		6 (37.5%)
TEMPERATURE TAKEN	16 (94.1%)	13 (76.5%)	14 (82.4%)	13 (76.5%)	14 (82.4%)	14 (82.4%)		16 (94.1%)
TEMPERATURE NOT TAKEN	1 (5.9%)	4 (23.5%)	3 (17.6%)	4 (23.5%)	3 (17.6%)	3 (17.6%)		1 (5.9%)

TABLE 7 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : SANTOSHAM, MATHURAM
STUDY : 000414
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (36 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
< 99	28 (80.0%)	25 (73.5%)	24 (82.8%)	27 (81.8%)	28 (90.3%)	25 (78.1%)		16 (45.7%)
99 - 99.9	7 (20.0%)	7 (20.6%)	2 (6.9%)	6 (18.2%)	3 (9.7%)	6 (18.8%)		13 (37.1%)
100 - 100.9	0 (0.0%)	2 (5.9%)	2 (6.9%)	0 (0.0%)	0 (0.0%)	1 (3.1%)		5 (14.3%)
101 - 101.9	0 (0.0%)	0 (0.0%)	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (2.9%)
TEMPERATURE TAKEN	35 (97.2%)	34 (94.4%)	29 (80.6%)	33 (91.7%)	31 (86.1%)	32 (88.9%)		35 (97.2%)
TEMPERATURE NOT TAKEN	1 (2.8%)	2 (5.6%)	7 (19.4%)	3 (8.3%)	5 (13.9%)	4 (11.1%)		1 (2.8%)

STUDY 004-15

PROGRAM: Haemophilus b Conjugate Vaccine (Neisseria meningitidis Outer Membrane Protein Complex), Study #0004-15.

PURPOSE: To evaluate the safety and immunogenicity of Haemophilus b Conjugate Vaccine (Neisseria meningitidis Outer Membrane Protein Complex) in healthy infants and children 2 months to 5 years of age.

VACCINE: Haemophilus b Conjugate Vaccine (Neisseria meningitidis Outer Membrane Protein Complex).

Lot 1069/C-P241 - (b) (4) mcg polysaccharide/ml
(b) (4) mcg meningococcal protein/ml
Lot 1080/C-P749 - (b) (4) mcg polysaccharide/ml
(b) (4) mcg meningococcal protein/ml

Diluent
Aluminum hydroxide diluent
Lot (b) (4)

INVESTIGATOR: Adnan Dajani, M.D.
Wayne State University
School of Medicine
Children's Hospital of Michigan
3901 Beaubien Blvd.
Detroit, Michigan 48201

SUB-INVESTIGATOR: Basim I. Asmar, M.D.

STUDY LOCATION: Children's Hospital of Michigan
3901 Beaubien Blvd.
Detroit, Michigan 48201

DATE INITIATED: April 20, 1987

DATE COMPLETED: In progress.

STUDY POPULATION: Healthy infants and children 2 to 71 months of age are included in the study.

STUDY PROCEDURE: Infants 2 to 11 months of age receive 2 injections of the vaccine given 2 months apart, while children 12 months of age and older receive a single injection. Vaccine is reconstituted in aluminum hydroxide and administered by intramuscular route. The dose for each injection is 15 mcg polysaccharide in the appropriate volume - 0.75 ml for Lot 1069/C-P241 and 0.5 ml for Lot 1080/C-P749.

Parents or guardians are required to record the vaccinee's temperature and any systemic or injection site reactions for 5 days after each injection. Unexpected or serious reactions are to be reported immediately to the study physician.

A blood sample is obtained immediately before each injection and one month after the last (or only) injection. Additional samples are obtained 7 to 10 months after the last injection for infants 2 to 11 months of age and at 15 to 18 months postvaccination for children 12 to 71 months of age.

All serum samples are assayed by Merck Sharp & Dohme Research Laboratories for antibody to H. influenzae type b capsular polysaccharide by radioimmunoassay (RIA). Selected samples are also tested for serum bactericidal activity, quantitation of IgG_1 and IgG_2 subclass, and IgM and total IgG antibodies. Testing for opsonophagocytic activity was done at the University of Alabama.

RESULTS: Demographic information and individual pre and postvaccination antibody data for each vaccinee enrolled in the study is reported in Tables 1 and 2.

1. Number Vaccinated:

Lot	Age	Injection No. 1	Injection No. 2
1069/C-P241	2-11 mo.	13	11
	12-71 mo.	12	--
1080/C-P749	2-11 mo.	19	15
	12-71 mo.	51	--

2. Serologic Results

Antibody responses (RIA) prior to and after vaccination are as follows:

Age	Time	% With Anti-PRP >0.15 mcg Ab/ml	% With Anti-PRP >1.0 mcg Ab/ml	GMT (mcg Ab/ml) All Vaccinees
2-11 mo.	Pre	13 (2/15)	0 (0/15)	0.07
	2 mo.	93 (14/15)	73 (11/15)	2.27
	3 mo.	100 (15/15)	93 (14/15)	5.23
12-71 mo.	Pre	48 (12/25)	4 (1/25)	0.16
	1 mo.	100 (25/25)	92 (23/25)	6.93

Antibody responses (by lot per age group) prior to vaccination through 10 months postvaccination are included in Tables 3 and 4.

RESULTS: (CONT.)

4. Clinical Results:

The frequencies of selected injection site and systemic reactions during the 48 hours after vaccination are as follows:

	% Vaccinees with Reactions		
	2 - 11 Months of Age		12 - 71 Months of Age
Type of Reaction	Injection 1	Injection 2	Injection 1
Injection Site			
Erythema >1 inch	0.0 (0/32)	0.0 (0/26)	0.0 (0/63)
Swelling >1 inch	0.0 (0/32)	0.0 (0/26)	3.2 (2/63)
Pain/Soreness	18.8 (6/32)	19.2 (5/26)	27.0 (17/63)
Systemic			
Irritability	31.3 (10/32)	26.9 (7/26)	27.0 (17/63)
Sleepiness/ Lethargy/Fatigue	21.9 (7/32)	15.4 (4/26)	20.6 (13/63)

Reaction frequencies and maximum temperatures recorded during the five days following each injection of vaccine are reported in Tables 5-7.

No serious or alarming reactions attributable to the vaccine were reported.

TABLE 1

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : DAJANI, ADNAN S.
STUDY : 000415
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	BLAC	(b) (6)	2M	0	(b) (6)	001	PREBLEED				< 125		< 5		0
					0		011	INJ 1	CP241	15 MCG						
					57		011	BLEED 1				555		5		4
					57		021	INJ 2	CP241	15 MCG						
					86		021	BLEED 2				2522		80		95
					329		071	BLEED 3				< 125				
	M	BLAC		3M	0		001	PREBLEED				< 125		< 2		0
					0		011	INJ 1	CP241	15 MCG						
					62		011	BLEED 1				1657		2		90
					62		021	INJ 2	CP241	15 MCG						
					111		021	BLEED 2				4461		>= 8		
	M	BLAC		9M	0		001	PREBLEED				< 125		< 5		0
					0		011	INJ 1	CP241	15 MCG						
					64		011	BLEED 1				2266		40		
					64		021	INJ 2	CP241	15 MCG						
					98		021	BLEED 2				28672				97
	F	CAUC		7M	0		001	PREBLEED				< 125		< 5		0
					0		011	INJ 1	CP241	15 MCG						
					56		011	BLEED 1				9609		20		97
					56		021	INJ 2	CP241	15 MCG						
					100		021	BLEED 2				5673				
					313		071	BLEED 3				1005				
	F	BLAC		10M	0		001	PREBLEED				< 125		< 2		
					0		011	INJ 1	CP241	15 MCG						
					58		011	BLEED 1				1320		8		
					58		021	INJ 2	CP241	15 MCG						
					93		021	BLEED 2				1653		8		
	M	BLAC		6M	0		001	PREBLEED				128		< 2		
					0		011	INJ 1	CP241	15 MCG						
					87		011	BLEED 1			05/	555	05/	< 2		
					87		021	INJ 2	CP241	15 MCG						
					121		021	BLEED 2			05/	3001	05/	8		
	M	BLAC		5M	0		001	PREBLEED				< 125		< 2		
					0		011	INJ 1	CP241	15 MCG						

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : DAJANI, ADNAN S.
STUDY : 000415
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	BLAC	(b) (6)	5M	81	(b) (6)	011	BLEED 1			05/	11065	05/	>= 32		
					81		021	INJ 2	CP241	15 MCG						
					227		071	BLEED 2			05/	6823				
	M	CAUC		9M	0		011	INJ 1	CP241	15 MCG						
	F	BLAC		9M	0		011	INJ 1	CP241	15 MCG						
	F	BLAC		5M	0		001	PREBLEED				< 125		< 2		
					0		011	INJ 1	CP241	15 MCG						
					89		011	BLEED 1			05/	14757	05/	2		
					89		021	INJ 2	CP241	15 MCG						
					125		021	BLEED 2			05/	14516	05/	2		
	F	BLAC		7M	0		001	PREBLEED				189		< 2		
					0		011	INJ 1	CP241	15 MCG						
					62		011	BLEED 1				6429		8		
					62		021	INJ 2	CP241	15 MCG						
					90		021	BLEED 2				26550		8		
	M	BLAC		4M	0		001	PREBLEED				< 125		< 2		
					0		011	INJ 1	CP241	15 MCG						
					58		011	BLEED 1				13905		8		
					58		021	INJ 2	CP241	15 MCG						
					93		021	BLEED 2				19734		8		
	F	BLAC		8M	0		001	PREBLEED				173		< 2		
					0		011	INJ 1	CP241	15 MCG						
					74		011	BLEED 1			05/	65747	05/	8		
					74		021	INJ 2	CP241	15 MCG						
					109		021	BLEED 2			05/	37722	05/	>= 32		
	M	BLAC		3M	0		001	PREBLEED				157		< 2		
					0		011	INJ 1	CP749	15 MCG						
					79		011	BLEED 1			05/	1934	05/	8		
					79		021	INJ 2	CP749	15 MCG						
					112		021	BLEED 2			05/	5340	05/	2		
	M	BLAC		6M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP749	15 MCG						

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : DAJANI, ADNAN S.
STUDY : 000415
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	BLAC	(b) (6)	6M	70	(b) (6)	021	INJ 2	CP749	15 MCG						
					133		021	BLEED 1			05/	2392				
	F	BLAC		9M	0		001	PREBLEED				182		< 2		
					0		011	INJ 1	CP749	15 MCG						
					66		011	BLEED 1				3241		>= 32		
					66		021	INJ 2	CP749	15 MCG						
					91		021	BLEED 2				12446		>= 32		
	F	BLAC		9M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP749	15 MCG						
					135		011	BLEED 1			05/	1224				
					135		021	INJ 2	CP749	15 MCG						
					170		021	BLEED 2			05/	2772				
	F	CAUC		10M	0		001	PREBLEED				< 125		< 2		
					0		011	INJ 1	CP749	15 MCG						
					62		011	BLEED 1				20410		>= 32		
					62		021	INJ 2	CP749	15 MCG						
					93		021	BLEED 2				19649		>= 32		
	F	BLAC		4M	0		001	PREBLEED				< 125		< 2		
					0		011	INJ 1	CP749	15 MCG						
					62		011	BLEED 1				7943				
					62		021	INJ 2	CP749	15 MCG						
					93		021	BLEED 2				24323		32		
	F	CAUC		4M	0		001	PREBLEED				< 125		< 2		
					0		011	INJ 1	CP749	15 MCG						
					72		011	BLEED 1			05/	1780	05/	8		
					72		021	INJ 2	CP749	15 MCG						
					96		021	BLEED 2			05/	1851	05/	8		
	F	BLAC		11M	0		001	PREBLEED				< 125		< 2		
					0		011	INJ 1	CP749	15 MCG						
					65		011	BLEED 1				6189		8		
					65		021	INJ 2	CP749	15 MCG						
					95		021	BLEED 2				6100		8		
	F	CAUC		8M	0		001	PREBLEED				< 125		< 2		

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : DAJANI, ADNAN S.
STUDY : 000415
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	F	CAUC	(b) (6)	8M	0	(b) (6)	011	INJ 1	CP749	15 MCG						
					59		011	BLEED 1				537		< 2		
					59		021	INJ 2	CP749	15 MCG						
					91		021	BLEED 2				3278		< 2		
	M	BLAC		10M	0		001	PREBLEED				< 125		< 2		
					0		011	INJ 1	CP749	15 MCG						
					62		011	BLEED 1				508		32		
					62		021	INJ 2	CP749	15 MCG						
					90		021	BLEED 2				1044		32		
	M	CAUC		3M	0		001	PREBLEED				< 125		< 2		
					0		011	INJ 1	CP749	15 MCG						
					63		011	BLEED 1				1698		8		
					63		021	INJ 2	CP749	15 MCG						
					98		021	BLEED 2				1317		< 2		
	F	CAUC		5M	0		001	PREBLEED				< 125		< 2		
					0		011	INJ 1	CP749	15 MCG						
					66		011	BLEED 1				< 125		< 2		
					66		021	INJ 2	CP749	15 MCG						
					99		021	BLEED 2				231		< 2		
	M	CAUC		5M	0		011	INJ 1	CP749	15 MCG						
					60		021	INJ 2	CP749	15 MCG						
	M	CAUC		5M	0		011	INJ 1	CP749	15 MCG						
					60		021	INJ 2	CP749	15 MCG						
	F	BLAC		8M	0		011	INJ 1	CP749	15 MCG						
					52		021	INJ 2	CP749	15 MCG						
	F	BLAC		11M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP749	15 MCG						
					62		011	BLEED 1				3987				
	F	BLAC		6M	0		011	INJ 1	CP749	15 MCG						
	M	BLAC		11M	0		011	INJ 1	CP749	15 MCG						
	M	CAUC		2M	0		011	INJ 1	CP749	15 MCG						

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : DAJANI, ADNAN S.
STUDY : 000415
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	BLAC	(b) (6)	14M	0	(b) (6)	011	INJ	1	CP241	15 MCG					
	M	BLAC		12M	0		001	PREBLEED				< 125		< 5		0
					0		011	INJ	1	CP241	15 MCG					
					34		011	BLEED	1			4346		10		98
	M	BLAC		17M	0		001	PREBLEED				< 125		< 5		0
					0		011	INJ	1	CP241	15 MCG					
					34		011	BLEED	1			1836		40		74
	F	BLAC		12M	0		001	PREBLEED				< 125		< 5		0
					0		011	INJ	1	CP241	15 MCG					
					30		011	BLEED	1			5934		160		99
	F	BLAC		20M	0		001	PREBLEED				< 125		< 5		
					0		011	INJ	1	CP241	15 MCG					
					54		011	BLEED	1			13486		80		
	F	CAUC		13M	0		001	PREBLEED				< 125		< 5		
					0		011	INJ	1	CP241	15 MCG					
					56		011	BLEED	1			16597		20		
	F	BLAC		12M	0		001	PREBLEED				< 125		< 5		
					0		011	INJ	1	CP241	15 MCG					
					33		011	BLEED	1			15064		160		
	F	BLAC		13M	0		001	PREBLEED				< 125		< 2		0
					0		011	INJ	1	CP241	15 MCG					
					30		011	BLEED	1			2060		>= 16		96
	M	BLAC		14M	0		001	PREBLEED				329		< 5		
					0		011	INJ	1	CP241	15 MCG					
					43		011	BLEED	1			21320		>= 80		
	F	BLAC		19M	0		001	PREBLEED				866		20		
					0		011	INJ	1	CP241	15 MCG					
					28		011	BLEED	1			17632		320		
	F	CAUC		18M	0		001	PREBLEED				371		< 5		
					0		011	INJ	1	CP241	15 MCG					

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : DAJANI, ADNAN S.
STUDY : 000415
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	F	CAUC	(b) (6)	18M	39	(b) (6)	011	BLEED 1				5740		20		
	M	BLAC		13M	0		001	PREBLEED				437		20		
					0		011	INJ 1	CP241	15 MCG						
					30		011	BLEED 1				5334		320		
	F	BLAC		20M	0		011	INJ 1	CP749	15 MCG						
	M	BLAC		16M	0		001	PREBLEED				< 125		< 5		10
					0		011	INJ 1	CP749	15 MCG						
					27		011	BLEED 1				8971		>= 80		99
	F	BLAC		18M	0		001	PREBLEED				< 125		< 5		
					0		011	INJ 1	CP749	15 MCG						
					28		011	BLEED 1				17175		>= 80		
	F	BLAC		12M	0		001	PREBLEED				< 125		< 5		3
					0		011	INJ 1	CP749	15 MCG						
					29		011	BLEED 1				2463		>= 80		100
	F	BLAC		21M	0		001	PREBLEED				1225		20		
					0		011	INJ 1	CP749	15 MCG						
					34		011	BLEED 1				26744		>= 80		
	F	CAUC		3Y	0		011	INJ 1	CP749	15 MCG						
	M	BLAC		14M	0		011	INJ 1	CP749	15 MCG						
	F	BLAC		12M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP749	15 MCG						
					62		011	BLEED 1				1739				
	M	CAUC		22M	0		001	PREBLEED				277		< 5		0
					0		011	INJ 1	CP749	15 MCG						
					32		011	BLEED 1				143155		>= 80		100
	F	CAUC		24M	0		011	INJ 1	CP749	15 MCG						
					32		D11	BLEED 1				2549				
	F	BLAC		22M	0		011	INJ 1	CP749	15 MCG						

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : DAJANI, ADNAN S.
STUDY : 000415
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	CAUC	(b) (6)	16M	0	(b) (6)	011	INJ 1	CP749	15 MCG						
	F	CAUC		3Y	0		011	INJ 1	CP749	15 MCG						
	F	CAUC		12M	0		001	PREBLEED				339		< 2		
					0		011	INJ 1	CP749	15 MCG						
					31		011	BLEED 1				2156		< 2		
	M	BLAC		12M	0		001	PREBLEED				340		< 5		9
					0		011	INJ 1	CP749	15 MCG						
					34		011	BLEED 1				4787		20		100
	M	CAUC		24M	0		011	INJ 1	CP749	15 MCG						
	M	CAUC		2Y	0		011	INJ 1	CP749	15 MCG						
	F	CAUC		15M	0		011	INJ 1	CP749	15 MCG						
	M	BLAC		20M	0		001	PREBLEED				362		< 5		35
					0		011	INJ 1	CP749	15 MCG						
					35		011	BLEED 1				92860		>= 80		100
	F	CAUC		18M	0		001	PREBLEED				757		< 5		
					0		011	INJ 1	CP749	15 MCG						
					33		011	BLEED 1				50655		>= 80		
	F	CAUC		12M	0		001	PREBLEED				189		< 5		22
					0		011	INJ 1	CP749	15 MCG						
					27		011	BLEED 1				507		20		79
	F	CAUC		2Y	0		011	INJ 1	CP749	15 MCG						
	F	BLAC		22M	0		011	INJ 1	CP749	15 MCG						
	M	BLAC		2Y	0		011	INJ 1	CP749	15 MCG						
	F	CAUC		24M	0		011	INJ 1	CP749	15 MCG						
	M	BLAC		15M	0		001	PREBLEED				296		< 5		16
					0		011	INJ 1	CP749	15 MCG						

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : DAJANI, ADNAN S.
STUDY : 000415
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	BLAC	(b) (6)	15M	27	(b) (6)	011	BLEED	1			10776		>= 80		100
	M	CAUC		22M	0		011	INJ	1	CP749 15 MCG						
	M	CAUC		12M	0		011	INJ	1	CP749 15 MCG						
	M	CAUC		2Y	0		011	INJ	1	CP749 15 MCG						
	M	BLAC		19M	0		011	INJ	1	CP749 15 MCG						
	M	BLAC		20M	0		011	INJ	1	CP749 15 MCG						
	F	BLAC		12M	0		001	PREBLEED				209				
					0		011	INJ	1	CP749 15 MCG						
					67		011	BLEED	1			10493				
	M	CAUC		16M	0		011	INJ	1	CP749 15 MCG						
	F	BLAC		15M	0		001	PREBLEED				135				
					0		011	INJ	1	CP749 15 MCG						
					31		011	BLEED	1			12967				
	M	CAUC		20M	0		011	INJ	1	CP749 15 MCG						
	M	CAUC		19M	0		001	PREBLEED				< 125		< 5		
					0		011	INJ	1	CP749 15 MCG						
					35		011	BLEED	1			4571		20		
	F	CAUC		12M	0		011	INJ	1	CP749 15 MCG						
	F	BLAC		12M	0		001	PREBLEED				< 125				
					0		011	INJ	1	CP749 15 MCG						
					36		011	BLEED	1			3420				
	M	CAUC		2Y	0		011	INJ	1	CP749 15 MCG						
	F	BLAC		24M	0		001	PREBLEED				< 125				
					0		011	INJ	1	CP749 15 MCG						
					52		011	BLEED	1			18626				
	F	OTHE		21M	0		001	PREBLEED				< 125		< 5		

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : DAJANI, ADNAN S.
STUDY : 000415
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	F	OTHE	(b) (6)	21M	0	(b) (6)	011	INJ	1	CP749	15 MCG					
					31		011	BLEED	1			4166		>= 80		
	M	BLAC		4Y	0		011	INJ	1	CP749	15 MCG					
	F	BLAC		12M	0		011	INJ	1	CP749	15 MCG					
	M	CAUC		2Y	0		011	INJ	1	CP749	15 MCG					
	M	CAUC		15M	0		011	INJ	1	CP749	15 MCG					
	M	BLAC		24M	0		011	INJ	1	CP749	15 MCG					
	M	CAUC		12M	0		001	PREBLEED				< 125				
					0		011	INJ	1	CP749	15 MCG					
					32		011	BLEED	1			191				
	M	CAUC		13M	0		001	PREBLEED					02/	< 125		
					0		011	INJ	1	CP749	15 MCG					
					34		011	BLEED	1				02/	1459		
	F	CAUC		3Y	0		011	INJ	1	CP749	15 MCG					
	F	BLAC		12M	0		011	INJ	1	CP749	15 MCG					
	F	BLAC		16M	0		011	INJ	1	CP749	15 MCG					

TABLE 2

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : DAJANI, ADNAN S.
STUDY : 000415
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	IGG1	CODE/	IGG2	CODE/	IGGM	CODE/IGG TOTAL
(b) (6)	M	BLAC	(b) (6)	2M	0	(b) (6)	011	INJ 1	CP241	15 MCG							
					57		021	INJ 2	CP241	15 MCG							
	M	BLAC		3M	0		011	INJ 1	CP241	15 MCG							
					62		021	INJ 2	CP241	15 MCG							
	M	BLAC		9M	0		011	INJ 1	CP241	15 MCG							
					64		021	INJ 2	CP241	15 MCG							
	F	CAUC		7M	0		011	INJ 1	CP241	15 MCG							
					56		021	INJ 2	CP241	15 MCG							
	F	BLAC		10M	0		011	INJ 1	CP241	15 MCG							
					58		021	INJ 2	CP241	15 MCG							
	M	BLAC		6M	0		011	INJ 1	CP241	15 MCG							
					87		021	INJ 2	CP241	15 MCG							
	M	BLAC		5M	0		011	INJ 1	CP241	15 MCG							
					81		021	INJ 2	CP241	15 MCG							
	M	CAUC		9M	0		011	INJ 1	CP241	15 MCG							
	F	BLAC		9M	0		011	INJ 1	CP241	15 MCG							
	F	BLAC		5M	0		011	INJ 1	CP241	15 MCG							
					89		021	INJ 2	CP241	15 MCG							
	F	BLAC		7M	0		011	INJ 1	CP241	15 MCG							
					62		021	INJ 2	CP241	15 MCG							
	M	BLAC		4M	0		011	INJ 1	CP241	15 MCG							
					58		021	INJ 2	CP241	15 MCG							
	F	BLAC		8M	0		011	INJ 1	CP241	15 MCG							
					74		021	INJ 2	CP241	15 MCG							
	M	BLAC		3M	0		001	PREBLEED				< 600				< 100	< 100
					0		011	INJ 1	CP749	15 MCG							
					79		011	BLEED 1			05/	929			05/	< 100	05/ 400

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : DAJANI, ADNAN S.
STUDY : 000415
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	IGG1	CODE/	IGG2	CODE/	IGGM	CODE/IGG TOTAL
(b) (6)	M	BLAC	(b) (6)	3M	79	(b) (6)	021	INJ 2	CP749	15 MCG							
					112		021	BLEED 2			05/	12224			05/	< 100	05/ 2643
	M	BLAC		6M	0		011	INJ 1	CP749	15 MCG							
					70		021	INJ 2	CP749	15 MCG							
	F	BLAC		9M	0		001	PREBLEED				< 600				< 100	< 100
					0		011	INJ 1	CP749	15 MCG							
					66		011	BLEED 1				10008				806	1692
					66		021	INJ 2	CP749	15 MCG							
					91		021	BLEED 2				27076				1045	5982
	F	BLAC		9M	0		011	INJ 1	CP749	15 MCG							
					135		021	INJ 2	CP749	15 MCG							
	F	CAUC		10M	0		011	INJ 1	CP749	15 MCG							
					62		021	INJ 2	CP749	15 MCG							
	F	BLAC		4M	0		011	INJ 1	CP749	15 MCG							
					62		021	INJ 2	CP749	15 MCG							
	F	CAUC		4M	0		011	INJ 1	CP749	15 MCG							
					72		021	INJ 2	CP749	15 MCG							
	F	BLAC		11M	0		011	INJ 1	CP749	15 MCG							
					65		021	INJ 2	CP749	15 MCG							
	F	CAUC		8M	0		011	INJ 1	CP749	15 MCG							
					59		021	INJ 2	CP749	15 MCG							
	M	BLAC		10M	0		011	INJ 1	CP749	15 MCG							
					62		021	INJ 2	CP749	15 MCG							
	M	CAUC		3M	0		011	INJ 1	CP749	15 MCG							
					63		021	INJ 2	CP749	15 MCG							
	F	CAUC		5M	0		011	INJ 1	CP749	15 MCG							
					66		021	INJ 2	CP749	15 MCG							
	M	CAUC		5M	0		011	INJ 1	CP749	15 MCG							

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : DAJANI, ADNAN S.
STUDY : 000415
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ IGG1	CODE/ IGG2	CODE/ IGGM	CODE/IGG TOTAL
(b) (6)	M	CAUC	(b) (6)	5M	60	(b) (6)	021	INJ 2	CP749	15 MCG				
	M	CAUC		5M	0		011	INJ 1	CP749	15 MCG				
					60		021	INJ 2	CP749	15 MCG				
	F	BLAC		8M	0		011	INJ 1	CP749	15 MCG				
					52		021	INJ 2	CP749	15 MCG				
	F	BLAC		11M	0		011	INJ 1	CP749	15 MCG				
	F	BLAC		6M	0		011	INJ 1	CP749	15 MCG				
	M	BLAC		11M	0		011	INJ 1	CP749	15 MCG				
	M	CAUC		2M	0		011	INJ 1	CP749	15 MCG				

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : DAJANI, ADNAN S.
STUDY : 000415
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ IGG1	CODE/ IGG2	CODE/ IGGM	CODE/IGG TOTAL
(b) (6)	M	BLAC	(b) (6)	14M	0	(b) (6)	011	INJ 1	CP241	15 MCG				
	M	BLAC		12M	0		001	PREBLEED			< 600	< 250	< 100	< 100
					0		011	INJ 1	CP241	15 MCG				
					34		011	BLEED 1			2413	< 250	289	1107
	M	BLAC		17M	0		001	PREBLEED				< 250	< 100	< 100
					0		011	INJ 1	CP241	15 MCG				
					34		011	BLEED 1				< 250	227	314
	F	BLAC		12M	0		001	PREBLEED				< 250	< 100	< 100
					0		011	INJ 1	CP241	15 MCG				
					30		011	BLEED 1				< 250	789	680
	F	BLAC		20M	0		011	INJ 1	CP241	15 MCG				
	F	CAUC		13M	0		001	PREBLEED			< 600	< 250	< 100	< 100
					0		011	INJ 1	CP241	15 MCG				
					56		011	BLEED 1			7636	< 250	215	2383
	F	BLAC		12M	0		001	PREBLEED			< 600		< 100	< 100
					0		011	INJ 1	CP241	15 MCG				
					33		011	BLEED 1			10819		501	3021
	F	BLAC		13M	0		001	PREBLEED					< 100	< 100
					0		011	INJ 1	CP241	15 MCG				
					30		011	BLEED 1					409	566
	M	BLAC		14M	0		001	PREBLEED					109	< 100
					0		011	INJ 1	CP241	15 MCG				
					43		011	BLEED 1					248	10226
	F	BLAC		19M	0		011	INJ 1	CP241	15 MCG				
	F	CAUC		18M	0		001	PREBLEED			< 600			
					0		011	INJ 1	CP241	15 MCG				
					39		011	BLEED 1			16196			
	M	BLAC		13M	0		011	INJ 1	CP241	15 MCG				
	F	BLAC		20M	0		011	INJ 1	CP749	15 MCG				

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : DAJANI, ADNAN S.
STUDY : 000415
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ IGG1	CODE/ IGG2	CODE/ IGGM	CODE/IGG TOTAL
(b) (6)	M	BLAC	(b) (6)	16M	0	(b) (6)	001	PREBLEED			< 600	< 250	< 100	< 100
					0		011	INJ 1	CP749	15 MCG				
					27		011	BLEED 1			8683	< 250	947	1591
	F	BLAC		18M	0		001	PREBLEED			< 600	< 250	705	< 100
					0		011	INJ 1	CP749	15 MCG				
					28		011	BLEED 1			23333	< 250	11689	2692
	F	BLAC		12M	0		001	PREBLEED			< 600	< 250	762	< 100
					0		011	INJ 1	CP749	15 MCG				
					29		011	BLEED 1			2403	< 250	7231	234
	F	BLAC		21M	0		001	PREBLEED			< 600	< 250	418	256
					0		011	INJ 1	CP749	15 MCG				
					34		011	BLEED 1			43913	1210	2704	59130
	F	CAUC		3Y	0		011	INJ 1	CP749	15 MCG				
	M	BLAC		14M	0		011	INJ 1	CP749	15 MCG				
	F	BLAC		12M	0		011	INJ 1	CP749	15 MCG				
	M	CAUC		22M	0		001	PREBLEED			< 600		< 100	< 100
					0		011	INJ 1	CP749	15 MCG				
					32		011	BLEED 1			215337		1212	27164
	F	CAUC		24M	0		011	INJ 1	CP749	15 MCG				
	F	BLAC		22M	0		011	INJ 1	CP749	15 MCG				
	M	CAUC		16M	0		011	INJ 1	CP749	15 MCG				
	F	CAUC		3Y	0		011	INJ 1	CP749	15 MCG				
	F	CAUC		12M	0		001	PREBLEED			< 600		141	< 100
					0		011	INJ 1	CP749	15 MCG				
					31		011	BLEED 1			11005		367	1467
	M	BLAC		12M	0		001	PREBLEED			< 600		< 100	< 100
					0		011	INJ 1	CP749	15 MCG				

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : DAJANI, ADNAN S.
STUDY : 000415
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ IGG1	CODE/ IGG2	CODE/ IGGM	CODE/IGG TOTAL
(b) (6)	M	BLAC	(b) (6)	12M	34	(b) (6)	011	BLEED	1		23973		2372	4298
	M	CAUC		24M	0		011	INJ	1	CP749 15 MCG				
	M	CAUC		2Y	0		011	INJ	1	CP749 15 MCG				
	F	CAUC		15M	0		011	INJ	1	CP749 15 MCG				
	M	BLAC		20M	0		001	PREBLEED			< 600		134	< 100
					0		011	INJ	1	CP749 15 MCG				
					35		011	BLEED	1		160483		1504	29980
	F	CAUC		18M	0		001	PREBLEED			< 600		132	< 100
					0		011	INJ	1	CP749 15 MCG				
					33		011	BLEED	1		18692		365	18116
	F	CAUC		12M	0		001	PREBLEED			< 600		118	< 100
					0		011	INJ	1	CP749 15 MCG				
					27		011	BLEED	1		< 600		699	< 100
	F	CAUC		2Y	0		011	INJ	1	CP749 15 MCG				
	F	BLAC		22M	0		011	INJ	1	CP749 15 MCG				
	M	BLAC		2Y	0		011	INJ	1	CP749 15 MCG				
	F	CAUC		24M	0		011	INJ	1	CP749 15 MCG				
	M	BLAC		15M	0		001	PREBLEED			< 600			
					0		011	INJ	1	CP749 15 MCG				
					27		011	BLEED	1		26379			
	M	CAUC		22M	0		011	INJ	1	CP749 15 MCG				
	M	CAUC		12M	0		011	INJ	1	CP749 15 MCG				
	M	CAUC		2Y	0		011	INJ	1	CP749 15 MCG				
	M	BLAC		19M	0		011	INJ	1	CP749 15 MCG				
	M	BLAC		20M	0		011	INJ	1	CP749 15 MCG				

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : DAJANI, ADNAN S.
STUDY : 000415
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ IGG1	CODE/ IGG2	CODE/ IGGM	CODE/IGG TOTAL
(b) (6)	F	BLAC	(b) (6)	12M	0	(b) (6)	011	INJ 1	CP749	15 MCG				
	M	CAUC		16M	0		011	INJ 1	CP749	15 MCG				
	F	BLAC		15M	0		001	PREBLEED					< 100	< 100
					0		011	INJ 1	CP749	15 MCG				
					31		011	BLEED 1					923	1362
	M	CAUC		20M	0		011	INJ 1	CP749	15 MCG				
	M	CAUC		19M	0		001	PREBLEED					< 100	< 100
					0		011	INJ 1	CP749	15 MCG				
					35		011	BLEED 1					< 100	8716
	F	CAUC		12M	0		011	INJ 1	CP749	15 MCG				
	F	BLAC		12M	0		001	PREBLEED			< 600		< 100	< 100
					0		011	INJ 1	CP749	15 MCG				
					36		011	BLEED 1			14278		943	1790
	M	CAUC		2Y	0		011	INJ 1	CP749	15 MCG				
	F	BLAC		24M	0		011	INJ 1	CP749	15 MCG				
	F	OTHE		21M	0		001	PREBLEED			< 600		802	< 100
					0		011	INJ 1	CP749	15 MCG				
					31		011	BLEED 1			7172		1575	1237
	M	BLAC		4Y	0		011	INJ 1	CP749	15 MCG				
	F	BLAC		12M	0		011	INJ 1	CP749	15 MCG				
	M	CAUC		2Y	0		011	INJ 1	CP749	15 MCG				
	M	CAUC		15M	0		011	INJ 1	CP749	15 MCG				
	M	BLAC		24M	0		011	INJ 1	CP749	15 MCG				
	M	CAUC		12M	0		011	INJ 1	CP749	15 MCG				
	M	CAUC		13M	0		011	INJ 1	CP749	15 MCG				

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : DAJANI, ADNAN S.
STUDY : 000415
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ IGG1	CODE/ IGG2	CODE/ IGGM	CODE/IGG TOTAL
(b) (6)	F	CAUC	(b) (6)	3Y	0	(b) (6)	011	INJ 1	CP749	15 MCG				
	F	BLAC		12M	0		011	INJ 1	CP749	15 MCG				
	F	BLAC		16M	0		011	INJ 1	CP749	15 MCG				

TABLE 3

ANTIBODY RESPONSES

INVESTIGATOR : DAJANI, ADNAN S.
STUDY : 000415
VACCINE : HIB CONJUGATE
ASSAY : RIA
LOT NUMBER : CP241
DOSE : 15 MCG
POPULATION : HEALTHY CHILDREN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
1- 6 MOS.	PRE INJ	0 (0/ 3)	0 (0/ 3)			0.063 (3)
	MONTH 2	100 (3/ 3)	67 (2/ 3)	100 (3/ 3)	18.7	2.338 (3)
	MONTH 3	100 (3/ 3)	100 (3/ 3)	100 (3/ 3)	48.4	6.055 (3)
7-11 MOS.	PRE INJ	25 (1/ 4)	0 (0/ 4)			0.082 (4)
	MONTH 2	100 (4/ 4)	100 (4/ 4)	100 (4/ 4)	26.6	3.687 (4)
	MONTH 3	100 (4/ 4)	100 (4/ 4)	100 (4/ 4)	66.3	9.192 (4)
	MONTH 7-10	100 (1/ 1)	100 (1/ 1)	100 (1/ 1)	8.0	1.005 (1)
12-71 MOS.	PRE INJ	44 (4/ 9)	0 (0/ 9)			0.152 (9)
	MONTH 1	100 (9/ 9)	100 (9/ 9)	100 (9/ 9)	28.4	6.355 (9)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 4

ANTIBODY RESPONSES

INVESTIGATOR : DAJANI, ADNAN S.
STUDY : 000415
VACCINE : HIB CONJUGATE
ASSAY : RIA
LOT NUMBER : CP749
DOSE : 15 MCG
POPULATION : HEALTHY CHILDREN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
1- 6 MOS.	PRE INJ	0 (0/ 3)	0 (0/ 3)			0.063 (3)
	MONTH 2	67 (2/ 3)	67 (2/ 3)	67 (2/ 3)	9.5	0.945 (3)
	MONTH 3	100 (3/ 3)	67 (2/ 3)	67 (2/ 3)	15.6	1.949 (3)
7-11 MOS.	PRE INJ	20 (1/ 5)	0 (0/ 5)			0.077 (5)
	MONTH 2	100 (5/ 5)	60 (3/ 5)	100 (5/ 5)	19.1	2.568 (5)
	MONTH 3	100 (5/ 5)	100 (5/ 5)	100 (5/ 5)	40.9	5.516 (5)
12-71 MOS.	PRE INJ	50 (8/ 16)	6 (1/ 16)			0.165 (16)
	MONTH 1	100 (16/ 16)	88 (14/ 16)	94 (15/ 16)	32.6	7.279 (16)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 5

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : DAJANI, ADNAN S.
STUDY : 000415
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	13	
VACCINEES WITH NO COMPLAINTS :	2	(15.4 %)
VACCINEES WITH COMPLAINTS :	11	(84.6 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 13 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	7	53.8
PAIN/SORENESS, INJ. SITE	4	30.8
SWELLING, INJ. SITE (<=1 IN.)	3	23.1
ERYTHEMA, INJ. SITE (<=1 IN.)	1	7.7
INDURATION, INJECTION SITE	1	7.7
WARMTH, INJECTION SITE	1	7.7
SYSTEMIC REACTIONS	9	69.2
DIARRHEA	5	38.5
IRRITABILITY	5	38.5
TEETHING	5	38.5
FATIGUE	4	30.8
WARM TO TOUCH	3	23.1
MILIARIA RUBRA	1	7.7
NASAL DISCHARGE	1	7.7
PROLONGED CRYING, >1/2 HR	1	7.7
VOMITING	1	7.7

TABLE 5 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : DAJANI, ADNAN S.
STUDY : 000415
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 2	
TOTAL VACCINEES :	11	
VACCINEES WITH NO COMPLAINTS :	3	(27.3 %)
VACCINEES WITH COMPLAINTS :	8	(72.7 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 11 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	3	27.3
ERYTHEMA, INJ. SITE (<=1 IN.)	1	9.1
ERYTHEMA, INJ. SITE (>1 INCH)	1	9.1
PAIN/SORENESS, INJ. SITE	1	9.1
SYSTEMIC REACTIONS	7	63.6
IRRITABILITY	4	36.4
TEETHING	4	36.4
DIARRHEA	2	18.2
HARM TO TOUCH	2	18.2
ANOREXIA	1	9.1
HYPERKINESIA	1	9.1
PROLONGED CRYING, >1/2 HR	1	9.1

TABLE 5 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : DAJANI, ADNAN S.
STUDY : 000415
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
POPULATION : HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	12	
VACCINEES WITH NO COMPLAINTS :	3	(25.0 %)
VACCINEES WITH COMPLAINTS :	9	(75.0 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 12 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	5	41.7
SWELLING, INJ. SITE (<=1 IN.)	4	33.3
PAIN/SORENESS, INJ. SITE	3	25.0
SWELLING, INJ. SITE (>1 INCH)	1	8.3
SYSTEMIC REACTIONS	6	50.0
FATIGUE	4	33.3
DIARRHEA	3	25.0
IRRITABILITY	3	25.0
WARM TO TOUCH	2	16.7
IMPETIGO	1	8.3
PALLOR	1	8.3
PROLONGED CRYING, >1/2 HR	1	8.3
TEETHING	1	8.3

TABLE 5 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : DAJANI, ADNAN S.
STUDY : 000415
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	19	
VACCINEES WITH NO COMPLAINTS :	8	(42.1 %)
VACCINEES WITH COMPLAINTS :	11	(57.9 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 19 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	8	42.1
ERYTHEMA, INJ. SITE (<=1 IN.)	6	31.6
SWELLING, INJ. SITE (<=1 IN.)	6	31.6
PAIN/SORENESS, INJ. SITE	2	10.5
SYSTEMIC REACTIONS	8	42.1
IRRITABILITY	5	26.3
FATIGUE	4	21.1
DIARRHEA	2	10.5
RASH	2	10.5
TEETHING	2	10.5

TABLE 5 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : DAJANI, ADNAN S.
STUDY : 000415
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
POPULATION : HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE	HIB CONJUGATE INJECTION: 2	
TOTAL VACCINEES	15	
VACCINEES WITH NO COMPLAINTS	6	(40.0 %)
VACCINEES WITH COMPLAINTS	9	(60.0 %)
VACCINEES WITH NO DATA	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 15 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	5	33.3
PAIN/SORENESS, INJ. SITE	4	26.7
SWELLING, INJ. SITE (<=1 IN.)	4	26.7
ERYTHEMA, INJ. SITE (<=1 IN.)	2	13.3
SYSTEMIC REACTIONS	8	53.3
IRRITABILITY	5	33.3
FATIGUE	4	26.7
WARM TO TOUCH	4	26.7
TEETHING	3	20.0
COUGH	1	6.7
DIARRHEA	1	6.7
NASAL CONGESTION	1	6.7
NASAL DISCHARGE	1	6.7
PROLONGED CRYING, >1/2 HR	1	6.7
URTICARIA	1	6.7
VOMITING	1	6.7
WHEEZING	1	6.7

TABLE 5 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : DAJANI, ADNAN S.
STUDY : 000415
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
POPULATION : HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	51	
VACCINEES WITH NO COMPLAINTS :	16	(31.4 %)
VACCINEES WITH COMPLAINTS :	35	(68.6 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 51 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	24	47.1
PAIN/SORENESS, INJ. SITE	15	29.4
ERYTHEMA, INJ. SITE (<=1 IN.)	14	27.5
SWELLING, INJ. SITE (<=1 IN.)	9	17.6
SWELLING, INJ. SITE (>1 INCH)	1	2.0
SYSTEMIC REACTIONS	28	54.9
IRRITABILITY	16	31.4
HARM TO TOUCH	11	21.6
FATIGUE	10	19.6
TEETHING	6	11.8
FEVER	4	7.8
OTITIS MEDIA	3	5.9
VOMITING	3	5.9
ATOPIC DERMATITIS	2	3.9
INSOMNIA	2	3.9
NASAL DISCHARGE	2	3.9
NAUSEA	2	3.9
PROLONGED CRYING, >1/2 HR	2	3.9
UPPER RESPIRATORY INFECTION, NOS	2	3.9
BRONCHIOLITIS, ACUTE	1	2.0
CONJUNCTIVITIS	1	2.0
COUGH	1	2.0
DIARRHEA	1	2.0
NERVOUSNESS	1	2.0
POLYDIPSIA	1	2.0
RASH	1	2.0
SNEEZING	1	2.0
WHEEZING	1	2.0

TABLE 6

CLINICAL COMPLAINTS

INVESTIGATOR : DAJANI, ADNAN S.
STUDY : 000415
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (13 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5	COMPLAINTS
LOCAL REACTIONS	6 (46.2%)	5 (38.5%)	1 (8.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	7 (53.8%)
ERYTHEMA, INJ. SITE (<=1 IN.)	0 (0.0%)	1 (7.7%)	1 (8.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.7%)
INDURATION, INJECTION SITE	0 (0.0%)	1 (7.7%)	1 (8.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.7%)
PAIN/SORENESS, INJ. SITE	4 (30.8%)	3 (23.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (30.8%)
SWELLING, INJ. SITE (<=1 IN.)	3 (23.1%)	2 (15.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (23.1%)
WARMTH, INJECTION SITE	1 (7.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.7%)
SYSTEMIC	8 (61.5%)	6 (46.2%)	6 (50.0%)	5 (45.5%)	4 (36.4%)	4 (36.4%)	9 (69.2%)
BODY AS A WHOLE/SITE UNSPEC.	5 (38.5%)	1 (7.7%)	2 (16.7%)	1 (9.1%)	1 (9.1%)	0 (0.0%)	5 (38.5%)
FATIGUE	3 (23.1%)	1 (7.7%)	2 (16.7%)	1 (9.1%)	1 (9.1%)	0 (0.0%)	4 (30.8%)
WARM TO TOUCH	2 (15.4%)	1 (7.7%)	1 (8.3%)	1 (9.1%)	1 (9.1%)	0 (0.0%)	3 (23.1%)
DIGESTIVE SYSTEM	5 (38.5%)	4 (30.8%)	5 (41.7%)	5 (45.5%)	4 (36.4%)	3 (27.3%)	6 (46.2%)

01023

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : DAJANI, ADNAN S.
STUDY : 000415
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (13 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		
DIARRHEA	3 (23.1%)	2 (15.4%)	2 (16.7%)	3 (27.3%)	2 (18.2%)	1 (9.1%)		5 (38.5%)
TEETHING	3 (23.1%)	4 (30.8%)	5 (41.7%)	3 (27.3%)	3 (27.3%)	3 (27.3%)		5 (38.5%)
VOMITING	1 (7.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (7.7%)
NERVOUS SYSTEM & PSYCHIATRIC	4 (30.8%)	4 (30.8%)	1 (8.3%)	1 (9.1%)	1 (9.1%)	0 (0.0%)		5 (38.5%)
IRRITABILITY	4 (30.8%)	4 (30.8%)	1 (8.3%)	1 (9.1%)	1 (9.1%)	0 (0.0%)		5 (38.5%)
PROLONGED CRYING, >1/2 HR	0 (0.0%)	0 (0.0%)	1 (8.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (7.7%)
RESPIRATORY SYSTEM	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (9.1%)	0 (0.0%)	0 (0.0%)		1 (7.7%)
NASAL DISCHARGE	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (9.1%)	0 (0.0%)	0 (0.0%)		1 (7.7%)
SKIN & SKIN APPENDAGE	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (9.1%)	1 (9.1%)		1 (7.7%)
MILIARIA RUBRA	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (9.1%)	1 (9.1%)		1 (7.7%)
VACCINEES WITH COMPLAINTS	9 (69.2%)	9 (69.2%)	7 (58.3%)	5 (45.5%)	4 (36.4%)	4 (36.4%)		11 (84.6%)
VACCINEES WITH NO COMPLAINTS	4 (30.8%)	4 (30.8%)	5 (41.7%)	6 (54.5%)	7 (63.6%)	7 (63.6%)		2 (15.4%)

01024

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : DAJANI, ADNAN S.
STUDY : 000415
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (13 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
TOTAL VACCINEES REPORTING	13	13	12	11	11	11		13
VACCINEES WITH NO DATA	0	0	1	2	2	2		0

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : DAJANI, ADNAN S.
STUDY : 000415
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (11 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
LOCAL REACTIONS	1 (9.1%)	2 (18.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (9.1%)		3 (27.3%)
ERYTHEMA, INJ. SITE (>1 INCH)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (9.1%)		1 (9.1%)
ERYTHEMA, INJ. SITE (<=1 IN.)	1 (9.1%)	1 (9.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (9.1%)
PAIN/SORENESS, INJ. SITE	0 (0.0%)	1 (9.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (9.1%)
SYSTEMIC	7 (63.6%)	6 (54.5%)	3 (27.3%)	3 (27.3%)	3 (27.3%)	3 (27.3%)		7 (63.6%)
BODY AS A WHOLE/SITE UNSPEC.	1 (9.1%)	2 (18.2%)	1 (9.1%)	1 (9.1%)	1 (9.1%)	1 (9.1%)		2 (18.2%)
HARM TO TOUCH	1 (9.1%)	2 (18.2%)	1 (9.1%)	1 (9.1%)	1 (9.1%)	1 (9.1%)		2 (18.2%)
DIGESTIVE SYSTEM	4 (36.4%)	4 (36.4%)	3 (27.3%)	3 (27.3%)	3 (27.3%)	3 (27.3%)		4 (36.4%)
ANOREXIA	1 (9.1%)	1 (9.1%)	1 (9.1%)	1 (9.1%)	1 (9.1%)	1 (9.1%)		1 (9.1%)
DIARRHEA	0 (0.0%)	2 (18.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (18.2%)
TEETHING	3 (27.3%)	3 (27.3%)	3 (27.3%)	3 (27.3%)	3 (27.3%)	3 (27.3%)		4 (36.4%)

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : DAJANI, ADNAN S.
STUDY : 000415
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (11 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		
NERVOUS SYSTEM & PSYCHIATRIC	3 (27.3%)	4 (36.4%)	1 (9.1%)	1 (9.1%)	1 (9.1%)	1 (9.1%)		5 (45.5%)
HYPERKINESIA	1 (9.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (9.1%)
IRRITABILITY	2 (18.2%)	4 (36.4%)	1 (9.1%)	1 (9.1%)	1 (9.1%)	1 (9.1%)		4 (36.4%)
PROLONGED CRYING, >1/2 HR	0 (0.0%)	1 (9.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (9.1%)
VACCINEES WITH COMPLAINTS	7 (63.6%)	6 (54.5%)	3 (27.3%)	3 (27.3%)	3 (27.3%)	4 (36.4%)		8 (72.7%)
VACCINEES WITH NO COMPLAINTS	4 (36.4%)	5 (45.5%)	8 (72.7%)	8 (72.7%)	8 (72.7%)	7 (63.6%)		3 (27.3%)
TOTAL VACCINEES REPORTING	11	11	11	11	11	11		11
VACCINEES WITH NO DATA	0	0	0	0	0	0		0

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : DAJANI, ADNAN S.
STUDY : 000415
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (12 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
LOCAL REACTIONS	5 (41.7%)	3 (25.0%)	1 (8.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		5 (41.7%)
PAIN/SORENESS, INJ. SITE	3 (25.0%)	2 (16.7%)	1 (8.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		3 (25.0%)
SWELLING, INJ. SITE (>1 INCH)	0 (0.0%)	1 (8.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (8.3%)
SWELLING, INJ. SITE (<=1 IN.)	4 (33.3%)	2 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		4 (33.3%)
SYSTEMIC	5 (41.7%)	5 (41.7%)	4 (33.3%)	2 (16.7%)	1 (8.3%)	2 (16.7%)		6 (50.0%)
BODY AS A WHOLE/SITE UNSPEC.	2 (16.7%)	1 (8.3%)	1 (8.3%)	1 (8.3%)	0 (0.0%)	0 (0.0%)		4 (33.3%)
FATIGUE	2 (16.7%)	1 (8.3%)	1 (8.3%)	1 (8.3%)	0 (0.0%)	0 (0.0%)		4 (33.3%)
HARM TO TOUCH	2 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (16.7%)
DIGESTIVE SYSTEM	2 (16.7%)	2 (16.7%)	2 (16.7%)	1 (8.3%)	0 (0.0%)	1 (8.3%)		3 (25.0%)
DIARRHEA	1 (8.3%)	2 (16.7%)	2 (16.7%)	1 (8.3%)	0 (0.0%)	1 (8.3%)		3 (25.0%)
TEETHING	1 (8.3%)	1 (8.3%)	1 (8.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (8.3%)

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : DAJANI, ADNAN S.
STUDY : 000415
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (12 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		
NERVOUS SYSTEM & PSYCHIATRIC	3 (25.0%)	1 (8.3%)	1 (8.3%)	1 (8.3%)	0 (0.0%)	0 (0.0%)		3 (25.0%)
IRRITABILITY	3 (25.0%)	0 (0.0%)	1 (8.3%)	1 (8.3%)	0 (0.0%)	0 (0.0%)		3 (25.0%)
PROLONGED CRYING, >1/2 HR	1 (8.3%)	1 (8.3%)	1 (8.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (8.3%)
SKIN & SKIN APPENDAGE	1 (8.3%)	2 (16.7%)	1 (8.3%)	1 (8.3%)	1 (8.3%)	1 (8.3%)		2 (16.7%)
IMPETIGO	1 (8.3%)	1 (8.3%)	1 (8.3%)	1 (8.3%)	1 (8.3%)	1 (8.3%)		1 (8.3%)
PALLOR	0 (0.0%)	1 (8.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (8.3%)
VACCINEES WITH COMPLAINTS	8 (66.7%)	6 (50.0%)	5 (41.7%)	2 (16.7%)	1 (8.3%)	2 (16.7%)		9 (75.0%)
VACCINEES WITH NO COMPLAINTS	4 (33.3%)	6 (50.0%)	7 (58.3%)	10 (83.3%)	11 (91.7%)	10 (83.3%)		3 (25.0%)
TOTAL VACCINEES REPORTING	12	12	12	12	12	12		12
VACCINEES WITH NO DATA	0	0	0	0	0	0		0

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : DAJANI, ADNAN S.
STUDY : 000415
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (19 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		
LOCAL REACTIONS	4 (21.1%)	6 (31.6%)	4 (21.1%)	3 (15.8%)	3 (16.7%)	1 (5.6%)		8 (42.1%)
ERYTHEMA, INJ. SITE (<=1 IN.)	3 (15.8%)	5 (26.3%)	3 (15.8%)	2 (10.5%)	2 (11.1%)	1 (5.6%)		6 (31.6%)
PAIN/SORENESS, INJ. SITE	1 (5.3%)	0 (0.0%)	1 (5.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (10.5%)
SWELLING, INJ. SITE (<=1 IN.)	2 (10.5%)	4 (21.1%)	3 (15.8%)	3 (15.8%)	2 (11.1%)	1 (5.6%)		6 (31.6%)
SYSTEMIC	6 (31.6%)	6 (31.6%)	5 (26.3%)	5 (26.3%)	3 (16.7%)	3 (16.7%)		8 (42.1%)
BODY AS A WHOLE/SITE UNSPEC.	2 (10.5%)	1 (5.3%)	1 (5.3%)	1 (5.3%)	1 (5.6%)	2 (11.1%)		4 (21.1%)
FATIGUE	2 (10.5%)	1 (5.3%)	1 (5.3%)	1 (5.3%)	1 (5.6%)	2 (11.1%)		4 (21.1%)
DIGESTIVE SYSTEM	2 (10.5%)	2 (10.5%)	2 (10.5%)	3 (15.8%)	1 (5.6%)	1 (5.6%)		3 (15.8%)
DIARRHEA	1 (5.3%)	1 (5.3%)	1 (5.3%)	2 (10.5%)	0 (0.0%)	0 (0.0%)		2 (10.5%)
TEETHING	2 (10.5%)	2 (10.5%)	2 (10.5%)	2 (10.5%)	1 (5.6%)	1 (5.6%)		2 (10.5%)
NERVOUS SYSTEM & PSYCHIATRIC	5 (26.3%)	2 (10.5%)	2 (10.5%)	2 (10.5%)	2 (11.1%)	2 (11.1%)		5 (26.3%)

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : DAJANI, ADNAN S.
STUDY : 000415
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (19 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
IRRITABILITY	5 (26.3%)	2 (10.5%)	2 (10.5%)	2 (10.5%)	2 (11.1%)	2 (11.1%)		5 (26.3%)
SKIN & SKIN APPENDAGE	0 (0.0%)	2 (10.5%)	1 (5.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (10.5%)
RASH	0 (0.0%)	2 (10.5%)	1 (5.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (10.5%)
VACCINEES WITH COMPLAINTS	9 (47.4%)	10 (52.6%)	6 (31.6%)	6 (31.6%)	4 (22.2%)	3 (16.7%)		11 (57.9%)
VACCINEES WITH NO COMPLAINTS	10 (52.6%)	9 (47.4%)	13 (68.4%)	13 (68.4%)	14 (77.8%)	15 (83.3%)		8 (42.1%)
TOTAL VACCINEES REPORTING	19	19	19	19	18	18		19
VACCINEES WITH NO DATA	0	0	0	0	1	1		0

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : DAJANI, ADNAN S.
STUDY : 000415
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (15 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
LOCAL REACTIONS	5 (33.3%)	3 (20.0%)	2 (13.3%)	2 (13.3%)	2 (13.3%)	1 (6.7%)		5 (33.3%)
ERYTHEMA, INJ. SITE (<=1 IN.)	2 (13.3%)	2 (13.3%)	1 (6.7%)	1 (6.7%)	1 (6.7%)	1 (6.7%)		2 (13.3%)
PAIN/SORENESS, INJ. SITE	4 (26.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		4 (26.7%)
SWELLING, INJ. SITE (<=1 IN.)	3 (20.0%)	3 (20.0%)	2 (13.3%)	2 (13.3%)	2 (13.3%)	1 (6.7%)		4 (26.7%)
SYSTEMIC	6 (40.0%)	3 (20.0%)	3 (20.0%)	2 (13.3%)	4 (26.7%)	2 (13.3%)		8 (53.3%)
BODY AS A WHOLE/SITE UNSPEC.	5 (33.3%)	3 (20.0%)	2 (13.3%)	2 (13.3%)	3 (20.0%)	2 (13.3%)		7 (46.7%)
FATIGUE	4 (26.7%)	2 (13.3%)	1 (6.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		4 (26.7%)
HARM TO TOUCH	2 (13.3%)	2 (13.3%)	2 (13.3%)	2 (13.3%)	3 (20.0%)	2 (13.3%)		4 (26.7%)
DIGESTIVE SYSTEM	1 (6.7%)	1 (6.7%)	2 (13.3%)	1 (6.7%)	2 (13.3%)	2 (13.3%)		5 (33.3%)
DIARRHEA	1 (6.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (6.7%)
TEETHING	0 (0.0%)	1 (6.7%)	2 (13.3%)	1 (6.7%)	1 (6.7%)	1 (6.7%)		3 (20.0%)

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : DAJANI, ADNAN S.
STUDY : 000415
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (15 VACCINEES) - INJECTION: 2						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5	COMPLAINTS
VOMITING	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (6.7%)	1 (6.7%)	1 (6.7%)
NERVOUS SYSTEM & PSYCHIATRIC	2 (13.3%)	1 (6.7%)	1 (6.7%)	2 (13.3%)	2 (13.3%)	2 (13.3%)	5 (33.3%)
IRRITABILITY	2 (13.3%)	1 (6.7%)	1 (6.7%)	2 (13.3%)	2 (13.3%)	2 (13.3%)	5 (33.3%)
PROLONGED CRYING, >1/2 HR	1 (6.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (6.7%)
RESPIRATORY SYSTEM	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (6.7%)	1 (6.7%)	1 (6.7%)	1 (6.7%)
COUGH	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (6.7%)	1 (6.7%)	1 (6.7%)	1 (6.7%)
NASAL CONGESTION	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (6.7%)	1 (6.7%)	1 (6.7%)	1 (6.7%)
NASAL DISCHARGE	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (6.7%)	1 (6.7%)	1 (6.7%)	1 (6.7%)
WHEEZING	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (6.7%)	1 (6.7%)	1 (6.7%)	1 (6.7%)
SKIN & SKIN APPENDAGE	0 (0.0%)	1 (6.7%)	1 (6.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (6.7%)
URTICARIA	0 (0.0%)	1 (6.7%)	1 (6.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (6.7%)
VACCINEES WITH COMPLAINTS	7 (46.7%)	6 (40.0%)	4 (26.7%)	4 (26.7%)	5 (33.3%)	3 (20.0%)	9 (60.0%)

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : DAJANI, ADNAN S.
STUDY : 000415
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (15 VACCINEES) - INJECTION: 2						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5	COMPLAINTS
VACCINEES WITH NO COMPLAINTS	8 (53.3%)	9 (60.0%)	11 (73.3%)	11 (73.3%)	10 (66.7%)	12 (80.0%)	6 (40.0%)
TOTAL VACCINEES REPORTING	15	15	15	15	15	15	15
VACCINEES WITH NO DATA	0	0	0	0	0	0	0

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : DAJANI, ADNAN S.
STUDY : 000415
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (51 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
LOCAL REACTIONS	15 (29.4%)	19 (37.3%)	9 (17.6%)	5 (10.0%)	4 (8.0%)	3 (6.0%)		24 (47.1%)
ERYTHEMA, INJ. SITE (<=1 IN.)	6 (11.8%)	13 (25.5%)	6 (11.8%)	2 (4.0%)	1 (2.0%)	1 (2.0%)		14 (27.5%)
PAIN/SORENESS, INJ. SITE	9 (17.6%)	11 (21.6%)	1 (2.0%)	2 (4.0%)	2 (4.0%)	1 (2.0%)		15 (29.4%)
SWELLING, INJ. SITE (>1 INCH)	0 (0.0%)	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (2.0%)
SWELLING, INJ. SITE (<=1 IN.)	7 (13.7%)	6 (11.8%)	4 (7.8%)	3 (6.0%)	3 (6.0%)	2 (4.0%)		9 (17.6%)
SYSTEMIC	20 (39.2%)	16 (31.4%)	14 (27.5%)	14 (28.0%)	13 (26.0%)	12 (24.0%)		28 (54.9%)
BODY AS A WHOLE/SITE UNSPEC.	9 (17.6%)	9 (17.6%)	2 (3.9%)	4 (8.0%)	6 (12.0%)	5 (10.0%)		16 (31.4%)
FATIGUE	7 (13.7%)	4 (7.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.0%)		10 (19.6%)
FEVER	1 (2.0%)	1 (2.0%)	0 (0.0%)	2 (4.0%)	2 (4.0%)	3 (6.0%)		4 (7.8%)
HARM TO TOUCH	6 (11.8%)	7 (13.7%)	2 (3.9%)	3 (6.0%)	5 (10.0%)	3 (6.0%)		11 (21.6%)
DIGESTIVE SYSTEM	7 (13.7%)	5 (9.8%)	5 (9.8%)	5 (10.0%)	5 (10.0%)	7 (14.0%)		10 (19.6%)

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : DAJANI, ADNAN S.
STUDY : 000415
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (51 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5	
DIARRHEA	0 (0.0%)	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.0%)
NAUSEA	0 (0.0%)	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.0%)	2 (3.9%)
POLYDIPSIA	1 (2.0%)	1 (2.0%)	1 (2.0%)	1 (2.0%)	1 (2.0%)	1 (2.0%)	1 (2.0%)
TEETHING	5 (9.8%)	3 (5.9%)	4 (7.8%)	4 (8.0%)	4 (8.0%)	4 (8.0%)	6 (11.8%)
VOMITING	1 (2.0%)	0 (0.0%)	1 (2.0%)	0 (0.0%)	0 (0.0%)	1 (2.0%)	3 (5.9%)
NERVOUS SYSTEM & PSYCHIATRIC	13 (25.5%)	5 (9.8%)	7 (13.7%)	8 (16.0%)	4 (8.0%)	3 (6.0%)	18 (35.3%)
INSOMNIA	1 (2.0%)	0 (0.0%)	0 (0.0%)	1 (2.0%)	1 (2.0%)	1 (2.0%)	2 (3.9%)
IRRITABILITY	12 (23.5%)	5 (9.8%)	7 (13.7%)	7 (14.0%)	2 (4.0%)	2 (4.0%)	16 (31.4%)
NERVOUSNESS	1 (2.0%)	1 (2.0%)	1 (2.0%)	1 (2.0%)	1 (2.0%)	0 (0.0%)	1 (2.0%)
PROLONGED CRYING, >1/2 HR	0 (0.0%)	0 (0.0%)	1 (2.0%)	0 (0.0%)	1 (2.0%)	0 (0.0%)	2 (3.9%)
RESPIRATORY SYSTEM	1 (2.0%)	1 (2.0%)	1 (2.0%)	3 (6.0%)	4 (8.0%)	4 (8.0%)	6 (11.8%)
BRONCHIOLITIS, ACUTE	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.0%)	1 (2.0%)	1 (2.0%)

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TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : DAJANI, ADNAN S.
STUDY : 000415
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (51 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
COUGH	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.0%)	1 (2.0%)	1 (2.0%)		1 (2.0%)
NASAL DISCHARGE	0 (0.0%)	0 (0.0%)	1 (2.0%)	1 (2.0%)	1 (2.0%)	1 (2.0%)		2 (3.9%)
SNEEZING	0 (0.0%)	0 (0.0%)	1 (2.0%)	1 (2.0%)	0 (0.0%)	0 (0.0%)		1 (2.0%)
UPPER RESPIRATORY INFECTION, NOS	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (4.0%)	1 (2.0%)	1 (2.0%)		2 (3.9%)
WHEEZING	1 (2.0%)	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (2.0%)
SKIN & SKIN APPENDAGE	1 (2.0%)	2 (3.9%)	3 (5.9%)	1 (2.0%)	1 (2.0%)	1 (2.0%)		3 (5.9%)
ATOPIC DERMATITIS	1 (2.0%)	2 (3.9%)	2 (3.9%)	1 (2.0%)	1 (2.0%)	1 (2.0%)		2 (3.9%)
RASH	0 (0.0%)	0 (0.0%)	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (2.0%)
SPECIAL SENSES	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (4.0%)	2 (4.0%)	2 (4.0%)		3 (5.9%)
CONJUNCTIVITIS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.0%)	1 (2.0%)		1 (2.0%)
OTITIS MEDIA	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (4.0%)	2 (4.0%)	2 (4.0%)		3 (5.9%)
VACCINEES WITH COMPLAINTS	26 (51.0%)	28 (54.9%)	18 (35.3%)	16 (32.0%)	15 (30.0%)	14 (28.0%)		35 (68.6%)

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : DAJANI, ADNAN S.
STUDY : 000415
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (51 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
VACCINEES WITH NO COMPLAINTS	25 (49.0%)	23 (45.1%)	33 (64.7%)	34 (68.0%)	35 (70.0%)	36 (72.0%)		16 (31.4%)
TOTAL VACCINEES REPORTING	51	51	51	50	50	50		51
VACCINEES WITH NO DATA	0	0	0	1	1	1		0

TABLE 7

MAXIMUM TEMPERATURES

INVESTIGATOR : DAJANI, ADNAN S.
STUDY : 000415
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (13 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		MAX TEMP
< 99	6 (54.5%)	7 (63.6%)	8 (72.7%)	7 (63.6%)	7 (63.6%)	7 (63.6%)		4 (36.4%)
99 - 99.9	5 (45.5%)	4 (36.4%)	3 (27.3%)	3 (27.3%)	3 (27.3%)	3 (27.3%)		6 (54.5%)
100 - 100.9	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (9.1%)		0 (0.0%)
102 - 102.9	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (9.1%)	1 (9.1%)	0 (0.0%)		1 (9.1%)
TEMPERATURE TAKEN	11 (84.6%)	11 (84.6%)	11 (84.6%)	11 (84.6%)	11 (84.6%)	11 (84.6%)		11 (84.6%)
TEMPERATURE NOT TAKEN	2 (15.4%)	2 (15.4%)	2 (15.4%)	2 (15.4%)	2 (15.4%)	2 (15.4%)		2 (15.4%)

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TABLE 7 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : DAJANI, ADNAN S.
STUDY : 000415
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (11 VACCINEES) - INJECTION 2							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
NORMAL	1 (11.1%)	1 (11.1%)	1 (14.3%)	1 (14.3%)	1 (14.3%)	1 (14.3%)		1 (11.1%)
< 99	3 (33.3%)	5 (55.6%)	3 (42.9%)	4 (57.1%)	4 (57.1%)	4 (57.1%)		3 (33.3%)
99 - 99.9	3 (33.3%)	1 (11.1%)	2 (28.6%)	1 (14.3%)	1 (14.3%)	1 (14.3%)		3 (33.3%)
100 - 100.9	1 (11.1%)	1 (11.1%)	1 (14.3%)	1 (14.3%)	1 (14.3%)	1 (14.3%)		1 (11.1%)
FEVER	1 (11.1%)	1 (11.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (11.1%)
TEMPERATURE TAKEN	9 (81.8%)	9 (81.8%)	7 (63.6%)	7 (63.6%)	7 (63.6%)	7 (63.6%)		9 (81.8%)
TEMPERATURE NOT TAKEN	2 (18.2%)	2 (18.2%)	4 (36.4%)	4 (36.4%)	4 (36.4%)	4 (36.4%)		2 (18.2%)

TABLE 7 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : DAJANI, ADNAN S.
STUDY : 000415
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (12 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
< 99	4 (36.4%)	6 (50.0%)	4 (33.3%)	6 (54.5%)	7 (63.6%)	7 (58.3%)		3 (25.0%)
99 - 99.9	5 (45.5%)	6 (50.0%)	8 (66.7%)	5 (45.5%)	4 (36.4%)	4 (33.3%)		6 (50.0%)
100 - 100.9	1 (9.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (8.3%)		2 (16.7%)
101 - 101.9	1 (9.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (8.3%)
TEMPERATURE TAKEN	11 (91.7%)	12 (100.0%)	12 (100.0%)	11 (91.7%)	11 (91.7%)	12 (100.0%)		12 (100.0%)
TEMPERATURE NOT TAKEN	1 (8.3%)	0 (0.0%)	0 (0.0%)	1 (8.3%)	1 (8.3%)	0 (0.0%)		0 (0.0%)

TABLE 7 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : DAJANI, ADNAN S.
STUDY : 000415
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (19 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
NORMAL	4 (22.2%)	4 (22.2%)	4 (23.5%)	4 (23.5%)	4 (23.5%)	4 (23.5%)		4 (22.2%)
< 99	7 (38.9%)	10 (55.6%)	8 (47.1%)	6 (35.3%)	9 (52.9%)	8 (47.1%)		6 (33.3%)
99 - 99.9	7 (38.9%)	4 (22.2%)	5 (29.4%)	7 (41.2%)	4 (23.5%)	5 (29.4%)		8 (44.4%)
TEMPERATURE TAKEN	18 (94.7%)	18 (94.7%)	17 (89.5%)	17 (89.5%)	17 (89.5%)	17 (89.5%)		18 (94.7%)
TEMPERATURE NOT TAKEN	1 (5.3%)	1 (5.3%)	2 (10.5%)	2 (10.5%)	2 (10.5%)	2 (10.5%)		1 (5.3%)

TABLE 7 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : DAJANI, ADNAN S.
STUDY : 000415
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 1-11 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (15 VACCINEES) - INJECTION 2							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
NORMAL	1 (7.7%)	1 (7.1%)	1 (7.1%)	1 (7.1%)	1 (7.1%)	1 (7.1%)		1 (7.1%)
< 99	6 (46.2%)	5 (35.7%)	5 (35.7%)	7 (50.0%)	5 (35.7%)	4 (28.6%)		3 (21.4%)
99 - 99.9	6 (46.2%)	7 (50.0%)	7 (50.0%)	4 (28.6%)	8 (57.1%)	7 (50.0%)		6 (42.9%)
100 - 100.9	0 (0.0%)	1 (7.1%)	1 (7.1%)	2 (14.3%)	0 (0.0%)	2 (14.3%)		4 (28.6%)
TEMPERATURE TAKEN	13 (86.7%)	14 (93.3%)	14 (93.3%)	14 (93.3%)	14 (93.3%)	14 (93.3%)		14 (93.3%)
TEMPERATURE NOT TAKEN	2 (13.3%)	1 (6.7%)	1 (6.7%)	1 (6.7%)	1 (6.7%)	1 (6.7%)		1 (6.7%)

TABLE 7 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : DAJANI, ADNAN S.
STUDY : 000415
VACCINE : HIB CONJUGATE
LOT NUMBER : CP749
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (51 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
NORMAL	3 (6.3%)	3 (6.3%)	3 (6.3%)	3 (6.4%)	2 (4.3%)	2 (4.3%)		3 (6.3%)
< 99	23 (47.9%)	23 (47.9%)	25 (52.1%)	27 (57.4%)	25 (54.3%)	27 (58.7%)		14 (29.2%)
99 - 99.9	18 (37.5%)	19 (39.6%)	18 (37.5%)	14 (29.8%)	14 (30.4%)	12 (26.1%)		18 (37.5%)
100 - 100.9	3 (6.3%)	2 (4.2%)	2 (4.2%)	1 (2.1%)	4 (8.7%)	3 (6.5%)		10 (20.8%)
101 - 101.9	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.1%)	0 (0.0%)	0 (0.0%)		0 (0.0%)
102 - 102.9	0 (0.0%)	1 (2.1%)	0 (0.0%)	1 (2.1%)	1 (2.2%)	1 (2.2%)		1 (2.1%)
103 - 103.9	1 (2.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (2.1%)
105 - 105.9	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.2%)		1 (2.1%)
TEMPERATURE TAKEN	48 (94.1%)	48 (94.1%)	48 (94.1%)	47 (92.2%)	46 (90.2%)	46 (90.2%)		48 (94.1%)
TEMPERATURE NOT TAKEN	3 (5.9%)	3 (5.9%)	3 (5.9%)	4 (7.8%)	5 (9.8%)	5 (9.8%)		3 (5.9%)

Haemophilus b Conjugate Vaccine
(Neisseria meningitidis Outer Membrane Protein Complex)

DOSE RANGING STUDIES

008-01 - Los Angeles, CA - Kwang Sik Kim, M.D.

Healthy children and infants 2-48 months of age were enrolled in this study. The children received one or two doses of either 7.5 mcg, 15 mcg or 30 mcg of Lot 1072/C-P298. Seventeen children 2-18 months of age received the first 7.5 mcg dose. Two children received a second dose two months later. Serologic data for one child show the child developed an antibody level >1.0 mcg/ml. Additional data are expected. Eight children 19-48 months of age received a single 7.5 mcg dose. One month following vaccination, 100% (7/7) had developed antibody titers >1.0 mcg/ml. The GMT prior to vaccination was 0.1 mcg/ml. The GMT postvaccination was 4.9 mcg/ml.

Fourteen children 2-18 months of age received the first 15 mcg dose of vaccine. Four children received the second dose 2 months later. One month following the first dose 75% (3/4) had developed antibody levels >1.0 mcg/ml. The GMT at that time for the 4 vaccinees was 2.461 mcg/ml. Twenty children 19-48 months of age received a single 15 mcg dose of vaccine. One month following vaccination, 93% (14/15) had developed antibody levels >1.0 mcg/ml. Prior to vaccination, the GMT was 0.1 mcg/ml. The GMT at 1 month was 4.1 mcg/ml.

Fifteen children 2-18 months of age received the first 30 mcg dose of vaccine. Serologic data were not available for these vaccinees at the time of data cutoff. Data are expected. Eight children 19-48 months of age received a single 30 mcg dose of vaccine. Prior to vaccination 16% (1/6) had antibody levels >1.0 mcg/ml. The GMT prior to vaccination was 0.9 mcg/ml. One month following vaccination, 83% (5/6) had developed antibody levels >1.0 mcg/ml. The GMT for those 6 children was 5.4 mcg/ml at 1 month.

No serious adverse experiences were reported in this study.

008-02 - Chicago, IL - Ram Yogev, M.D.

Healthy children 2-59 months of age were enrolled in this study. Each child received one or two doses of either 7.5 mcg, 15 mcg or 30 mcg of Lot 1072/C-P298. Sixty children 2-18 months of age received the first 7.5 mcg dose of vaccine. Eight children received the second dose 2 months later. Available serologic data show that 86% (6/7) had developed antibody titers >1.0 mcg/ml 1 month after the second dose. Twenty-four children 19-59 months of age received a single 7.5 mcg dose of vaccine. Prior to vaccination 18% had antibody titers >1.0 mcg/ml. The GMT prior to vaccination was 0.156 mcg/ml. One month after vaccination 94% (16/17) had antibody levels >1.0 mcg/ml. The GMT for the 17 vaccinees was 4.917 mcg/ml.

Forty-one children 2-18 months of age received the first 15 mcg dose of vaccine. Twelve children received the second dose 2 months later. Prior to vaccination the GMT for the 2-6 month age group was 0.157 mcg/ml; the GMT for the 7-12 month age group was 0.085 mcg/ml, and the GMT for the 13-18 month age group was 0.063 mcg/ml. One month after the second injection 100% (11/11) had developed antibody levels >1.0 mcg/ml. The GMT for the 2-6 month age group (n=4) was 2.295 mcg/ml; the GMT for the 7-12 month age group (n=4) was 5.068 mcg/ml, and the GMT for the 13-18 month age group (n=3) was 11.825 mcg/ml. Twenty-four children 19-59 months of age received a single 15 mcg dose of vaccine. The prevaccination GMT was 0.161 mcg/ml. One month after vaccination 94% (16/17) had developed antibody titers >1.0 mcg/ml. The GMT at 1 month was 9.625 mcg/ml.

Seven children 7-18 months of age received the first 30 mcg dose of vaccine. No serologic data were available for these vaccinees at the time of data cutoff. Data are expected. Twenty-one children 19-59 months of age received a single 30 mcg dose. Prior to vaccination 13% (2/16) had antibody titers >1.0 mcg/ml. The GMT was 0.149 mcg/ml. One month following vaccination 94% (15/16) had antibody levels >1.0 mcg/ml. The GMT at that time was 18.125 mcg/ml.

Serious adverse experiences were reported for one child who developed rash, fever to 104°, decreased appetite and vomiting. The investigator felt these experiences were unrelated to use of the vaccine.

STUDY 008-01

PROGRAM: Haemophilus b Conjugate Vaccine (Neisseria meningitidis Outer Membrane Protein Complex), Study 008-01

PURPOSE: To evaluate the effect of dose of polysaccharide on the safety and immunogenicity of Haemophilus b conjugate vaccine (Neisseria meningitidis outer membrane protein complex) in infants and children 2 to 71 months of age.

VACCINE: Haemophilus b Conjugate Vaccine (Neisseria meningitidis Outer Membrane Protein Complex), (PRP-OMPC)
Lot 1072/C-P298/37359 – (b) (4) mcg polysaccharide/ml
mcg meningococcal protein/ml

Aluminum hydroxide diluent
Lot (b) (4)

INVESTIGATOR: Kwang Sik Kim, M.D.
Victor K. Wong, M.D.
Childrens Hospital of Los Angeles
4650 Sunset Boulevard
Los Angeles, California 90027

SUB-INVESTIGATORS: Evan Steinberg, M.D.
Kaiser Foundation Hospital
1505 North Edgemont
Los Angeles, California 90027

Robert Adler, M.D.
Childrens Hospital of Los Angeles
4650 Sunset Boulevard
Los Angeles, California

STUDY LOCATION:	Childrens Hospital of Los Angeles 4650 Sunset Boulevard Los Angeles, California 90027 Kaiser Foundation Hospital 1505 North Edgemont Los Angeles, California 90027
DATE STUDY INITIATED:	March 30, 1988
DATE STUDY COMPLETED:	In progress.
STUDY POPULATION:	Healthy infants and children 2 to 71 months of age are included in the study. The study population has been amended to include children with documented lack of immunologic response to prior vaccination with any other Haemophilus b vaccine (<2-fold rise in anti-PRP and <1.0 mcg/ml anti-PRP).
STUDY PROCEDURE:	Infants and children are randomized to receive PRP-OMPC vaccine containing 7.5, 15 or 30 mcg polysaccharide. Approximately 50 children are assigned to each dose. Infants 2 to 18 months of age receive two injections of PRP-OMPC vaccine given 2 months apart, while children 19 months of age and older receive a single injection. Vaccine is reconstituted in aluminum hydroxide in the appropriate volume and administered by intramuscular route. The dose for each injection is 7.5, 15, or 30 mcg of polysaccharide in 0.5 ml. The parent or guardian is required to record the vaccine recipient's temperature and any reactions at the injection site or systemic complaints for 5 days after each injection of vaccine. Unexpected or serious reactions are to be reported immediately to the study physician. Serious adverse experiences in the 14 days following each injection of vaccine are required to be reported by the investigator.

A blood sample is obtained prior to each injection of vaccine and 1 month after the last injection or after a single injection of vaccine. All serum samples are assayed for antibody to the capsular polysaccharide of Haemophilus influenzae type b by radioimmunoassay. Selected samples may be tested for bactericidal and opsonophagocytic activity, immunoglobulin isotype and subclass IgG. Opsonophagocytic assays are performed at the University of Alabama. All other assays are performed at Merck Sharp & Dohme Research Laboratories.

RESULTS:

Demographic information and individual pre and postimmunization antibody data for each vaccine recipient are presented in Table 1.

1. Current status:

Dose (mcg)	Age	No. Vaccinated	
		Injection 1	Injection 2
7.5	2-18 Mos.	17	2
	19-71 Mos.	7 (1)*	-
15	2-18 Mos.	14	4
	19-71 Mos.	1 (19)	-
30	2-18 Mos.	15	0
	19-71 Mos.	7 (1)	-

* Parentheses represent additional vaccine recipients who were licensed nonconjugated PRP vaccine nonresponders.

RESULTS (CONT.)

2. Serologic results:

Anti-PRP responses prior to each injection of vaccine and 1 month after the last or after a single injection of vaccine are as follows:

Age (Months)	Dose (mcg)	Time	% With Anti-PRP >0.15 mcg/ml	% With Anti-PRP >1.0 mcg/ml	GMT (mcg/ml) All Vaccinees
2-18	7.5	Pre	50 (1/2)	0 (0/1)	0.10
		Post 1	100 (1/1)	100 (1/1)	2.29
		Post 2	100 (1/1)	0 (0/1)	0.77
	15	Pre	0 (0/4)	0 (0/4)	0.08
		Post 1	100 (4/4)	75 (3/4)	2.46
		Post 2	100 (3/3)	67 (2/3)	2.73
19-71	7.5	Pre	17 (1/6)	0 (0/6)	0.09
		Post	100 (6/6)	100 (6/6)	5.52
	15	Pre	0 (0/1)	0 (0/1)	0.06
		Post	100 (1/1)	0 (0/1)	0.64
	30	Pre	20 (1/5)	20 (1/5)	0.19
		Post	100 (5/5)	80 (4/5)	5.96

Antibody response summary statistics for previously unvaccinated subjects are presented in Tables 2-4. Antibody responses among licensed nonconjugated PRP vaccine nonresponders are presented in Tables 5-7.

RESULTS: (CONT.)

3. Clinical results:

The incidence of selected injection site and systemic reactions occurring within 2 days after vaccination are as follows:

Type of Reaction	% of Vaccinees with Reaction							
	2-18 Mos.					12-71 Mos.		
	Injection 1			Injection 2				
	7.5 n=11	15 n=8	30 n=10	7.5 n=1	15 n=1	7.5 n=7	15* n=16	30 n=6
Injection Site:	9	0	0	0	0	14	38	67
Pain/Soreness	0	0	0	0	0	0	0	0
Erythema >1 inch	0	0	0	0	0	0	0	0
Swelling >1 inch	0	0	0	0	0	0	0	0
Induration	0	0	0	0	0	0	0	0
Systemic:								
Irritability	9	25	20	0	100	0	13	0
Sleepiness/Lethargy/ Fatigue	36	0	10	0	0	14	25	17

* Licensed nonconjugated PRP vaccine nonresponders.

The frequencies of all clinical reactions and maximum temperatures occurring during the 5 days following each injection of vaccine are presented in Tables 8-10 by dose.

No serious or alarming reactions attributable to vaccine have been reported.

TABLE 1

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : KIM, KWANG S.
STUDY : 000801
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA
(b) (6)	F	HISP	(b) (6)	2M	0	(b) (6)	011	INJ	1	CP298	30 MCG	
	F	CAUC		2M	0		011	INJ	1	CP298	7.5 MCG	
					56		021	INJ	2	CP298	7.5 MCG	
	F	CAUC		4M	0		001	PREBLEED				< 125
					0		011	INJ	1	CP298	15 MCG	
					64		011	BLEED	1			1373
					64		021	INJ	2	CP298	15 MCG	
					97		021	BLEED	2			1581
	M	CAUC		2M	0		011	INJ	1	CP298	30 MCG	
	F	BLAC		2M	0		011	INJ	1	CP298	7.5 MCG	
	M	HISP		3M	0		001	PREBLEED				< 125
					0		011	INJ	1	CP298	15 MCG	
					56		011	BLEED	1			289
					56		021	INJ	2	CP298	15 MCG	
					100		021	BLEED	2			604
	F	HISP		4M	0		001	PREBLEED				126
					0		011	INJ	1	CP298	15 MCG	
					63		011	BLEED	1			21544
					63		021	INJ	2	CP298	15 MCG	
					91		021	BLEED	2			21273
	F	HISP		2M	0		011	INJ	1	CP298	7.5 MCG	
	M	HISP		2M	0		011	INJ	1	CP298	30 MCG	
	M	BLAC		2M	0		011	INJ	1	CP298	30 MCG	
	F	BLAC		6M	0		011	INJ	1	CP298	15 MCG	
	M	HISP		2M	0		011	INJ	1	CP298	7.5 MCG	
	F	BLAC		4M	0		011	INJ	1	CP298	7.5 MCG	
	F	CAUC		2M	0		011	INJ	1	CP298	15 MCG	

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : KIM, KNANG S.
STUDY : 000801
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT		LOT	DOSE	CODE/	RIA
(b) (6)	M	BLAC	(b) (6)	4M	0	(b) (6)	011	INJ	1	CP298	30 MCG		
	M	HISP		5M	0		011	INJ	1	CP298	30 MCG		
	M	HISP		4M	0		011	INJ	1	CP298	15 MCG		
	M	CAUC		5M	0		011	INJ	1	CP298	7.5 MCG		
	F	HISP		2M	0		011	INJ	1	CP298	15 MCG		
	M	OTHE		12M	0		011	INJ	1	CP298	30 MCG		
	M	HISP		6M	0		011	INJ	1	CP298	15 MCG		
	M	CAUC		11M	0		011	INJ	1	CP298	7.5 MCG		
	F	HISP		7M	0		001	PREBLEED					< 125
					0		011	INJ	1	CP298	15 MCG		
					63		011	BLEED	1				4288
					63		021	INJ	2	CP298	15 MCG		
					83		021	BLEED	2				8978
	F	HISP		4M	0		011	INJ	1	CP298	7.5 MCG		
	M	CAUC		10M	0		011	INJ	1	CP298	30 MCG		
	F	HISP		12M	0		011	INJ	1	CP298	15 MCG		
	M	CAUC		8M	0		011	INJ	1	CP298	7.5 MCG		
	M	HISP		7M	0		011	INJ	1	CP298	30 MCG		
	M	CAUC		10M	0		011	INJ	1	CP298	7.5 MCG		
	M	BLAC		6M	0		011	INJ	1	CP298	30 MCG		
	M	BLAC		7M	0		011	INJ	1	CP298	15 MCG		
	F	BLAC		8M	0		011	INJ	1	CP298	30 MCG		
	M	BLAC		11M	0		011	INJ	1	CP298	7.5 MCG		

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : KIM, KWANG S.
STUDY : 000801
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA
(b) (6)	F	HISP	(b) (6)	13M	0	(b) (6)	011	INJ	1	CP298	30 MCG	
	M	BLAC		13M	0		001	PREBLEED				< 125
					0		011	INJ	1	CP298	7.5 MCG	
					63		011	BLEED	1			766
					63		021	INJ	2	CP298	7.5 MCG	
					89		021	BLEED	2			3449
	M	BLAC		12M	0		011	INJ	1	CP298	15 MCG	
	F	BLAC		12M	0		011	INJ	1	CP298	30 MCG	
	F	BLAC		16M	0		011	INJ	1	CP298	7.5 MCG	
	M	HISP		13M	0		011	INJ	1	CP298	7.5 MCG	
	M	HISP		16M	0		011	INJ	1	CP298	30 MCG	
	M	HISP		16M	0		011	INJ	1	CP298	30 MCG	
	F	BLAC		14M	0		011	INJ	1	CP298	15 MCG	
	M	CAUC		16M	0		011	INJ	1	CP298	7.5 MCG	
	F	HISP		12M	0		011	INJ	1	CP298	15 MCG	
	F	HISP		18M	0		001	PREBLEED				< 125
					0		011	INJ	1	CP298	7.5 MCG	
					18		011	BLEED	1			4766
	M	BLAC		18M	0		001	PREBLEED				161
					0		011	INJ	1	CP298	7.5 MCG	
					29		011	BLEED	1			2290

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : KIM, KWANG S.
STUDY : 000801
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA
(b) (6)	F	BLAC	(b) (6)	2Y	0	(b) (6)	001	PREBLEED				< 125
					0		011	INJ 1	CP298	30 MCG		
					32		011	BLEED 1				671
	M	BLAC		23M	0		001	PREBLEED				< 125
					0		011	INJ 1	CP298	15 MCG		
					23		011	BLEED 1				638
	M	HISP		19M	0		001	PREBLEED				< 125
					0		011	INJ 1	CP298	7.5 MCG		
					30		011	BLEED 1				2518
	F	CAUC		2Y	0		001	PREBLEED				< 125
					0		011	INJ 1	CP298	30 MCG		
					27		011	BLEED 1				12564
	M	BLAC		2Y	0		001	PREBLEED				< 125
					0		011	INJ 1	CP298	7.5 MCG		
					22		011	BLEED 1				25050
	M	CAUC		2Y	0		001	PREBLEED				6305
					0		011	INJ 1	CP298	30 MCG		
					28		011	BLEED 1				17307
	M	CAUC		19M	0		001	PREBLEED				< 125
					0		011	INJ 1	CP298	30 MCG		
					28		011	BLEED 1				3935
	F	HISP		20M	0		001	PREBLEED				< 125
					0		011	INJ 1	CP298	7.5 MCG		
					40		011	BLEED 1				3587
	F	CAUC		19M	0		001	PREBLEED				149
					0		011	INJ 1	CP298	7.5 MCG		
					30		011	BLEED 1				1251
	M	OTHE		2Y	0		001	PREBLEED				142
					0		011	INJ 1	CP298	30 MCG		
					26		011	BLEED 1				13056
	F	HISP		2Y	0		001	PREBLEED				< 125

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : KIM, KWANG S.
STUDY : 000801
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA
(b) (6)	F	HISP	(b) (6)	2Y	0	(b) (6)	011	INJ 1	CP298	30 MCG		
					50		011	BLEED 1				2568
	F	CAUC		22M	0		001	PREBLEED				267
					0		011	INJ 1	CP298	7.5 MCG		
					20		011	BLEED 1				441
	F	BLAC		21M	0		011	INJ 1	CP298	30 MCG		
	M	BLAC		22M	0		001	PREBLEED				204
					0		011	INJ 1	CP298	7.5 MCG		
					27		011	BLEED 1				45036
	F	BLAC		2Y	0		001	PREBLEED				< 125
					0		011	INJ 1	CP298	7.5 MCG		
					36		011	BLEED 1				2208

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : KIM, KWANG S.
STUDY : 000801
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HIB POLYS VACC NON-RESPONDERS

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA
(b) (6)	F	HISP	(b) (6)	2Y	0	(b) (6)	001	PREBLEED				< 125
					0		011	INJ 1	CP298	15 MCG		
					26		011	BLEED 1				1694
	M	HISP		2Y	0		001	PREBLEED				< 125
					0		011	INJ 1	CP298	15 MCG		
					30		011	BLEED 1				10350
	M	CAUC		2Y	0		001	PREBLEED				< 125
					0		011	INJ 1	CP298	15 MCG		
					30		011	BLEED 1				3208
	M	BLAC		2Y	0		001	PREBLEED				< 125
					0		011	INJ 1	CP298	7.5 MCG		
					34		011	BLEED 1				2399
	M	CAUC		22M	0		001	PREBLEED				< 125
					0		011	INJ 1	CP298	15 MCG		
					21		011	BLEED 1				3735
	F	CAUC		2Y	0		001	PREBLEED				144
					0		011	INJ 1	CP298	15 MCG		
					33		011	BLEED 1				8246
	M	HISP		2Y	0		001	PREBLEED				< 125
					0		011	INJ 1	CP298	15 MCG		
					29		011	BLEED 1				14878
	M	HISP		2Y	-31		001	PREBLEED				392
					0		011	INJ 1	CP298	30 MCG		
					28		011	BLEED 1				3266
	F	HISP		2Y	0		001	PREBLEED				< 125
					0		011	INJ 1	CP298	15 MCG		
					34		011	BLEED 1				21419
	M	HISP		2Y	0		001	PREBLEED				< 125
					0		011	INJ 1	CP298	15 MCG		
					58		011	BLEED 1				1984
	M	HISP		2Y	0		001	PREBLEED				187

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : KIM, KWANG S.
STUDY : 000801
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HIB POLYS VACC NON-RESPONDERS

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA
(b) (6)	M	HISP	(b) (6)	2Y	0	(b) (6)	011	INJ	1	CP298	15 MCG	
					28		011	BLEED	1			1138
	F	HISP		2Y	0		001	PREBLEED				361
					0		011	INJ	1	CP298	15 MCG	
					29		011	BLEED	1			3161
	F	BLAC		3Y	0		001	PREBLEED				389
					0		011	INJ	1	CP298	15 MCG	
					30		011	BLEED	1			4290
	M	CAUC		2Y	-41		001	PREBLEED				449
					0		011	INJ	1	CP298	15 MCG	
					45		011	BLEED	1			1721
	F	HISP		3Y	0		011	INJ	1	CP298	15 MCG	
	M	HISP		2Y	0		001	PREBLEED				< 125
					0		011	INJ	1	CP298	15 MCG	
					49		011	BLEED	1			37923
	M	HISP		2Y	0		011	INJ	1	CP298	15 MCG	
					36		011	BLEED	1			5711
	M	HISP		3Y	0		001	PREBLEED				336
					0		011	INJ	1	CP298	15 MCG	
					28		011	BLEED	1			2065
	F	CAUC		2Y	0		001	PREBLEED				< 125
					0		011	INJ	1	CP298	15 MCG	
					21		011	BLEED	1			1876
	M	BLAC		3Y	0		011	INJ	1	CP298	15 MCG	
	F	HISP		2Y	0		011	INJ	1	CP298	15 MCG	

TABLE 2

A N T I B O D Y R E S P O N S E S

INVESTIGATOR : KIM, KHANG S.
STUDY : 000801
VACCINE : HIB CONJUGATE
ASSAY : RIA
DOSE : 7.5 MCG
POPULATION : HEALTHY CHILDREN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
13-18 MOS.	PRE INJ	50 (1/ 2)	0 (0/ 2)			0.100 (2)
	1 MONTH	100 (1/ 1)	100 (1/ 1)	100 (1/ 1)	14.2	2.290 (1)
	2 MONTHS	100 (1/ 1)	0 (0/ 1)	100 (1/ 1)	6.1	0.766 (1)
	3 MONTHS	100 (1/ 1)	100 (1/ 1)	100 (1/ 1)	27.6	3.449 (1)
19-59 MOS.	PRE INJ	17 (1/ 6)	0 (0/ 6)			0.088 (6)
	1 MONTH	100 (6/ 6)	100 (6/ 6)	100 (6/ 6)	39.5	5.515 (6)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 3

ANTIBODY RESPONSES

INVESTIGATOR : KIM, KWANG S.
STUDY : 000801
VACCINE : HIB CONJUGATE
ASSAY : RIA
DOSE : 15 MCG
POPULATION : HEALTHY CHILDREN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
2- 6 MOS.	PRE INJ	0 (0/ 3)	0 (0/ 3)			0.079 (3)
	2 MONTHS	100 (3/ 3)	67 (2/ 3)	100 (3/ 3)	16.3	2.045 (3)
	3 MONTHS	100 (3/ 3)	67 (2/ 3)	100 (3/ 3)	21.8	2.729 (3)
7-12 MOS.	PRE INJ	0 (0/ 1)	0 (0/ 1)			0.063 (1)
	2 MONTHS	100 (1/ 1)	100 (1/ 1)	100 (1/ 1)	34.3	4.288 (1)
19-59 MOS.	PRE INJ	0 (0/ 1)	0 (0/ 1)			0.063 (1)
	1 MONTH	100 (1/ 1)	0 (0/ 1)	100 (1/ 1)	5.1	0.638 (1)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 4

ANTIBODY RESPONSES

INVESTIGATOR : KIM, KHANG S.
STUDY : 000801
VACCINE : HIB CONJUGATE
ASSAY : RIA
DOSE : 30 MCG
POPULATION : HEALTHY CHILDREN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
19-59 MOS.	PRE INJ	20 (1/ 5)	20 (1/ 5)			0.185 (5)
	1 MONTH	100 (5/ 5)	80 (4/ 5)	100 (5/ 5)	21.2	5.956 (5)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE,
AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 5

ANTIBODY RESPONSES

INVESTIGATOR : KIM, KWANG S.
STUDY : 000801
VACCINE : HIB CONJUGATE
ASSAY : RIA
DOSE : 7.5 MCG
POPULATION : HIB POLYS VACC NON-RESPONDERS

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
19-59 MOS.	PRE INJ	0 (0/ 1)	0 (0/ 1)			0.063 (1)
	1 MONTH	100 (1/ 1)	100 (1/ 1)	100 (1/ 1)	19.2	2.399 (1)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 6

A N T I B O D Y R E S P O N S E S

INVESTIGATOR : KIM, KWANG S.
STUDY : 000801
VACCINE : HIB CONJUGATE
ASSAY : RIA
DOSE : 15 MCG
POPULATION : HIB POLYS VACC NON-RESPONDERS

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
19-59 MOS.	PRE INJ	36 (5/ 14)	0 (0/ 14)			0.120 (14)
	1 MONTH	100 (14/ 14)	100 (14/ 14)	100 (14/ 14)	26.0	4.642 (14)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 7

ANTIBODY RESPONSES

INVESTIGATOR : KIM, KWANG S.
STUDY : 000801
VACCINE : HIB CONJUGATE
ASSAY : RIA
DOSE : 30 MCG
POPULATION : HIB POLYS VACC NON-RESPONDERS

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
19-59 MOS.	PRE INJ	100 (1/ 1)	0 (0/ 1)			0.392 (1)
	1 MONTH	100 (1/ 1)	100 (1/ 1)	100 (1/ 1)	8.3	3.266 (1)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 8

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : KIM, KWANG S.
STUDY : 000801
VACCINE : HIB CONJUGATE
DOSE : 7.5 MCG
POPULATION : HEALTHY CHILDREN
AGE RANGE : 2- 6 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES	7	
VACCINEES WITH NO COMPLAINTS	1	(25.0 %)
VACCINEES WITH COMPLAINTS	3	(75.0 %)
VACCINEES WITH NO DATA	3	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 4 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	0	0.0
SYSTEMIC REACTIONS	3	75.0
FATIGUE	2	50.0
DIARRHEA	1	25.0
INFECTIOUS GASTROENTERITIS	1	25.0
PROLONGED CRYING, >1/2 HR	1	25.0
URTICARIA	1	25.0
WARM TO TOUCH	1	25.0

TABLE 8 (cont.)

C L I N I C A L C O M P L A I N T S B Y F R E Q U E N C Y

INVESTIGATOR : KIM, KWANG S.
STUDY : 000801
VACCINE : HIB CONJUGATE
DOSE : 7.5 MCG
POPULATION : HEALTHY CHILDREN
AGE RANGE : 7-12 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	4	
VACCINEES WITH NO COMPLAINTS :	3	(100.0 %)
VACCINEES WITH COMPLAINTS :	0	(0.0 %)
VACCINEES WITH NO DATA :	1	

CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 3 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	0	0.0

TABLE 8 (cont.)

C L I N I C A L C O M P L A I N T S B Y F R E Q U E N C Y

INVESTIGATOR : KIM, KWANG S.
STUDY : 000801
VACCINE : HIB CONJUGATE
DOSE : 7.5 MCG
POPULATION : HEALTHY CHILDREN
AGE RANGE : 13-18 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	6	
VACCINEES WITH NO COMPLAINTS :	1	(25.0 %)
VACCINEES WITH COMPLAINTS :	3	(75.0 %)
VACCINEES WITH NO DATA :	2	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 4 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	1	25.0
PAIN/SORENESS, INJ. SITE	1	25.0
SYSTEMIC REACTIONS	3	75.0
FATIGUE	2	50.0
DIARRHEA	1	25.0
IRRITABILITY	1	25.0
PROLONGED CRYING, >1/2 HR	1	25.0
UNUSUAL HIGH-PITCHED CRYING	1	25.0
VOMITING	1	25.0
WARM TO TOUCH	1	25.0

TABLE 8 (cont.)

C L I N I C A L C O M P L A I N T S B Y F R E Q U E N C Y

INVESTIGATOR : KIM, KWANG S.
STUDY : 000801
VACCINE : HIB CONJUGATE
DOSE : 7.5 MCG
POPULATION : HEALTHY CHILDREN
AGE RANGE : 13-18 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 2	
TOTAL VACCINEES :	1	
VACCINEES WITH NO COMPLAINTS :	1	(100.0 %)
VACCINEES WITH COMPLAINTS :	0	(0.0 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 1 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	0	0.0

TABLE 8 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : KIM, KWANG S.
STUDY : 000801
VACCINE : HIB CONJUGATE
DOSE : 7.5 MCG
POPULATION : HEALTHY CHILDREN
AGE RANGE : 19-59 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	7	
VACCINEES WITH NO COMPLAINTS :	5	(71.4 %)
VACCINEES WITH COMPLAINTS :	2	(28.6 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 7 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	1	14.3
PAIN/SORENESS, INJ. SITE	1	14.3
SWELLING, INJ. SITE (<=1 IN.)	1	14.3
SYSTEMIC REACTIONS	1	14.3
FATIGUE	1	14.3

TABLE 8 (cont.)

C L I N I C A L C O M P L A I N T S B Y F R E Q U E N C Y

INVESTIGATOR : KIM, KWANG S.
STUDY : 000801
VACCINE : HIB CONJUGATE
DOSE : 7.5 MCG
POPULATION : HIB POLYS VACC NON-RESPONDERS
AGE RANGE : 19-59 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	1	
VACCINEES WITH NO COMPLAINTS :	1	(100.0 %)
VACCINEES WITH COMPLAINTS :	0	(0.0 %)
VACCINEES WITH NO DATA :	0	

CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 1 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	0	0.0

TABLE 8 (cont.)

C L I N I C A L C O M P L A I N T S B Y F R E Q U E N C Y

INVESTIGATOR : KIM, KWANG S.
STUDY : 000801
VACCINE : HIB CONJUGATE
DOSE : 15 MCG
POPULATION : HEALTHY CHILDREN
AGE RANGE : 2- 6 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	8	
VACCINEES WITH NO COMPLAINTS :	2	(40.0 %)
VACCINEES WITH COMPLAINTS :	3	(60.0 %)
VACCINEES WITH NO DATA :	3	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 5 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	2	40.0
ERYTHEMA, INJ. SITE (<=1 IN.)	2	40.0
PAIN/SORENESS, INJ. SITE	1	20.0
SWELLING, INJ. SITE (<=1 IN.)	1	20.0
SWELLING, INJ. SITE (>1 INCH)	1	20.0
SYSTEMIC REACTIONS	2	40.0
IRRITABILITY	2	40.0
PROLONGED CRYING, >1/2 HR	2	40.0
DIARRHEA	1	20.0
INFECTIOUS GASTROENTERITIS	1	20.0
VOMITING	1	20.0
WARM TO TOUCH	1	20.0

TABLE 8 (cont.)

C L I N I C A L C O M P L A I N T S B Y F R E Q U E N C Y

INVESTIGATOR : KIM, KWANG S.
STUDY : 000801
VACCINE : HIB CONJUGATE
DOSE : 15 MCG
POPULATION : HEALTHY CHILDREN
AGE RANGE : 2- 6 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 2	
TOTAL VACCINEES :	3	
VACCINEES WITH NO COMPLAINTS :	0	(0.0 %)
VACCINEES WITH COMPLAINTS :	1	(100.0 %)
VACCINEES WITH NO DATA :	2	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 1 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	0	0.0
SYSTEMIC REACTIONS	1	100.0
IRRITABILITY	1	100.0
WARM TO TOUCH	1	100.0

TABLE 8 (cont.)

C L I N I C A L C O M P L A I N T S B Y F R E Q U E N C Y

INVESTIGATOR : KIM, KWANG S.
STUDY : 000801
VACCINE : HIB CONJUGATE
DOSE : 15 MCG
POPULATION : HEALTHY CHILDREN
AGE RANGE : 7-12 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	5	
VACCINEES WITH NO COMPLAINTS :	2	(66.7 %)
VACCINEES WITH COMPLAINTS :	1	(33.3 %)
VACCINEES WITH NO DATA :	2	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 3 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	1	33.3
SWELLING, INJ. SITE (<=1 IN.)	1	33.3

TABLE 8 (cont.)

C L I N I C A L C O M P L A I N T S B Y F R E Q U E N C Y

INVESTIGATOR : KIM, KWANG S.
STUDY : 000801
VACCINE : HIB CONJUGATE
DOSE : 15 MCG
POPULATION : HEALTHY CHILDREN
AGE RANGE : 19-59 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	1	
VACCINEES WITH NO COMPLAINTS :	1	(100.0 %)
VACCINEES WITH COMPLAINTS :	0	(0.0 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 1 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	0	0.0

TABLE 8 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : KIM, KWANG S.
STUDY : 000801
VACCINE : HIB CONJUGATE
DOSE : 15 MCG
POPULATION : HIB POLYS VACC NON-RESPONDERS
AGE RANGE : 19-59 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES	19	
VACCINEES WITH NO COMPLAINTS	8	(50.0 %)
VACCINEES WITH COMPLAINTS	8	(50.0 %)
VACCINEES WITH NO DATA	3	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 16 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	6	37.5
PAIN/SORENESS, INJ. SITE	6	37.5
SWELLING, INJ. SITE (<=1 IN.)	3	18.8
ERYTHEMA, INJ. SITE (<=1 IN.)	2	12.5
SYSTEMIC REACTIONS	7	43.8
FATIGUE	4	25.0
WARM TO TOUCH	4	25.0
IRRITABILITY	3	18.8
PROLONGED CRYING, >1/2 HR	2	12.5
VIRUS INFECTION	1	6.3

TABLE 8 (cont.)

C L I N I C A L C O M P L A I N T S B Y F R E Q U E N C Y

INVESTIGATOR : KIM, KWANG S.
STUDY : 000801
VACCINE : HIB CONJUGATE
DOSE : 30 MCG
POPULATION : HEALTHY CHILDREN
AGE RANGE : 2- 6 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	7	
VACCINEES WITH NO COMPLAINTS :	4	(80.0 %)
VACCINEES WITH COMPLAINTS :	1	(20.0 %)
VACCINEES WITH NO DATA :	2	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 5 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	0	0.0
SYSTEMIC REACTIONS	1	20.0
CRYING	1	20.0
FATIGUE	1	20.0
IRRITABILITY	1	20.0
NASAL DISCHARGE	1	20.0
PROLONGED CRYING, >1/2 HR	1	20.0
VIRUS INFECTION	1	20.0
VOMITING	1	20.0
WARM TO TOUCH	1	20.0

TABLE 8 (cont.)

C L I N I C A L C O M P L A I N T S B Y F R E Q U E N C Y

INVESTIGATOR : KIM, KWANG S.
STUDY : 000801
VACCINE : HIB CONJUGATE
DOSE : 30 MCG
POPULATION : HEALTHY CHILDREN
AGE RANGE : 7-12 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	5	
VACCINEES WITH NO COMPLAINTS :	2	(66.7 %)
VACCINEES WITH COMPLAINTS :	1	(33.3 %)
VACCINEES WITH NO DATA :	2	

CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 3 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	0	0.0
SYSTEMIC REACTIONS	1	33.3
DIARRHEA	1	33.3
IRRITABILITY	1	33.3
WARM TO TOUCH	1	33.3

TABLE 8 (cont.)

C L I N I C A L C O M P L A I N T S B Y F R E Q U E N C Y

INVESTIGATOR : KIM, KWANG S.
STUDY : 000801
VACCINE : HIB CONJUGATE
DOSE : 30 MCG
POPULATION : HEALTHY CHILDREN
AGE RANGE : 13-18 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	3	
VACCINEES WITH NO COMPLAINTS :	2	(100.0 %)
VACCINEES WITH COMPLAINTS :	0	(0.0 %)
VACCINEES WITH NO DATA :	1	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 2 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	0	0.0

TABLE 8 (cont.)

C L I N I C A L C O M P L A I N T S B Y F R E Q U E N C Y

INVESTIGATOR : KIM, KWANG S.
STUDY : 000801
VACCINE : HIB CONJUGATE
DOSE : 30 MCG
POPULATION : HEALTHY CHILDREN
AGE RANGE : 19-59 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	7	
VACCINEES WITH NO COMPLAINTS :	2	(33.3 %)
VACCINEES WITH COMPLAINTS :	4	(66.7 %)
VACCINEES WITH NO DATA :	1	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 6 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	4	66.7
PAIN/SORENESS, INJ. SITE	4	66.7
SWELLING, INJ. SITE (<=1 IN.)	2	33.3
SYSTEMIC REACTIONS	3	50.0
FATIGUE	1	16.7
GAIT ABNORMALITIES	1	16.7
WARM TO TOUCH	1	16.7

TABLE 8 (cont.)

C L I N I C A L C O M P L A I N T S B Y F R E Q U E N C Y

INVESTIGATOR : KIM, KWANG S.
STUDY : 000801
VACCINE : HIB CONJUGATE
DOSE : 30 MCG
POPULATION : HIB POLYS VACC NON-RESPONDERS
AGE RANGE : 19-59 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	1	
VACCINEES WITH NO COMPLAINTS :	0	(0.0 %)
VACCINEES WITH COMPLAINTS :	1	(100.0 %)
VACCINEES WITH NO DATA :	0	

CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 1 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	0	0.0
SYSTEMIC REACTIONS	1	100.0
IRRITABILITY	1	100.0
WARM TO TOUCH.	1	100.0

TABLE 9

CLINICAL COMPLAINTS

INVESTIGATOR : KIM, KWANG S.
STUDY : 000801
VACCINE : HIB CONJUGATE
DOSE : 7.5 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2- 6 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (7 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH COMPLAINTS **********
CLINICAL COMPLAINTS	0	1	2	3	4	5	
SYSTEMIC	3 (75.0%)	3 (75.0%)	1 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (75.0%)
BODY AS A WHOLE/SITE UNSPEC.	2 (50.0%)	1 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (50.0%)
FATIGUE	1 (25.0%)	1 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (50.0%)
WARM TO TOUCH	1 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (25.0%)
DIGESTIVE SYSTEM	1 (25.0%)	1 (25.0%)	1 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (25.0%)
DIARRHEA	1 (25.0%)	1 (25.0%)	1 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (25.0%)
INFECTIOUS GASTROENTERITIS	1 (25.0%)	1 (25.0%)	1 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (25.0%)
NERVOUS SYSTEM & PSYCHIATRIC	0 (0.0%)	1 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (25.0%)
PROLONGED CRYING, >1/2 HR	0 (0.0%)	1 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (25.0%)
SKIN & SKIN APPENDAGE	0 (0.0%)	1 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (25.0%)
URTICARIA	0 (0.0%)	1 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (25.0%)

TABLE 9 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : KIM, KWANG S.
STUDY : 000801
VACCINE : HIB CONJUGATE
DOSE : 7.5 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2- 6 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (7 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS **********
VACCINEES WITH COMPLAINTS	3 (75.0%)	3 (75.0%)	1 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		3 (75.0%)
VACCINEES WITH NO COMPLAINTS	1 (25.0%)	1 (25.0%)	3 (75.0%)	4 (100.0%)	4 (100.0%)	4 (100.0%)		1 (25.0%)
TOTAL VACCINEES REPORTING	4	4	4	4	4	4		4
VACCINEES WITH NO DATA	3	3	3	3	3	3		3

TABLE 9 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : KIM, KWANG S.
STUDY : 000801
VACCINE : HIB CONJUGATE
DOSE : 7.5 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 7-12 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (4 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		**********
VACCINEES WITH COMPLAINTS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)
VACCINEES WITH NO COMPLAINTS	3 (100.0%)	3 (100.0%)	3 (100.0%)	3 (100.0%)	3 (100.0%)	3 (100.0%)		3 (100.0%)
TOTAL VACCINEES REPORTING	3	3	3	3	3	3		3
VACCINEES WITH NO DATA	1	1	1	1	1	1		1

01092

TABLE 9 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : KIM, KWANG S.
STUDY : 000801
VACCINE : HIB CONJUGATE
DOSE : 7.5 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 13-18 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (6 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
LOCAL REACTIONS	0 (0.0%)	1 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (25.0%)
PAIN/SORENESS, INJ. SITE	0 (0.0%)	1 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (25.0%)
SYSTEMIC	2 (50.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)		3 (75.0%)
BODY AS A WHOLE/SITE UNSPEC.	1 (25.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)		2 (50.0%)
FATIGUE	1 (25.0%)	1 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (50.0%)
WARM TO TOUCH	0 (0.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)		1 (25.0%)
DIGESTIVE SYSTEM	0 (0.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)	0 (0.0%)	0 (0.0%)		1 (25.0%)
DIARRHEA	0 (0.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)	0 (0.0%)	0 (0.0%)		1 (25.0%)
VOMITING	0 (0.0%)	1 (25.0%)	1 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (25.0%)
NERVOUS SYSTEM & PSYCHIATRIC	1 (25.0%)	1 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (50.0%)
IRRITABILITY	1 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (25.0%)

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TABLE 9 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : KIM, KWANG S.
STUDY : 000801
VACCINE : HIB CONJUGATE
DOSE : 7.5 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 13-18 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (6 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		
PROLONGED CRYING, >1/2 HR	1 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (25.0%)
UNUSUAL HIGH-PITCHED CRYING	0 (0.0%)	1 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (25.0%)
VACCINEES WITH COMPLAINTS	2 (50.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)		3 (75.0%)
VACCINEES WITH NO COMPLAINTS	2 (50.0%)	3 (75.0%)	3 (75.0%)	3 (75.0%)	3 (75.0%)	3 (75.0%)		1 (25.0%)
TOTAL VACCINEES REPORTING	4	4	4	4	4	4		4
VACCINEES WITH NO DATA	2	2	2	2	2	2		2

TABLE 9 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : KIM, KWANG S.
STUDY : 000801
VACCINE : HIB CONJUGATE
DOSE : 7.5 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 13-18 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (1 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		**********
VACCINEES WITH COMPLAINTS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)
VACCINEES WITH NO COMPLAINTS	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)		1 (100.0%)
TOTAL VACCINEES REPORTING	1	1	1	1	1	1		1
VACCINEES WITH NO DATA	0	0	0	0	0	0		0

TABLE 9 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : KIM, KWANG S.
STUDY : 000801
VACCINE : HIB CONJUGATE
DOSE : 7.5 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE 19-59 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (7 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		
LOCAL REACTIONS	1 (14.3%)	1 (14.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (14.3%)
PAIN/SORENESS, INJ. SITE	1 (14.3%)	1 (14.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (14.3%)
SWELLING, INJ. SITE (<=1 IN.)	1 (14.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (14.3%)
SYSTEMIC	1 (14.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (14.3%)
BODY AS A WHOLE/SITE UNSPEC.	1 (14.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (14.3%)
FATIGUE	1 (14.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (14.3%)
VACCINEES WITH COMPLAINTS	2 (28.6%)	1 (14.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (28.6%)
VACCINEES WITH NO COMPLAINTS	5 (71.4%)	6 (85.7%)	7 (100.0%)	7 (100.0%)	7 (100.0%)	7 (100.0%)		5 (71.4%)
TOTAL VACCINEES REPORTING	7	7	7	7	7	7		7
VACCINEES WITH NO DATA	0	0	0	0	0	0		0

TABLE 9 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : KIM, KWANG S.
STUDY : 000801
VACCINE : HIB CONJUGATE
DOSE : 15 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2- 6 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (8 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		
LOCAL REACTIONS	2 (40.0%)	0 (0.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	0 (0.0%)		2 (40.0%)
ERYTHEMA, INJ. SITE (<=1 IN.)	1 (20.0%)	0 (0.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	0 (0.0%)		2 (40.0%)
PAIN/SORENESS, INJ. SITE	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)		1 (20.0%)
SWELLING, INJ. SITE (>1 INCH)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)		1 (20.0%)
SWELLING, INJ. SITE (<=1 IN.)	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (20.0%)
SYSTEMIC	2 (40.0%)	2 (40.0%)	2 (40.0%)	2 (40.0%)	1 (20.0%)	1 (20.0%)		2 (40.0%)
BODY AS A WHOLE/SITE UNSPEC.	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (20.0%)
WARM TO TOUCH	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (20.0%)
DIGESTIVE SYSTEM	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)		1 (20.0%)
DIARRHEA	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)		1 (20.0%)
INFECTIOUS GASTROENTERITIS	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)		1 (20.0%)

TABLE 9 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : KIM, KWANG S.
STUDY : 000801
VACCINE : HIB CONJUGATE
DOSE : 15 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2- 6 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (8 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
VOMITING	0 (0.0%)	0 (0.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)		1 (20.0%)
NERVOUS SYSTEM & PSYCHIATRIC	2 (40.0%)	1 (20.0%)	2 (40.0%)	2 (40.0%)	1 (20.0%)	1 (20.0%)		2 (40.0%)
IRRITABILITY	2 (40.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)		2 (40.0%)
PROLONGED CRYING, >1/2 HR	1 (20.0%)	1 (20.0%)	2 (40.0%)	2 (40.0%)	1 (20.0%)	1 (20.0%)		2 (40.0%)
VACCINEES WITH COMPLAINTS	3 (60.0%)	2 (40.0%)	2 (40.0%)	2 (40.0%)	1 (20.0%)	1 (20.0%)		3 (60.0%)
VACCINEES WITH NO COMPLAINTS	2 (40.0%)	3 (60.0%)	3 (60.0%)	3 (60.0%)	4 (80.0%)	4 (80.0%)		2 (40.0%)
TOTAL VACCINEES REPORTING	5	5	5	5	5	5		5
VACCINEES WITH NO DATA	3	3	3	3	3	3		3

TABLE 9 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : KIM, KWANG S.
STUDY : 000801
VACCINE : HIB CONJUGATE
DOSE : 15 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2- 6 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (3 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		**********
SYSTEMIC	1 (100.0%)	1 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (100.0%)		1 (100.0%)
BODY AS A WHOLE/SITE UNSPEC.	1 (100.0%)	1 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (100.0%)		1 (100.0%)
WARM TO TOUCH	1 (100.0%)	1 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (100.0%)		1 (100.0%)
NERVOUS SYSTEM & PSYCHIATRIC	1 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (100.0%)
IRRITABILITY	1 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (100.0%)
VACCINEES WITH COMPLAINTS	1 (100.0%)	1 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (100.0%)		1 (100.0%)
VACCINEES WITH NO COMPLAINTS	0 (0.0%)	0 (0.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	0 (0.0%)		0 (0.0%)
TOTAL VACCINEES REPORTING	1	1	1	1	1	1		1
VACCINEES WITH NO DATA	2	2	2	2	2	2		2

TABLE 9 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : KIM, KWANG S.
STUDY : 000801
VACCINE : HIB CONJUGATE
DOSE : 15 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 7-12 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (5 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
LOCAL REACTIONS	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (33.3%)
SWELLING, INJ. SITE (<=1 IN.)	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (33.3%)
VACCINEES WITH COMPLAINTS	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (33.3%)
VACCINEES WITH NO COMPLAINTS	3 (100.0%)	2 (66.7%)	3 (100.0%)	3 (100.0%)	3 (100.0%)	3 (100.0%)		2 (66.7%)
TOTAL VACCINEES REPORTING	3	3	3	3	3	3		3
VACCINEES WITH NO DATA	2	2	2	2	2	2		2

TABLE 9 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : KIM, KWANG S.
STUDY : 000801
VACCINE : HIB CONJUGATE
DOSE : 15 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE 19-59 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (1 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		**********
VACCINEES WITH COMPLAINTS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)
VACCINEES WITH NO COMPLAINTS	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)		1 (100.0%)
TOTAL VACCINEES REPORTING	1	1	1	1	1	1		1
VACCINEES WITH NO DATA	0	0	0	0	0	0		0

TABLE 9 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : KIM, KWANG S.
STUDY : 000801
VACCINE : HIB CONJUGATE
DOSE : 30 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2- 6 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (7 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5	**********
SYSTEMIC	0 (0.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)
BODY AS A WHOLE/SITE UNSPEC.	0 (0.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)
FATIGUE	0 (0.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)
VIRUS INFECTION	0 (0.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)
WARM TO TOUCH	0 (0.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)	1 (20.0%)
DIGESTIVE SYSTEM	0 (0.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)
VOMITING	0 (0.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)
NERVOUS SYSTEM & PSYCHIATRIC	0 (0.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)
CRYING	0 (0.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)
IRRITABILITY	0 (0.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)
PROLONGED CRYING, >1/2 HR	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)

TABLE 9 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : KIM, KWANG S.
STUDY : 000801
VACCINE : HIB CONJUGATE
DOSE : 30 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2- 6 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (7 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		
RESPIRATORY SYSTEM	0 (0.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)		1 (20.0%)
NASAL DISCHARGE	0 (0.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)		1 (20.0%)
VACCINEES WITH COMPLAINTS	0 (0.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)		1 (20.0%)
VACCINEES WITH NO COMPLAINTS	5 (100.0%)	4 (80.0%)	4 (80.0%)	4 (80.0%)	4 (80.0%)	4 (80.0%)		4 (80.0%)
TOTAL VACCINEES REPORTING	5	5	5	5	5	5		5
VACCINEES WITH NO DATA	2	2	2	2	2	2		2

01094

TABLE 9 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : KIM, KWANG S.
STUDY : 000801
VACCINE : HIB CONJUGATE
DOSE : 30 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 7-12 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (5 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		**********
SYSTEMIC	1 (33.3%)	1 (33.3%)	1 (33.3%)	1 (33.3%)	0 (0.0%)	0 (0.0%)		1 (33.3%)
BODY AS A WHOLE/SITE UNSPEC.	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (33.3%)
WARM TO TOUCH	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (33.3%)
DIGESTIVE SYSTEM	1 (33.3%)	1 (33.3%)	1 (33.3%)	1 (33.3%)	0 (0.0%)	0 (0.0%)		1 (33.3%)
DIARRHEA	1 (33.3%)	1 (33.3%)	1 (33.3%)	1 (33.3%)	0 (0.0%)	0 (0.0%)		1 (33.3%)
NERVOUS SYSTEM & PSYCHIATRIC	1 (33.3%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (33.3%)
IRRITABILITY	1 (33.3%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (33.3%)
VACCINEES WITH COMPLAINTS	1 (33.3%)	1 (33.3%)	1 (33.3%)	1 (33.3%)	0 (0.0%)	0 (0.0%)		1 (33.3%)
VACCINEES WITH NO COMPLAINTS	2 (66.7%)	2 (66.7%)	2 (66.7%)	2 (66.7%)	3 (100.0%)	3 (100.0%)		2 (66.7%)
TOTAL VACCINEES REPORTING	3	3	3	3	3	3		3

TABLE 9 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : KIM, KWANG S.
STUDY : 000801
VACCINE : HIB CONJUGATE
DOSE : 30 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 7-12 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (5 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
VACCINEES WITH NO DATA	2	2	2	2	2	2		2

TABLE 9 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : KIM, KWANG S.
STUDY : 000801
VACCINE : HIB CONJUGATE
DOSE : 30 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 13-18 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (3 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		**********
VACCINEES WITH COMPLAINTS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)
VACCINEES WITH NO COMPLAINTS	2 (100.0%)	2 (100.0%)	2 (100.0%)	2 (100.0%)	2 (100.0%)	2 (100.0%)		2 (100.0%)
TOTAL VACCINEES REPORTING	2	2	2	2	2	2		2
VACCINEES WITH NO DATA	1	1	1	1	1	1		1

TABLE 9 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : KIM, KWANG S.
STUDY : 000801
VACCINE : HIB CONJUGATE
DOSE : 30 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE 19-59 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (7 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		
LOCAL REACTIONS	3 (50.0%)	3 (50.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		4 (66.7%)
PAIN/SORENESS, INJ. SITE	3 (50.0%)	3 (50.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		4 (66.7%)
SWELLING, INJ. SITE (<=1 IN.)	2 (33.3%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (33.3%)
SYSTEMIC	2 (33.3%)	2 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		3 (50.0%)
BODY AS A WHOLE/SITE UNSPEC.	1 (16.7%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (33.3%)
FATIGUE	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (16.7%)
WARM TO TOUCH	0 (0.0%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (16.7%)
NERVOUS SYSTEM & PSYCHIATRIC	1 (16.7%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (16.7%)
GAIT ABNORMALITIES	1 (16.7%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (16.7%)
VACCINEES WITH COMPLAINTS	4 (66.7%)	3 (50.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		4 (66.7%)
VACCINEES WITH NO COMPLAINTS	2 (33.3%)	3 (50.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)		2 (33.3%)

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TABLE 9 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : KIM, KWANG S.
STUDY : 000801
VACCINE : HIB CONJUGATE
DOSE : 30 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE 19-59 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (7 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS **********
TOTAL VACCINEES REPORTING	6	6	6	6	6	6		6
VACCINEES WITH NO DATA	1	1	1	1	1	1		1

TABLE 9 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : KIM, KWANG S.
STUDY : 000801
VACCINE : HIB CONJUGATE
DOSE : 7.5 MCG
PATIENT CLASS: HIB POLYS VACC NON-RESPONDERS
AGE RANGE 19-59 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (1 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5	COMPLAINTS **********
VACCINEES WITH COMPLAINTS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
VACCINEES WITH NO COMPLAINTS	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)
TOTAL VACCINEES REPORTING	1	1	1	1	1	1	1
VACCINEES WITH NO DATA	0	0	0	0	0	0	0

TABLE 9 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : KIM, KWANG S.
STUDY : 000801
VACCINE : HIB CONJUGATE
DOSE : 15 MCG
PATIENT CLASS: HIB POLYS VACC NON-RESPONDERS
AGE RANGE 19-59 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (19 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5	**********	**********
LOCAL REACTIONS	6 (37.5%)	1 (6.3%)	1 (6.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		6 (37.5%)
ERYTHEMA, INJ. SITE (<=1 IN.)	2 (12.5%)	1 (6.3%)	1 (6.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (12.5%)
PAIN/SORENESS, INJ. SITE	6 (37.5%)	1 (6.3%)	1 (6.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		6 (37.5%)
SWELLING, INJ. SITE (<=1 IN.)	3 (18.8%)	1 (6.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		3 (18.8%)
SYSTEMIC	7 (43.8%)	2 (12.5%)	2 (12.5%)	2 (12.5%)	2 (12.5%)	2 (12.5%)		7 (43.8%)
BODY AS A WHOLE/SITE UNSPEC.	6 (37.5%)	2 (12.5%)	2 (12.5%)	2 (12.5%)	2 (12.5%)	2 (12.5%)		6 (37.5%)
FATIGUE	4 (25.0%)	0 (0.0%)	0 (0.0%)	1 (6.3%)	0 (0.0%)	1 (6.3%)		4 (25.0%)
VIRUS INFECTION	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (6.3%)	1 (6.3%)		1 (6.3%)
WARM TO TOUCH	3 (18.8%)	2 (12.5%)	2 (12.5%)	2 (12.5%)	2 (12.5%)	2 (12.5%)		4 (25.0%)
NERVOUS SYSTEM & PSYCHIATRIC	4 (25.0%)	1 (6.3%)	0 (0.0%)	1 (6.3%)	1 (6.3%)	1 (6.3%)		5 (31.3%)
IRRITABILITY	2 (12.5%)	1 (6.3%)	0 (0.0%)	1 (6.3%)	1 (6.3%)	1 (6.3%)		3 (18.8%)

TABLE 9 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : KIM, KWANG S.
STUDY : 000801
VACCINE : HIB CONJUGATE
DOSE : 15 MCG
PATIENT CLASS: HIB POLYS VACC NON-RESPONDERS
AGE RANGE 19-59 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (19 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
PROLONGED CRYING, >1/2 HR	2 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (12.5%)
VACCINEES WITH COMPLAINTS	8 (50.0%)	2 (12.5%)	2 (12.5%)	2 (12.5%)	2 (12.5%)	2 (12.5%)		8 (50.0%)
VACCINEES WITH NO COMPLAINTS	8 (50.0%)	14 (87.5%)	14 (87.5%)	14 (87.5%)	14 (87.5%)	14 (87.5%)		8 (50.0%)
TOTAL VACCINEES REPORTING	16	16	16	16	16	16		16
VACCINEES WITH NO DATA	3	3	3	3	3	3		3

TABLE 9 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : KIM, KWANG S.
STUDY : 000801
VACCINE : HIB CONJUGATE
DOSE : 30 MCG
PATIENT CLASS: HIB POLYS VACC NON-RESPONDERS
AGE RANGE 19-59 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (1 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		**********
SYSTEMIC	1 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (100.0%)
BODY AS A WHOLE/SITE UNSPEC.	1 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (100.0%)
WARM TO TOUCH	1 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (100.0%)
NERVOUS SYSTEM & PSYCHIATRIC	1 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (100.0%)
IRRITABILITY	1 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (100.0%)
VACCINEES WITH COMPLAINTS	1 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (100.0%)
VACCINEES WITH NO COMPLAINTS	0 (0.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)		0 (0.0%)
TOTAL VACCINEES REPORTING	1	1	1	1	1	1		1
VACCINEES WITH NO DATA	0	0	0	0	0	0		0

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TABLE 10

MAXIMUM TEMPERATURES

INVESTIGATOR : KIM, KWANG S.
STUDY : 000801
VACCINE : HIB CONJUGATE
DOSE : 7.5 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2- 6 MOS.

MAX TEMPERATURE (DEG F, ORAL)	NUMBER OF VACCINEES (7 VACCINEES) - INJECTION 1							NUMBER WITH MAX TEMP
	DAYS POST VACCINATION							
	0	1	2	3	4	5		
< 99	3 (75.0%)	3 (75.0%)	3 (75.0%)	3 (75.0%)	3 (75.0%)	3 (75.0%)		3 (75.0%)
99 - 99.9	1 (25.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)		1 (25.0%)
TEMPERATURE TAKEN	4 (57.1%)	4 (57.1%)	4 (57.1%)	4 (57.1%)	4 (57.1%)	4 (57.1%)		4 (57.1%)
TEMPERATURE NOT TAKEN	3 (42.9%)	3 (42.9%)	3 (42.9%)	3 (42.9%)	3 (42.9%)	3 (42.9%)		3 (42.9%)

TABLE 10 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : KIM, KWANG S.
STUDY : 000801
VACCINE : HIB CONJUGATE
DOSE : 7.5 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 7-12 MOS.

MAX TEMPERATURE (DEG F, ORAL)	NUMBER OF VACCINEES (4 VACCINEES) - INJECTION 1							NUMBER WITH MAX TEMP
	DAYS POST VACCINATION							
	0	1	2	3	4	5		
NORMAL	2 (66.7%)	2 (66.7%)	2 (66.7%)	2 (66.7%)	2 (66.7%)	2 (66.7%)		2 (66.7%)
< 99	1 (33.3%)	1 (33.3%)	1 (33.3%)	1 (33.3%)	1 (33.3%)	1 (33.3%)		1 (33.3%)
TEMPERATURE TAKEN	3 (75.0%)	3 (75.0%)	3 (75.0%)	3 (75.0%)	3 (75.0%)	3 (75.0%)		3 (75.0%)
TEMPERATURE NOT TAKEN	1 (25.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)		1 (25.0%)

TABLE 10 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : KIM, KWANG S.
STUDY : 000801
VACCINE : HIB CONJUGATE
DOSE : 7.5 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 13-18 MOS.

MAX TEMPERATURE (DEG F, ORAL)	NUMBER OF VACCINEES (6 VACCINEES) - INJECTION 1							NUMBER WITH MAX TEMP
	DAYS POST VACCINATION							
	0	1	2	3	4	5		
NORMAL	1 (50.0%)	1 (33.3%)	1 (33.3%)	1 (33.3%)	1 (33.3%)	1 (33.3%)		1 (33.3%)
< 99	1 (50.0%)	1 (33.3%)	2 (66.7%)	1 (33.3%)	2 (66.7%)	2 (66.7%)		0 (0.0%)
99 - 99.9	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)		1 (33.3%)
100 - 100.9	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (33.3%)
TEMPERATURE TAKEN	2 (33.3%)	3 (50.0%)	3 (50.0%)	3 (50.0%)	3 (50.0%)	3 (50.0%)		3 (50.0%)
TEMPERATURE NOT TAKEN	4 (66.7%)	3 (50.0%)	3 (50.0%)	3 (50.0%)	3 (50.0%)	3 (50.0%)		3 (50.0%)

TABLE 10 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : KIM, KWANG S.
STUDY : 000801
VACCINE : HIB CONJUGATE
DOSE : 7.5 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 13-18 MOS.

MAX TEMPERATURE (DEG F, ORAL)	NUMBER OF VACCINEES (1 VACCINEES) - INJECTION 2							NUMBER WITH MAX TEMP
	DAYS POST VACCINATION							
	0	1	2	3	4	5		
NORMAL	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)		1 (100.0%)
TEMPERATURE TAKEN	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)		1 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)

TABLE 10 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : KIM, KWANG S.
STUDY : 000801
VACCINE : HIB CONJUGATE
DOSE : 7.5 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE 19-59 MOS.

MAX TEMPERATURE (DEG F, ORAL)	NUMBER OF VACCINEES (7 VACCINEES) - INJECTION 1							NUMBER WITH MAX TEMP
	DAYS POST VACCINATION							
	0	1	2	3	4	5		
NORMAL	5 (71.4%)	5 (71.4%)	5 (71.4%)	5 (71.4%)	5 (71.4%)	5 (71.4%)		5 (71.4%)
< 99	2 (28.6%)	1 (14.3%)	2 (28.6%)	2 (28.6%)	2 (28.6%)	2 (28.6%)		1 (14.3%)
99 - 99.9	0 (0.0%)	1 (14.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (14.3%)
TEMPERATURE TAKEN	7 (100.0%)	7 (100.0%)	7 (100.0%)	7 (100.0%)	7 (100.0%)	7 (100.0%)		7 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)

TABLE 10 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : KIM, KWANG S.
STUDY : 000801
VACCINE : HIB CONJUGATE
DOSE : 15 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2- 6 MOS.

MAX TEMPERATURE (DEG F, ORAL)	NUMBER OF VACCINEES (8 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
	0	1	2	3	4	5		
NORMAL	2 (40.0%)	2 (40.0%)	2 (40.0%)	2 (40.0%)	2 (40.0%)	2 (40.0%)		2 (40.0%)
< 99	1 (20.0%)	2 (40.0%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	3 (60.0%)		1 (20.0%)
99 - 99.9	1 (20.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)	0 (0.0%)		0 (0.0%)
100 - 100.9	1 (20.0%)	0 (0.0%)	2 (40.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)		1 (20.0%)
101 - 101.9	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (20.0%)	1 (20.0%)	0 (0.0%)		1 (20.0%)
TEMPERATURE TAKEN	5 (62.5%)	5 (62.5%)	5 (62.5%)	5 (62.5%)	5 (62.5%)	5 (62.5%)		5 (62.5%)
TEMPERATURE NOT TAKEN	3 (37.5%)	3 (37.5%)	3 (37.5%)	3 (37.5%)	3 (37.5%)	3 (37.5%)		3 (37.5%)

TABLE 10 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : KIM, KWANG S.
STUDY : 000801
VACCINE : HIB CONJUGATE
DOSE : 15 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2- 6 MOS.

MAX TEMPERATURE (DEG F, ORAL)	NUMBER OF VACCINEES (3 VACCINEES) - INJECTION 2							NUMBER WITH MAX TEMP
	DAYS POST VACCINATION							
	0	1	2	3	4	5		
< 99	0 (0.0%)	0 (0.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	0 (0.0%)		0 (0.0%)
100 - 100.9	1 (100.0%)	1 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (100.0%)		1 (100.0%)
TEMPERATURE TAKEN	1 (33.3%)	1 (33.3%)	1 (33.3%)	1 (33.3%)	1 (33.3%)	1 (33.3%)		1 (33.3%)
TEMPERATURE NOT TAKEN	2 (66.7%)	2 (66.7%)	2 (66.7%)	2 (66.7%)	2 (66.7%)	2 (66.7%)		2 (66.7%)

TABLE 10 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : KIM, KWANG S.
STUDY : 000801
VACCINE : HIB CONJUGATE
DOSE : 15 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 7-12 MOS.

MAX TEMPERATURE (DEG F, ORAL)	NUMBER OF VACCINEES (5 VACCINEES) - INJECTION 1							NUMBER WITH MAX TEMP
	DAYS POST VACCINATION							
	D	1	2	3	4	5		
< 99	3 (100.0%)	1 (33.3%)	2 (66.7%)	2 (66.7%)	3 (100.0%)	2 (66.7%)		1 (33.3%)
99 - 99.9	0 (0.0%)	0 (0.0%)	1 (33.3%)	1 (33.3%)	0 (0.0%)	1 (33.3%)		0 (0.0%)
100 - 100.9	0 (0.0%)	2 (66.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (66.7%)
TEMPERATURE TAKEN	3 (60.0%)	3 (60.0%)	3 (60.0%)	3 (60.0%)	3 (60.0%)	3 (60.0%)		3 (60.0%)
TEMPERATURE NOT TAKEN	2 (40.0%)	2 (40.0%)	2 (40.0%)	2 (40.0%)	2 (40.0%)	2 (40.0%)		2 (40.0%)

TABLE 10 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : KIM, KWANG S.
STUDY : 000801
VACCINE : HIB CONJUGATE
DOSE : 15 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE 19-59 MOS.

MAX TEMPERATURE (DEG F, ORAL)	NUMBER OF VACCINEES (1 VACCINEES) - INJECTION 1							NUMBER WITH MAX TEMP
	DAYS POST VACCINATION							
	0	1	2	3	4	5		
NORMAL	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)		1 (100.0%)
TEMPERATURE TAKEN	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)		1 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)

TABLE 10 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : KIM, KWANG S.
STUDY : 000801
VACCINE : HIB CONJUGATE
DOSE : 30 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2- 6 MOS.

MAX TEMPERATURE (DEG F, ORAL)	NUMBER OF VACCINEES (7 VACCINEES) - INJECTION 1							NUMBER WITH MAX TEMP
	DAYS POST VACCINATION							
	0	1	2	3	4	5		
NORMAL	1 (25.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)		1 (25.0%)
< 99	3 (75.0%)	3 (75.0%)	1 (25.0%)	3 (75.0%)	2 (50.0%)	3 (75.0%)		1 (25.0%)
99 - 99.9	0 (0.0%)	0 (0.0%)	2 (50.0%)	0 (0.0%)	1 (25.0%)	0 (0.0%)		2 (50.0%)
TEMPERATURE TAKEN	4 (57.1%)	4 (57.1%)	4 (57.1%)	4 (57.1%)	4 (57.1%)	4 (57.1%)		4 (57.1%)
TEMPERATURE NOT TAKEN	3 (42.9%)	3 (42.9%)	3 (42.9%)	3 (42.9%)	3 (42.9%)	3 (42.9%)		3 (42.9%)

TABLE 10 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : KIM, KWANG S.
STUDY : 000801
VACCINE : HIB CONJUGATE
DOSE : 30 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 7-12 MOS.

MAX TEMPERATURE (DEG F, ORAL)	NUMBER OF VACCINEES (5 VACCINEES) - INJECTION 1							NUMBER WITH MAX TEMP
	DAYS POST VACCINATION							
	0	1	2	3	4	5		
NORMAL	2 (66.7%)	2 (66.7%)	2 (66.7%)	2 (66.7%)	2 (66.7%)	2 (66.7%)		2 (66.7%)
< 99	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)
99 - 99.9	0 (0.0%)	0 (0.0%)	1 (33.3%)	1 (33.3%)	1 (33.3%)	1 (33.3%)		0 (0.0%)
100 - 100.9	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (33.3%)
TEMPERATURE TAKEN	3 (60.0%)	3 (60.0%)	3 (60.0%)	3 (60.0%)	3 (60.0%)	3 (60.0%)		3 (60.0%)
TEMPERATURE NOT TAKEN	2 (40.0%)	2 (40.0%)	2 (40.0%)	2 (40.0%)	2 (40.0%)	2 (40.0%)		2 (40.0%)

TABLE 10 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : KIM, KHANG S.
STUDY : 000801
VACCINE : HIB CONJUGATE
DOSE : 30 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 13-18 MOS.

MAX TEMPERATURE (DEG F, ORAL)	NUMBER OF VACCINEES (3 VACCINEES) - INJECTION 1							NUMBER WITH MAX TEMP
	DAYS POST VACCINATION							
	0	1	2	3	4	5		
NORMAL	1 (50.0%)	1 (50.0%)	1 (50.0%)	1 (50.0%)	1 (50.0%)	1 (50.0%)		1 (50.0%)
< 99	0 (0.0%)	0 (0.0%)	1 (50.0%)	1 (50.0%)	0 (0.0%)	1 (50.0%)		0 (0.0%)
99 - 99.9	1 (50.0%)	1 (50.0%)	0 (0.0%)	0 (0.0%)	1 (50.0%)	0 (0.0%)		1 (50.0%)
TEMPERATURE TAKEN	2 (66.7%)	2 (66.7%)	2 (66.7%)	2 (66.7%)	2 (66.7%)	2 (66.7%)		2 (66.7%)
TEMPERATURE NOT TAKEN	1 (33.3%)	1 (33.3%)	1 (33.3%)	1 (33.3%)	1 (33.3%)	1 (33.3%)		1 (33.3%)

TABLE 10 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : KIM, KHANG S.
STUDY : 000801
VACCINE : HIB CONJUGATE
DOSE : 30 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE 19-59 MOS.

MAX TEMPERATURE (DEG F, ORAL)	NUMBER OF VACCINEES (7 VACCINEES) - INJECTION 1							NUMBER WITH MAX TEMP
	DAYS POST VACCINATION							
	0	1	2	3	4	5		
NORMAL	2 (33.3%)	2 (33.3%)	2 (33.3%)	2 (33.3%)	2 (33.3%)	2 (33.3%)		2 (33.3%)
< 99	4 (66.7%)	3 (50.0%)	4 (66.7%)	4 (66.7%)	4 (66.7%)	4 (66.7%)		3 (50.0%)
99 - 99.9	0 (0.0%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (16.7%)
TEMPERATURE TAKEN	6 (85.7%)	6 (85.7%)	6 (85.7%)	6 (85.7%)	6 (85.7%)	6 (85.7%)		6 (85.7%)
TEMPERATURE NOT TAKEN	1 (14.3%)	1 (14.3%)	1 (14.3%)	1 (14.3%)	1 (14.3%)	1 (14.3%)		1 (14.3%)

TABLE 10 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : KIM, KHANG S.
STUDY : 000801
VACCINE : HIB CONJUGATE
DOSE : 15 MCG
PATIENT CLASS: HIB POLYS VACC NON-RESPONDERS
AGE RANGE 19-59 MOS.

MAX TEMPERATURE (DEG F, ORAL)	NUMBER OF VACCINEES (19 VACCINEES) - INJECTION 1 — DAYS POST VACCINATION 0	1	2	3	4	5		NUMBER WITH MAX TEMP
NORMAL	3 (18.8%)	4 (25.0%)	5 (31.3%)	5 (31.3%)	4 (25.0%)	4 (25.0%)		3 (18.8%)
< 99	7 (43.8%)	7 (43.8%)	8 (50.0%)	7 (43.8%)	8 (50.0%)	8 (50.0%)		6 (37.5%)
99 - 99.9	2 (12.5%)	5 (31.3%)	2 (12.5%)	4 (25.0%)	2 (12.5%)	1 (6.3%)		3 (18.8%)
100 - 100.9	3 (18.8%)	0 (0.0%)	1 (6.3%)	0 (0.0%)	1 (6.3%)	1 (6.3%)		1 (6.3%)
101 - 101.9	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (6.3%)		0 (0.0%)
102 - 102.9	1 (6.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (6.3%)		2 (12.5%)
103 - 103.9	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (6.3%)	0 (0.0%)		1 (6.3%)
TEMPERATURE TAKEN	16 (84.2%)	16 (84.2%)	16 (84.2%)	16 (84.2%)	16 (84.2%)	16 (84.2%)		16 (84.2%)
TEMPERATURE NOT TAKEN	3 (15.8%)	3 (15.8%)	3 (15.8%)	3 (15.8%)	3 (15.8%)	3 (15.8%)		3 (15.8%)

TABLE 10 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : KIM, KHANG S.
STUDY : 000801
VACCINE : HIB CONJUGATE
DOSE : 30 MCG
PATIENT CLASS: HIB POLYS VACC NON-RESPONDERS
AGE RANGE 19-59 MOS.

MAX TEMPERATURE (DEG F, ORAL)	NUMBER OF VACCINEES (1 VACCINEES) - INJECTION 1							NUMBER WITH MAX TEMP
	DAYS POST VACCINATION							
	0	1	2	3	4	5		
< 99	0 (0.0%)	0 (0.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)		0 (0.0%)
99 - 99.9	0 (0.0%)	1 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)
102 - 102.9	1 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (100.0%)
TEMPERATURE TAKEN	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)		1 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)

TABLE 10 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : KIM, KWANG S.
STUDY : 000801
VACCINE : HIB CONJUGATE
DOSE : 7.5 MCG
PATIENT CLASS: HIB POLYS VACC NON-RESPONDERS
AGE RANGE 19-59 MOS.

MAX TEMPERATURE (DEG F, ORAL)	NUMBER OF VACCINEES (1 VACCINEES) - INJECTION 1							NUMBER WITH MAX TEMP
	DAYS POST VACCINATION							
	0	1	2	3	4	5		
< 99	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)		1 (100.0%)
TEMPERATURE TAKEN	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)		1 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)

STUDY 008-02

PROGRAM: Haemophilus b Conjugate Vaccine (Neisseria meningitidis Outer Membrane Protein Complex), Study 008-02

PURPOSE: To evaluate the effect of dose of polysaccharide on safety and immunogenicity of Haemophilus b conjugate vaccine (Neisseria meningitidis outer membrane protein complex) in infants and children 2 to 71 months of age.

VACCINE: Haemophilus b Conjugate Vaccine (Neisseria meningitidis Outer Membrane Protein Complex), (PRP-OMPC)

Lot 1072/C-P298/37359 - (b) (4) mcg polysaccharide/ml
mcg meningococcal/protein/ml

Aluminum hydroxide diluent
Lot (b) (4)

INVESTIGATOR: Ram Yogev, M.D.
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SUB-INVESTIGATORS: Ellen G. Chadwick, M.D.
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STUDY LOCATION: The Children's Memorial Hospital
2300 Children's Plaza
Chicago, Illinois 60614

DATE STUDY INITIATED:	February 25, 1988
DATE STUDY COMPLETED:	In progress.
STUDY POPULATION:	Healthy infants and children 2 to 71 months of age are included in the study.
STUDY PROCEDURE:	Infants and children are randomized to receive PRP-OMPC vaccine containing 7.5, 15 or 30 mcg polysaccharide. Approximately 50 children are assigned to each dose.

Infants 2 to 18 months of age receive two injections of PRP-OMPC vaccine given 2 months apart, while children 19 months of age and older receive a single injection. Vaccine is reconstituted in aluminum hydroxide in the appropriate volume and administered by intramuscular route. The dose for each injection is 7.5, 15, or 30 mcg of polysaccharide in 0.5 ml.

The parent or guardian is required to record the vaccine recipient's temperature and any reactions at the injection site or systemic complaints for 5 days after each injection of vaccine. Unexpected or serious reactions are to be reported immediately to the study physician. Serious adverse experiences in the 14 days following each injection of vaccine are required to be reported by the investigator.

A blood sample is obtained prior to each injection of vaccine and 1 month after the last injection or after a single injection of vaccine. All serum samples are assayed for antibody to the capsular polysaccharide of Haemophilus influenzae type b by radioimmunoassay. Selected samples may be tested for bactericidal and opsonophagocytic activity, immunoglobulin isotype and subclass IgG. Opsonophagocytic assays are performed at the University of Alabama. All other assays are performed at Merck Sharp & Dohme Research Laboratories.

RESULTS: Demographic information and individual pre and postimmunization antibody data for each vaccine recipient are presented in Table 1.

1. Current status:

Dose	Age	No. Vaccinated	
		Injection 1	Injection 2
7.5	2-18 Mos.	60	8
	19-71 Mos.	24	--
15	2-18 Mos.	41	12
	19-71 Mos.	24	--
30	2-18 Mos.	7	0
	19-71 Mos.	21	--

2. Serologic results:

Anti-PRP responses prior to each injection of vaccine and 1 month after the last or after a single injection of vaccine are as follows:

Age (Months)	Dose (mcg)	Time	% With Anti-PRP >0.15 mcg/ml	% With Anti-PRP >1.0 mcg/ml	GMT (mcg/ml) All Vaccinees
2-18	7.5	Pre	18 (3/17)	0 (0/17)	0.09
		Post 1	100 (17/17)	88 (15/17)	3.02
		Post 2	100 (7/7)	86 (6/7)	6.28
	15	Pre	22 (4/18)	0 (0/18)	0.09
		Post 1	100 (18/18)	78 (14/18)	2.17
		Post 2	100 (11/11)	91 (10/11)	4.79
19-71	7.5	Pre	29 (5/17)	18 (3/17)	0.16
		Post	100 (17/17)	94 (16/17)	4.92
	15	Pre	53 (9/17)	0 (0/17)	0.16
		Post	100 (17/17)	94 (16/17)	9.63
	30	Pre	38 (6/16)	13 (2/16)	0.15
		Post	100 (16/16)	94 (15/16)	18.13

RESULTS: (CONT.)

Antibody response summary statistics are presented in Tables 2-4.

3. Clinical results:

The incidence of selected injection site and systemic reactions occurring within 2 days after vaccination are as follows:

Type of Reaction	% of Vaccinees with Reaction							
	2-18 Mos.					12-71 Mos.		
	Injection 1			Injection 2				
	7.5	15	30	7.5	15	7.5	15	30
	n=60	n=41	n=3	n=7	n=10	n=24	n=24	n=21
Injection Site:								
Pain/Soreness	10	0	0	0	10	8	25	19
Erythema >1 inch	0	2	0	0	0	0	0	0
Swelling >1 inch	0	0	0	0	0	0	0	0
Induration	0	0	0	0	0	0	0	0
Systemic:								
Irritability	15	27	0	0	20	17	13	5
Sleepiness/Lethargy/ Fatigue	10	12	0	0	10	4	13	5

The frequencies of all clinical reactions and maximum temperatures occurring during the 5 days following each injection of vaccine are presented in Tables 5-7 by dose.

No serious or alarming reactions attributable to vaccine have been reported. One serious adverse experience not related to vaccination was reported. Case no. (b) (6), a 9 month old male infant, developed a fever of 103-104°F one day after receiving a second 7.5 mcg dose of PRP-OMPC vaccine. The infant was hospitalized the next day with a maculo papular rash on face and body (confluent on back, chest and groin), vomiting (1X) and temperature of 37.8°C rectal. Within one day the rash was disappearing and the child was discharged.

TABLE 1

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : YOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA
(b) (6)	F	CAUC	(b) (6)	3M	0	(b) (6)	001	PREBLEED				< 125
					0		011	INJ 1	CP298	7.5 MCG		
					55		011	BLEED 1				395
					55		021	INJ 2	CP298	7.5 MCG		
					103		021	BLEED 2				588
	M	CAUC		4M	0		001	PREBLEED				310
					0		011	INJ 1	CP298	15 MCG		
					57		011	BLEED 1				2917
					57		021	INJ 2	CP298	15 MCG		
					84		021	BLEED 2				1133
	F	CAUC		4M	0		001	PREBLEED				210
					0		011	INJ 1	CP298	15 MCG		
					56		011	BLEED 1				5441
					56		021	INJ 2	CP298	15 MCG		
					84		021	BLEED 2				5384
	M	CAUC		5M	0		001	PREBLEED				< 125
					0		011	INJ 1	CP298	7.5 MCG		
					80		011	BLEED 1				9842
	M	BLAC		4M	0		001	PREBLEED				< 125
					0		011	INJ 1	CP298	15 MCG		
					56		011	BLEED 1				1224
					56		021	INJ 2	CP298	15 MCG		
					84		021	BLEED 2				2591
	M	HISP		2M	0		001	PREBLEED				< 125
					0		011	INJ 1	CP298	7.5 MCG		
					56		011	BLEED 1				916
					56		021	INJ 2	CP298	7.5 MCG		
					81		021	BLEED 2				1356
	F	HISP		2M	0		001	PREBLEED				372
					0		011	INJ 1	CP298	15 MCG		
					56		011	BLEED 1				862
					56		021	INJ 2	CP298	15 MCG		
					81		021	BLEED 2				1754
	F	HISP		6M	0		001	PREBLEED				< 125

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : YOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA
(b) (6)	F	HISP	(b) (6)	6M	0	(b) (6)	011	INJ 1	CP298	7.5 MCG		
					56		011	BLEED 1				1483
					56		021	INJ 2	CP298	7.5 MCG		
					97		021	BLEED 2				5974
	F	CAUC		4M	0		001	PREBLEED				< 125
					0		011	INJ 1	CP298	15 MCG		
					56		011	BLEED 1				3749
					56		021	INJ 2	CP298	15 MCG		
	F	CAUC		3M	0		001	PREBLEED				< 125
					0		011	INJ 1	CP298	7.5 MCG		
					60		011	BLEED 1				6186
	F	HISP		4M	0		001	PREBLEED				< 125
					0		011	INJ 1	CP298	7.5 MCG		
					63		011	BLEED 1				12416
	M	HISP		5M	0		011	INJ 1	CP298	15 MCG		
					63		011	BLEED 1				26218
	M	HISP		5M	0		001	PREBLEED				< 125
					0		011	INJ 1	CP298	7.5 MCG		
					63		011	BLEED 1				1816
	F	CAUC		4M	0		001	PREBLEED				< 125
					0		011	INJ 1	CP298	15 MCG		
					56		011	BLEED 1				1639
	M	HISP		3M	0		001	PREBLEED				< 125
					0		011	INJ 1	CP298	7.5 MCG		
					63		011	BLEED 1				9074
	F	CAUC		2M	0		001	PREBLEED				< 125
					0		011	INJ 1	CP298	15 MCG		
					62		011	BLEED 1				7868
	F	CAUC		4M	0		001	PREBLEED				< 125
					0		011	INJ 1	CP298	15 MCG		
					56		011	BLEED 1				2138

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : YOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA
(b) (6)	F	CAUC	(b) (6)	4M	0	(b) (6)	011	INJ	1	CP298 7.5 MCG		
	F	CAUC		2M	0		001	PREBLEED				838
					0		011	INJ	1	CP298 7.5 MCG		
					63		011	BLEED	1			1017
	M	HISP		4M	0		001	PREBLEED				< 125
					0		011	INJ	1	CP298 15 MCG		
					56		011	BLEED	1			1073
	M	HISP		2M	0		011	INJ	1	CP298 15 MCG		
	M	HISP		2M	0		011	INJ	1	CP298 7.5 MCG		
	M	CAUC		6M	0		001	PREBLEED				< 125
					0		011	INJ	1	CP298 7.5 MCG		
					58		011	BLEED	1			1238
	F	CAUC		6M	0		011	INJ	1	CP298 15 MCG		
	F	CAUC		5M	0		011	INJ	1	CP298 7.5 MCG		
	F	BLAC		6M	0		011	INJ	1	CP298 15 MCG		
	M	CAUC		2M	0		011	INJ	1	CP298 15 MCG		
	F	HISP		2M	0		011	INJ	1	CP298 7.5 MCG		
	M	HISP		2M	0		011	INJ	1	CP298 7.5 MCG		
	M	CAUC		4M	0		011	INJ	1	CP298 15 MCG		
	M	CAUC		5M	0		011	INJ	1	CP298 15 MCG		
	M	HISP		5M	0		011	INJ	1	CP298 7.5 MCG		
	M	HISP		2M	0		011	INJ	1	CP298 15 MCG		
	F	CAUC		6M	0		011	INJ	1	CP298 7.5 MCG		
	M	CAUC		5M	0		011	INJ	1	CP298 7.5 MCG		

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : YOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA
(b) (6)	F	CAUC	(b) (6)	3M	0	(b) (6)	011	INJ 1	CP298	7.5 MCG		
	M	CAUC		5M	0		011	INJ 1	CP298	7.5 MCG		
	M	HISP		4M	0		011	INJ 1	CP298	7.5 MCG		
	M	HISP		4M	0		011	INJ 1	CP298	7.5 MCG		
	F	HISP		5M	0		011	INJ 1	CP298	7.5 MCG		
	F	CAUC		2M	0		011	INJ 1	CP298	7.5 MCG		
	M	CAUC		6M	0		011	INJ 1	CP298	7.5 MCG		
	M	HISP		11M	0		011	INJ 1	CP298	30 MCG		
	M	CAUC		7M	0		001	PREBLEED				< 125
					0		011	INJ 1	CP298	15 MCG		
					56		011	BLEED 1				355
					56		021	INJ 2	CP298	15 MCG		
					88		021	BLEED 2				895
	M	CAUC		11M	0		001	PREBLEED				498
					0		011	INJ 1	CP298	7.5 MCG		
					57		011	BLEED 1				7822
					57		021	INJ 2	CP298	7.5 MCG		
					85		021	BLEED 2				36006
	M	CAUC		10M	0		001	PREBLEED				< 125
					0		011	INJ 1	CP298	15 MCG		
					56		011	BLEED 1				1860
					56		021	INJ 2	CP298	15 MCG		
					84		021	BLEED 2				4592
	M	HISP		9M	0		001	PREBLEED				< 125
					0		011	INJ 1	CP298	7.5 MCG		
					63		011	BLEED 1				3788
					91		011	BLEED 2				16765
	M	HISP		10M	0		001	PREBLEED				< 125

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : YOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA
(b) (6)	M	HISP	(b) (6)	10M	0	(b) (6)	011	INJ	1	CP298	15 MCG	
					56		011	BLEED	1			10088
					56		021	INJ	2	CP298	15 MCG	
					84		021	BLEED	2			115536
	M	CAUC		10M	0		011	INJ	1	CP298	30 MCG	
	F	CAUC		12M	0		001	PREBLEED				< 125
					0		011	INJ	1	CP298	7.5 MCG	
					59		011	BLEED	1			3863
					59		021	INJ	2	CP298	7.5 MCG	
					92		021	BLEED	2			6211
	F	OTHE		9M	0		001	PREBLEED				214
					0		011	INJ	1	CP298	15 MCG	
					55		011	BLEED	1			1315
					55		021	INJ	2	CP298	15 MCG	
					84		021	BLEED	2			1389
	M	CAUC		7M	0		011	INJ	1	CP298	30 MCG	
	F	CAUC		9M	0		001	PREBLEED				< 125
					0		011	INJ	1	CP298	7.5 MCG	
					63		011	BLEED	1			4130
	M	BLAC		10M	0		001	PREBLEED				< 125
					0		011	INJ	1	CP298	15 MCG	
					56		011	BLEED	1			832
	F	BLAC		12M	0		011	INJ	1	CP298	30 MCG	
	M	CAUC		11M	0		001	PREBLEED				< 125
					0		011	INJ	1	CP298	7.5 MCG	
					65		011	BLEED	1			2146
	F	CAUC		12M	0		001	PREBLEED				< 125
					0		011	INJ	1	CP298	7.5 MCG	
					56		011	BLEED	1			2786
	M	CAUC		9M	0		001	PREBLEED				135

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : YOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT		LOT	DOSE	CODE/	RIA
(b) (6)	M	CAUC	(b) (6)	9M	0	(b) (6)	011	INJ	1	CP298	15 MCG		
					63		011	BLEED	1				1515
	F	CAUC		9M	0		011	INJ	1	CP298	30 MCG		
	M	HISP		7M	0		011	INJ	1	CP298	7.5 MCG		
	F	HISP		11M	0		011	INJ	1	CP298	15 MCG		
	F	CAUC		8M	0		011	INJ	1	CP298	30 MCG		
	M	CAUC		9M	0		011	INJ	1	CP298	7.5 MCG		
	F	CAUC		8M	0		011	INJ	1	CP298	15 MCG		
	F	HISP		10M	0		011	INJ	1	CP298	7.5 MCG		
	F	CAUC		7M	0		011	INJ	1	CP298	15 MCG		
	F	OTHE		8M	0		011	INJ	1	CP298	15 MCG		
	F	CAUC		10M	0		011	INJ	1	CP298	7.5 MCG		
	M	HISP		8M	0		011	INJ	1	CP298	7.5 MCG		
	M	HISP		7M	0		011	INJ	1	CP298	15 MCG		
	M	CAUC		11M	0		011	INJ	1	CP298	15 MCG		
	F	CAUC		12M	0		011	INJ	1	CP298	7.5 MCG		
	F	HISP		7M	0		011	INJ	1	CP298	15 MCG		
	M	CAUC		7M	0		011	INJ	1	CP298	7.5 MCG		
	M	CAUC		11M	0		011	INJ	1	CP298	7.5 MCG		
	M	CAUC		12M	0		011	INJ	1	CP298	15 MCG		
	F	HISP		8M	0		011	INJ	1	CP298	15 MCG.		

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : YOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA
(b) (6)	M	HISP	(b) (6)	11M	0	(b) (6)	011	INJ	1 CP298	7.5 MCG		
	M	CAUC		11M	0		011	INJ	1 CP298	15 MCG		
	M	HISP		11M	0		011	INJ	1 CP298	7.5 MCG		
	F	CAUC		9M	0		011	INJ	1 CP298	7.5 MCG		
	F	CAUC		11M	0		011	INJ	1 CP298	7.5 MCG		
	M	CAUC		9M	0		011	INJ	1 CP298	7.5 MCG		
	M	CAUC		10M	0		011	INJ	1 CP298	7.5 MCG		
	F	CAUC		7M	0		011	INJ	1 CP298	7.5 MCG		
	F	CAUC		7M	0		011	INJ	1 CP298	7.5 MCG		
	M	CAUC		10M	0		011	INJ	1 CP298	7.5 MCG		
	F	CAUC		7M	0		011	INJ	1 CP298	7.5 MCG		
	F	CAUC		12M	0		011	INJ	1 CP298	7.5 MCG		
	M	BLAC		13M	0		001	PREBLEED				< 125
					0		011	INJ	1 CP298	15 MCG		
					56		011	BLEED	1			885
					56		021	INJ	2 CP298	15 MCG		
					84		021	BLEED	2			4542
	M	CAUC		16M	0		001	PREBLEED				393
					0		011	INJ	1 CP298	7.5 MCG		
					64		011	BLEED	1			6328
					64		021	INJ	2 CP298	7.5 MCG		
					100		021	BLEED	2			12459
	F	HISP		18M	0		011	INJ	1 CP298	30 MCG		
	M	HISP		13M	0		001	PREBLEED				< 125
					0		011	INJ	1 CP298	7.5 MCG		

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : YOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA
(b) (6)	M	HISP	(b) (6)	13M	56	(b) (6)	011	BLEED	1			9640
					56		021	INJ	2	CP298	7.5 MCG	
					84		021	BLEED	2			28965
	M	CAUC		18M	0		001	PREBLEED				< 125
					0		011	INJ	1	CP298	15 MCG	
					60		011	BLEED	1			23314
					60		021	INJ	2	CP298	15 MCG	
					87		021	BLEED	2			42759
	F	HISP		13M	0		001	PREBLEED				< 125
					0		011	INJ	1	CP298	15 MCG	
					56		011	BLEED	1			2735
					56		021	INJ	2	CP298	15 MCG	
					91		021	BLEED	2			8514
	M	HISP		12M	0		011	INJ	1	CP298	7.5 MCG	
					56		021	INJ	2	CP298	7.5 MCG	
	F	HISP		14M	0		011	INJ	1	CP298	15 MCG	
	F	CAUC		13M	0		011	INJ	1	CP298	7.5 MCG	
	F	CAUC		14M	0		011	INJ	1	CP298	15 MCG	
	M	HISP		16M	0		011	INJ	1	CP298	7.5 MCG	
	F	CAUC		12M	0		011	INJ	1	CP298	7.5 MCG	
	M	HISP		17M	0		011	INJ	1	CP298	7.5 MCG	
	M	HISP		16M	0		011	INJ	1	CP298	7.5 MCG	
	M	CAUC		13M	0		011	INJ	1	CP298	15 MCG	
	F	OTHE		13M	0		011	INJ	1	CP298	7.5 MCG	
	M	CAUC		14M	0		011	INJ	1	CP298	15 MCG	
	M	HISP		16M	0		011	INJ	1	CP298	7.5 MCG	

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : YOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
REGIMEN : 2 INJ. TWO MOS. APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA
(b) (6)	F	CAUC	(b) (6)	13M 0	(b) (6)		011 INJ	1	CP298	15 MCG	

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : YOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA
(b) (6)	M	HISP	(b) (6)	3Y	0	(b) (6)	001	PREBLEED				1603
					0		011	INJ 1	CP298	7.5 MCG		
					28		011	BLEED 1				4852
	M	HISP		3Y	0		011	INJ 1	CP298	30 MCG		
	F	CAUC		24M	0		001	PREBLEED				< 125
					0		011	INJ 1	CP298	15 MCG		
					28		011	BLEED 1				16316
	M	HISP		2Y	0		001	PREBLEED				< 125
					0		011	INJ 1	CP298	30 MCG		
					28		011	BLEED 1				3944
	M	CAUC		24M	0		001	PREBLEED				< 125
					0		011	INJ 1	CP298	15 MCG		
					27		011	BLEED 1				9119
	F	CAUC		2Y	0		001	PREBLEED				< 125
					0		011	INJ 1	CP298	7.5 MCG		
					29		011	BLEED 1				2883
	M	CAUC		24M	0		001	PREBLEED				205
					0		011	INJ 1	CP298	15 MCG		
					30		011	BLEED 1				10693
	F	CAUC		2Y	0		001	PREBLEED				1146
					0		011	INJ 1	CP298	7.5 MCG		
					26		011	BLEED 1				14614
	F	HISP		24M	0		001	PREBLEED				< 125
					0		011	INJ 1	CP298	30 MCG		
					28		011	BLEED 1				6226
	F	HISP		2Y	0		001	PREBLEED				568
					0		011	INJ 1	CP298	7.5 MCG		
					28		011	BLEED 1				2527
	F	HISP		24M	0		001	PREBLEED				< 125
					0		011	INJ 1	CP298	30 MCG		

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : YOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA
(b) (6)	F	HISP	(b) (6)	24M	28	(b) (6)	011	BLEED 1				19032
	M	HISP		21M	0		001	PREBLEED				758
					0		011	INJ 1	CP298	15 MCG		
					28		011	BLEED 1				44755
	M	BLAC		24M	0		001	PREBLEED				584
					0		011	INJ 1	CP298	15 MCG		
					36		011	BLEED 1				11403
	M	CAUC		3Y	0		001	PREBLEED				< 125
					0		011	INJ 1	CP298	7.5 MCG		
					29		011	BLEED 1				5409
	M	HISP		2Y	0		001	PREBLEED				< 125
					0		011	INJ 1	CP298	30 MCG		
					28		011	BLEED 1				28872
	F	HISP		3Y	0		001	PREBLEED				296
					0		011	INJ 1	CP298	30 MCG		
					28		011	BLEED 1				54159
	F	CAUC		4Y	0		001	PREBLEED				314
					0		011	INJ 1	CP298	15 MCG		
					35		011	BLEED 1				18790
	M	HISP		24M	0		001	PREBLEED				< 125
					0		011	INJ 1	CP298	7.5 MCG		
					31		011	BLEED 1				3131
	M	HISP		3Y	0		001	PREBLEED				7380
					0		011	INJ 1	CP298	7.5 MCG		
					33		011	BLEED 1				27475
	M	HISP		4Y	0		001	PREBLEED				3600
					0		011	INJ 1	CP298	30 MCG		
					28		011	BLEED 1				118433
	F	HISP		24M	0		001	PREBLEED				239
					0		011	INJ 1	CP298	15 MCG		

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : YOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA
(b) (6)	F	HISP	(b) (6)	24M	37	(b) (6)	011	BLEED 1				26963
	F	BLAC		2Y	0		001	PREBLEED				< 125
					0		011	INJ 1	CP298	30 MCG		
					34		011	BLEED 1				42907
	M	BLAC		3Y	0		001	PREBLEED				261
					0		011	INJ 1	CP298	15 MCG		
					28		011	BLEED 1				1241
	M	CAUC		24M	0		001	PREBLEED				< 125
					0		011	INJ 1	CP298	7.5 MCG		
					25		011	BLEED 1				21044
	M	HISP		24M	0		001	PREBLEED				696
					0		011	INJ 1	CP298	7.5 MCG		
					35		011	BLEED 1				10860
	F	HISP		2Y	0		001	PREBLEED				< 125
					0		011	INJ 1	CP298	15 MCG		
					28		011	BLEED 1				7387
	M	HISP		2Y	0		001	PREBLEED				209
					0		011	INJ 1	CP298	30 MCG		
					28		011	BLEED 1				912
	F	HISP		2Y	0		001	PREBLEED				< 125
					0		011	INJ 1	CP298	30 MCG		
					28		011	BLEED 1				5441
	F	HISP		3Y	0		001	PREBLEED				373
					0		011	INJ 1	CP298	15 MCG		
					28		011	BLEED 1				68585
	M	HISP		3Y	0		001	PREBLEED				< 125
					0		011	INJ 1	CP298	7.5 MCG		
					41		011	BLEED 1				10622
	F	HISP		19M	0		001	PREBLEED				< 125
					0		011	INJ 1	CP298	7.5 MCG		

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : YOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA
(b) (6)	F	HISP	(b) (6)	19M	21	(b) (6)	011	BLEEO	1			4681
	M	HISP		4Y	0		001	PREBLEED				< 125
					0		011	INJ	1	CP298	15 MCG	
					31		011	BLEED	1			3710
	F	HISP		24M	0		001	PREBLEED				134
					0		011	INJ	1	CP298	30 MCG	
					35		011	BLEEO	1			39327
	M	HISP		24M	0		001	PREBLEED				< 125
					0		011	INJ	1	CP298	7.5 MCG	
					28		011	BLEED	1			2108
	F	HISP		24M	0		001	PREBLEED				< 125
					0		011	INJ	1	CP298	30 MCG	
					28		011	BLEEO	1			11200
	M	HISP		2Y	0		001	PREBLEED				< 125
					0		011	INJ	1	CP298	15 MCG	
					29		011	BLEED	1			444
	F	HISP		4Y	0		011	INJ	1	CP298	30 MCG	
	F	CAUC		19M	0		011	INJ	1	CP298	15 MCG	
	M	HISP		24M	0		001	PREBLEED				< 125
					0		011	INJ	1	CP298	7.5 MCG	
					28		011	BLEED	1			1233
	F	HISP		2Y	0		001	PREBLEED				< 125
					D		011	INJ	1	CP298	30 MCG	
					28		011	BLEED	1			157039
	M	CAUC		24M	0		001	PREBLEED				< 125
					0		011	INJ	1	CP298	7.5 MCG	
					28		011	BLEED	1			4181
	M	CAUC		3Y	0		001	PREBLEED				< 125
					0		011	INJ	1	CP298	15 MCG	

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : YOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA
(b) (6)	M	CAUC	(b) (6)	3Y	31	(b) (6)	011	BLEED 1				3896
	F	HISP		4Y	0		001	PREBLEED				299
					0		011	INJ 1	CP298	30 MCG		
					28		011	BLEED 1				20476
	F	CAUC		19M	0		001	PREBLEED				< 125
					0		011	INJ 1	CP298	7.5 MCG		
					30		011	BLEED 1				475
	M	CAUC		4Y	0		001	PREBLEED				< 125
					0		011	INJ 1	CP298	15 MCG		
					28		011	BLEED 1				9124
	M	CAUC		21M	0		001	PREBLEED				< 125
					0		011	INJ 1	CP298	15 MCG		
					28		011	BLEED 1				3238
	M	HISP		24M	0		001	PREBLEED				< 125
					0		011	INJ 1	CP298	7.5 MCG		
					46		011	BLEED 1				2488
	M	HISP		21M	0		001	PREBLEED				260
					0		011	INJ 1	CP298	30 MCG		
					35		011	BLEED 1				13306
	F	HISP		2Y	0		001	PREBLEED				< 125
					0		011	INJ 1	CP298	7.5 MCG		
					28		011	BLEED 1				16384
	M	HISP		2Y	0		001	PREBLEED				883
					0		011	INJ 1	CP298	15 MCG		
					35		011	BLEED 1				31965
	F	HISP		4Y	0		001	PREBLEED				1741
					0		011	INJ 1	CP298	30 MCG		
					28		011	BLEED 1				80883
	F	BLAC		2Y	0		001	PREBLEED				230
					0		011	INJ 1	CP298	15 MCG		

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : YOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
REGIMEN : ONE INJECTION
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA
(b) (6)	F	BLAC	(b) (6)	2Y	36	(b) (6)	011	BLEED	1			33299
	F	CAUC		3Y	0		011	INJ	1	CP298	7.5 MCG	
	F	CAUC		20M	0		001	PREBLEED				< 125
					0		011	INJ	1	CP298	30 MCG	
					28		011	BLEED	1			4831
	M	HISP		3Y	0		011	INJ	1	CP298	15 MCG	
	F	BLAC		24M	0		011	INJ	1	CP298	30 MCG	
	F	HISP		2Y	0		011	INJ	1	CP298	7.5 MCG	
	F	HISP		21M	0		011	INJ	1	CP298	15 MCG	
	F	BLAC		24M	0		011	INJ	1	CP298	30 MCG	
	F	CAUC		2Y	0		011	INJ	1	CP298	30 MCG	
	F	HISP		2Y	0		011	INJ	1	CP298	7.5 MCG	
	F	HISP		20M	0		011	INJ	1	CP298	15 MCG	
	F	CAUC		2Y	0		011	INJ	1	CP298	15 MCG	
	M	HISP		3Y	0		011	INJ	1	CP298	7.5 MCG	
	F	HISP		4Y	0		011	INJ	1	CP298	7.5 MCG	
	F	CAUC		19M	0		011	INJ	1	CP298	15 MCG	
	F	BLAC		23M	0		011	INJ	1	CP298	15 MCG	
	F	HISP		3Y	0		011	INJ	1	CP298	7.5 MCG	
	F	HISP		20M	0		011	INJ	1	CP298	7.5 MCG	

TABLE 2

ANTIBODY RESPONSES

INVESTIGATOR : YOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
ASSAY : RIA
DOSE : 7.5 MCG
POPULATION : HEALTHY CHILDREN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
2- 6 MOS.	PRE INJ	11 (1/ 9)	0 (0/ 9)			0.083 (9)
	MONTH 2	100 (9/ 9)	78 (7/ 9)	89 (8/ 9)	13.7	2.117 (9)
	MONTH 3	100 (3/ 3)	67 (2/ 3)	100 (3/ 3)	13.5	1.683 (3)
7-12 MOS.	PRE INJ	17 (1/ 6)	0 (0/ 6)			0.088 (6)
	MONTH 2	100 (6/ 6)	100 (6/ 6)	100 (6/ 6)	23.9	3.760 (6)
	MONTH 3	100 (2/ 2)	100 (2/ 2)	100 (2/ 2)	59.9	14.954 (2)
13-18 MOS.	PRE INJ	50 (1/ 2)	0 (0/ 2)			0.157 (2)
	MONTH 2	100 (2/ 2)	100 (2/ 2)	100 (2/ 2)	35.2	7.810 (2)
	MONTH 3	100 (2/ 2)	100 (2/ 2)	100 (2/ 2)	85.7	18.997 (2)
19-59 MOS.	PRE INJ	29 (5/ 17)	18 (3/ 17)			0.156 (17)
	MONTH 1	100 (17/ 17)	94 (16/ 17)	100 (17/ 17)	19.3	4.917 (17)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 3

ANTIBODY RESPONSES

INVESTIGATOR : YOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
ASSAY : RIA
DOSE : 15 MCG
POPULATION : HEALTHY CHILDREN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
2- 6 MOS.	PRE INJ	33 (3/ 9)	0 (0/ 9)			0.104 (9)
	MONTH 2	100 (9/ 9)	89 (8/ 9)	100 (9/ 9)	14.0	2.308 (9)
	MONTH 3	100 (4/ 4)	100 (4/ 4)	100 (4/ 4)	9.8	2.295 (4)
7-12 MOS.	PRE INJ	17 (1/ 6)	0 (0/ 6)			0.087 (6)
	MONTH 2	100 (6/ 6)	67 (4/ 6)	100 (6/ 6)	10.8	1.492 (6)
	MONTH 3	100 (4/ 4)	75 (3/ 4)	100 (4/ 4)	35.4	5.068 (4)
13-18 MOS.	PRE INJ	0 (0/ 3)	0 (0/ 3)			0.063 (3)
	MONTH 2	100 (3/ 3)	67 (2/ 3)	100 (3/ 3)	30.7	3.836 (3)
	MONTH 3	100 (3/ 3)	100 (3/ 3)	100 (3/ 3)	94.6	11.825 (3)
19-59 MOS.	PRE INJ	53 (9/ 17)	0 (0/ 17)			0.161 (17)
	MONTH 1	100 (17/ 17)	94 (16/ 17)	100 (17/ 17)	43.3	9.625 (17)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 4

ANTIBODY RESPONSES

INVESTIGATOR : YOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
ASSAY : RIA
DOSE : 30 MCG
POPULATION : HEALTHY CHILDREN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
19-59 MOS.	PRE INJ	38 (6/ 16)	13 (2/ 16)			0.149 (16)
	MONTH 1	100 (16/ 16)	94 (15/ 16)	100 (16/ 16)	82.4	18.125 (16)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 5

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : YOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
DOSE : 7.5 MCG
POPULATION : HEALTHY CHILDREN
AGE RANGE : 2- 6 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	25	
VACCINEES WITH NO COMPLAINTS :	14	(56.0 %)
VACCINEES WITH COMPLAINTS :	11	(44.0 %)
VACCINEES WITH NO DATA :	0	

CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 25 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	7	28.0
ERYTHEMA, INJ. SITE (<=1 IN.)	7	28.0
SWELLING, INJ. SITE (<=1 IN.)	4	16.0
SYSTEMIC REACTIONS	10	40.0
IRRITABILITY	6	24.0
FATIGUE	3	12.0
COMMON COLD	2	8.0
DIARRHEA	2	8.0
VOMITING	2	8.0
WARM TO TOUCH	2	8.0
ATOPIC DERMATITIS	1	4.0
BRONCHIOLITIS, ACUTE	1	4.0
EAR FLUID	1	4.0
NASAL CONGESTION	1	4.0
RASH	1	4.0
SNEEZING	1	4.0
WHEEZING	1	4.0

TABLE 5 (cont.)

C L I N I C A L C O M P L A I N T S B Y F R E Q U E N C Y

INVESTIGATOR : YOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
DOSE : 7.5 MCG
POPULATION : HEALTHY CHILDREN
AGE RANGE : 2- 6 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 2	
TOTAL VACCINEES :	3	
VACCINEES WITH NO COMPLAINTS :	3	(100.0 %)
VACCINEES WITH COMPLAINTS :	0	(0.0 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 3 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	0	0.0

TABLE 5 (cont.)

C L I N I C A L C O M P L A I N T S B Y F R E Q U E N C Y

INVESTIGATOR : VOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
DOSE : 7.5 MCG
POPULATION : HEALTHY CHILDREN
AGE RANGE : 7-12 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	27	
VACCINEES WITH NO COMPLAINTS :	11	(40.7 %)
VACCINEES WITH COMPLAINTS :	16	(59.3 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 27 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	14	51.9
ERYTHEMA, INJ. SITE (<=1 IN.)	10	37.0
PAIN/SORENESS, INJ. SITE	5	18.5
SWELLING, INJ. SITE (<=1 IN.)	5	18.5
SYSTEMIC REACTIONS	10	37.0
IRRITABILITY	4	14.8
WARM TO TOUCH	4	14.8
WHEEZING	3	11.1
FATIGUE	2	7.4
VOMITING	2	7.4
ANOREXIA	1	3.7
CRYING, EXCESSIVE	1	3.7
DIARRHEA	1	3.7
INSOMNIA	1	3.7
NAUSEA	1	3.7
RASH	1	3.7
TEETHING	1	3.7

TABLE 5 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : YOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
DOSE : 7.5 MCG
POPULATION : HEALTHY CHILDREN
AGE RANGE : 7-12 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 2	
TOTAL VACCINEES :	3	
VACCINEES WITH NO COMPLAINTS :	2	(100.0 %)
VACCINEES WITH COMPLAINTS :	0	(0.0 %)
VACCINEES WITH NO DATA :	1	

CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 2 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	0	0.0

TABLE 5 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : YOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
DOSE : 7.5 MCG
POPULATION : HEALTHY CHILDREN
AGE RANGE : 13-18 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	8	
VACCINEES WITH NO COMPLAINTS :	4	(50.0 %)
VACCINEES WITH COMPLAINTS :	4	(50.0 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 8 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	2	25.0
SWELLING, INJ. SITE (<=1 IN.)	2	25.0
ERYTHEMA, INJ. SITE (<=1 IN.)	1	12.5
PAIN/SORENESS, INJ. SITE	1	12.5
SYSTEMIC REACTIONS	3	37.5
FATIGUE	3	37.5
IRRITABILITY	2	25.0
NAUSEA	2	25.0
PROLONGED CRYING, >1/2 HR	2	25.0
VOMITING	2	25.0
WARM TO TOUCH	2	25.0
DIARRHEA	1	12.5
UNUSUAL HIGH-PITCHED CRYING	1	12.5
WHEEZING	1	12.5

TABLE 5 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : YOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
DOSE : 7.5 MCG
POPULATION : HEALTHY CHILDREN
AGE RANGE : 13-18 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 2	
TOTAL VACCINEES :	2	
VACCINEES WITH NO COMPLAINTS :	2	(100.0 %)
VACCINEES WITH COMPLAINTS :	0	(0.0 %)
VACCINEES WITH NO DATA :	0	

CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 2 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	0	0.0

TABLE 5 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : YOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
DOSE : 7.5 MCG
POPULATION : HEALTHY CHILDREN
AGE RANGE : 19-59 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	24	
VACCINEES WITH NO COMPLAINTS :	18	(75.0 %)
VACCINEES WITH COMPLAINTS :	6	(25.0 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 24 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	3	12.5
PAIN/SORENESS, INJ. SITE	2	8.3
SWELLING, INJ. SITE (<=1 IN.)	2	8.3
ERYTHEMA, INJ. SITE (<=1 IN.)	1	4.2
SYSTEMIC REACTIONS	5	20.8
IRRITABILITY	4	16.7
WARM TO TOUCH	2	8.3
FATIGUE	1	4.2
URTICARIA	1	4.2

TABLE 5 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : YOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
DOSE : 15 MCG
POPULATION : HEALTHY CHILDREN
AGE RANGE : 2- 6 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	17	
VACCINEES WITH NO COMPLAINTS :	6	(35.3 %)
VACCINEES WITH COMPLAINTS :	11	(64.7 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 17 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	8	47.1
ERYTHEMA, INJ. SITE (<=1 IN.)	7	41.2
SWELLING, INJ. SITE (<=1 IN.)	4	23.5
ERYTHEMA, INJ. SITE (>1 INCH)	1	5.9
SYSTEMIC REACTIONS	10	58.8
IRRITABILITY	7	41.2
WARM TO TOUCH	7	41.2
FATIGUE	4	23.5
COUGH	1	5.9
HYPERHYDROSIS	1	5.9
NASAL DISCHARGE	1	5.9
PROLONGED CRYING, >1/2 HR	1	5.9
RASH	1	5.9
TEETHING	1	5.9
UNUSUAL HIGH-PITCHED CRYING	1	5.9
VOMITING	1	5.9

TABLE 5 (cont.)

C L I N I C A L C O M P L A I N T S B Y F R E Q U E N C Y

INVESTIGATOR : YOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
DOSE : 15 MCG
POPULATION : HEALTHY CHILDREN
AGE RANGE : 2- 6 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 2	
TOTAL VACCINEES :	5	
VACCINEES WITH NO COMPLAINTS :	1	(25.0 %)
VACCINEES WITH COMPLAINTS :	3	(75.0 %)
VACCINEES WITH NO DATA :	1	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 4 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	1	25.0
ERYTHEMA, INJ. SITE (<=1 IN.)	1	25.0
PAIN/SORENESS, INJ. SITE	1	25.0
SYSTEMIC REACTIONS	2	50.0
FEVER	1	25.0
IRRITABILITY	1	25.0

TABLE 5 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : YOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
DOSE : 15 MCG
POPULATION : HEALTHY CHILDREN
AGE RANGE : 7-12 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	16	
VACCINEES WITH NO COMPLAINTS :	6	(37.5 %)
VACCINEES WITH COMPLAINTS :	10	(62.5 %)
VACCINEES WITH NO DATA :	0	

CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 16 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	6	37.5
ERYTHEMA, INJ. SITE (<=1 IN.)	5	31.3
SWELLING, INJ. SITE (<=1 IN.)	3	18.8
SYSTEMIC REACTIONS	9	56.3
IRRITABILITY	4	25.0
DIARRHEA	2	12.5
WARM TO TOUCH	2	12.5
COMMON COLD	1	6.3
NASAL DISCHARGE	1	6.3
NAUSEA	1	6.3
OTITIS MEDIA	1	6.3
POLYDIPSIA	1	6.3
RASH	1	6.3
SNEEZING	1	6.3
TEETHING	1	6.3
UNUSUAL HIGH-PITCHED CRYING	1	6.3
URINARY FREQUENCY	1	6.3

TABLE 5 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : YOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
DOSE : 15 MCG
POPULATION : HEALTHY CHILDREN
AGE RANGE : 7-12 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE	HIB CONJUGATE INJECTION: 2	
TOTAL VACCINEES	4	
VACCINEES WITH NO COMPLAINTS	2	(66.7 %)
VACCINEES WITH COMPLAINTS	1	(33.3 %)
VACCINEES WITH NO DATA	1	

CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 3 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	1	33.3
ERYTHEMA, INJ. SITE (<=1 IN.)	1	33.3
SWELLING, INJ. SITE (<=1 IN.)	1	33.3
SYSTEMIC REACTIONS	1	33.3
IRRITABILITY	1	33.3

TABLE 5 (cont.)

C L I N I C A L C O M P L A I N T S B Y F R E Q U E N C Y

INVESTIGATOR : YOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
DOSE : 15 MCG
POPULATION : HEALTHY CHILDREN
AGE RANGE : 13-18 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	8	
VACCINEES WITH NO COMPLAINTS :	5	(62.5 %)
VACCINEES WITH COMPLAINTS :	3	(37.5 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 8 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	1	12.5
SWELLING, INJ. SITE (<=1 IN.)	1	12.5
SYSTEMIC REACTIONS	3	37.5
FATIGUE	2	25.0
UNUSUAL HIGH-PITCHED CRYING	2	25.0
IRRITABILITY	1	12.5
WARM TO TOUCH	1	12.5

TABLE 5 (cont.)

C L I N I C A L C O M P L A I N T S B Y F R E Q U E N C Y

INVESTIGATOR : YOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
DOSE : 15 MCG
POPULATION : HEALTHY CHILDREN
AGE RANGE : 19-59 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	24	
VACCINEES WITH NO COMPLAINTS :	11	(45.8 %)
VACCINEES WITH COMPLAINTS :	13	(54.2 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 24 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	8	33.3
PAIN/SORENESS, INJ. SITE	6	25.0
ERYTHEMA, INJ. SITE (<=1 IN.)	5	20.8
SWELLING, INJ. SITE (<=1 IN.)	4	16.7
WARMTH, INJECTION SITE	1	4.2
SYSTEMIC REACTIONS	9	37.5
IRRITABILITY	4	16.7
FATIGUE	3	12.5
DIARRHEA	2	8.3
VOMITING	2	8.3
WARM TO TOUCH	2	8.3
INFECTIOUS GASTROENTERITIS	1	4.2
RASH	1	4.2
WHEEZING	1	4.2

TABLE 5 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : YOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
DOSE : 30 MCG
POPULATION : HEALTHY CHILDREN
AGE RANGE : 7-12 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES	6	
VACCINEES WITH NO COMPLAINTS	2	(100.0 %)
VACCINEES WITH COMPLAINTS	0	(0.0 %)
VACCINEES WITH NO DATA	4	

CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 2 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	0	0.0

TABLE 5 (cont.)

C L I N I C A L C O M P L A I N T S B Y F R E Q U E N C Y

INVESTIGATOR : YOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
DOSE : 30 MCG
POPULATION : HEALTHY CHILDREN
AGE RANGE : 13-18 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	1	
VACCINEES WITH NO COMPLAINTS :	1	(100.0 %)
VACCINEES WITH COMPLAINTS :	0	(0.0 %)
VACCINEES WITH NO DATA :	0	

CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 1 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	0	0.0

TABLE 5 (cont.)

C L I N I C A L C O M P L A I N T S B Y F R E Q U E N C Y

INVESTIGATOR : VOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
DOSE : 30 MCG
POPULATION : HEALTHY CHILDREN
AGE RANGE : 19-59 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	21	
VACCINEES WITH NO COMPLAINTS :	13	(61.9 %)
VACCINEES WITH COMPLAINTS :	8	(38.1 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 21 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	7	33.3
PAIN/SORENESS, INJ. SITE	4	19.0
SWELLING, INJ. SITE (<=1 IN.)	3	14.3
ERYTHEMA, INJ. SITE (<=1 IN.)	2	9.5
SYSTEMIC REACTIONS	4	19.0
WARM TO TOUCH	2	9.5
FATIGUE	1	4.8
IRRITABILITY	1	4.8
WHEEZING	1	4.8

TABLE 6

CLINICAL COMPLAINTS

INVESTIGATOR : YOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
DOSE : 7.5 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2- 6 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (25 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
LOCAL REACTIONS	2 (8.0%)	6 (24.0%)	2 (10.0%)	1 (5.0%)	1 (5.0%)	1 (5.0%)		7 (28.0%)
ERYTHEMA, INJ. SITE (<=1 IN.)	2 (8.0%)	6 (24.0%)	2 (10.0%)	1 (5.0%)	1 (5.0%)	1 (5.0%)		7 (28.0%)
SWELLING, INJ. SITE (<=1 IN.)	0 (0.0%)	4 (16.0%)	1 (5.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		4 (16.0%)
SYSTEMIC	5 (20.0%)	5 (20.0%)	1 (5.0%)	1 (5.0%)	4 (20.0%)	2 (10.0%)		10 (40.0%)
BODY AS A WHOLE/SITE UNSPEC.	3 (12.0%)	2 (8.0%)	0 (0.0%)	0 (0.0%)	1 (5.0%)	1 (5.0%)		5 (20.0%)
FATIGUE	1 (4.0%)	1 (4.0%)	0 (0.0%)	0 (0.0%)	1 (5.0%)	1 (5.0%)		3 (12.0%)
WARM TO TOUCH	2 (8.0%)	1 (4.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (8.0%)
DIGESTIVE SYSTEM	1 (4.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (5.0%)	1 (5.0%)		3 (12.0%)
DIARRHEA	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (5.0%)	1 (5.0%)		2 (8.0%)
VOMITING	1 (4.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (5.0%)		2 (8.0%)
NERVOUS SYSTEM & PSYCHIATRIC	2 (8.0%)	2 (8.0%)	1 (5.0%)	1 (5.0%)	3 (15.0%)	1 (5.0%)		6 (24.0%)

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : YOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
DOSE : 7.5 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2- 6 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (25 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
IRRITABILITY	2 (8.0%)	2 (8.0%)	1 (5.0%)	1 (5.0%)	3 (15.0%)	1 (5.0%)		6 (24.0%)
RESPIRATORY SYSTEM	0 (0.0%)	1 (4.0%)	1 (5.0%)	1 (5.0%)	1 (5.0%)	1 (5.0%)		3 (12.0%)
BRONCHIOLITIS, ACUTE	0 (0.0%)	1 (4.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (4.0%)
COMMON COLD	0 (0.0%)	0 (0.0%)	1 (5.0%)	1 (5.0%)	1 (5.0%)	1 (5.0%)		2 (8.0%)
NASAL CONGESTION	0 (0.0%)	0 (0.0%)	1 (5.0%)	1 (5.0%)	0 (0.0%)	0 (0.0%)		1 (4.0%)
SNEEZING	0 (0.0%)	0 (0.0%)	1 (5.0%)	1 (5.0%)	0 (0.0%)	0 (0.0%)		1 (4.0%)
WHEEZING	0 (0.0%)	1 (4.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (4.0%)
SKIN & SKIN APPENDAGE	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (10.0%)	0 (0.0%)		2 (8.0%)
ATOPIC DERMATITIS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (5.0%)	0 (0.0%)		1 (4.0%)
RASH	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (5.0%)	0 (0.0%)		1 (4.0%)
SPECIAL SENSES	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (5.0%)		1 (4.0%)
EAR FLUID	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (5.0%)		1 (4.0%)

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : YOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
DOSE : 7.5 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2- 6 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (25 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS **********
VACCINEES WITH COMPLAINTS	5 (20.0%)	8 (32.0%)	3 (15.0%)	2 (10.0%)	5 (25.0%)	2 (10.0%)		11 (44.0%)
VACCINEES WITH NO COMPLAINTS	20 (80.0%)	17 (68.0%)	17 (85.0%)	18 (90.0%)	15 (75.0%)	18 (90.0%)		14 (56.0%)
TOTAL VACCINEES REPORTING	25	25	20	20	20	20		25
VACCINEES WITH NO DATA	0	0	5	5	5	5		0

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : YOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
DOSE : 7.5 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2- 6 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (3 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		**********
VACCINEES WITH COMPLAINTS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)
VACCINEES WITH NO COMPLAINTS	3 (100.0%)	3 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		3 (100.0%)
TOTAL VACCINEES REPORTING	3	3	0	0	0	0		3
VACCINEES WITH NO DATA	0	0	3	3	3	3		0

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : YOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
DOSE : 7.5 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 7-12 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (27 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
LOCAL REACTIONS	6 (22.2%)	12 (44.4%)	9 (40.9%)	4 (18.2%)	2 (9.1%)	2 (9.1%)		14 (51.9%)
ERYTHEMA, INJ. SITE (<=1 IN.)	2 (7.4%)	9 (33.3%)	6 (27.3%)	2 (9.1%)	1 (4.5%)	1 (4.5%)		10 (37.0%)
PAIN/SORENESS, INJ. SITE	3 (11.1%)	4 (14.8%)	3 (13.6%)	1 (4.5%)	1 (4.5%)	1 (4.5%)		5 (18.5%)
SWELLING, INJ. SITE (<=1 IN.)	3 (11.1%)	2 (7.4%)	4 (18.2%)	3 (13.6%)	2 (9.1%)	2 (9.1%)		5 (18.5%)
SYSTEMIC	6 (22.2%)	4 (14.8%)	8 (36.4%)	5 (22.7%)	4 (18.2%)	4 (18.2%)		10 (37.0%)
BODY AS A WHOLE/SITE UNSPEC.	4 (14.8%)	1 (3.7%)	3 (13.6%)	3 (13.6%)	2 (9.1%)	2 (9.1%)		4 (14.8%)
FATIGUE	2 (7.4%)	1 (3.7%)	1 (4.5%)	2 (9.1%)	1 (4.5%)	1 (4.5%)		2 (7.4%)
WARM TO TOUCH	4 (14.8%)	1 (3.7%)	2 (9.1%)	1 (4.5%)	1 (4.5%)	1 (4.5%)		4 (14.8%)
DIGESTIVE SYSTEM	3 (11.1%)	1 (3.7%)	1 (4.5%)	2 (9.1%)	1 (4.5%)	1 (4.5%)		4 (14.8%)
ANOREXIA	1 (3.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (3.7%)
DIARRHEA	1 (3.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (3.7%)

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : VOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
DOSE : 7.5 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 7-12 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (27 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		
NAUSEA	1 (3.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (3.7%)
TEETHING	1 (3.7%)	1 (3.7%)	1 (4.5%)	1 (4.5%)	1 (4.5%)	1 (4.5%)		1 (3.7%)
VOMITING	1 (3.7%)	0 (0.0%)	0 (0.0%)	1 (4.5%)	0 (0.0%)	0 (0.0%)		2 (7.4%)
NERVOUS SYSTEM & PSYCHIATRIC	2 (7.4%)	3 (11.1%)	4 (18.2%)	1 (4.5%)	1 (4.5%)	1 (4.5%)		5 (18.5%)
CRYING, EXCESSIVE	1 (3.7%)	1 (3.7%)	1 (4.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (3.7%)
INSOMNIA	0 (0.0%)	1 (3.7%)	1 (4.5%)	1 (4.5%)	1 (4.5%)	0 (0.0%)		1 (3.7%)
IRRITABILITY	1 (3.7%)	2 (7.4%)	3 (13.6%)	1 (4.5%)	1 (4.5%)	1 (4.5%)		4 (14.8%)
RESPIRATORY SYSTEM	1 (3.7%)	1 (3.7%)	2 (9.1%)	2 (9.1%)	2 (9.1%)	2 (9.1%)		3 (11.1%)
WHEEZING	1 (3.7%)	1 (3.7%)	2 (9.1%)	2 (9.1%)	2 (9.1%)	2 (9.1%)		3 (11.1%)
SKIN & SKIN APPENDAGE	0 (0.0%)	0 (0.0%)	1 (4.5%)	1 (4.5%)	1 (4.5%)	1 (4.5%)		1 (3.7%)
RASH	0 (0.0%)	0 (0.0%)	1 (4.5%)	1 (4.5%)	1 (4.5%)	1 (4.5%)		1 (3.7%)
VACCINEES WITH COMPLAINTS	10 (37.0%)	13 (48.1%)	12 (54.5%)	8 (36.4%)	5 (22.7%)	5 (22.7%)		16 (59.3%)

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : YOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
DOSE : 7.5 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 7-12 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (27 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		**********
VACCINEES WITH NO COMPLAINTS	17 (63.0%)	14 (51.9%)	10 (45.5%)	14 (63.6%)	17 (77.3%)	17 (77.3%)		11 (40.7%)
TOTAL VACCINEES REPORTING	27	27	22	22	22	22		27
VACCINEES WITH NO DATA	0	0	5	5	5	5		0

011643

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : YOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
DOSE : 7.5 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 7-12 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (3 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		**********
VACCINEES WITH COMPLAINTS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)
VACCINEES WITH NO COMPLAINTS	2 (100.0%)	2 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)		2 (100.0%)
TOTAL VACCINEES REPORTING	2	2	1	1	1	1		2
VACCINEES WITH NO DATA	1	1	2	2	2	2		1

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : YOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
DOSE : 7.5 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 13-18 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (8 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		
LOCAL REACTIONS	1 (12.5%)	2 (25.0%)	0 (0.0%)	1 (14.3%)	1 (14.3%)	1 (14.3%)		2 (25.0%)
ERYTHEMA, INJ. SITE (<=1 IN.)	0 (0.0%)	1 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (12.5%)
PAIN/SORENESS, INJ. SITE	0 (0.0%)	1 (12.5%)	0 (0.0%)	1 (14.3%)	1 (14.3%)	1 (14.3%)		1 (12.5%)
SWELLING, INJ. SITE (<=1 IN.)	1 (12.5%)	1 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (25.0%)
SYSTEMIC	1 (12.5%)	1 (12.5%)	1 (14.3%)	1 (14.3%)	1 (14.3%)	1 (14.3%)		3 (37.5%)
BODY AS A WHOLE/SITE UNSPEC.	1 (12.5%)	1 (12.5%)	0 (0.0%)	1 (14.3%)	1 (14.3%)	1 (14.3%)		3 (37.5%)
FATIGUE	1 (12.5%)	1 (12.5%)	0 (0.0%)	1 (14.3%)	1 (14.3%)	1 (14.3%)		3 (37.5%)
WARM TO TOUCH	1 (12.5%)	0 (0.0%)	0 (0.0%)	1 (14.3%)	1 (14.3%)	1 (14.3%)		2 (25.0%)
DIGESTIVE SYSTEM	1 (12.5%)	0 (0.0%)	1 (14.3%)	1 (14.3%)	1 (14.3%)	1 (14.3%)		2 (25.0%)
DIARRHEA	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (14.3%)		1 (12.5%)
NAUSEA	1 (12.5%)	0 (0.0%)	0 (0.0%)	1 (14.3%)	1 (14.3%)	1 (14.3%)		2 (25.0%)

01166

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : YOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
DOSE : 7.5 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 13-18 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (8 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
VOMITING	1 (12.5%)	0 (0.0%)	1 (14.3%)	1 (14.3%)	1 (14.3%)	1 (14.3%)		2 (25.0%)
NERVOUS SYSTEM & PSYCHIATRIC	1 (12.5%)	1 (12.5%)	0 (0.0%)	1 (14.3%)	1 (14.3%)	1 (14.3%)		3 (37.5%)
IRRITABILITY	0 (0.0%)	1 (12.5%)	0 (0.0%)	1 (14.3%)	1 (14.3%)	1 (14.3%)		2 (25.0%)
PROLONGED CRYING, >1/2 HR	1 (12.5%)	0 (0.0%)	0 (0.0%)	1 (14.3%)	1 (14.3%)	1 (14.3%)		2 (25.0%)
UNUSUAL HIGH-PITCHED CRYING	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (14.3%)	1 (14.3%)	1 (14.3%)		1 (12.5%)
RESPIRATORY SYSTEM	1 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (12.5%)
WHEEZING	1 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (12.5%)
VACCINEES WITH COMPLAINTS	1 (12.5%)	3 (37.5%)	1 (14.3%)	2 (28.6%)	2 (28.6%)	2 (28.6%)		4 (50.0%)
VACCINEES WITH NO COMPLAINTS	7 (87.5%)	5 (62.5%)	6 (85.7%)	5 (71.4%)	5 (71.4%)	5 (71.4%)		4 (50.0%)
TOTAL VACCINEES REPORTING	8	8	7	7	7	7		8
VACCINEES WITH NO DATA	0	0	1	1	1	1		0

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : YOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
DOSE : 7.5 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 13-18 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (2 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		**********
VACCINEES WITH COMPLAINTS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)
VACCINEES WITH NO COMPLAINTS	2 (100.0%)	2 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)		2 (100.0%)
TOTAL VACCINEES REPORTING	2	2	1	1	1	1		2
VACCINEES WITH NO DATA	0	0	1	1	1	1		0

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : YOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
DOSE : 7.5 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 19-59 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (24 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5	COMPLAINTS
LOCAL REACTIONS	2 (8.3%)	2 (8.3%)	1 (5.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (12.5%)
ERYTHEMA, INJ. SITE (<=1 IN.)	1 (4.2%)	1 (4.2%)	1 (5.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (4.2%)
PAIN/SORENESS, INJ. SITE	1 (4.2%)	1 (4.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (8.3%)
SWELLING, INJ. SITE (<=1 IN.)	2 (8.3%)	1 (4.2%)	1 (5.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (8.3%)
SYSTEMIC	3 (12.5%)	5 (20.8%)	3 (15.0%)	2 (10.0%)	2 (10.0%)	2 (10.0%)	5 (20.8%)
BODY AS A WHOLE/SITE UNSPEC.	1 (4.2%)	2 (8.3%)	2 (10.0%)	1 (5.0%)	1 (5.0%)	1 (5.0%)	2 (8.3%)
FATIGUE	1 (4.2%)	1 (4.2%)	1 (5.0%)	1 (5.0%)	1 (5.0%)	0 (0.0%)	1 (4.2%)
HARM TO TOUCH	1 (4.2%)	2 (8.3%)	2 (10.0%)	0 (0.0%)	1 (5.0%)	1 (5.0%)	2 (8.3%)
NERVOUS SYSTEM & PSYCHIATRIC	2 (8.3%)	4 (16.7%)	2 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (16.7%)
IRRITABILITY	2 (8.3%)	4 (16.7%)	2 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (16.7%)
SKIN & SKIN APPENDAGE	1 (4.2%)	1 (4.2%)	1 (5.0%)	1 (5.0%)	1 (5.0%)	1 (5.0%)	1 (4.2%)

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : YOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
DOSE : 7.5 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 19-59 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (24 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
URTICARIA	1 (4.2%)	1 (4.2%)	1 (5.0%)	1 (5.0%)	1 (5.0%)	1 (5.0%)		1 (4.2%)
VACCINEES WITH COMPLAINTS	4 (16.7%)	5 (20.8%)	3 (15.0%)	2 (10.0%)	2 (10.0%)	2 (10.0%)		6 (25.0%)
VACCINEES WITH NO COMPLAINTS	20 (83.3%)	19 (79.2%)	17 (85.0%)	18 (90.0%)	18 (90.0%)	18 (90.0%)		18 (75.0%)
TOTAL VACCINEES REPORTING	24	24	20	20	20	20		24
VACCINEES WITH NO DATA	0	0	4	4	4	4		0

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : YOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
DOSE : 15 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2- 6 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (17 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		
LOCAL REACTIONS	4 (23.5%)	7 (41.2%)	4 (25.0%)	1 (6.3%)	1 (6.3%)	1 (6.3%)		8 (47.1%)
ERYTHEMA, INJ. SITE (>1 INCH)	0 (0.0%)	1 (5.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (5.9%)
ERYTHEMA, INJ. SITE (<=1 IN.)	3 (17.6%)	5 (29.4%)	3 (18.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		7 (41.2%)
SWELLING, INJ. SITE (<=1 IN.)	2 (11.8%)	2 (11.8%)	2 (12.5%)	1 (6.3%)	1 (6.3%)	1 (6.3%)		4 (23.5%)
SYSTEMIC	5 (29.4%)	4 (23.5%)	4 (25.0%)	4 (25.0%)	4 (25.0%)	4 (25.0%)		10 (58.8%)
BODY AS A WHOLE/SITE UNSPEC.	5 (29.4%)	3 (17.6%)	3 (18.8%)	1 (6.3%)	2 (12.5%)	2 (12.5%)		9 (52.9%)
FATIGUE	2 (11.8%)	2 (11.8%)	2 (12.5%)	1 (6.3%)	2 (12.5%)	1 (6.3%)		4 (23.5%)
WARM TO TOUCH	4 (23.5%)	2 (11.8%)	1 (6.3%)	0 (0.0%)	0 (0.0%)	1 (6.3%)		7 (41.2%)
DIGESTIVE SYSTEM	0 (0.0%)	0 (0.0%)	1 (6.3%)	1 (6.3%)	1 (6.3%)	2 (12.5%)		2 (11.8%)
TEETHING	0 (0.0%)	0 (0.0%)	1 (6.3%)	1 (6.3%)	1 (6.3%)	1 (6.3%)		1 (5.9%)
VOMITING	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (6.3%)		1 (5.9%)

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : YOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
DOSE : 15 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2- 6 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (17 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		
NERVOUS SYSTEM & PSYCHIATRIC	3 (17.6%)	1 (5.9%)	3 (18.8%)	2 (12.5%)	1 (6.3%)	1 (6.3%)		7 (41.2%)
IRRITABILITY	2 (11.8%)	1 (5.9%)	3 (18.8%)	2 (12.5%)	1 (6.3%)	0 (0.0%)		7 (41.2%)
PROLONGED CRYING, >1/2 HR	0 (0.0%)	0 (0.0%)	1 (6.3%)	1 (6.3%)	1 (6.3%)	1 (6.3%)		1 (5.9%)
UNUSUAL HIGH-PITCHED CRYING	1 (5.9%)	1 (5.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (5.9%)
RESPIRATORY SYSTEM	0 (0.0%)	1 (5.9%)	1 (6.3%)	1 (6.3%)	1 (6.3%)	1 (6.3%)		1 (5.9%)
COUGH	0 (0.0%)	1 (5.9%)	1 (6.3%)	1 (6.3%)	1 (6.3%)	1 (6.3%)		1 (5.9%)
NASAL DISCHARGE	0 (0.0%)	1 (5.9%)	1 (6.3%)	0 (0.0%)	0 (0.0%)	1 (6.3%)		1 (5.9%)
SKIN & SKIN APPENDAGE	1 (5.9%)	0 (0.0%)	0 (0.0%)	1 (6.3%)	1 (6.3%)	1 (6.3%)		2 (11.8%)
HYPERHYDROSIS	1 (5.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (5.9%)
RASH	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (6.3%)	1 (6.3%)	1 (6.3%)		1 (5.9%)
VACCINEES WITH COMPLAINTS	7 (41.2%)	9 (52.9%)	7 (43.8%)	4 (25.0%)	4 (25.0%)	4 (25.0%)		11 (64.7%)
VACCINEES WITH NO COMPLAINTS	10 (58.8%)	8 (47.1%)	9 (56.3%)	12 (75.0%)	12 (75.0%)	12 (75.0%)		6 (35.3%)

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : YOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
DOSE : 15 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2- 6 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (17 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		**********
TOTAL VACCINEES REPORTING	17	17	16	16	16	16		17
VACCINEES WITH NO DATA	0	0	1	1	1	1		0

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : YOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
DOSE : 15 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2- 6 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (5 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		
LOCAL REACTIONS	0 (0.0%)	1 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (25.0%)
ERYTHEMA, INJ. SITE (<=1 IN.)	0 (0.0%)	1 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (25.0%)
PAIN/SORENESS, INJ. SITE	0 (0.0%)	1 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (25.0%)
SYSTEMIC	1 (25.0%)	2 (50.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (50.0%)
BODY AS A WHOLE/SITE UNSPEC.	1 (25.0%)	1 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (25.0%)
FEVER	1 (25.0%)	1 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (25.0%)
NERVOUS SYSTEM & PSYCHIATRIC	0 (0.0%)	1 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (25.0%)
IRRITABILITY	0 (0.0%)	1 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (25.0%)
VACCINEES WITH COMPLAINTS	1 (25.0%)	3 (75.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		3 (75.0%)
VACCINEES WITH NO COMPLAINTS	3 (75.0%)	1 (25.0%)	2 (100.0%)	2 (100.0%)	2 (100.0%)	2 (100.0%)		1 (25.0%)
TOTAL VACCINEES REPORTING	4	4	2	2	2	2		4

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : YOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
DOSE : 15 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2- 6 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (5 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
VACCINEES WITH NO DATA	1	1	3	3	3	3		1

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : VOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
DOSE : 15 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 7-12 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (16 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
LOCAL REACTIONS	3 (18.8%)	5 (31.3%)	5 (35.7%)	2 (15.4%)	1 (7.7%)	1 (7.7%)		6 (37.5%)
ERYTHEMA, INJ. SITE (<=1 IN.)	3 (18.8%)	4 (25.0%)	5 (35.7%)	1 (7.7%)	0 (0.0%)	0 (0.0%)		5 (31.3%)
SWELLING, INJ. SITE (<=1 IN.)	1 (6.3%)	2 (12.5%)	2 (14.3%)	1 (7.7%)	1 (7.7%)	1 (7.7%)		3 (18.8%)
SYSTEMIC	4 (25.0%)	5 (31.3%)	4 (28.6%)	4 (30.8%)	2 (15.4%)	1 (7.7%)		9 (56.3%)
BODY AS A WHOLE/SITE UNSPEC.	1 (6.3%)	2 (12.5%)	2 (14.3%)	1 (7.7%)	0 (0.0%)	0 (0.0%)		2 (12.5%)
WARM TO TOUCH	1 (6.3%)	2 (12.5%)	2 (14.3%)	1 (7.7%)	0 (0.0%)	0 (0.0%)		2 (12.5%)
DIGESTIVE SYSTEM	1 (6.3%)	3 (18.8%)	2 (14.3%)	1 (7.7%)	0 (0.0%)	0 (0.0%)		4 (25.0%)
DIARRHEA	0 (0.0%)	1 (6.3%)	1 (7.1%)	1 (7.7%)	0 (0.0%)	0 (0.0%)		2 (12.5%)
NAUSEA	0 (0.0%)	1 (6.3%)	1 (7.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (6.3%)
POLYDIPSIA	0 (0.0%)	0 (0.0%)	1 (7.1%)	1 (7.7%)	0 (0.0%)	0 (0.0%)		1 (6.3%)
TEETHING	1 (6.3%)	1 (6.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (6.3%)

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : YOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
DOSE : 15 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 7-12 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (16 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		
NERVOUS SYSTEM & PSYCHIATRIC	4 (25.0%)	2 (12.5%)	2 (14.3%)	0 (0.0%)	1 (7.7%)	0 (0.0%)		5 (31.3%)
IRRITABILITY	4 (25.0%)	2 (12.5%)	1 (7.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		4 (25.0%)
UNUSUAL HIGH-PITCHED CRYING	0 (0.0%)	0 (0.0%)	1 (7.1%)	0 (0.0%)	1 (7.7%)	0 (0.0%)		1 (6.3%)
RESPIRATORY SYSTEM	0 (0.0%)	1 (6.3%)	1 (7.1%)	2 (15.4%)	1 (7.7%)	0 (0.0%)		2 (12.5%)
COMMON COLD	0 (0.0%)	1 (6.3%)	1 (7.1%)	1 (7.7%)	1 (7.7%)	0 (0.0%)		1 (6.3%)
NASAL DISCHARGE	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.7%)	0 (0.0%)	0 (0.0%)		1 (6.3%)
SNEEZING	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.7%)	0 (0.0%)	0 (0.0%)		1 (6.3%)
SKIN & SKIN APPENDAGE	0 (0.0%)	1 (6.3%)	1 (7.1%)	1 (7.7%)	1 (7.7%)	1 (7.7%)		1 (6.3%)
RASH	0 (0.0%)	1 (6.3%)	1 (7.1%)	1 (7.7%)	1 (7.7%)	1 (7.7%)		1 (6.3%)
SPECIAL SENSES	0 (0.0%)	1 (6.3%)	1 (7.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (6.3%)
OTITIS MEDIA	0 (0.0%)	1 (6.3%)	1 (7.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (6.3%)
UROGENITAL SYSTEM	0 (0.0%)	0 (0.0%)	1 (7.1%)	1 (7.7%)	0 (0.0%)	0 (0.0%)		1 (6.3%)

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : YOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
DOSE : 15 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 7-12 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (16 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		
URINARY FREQUENCY	0 (0.0%)	0 (0.0%)	1 (7.1%)	1 (7.7%)	0 (0.0%)	0 (0.0%)		1 (6.3%)
VACCINEES WITH COMPLAINTS	6 (37.5%)	8 (50.0%)	6 (42.9%)	5 (38.5%)	3 (23.1%)	2 (15.4%)		10 (62.5%)
VACCINEES WITH NO COMPLAINTS	10 (62.5%)	8 (50.0%)	8 (57.1%)	8 (61.5%)	10 (76.9%)	11 (84.6%)		6 (37.5%)
TOTAL VACCINEES REPORTING	16	16	14	13	13	13		16
VACCINEES WITH NO DATA	0	0	2	3	3	3		0

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : YOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
DOSE : 15 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 7-12 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (4 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		
LOCAL REACTIONS	0 (0.0%)	1 (33.3%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	0 (0.0%)		1 (33.3%)
ERYTHEMA, INJ. SITE (<=1 IN.)	0 (0.0%)	1 (33.3%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	0 (0.0%)		1 (33.3%)
SWELLING, INJ. SITE (<=1 IN.)	0 (0.0%)	1 (33.3%)	1 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (33.3%)
SYSTEMIC	0 (0.0%)	0 (0.0%)	1 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (33.3%)
NERVOUS SYSTEM & PSYCHIATRIC	0 (0.0%)	0 (0.0%)	1 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (33.3%)
IRRITABILITY	0 (0.0%)	0 (0.0%)	1 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (33.3%)
VACCINEES WITH COMPLAINTS	0 (0.0%)	1 (33.3%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	0 (0.0%)		1 (33.3%)
VACCINEES WITH NO COMPLAINTS	3 (100.0%)	2 (66.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (100.0%)		2 (66.7%)
TOTAL VACCINEES REPORTING	3	3	1	1	1	1		3
VACCINEES WITH NO DATA	1	1	3	3	3	3		1

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : YOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
DOSE : 15 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 13-18 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (8 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		
LOCAL REACTIONS	1 (12.5%)	1 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (12.5%)
SWELLING, INJ. SITE (<=1 IN.)	1 (12.5%)	1 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (12.5%)
SYSTEMIC	1 (12.5%)	2 (25.0%)	1 (16.7%)	1 (16.7%)	1 (16.7%)	1 (16.7%)		3 (37.5%)
BODY AS A WHOLE/SITE UNSPEC.	1 (12.5%)	2 (25.0%)	1 (16.7%)	1 (16.7%)	0 (0.0%)	0 (0.0%)		2 (25.0%)
FATIGUE	1 (12.5%)	2 (25.0%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (25.0%)
WARM TO TOUCH	0 (0.0%)	1 (12.5%)	1 (16.7%)	1 (16.7%)	0 (0.0%)	0 (0.0%)		1 (12.5%)
NERVOUS SYSTEM & PSYCHIATRIC	1 (12.5%)	1 (12.5%)	0 (0.0%)	0 (0.0%)	1 (16.7%)	1 (16.7%)		3 (37.5%)
IRRITABILITY	0 (0.0%)	1 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (12.5%)
UNUSUAL HIGH-PITCHED CRYING	1 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)	1 (16.7%)		2 (25.0%)
VACCINEES WITH COMPLAINTS	2 (25.0%)	2 (25.0%)	1 (16.7%)	1 (16.7%)	1 (16.7%)	1 (16.7%)		3 (37.5%)
VACCINEES WITH NO COMPLAINTS	6 (75.0%)	6 (75.0%)	5 (83.3%)	5 (83.3%)	5 (83.3%)	5 (83.3%)		5 (62.5%)

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : VOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
DOSE : 15 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 13-18 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (8 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS **********
TOTAL VACCINEES REPORTING	8	8	6	6	6	6		8
VACCINEES WITH NO DATA	0	0	2	2	2	2		0

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : VOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
DOSE : 15 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 13-18 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (3 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
LOCAL REACTIONS	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (33.3%)
SWELLING, INJ. SITE (<=1 IN.)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (33.3%)
SYSTEMIC	0 (0.0%)	1 (33.3%)	0 (0.0%)	1 (50.0%)	1 (50.0%)	1 (50.0%)		1 (33.3%)
BODY AS A WHOLE/SITE UNSPEC.	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (33.3%)
FATIGUE	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (33.3%)
NERVOUS SYSTEM & PSYCHIATRIC	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (50.0%)	1 (50.0%)	1 (50.0%)		1 (33.3%)
CRYING, EXCESSIVE	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (50.0%)	1 (50.0%)	0 (0.0%)		1 (33.3%)
PROLONGED CRYING, >1/2 HR	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (50.0%)	1 (50.0%)	1 (50.0%)		1 (33.3%)
VACCINEES WITH COMPLAINTS	1 (33.3%)	1 (33.3%)	0 (0.0%)	1 (50.0%)	1 (50.0%)	1 (50.0%)		1 (33.3%)
VACCINEES WITH NO COMPLAINTS	2 (66.7%)	2 (66.7%)	2 (100.0%)	1 (50.0%)	1 (50.0%)	1 (50.0%)		2 (66.7%)
TOTAL VACCINEES REPORTING	3	3	2	2	2	2		3

PATIENT COUNT CLINICAL COMPLAINTS

INVESTIGATOR : YOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
DOSE : 15 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 13-18 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (3 VACCINEES) - INJECTION: 2						
	DAYS POST VACCINATION						NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5	**********
VACCINEES WITH NO DATA	0	0	1	1	1	1	0

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : YOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
DOSE : 15 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 19-59 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (24 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5	COMPLAINTS
INFECTIOUS GASTROENTERITIS	0 (0.0%)	0 (0.0%)	1 (5.0%)	1 (5.0%)	1 (5.0%)	1 (5.0%)	1 (4.2%)
VOMITING	0 (0.0%)	0 (0.0%)	1 (5.0%)	1 (5.0%)	1 (5.0%)	2 (10.0%)	2 (8.3%)
NERVOUS SYSTEM & PSYCHIATRIC	3 (12.5%)	0 (0.0%)	0 (0.0%)	1 (5.0%)	1 (5.0%)	1 (5.0%)	4 (16.7%)
IRRITABILITY	3 (12.5%)	0 (0.0%)	0 (0.0%)	1 (5.0%)	1 (5.0%)	1 (5.0%)	4 (16.7%)
RESPIRATORY SYSTEM	0 (0.0%)	1 (4.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (4.2%)
WHEEZING	0 (0.0%)	1 (4.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (4.2%)
SKIN & SKIN APPENDAGE	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (5.0%)	1 (5.0%)	1 (5.0%)	1 (4.2%)
RASH	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (5.0%)	1 (5.0%)	1 (5.0%)	1 (4.2%)
VACCINEES WITH COMPLAINTS	9 (37.5%)	8 (33.3%)	5 (25.0%)	4 (20.0%)	3 (15.0%)	3 (15.0%)	13 (54.2%)
VACCINEES WITH NO COMPLAINTS	15 (62.5%)	16 (66.7%)	15 (75.0%)	16 (80.0%)	17 (85.0%)	17 (85.0%)	11 (45.8%)
TOTAL VACCINEES REPORTING	24	24	20	20	20	20	24

011984

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : YOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
DOSE : 15 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 19-59 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (24 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5	COMPLAINTS
VACCINEES WITH NO DATA	0	0	4	4	4	4	0

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : YOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
DOSE : 30 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 7-12 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (6 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS **********
VACCINEES WITH COMPLAINTS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)
VACCINEES WITH NO COMPLAINTS	2 (100.0%)	2 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (100.0%)
TOTAL VACCINEES REPORTING	2	2	0	0	0	0		2
VACCINEES WITH NO DATA	4	4	6	6	6	6		4

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : YOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
DOSE : 30 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 13-18 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (1 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		**********
VACCINEES WITH COMPLAINTS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)
VACCINEES WITH NO COMPLAINTS	1 (100.0%)	1 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (100.0%)
TOTAL VACCINEES REPORTING	1	1	0	0	0	0		1
VACCINEES WITH NO DATA	0	0	1	1	1	1		0

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : YOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
DOSE : 30 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 19-59 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (21 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5	COMPLAINTS
LOCAL REACTIONS	5 (23.8%)	5 (23.8%)	1 (5.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	7 (33.3%)
ERYTHEMA, INJ. SITE (<=1 IN.)	0 (0.0%)	2 (9.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (9.5%)
PAIN/SORENESS, INJ. SITE	4 (19.0%)	3 (14.3%)	1 (5.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (19.0%)
SWELLING, INJ. SITE (<=1 IN.)	3 (14.3%)	2 (9.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (14.3%)
SYSTEMIC	3 (14.3%)	0 (0.0%)	1 (5.3%)	1 (5.3%)	1 (5.3%)	1 (5.3%)	4 (19.0%)
BODY AS A WHOLE/SITE UNSPEC.	3 (14.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (14.3%)
FATIGUE	1 (4.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (4.8%)
HARM TO TOUCH	2 (9.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (9.5%)
NERVOUS SYSTEM & PSYCHIATRIC	1 (4.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (4.8%)
IRRITABILITY	1 (4.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (4.8%)
RESPIRATORY SYSTEM	0 (0.0%)	0 (0.0%)	1 (5.3%)	1 (5.3%)	1 (5.3%)	1 (5.3%)	1 (4.8%)

TABLE 6 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : YOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
DOSE : 30 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 19-59 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (21 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
WHEEZING	0 (0.0%)	0 (0.0%)	1 (5.3%)	1 (5.3%)	1 (5.3%)	1 (5.3%)		1 (4.8%)
VACCINEES WITH COMPLAINTS	6 (28.6%)	5 (23.8%)	2 (10.5%)	1 (5.3%)	1 (5.3%)	1 (5.3%)		8 (38.1%)
VACCINEES WITH NO COMPLAINTS	15 (71.4%)	16 (76.2%)	17 (89.5%)	18 (94.7%)	18 (94.7%)	18 (94.7%)		13 (61.9%)
TOTAL VACCINEES REPORTING	21	21	19	19	19	19		21
VACCINEES WITH NO DATA	0	0	2	2	2	2		0

01189

TABLE 7

MAXIMUM TEMPERATURES

INVESTIGATOR : YOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
DOSE : 7.5 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2- 6 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (25 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
NORMAL	2 (10.0%)	2 (10.0%)	2 (10.0%)	2 (10.0%)	2 (10.0%)	2 (10.0%)		2 (10.0%)
≤ 99	11 (55.0%)	14 (70.0%)	14 (70.0%)	15 (75.0%)	15 (75.0%)	13 (65.0%)		9 (45.0%)
99 - 99.9	3 (15.0%)	2 (10.0%)	3 (15.0%)	3 (15.0%)	3 (15.0%)	3 (15.0%)		3 (15.0%)
100 - 100.9	4 (20.0%)	2 (10.0%)	1 (5.0%)	0 (0.0%)	0 (0.0%)	1 (5.0%)		5 (25.0%)
101 - 101.9	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (5.0%)		1 (5.0%)
TEMPERATURE TAKEN	20 (80.0%)	20 (80.0%)	20 (80.0%)	20 (80.0%)	20 (80.0%)	20 (80.0%)		20 (80.0%)
TEMPERATURE NOT TAKEN	5 (20.0%)	5 (20.0%)	5 (20.0%)	5 (20.0%)	5 (20.0%)	5 (20.0%)		5 (20.0%)

TABLE 7 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : YOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
DOSE : 7.5 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 7-12 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (27 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
NORMAL	3 (14.3%)	2 (10.0%)	2 (10.0%)	2 (10.0%)	2 (10.0%)	2 (10.0%)		2 (9.5%)
< 99	14 (66.7%)	14 (70.0%)	13 (65.0%)	14 (70.0%)	16 (80.0%)	17 (85.0%)		11 (52.4%)
99 - 99.9	3 (14.3%)	3 (15.0%)	5 (25.0%)	3 (15.0%)	1 (5.0%)	0 (0.0%)		5 (23.8%)
100 - 100.9	1 (4.8%)	1 (5.0%)	0 (0.0%)	1 (5.0%)	1 (5.0%)	1 (5.0%)		3 (14.3%)
TEMPERATURE TAKEN	21 (77.8%)	20 (74.1%)	20 (74.1%)	20 (74.1%)	20 (74.1%)	20 (74.1%)		21 (77.8%)
TEMPERATURE NOT TAKEN	6 (22.2%)	7 (25.9%)	7 (25.9%)	7 (25.9%)	7 (25.9%)	7 (25.9%)		6 (22.2%)

TABLE 7 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : YOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
DOSE : 7.5 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 13-18 MOS.

VACCINE : HIB CONJUGATE — NUMBER OF VACCINEES (8 VACCINEES) - INJECTION 1

MAX TEMPERATURE (DEG F, ORAL)	DAYS POST VACCINATION 0	1	2	3	4	5		NUMBER WITH MAX TEMP
NORMAL	2 (33.3%)	2 (28.6%)	2 (28.6%)	2 (28.6%)	2 (28.6%)	2 (28.6%)		2 (28.6%)
< 99	3 (50.0%)	3 (42.9%)	4 (57.1%)	1 (14.3%)	2 (28.6%)	2 (28.6%)		0 (0.0%)
99 - 99.9	0 (0.0%)	2 (28.6%)	1 (14.3%)	4 (57.1%)	2 (28.6%)	2 (28.6%)		3 (42.9%)
100 - 100.9	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (14.3%)	0 (0.0%)		1 (14.3%)
101 - 101.9	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (14.3%)		0 (0.0%)
102 - 102.9	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (14.3%)
TEMPERATURE TAKEN	6 (75.0%)	7 (87.5%)	7 (87.5%)	7 (87.5%)	7 (87.5%)	7 (87.5%)		7 (87.5%)
TEMPERATURE NOT TAKEN	2 (25.0%)	1 (12.5%)	1 (12.5%)	1 (12.5%)	1 (12.5%)	1 (12.5%)		1 (12.5%)

TABLE 7 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : YOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
DOSE : 7.5 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 13-18 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (2 VACCINEES) - INJECTION 2							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
< 99	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)		1 (100.0%)
TEMPERATURE TAKEN	1 (50.0%)	1 (50.0%)	1 (50.0%)	1 (50.0%)	1 (50.0%)	1 (50.0%)		1 (50.0%)
TEMPERATURE NOT TAKEN	1 (50.0%)	1 (50.0%)	1 (50.0%)	1 (50.0%)	1 (50.0%)	1 (50.0%)		1 (50.0%)

TABLE 7 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : YOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
DOSE : 7.5 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 19-59 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (24 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		WITH MAX TEMP
NORMAL	7 (38.9%)	7 (38.9%)	8 (44.4%)	8 (44.4%)	7 (38.9%)	7 (38.9%)		7 (38.9%)
< 99	8 (44.4%)	7 (38.9%)	7 (38.9%)	7 (38.9%)	8 (44.4%)	9 (50.0%)		6 (33.3%)
99 - 99.9	2 (11.1%)	4 (22.2%)	3 (16.7%)	2 (11.1%)	1 (5.6%)	2 (11.1%)		3 (16.7%)
100 - 100.9	1 (5.6%)	0 (0.0%)	0 (0.0%)	1 (5.6%)	2 (11.1%)	0 (0.0%)		2 (11.1%)
TEMPERATURE TAKEN	18 (75.0%)	18 (75.0%)	18 (75.0%)	18 (75.0%)	18 (75.0%)	18 (75.0%)		18 (75.0%)
TEMPERATURE NOT TAKEN	6 (25.0%)	6 (25.0%)	6 (25.0%)	6 (25.0%)	6 (25.0%)	6 (25.0%)		6 (25.0%)

TABLE 7 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : YOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
DOSE : 15 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2- 6 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (17 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
NORMAL	2 (12.5%)	2 (12.5%)	2 (12.5%)	2 (12.5%)	2 (12.5%)	2 (13.3%)		2 (12.5%)
< 99	11 (68.8%)	10 (62.5%)	10 (62.5%)	10 (62.5%)	11 (68.8%)	9 (60.0%)		6 (37.5%)
99 - 99.9	3 (18.8%)	3 (18.8%)	2 (12.5%)	3 (18.8%)	3 (18.8%)	4 (26.7%)		6 (37.5%)
100 - 100.9	0 (0.0%)	1 (6.3%)	1 (6.3%)	1 (6.3%)	0 (0.0%)	0 (0.0%)		1 (6.3%)
101 - 101.9	0 (0.0%)	0 (0.0%)	1 (6.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (6.3%)
TEMPERATURE TAKEN	16 (94.1%)	16 (94.1%)	16 (94.1%)	16 (94.1%)	16 (94.1%)	15 (88.2%)		16 (94.1%)
TEMPERATURE NOT TAKEN	1 (5.9%)	1 (5.9%)	1 (5.9%)	1 (5.9%)	1 (5.9%)	2 (11.8%)		1 (5.9%)

TABLE 7 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : YOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
DOSE : 15 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2- 6 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (5 VACCINEES) - INJECTION 2							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
< 99	2 (100.0%)	2 (66.7%)	2 (100.0%)	2 (100.0%)	2 (100.0%)	2 (100.0%)		2 (66.7%)
FEVER	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (33.3%)
TEMPERATURE TAKEN	2 (40.0%)	3 (60.0%)	2 (40.0%)	2 (40.0%)	2 (40.0%)	2 (40.0%)		3 (60.0%)
TEMPERATURE NOT TAKEN	3 (60.0%)	2 (40.0%)	3 (60.0%)	3 (60.0%)	3 (60.0%)	3 (60.0%)		2 (40.0%)

TABLE 7 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : YOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
DOSE : 15 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 7-12 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (16 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
NORMAL	2 (18.2%)	2 (16.7%)	2 (16.7%)	2 (16.7%)	2 (16.7%)	2 (20.0%)		2 (16.7%)
< 99	7 (63.6%)	6 (50.0%)	8 (66.7%)	8 (66.7%)	8 (66.7%)	8 (80.0%)		5 (41.7%)
99 - 99.9	2 (18.2%)	3 (25.0%)	1 (8.3%)	2 (16.7%)	2 (16.7%)	0 (0.0%)		4 (33.3%)
101 - 101.9	0 (0.0%)	1 (8.3%)	1 (8.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (8.3%)
TEMPERATURE TAKEN	11 (68.8%)	12 (75.0%)	12 (75.0%)	12 (75.0%)	12 (75.0%)	10 (62.5%)		12 (75.0%)
TEMPERATURE NOT TAKEN	5 (31.3%)	4 (25.0%)	4 (25.0%)	4 (25.0%)	4 (25.0%)	6 (37.5%)		4 (25.0%)

TABLE 7 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : YOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
DOSE : 15 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 7-12 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (4 VACCINEES) - INJECTION 2							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
< 99	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	0 (0.0%)	1 (100.0%)		0 (0.0%)
99 - 99.9	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (100.0%)	0 (0.0%)		1 (100.0%)
TEMPERATURE TAKEN	1 (25.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)		1 (25.0%)
TEMPERATURE NOT TAKEN	3 (75.0%)	3 (75.0%)	3 (75.0%)	3 (75.0%)	3 (75.0%)	3 (75.0%)		3 (75.0%)

TABLE 7 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : YOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
DOSE : 15 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 13-18 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (8 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
NORMAL	1 (25.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)	1 (25.0%)		1 (25.0%)
< 99	0 (0.0%)	0 (0.0%)	1 (25.0%)	1 (25.0%)	0 (0.0%)	1 (25.0%)		0 (0.0%)
99 - 99.9	2 (50.0%)	2 (50.0%)	2 (50.0%)	1 (25.0%)	3 (75.0%)	2 (50.0%)		1 (25.0%)
100 - 100.9	1 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (25.0%)
101 - 101.9	0 (0.0%)	1 (25.0%)	0 (0.0%)	1 (25.0%)	0 (0.0%)	0 (0.0%)		1 (25.0%)
TEMPERATURE TAKEN	4 (50.0%)	4 (50.0%)	4 (50.0%)	4 (50.0%)	4 (50.0%)	4 (50.0%)		4 (50.0%)
TEMPERATURE NOT TAKEN	4 (50.0%)	4 (50.0%)	4 (50.0%)	4 (50.0%)	4 (50.0%)	4 (50.0%)		4 (50.0%)

TABLE 7 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : YOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
DOSE : 15 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 13-18 MOS.

VACCINE : HIB CONJUGATE

MAX TEMPERATURE (DEG F, ORAL)	NUMBER OF VACCINEES (3 VACCINEES) - INJECTION 2							NUMBER WITH MAX TEMP
	DAYS POST VACCINATION							
	0	1	2	3	4	5		
99 - 99.9	0 (0.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	0 (0.0%)		0 (0.0%)
100 - 100.9	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (100.0%)		1 (100.0%)
TEMPERATURE TAKEN	0 (0.0%)	1 (33.3%)	1 (33.3%)	1 (33.3%)	1 (33.3%)	1 (33.3%)		1 (33.3%)
TEMPERATURE NOT TAKEN	3 (100.0%)	2 (66.7%)	2 (66.7%)	2 (66.7%)	2 (66.7%)	2 (66.7%)		2 (66.7%)

TABLE 7 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : YOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
DOSE : 15 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 19-59 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (24 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5	
NORMAL	4 (22.2%)	5 (26.3%)	4 (21.1%)	4 (21.1%)	4 (21.1%)	4 (21.1%)	4 (21.1%)
< 99	10 (55.6%)	7 (36.8%)	9 (47.4%)	10 (52.6%)	11 (57.9%)	9 (47.4%)	1 (5.3%)
99 - 99.9	4 (22.2%)	7 (36.8%)	4 (21.1%)	3 (15.8%)	3 (15.8%)	4 (21.1%)	10 (52.6%)
100 - 100.9	0 (0.0%)	0 (0.0%)	1 (5.3%)	1 (5.3%)	0 (0.0%)	0 (0.0%)	2 (10.5%)
101 - 101.9	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (5.3%)	1 (5.3%)	2 (10.5%)	1 (5.3%)
102 - 102.9	0 (0.0%)	0 (0.0%)	1 (5.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (5.3%)
TEMPERATURE TAKEN	18 (75.0%)	19 (79.2%)	19 (79.2%)	19 (79.2%)	19 (79.2%)	19 (79.2%)	19 (79.2%)
TEMPERATURE NOT TAKEN	6 (25.0%)	5 (20.8%)	5 (20.8%)	5 (20.8%)	5 (20.8%)	5 (20.8%)	5 (20.8%)

TABLE 7 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : YOGEV, RAM
STUDY : 000802
VACCINE : HIB CONJUGATE
DOSE : 30 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 19-59 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (21 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		MAX TEMP
NORMAL	8 (44.4%)	8 (42.1%)	8 (42.1%)	8 (42.1%)	8 (42.1%)	8 (42.1%)		8 (42.1%)
< 99	6 (33.3%)	6 (31.6%)	8 (42.1%)	7 (36.8%)	6 (31.6%)	9 (47.4%)		5 (26.3%)
99 - 99.9	4 (22.2%)	5 (26.3%)	3 (15.8%)	4 (21.1%)	4 (21.1%)	2 (10.5%)		5 (26.3%)
100 - 100.9	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (5.3%)	0 (0.0%)		1 (5.3%)
TEMPERATURE TAKEN	18 (85.7%)	19 (90.5%)	19 (90.5%)	19 (90.5%)	19 (90.5%)	19 (90.5%)		19 (90.5%)
TEMPERATURE NOT TAKEN	3 (14.3%)	2 (9.5%)	2 (9.5%)	2 (9.5%)	2 (9.5%)	2 (9.5%)		2 (9.5%)

Haemophilus b Conjugate Vaccine
(Neisseria meningitidis Outer Membrane Protein Complex)

INTERACTION STUDIES

010-02 - Pittsburgh, PA - Ellen R. Wald, M.D.

Healthy children 13-22 months of age were randomly assigned to one of two groups. Twenty-three children received one 15 mcg dose of Lot 1080/C-P749 concurrently with MMR®II. Twenty-two children received one 15 mcg dose of Lot 1080/C-P749 and MMR®II 4 weeks apart. Of those receiving the vaccines concurrently, 94% (16/17) had developed antibody titers >1.0 mcg/ml 1 month following vaccination. The GMT prior to vaccination was 0.141 mcg/ml. The GMT at one month was 4.630 mcg/ml.

Of those children receiving the vaccines four weeks apart, 6% (1/18) had an antibody titer >1.0 mcg/ml prior to vaccination. The GMT prior to vaccination was 0.110 mcg/ml. One month following vaccination 89% (16/18) had antibody titers >1.0 mcg/ml. Two months following vaccination 88% (7/8) had antibody titers >1.0 mcg/ml. The GMT was 3.042 mcg/ml 1 month following vaccination and 2.438 mcg/ml 2 months following vaccination.

No serious adverse experiences were reported in this study.

011-01 Pittsburgh, PA - Barry Dashefsky, M.D.

Healthy children 17-24 months of age were randomly assigned to one of two groups. Twenty-three children received one 15 mcg dose of Lot 1080/C-P749 concurrently with DTP and OPV. Twenty-six children received one 15 mcg dose of Lot 1080/C-P749 and DTP/OPV four weeks apart. Of those receiving the vaccines concurrently, 6% (1/16) had antibody titer >1.0 mcg/ml prior to vaccination. The GMT prior to vaccination was 0.114 mcg/ml. One month following vaccination, 88% (14/16) had antibody levels >1.0 mcg/ml. The GMT at that time was 5.020 mcg/ml. Of those children receiving the vaccines four weeks apart, 85% (17/20) developed antibody titers >1.0 mcg/ml one month following vaccination. Two months following vaccination 75% (9/12) had antibody titers >1.0 mcg/ml. The GMT prior to vaccination was 0.079 mcg/ml. The GMT at 1 month was 5.161 mcg/ml and at 2 months 6.644 mcg/ml.

No serious adverse experiences were reported in this study.

STUDY 010-02

PROGRAM: Haemophilus b Conjugate Vaccine, (Neisseria meningitidis Outer Membrane Protein Complex), Study 010-02

PURPOSE: To compare clinical reaction rates and antibody responses to Haemophilus b conjugate vaccine (Neisseria meningitidis outer membrane protein complex) and measles, mumps, and rubella virus vaccine (MMR) administered concurrently or at separate times.

VACCINES:

1. Haemophilus b Conjugate Vaccine (Neisseria meningitidis Outer Membrane Protein Complex) (PRP-OMPC)

   Lot 1080/C-P749 - (b) (4) mcg polysaccharide/ml
   mcg meningococcal protein/ml

   Aluminum hydroxide diluent
   Lot (b) (4)

2. Measles, Mumps and Rubella Virus Vaccine

   MMR®II
   Merck Sharp & Dohme
   Lot 0331P

INVESTIGATOR: Ellen R. Wald, M.D.
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SUB-INVESTIGATOR: Barry Dashefsky, M.D.
Michael Green, M.D.
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3705 Fifth Avenue
Pittsburgh, PA 15213

STUDY LOCATION: Children's Hospital of Pittsburgh
3705 Fifth Avenue
Pittsburgh, PA 15213

DATE INITIATED: March 30, 1988

DATE COMPLETED: In progress.

STUDY POPULATION: Healthy children at least 15 months of age who have not previously received MMR vaccine are included in the study.

STUDY PROCEDURE: Children are randomly assigned to receive PRP-OMPC and MMR vaccines at the same time (at separate sites) or 4 weeks apart. Approximately 75 children are assigned to each regimen.

All children receive a single 0.5 ml (15 mcg polysaccharide) injection of PRP-OMPC vaccine reconstituted in aluminum hydroxide. A single 0.5 ml subcutaneous injection of MMR is given at the same time as PRP-OMPC vaccine (at a separate site) or 4 weeks later.

The parent or guardian is required to record the vaccine recipient's temperature and any reactions at the injection site or systemic complaints for 5 days after each injection of vaccine. Unexpected or serious reactions are to be reported immediately to the study physician. Serious adverse experiences in the 14 days following each injection of vaccine are required to be reported by the investigator.

A blood sample is obtained immediately prior to and 1 month after each injection of vaccine. All serum samples are assayed for antibody to the capsular polysaccharide of Haemophilus influenzae type b radioimmunoassay, measles and rubella virus by hemagglutination inhibition assay and mumps virus by ELISA. Selected samples are also tested for bactericidal and opsonophagocytic activity, immunoglobulin isotype and subclass IgG. Assays for opsonophagocytic activity are performed at the University of Alabama. All other assays are performed at Merck Sharp and Dohme Research Laboratories.

RESULTS: Demographic information and individual pre and postimmunization antibody data for each vaccine recipient are presented in Tables 1-3.

1. Current status:

Regimen	No. Vaccinated PRP-OMPC	MMR
Concurrent	23	23
Separate	22	10

2. Serologic results:

Anti-PRP responses prior to and 1 month after PRP-OMPC vaccination are as follows:

Regimen	Time	% With Anti-PRP >0.15 mcg/ml	% With Anti-PRP >1.0 mcg/ml	GMT (mcg/ml) All Vaccinees
Concurrent	Pre	47 (8/17)	0 (0/17)	0.14
	Post	100 (17/17)	94 (16/17)	4.63
Separate	Pre	22 (4/18)	6 (1/18)	0.11
	Post	100 (18/18)	89 (16/18)	3.04

Antibody responses to PRP, measles, mumps and rubella are presented in Tables 4-6.

3. Clinical results:

The incidence of selected injection site and systemic reactions occurring within 2 days after vaccination are as follows:

RESULTS
(CONT.)

Type of Reaction	% of Vaccinees with Reaction			
	Concurrent		Separate	
Injection Site:	PRP-OMPC	MMR	PRP-OMPC	MMR
Pain/Soreness	13 (3/23)	0 (0/23)	5 (1/22)	10 (1/10)
Erythema > 1 inch	4 (1/23)	0 (0/23)	0 (0/22)	0 (0/10)
Swelling > 1 inch	0 (0/23)	0 (0/23)	0 (0/22)	0 (0/10)
Induration	0 (0/23)	0 (0/23)	0 (0/22)	0 (0/10)
Systemic:			PRP-OMPC	MMR
Irritability	22 (5/23)		36 (8/22)	10 (1/10)
Sleepiness/Lethargy/ Fatigue	9 (2/23)		9 (2/22)	10 (1/10)

The frequencies of all clinical reactions and maximum temperatures occurring during the five days following each injection of PRP-OMC vaccine and/or MMR vaccine are presented in Tables 7-9.

No serious or alarming reactions attributable to vaccine have been reported.

TABLE 1

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : WALD,ELLEN
STUDY : 001002
VACCINE : HIB/MMR CONCURRENTLY
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	IGG1
(b) (6)	M	BLAC	(b) (6)	14M	0	(b) (6)	001	PREBLEED				341		< 5		< 600
					0		011	INJ 1	0331P							
					0		011	INJ 1	CP749	15 MCG						
					36		011	BLEED 1				5630		20		4358
	F	BLAC		14M	0		001	PREBLEED				401				
					0		011	INJ 1	CP749	15 MCG						
					0		011	INJ 1	0331P							
					28		011	BLEED 1				1859				
	F	CAUC		15M	0		001	PREBLEED				< 125		< 5		< 600
					0		011	INJ 1	CP749	15 MCG						
					0		011	INJ 1	0331P							
					29		011	BLEED 1				2480		20		4625
	M	CAUC		18M	0		001	PREBLEED				156				
					0		011	INJ 1	CP749	15 MCG						
					0		011	INJ 1	0331P							
					91		011	BLEED 1				4826				
	F	CAUC		16M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP749	15 MCG						
					0		011	INJ 1	0331P							
					30		011	BLEED 1				208				
	M	BLAC		15M	0		001	PREBLEED				188		< 5		
					0		011	INJ 1	CP749	15 MCG						
					0		011	INJ 1	0331P							
					35		011	BLEED 1				2278		20		
	F	CAUC		15M	0		001	PREBLEED				223		< 5		
					0		011	INJ 1	CP749	15 MCG						
					0		011	INJ 1	0331P							
					29		011	BLEED 1				8362		20		
	M	CAUC		15M	0		001	PREBLEED				< 125		< 5		
					0		011	INJ 1	CP749	15 MCG						
					0		011	INJ 1	0331P							
					28		011	BLEED 1				27645		>= 80		
	M	CAUC		14M	0		011	INJ 1	CP749	15 MCG						

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : WALD,ELLEN
STUDY : 001002
VACCINE : HIB/MMR CONCURRENTLY
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	IGG1
(b) (6)	M	CAUC	(b) (6)	14M	0	(b) (6)	011	INJ	1	0331P						
	F	OTHE		15M	0		001	PREBLEED				990		< 5		
					0		011	INJ	1	CP749	15 MCG					
					0		011	INJ	1	0331P						
					33		011	BLEED	1			21671		>= 80		
	F	BLAC		16M	0		011	INJ	1	CP749	15 MCG					
					0		011	INJ	1	0331P						
	F	BLAC		22M	0		001	PREBLEED				< 125				
					0		011	INJ	1	CP749	15 MCG					
					0		011	INJ	1	0331P						
					46		011	BLEED	1			5452				
	M	BLAC		19M	0		001	PREBLEED				< 125		< 5		
					0		011	INJ	1	CP749	15 MCG					
					0		011	INJ	1	0331P						
					33		011	BLEED	1			15759		>= 80		
	M	BLAC		15M	0		011	INJ	1	CP749	15 MCG					
					0		011	INJ	1	0331P						
	F	BLAC		18M	0		001	PREBLEED				< 125				
					0		011	INJ	1	CP749	15 MCG					
					0		011	INJ	1	0331P						
					78		011	BLEED	1			3229				
	F	BLAC		19M	0		001	PREBLEED				< 125				
					0		011	INJ	1	CP749	15 MCG					
					0		011	INJ	1	0331P						
					34		011	BLEED	1			23795				
	F	BLAC		18M	0		001	PREBLEED				286				
					0		011	INJ	1	CP749	15 MCG					
					0		011	INJ	1	0331P						
					33		011	BLEED	1			2837				
	M	CAUC		15M	0		001	PREBLEED				< 125				
					0		011	INJ	1	CP749	15 MCG					
					0		011	INJ	1	0331P						

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : WALD,ELLEN
STUDY : 001002
VACCINE : HIB/MMR CONCURRENTLY
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	IGG1
(b) (6)	M	CAUC	(b) (6)	15M	28	(b) (6)	011	BLEED 1				2329				
	M	BLAC		15M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP749	15 MCG						
					0		011	INJ 1	0331P							
					44		011	BLEED 1				1313				
	F	BLAC		17M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP749	15 MCG						
					0		011	INJ 1	0331P							
					32		011	BLEED 1				5101				
	M	BLAC		17M	0		001	PREBLEED				210				
					0		011	INJ 1	CP749	15 MCG						
					0		011	INJ 1	0331P							
					32		011	BLEED 1				7906				
	M	BLAC		19M	0		011	INJ 1	CP749	15 MCG						
					0		011	INJ 1	0331P							
	M	OTHE		15M	0		001	PREBLEED				654				
					0		011	INJ 1	CP749	15 MCG						
					0		011	INJ 1	0331P							
					33		011	BLEED 1				4689				

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : HALD,ELLEN
STUDY : 001002
VACCINE : HIB AND MMR 4 WEEKS APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	IGG1
(b) (6)	F	BLAC	(b) (6)	15M	0	(b) (6)	001	PREBLEED				< 125		< 5		
					0		011	INJ 1	CP749	15 MCG						
					32		011	BLEED 1				2118		< 5		
					32		021	INJ 2	0331P							
					71		021	BLEED 2				1688		< 5		
	M	BLAC		14M	0		011	INJ 1	CP749	15 MCG						
	F	BLAC		13M	0		001	PREBLEED				140				
					0		011	INJ 1	CP749	15 MCG						
					38		011	BLEED 1				3977				
					38		021	INJ 2	0331P							
					73		021	BLEED 2				2098				
	M	BLAC		15M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP749	15 MCG						
					43		011	BLEED 1				1629				
					43		021	INJ 2	0331P							
	F	BLAC		15M	0		001	PREBLEED				131				
					0		011	INJ 1	CP749	15 MCG						
					31		011	BLEED 1				9304				
					31		021	INJ 2	0331P							
					87		021	BLEED 2				11651				
	F	CAUC		14M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP749	15 MCG						
					28		011	BLEED 1				31942				
					28		021	INJ 2	0331P							
					64		021	BLEED 2				13904				
	M	BLAC		15M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP749	15 MCG						
					28		011	BLEED 1				952				
					28		021	INJ 2	0331P							
					66		021	BLEED 2				2950				
	M	CAUC		14M	0		011	INJ 1	CP749	15 MCG						
	F	BLAC		15M	0		011	INJ 1	CP749	15 MCG						
	F	BLAC		14M	0		001	PREBLEED				245				

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : WALD,ELLEN
STUDY : 001002
VACCINE : HIB AND MMR 4 WEEKS APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	IGG1
(b) (6)	F	BLAC	(b) (6)	14M	0	(b) (6)	011	INJ	1 CP749	15 MCG						
					33		011	BLEED	1			896				
					33		021	INJ	2 0331P							
					61		021	BLEED	2			714				
	F	BLAC		15M	0		001	PREBLEED				458				
					0		011	INJ	1 CP749	15 MCG						
					31		011	BLEED	1			2666				
					31		021	INJ	2 0331P							
					59		021	BLEED	2			4467				
	F	CAUC		16M	0		001	PREBLEED				< 125				
					0		011	INJ	1 CP749	15 MCG						
					35		011	BLEED	1			1247				
					35		021	INJ	2 0331P							
					77		021	BLEED	2			2425				
	F	BLAC		13M	0		001	PREBLEED				< 125				
					0		011	INJ	1 CP749	15 MCG						
					29		011	BLEED	1			1082				
					29		021	INJ	2 0331P							
					59		021	BLEED	2			1112				
	M	BLAC		15M	0		001	PREBLEED				< 125				
					0		011	INJ	1 CP749	15 MCG						
					34		011	BLEED	1			12995				
	M	CAUC		14M	0		001	PREBLEED				138				
					0		011	INJ	1 CP749	15 MCG						
					32		011	BLEED	1			2773				
	F	BLAC		15M	0		001	PREBLEED				< 125				
					0		011	INJ	1 CP749	15 MCG						
					33		011	BLEED	1			5923				
	M	CAUC		14M	0		001	PREBLEED				1766				
					0		011	INJ	1 CP749	15 MCG						
					31		011	BLEED	1			4862				
	M	BLAC		15M	0		001	PREBLEED				< 125				
					0		011	INJ	1 CP749	15 MCG						

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : WALD,ELLEN
STUDY : 001002
VACCINE : HIB AND MMR 4 WEEKS APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	IGG1
(b) (6)	M	BLAC	(b) (6)	15M	44	(b) (6)	011	BLEED	1			1589				
	F	BLAC		15M	0		001	PREBLEED				< 125				
					0		011	INJ	1	CP749	15 MCG					
					30		011	BLEED	1			2860				
	M	BLAC		14M	0		011	INJ	1	CP749	15 MCG					
	M	CAUC		14M	0		001	PREBLEED				196				
					0		011	INJ	1	CP749	15 MCG					
					28		011	BLEED	1			1373				
	M	BLAC		14M	0		001	PREBLEED				< 125				
					0		011	INJ	1	CP749	15 MCG					
					42		011	BLEED	1			6155				

TABLE 2

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : WALD,ELLEN
STUDY : 001002
VACCINE : HIB/MMR CONCURRENTLY
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ IGG2	CODE/ OPSO	CODE/IGG TOTAL	CODE/ IGGM
(b) (6)	M	BLAC	(b) (6)	14M	0	(b) (6)	001	PREBLEED			< 250	3	< 100	< 100
					0		011	INJ 1	0331P					
					0		011	INJ 1	CP749	15 MCG				
					36		011	BLEED 1			< 250	99	632	327
	F	BLAC		14M	0		001	PREBLEED			< 250			
					0		011	INJ 1	CP749	15 MCG				
					0		011	INJ 1	0331P					
					28		011	BLEED 1			< 250			
	F	CAUC		15M	0		001	PREBLEED			< 250	0	< 100	< 100
					0		011	INJ 1	CP749	15 MCG				
					0		011	INJ 1	0331P					
					29		011	BLEED 1			< 250	99	1047	633
	M	CAUC		18M	0		011	INJ 1	CP749	15 MCG				
					0		011	INJ 1	0331P					
	F	CAUC		16M	0		011	INJ 1	CP749	15 MCG				
					0		011	INJ 1	0331P					
	M	BLAC		15M	0		001	PREBLEED			< 250		< 100	< 100
					0		011	INJ 1	CP749	15 MCG				
					0		011	INJ 1	0331P					
					35		011	BLEED 1			< 250		219	3549
	F	CAUC		15M	0		001	PREBLEED			< 250	0	< 100	< 100
					0		011	INJ 1	CP749	15 MCG				
					0		011	INJ 1	0331P					
					29		011	BLEED 1			< 250	40	499	2002
	M	CAUC		15M	0		001	PREBLEED			< 250	0	< 100	< 100
					0		011	INJ 1	CP749	15 MCG				
					0		011	INJ 1	0331P					
					28		011	BLEED 1			< 250	100	4279	1066
	M	CAUC		14M	0		011	INJ 1	CP749	15 MCG				
					0		011	INJ 1	0331P					
	F	OTHE		15M	0		001	PREBLEED			< 250		< 100	158
					0		011	INJ 1	CP749	15 MCG				

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : WALD,ELLEN
STUDY : 001002
VACCINE : HIB/MMR CONCURRENTLY
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ IGG2	CODE/ OPSO	CODE/IGG TOTAL	CODE/ IGGM
(b) (6)	F	OTHE	(b) (6)	15M	0	(b) (6)	011	INJ 1	0331P					
					33		011	BLEED 1			406		675	859
	F	BLAC		16M	0		011	INJ 1	CP749	15 MCG				
					0		011	INJ 1	0331P					
	F	BLAC		22M	0		001	PREBLEED			< 250	0		
					0		011	INJ 1	CP749	15 MCG				
					0		011	INJ 1	0331P					
					46		011	BLEED 1			421	100		
	M	BLAC		19M	0		001	PREBLEED			< 250		< 100	203
					0		011	INJ 1	CP749	15 MCG				
					0		011	INJ 1	0331P					
					33		011	BLEED 1			837		472	1271
	M	BLAC		15M	0		011	INJ 1	CP749	15 MCG				
					0		011	INJ 1	0331P					
	F	BLAC		18M	0		011	INJ 1	CP749	15 MCG				
					0		011	INJ 1	0331P					
	F	BLAC		19M	0		011	INJ 1	CP749	15 MCG				
					0		011	INJ 1	0331P					
	F	BLAC		18M	0		011	INJ 1	CP749	15 MCG				
					0		011	INJ 1	0331P					
	M	CAUC		15M	0		011	INJ 1	CP749	15 MCG				
					0		011	INJ 1	0331P					
	M	BLAC		15M	0		011	INJ 1	CP749	15 MCG				
					0		011	INJ 1	0331P					
	F	BLAC		17M	0		011	INJ 1	CP749	15 MCG				
					0		011	INJ 1	0331P					
	M	BLAC		17M	0		011	INJ 1	CP749	15 MCG				
					0		011	INJ 1	0331P					
	M	BLAC		19M	0		011	INJ 1	CP749	15 MCG				

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : WALD,ELLEN
STUDY : 001002
VACCINE : HIB/MMR CONCURRENTLY
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ IGG2	CODE/ OPSO	CODE/IGG TOTAL	CODE/ IGGM
(b) (6)	M	BLAC	(b) (6)	19M	0	(b) (6)	011	INJ	1	0331P				
	M	OTHE		15M	0		011	INJ	1	CP749	15 MCG			
					0		011	INJ	1	0331P				

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : WALD,ELLEN
STUDY : 001002
VACCINE : HIB AND MMR 4 WEEKS APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	IGG2	CODE/	OPSO	CODE/IGG TOTAL	CODE/	IGGM
(b) (6)	F	BLAC	(b) (6)	15M	0	(b) (6)	001	PREBLEED				< 250			< 100		182
					0		D11	INJ 1	CP749	15 MCG							
					32		011	BLEED 1				< 250			573		773
					32		021	INJ 2	0331P								
					71		021	BLEED 2			01/	QNS			427		120
	M	BLAC		14M	0		011	INJ 1	CP749	15 MCG							
	F	BLAC		13M	0		001	PREBLEED				< 250					
					0		011	INJ 1	CP749	15 MCG							
					38		011	BLEED 1				274					
					38		021	INJ 2	0331P								
					73		021	BLEED 2			01/	QNS					
	M	BLAC		15M	0		011	INJ 1	CP749	15 MCG							
					43		021	INJ 2	0331P								
	F	BLAC		15M	0		011	INJ 1	CP749	15 MCG							
					31		021	INJ 2	0331P								
	F	CAUC		14M	0		001	PREBLEED				< 250		0			
					0		011	INJ 1	CP749	15 MCG							
					28		011	BLEED 1				290					
					28		021	INJ 2	0331P								
					64		021	BLEED 2				375		100			
	M	BLAC		15M	0		001	PREBLEED				< 250		0			
					0		011	INJ 1	CP749	15 MCG							
					28		011	BLEED 1				< 250					
					28		021	INJ 2	0331P								
					66		021	BLEED 2				352		98			
	M	CAUC		14M	0		011	INJ 1	CP749	15 MCG							
	F	BLAC		15M	0		011	INJ 1	CP749	15 MCG							
	F	BLAC		14M	0		001	PREBLEED				< 250					
					0		011	INJ 1	CP749	15 MCG							
					33		011	BLEED 1				< 250					
					33		021	INJ 2	0331P								
					61		021	BLEED 2				< 250					

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : WALD,ELLEN
STUDY : 001002
VACCINE : HIB AND MMR 4 WEEKS APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ IGG2	CODE/ OPSO	CODE/IGG TOTAL	CODE/ IGGM
(b) (6)	F	BLAC	(b) (6)	15M	0	(b) (6)	011	INJ	1 CP749	15 MCG				
					31		021	INJ	2 0331P					
	F	CAUC		16M	0		011	INJ	1 CP749	15 MCG				
					35		021	INJ	2 0331P					
	F	BLAC		13M	0		011	INJ	1 CP749	15 MCG				
					29		021	INJ	2 0331P					
	M	BLAC		15M	0		011	INJ	1 CP749	15 MCG				
	M	CAUC		14M	0		011	INJ	1 CP749	15 MCG				
	F	BLAC		15M	0		011	INJ	1 CP749	15 MCG				
	M	CAUC		14M	0		011	INJ	1 CP749	15 MCG				
	M	BLAC		15M	0		011	INJ	1 CP749	15 MCG				
	F	BLAC		15M	0		011	INJ	1 CP749	15 MCG				
	M	BLAC		14M	0		011	INJ	1 CP749	15 MCG				
	M	CAUC		14M	0		011	INJ	1 CP749	15 MCG				
	M	BLAC		14M	0		011	INJ	1 CP749	15 MCG				

TABLE 3

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : WALD,ELLEN
STUDY : 001002
VACCINE : HIB/MMR CONCURRENTLY
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	MEASLES - HI CODE/	MEASLES - HI	RUBELLA - HI CODE/	RUBELLA - HI	MUMPS-ELI CODE/	MUMPS-ELI SA
(b) (6)	M	BLAC	(b) (6)	14M	0	(b) (6)	001	PREBLEED				< 5		< 8		< 2
					0		011	INJ 1	0331P							
					0		011	INJ 1	CP749	15 MCG						
					36		011	BLEED 1				160		64		35.6
	F	BLAC		14M	0		001	PREBLEED				< 5		< 8		< 2
					0		011	INJ 1	CP749	15 MCG						
					0		011	INJ 1	0331P							
					28		011	BLEED 1			01/	QNS	01/	QNS		131
	F	CAUC		15M	0		001	PREBLEED				< 5		< 8		< 2
					0		011	INJ 1	CP749	15 MCG						
					0		011	INJ 1	0331P							
					29		011	BLEED 1				80		64		26.3
	M	CAUC		18M	0		001	PREBLEED				< 5		< 8		< 2
					0		011	INJ 1	CP749	15 MCG						
					0		011	INJ 1	0331P							
					91		011	BLEED 1				< 5		256		31.8
	F	CAUC		16M	0		001	PREBLEED				< 5		< 8		< 2
					0		011	INJ 1	CP749	15 MCG						
					0		011	INJ 1	0331P							
					30		011	BLEED 1				20		32		20.9
	M	BLAC		15M	0		001	PREBLEED				< 5		< 8		< 2
					0		011	INJ 1	CP749	15 MCG						
					0		011	INJ 1	0331P							
					35		011	BLEED 1				160		128		17
	F	CAUC		15M	0		001	PREBLEED				< 5		< 8		< 2
					0		011	INJ 1	CP749	15 MCG						
					0		011	INJ 1	0331P							
					29		D11	BLEED 1				20		32		29.7
	M	CAUC		15M	0		001	PREBLEED				< 5		< 8		< 2
					0		011	INJ 1	CP749	15 MCG						
					0		011	INJ 1	0331P							
					28		011	BLEED 1				80		64		7.3
	M	CAUC		14M	0		011	INJ 1	CP749	15 MCG						

TABLE 3 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : WALD,ELLEN
STUDY : 001002
VACCINE : HIB/MMR CONCURRENTLY
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	MEASLES - RUBELLA - MUMPS-ELI CODE/ HI	CODE/ HI	CODE/ SA
(b) (6)	M	CAUC	(b) (6)	14M	0	(b) (6)	011	INJ 1	0331P				
	F	OTHE		15M	0		001	PREBLEED			< 5	< 8	< 2
					0		011	INJ 1	CP749	15 MCG			
					0		011	INJ 1	0331P				
					33		011	BLEED 1			160	128	40.7
	F	BLAC		16M	0		011	INJ 1	CP749	15 MCG			
					0		011	INJ 1	0331P				
	F	BLAC		22M	0		001	PREBLEED			< 5	< 8	< 2
					0		011	INJ 1	CP749	15 MCG			
					0		011	INJ 1	0331P				
					46		011	BLEED 1			80	128	200
	M	BLAC		19M	0		001	PREBLEED			< 5	< 8	< 2
					0		011	INJ 1	CP749	15 MCG			
					0		011	INJ 1	0331P				
					33		011	BLEED 1			40	64	39.8
	M	BLAC		15M	0		011	INJ 1	CP749	15 MCG			
					0		011	INJ 1	0331P				
	F	BLAC		18M	0		001	PREBLEED			< 5	< 8	< 2
					0		011	INJ 1	CP749	15 MCG			
					0		011	INJ 1	0331P				
					78		011	BLEED 1			80	64	229
	F	BLAC		19M	0		001	PREBLEED			< 5	< 8	< 2
					0		011	INJ 1	CP749	15 MCG			
					0		011	INJ 1	0331P				
					34		011	BLEED 1			160	128	20.8
	F	BLAC		18M	0		001	PREBLEED			< 5	< 8	< 2
					0		011	INJ 1	CP749	15 MCG			
					0		011	INJ 1	0331P				
					33		011	BLEED 1			80	256	206
	M	CAUC		15M	0		001	PREBLEED			< 5	< 8	< 2
					0		011	INJ 1	CP749	15 MCG			
					0		011	INJ 1	0331P				

TABLE 3 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : WALD,ELLEN
STUDY : 001002
VACCINE : HIB/MMR CONCURRENTLY
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	MEASLES - RUBELLA - CODE/	HI	CODE/	HI	MUMPS-ELI CODE/	SA
(b) (6)	M	CAUC	(b) (6)	15M	28	(b) (6)	011	BLEED 1				80		128		41.9
	M	BLAC		15M	0		001	PREBLEED				< 5		< 8		< 2
					0		011	INJ 1	CP749	15 MCG						
					0		011	INJ 1	0331P							
					44		011	BLEED 1				20		256		178
	F	BLAC		17M	0		001	PREBLEED				< 5		< 8		
					0		011	INJ 1	CP749	15 MCG						
					0		011	INJ 1	0331P							
					32		011	BLEED 1				160		128		
	M	BLAC		17M	0		001	PREBLEED				< 5		< 8		
					0		011	INJ 1	CP749	15 MCG						
					0		011	INJ 1	0331P							
					32		011	BLEED 1				160		256		
	M	BLAC		19M	0		011	INJ 1	CP749	15 MCG						
					0		011	INJ 1	0331P							
	M	OTHE		15M	0		001	PREBLEED				< 5		< 8		
					0		011	INJ 1	CP749	15 MCG						
					0		011	INJ 1	0331P							
					33		011	BLEED 1				80		32		

TABLE 3 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : WALD,ELLEN
STUDY : 001002
VACCINE : HIB AND MMR 4 WEEKS APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	MEASLES - CODE/	MEASLES - HI	RUBELLA - CODE/	RUBELLA - HI	MUMPS-ELI CODE/	MUMPS-ELI SA
(b) (6)	F	BLAC	(b) (6)	15M	0	(b) (6)	001	PREBLEED				< 5		< 8		< 2
					0		011	INJ 1	CP749	15 MCG						
					32		011	BLEED 1				< 5		< 8		< 2
					32		021	INJ 2	0331P							
					71		021	BLEED 2				160		128		15.8
	M	BLAC		14M	0		011	INJ 1	CP749	15 MCG						
	F	BLAC		13M	0		001	PREBLEED				< 5		< 8		< 2
					0		011	INJ 1	CP749	15 MCG						
					38		011	BLEED 1				< 5		< 8		< 2
					38		021	INJ 2	0331P							
					73		021	BLEED 2				80		128		240
	M	BLAC		15M	0		001	PREBLEED				< 5		< 8		
					0		011	INJ 1	CP749	15 MCG						
					43		011	BLEED 1				< 5		< 8		
					43		021	INJ 2	0331P							
	F	BLAC		15M	0		001	PREBLEED				< 5		< 8		< 2
					0		011	INJ 1	CP749	15 MCG						
					31		011	BLEED 1				< 5		< 8		< 2
					31		021	INJ 2	0331P							
					87		021	BLEED 2				160		256		190
	F	CAUC		14M	0		001	PREBLEED				< 5		< 8		< 2
					0		011	INJ 1	CP749	15 MCG						
					28		011	BLEED 1				< 5		< 8		< 2
					28		021	INJ 2	0331P							
					64		021	BLEED 2				160		64		135
	M	BLAC		15M	0		001	PREBLEED				< 5		< 8		< 2
					0		011	INJ 1	CP749	15 MCG						
					28		011	BLEED 1				< 5		< 8		< 2
					28		021	INJ 2	0331P							
					66		021	BLEED 2				640		128		406
	M	CAUC		14M	0		011	INJ 1	CP749	15 MCG						
	F	BLAC		15M	0		011	INJ 1	CP749	15 MCG						
	F	BLAC		14M	0		001	PREBLEED				< 5		< 8		< 2

TABLE 3 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : WALD,ELLEN
STUDY : 001002
VACCINE : HIB AND MMR 4 WEEKS APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	MEASLES - RUBELLA - MUMPS-ELI CODE/ HI	CODE/ HI	CODE/ SA
(b) (6)	F	BLAC	(b) (6)	14M	0	(b) (6)	011	INJ 1	CP749	15 MCG			
					33		011	BLEED 1			< 5	< 8	< 2
					33		021	INJ 2	0331P				
					61		021	BLEED 2			160	128	111
	F	BLAC		15M	0		001	PREBLEED			< 5	< 8	< 2
					0		011	INJ 1	CP749	15 MCG			
					31		011	BLEED 1			< 5	< 8	< 2
					31		021	INJ 2	0331P				
					59		021	BLEED 2			80	128	8.9
	F	CAUC		16M	0		001	PREBLEED			< 5	< 8	< 2
					0		011	INJ 1	CP749	15 MCG			
					35		011	BLEED 1			< 5	< 8	< 2
					35		021	INJ 2	0331P				
					77		021	BLEED 2			80	64	49.2
	F	BLAC		13M	0		001	PREBLEED			< 5	< 8	< 2
					0		011	INJ 1	CP749	15 MCG			
					29		011	BLEED 1			< 5	< 8	< 2
					29		021	INJ 2	0331P				
					59		021	BLEED 2			320	256	32.5
	M	BLAC		15M	0		001	PREBLEED			< 5	< 8	
					0		011	INJ 1	CP749	15 MCG			
					34		011	BLEED 1			< 5	< 8	
	M	CAUC		14M	0		001	PREBLEED			< 5	< 8	
					0		011	INJ 1	CP749	15 MCG			
					32		011	BLEED 1			< 5	< 8	
	F	BLAC		15M	0		001	PREBLEED			< 5	< 8	
					0		011	INJ 1	CP749	15 MCG			
					33		011	BLEED 1			< 5	< 8	
	M	CAUC		14M	0		001	PREBLEED			< 5	< 8	
					0		011	INJ 1	CP749	15 MCG			
					31		011	BLEED 1			< 5	< 8	
	M	BLAC		15M	0		001	PREBLEED			< 5	< 8	
					0		011	INJ 1	CP749	15 MCG			

TABLE 3 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : WALD,ELLEN
STUDY : 001002
VACCINE : HIB AND MMR 4 WEEKS APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	MEASLES - CODE/	MEASLES - HI	RUBELLA - CODE/	RUBELLA - HI	MUMPS-ELI CODE/	MUMPS-ELI SA
(b) (6)	M	BLAC	(b) (6)	15M	44	(b) (6)	011	BLEED 1				< 5		< 8		
	F	BLAC		15M	0		001	PREBLEED				< 5		< 8		
					0		011	INJ 1	CP749	15 MCG						
					30		011	BLEED 1				< 5		< 8		
	M	BLAC		14M	0		011	INJ 1	CP749	15 MCG						
	M	CAUC		14M	0		001	PREBLEED				< 5		< 8		
					0		011	INJ 1	CP749	15 MCG						
					28		011	BLEED 1				< 5		< 8		
	M	BLAC		14M	0		001	PREBLEED				< 5		< 8		
					0		011	INJ 1	CP749	15 MCG						
					42		011	BLEED 1				< 5		< 8		

TABLE 4

A N T I B O D Y R E S P O N S E S

INVESTIGATOR : WALD,ELLEN
STUDY : 001002
VACCINE : HIB/MMR CONCURRENTLY
ASSAY : RIA
POPULATION : HEALTHY CHILDREN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
13-22 MOS.	PRE INJ	47 (8/ 17)	0 (0/ 17)			0.141 (17)
	1 MONTH	100 (17/ 17)	94 (16/ 17)	94 (16/ 17)	22.8	4.630 (17)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 5

ANTIBODY RESPONSES

INVESTIGATOR : WALD,ELLEN
STUDY : 001002
VACCINE : HIB AND MMR 4 WEEKS APART
ASSAY : RIA
POPULATION : HEALTHY CHILDREN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
13-22 MOS.	PRE INJ	22 (4/ 18)	6 (1/ 18)			0.110 (18)
	1 MONTH	100 (18/ 18)	89 (16/ 18)	100 (18/ 18)	18.1	3.042 (18)
	2 MONTHS	100 (8/ 8)	88 (7/ 8)	100 (8/ 8)	15.0	2.438 (8)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 6

Antibody Responses to Individual Viral Vaccine Antigens Following Administration of MMR Alone or Concurrently with PRP-OMPC Vaccine

Antigen	Vaccination Regimen	No. of Subjects	Seroconversion Rate	Antibody GMT
Measles	Concurrent	16	100 (16/16)	76.6
	4 Weeks Apart	8	100 (8/8)	160.0
Mumps	Concurrent	14	100 (14/14)	43.9
	4 Weeks Apart	8	100 (8/8)	65.2
Rubella	Concurrent	16	100 (16/16)	94.5
	4 Weeks Apart	8	100 (8/8)	117.4

TABLE 7

C L I N I C A L C O M P L A I N T S B Y F R E Q U E N C Y

INVESTIGATOR : WALD,ELLEN
STUDY : 001002
VACCINE : HIB/MMR CONCURRENTLY
POPULATION : HEALTHY CHILDREN
AGE RANGE : 13-22 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	23	
VACCINEES WITH NO COMPLAINTS :	19	(82.6 %)
VACCINEES WITH COMPLAINTS :	4	(17.4 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS BY BODY SYSTEM	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 23 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	4	17.4
PAIN/SORENESS, INJ. SITE	3	13.0
ERYTHEMA, INJ. SITE (<=1 IN.)	1	4.3
ERYTHEMA, INJ. SITE (>1 INCH)	1	4.3
SWELLING, INJ. SITE (<=1 IN.)	0	0.0

TABLE 7 (cont

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : WALD,ELLEN
STUDY : 001002
VACCINE : HIB/MMR CONCURRENTLY
POPULATION : HEALTHY CHILDREN
AGE RANGE : 13-22 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	MMR INJECTION: 1	
TOTAL VACCINEES :	23	
VACCINEES WITH NO COMPLAINTS :	23	(100.0 %)
VACCINEES WITH COMPLAINTS :	0	(0.0 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS BY BODY SYSTEM	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 23 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	0	0.0
ERYTHEMA, INJ. SITE (<=1 IN.)	0	0.0
ERYTHEMA, INJ. SITE (>1 INCH)	0	0.0
PAIN/SORENESS, INJ. SITE	0	0.0
SWELLING, INJ. SITE (<=1 IN.)	0	0.0

TABLE 7 (cont.)

C L I N I C A L C O M P L A I N T S B Y F R E Q U E N C Y

INVESTIGATOR : WALD,ELLEN
STUDY : 001002
VACCINE : HIB AND MMR 4 WEEKS APART
POPULATION : HEALTHY CHILDREN
AGE RANGE : 13-22 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	22	
VACCINEES WITH NO COMPLAINTS :	8	(36.4 %)
VACCINEES WITH COMPLAINTS :	14	(63.6 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS BY BODY SYSTEM	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 22 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	5	22.7
SWELLING, INJ. SITE (<=1 IN.)	4	18.2
ERYTHEMA, INJ. SITE (<=1 IN.)	3	13.6
PAIN/SORENESS, INJ. SITE	1	4.5
ERYTHEMA, INJ. SITE (>1 INCH)	0	0.0
SYSTEMIC REACTIONS	14	63.6
IRRITABILITY	8	36.4
WARM TO TOUCH	6	27.3
DIARRHEA	3	13.6
FATIGUE	2	9.1
ANOREXIA	1	4.5
ASTHMA	1	4.5
OTITIS MEDIA	1	4.5
TEETHING	1	4.5
COUGH	0	0.0
ENDOPHTHALMITIS	0	0.0
NASAL CONGESTION	0	0.0
NASAL DISCHARGE	0	0.0
RASH	0	0.0
UNUSUAL HIGH-PITCHED CRYING	0	0.0
UPPER RESPIRATORY INFECTION, NOS	0	0.0

TABLE 7 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : WALD,ELLEN
STUDY : 001002
VACCINE : HIB AND MMR 4 WEEKS APART
POPULATION : HEALTHY CHILDREN
AGE RANGE : 13-22 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	MMR INJECTION: 2	
TOTAL VACCINEES :	10	
VACCINEES WITH NO COMPLAINTS :	5	(50.0 %)
VACCINEES WITH COMPLAINTS :	5	(50.0 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS BY BODY SYSTEM	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 10 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	1	10.0
PAIN/SORENESS, INJ. SITE	1	10.0
SWELLING, INJ. SITE (<=1 IN.)	1	10.0
ERYTHEMA, INJ. SITE (<=1 IN.)	0	0.0
ERYTHEMA, INJ. SITE (>1 INCH)	0	0.0
SYSTEMIC REACTIONS	5	50.0
NASAL DISCHARGE	3	30.0
COUGH	1	10.0
FATIGUE	1	10.0
IRRITABILITY	1	10.0
RASH	1	10.0
UNUSUAL HIGH-PITCHED CRYING	1	10.0
WARM TO TOUCH	1	10.0
ANOREXIA	0	0.0
ASTHMA	0	0.0
DIARRHEA	0	0.0
ENDOPHTHALMITIS	0	0.0
NASAL CONGESTION	0	0.0
OTITIS MEDIA	0	0.0
TEETHING	0	0.0
UPPER RESPIRATORY INFECTION, NOS	0	0.0

TABLE 8

CLINICAL COMPLAINTS

INVESTIGATOR : WALD,ELLEN
STUDY : 001002
VACCINE : HIB/MMR CONCURRENTLY
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 13-22 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (23 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5	
LOCAL REACTIONS	1 (4.5%)	3 (13.6%)	2 (8.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (17.4%)
ERYTHEMA, INJ. SITE (>1 INCH)	0 (0.0%)	1 (4.5%)	1 (4.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (4.3%)
ERYTHEMA, INJ. SITE (<=1 IN.)	0 (0.0%)	1 (4.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (4.3%)
PAIN/SORENESS, INJ. SITE	1 (4.5%)	2 (9.1%)	1 (4.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (13.0%)
VACCINEES WITH COMPLAINTS	1 (4.5%)	3 (13.6%)	2 (8.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (17.4%)
VACCINEES WITH NO COMPLAINTS	21 (95.5%)	19 (86.4%)	21 (91.3%)	23 (100.0%)	23 (100.0%)	23 (100.0%)	19 (82.6%)
TOTAL VACCINEES REPORTING	22	22	23	23	23	23	23
VACCINEES WITH NO DATA	1	1	0	0	0	0	0

TABLE 8 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : WALD,ELLEN
STUDY : 001002
VACCINE : HIB/MMR CONCURRENTLY
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 13-22 MOS.

VACCINE : MMR	NUMBER OF VACCINEES (23 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5	COMPLAINTS
							**********
VACCINEES WITH COMPLAINTS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
VACCINEES WITH NO COMPLAINTS	22 (100.0%)	22 (100.0%)	23 (100.0%)	23 (100.0%)	23 (100.0%)	23 (100.0%)	23 (100.0%)
TOTAL VACCINEES REPORTING	22	22	23	23	23	23	23
VACCINEES WITH NO DATA	1	1	0	0	0	0	0

TABLE 8 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : WALD,ELLEN
STUDY : 001002
VACCINE : HIB/MMR CONCURRENTLY
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 13-22 MOS.

VACCINE : HIB/MMR CONCURRENTLY	NUMBER OF VACCINEES (23 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5	**********
SYSTEMIC	6 (26.1%)	6 (26.1%)	5 (21.7%)	3 (13.0%)	5 (21.7%)	5 (21.7%)	11 (47.8%)
BODY AS A WHOLE/SITE UNSPEC.	3 (13.0%)	2 (8.7%)	2 (8.7%)	1 (4.3%)	1 (4.3%)	1 (4.3%)	6 (26.1%)
FATIGUE	1 (4.3%)	0 (0.0%)	1 (4.3%)	1 (4.3%)	1 (4.3%)	1 (4.3%)	2 (8.7%)
HARM TO TOUCH	2 (8.7%)	2 (8.7%)	1 (4.3%)	1 (4.3%)	0 (0.0%)	1 (4.3%)	5 (21.7%)
DIGESTIVE SYSTEM	0 (0.0%)	0 (0.0%)	1 (4.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (4.3%)
DIARRHEA	0 (0.0%)	0 (0.0%)	1 (4.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (4.3%)
NERVOUS SYSTEM & PSYCHIATRIC	3 (13.0%)	3 (13.0%)	1 (4.3%)	1 (4.3%)	1 (4.3%)	1 (4.3%)	6 (26.1%)
IRRITABILITY	3 (13.0%)	3 (13.0%)	1 (4.3%)	1 (4.3%)	1 (4.3%)	1 (4.3%)	6 (26.1%)
RESPIRATORY SYSTEM	1 (4.3%)	1 (4.3%)	2 (8.7%)	2 (8.7%)	2 (8.7%)	2 (8.7%)	2 (8.7%)
NASAL CONGESTION	1 (4.3%)	1 (4.3%)	1 (4.3%)	1 (4.3%)	1 (4.3%)	1 (4.3%)	1 (4.3%)
NASAL DISCHARGE	1 (4.3%)	1 (4.3%)	1 (4.3%)	1 (4.3%)	1 (4.3%)	1 (4.3%)	1 (4.3%)

TABLE 8 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : WALD,ELLEN
STUDY : 001002
VACCINE : HIB/MMR CONCURRENTLY
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 13-22 MOS.

VACCINE : HIB/MMR CONCURRENTLY	NUMBER OF VACCINEES (23 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
UPPER RESPIRATORY INFECTION, NOS	0 (0.0%)	0 (0.0%)	1 (4.3%)	1 (4.3%)	1 (4.3%)	1 (4.3%)		1 (4.3%)
SKIN & SKIN APPENDAGE	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (8.7%)	2 (8.7%)		2 (8.7%)
RASH	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (8.7%)	2 (8.7%)		2 (8.7%)
SPECIAL SENSES	1 (4.3%)	2 (8.7%)	1 (4.3%)	1 (4.3%)	1 (4.3%)	1 (4.3%)		2 (8.7%)
ENDOPHTHALMITIS	0 (0.0%)	1 (4.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (4.3%)
OTITIS MEDIA	1 (4.3%)	1 (4.3%)	1 (4.3%)	1 (4.3%)	1 (4.3%)	1 (4.3%)		1 (4.3%)
VACCINEES WITH COMPLAINTS	6 (26.1%)	6 (26.1%)	5 (21.7%)	3 (13.0%)	5 (21.7%)	5 (21.7%)		11 (47.8%)
VACCINEES WITH NO COMPLAINTS	17 (73.9%)	17 (73.9%)	18 (78.3%)	20 (87.0%)	18 (78.3%)	18 (78.3%)		12 (52.2%)
TOTAL VACCINEES REPORTING	23	23	23	23	23	23		23
VACCINEES WITH NO DATA	0	0	0	0	0	0		0

TABLE 8 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : WALD,ELLEN
STUDY : 001002
VACCINE : HIB AND MMR 4 WEEKS APART
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 13-22 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (22 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
LOCAL REACTIONS	4 (18.2%)	4 (19.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		5 (22.7%)
ERYTHEMA, INJ. SITE (<=1 IN.)	3 (13.6%)	2 (9.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		3 (13.6%)
PAIN/SORENESS, INJ. SITE	1 (4.5%)	1 (4.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (4.5%)
SWELLING, INJ. SITE (<=1 IN.)	3 (13.6%)	3 (14.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		4 (18.2%)
SYSTEMIC	8 (36.4%)	7 (33.3%)	6 (27.3%)	5 (22.7%)	5 (22.7%)	5 (22.7%)		13 (59.1%)
BODY AS A WHOLE/SITE UNSPEC.	3 (13.6%)	5 (23.8%)	2 (9.1%)	1 (4.5%)	2 (9.1%)	1 (4.5%)		7 (31.8%)
FATIGUE	2 (9.1%)	2 (9.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (9.1%)
HARM TO TOUCH	2 (9.1%)	4 (19.0%)	2 (9.1%)	1 (4.5%)	2 (9.1%)	1 (4.5%)		6 (27.3%)
DIGESTIVE SYSTEM	1 (4.5%)	2 (9.5%)	1 (4.5%)	2 (9.1%)	1 (4.5%)	2 (9.1%)		5 (22.7%)
ANOREXIA	1 (4.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (4.5%)
DIARRHEA	0 (0.0%)	2 (9.5%)	1 (4.5%)	2 (9.1%)	1 (4.5%)	1 (4.5%)		3 (13.6%)

TABLE 8 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : WALD,ELLEN
STUDY : 001002
VACCINE : HIB AND MMR 4 WEEKS APART
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 13-22 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (22 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
TEETHING	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (4.5%)		1 (4.5%)
NERVOUS SYSTEM & PSYCHIATRIC	6 (27.3%)	3 (14.3%)	3 (13.6%)	2 (9.1%)	1 (4.5%)	1 (4.5%)		7 (31.8%)
IRRITABILITY	6 (27.3%)	3 (14.3%)	3 (13.6%)	2 (9.1%)	1 (4.5%)	1 (4.5%)		7 (31.8%)
RESPIRATORY SYSTEM	1 (4.5%)	1 (4.8%)	1 (4.5%)	1 (4.5%)	1 (4.5%)	1 (4.5%)		1 (4.5%)
ASTHMA	1 (4.5%)	1 (4.8%)	1 (4.5%)	1 (4.5%)	1 (4.5%)	1 (4.5%)		1 (4.5%)
SPECIAL SENSES	1 (4.5%)	1 (4.8%)	1 (4.5%)	1 (4.5%)	1 (4.5%)	1 (4.5%)		1 (4.5%)
OTITIS MEDIA	1 (4.5%)	1 (4.8%)	1 (4.5%)	1 (4.5%)	1 (4.5%)	1 (4.5%)		1 (4.5%)
VACCINEES WITH COMPLAINTS	9 (40.9%)	9 (42.9%)	6 (27.3%)	5 (22.7%)	5 (22.7%)	5 (22.7%)		13 (59.1%)
VACCINEES WITH NO COMPLAINTS	13 (59.1%)	12 (57.1%)	16 (72.7%)	17 (77.3%)	17 (77.3%)	17 (77.3%)		9 (40.9%)
TOTAL VACCINEES REPORTING	22	21	22	22	22	22		22
VACCINEES WITH NO DATA	0	1	0	0	0	0		0

TABLE 8 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : WALD,ELLEN
STUDY : 001002
VACCINE : HIB AND MMR 4 WEEKS APART
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 13-22 MOS.

VACCINE : MMR	NUMBER OF VACCINEES (10 VACCINEES) - INJECTION: 2						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5	COMPLAINTS
LOCAL REACTIONS	1 (10.0%)	1 (10.0%)	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (10.0%)
PAIN/SORENESS, INJ. SITE	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (10.0%)
SWELLING, INJ. SITE (<=1 IN.)	1 (10.0%)	1 (10.0%)	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (10.0%)
SYSTEMIC	4 (40.0%)	4 (40.0%)	3 (30.0%)	3 (30.0%)	4 (40.0%)	3 (30.0%)	5 (50.0%)
BODY AS A WHOLE/SITE UNSPEC.	1 (10.0%)	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (10.0%)
FATIGUE	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (10.0%)
HARM TO TOUCH	1 (10.0%)	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (10.0%)
NERVOUS SYSTEM & PSYCHIATRIC	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (10.0%)	1 (10.0%)	2 (20.0%)
IRRITABILITY	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (10.0%)	1 (10.0%)	1 (10.0%)
UNUSUAL HIGH-PITCHED CRYING	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (10.0%)
RESPIRATORY SYSTEM	3 (30.0%)	3 (30.0%)	3 (30.0%)	3 (30.0%)	3 (30.0%)	2 (20.0%)	3 (30.0%)

TABLE 8 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : WALD,ELLEN
STUDY : 001002
VACCINE : HIB AND MMR 4 WEEKS APART
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 13-22 MOS.

VACCINE : MMR	NUMBER OF VACCINEES (10 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		
COUGH	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (10.0%)		1 (10.0%)
NASAL DISCHARGE	3 (30.0%)	3 (30.0%)	3 (30.0%)	3 (30.0%)	3 (30.0%)	2 (20.0%)		3 (30.0%)
SKIN & SKIN APPENDAGE	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (10.0%)
RASH	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (10.0%)
VACCINEES WITH COMPLAINTS	4 (40.0%)	4 (40.0%)	4 (40.0%)	3 (30.0%)	4 (40.0%)	3 (30.0%)		5 (50.0%)
VACCINEES WITH NO COMPLAINTS	6 (60.0%)	6 (60.0%)	6 (60.0%)	7 (70.0%)	6 (60.0%)	7 (70.0%)		5 (50.0%)
TOTAL VACCINEES REPORTING	10	10	10	10	10	10		10
VACCINEES WITH NO DATA	0	0	0	0	0	0		0

TABLE 8 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : WALD,ELLEN
STUDY : 001002
VACCINE : HIB AND MMR 4 WEEKS APART
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 13-22 MOS.

VACCINE : HIB AND MMR 4 WEEKS APART	NUMBER OF VACCINEES (22 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
SYSTEMIC	0 (0.0%)	1 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (100.0%)
NERVOUS SYSTEM & PSYCHIATRIC	0 (0.0%)	1 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (100.0%)
IRRITABILITY	0 (0.0%)	1 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (100.0%)
VACCINEES WITH COMPLAINTS	0 (0.0%)	1 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (100.0%)
VACCINEES WITH NO COMPLAINTS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)
TOTAL VACCINEES REPORTING	0	1	0	0	0	0		1
VACCINEES WITH NO DATA	22	21	22	22	22	22		21

TABLE 9

MAXIMUM TEMPERATURES

INVESTIGATOR : WALD,ELLEN
STUDY : 001002
VACCINE : HIB/MMR CONCURRENTLY
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 13-22 MOS.

VACCINE : HIB/MMR CONCURRENTLY	NUMBER OF VACCINEES (23 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
NORMAL	1 (16.7%)	2 (33.3%)	1 (16.7%)	1 (20.0%)	1 (20.0%)	1 (25.0%)		1 (14.3%)
< 99	5 (83.3%)	2 (33.3%)	4 (66.7%)	4 (80.0%)	2 (40.0%)	3 (75.0%)		2 (28.6%)
99 - 99.9	0 (0.0%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	1 (20.0%)	0 (0.0%)		2 (28.6%)
100 - 100.9	0 (0.0%)	1 (16.7%)	1 (16.7%)	0 (0.0%)	1 (20.0%)	0 (0.0%)		2 (28.6%)
TEMPERATURE TAKEN	6 (26.1%)	6 (26.1%)	6 (26.1%)	5 (21.7%)	5 (21.7%)	4 (17.4%)		7 (30.4%)
TEMPERATURE NOT TAKEN	17 (73.9%)	17 (73.9%)	17 (73.9%)	18 (78.3%)	18 (78.3%)	19 (82.6%)		16 (69.6%)

TABLE 9 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : WALD,ELLEN
STUDY : 001002
VACCINE : HIB AND MMR 4 WEEKS APART
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 13-22 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (22 VACCINEES) - INJECTION 1						
	DAYS POST VACCINATION						NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5	
NORMAL	1 (14.3%)	3 (50.0%)	3 (50.0%)	3 (60.0%)	3 (60.0%)	3 (60.0%)	1 (14.3%)
< 99	4 (57.1%)	2 (33.3%)	2 (33.3%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	3 (42.9%)
99 - 99.9	1 (14.3%)	1 (16.7%)	1 (16.7%)	1 (20.0%)	1 (20.0%)	1 (20.0%)	2 (28.6%)
100 - 100.9	1 (14.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (14.3%)
TEMPERATURE TAKEN	7 (31.8%)	6 (27.3%)	6 (27.3%)	5 (22.7%)	5 (22.7%)	5 (22.7%)	7 (31.8%)
TEMPERATURE NOT TAKEN	15 (68.2%)	16 (72.7%)	16 (72.7%)	17 (77.3%)	17 (77.3%)	17 (77.3%)	15 (68.2%)

TABLE 9 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : WALD,ELLEN
STUDY : 001002
VACCINE : HIB AND MMR 4 WEEKS APART
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 13-22 MOS.

VACCINE : MMR	NUMBER OF VACCINEES (10 VACCINEES) - INJECTION 2							
	DAYS POST VACCINATION							NUMBER WITH
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		MAX TEMP
NORMAL	1 (50.0%)	1 (50.0%)	1 (50.0%)	1 (50.0%)	1 (50.0%)	1 (50.0%)		1 (50.0%)
< 99	1 (50.0%)	1 (50.0%)	1 (50.0%)	1 (50.0%)	1 (50.0%)	1 (50.0%)		1 (50.0%)
TEMPERATURE TAKEN	2 (20.0%)	2 (20.0%)	2 (20.0%)	2 (20.0%)	2 (20.0%)	2 (20.0%)		2 (20.0%)
TEMPERATURE NOT TAKEN	8 (80.0%)	8 (80.0%)	8 (80.0%)	8 (80.0%)	8 (80.0%)	8 (80.0%)		8 (80.0%)

PROGRAM: Haemophilus b Conjugate Vaccine, (Neisseria meningitidis Outer Membrane Protein Complex), Study 011-01

PURPOSE: To compare clinical reaction rates and antibody responses to Haemophilus b conjugate vaccine (Neisseria meningitidis outer membrane protein complex), diphtheria and tetanus toxoids and pertussis vaccine (DTP), and live oral trivalent poliovirus vaccine (OPV) administered currently or at separate times.

VACCINES:

1. Haemophilus b Conjugate Vaccine, (Neisseria meningitidis Outer Membrane Protein Complex) (PRP-OMPC)

   Lot 1080/C-P749 - (b) (4) mcg polysaccharide/ml
   mcg meningococcal protein/ml

   Aluminum hydroxide diluent
   Lot (b) (4)

2. Diphtheria and Tetanus Toxoids and Pertussis Vaccine (DTP)

   TRI-IMMUNOL®
   Lederle Laboratories
   Lot 187-664

3. Poliovirus Vaccine Live Oral Trivalent (OPV)

   ORIMUNE®
   Lederle Laboratories
   Lot 0557F
   Lot 178-612

INVESTIGATOR: Barry Dashefsky, M.D.
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STUDY LOCATION: Children's Hospital of Pittsburgh
3705 Fifth Avenue
Pittsburgh, PA 15213

DATE INITIATED: February 8, 1988

DATE COMPLETED: In progress.

STUDY POPULATION: Healthy children at least 17 months of age who have not previously received a DTP or OPV vaccine booster are included in the study.

STUDY PROCEDURE: Children are randomly assigned to receive PRP-OMPC vaccine and DTP/OPV vaccines at the same time or 4 weeks apart. Approximately 75 children are assigned to each regimen.

All children receive a single 0.5 ml (15 mcg polysaccharide) injection of PRP-OMPC vaccine reconstituted in aluminum hydroxide. A single 0.5 ml intramuscular injection of DTP vaccine and a 0.5 ml oral dose of OPV vaccine are given at the same time (at separate sites) or 4 weeks later.

The parent or guardian is required to record the vaccine recipient's temperature and any reactions at the injection site or systemic complaints for 5 days after each injection of vaccine. Unexpected or serious reactions are to be reported immediately to the study physician. Serious adverse experiences in the 14 days following each injection of vaccine are required to be reported by the investigator.

A blood sample is obtained immediately prior to and 1 month after each injection of vaccine. All serum samples are assayed for antibody to the capsular polysaccharide of Haemophilus influenzae type b by radioimmunoassay, diphtheria and tetanus toxoids by

STUDY PROCEDURE: (CONT.)

enzyme immunoassay, and to pertussis and polio virus. Selected samples are also tested for bactericidal and opsonophagocytic activity, immunoglobulin isotype and subclass IgG. Assays for DTP and OPV are performed at (b) (4) (b) (4) and for opsonophagocytic activity at the University of Alabama. All other assays are performed at Merck Sharp & Dohme Research Laboratories.

RESULTS:

Demographic information and individual pre and postimmunization antibody data for each vaccine recipient are presented in Tables 1-3.

1. Current status:

Regimen	No. Vaccinated PRP-OMPC	DTP/OPV
Concurrent	21	23*
Separate	26	18

*Two children received DT vaccine only.

2. Serologic results:

Anti-PRP responses prior to and 1 month after PRP-OMPC vaccination are as follows:

Regimen	Time	% With Anti-PRP >0.15 mcg/ml	% With Anti-PRP >1.0 mcg/ml	GMT (mcg/ml) All Vaccinees
Concurrent	Pre	25 (4/16)	6 (1/16)	0.11
	Post	100 (16/16)	88 (14/16)	5.02
Separate	Pre	21 (4/19)	0 (0/19)	0.08
	Post	100 (19/19)	90 (17/19)	6.51

Antibody responses to PRP, diphtheria and tetanus are presented in Table 4-6. Antibody responses to pertusis and polio virus are not yet available.

3. Clinical results:

The incidence of selected injection site and systemic reactions occurring within 2 days after vaccination are as follows:

Type of Reaction	% of Vaccinees with Reaction			
	Concurrent		Separate	
Injection Site:	PRP-OMPC	DTP/OPV	PRP-OMPC	DTP/OPV
Pain/Soreness	33 (7/21)	57 (12/21)	23 (6/26)	44 (7/16)
Erythema >1 inch	0 (0/21)	0 (0/21)	0 (0/26)	0 (0/16)
Swelling >1 inch	0 (0/21)	0 (0/21)	0 (0/26)	0 (0/16)
Induration	0 (0/21)	0 (0/21)	0 (0/26)	0 (0/16)
Systemic:			PRP-OMPC	DTP/OPV
Irritability	71 (15/21)		35 (9/26)	25 (4/16)
Sleepiness/Lethargy/ Fatigue	33 (7/21)		19 (5/26)	13 (2/16)

The frequencies of all clinical reactions and maximum temperatures occurring during the five days following each injection of PRP-OMPC vaccine and/or DTP/OPV vaccines are presented in Tables 7-9.

No serious or alarming reactions attributable to vaccination have been reported.

TABLE 1

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : DASHEFSKY,BARRY
STUDY : 001101
VACCINE : HIB/DTP/OPV CONCURRENTLY
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	IGG1
(b) (6)	M	BLAC	(b) (6)	18M	0	(b) (6)	001	PREBLEED				144		< 5		< 600
					0		011	INJ 1	CP749	15 MCG						
					0		011	INJ 1	87664							
					0		011	INJ 1	78612							
					30		011	BLEED 1				33759		>= 80		45161
	F	BLAC		19M	0		011	INJ 1	CP749	15 MCG						
					0		011	INJ 1	87664							
					0		011	INJ 1	78612							
	M	CAUC		20M	0		001	PREBLEED				< 125		< 5		
					0		011	INJ 1	CP749	15 MCG						
					0		011	INJ 1	87664							
					0		011	INJ 1	78612							
					28		011	BLEED 1				9904		20		
	M	CAUC		18M	0		001	PREBLEED				128		< 5		< 600
					0		011	INJ 1	CP749	15 MCG						
					0		011	INJ 1	87664							
					0		011	INJ 1	78612							
					28		011	BLEED 1				4538		>= 80		< 1200
	F	CAUC		19M	0		001	PREBLEED				< 125		< 5		< 600
					0		011	INJ 1	CP749	15 MCG						
					0		011	INJ 1	87664							
					0		011	INJ 1	78612							
					28		011	BLEED 1				647		>= 80		< 1200
	F	BLAC		17M	0		001	PREBLEED				< 125		< 5		< 600
					0		011	INJ 1	CP749	15 MCG						
					0		011	INJ 1	87664							
					0		011	INJ 1	78612							
					28		011	BLEED 1				21740		>= 80		18449
	M	CAUC		18M	0		001	PREBLEED				< 125		< 5		< 600
					0		011	INJ 1	CP749	15 MCG						
					0		011	INJ 1	87664							
					0		011	INJ 1	78612							
					28		011	BLEED 1				29848		>= 80		7824
	F	BLAC		18M	0		001	PREBLEED				< 125				

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : DASHEFSKY,BARRY
STUDY : 001101
VACCINE : HIB/DTP/OPV CONCURRENTLY
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ RIA	CODE/ SBA	CODE/ IGG1
(b) (6)	F	BLAC	(b) (6)	18M	0	(b) (6)	011	INJ 1	CP749	15 MCG			
					0		011	INJ 1	87664				
					0		011	INJ 1	78612				
					33		011	BLEED 1			13517		
	F	BLAC		19M	0		011	INJ 1	CP749	15 MCG			
					0		011	INJ 1	87664				
					0		011	INJ 1	78612				
	M	BLAC		19M	0		001	PREBLEED			136		
					0		011	INJ 1	CP749	15 MCG			
					0		011	INJ 1	87664				
					0		011	INJ 1	78612				
					50		011	BLEED 1			19565		
	M	BLAC		19M	0		001	PREBLEED			< 125	< 5	< 600
					0		011	INJ 1	CP749	15 MCG			
					0		011	INJ 1	87664				
					0		011	INJ 1	78612				
					35		011	BLEED 1			1230	< 5	< 1200
	M	BLAC		21M	0		001	PREBLEED			< 125	< 5	< 600
					0		011	INJ 1	CP749	15 MCG			
					0		011	INJ 1	87664				
					0		011	INJ 1	78612				
					35		011	BLEED 1			1699	20	3439
	F	CAUC		18M	0		001	PREBLEED			< 125		
					0		011	INJ 1	CP749	15 MCG			
					0		011	INJ 1	87664				
					0		011	INJ 1	78612				
					35		011	BLEED 1			1141		
	F	CAUC		17M	0		001	PREBLEED			< 125		
					0		011	INJ 1	CP749	15 MCG			
					0		011	INJ 1	87664				
					0		011	INJ 1	84609				
					29		011	BLEED 1			3057		
	M	BLAC		19M	0		001	PREBLEED			1657		
					0		011	INJ 1	CP749	15 MCG			

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : DASHEFSKY,BARRY
STUDY : 001101
VACCINE : HIB/DTP/OPV CONCURRENTLY
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	IGG1
(b) (6)	M	BLAC	(b) (6)	19M	0	(b) (6)	011	INJ	1	87664						
					0		011	INJ	1	84609						
					30		011	BLEED	1			11276				
	F	BLAC		18M	0		001	PREBLEED				329				
					0		011	INJ	1	CP749	15 MCG					
					0		011	INJ	1	87664						
					0		011	INJ	1	78612						
					32		011	BLEED	1			699				
	M	BLAC		20M	0		001	PREBLEED				416				
					0		011	INJ	1	CP749	15 MCG					
					0		011	INJ	1	87664						
					0		011	INJ	1	78612						
					31		011	BLEED	1			13695				
	M	CAUC		19M	0		011	INJ	1	CP749	15 MCG					
					0		011	INJ	1	87664						
					0		011	INJ	1	78612						
	F	BLAC		19M	0		001	PREBLEED				212				
					0		011	INJ	1	CP749	15 MCG					
					0		011	INJ	1	87664						
					0		011	INJ	1	78612						
					28		011	BLEED	1			1682				
	F	BLAC		23M	0		011	INJ	1	CP749	15 MCG					
					0		011	INJ	1	87664						
					0		011	INJ	1	78612						
	M	CAUC		18M	0		001	PREBLEED				< 125				
					0		011	INJ	1	CP749	15 MCG					
					0		011	INJ	1	87664						
					0		011	INJ	1	78612						
					34		011	BLEED	1			14261				

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : DASHEFSKY,BARRY
STUDY : 001101
VACCINE : HIB/DT/OPV CONCURRENTLY
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	IGG1
(b) (6)	F	BLAC	(b) (6)	18M	0	(b) (6)	001	PREBLEED				< 125				
					0		011	INJ 1	CP749	15 MCG						
					0		011	INJ 1	81038							
					0		011	INJ 1	78612							
					41		011	BLEED 1				1529				
	F	CAUC		17M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP749	15 MCG						
					0		011	INJ 1	81038							
					0		011	INJ 1	78612							
					29		011	BLEED 1				1572				

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : DASHEFSKY,BARRY
STUDY : 001101
VACCINE : HIB AND DTP/OPV 4 WEEKS APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ RIA	CODE/ SBA	CODE/ IGG1
(b) (6)	F	OTHE	(b) (6)	17M	0	(b) (6)	001	PREBLEED			157	< 5	< 600
					0		011	INJ 1	CP749	15 MCG			
					28		011	BLEED 1			5468	20	7369
					28		021	INJ 2	87664				
					28		021	INJ 2	78612				
					67		021	BLEED 2			17012	5	31660
	F	CAUC		17M	0		001	PREBLEED			< 125	< 5	< 600
					0		011	INJ 1	CP749	15 MCG			
					29		011	BLEED 1			334	< 5	< 1200
					29		021	INJ 2	87664				
					29		021	INJ 2	78612				
					64		021	BLEED 2			409	< 5	< 1200
	F	CAUC		19M	0		001	PREBLEED			< 125	< 5	< 600
					0		011	INJ 1	CP749	15 MCG			
					28		011	BLEED 1			115797	>= 80	> 2400
					28		021	INJ 2	87664				
					28		021	INJ 2	78612				
					63		021	BLEED 2			105167	20	> 2400
	F	BLAC		19M	0		001	PREBLEED			< 125		
					0		011	INJ 1	CP749	15 MCG			
					28		011	BLEED 1			73437		
					28		021	INJ 2	87664				
					28		021	INJ 2	78612				
					74		021	BLEED 2			34170		
	F	BLAC		17M	0		001	PREBLEED			< 125	< 5	< 600
					0		011	INJ 1	CP749	15 MCG			
					28		011	BLEED 1			11216	>= 80	5622
					28		021	INJ 2	87664				
					28		021	INJ 2	78612				
					49		021	BLEED 2			7960	>= 80	4122
	M	BLAC		17M	0		001	PREBLEED			< 125		
					0		011	INJ 1	CP749	15 MCG			
					36		011	BLEED 1			33853		
					36		021	INJ 2	87664				
					36		021	INJ 2	84609				
					92		021	BLEED 2			5738		

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : DASHEFSKY,BARRY
STUDY : 001101
VACCINE : HIB AND DTP/OPV 4 WEEKS APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	IGG1
(b) (6)	F	BLAC	(b) (6)	18M	0	(b) (6)	001	PREBLEED				< 125				
					0		011	INJ 1	CP749	15 MCG						
					28		011	BLEED 1				5053				
					28		021	INJ 2	87664							
					28		021	INJ 2	84609							
					62		021	BLEED 2				11995				
	F	BLAC		17M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP749	15 MCG						
					55		011	BLEED 1			05/	2226				
					55		021	INJ 2	87664							
					55		021	INJ 2	78612							
	F	BLAC		18M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP749	15 MCG						
					35		011	BLEED 1				6667				
					35		021	INJ 2	87664							
					35		021	INJ 2	78612							
					91		021	BLEED 2				7688				
	F	BLAC		20M	0		001	PREBLEED				157				
					0		011	INJ 1	CP749	15 MCG						
					46		011	BLEED 1				894				
					46		021	INJ 2	87664							
					46		021	INJ 2	78612							
					95		021	BLEED 2				910				
	M	CAUC		20M	0		001	PREBLEED				233				
					0		011	INJ 1	CP749	15 MCG						
					33		011	BLEED 1				10191				
					33		021	INJ 2	87664							
					33		021	INJ 2	78612							
					69		021	BLEED 2				21578				
	F	BLAC		18M	0		001	PREBLEED				< 125				
					0		011	INJ 1	CP749	15 MCG						
					32		011	BLEED 1				3795				
					32		021	INJ 2	87664							
					32		021	INJ 2	78612							
					60		021	BLEED 2				6019				
	F	BLAC		19M	0		001	PREBLEED				< 125				

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : DASHEFSKY,BARRY
STUDY : 001101
VACCINE : HIB AND DTP/OPV 4 WEEKS APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	IGG1
(b) (6)	F	BLAC	(b) (6)	19M	0	(b) (6)	011	INJ	1	CP749	15 MCG					
					28		011	BLEED	1			1109				
					28		021	INJ	2	87664						
					28		021	INJ	2	78612						
	M	CAUC		20M	0		001	PREBLEED				< 125				
					0		011	INJ	1	CP749	15 MCG					
					30		011	BLEED	1			< 125				
					30		021	INJ	2	87664						
					30		021	INJ	2	78618						
					65		021	BLEED	2			947				
	F	BLAC		17M	0		001	PREBLEED				< 125				
					0		011	INJ	1	CP749	15 MCG					
					30		011	BLEED	1			1770				
					30		021	INJ	2	87664						
					30		021	INJ	2	78612						
					66		021	BLEED	2			1791				
	F	BLAC		17M	0		001	PREBLEED				< 125				
					0		011	INJ	1	CP749	15 MCG					
					29		011	BLEED	1			37558				
					29		021	INJ	2	B7664						
					29		021	INJ	2	78612						
					66		021	BLEED	2			15450				
	F	BLAC		19M	0		001	PREBLEED				< 125				
					0		011	INJ	1	CP749	15 MCG					
					28		011	BLEED	1			2781				
					28		021	INJ	2	87664						
					28		021	INJ	2	78612						
	M	CAUC		24M	0		001	PREBLEED				< 125				
					0		011	INJ	1	CP749	15 MCG					
					40		011	BLEED	1			4337				
	F	BLAC		19M	0		001	PREBLEED				< 125				
					0		011	INJ	1	CP749	15 MCG					
	F	BLAC		20M	0		001	PREBLEED				< 125				
					0		011	INJ	1	CP749	15 MCG					

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : DASHEFSKY,BARRY
STUDY : 001101
VACCINE : HIB AND DTP/OPV 4 WEEKS APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	IGG1
(b) (6)	F	BLAC	(b) (6)	20M	45	(b) (6)	011	BLEED	1			7490				
	M	BLAC		22M	0		011	INJ	1	CP749 15 MCG						
	F	CAUC		23M	0		011	INJ	1	CP749 15 MCG						
					60		011	BLEED	1			16888				
	F	CAUC		21M	0		001	PREBLEED				315		< 5		
					0		011	INJ	1	CP749 15 MCG						
					28		011	BLEED	1			10086		>= 80		
	M	CAUC		18M	0		001	PREBLEED				< 125				
					0		011	INJ	1	CP749 15 MCG						
					34		011	BLEED	1			6236				
	F	CAUC		17M	0		011	INJ	1	CP749 15 MCG						
	M	BLAC		19M	0		011	INJ	1	CP749 15 MCG						

TABLE 2

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : DASHEFSKY,BARRY
STUDY : 001101
VACCINE : HIB/DTP/OPV CONCURRENTLY
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/IGG2	CODE/IGG TOTAL	CODE/IGGM
(b) (6)	M	BLAC	(b) (6)	18M	0	(b) (6)	011	INJ 1	CP749	15 MCG			
					0		011	INJ 1	87664				
					0		011	INJ 1	78612				
	F	BLAC		19M	0		011	INJ 1	CP749	15 MCG			
					0		011	INJ 1	87664				
					0		011	INJ 1	78612				
	M	CAUC		20M	0		011	INJ 1	CP749	15 MCG			
					0		011	INJ 1	87664				
					0		011	INJ 1	78612				
	M	CAUC		18M	0		001	PREBLEED				< 100	814
					0		011	INJ 1	CP749	15 MCG			
					0		011	INJ 1	87664				
					0		011	INJ 1	78612				
					28		011	BLEED 1				301	1373
	F	CAUC		19M	0		001	PREBLEED				< 100	492
					0		011	INJ 1	CP749	15 MCG			
					0		011	INJ 1	87664				
					0		011	INJ 1	78612				
					28		011	BLEED 1				< 100	1027
	F	BLAC		17M	0		001	PREBLEED				< 100	< 100
					0		011	INJ 1	CP749	15 MCG			
					0		011	INJ 1	87664				
					0		011	INJ 1	78612				
					28		011	BLEED 1				2482	2925
	M	CAUC		18M	0		001	PREBLEED				< 100	< 100
					0		011	INJ 1	CP749	15 MCG			
					0		011	INJ 1	87664				
					0		011	INJ 1	78612				
					28		011	BLEED 1				1865	1965
	F	BLAC		18M	0		011	INJ 1	CP749	15 MCG			
					0		011	INJ 1	87664				
					0		011	INJ 1	78612				
	F	BLAC		19M	0		011	INJ 1	CP749	15 MCG			

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : DASHEFSKY,BARRY
STUDY : 001101
VACCINE : HIB/DTP/OPV CONCURRENTLY
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ IGG2	CODE/IGG	TOTAL CODE/ IGGM
(b) (6)	F	BLAC	(b) (6)	19M	0	(b) (6)	011	INJ	1 87664				
					0		011	INJ	1 78612				
	M	BLAC		19M	0		011	INJ	1 CP749	15 MCG			
					0		011	INJ	1 87664				
					0		011	INJ	1 78612				
	M	BLAC		19M	0		001	PREBLEED				< 100	< 100
					0		011	INJ	1 CP749	15 MCG			
					0		011	INJ	1 87664				
					0		011	INJ	1 78612				
					35		011	BLEED	1			116	652
	M	BLAC		21M	0		001	PREBLEED			< 250	< 100	< 100
					0		011	INJ	1 CP749	15 MCG			
					0		011	INJ	1 87664				
					0		011	INJ	1 78612				
					35		011	BLEED	1		< 250	165	447
	F	CAUC		18M	0		011	INJ	1 CP749	15 MCG			
					0		011	INJ	1 87664				
					0		011	INJ	1 78612				
	F	CAUC		17M	0		011	INJ	1 CP749	15 MCG			
					0		011	INJ	1 87664				
					0		011	INJ	1 84609				
	M	BLAC		19M	0		011	INJ	1 CP749	15 MCG			
					0		011	INJ	1 87664				
					0		011	INJ	1 84609				
	F	BLAC		18M	0		011	INJ	1 CP749	15 MCG			
					0		011	INJ	1 87664				
					0		011	INJ	1 78612				
	M	BLAC		20M	0		011	INJ	1 CP749	15 MCG			
					0		011	INJ	1 87664				
					0		011	INJ	1 78612				
	M	CAUC		19M	0		011	INJ	1 CP749	15 MCG			
					0		011	INJ	1 87664				

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : DASHEFSKY,BARRY
STUDY : 001101
VACCINE : HIB/DTP/OPV CONCURRENTLY
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ IGG2	CODE/IGG TOTAL	CODE/ IGGM
(b) (6)	M	CAUC	(b) (6)	19M	0	(b) (6)	011	INJ	1	78612			
	F	BLAC		19M	0		011	INJ	1	CP749	15 MCG		
					0		011	INJ	1	87664			
					0		011	INJ	1	78612			
	F	BLAC		23M	0		011	INJ	1	CP749	15 MCG		
					0		011	INJ	1	87664			
					0		011	INJ	1	78612			
	M	CAUC		18M	0		011	INJ	1	CP749	15 MCG		
					0		011	INJ	1	87664			
					0		011	INJ	1	78612			

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : DASHEFSKY,BARRY
STUDY : 001101
VACCINE : HIB AND DTP/OPV 4 WEEKS APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/IGG2 TOTAL	CODE/IGGM
(b) (6)	F	OTHE	(b) (6)	17M	0	(b) (6)	001	PREBLEED			< 100	133
					0		011	INJ 1	CP749	15 MCG		
					28		011	BLEED 1			565	16580
					28		021	INJ 2	87664			
					28		021	INJ 2	78612			
					67		021	BLEED 2			2614	1327
	F	CAUC		17M	0		001	PREBLEED			< 100	< 100
					0		011	INJ 1	CP749	15 MCG		
					29		011	BLEED 1			< 100	< 100
					29		021	INJ 2	87664			
					29		021	INJ 2	78612			
					64		021	BLEED 2			< 100	134
	F	CAUC		19M	0		011	INJ 1	CP749	15 MCG		
					28		021	INJ 2	87664			
					28		021	INJ 2	78612			
	F	BLAC		19M	0		011	INJ 1	CP749	15 MCG		
					28		021	INJ 2	87664			
					28		021	INJ 2	78612			
	F	BLAC		17M	0		001	PREBLEED			< 100	< 100
					D		011	INJ 1	CP749	15 MCG		
					28		011	BLEED 1			509	1248
					28		021	INJ 2	87664			
					28		021	INJ 2	78612			
					49		021	BLEED 2			601	890
	M	BLAC		17M	0		011	INJ 1	CP749	15 MCG		
					36		021	INJ 2	87664			
					36		021	INJ 2	84609			
	F	BLAC		18M	0		011	INJ 1	CP749	15 MCG		
					28		021	INJ 2	87664			
					28		021	INJ 2	84609			
	F	BLAC		17M	0		011	INJ 1	CP749	15 MCG		
					55		021	INJ 2	87664			
					55		021	INJ 2	78612			
	F	BLAC		18M	0		011	INJ 1	CP749	15 MCG		

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : DASHEFSKY,BARRY
STUDY : 001101
VACCINE : HIB AND DTP/OPV 4 WEEKS APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ IGG2	CODE/IGG TOTAL	CODE/ IGGM
(b) (6)	F	BLAC	(b) (6)	18M	35	(b) (6)	021	INJ	2	87664			
					35		021	INJ	2	78612			
	F	BLAC		20M	0		011	INJ	1	CP749	15 MCG		
					46		021	INJ	2	87664			
					46		021	INJ	2	78612			
	M	CAUC		20M	0		011	INJ	1	CP749	15 MCG		
					33		021	INJ	2	87664			
					33		021	INJ	2	78612			
	F	BLAC		18M	0		011	INJ	1	CP749	15 MCG		
					32		021	INJ	2	87664			
					32		021	INJ	2	78612			
	F	BLAC		19M	0		011	INJ	1	CP749	15 MCG		
					28		021	INJ	2	87664			
					28		021	INJ	2	78612			
	M	CAUC		20M	0		011	INJ	1	CP749	15 MCG		
					30		021	INJ	2	87664			
					30		021	INJ	2	78618			
	F	BLAC		17M	0		011	INJ	1	CP749	15 MCG		
					30		021	INJ	2	87664			
					30		021	INJ	2	78612			
	F	BLAC		17M	0		011	INJ	1	CP749	15 MCG		
					29		021	INJ	2	87664			
					29		021	INJ	2	78612			
	F	BLAC		19M	0		011	INJ	1	CP749	15 MCG		
					28		021	INJ	2	87664			
					28		021	INJ	2	78612			
	M	CAUC		24M	0		011	INJ	1	CP749	15 MCG		
	F	BLAC		19M	0		011	INJ	1	CP749	15 MCG		
	F	BLAC		20M	0		011	INJ	1	CP749	15 MCG		
	M	BLAC		22M	0		011	INJ	1	CP749	15 MCG		

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : DASHEFSKY,BARRY
STUDY : 001101
VACCINE : HIB AND DTP/OPV 4 WEEKS APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ IGG2	CODE/IGG	TOTAL	CODE/ IGGM
(b) (6)	F	CAUC	(b) (6)	23M	0	(b) (6)	011	INJ	1 CP749	15 MCG				
	F	CAUC		21M	0		011	INJ	1 CP749	15 MCG				
	M	CAUC		18M	0		011	INJ	1 CP749	15 MCG				
	F	CAUC		17M	0		011	INJ	1 CP749	15 MCG				
	M	BLAC		19M	0		011	INJ	1 CP749	15 MCG				

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : DASHEFSKY,BARRY
STUDY : 001101
VACCINE : HIB/DT/OPV CONCURRENTLY
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ IGG2	CODE/IGG TOTAL CODE/ IGGM
(b) (6)	F	BLAC	(b) (6)	18M	0	(b) (6)	011	INJ	1	CP749	15 MCG	
					0		011	INJ	1	81038		
					0		011	INJ	1	78612		
	F	CAUC		17M	0		011	INJ	1	CP749	15 MCG	
					0		011	INJ	1	81038		
					0		011	INJ	1	78612		

TABLE 3

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : DASHEFSKY,BARRY
STUDY : 001101
VACCINE : HIB/DTP/OPV CONCURRENTLY
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/DIPTHERIA	CODE/ TETANUS
(b) (6)	M	BLAC	(b) (6)	18M	0	(b) (6)	001	PREBLEED			0.91	0.96
					0		011	INJ 1	CP749	15 MCG		
					0		011	INJ 1	87664			
					0		011	INJ 1	78612			
					30		011	BLEED 1			94	28
	F	BLAC		19M	0		011	INJ 1	CP749	15 MCG		
					0		011	INJ 1	87664			
					0		011	INJ 1	78612			
	M	CAUC		20M	0		001	PREBLEED			1.53	0.37
					0		011	INJ 1	CP749	15 MCG		
					0		011	INJ 1	87664			
					0		011	INJ 1	78612			
					28		011	BLEED 1			75	12
	M	CAUC		18M	0		001	PREBLEED			0.64	0.35
					0		011	INJ 1	CP749	15 MCG		
					0		011	INJ 1	87664			
					0		011	INJ 1	78612			
					28		011	BLEED 1			40	16
	F	CAUC		19M	0		001	PREBLEED			1.23	0.33
					0		011	INJ 1	CP749	15 MCG		
					0		011	INJ 1	87664			
					0		011	INJ 1	78612			
					28		011	BLEED 1			45	25
	F	BLAC		17M	0		001	PREBLEED			0.04	0.18
					0		011	INJ 1	CP749	15 MCG		
					0		011	INJ 1	87664			
					0		011	INJ 1	78612			
					28		011	BLEED 1			6.2	9.8
	M	CAUC		18M	0		001	PREBLEED			0.32	0.2
					0		011	INJ 1	CP749	15 MCG		
					0		011	INJ 1	87664			
					0		011	INJ 1	78612			
					28		011	BLEED 1			30	17
	F	BLAC		18M	0		001	PREBLEED			1.09	0.29

TABLE 3 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : DASHEFSKY,BARRY
STUDY : 001101
VACCINE : HIB/DTP/OPV CONCURRENTLY
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT		LOT	DOSE	CODE/DIPTHERIA	CODE/ TETANUS
(b) (6)	F	BLAC	(b) (6)	18M	0	(b) (6)	011	INJ	1	CP749	15 MCG		
					0		011	INJ	1	87664			
					0		011	INJ	1	78612			
					33		011	BLEED	1			35	7.1
	F	BLAC		19M	0		011	INJ	1	CP749	15 MCG		
					0		011	INJ	1	87664			
					0		011	INJ	1	78612			
	M	BLAC		19M	0		001	PREBLEED				0.79	0.43
					0		011	INJ	1	CP749	15 MCG		
					0		011	INJ	1	87664			
					0		011	INJ	1	78612			
					50		011	BLEED	1			35	14
	M	BLAC		19M	0		001	PREBLEED				0.79	0.15
					0		011	INJ	1	CP749	15 MCG		
					0		011	INJ	1	87664			
					0		011	INJ	1	78612			
					35		011	BLEED	1			30	7
	M	BLAC		21M	0		001	PREBLEED				1.25	0.32
					0		011	INJ	1	CP749	15 MCG		
					0		011	INJ	1	87664			
					0		011	INJ	1	78612			
					35		011	BLEED	1			11	9
	F	CAUC		18M	0		001	PREBLEED				0.2	0.09
					0		011	INJ	1	CP749	15 MCG		
					0		011	INJ	1	87664			
					0		011	INJ	1	78612			
					35		011	BLEED	1			25	8.25
	F	CAUC		17M	0		001	PREBLEED				1.87	0.28
					0		011	INJ	1	CP749	15 MCG		
					0		011	INJ	1	87664			
					0		011	INJ	1	84609			
					29		011	BLEED	1			30	4.3
	M	BLAC		19M	0		001	PREBLEED				0.43	0.11
					0		011	INJ	1	CP749	15 MCG		

TABLE 3 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : DASHEFSKY,BARRY
STUDY : 001101
VACCINE : HIB/DTP/OPV CONCURRENTLY
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT		LOT	DOSE	CODE/DIPTHERIA	CODE/ TETANUS
(b) (6)	M	BLAC	(b) (6)	19M	0	(b) (6)	011	INJ	1	87664			
					0		011	INJ	1	84609			
					30		011	BLEED	1			9.4	6.5
	F	BLAC		18M	0		001	PREBLEED				0.53	0.07
					0		011	INJ	1	CP749	15 MCG		
					0		011	INJ	1	87664			
					0		011	INJ	1	78612			
					32		011	BLEED	1			30	1.7
	M	BLAC		20M	0		011	PREBLEED				0.14	0.11
					0		011	INJ	1	CP749	15 MCG		
					0		011	INJ	1	87664			
					0		011	INJ	1	78612			
					31		021	BLEED	1			12	15
	M	CAUC		19M	0		011	PREBLEED				0.11	0.13
					0		011	INJ	1	CP749	15 MCG		
					0		011	INJ	1	87664			
					0		011	INJ	1	78612			
					30		021	BLEED	1			20	20
	F	BLAC		19M	0		011	PREBLEED				0.22	0.24
					0		011	INJ	1	CP749	15 MCG		
					0		011	INJ	1	87664			
					0		011	INJ	1	78612			
					28		021	BLEED	1			3.3	4.2
	F	BLAC		23M	0		011	INJ	1	CP749	15 MCG		
					0		011	INJ	1	87664			
					0		011	INJ	1	78612			
	M	CAUC		18M	0		011	INJ	1	CP749	15 MCG		
					0		011	INJ	1	87664			
					0		011	INJ	1	78612			

TABLE 3 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : DASHEFSKY,BARRY
STUDY : 001101
VACCINE : HIB AND DTP/OPV 4 WEEKS APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT		LOT	DOSE	CODE/DIPTHERIA	CODE/ TETANUS
(b) (6)	F	OTHE	(b) (6)	17M	0	(b) (6)	011	INJ	1	CP749	15 MCG		
					28		011	BLEED	1			0.67	0.36
					28		021	INJ	2	87664			
					28		021	INJ	2	78612			
					67		021	BLEED	2			11	3
	F	CAUC		17M	0		011	INJ	1	CP749	15 MCG		
					29		011	BLEED	1			0.6	0.23
					29		021	INJ	2	87664			
					29		021	INJ	2	78612			
					64		021	BLEED	2			15	9.3
	F	CAUC		19M	0		011	INJ	1	CP749	15 MCG		
					28		011	BLEED	1			0.64	0.19
					28		021	INJ	2	87664			
					28		021	INJ	2	78612			
					63		021	BLEED	2			13	8.5
	F	BLAC		19M	0		011	INJ	1	CP749	15 MCG		
					28		011	BLEED	1			1.28	0.64
					28		021	INJ	2	87664			
					28		021	INJ	2	78612			
					74		021	BLEED	2			25	12
	F	BLAC		17M	0		011	INJ	1	CP749	15 MCG		
					28		011	BLEED	1			1	0.18
					28		021	INJ	2	87664			
					28		021	INJ	2	78612			
					49		021	BLEED	2			13	9.3
	M	BLAC		17M	0		011	INJ	1	CP749	15 MCG		
					36		011	BLEED	1			3.7	1.7
					36		021	INJ	2	87664			
					36		021	INJ	2	84609			
					92		021	BLEED	2			14	4.3
	F	BLAC		18M	0		011	INJ	1	CP749	15 MCG		
					28		011	BLEED	1			0.52	0.19
					28		021	INJ	2	87664			
					28		021	INJ	2	84609			
					62		021	BLEED	2			9.1	12

TABLE 3 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : DASHEFSKY,BARRY
STUDY : 001101
VACCINE : HIB AND DTP/OPV 4 WEEKS APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT		LOT	DOSE	CODE/DIPTHERIA	CODE/ TETANUS
(b) (6)	F	BLAC	(b) (6)	17M	0	(b) (6)	011	INJ	1	CP749	15 MCG		
					55		021	INJ	2	87664			
					55		021	INJ	2	78612			
	F	BLAC		18M	0		011	INJ	1	CP749	15 MCG		
					35		011	BLEED	1			0.59	0.31
					35		021	INJ	2	87664			
					35		021	INJ	2	78612			
					91		021	BLEED	2			4.5	3.8
	F	BLAC		20M	0		011	INJ	1	CP749	15 MCG		
					46		011	BLEED	1			4.4	0.76
					46		021	INJ	2	87664			
					46		021	INJ	2	78612			
					95		021	BLEED	2			30	3.2
	M	CAUC		20M	0		011	INJ	1	CP749	15 MCG		
					33		011	BLEED	1			4	1.2
					33		021	INJ	2	87664			
					33		021	INJ	2	78612			
					69		021	BLEED	2			40	6.7
	F	BLAC		18M	0		011	INJ	1	CP749	15 MCG		
					32		011	BLEED	1			30	0.29
					32		021	INJ	2	87664			
					32		021	INJ	2	78612			
					60		021	BLEED	2			25	20
	F	BLAC		19M	0		011	INJ	1	CP749	15 MCG		
					28		021	INJ	2	87664			
					28		021	INJ	2	78612			
	M	CAUC		20M	0		011	INJ	1	CP749	15 MCG		
					30		011	BLEED	1			0.16	0.26
					30		021	INJ	2	87664			
					30		021	INJ	2	78618			
					65		021	BLEED	2			20	12
	F	BLAC		17M	0		011	PREBLEED				0.45	0.15
					0		011	INJ	1	CP749	15 MCG		
					30		021	INJ	2	87664			

TABLE 3 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : DASHEFSKY,BARRY
STUDY : 001101
VACCINE : HIB AND DTP/OPV 4 WEEKS APART
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT		LOT	DOSE	CODE/DIPTHERIA	CODE/ TETANUS
(b) (6)	F	BLAC	(b) (6)	17M	30	(b) (6)	021	INJ	2	78612			
					58		021	BLEED	1			25	3.1
	F	BLAC		17M	0		011	INJ	1	CP749	15 MCG		
					29		011	BLEED	1			1	0.28
					29		021	INJ	2	87664			
					29		021	INJ	2	78612			
					66		021	BLEED	2			45	10
	F	BLAC		19M	0		011	INJ	1	CP749	15 MCG		
					28		021	INJ	2	87664			
					28		021	INJ	2	78612			
	M	CAUC		24M	0		011	INJ	1	CP749	15 MCG		
	F	BLAC		19M	0		011	INJ	1	CP749	15 MCG		
	F	BLAC		20M	0		011	INJ	1	CP749	15 MCG		
	M	BLAC		22M	0		011	INJ	1	CP749	15 MCG		
	F	CAUC		23M	0		011	INJ	1	CP749	15 MCG		
	F	CAUC		21M	0		011	INJ	1	CP749	15 MCG		
	M	CAUC		18M	0		011	INJ	1	CP749	15 MCG		
	F	CAUC		17M	0		011	INJ	1	CP749	15 MCG		
	M	BLAC		19M	0		011	INJ	1	CP749	15 MCG		

TABLE 3 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : DASHEFSKY,BARRY
STUDY : 001101
VACCINE : HIB/DT/OPV CONCURRENTLY
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT		LOT	DOSE	CODE/DIPTHERIA	CODE/ TETANUS
(b) (6)	F	BLAC	(b) (6)	18M	0	(b) (6)	001	PREBLEED				4.3	0.34
					0		011	INJ	1	CP749	15 MCG		
					0		011	INJ	1	81038			
					0		011	INJ	1	78612			
					41		011	BLEED	1			25	3.3
	F	CAUC		17M	0		011	INJ	1	CP749	15 MCG		
					0		011	INJ	1	81038			
					0		011	INJ	1	78612			

TABLE 4

A N T I B O D Y R E S P O N S E S

INVESTIGATOR : DASHEFSKY,BARRY
STUDY : 001101
VACCINE : HIB/DTP/OPV CONCURRENTLY
ASSAY : RIA
POPULATION : HEALTHY CHILDREN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
17-24 MOS.	PRE INJ	25 (4/ 16)	6 (1/ 16)			0.114 (16)
	1 MONTH	100 (16/ 16)	88 (14/ 16)	100 (16/ 16)	28.6	5.020 (16)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 5

ANTIBODY RESPONSES

INVESTIGATOR : DASHEFSKY,BARRY
STUDY : 001101
VACCINE : HIB AND DTP/OPV 4 WEEKS APART
ASSAY : RIA
POPULATION : HEALTHY CHILDREN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
17-24 MOS.	PRE INJ	20 (4/ 20)	0 (0/ 20)			0.079 (20)
	1 MONTH	95 (19/ 20)	85 (17/ 20)	95 (19/ 20)	38.7	5.161 (20)
	2 MONTHS	100 (12/ 12)	75 (9/ 12)	100 (12/ 12)	48.6	6.644 (12)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 6

Antibody Responses to Diphtheria and Tetanus Toxoids Following Administration of DTP/OPV Vaccines Alone or Concurrently with PRP-OMPC Vaccine

Toxoid	Time	Vaccination Regimen	No. of Subjects	% With >4-Fold Rise	Geometric Mean Fold Rise	Antibody GMT (U/L)
Diphtheria	Pre	Concurrent	16	--	--	0.46
		4 Weeks Apart	11	--	--	0.91
	1 Mo.	Concurrent	16	100 (16/16)	48.84	22.58
		4 Weeks Apart	11	100 (11/11)	21.72	19.68
Tetanus	Pre	Concurrent	16	--	--	0.21
		4 Weeks Apart	11	--	--	0.34
	1 Mo.	Concurrent	16	100 (16/16)	45.69	9.57
		4 Weeks Apart	11	100 (11/11)	25.08	8.48

TABLE 7

C L I N I C A L C O M P L A I N T S B Y F R E Q U E N C Y

INVESTIGATOR : DASHEFSKY,BARRY
STUDY : 001101
VACCINE : HIB/DTP/OPV CONCURRENTLY
POPULATION : HEALTHY CHILDREN
AGE RANGE : 17-24 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	21	
VACCINEES WITH NO COMPLAINTS :	13	(61.9 %)
VACCINEES WITH COMPLAINTS :	8	(38.1 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS BY BODY SYSTEM	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 21 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	8	38.1
PAIN/SORENESS, INJ. SITE	7	33.3
SWELLING, INJ. SITE (<=1 IN.)	3	14.3
ERYTHEMA, INJ. SITE (<=1 IN.)	2	9.5

TABLE 7 (cont.)

C L I N I C A L C O M P L A I N T S B Y F R E Q U E N C Y

INVESTIGATOR : DASHEFSKY,BARRY
STUDY : 001101
VACCINE : HIB/DTP/OPV CONCURRENTLY
POPULATION : HEALTHY CHILDREN
AGE RANGE : 17-24 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	DTP INJECTION: 1	
TOTAL VACCINEES :	21	
VACCINEES WITH NO COMPLAINTS :	6	(28.6 %)
VACCINEES WITH COMPLAINTS :	15	(71.4 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS BY BODY SYSTEM	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 21 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	15	71.4
PAIN/SORENESS, INJ. SITE	12	57.1
SWELLING, INJ. SITE (<=1 IN.)	6	28.6
ERYTHEMA, INJ. SITE (<=1 IN.)	5	23.8

TABLE 7 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : DASHEFSKY,BARRY
STUDY : 001101
VACCINE : HIB/DTP/OPV CONCURRENTLY
POPULATION : HEALTHY CHILDREN
AGE RANGE : 17-24 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB/DTP/OPV CONCURRENTLY INJECTION: 1	
TOTAL VACCINEES :	21	
VACCINEES WITH NO COMPLAINTS :	3	(14.3 %)
VACCINEES WITH COMPLAINTS :	18	(85.7 %)
VACCINEES WITH NO DATA :	0	

CLINICAL COMPLAINTS BY BODY SYSTEM	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 21 VACCINEES
SYSTEMIC REACTIONS	18	85.7
IRRITABILITY	16	76.2
WARM TO TOUCH	9	42.9
FATIGUE	8	38.1
DIARRHEA	6	28.6
VOMITING	2	9.5
CONTUSION	1	4.8
COUGH	1	4.8
DIZZINESS	1	4.8
NAUSEA	1	4.8
RASH	1	4.8
SPASM	1	4.8
VIRUS INFECTION	1	4.8
WHEEZING	1	4.8
ASTHENIA	0	0.0
ASTHMA	0	0.0
ATOPIC DERMATITIS	0	0.0
COMMON COLD	0	0.0
MYRINGOTOMY	0	0.0
NASAL DISCHARGE	0	0.0
OTITIS MEDIA	0	0.0
PROLONGED CRYING, >1/2 HR	0	0.0
SINUSITIS	0	0.0
UNUSUAL HIGH-PITCHED CRYING	0	0.0

TABLE 7 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : DASHEFSKY,BARRY
STUDY : 001101
VACCINE : HIB AND DTP/OPV 4 WEEKS APART
POPULATION : HEALTHY CHILDREN
AGE RANGE : 17-24 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	26	
VACCINEES WITH NO COMPLAINTS :	11	(42.3 %)
VACCINEES WITH COMPLAINTS :	15	(57.7 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS BY BODY SYSTEM	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 26 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	8	30.8
ERYTHEMA, INJ. SITE (<=1 IN.)	7	26.9
PAIN/SORENESS, INJ. SITE	6	23.1
SWELLING, INJ. SITE (<=1 IN.)	3	11.5
SYSTEMIC REACTIONS	14	53.8
IRRITABILITY	9	34.6
FATIGUE	7	26.9
DIARRHEA	4	15.4
VOMITING	4	15.4
OTITIS MEDIA	3	11.5
WARM TO TOUCH	3	11.5
PROLONGED CRYING, >1/2 HR	2	7.7
RASH	2	7.7
ASTHENIA	1	3.8
ASTHMA	1	3.8
COUGH	1	3.8
NASAL DISCHARGE	1	3.8
NAUSEA	1	3.8
SINUSITIS	1	3.8
WHEEZING	1	3.8
ATOPIC DERMATITIS	0	0.0
COMMON COLD	0	0.0
CONTUSION	0	0.0
DIZZINESS	0	0.0
MYRINGOTOMY	0	0.0
SPASM	0	0.0
UNUSUAL HIGH-PITCHED CRYING	0	0.0
VIRUS INFECTION	0	0.0

TABLE 7 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : DASHEFSKY,BARRY
STUDY : 001101
VACCINE : HIB AND DTP/OPV 4 WEEKS APART
POPULATION : HEALTHY CHILDREN
AGE RANGE : 17-24 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	DTP INJECTION: 2	
TOTAL VACCINEES :	17	
VACCINEES WITH NO COMPLAINTS :	4	(25.0 %)
VACCINEES WITH COMPLAINTS :	12	(75.0 %)
VACCINEES WITH NO DATA :	1	
CLINICAL COMPLAINTS BY BODY SYSTEM	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 16 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	9	56.3
PAIN/SORENESS, INJ. SITE	7	43.8
ERYTHEMA, INJ. SITE (<=1 IN.)	3	18.8
SWELLING, INJ. SITE (<=1 IN.)	2	12.5
SYSTEMIC REACTIONS	7	43.8
IRRITABILITY	4	25.0
WARM TO TOUCH	4	25.0
FATIGUE	2	12.5
ATOPIC DERMATITIS	1	6.3
COMMON COLD	1	6.3
MYRINGOTOMY	1	6.3
OTITIS MEDIA	1	6.3
PROLONGED CRYING, >1/2 HR	1	6.3
UNUSUAL HIGH-PITCHED CRYING	1	6.3
ASTHENIA	0	0.0
ASTHMA	0	0.0
CONTUSION	0	0.0
COUGH	0	0.0
DIARRHEA	0	0.0
DIZZINESS	0	0.0
NASAL DISCHARGE	0	0.0
NAUSEA	0	0.0
RASH	0	0.0
SINUSITIS	0	0.0
SPASM	0	0.0
VIRUS INFECTION	0	0.0
VOMITING	0	0.0
WHEEZING	0	0.0

TABLE 7 (cont.)

C L I N I C A L C O M P L A I N T S B Y F R E Q U E N C Y

INVESTIGATOR : DASHEFSKY,BARRY
STUDY : 001101
VACCINE : HIB/DT/OPV CONCURRENTLY
POPULATION : HEALTHY CHILDREN
AGE RANGE : 17-24 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	2	
VACCINEES WITH NO COMPLAINTS :	2	(100.0 %)
VACCINEES WITH COMPLAINTS :	0	(0.0 %)
VACCINEES WITH NO DATA :	0	

CLINICAL COMPLAINTS BY BODY SYSTEM	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 2 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	0	0.0
ERYTHEMA, INJ. SITE (<=1 IN.)	0	0.0
PAIN/SORENESS, INJ. SITE	0	0.0
SWELLING, INJ. SITE (<=1 IN.)	0	0.0

TABLE 7 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : DASHEFSKY,BARRY
STUDY : 001101
VACCINE : HIB/DT/OPV CONCURRENTLY
POPULATION : HEALTHY CHILDREN
AGE RANGE : 17-24 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	DT	
	INJECTION: 1	
TOTAL VACCINEES :	2	
VACCINEES WITH NO COMPLAINTS :	2	(100.0 %)
VACCINEES WITH COMPLAINTS :	0	(0.0 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS BY BODY SYSTEM	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 2 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	0	0.0
ERYTHEMA, INJ. SITE (<=1 IN.)	0	0.0
PAIN/SORENESS, INJ. SITE	0	0.0
SWELLING, INJ. SITE (<=1 IN.)	0	0.0

TABLE 7 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : DASHEFSKY,BARRY
STUDY : 001101
VACCINE : HIB/DT/OPV CONCURRENTLY
POPULATION : HEALTHY CHILDREN
AGE RANGE : 17-24 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB/DT/OPV CONCURRENTLY INJECTION: 1	
TOTAL VACCINEES :	2	
VACCINEES WITH NO COMPLAINTS :	1	(50.0 %)
VACCINEES WITH COMPLAINTS :	1	(50.0 %)
VACCINEES WITH NO DATA :	0	

CLINICAL COMPLAINTS BY BODY SYSTEM	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 2 VACCINEES
SYSTEMIC REACTIONS	1	50.0
IRRITABILITY	1	50.0
OTITIS MEDIA	1	50.0
ASTHENIA	0	0.0
ASTHMA	0	0.0
ATOPIC DERMATITIS	0	0.0
COMMON COLD	0	0.0
CONTUSION	0	0.0
COUGH	0	0.0
DIARRHEA	0	0.0
DIZZINESS	0	0.0
FATIGUE	0	0.0
MYRINGOTOMY	0	0.0
NASAL DISCHARGE	0	0.0
NAUSEA	0	0.0
PROLONGED CRYING, >1/2 HR	0	0.0
RASH	0	0.0
SINUSITIS	0	0.0
SPASM	0	0.0
UNUSUAL HIGH-PITCHED CRYING	0	0.0
VIRUS INFECTION	0	0.0
VOMITING	0	0.0
WARM TO TOUCH	0	0.0
WHEEZING	0	0.0

TABLE 8

CLINICAL COMPLAINTS

INVESTIGATOR : DASHEFSKY,BARRY
STUDY : 001101
VACCINE : HIB/DTP/OPV CONCURRENTLY
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 17-24 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (21 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
LOCAL REACTIONS	6 (28.6%)	7 (33.3%)	1 (4.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		8 (38.1%)
ERYTHEMA, INJ. SITE (<=1 IN.)	1 (4.8%)	2 (9.5%)	1 (4.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (9.5%)
PAIN/SORENESS, INJ. SITE	5 (23.8%)	6 (28.6%)	1 (4.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		7 (33.3%)
SWELLING, INJ. SITE (<=1 IN.)	2 (9.5%)	3 (14.3%)	1 (4.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		3 (14.3%)
VACCINEES WITH COMPLAINTS	6 (28.6%)	7 (33.3%)	1 (4.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		8 (38.1%)
VACCINEES WITH NO COMPLAINTS	15 (71.4%)	14 (66.7%)	20 (95.2%)	21 (100.0%)	21 (100.0%)	21 (100.0%)		13 (61.9%)
TOTAL VACCINEES REPORTING	21	21	21	21	21	21		21
VACCINEES WITH NO DATA	0	0	0	0	0	0		0

TABLE 8 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : DASHEFSKY,BARRY
STUDY : 001101
VACCINE : HIB/DTP/OPV CONCURRENTLY
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 17-24 MOS.

VACCINE : DTP	NUMBER OF VACCINEES (21 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
LOCAL REACTIONS	12 (57.1%)	11 (52.4%)	1 (4.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		15 (71.4%)
ERYTHEMA, INJ. SITE (<=1 IN.)	3 (14.3%)	4 (19.0%)	1 (4.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		5 (23.8%)
PAIN/SORENESS, INJ. SITE	9 (42.9%)	9 (42.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		12 (57.1%)
SWELLING, INJ. SITE (<=1 IN.)	5 (23.8%)	6 (28.6%)	1 (4.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		6 (28.6%)
VACCINEES WITH COMPLAINTS	12 (57.1%)	11 (52.4%)	1 (4.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		15 (71.4%)
VACCINEES WITH NO COMPLAINTS	9 (42.9%)	10 (47.6%)	20 (95.2%)	21 (100.0%)	21 (100.0%)	21 (100.0%)		6 (28.6%)
TOTAL VACCINEES REPORTING	21	21	21	21	21	21		21
VACCINEES WITH NO DATA	0	0	0	0	0	0		0

TABLE 8 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : DASHEFSKY,BARRY
STUDY : 001101
VACCINE : HIB/DTP/OPV CONCURRENTLY
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 17-24 MOS.

VACCINE : HIB/DTP/OPV CONCURRENTLY	NUMBER OF VACCINEES (21 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5	**********
SYSTEMIC	16 (76.2%)	14 (70.0%)	7 (33.3%)	7 (33.3%)	4 (19.0%)	7 (33.3%)	18 (85.7%)
BODY AS A WHOLE/SITE UNSPEC.	12 (57.1%)	9 (45.0%)	2 (9.5%)	3 (14.3%)	2 (9.5%)	0 (0.0%)	13 (61.9%)
FATIGUE	7 (33.3%)	4 (20.0%)	1 (4.8%)	2 (9.5%)	2 (9.5%)	0 (0.0%)	8 (38.1%)
VIRUS INFECTION	1 (4.8%)	1 (5.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (4.8%)
WARM TO TOUCH	7 (33.3%)	6 (30.0%)	2 (9.5%)	2 (9.5%)	1 (4.8%)	0 (0.0%)	9 (42.9%)
DIGESTIVE SYSTEM	0 (0.0%)	2 (10.0%)	4 (19.0%)	3 (14.3%)	2 (9.5%)	4 (19.0%)	7 (33.3%)
DIARRHEA	0 (0.0%)	2 (10.0%)	3 (14.3%)	3 (14.3%)	2 (9.5%)	4 (19.0%)	6 (28.6%)
NAUSEA	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (4.8%)	0 (0.0%)	1 (4.8%)
VOMITING	0 (0.0%)	0 (0.0%)	1 (4.8%)	0 (0.0%)	1 (4.8%)	0 (0.0%)	2 (9.5%)
NERVOUS SYSTEM & PSYCHIATRIC	14 (66.7%)	8 (40.0%)	2 (9.5%)	1 (4.8%)	1 (4.8%)	1 (4.8%)	16 (76.2%)
DIZZINESS	0 (0.0%)	0 (0.0%)	1 (4.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (4.8%)

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TABLE 8 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : DASHEFSKY,BARRY
STUDY : 001101
VACCINE : HIB/DTP/OPV CONCURRENTLY
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 17-24 MOS.

VACCINE : HIB/DTP/OPV CONCURRENTLY	NUMBER OF VACCINEES (21 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
IRRITABILITY	14 (66.7%)	8 (40.0%)	1 (4.8%)	1 (4.8%)	1 (4.8%)	1 (4.8%)		16 (76.2%)
SPASM	1 (4.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (4.8%)
RESPIRATORY SYSTEM	0 (0.0%)	1 (5.0%)	2 (9.5%)	1 (4.8%)	1 (4.8%)	2 (9.5%)		2 (9.5%)
COUGH	0 (0.0%)	1 (5.0%)	1 (4.8%)	1 (4.8%)	1 (4.8%)	1 (4.8%)		1 (4.8%)
WHEEZING	0 (0.0%)	0 (0.0%)	1 (4.8%)	0 (0.0%)	0 (0.0%)	1 (4.8%)		1 (4.8%)
SKIN & SKIN APPENDAGE	1 (4.8%)	0 (0.0%)	0 (0.0%)	1 (4.8%)	0 (0.0%)	0 (0.0%)		2 (9.5%)
CONTUSION	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (4.8%)	0 (0.0%)	0 (0.0%)		1 (4.8%)
RASH	1 (4.8%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (4.8%)
VACCINEES WITH COMPLAINTS	16 (76.2%)	14 (70.0%)	7 (33.3%)	7 (33.3%)	4 (19.0%)	7 (33.3%)		18 (85.7%)
VACCINEES WITH NO COMPLAINTS	5 (23.8%)	6 (30.0%)	14 (66.7%)	14 (66.7%)	17 (81.0%)	14 (66.7%)		3 (14.3%)
TOTAL VACCINEES REPORTING	21	20	21	21	21	21		21

TABLE 8 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : DASHEFSKY,BARRY
STUDY : 001101
VACCINE : HIB/DTP/OPV CONCURRENTLY
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 17-24 MOS.

VACCINE : HIB/DTP/OPV CONCURRENTLY	NUMBER OF VACCINEES (21 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
VACCINEES WITH NO DATA	0	1	0	0	0	0		0

TABLE 8 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : DASHEFSKY,BARRY
STUDY : 001101
VACCINE : HIB AND DTP/OPV 4 WEEKS APART
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 17-24 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (26 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
LOCAL REACTIONS	7 (26.9%)	6 (23.1%)	2 (7.7%)	1 (3.8%)	1 (3.8%)	1 (4.0%)		8 (30.8%)
ERYTHEMA, INJ. SITE (<=1 IN.)	5 (19.2%)	6 (23.1%)	2 (7.7%)	1 (3.8%)	1 (3.8%)	1 (4.0%)		7 (26.9%)
PAIN/SORENESS, INJ. SITE	5 (19.2%)	4 (15.4%)	2 (7.7%)	1 (3.8%)	0 (0.0%)	0 (0.0%)		6 (23.1%)
SWELLING, INJ. SITE (<=1 IN.)	1 (3.8%)	3 (11.5%)	1 (3.8%)	1 (3.8%)	1 (3.8%)	1 (4.0%)		3 (11.5%)
SYSTEMIC	11 (42.3%)	9 (34.6%)	9 (34.6%)	9 (34.6%)	9 (34.6%)	7 (28.0%)		14 (53.8%)
BODY AS A WHOLE/SITE UNSPEC.	5 (19.2%)	3 (11.5%)	1 (3.8%)	2 (7.7%)	2 (7.7%)	1 (4.0%)		7 (26.9%)
ASTHENIA	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.8%)	1 (4.0%)		1 (3.8%)
FATIGUE	4 (15.4%)	3 (11.5%)	1 (3.8%)	2 (7.7%)	1 (3.8%)	1 (4.0%)		6 (23.1%)
WARM TO TOUCH	1 (3.8%)	0 (0.0%)	1 (3.8%)	1 (3.8%)	2 (7.7%)	1 (4.0%)		3 (11.5%)
DIGESTIVE SYSTEM	1 (3.8%)	2 (7.7%)	1 (3.8%)	4 (15.4%)	4 (15.4%)	4 (16.0%)		6 (23.1%)
DIARRHEA	1 (3.8%)	2 (7.7%)	1 (3.8%)	3 (11.5%)	3 (11.5%)	3 (12.0%)		4 (15.4%)

TABLE 8 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : DASHEFSKY,BARRY
STUDY : 001101
VACCINE : HIB AND DTP/OPV 4 WEEKS APART
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 17-24 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (26 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5	COMPLAINTS
NAUSEA	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.8%)	1 (3.8%)	0 (0.0%)	1 (3.8%)
VOMITING	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (11.5%)	2 (7.7%)	1 (4.0%)	4 (15.4%)
NERVOUS SYSTEM & PSYCHIATRIC	8 (30.8%)	5 (19.2%)	5 (19.2%)	4 (15.4%)	3 (11.5%)	1 (4.0%)	9 (34.6%)
IRRITABILITY	8 (30.8%)	5 (19.2%)	5 (19.2%)	4 (15.4%)	3 (11.5%)	1 (4.0%)	9 (34.6%)
PROLONGED CRYING, >1/2 HR	1 (3.8%)	0 (0.0%)	1 (3.8%)	1 (3.8%)	0 (0.0%)	0 (0.0%)	2 (7.7%)
RESPIRATORY SYSTEM	0 (0.0%)	0 (0.0%)	1 (3.8%)	3 (11.5%)	4 (15.4%)	2 (8.0%)	4 (15.4%)
ASTHMA	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.8%)	0 (0.0%)	1 (3.8%)
COUGH	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.8%)	0 (0.0%)	1 (3.8%)
NASAL DISCHARGE	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.8%)	1 (3.8%)	0 (0.0%)	1 (3.8%)
SINUSITIS	0 (0.0%)	0 (0.0%)	1 (3.8%)	1 (3.8%)	1 (3.8%)	1 (4.0%)	1 (3.8%)
WHEEZING	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.8%)	1 (3.8%)	1 (4.0%)	1 (3.8%)
SKIN & SKIN APPENDAGE	0 (0.0%)	1 (3.8%)	2 (7.7%)	1 (3.8%)	0 (0.0%)	0 (0.0%)	2 (7.7%)

TABLE 8 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : DASHEFSKY,BARRY
STUDY : 001101
VACCINE : HIB AND DTP/OPV 4 WEEKS APART
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 17-24 MOS.

VACCINE : HIB CONJUGATE — NUMBER OF VACCINEES (26 VACCINEES) - INJECTION: 1

CLINICAL COMPLAINTS	DAYS POST VACCINATION 0	1	2	3	4	5		NUMBER WITH COMPLAINTS
RASH	0 (0.0%)	1 (3.8%)	2 (7.7%)	1 (3.8%)	0 (0.0%)	0 (0.0%)		2 (7.7%)
SPECIAL SENSES	2 (7.7%)	2 (7.7%)	2 (7.7%)	3 (11.5%)	3 (11.5%)	2 (8.0%)		3 (11.5%)
OTITIS MEDIA	2 (7.7%)	2 (7.7%)	2 (7.7%)	3 (11.5%)	3 (11.5%)	2 (8.0%)		3 (11.5%)
VACCINEES WITH COMPLAINTS	13 (50.0%)	11 (42.3%)	9 (34.6%)	10 (38.5%)	10 (38.5%)	8 (32.0%)		15 (57.7%)
VACCINEES WITH NO COMPLAINTS	13 (50.0%)	15 (57.7%)	17 (65.4%)	16 (61.5%)	16 (61.5%)	17 (68.0%)		11 (42.3%)
TOTAL VACCINEES REPORTING	26	26	26	26	26	25		26
VACCINEES WITH NO DATA	0	0	0	0	0	1		0

TABLE 8 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : DASHEFSKY,BARRY
STUDY : 001101
VACCINE : HIB AND DTP/OPV 4 WEEKS APART
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 17-24 MOS.

VACCINE : DTP	NUMBER OF VACCINEES (17 VACCINEES) - INJECTION: 2						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5	COMPLAINTS
LOCAL REACTIONS	8 (50.0%)	7 (43.8%)	3 (18.8%)	1 (6.3%)	0 (0.0%)	0 (0.0%)	9 (56.3%)
ERYTHEMA, INJ. SITE (<=1 IN.)	3 (18.8%)	2 (12.5%)	1 (6.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (18.8%)
PAIN/SORENESS, INJ. SITE	6 (37.5%)	6 (37.5%)	3 (18.8%)	1 (6.3%)	0 (0.0%)	0 (0.0%)	7 (43.8%)
SWELLING, INJ. SITE (<=1 IN.)	2 (12.5%)	2 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (12.5%)
SYSTEMIC	5 (31.3%)	5 (31.3%)	3 (18.8%)	1 (6.3%)	1 (6.7%)	1 (6.7%)	7 (43.8%)
BODY AS A WHOLE/SITE UNSPEC.	4 (25.0%)	2 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (25.0%)
FATIGUE	2 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (12.5%)
WARM TO TOUCH	3 (18.8%)	2 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (25.0%)
NERVOUS SYSTEM & PSYCHIATRIC	4 (25.0%)	4 (25.0%)	1 (6.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (25.0%)
IRRITABILITY	4 (25.0%)	4 (25.0%)	1 (6.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	4 (25.0%)
PROLONGED CRYING, >1/2 HR	1 (6.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (6.3%)

TABLE 8 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : DASHEFSKY,BARRY
STUDY. : 001101
VACCINE : HIB AND DTP/OPV 4 WEEKS APART
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 17-24 MOS.

VACCINE : DTP	NUMBER OF VACCINEES (17 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
UNUSUAL HIGH-PITCHED CRYING	1 (6.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (6.3%)
RESPIRATORY SYSTEM	0 (0.0%)	0 (0.0%)	1 (6.3%)	1 (6.3%)	1 (6.7%)	1 (6.7%)		1 (6.3%)
COMMON COLD	0 (0.0%)	0 (0.0%)	1 (6.3%)	1 (6.3%)	1 (6.7%)	1 (6.7%)		1 (6.3%)
SKIN & SKIN APPENDAGE	0 (0.0%)	1 (6.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (6.3%)
ATOPIC DERMATITIS	0 (0.0%)	1 (6.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (6.3%)
SPECIAL SENSES	1 (6.3%)	1 (6.3%)	1 (6.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (6.3%)
MYRINGOTOMY	0 (0.0%)	0 (0.0%)	1 (6.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (6.3%)
OTITIS MEDIA	1 (6.3%)	1 (6.3%)	1 (6.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (6.3%)
VACCINEES WITH COMPLAINTS	10 (62.5%)	9 (56.3%)	5 (31.3%)	2 (12.5%)	1 (6.7%)	1 (6.7%)		12 (75.0%)
VACCINEES WITH NO COMPLAINTS	6 (37.5%)	7 (43.8%)	11 (68.8%)	14 (87.5%)	14 (93.3%)	14 (93.3%)		4 (25.0%)
TOTAL VACCINEES REPORTING	16	16	16	16	15	15		16

TABLE 8 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : DASHEFSKY,BARRY
STUDY : 001101
VACCINE : HIB AND DTP/OPV 4 WEEKS APART
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 17-24 MOS.

VACCINE : DTP	NUMBER OF VACCINEES (17 VACCINEES) - INJECTION: 2						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5	COMPLAINTS
VACCINEES WITH NO DATA	1	1	1	1	2	2	1

01210

TABLE 8 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : DASHEFSKY,BARRY
STUDY : 001101
VACCINE : HIB AND DTP/OPV 4 WEEKS APART
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 17-24 MOS.

VACCINE : HIB AND DTP/OPV 4 WEEKS A	ART NUMBER OF VACCINEES (26 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5	COMPLAINTS
							**********
SYSTEMIC	1 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (100.0%)
BODY AS A WHOLE/SITE UNSPEC.	1 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (100.0%)
FATIGUE	1 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (100.0%)
VACCINEES WITH COMPLAINTS	1 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (100.0%)
VACCINEES WITH NO COMPLAINTS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
TOTAL VACCINEES REPORTING	1	0	0	0	0	0	1
VACCINEES WITH NO DATA	25	26	26	26	26	26	25

TABLE 8 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : DASHEFSKY,BARRY
STUDY : 001101
VACCINE : HIB/DT/OPV CONCURRENTLY
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 17-24 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (2 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5	COMPLAINTS
VACCINEES WITH COMPLAINTS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
VACCINEES WITH NO COMPLAINTS	2 (100.0%)	2 (100.0%)	2 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	2 (100.0%)
TOTAL VACCINEES REPORTING	2	2	2	1	1	1	2
VACCINEES WITH NO DATA	0	0	0	1	1	1	0

TABLE 8 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : DASHEFSKY,BARRY
STUDY : 001101
VACCINE : HIB/DT/OPV CONCURRENTLY
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 17-24 MOS.

VACCINE : DTP	NUMBER OF VACCINEES (2 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5	**********
VACCINEES WITH COMPLAINTS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
VACCINEES WITH NO COMPLAINTS	2 (100.0%)	2 (100.0%)	2 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	2 (100.0%)
TOTAL VACCINEES REPORTING	2	2	2	1	1	1	2
VACCINEES WITH NO DATA	0	0	0	1	1	1	0

TABLE 8 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : DASHEFSKY,BARRY
STUDY : 001101
VACCINE : HIB/DT/OPV CONCURRENTLY
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 17-24 MOS.

VACCINE : HIB/DT/OPV CONCURRENTLY	NUMBER OF VACCINEES (2 VACCINEES) - INJECTION: 1						
	DAYS POST VACCINATION						NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5	**********
SYSTEMIC	1 (50.0%)	1 (50.0%)	1 (50.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (50.0%)
NERVOUS SYSTEM & PSYCHIATRIC	1 (50.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (50.0%)
IRRITABILITY	1 (50.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (50.0%)
SPECIAL SENSES	1 (50.0%)	1 (50.0%)	1 (50.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (50.0%)
OTITIS MEDIA	1 (50.0%)	1 (50.0%)	1 (50.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (50.0%)
VACCINEES WITH COMPLAINTS	1 (50.0%)	1 (50.0%)	1 (50.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (50.0%)
VACCINEES WITH NO COMPLAINTS	1 (50.0%)	1 (50.0%)	1 (50.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (50.0%)
TOTAL VACCINEES REPORTING	2	2	2	1	1	1	2
VACCINEES WITH NO DATA	0	0	0	1	1	1	0

TABLE 9

MAXIMUM TEMPERATURES

INVESTIGATOR : DASHEFSKY,BARRY
STUDY : 001101
VACCINE : HIB/DTP/OPV CONCURRENTLY
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 17-24 MOS.

VACCINE : HIB/DTP/OPV CONCURRENTLY	NUMBER OF VACCINEES (21 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
NORMAL	0 (0.0%)	1 (10.0%)	2 (20.0%)	2 (22.2%)	2 (22.2%)	2 (28.6%)		0 (0.0%)
< 99	5 (45.5%)	4 (40.0%)	5 (50.0%)	5 (55.6%)	6 (66.7%)	5 (71.4%)		4 (30.8%)
99 - 99.9	3 (27.3%)	4 (40.0%)	2 (20.0%)	1 (11.1%)	0 (0.0%)	0 (0.0%)		4 (30.8%)
100 - 100.9	1 (9.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (7.7%)
101 - 101.9	1 (9.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (11.1%)	0 (0.0%)		2 (15.4%)
102 - 102.9	1 (9.1%)	1 (10.0%)	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (7.7%)
103 - 103.9	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (11.1%)	0 (0.0%)	0 (0.0%)		1 (7.7%)
TEMPERATURE TAKEN	11 (52.4%)	10 (47.6%)	10 (47.6%)	9 (42.9%)	9 (42.9%)	7 (33.3%)		13 (61.9%)
TEMPERATURE NOT TAKEN	10 (47.6%)	11 (52.4%)	11 (52.4%)	12 (57.1%)	12 (57.1%)	14 (66.7%)		8 (38.1%)

TABLE 9 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : DASHEFSKY,BARRY
STUDY : 001101
VACCINE : HIB AND DTP/OPV 4 WEEKS APART
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 17-24 MOS.

VACCINE : HIB CONJUGATE

MAX TEMPERATURE (DEG F, ORAL)	NUMBER OF VACCINEES (26 VACCINEES) - INJECTION 1 — DAYS POST VACCINATION 0	1	2	3	4	5		NUMBER WITH MAX TEMP
NORMAL	4 (30.8%)	4 (30.8%)	4 (30.8%)	4 (33.3%)	4 (33.3%)	4 (33.3%)		4 (28.6%)
< 99	5 (38.5%)	5 (38.5%)	4 (30.8%)	3 (25.0%)	3 (25.0%)	4 (33.3%)		0 (0.0%)
99 - 99.9	2 (15.4%)	3 (23.1%)	3 (23.1%)	2 (16.7%)	3 (25.0%)	4 (33.3%)		4 (28.6%)
100 - 100.9	1 (7.7%)	0 (0.0%)	1 (7.7%)	2 (16.7%)	1 (8.3%)	0 (0.0%)		4 (28.6%)
101 - 101.9	0 (0.0%)	1 (7.7%)	0 (0.0%)	0 (0.0%)	1 (8.3%)	0 (0.0%)		0 (0.0%)
102 - 102.9	1 (7.7%)	0 (0.0%)	1 (7.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (7.1%)
104 - 104.9	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (8.3%)	0 (0.0%)	0 (0.0%)		1 (7.1%)
TEMPERATURE TAKEN	13 (50.0%)	13 (50.0%)	13 (50.0%)	12 (46.2%)	12 (46.2%)	12 (46.2%)		14 (53.8%)
TEMPERATURE NOT TAKEN	13 (50.0%)	13 (50.0%)	13 (50.0%)	14 (53.8%)	14 (53.8%)	14 (53.8%)		12 (46.2%)

TABLE 9 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : DASHEFSKY,BARRY
STUDY : 001101
VACCINE : HIB AND DTP/OPV 4 WEEKS APART
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 17-24 MOS.

VACCINE : OPV — NUMBER OF VACCINEES (17 VACCINEES) - INJECTION 2

MAX TEMPERATURE (DEG F, ORAL)	DAYS POST VACCINATION 0	1	2	3	4	5		NUMBER WITH MAX TEMP
< 99	0 (0.0%)	1 (50.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)		0 (0.0%)
99 - 99.9	1 (50.0%)	1 (50.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (50.0%)
100 - 100.9	1 (50.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (50.0%)
TEMPERATURE TAKEN	2 (11.8%)	2 (11.8%)	1 (5.9%)	1 (5.9%)	1 (5.9%)	1 (5.9%)		2 (11.8%)
TEMPERATURE NOT TAKEN	15 (88.2%)	15 (88.2%)	16 (94.1%)	16 (94.1%)	16 (94.1%)	16 (94.1%)		15 (88.2%)

TABLE 9 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : DASHEFSKY,BARRY
STUDY : 001101
VACCINE : HIB/DT/OPV CONCURRENTLY
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 17-24 MOS.

VACCINE : HIB/DT/OPV CONCURRENTLY	NUMBER OF VACCINEES (2 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
NORMAL	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)		1 (100.0%)
TEMPERATURE TAKEN	1 (50.0%)	1 (50.0%)	1 (50.0%)	1 (50.0%)	1 (50.0%)	1 (50.0%)		1 (50.0%)
TEMPERATURE NOT TAKEN	1 (50.0%)	1 (50.0%)	1 (50.0%)	1 (50.0%)	1 (50.0%)	1 (50.0%)		1 (50.0%)

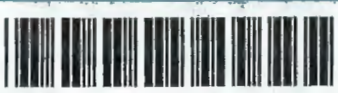
NOTE: There is no missing material. There was an error in numbering.

PRODUCT LICENSE APPLICATION

PLA-0002-XXX-HC48 vol. 5

Merck and Co., Inc.
Haemophilus b Conjugate Vaccine
(Meningococcal Protein Conjugate)

8.5-8



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August 31, 1988

Clinical Report
in Support of a Product License Application
for
PEDVAX-HIB ™
Haemophilus b Conjugate Vaccine
(*Neisseria meningitidis* Outer Membrane Protein Complex)

Volume 4 of 4

Merck Sharp & Dohme Research Laboratories

Rec
8/31/88
DPC

Haemophilus b Conjugate Vaccine
(Neisseria meningitidis Outer Membrane Protein Complex)

POLYSACCHARIDE VACCINE FAILURE STUDY

006-01 - St. Louis, MO - Dan Granoff, M.D.

Healthy children 12-71 months of age entered this study. All children had a history of invasive Hib disease following immunization with polysaccharide vaccine. Eight children received two doses (15 mcg) of Lot 1069/C-P241 two months apart. Prior to vaccination no child (0/7) had antibody titers >1.0 mcg/ml. The GMT prior to vaccination was 0.111 mcg/ml. One to three months following the second dose 100% (7/7) had antibody titers >1.0 mcg/ml. The GMT at that time for the 7 vaccinees was 11.990 mcg/ml.

Eight children received the first dose of Lot 1072/C-P298. Seven children received the second injection two months later. Prior to vaccination, no child (0/6) had an antibody titer >1.0 mcg/ml. The GMT was 0.289 mcg/ml. One to three months following the second dose 100% (4/4) had antibody levels >1.0 mcg/ml. The GMT at that time for the 5 vaccinees was 9.155 mcg/ml.

Eleven children received a single dose of polysaccharide vaccine (25 mcg) followed by a 15 mcg dose of Lot 1069/C-P241 or Lot 1072/C-P298 at two months. Another 5 children received only the first dose. Prior to vaccination, no child (0/13) had an antibody titer >1.0 mcg/ml. The GMT was 0.167 mcg/ml. One to three months following the second dose 88% (7/8) had developed titers >1.0 mcg/ml. The GMT at that time for the 8 vaccinees was 2.478 mcg/ml.

No serious adverse experiences were reported in this study.

STUDY 006-01

PROGRAM: Haemophilus b Conjugate Vaccine (Neisseria meningitidis Outer Membrane Protein Complex), Study 006-01

PURPOSE: To evaluate the safety and immunogenicity of Haemophilus b conjugate vaccine (Neisseria meningitidis outer membrane protein complex) in children who developed invasive Hib disease following immunization with licensed Haemophilus b nonconjugated polysaccharide vaccines.

VACCINE: Haemophilus b Conjugate Vaccine (Neisseria meningitidis Outer Membrane Protein Complex) (PRP-OMPC)

Lot 1069/C-P241 - (b) (4) mcg polysaccharide/ml
(b) (4) mcg meningococcal protein/ml

Lot 1072/C-P298 - (b) (4) mcg polysaccharide/ml
(b) (4) mcg meningococcal protein/ml

Aluminum hydroxide diluent
Lot (b) (4)

INVESTIGATOR: Dan M. Granoff, M.D.
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STUDY LOCATION: Coordinating Center:
St. Louis Children's Hospital
400 South Kingshighway Boulevard
St. Louis, Missouri 63110

DATE INITIATED: June 26, 1987

DATE COMPLETED: In progress.

STUDY POPULATION: Healthy children 2 to 5 years of age who developed invasive Hib disease 3 weeks to 24 months following immunization with licensed Haemophilus b nonconjugated polysaccharide (PRP) vaccines, and who had anti-PRP levels <2 mcg/ml are includcd in the study. Children are recruited and vaccinated by physicians located throughout the United States.

STUDY PROCEDURE: Children are randomly assigned to receive a PRP-OMPC vaccine or licensed nonconjugated PRP vaccine. Children in the PRP-OMPC vaccine group receive two 0.5 ml (15 mcg polysaccharide) injections of vaccine reconstituted in aluminum hydroxide, 2 to 3 months apart, while children in the nonconjugated PRP vaccine group receive a single 0.5 ml (25 mcg polysaccharide) intramuscular injection of the vaccine. Children in the nonconjugated PRP vaccine group who fail to develop 2 mcg/ml anti-PRP are switched to the PRP-OMPC vaccine arm of the study.

STUDY PROCEDURE: (CONT.)

The parent or guardian is required to record the vaccine recipient's temperature and any reactions at the injection site or systemic complaints for days after each injection of vaccine. Unexpected or serious reactions are to be reported immediately to the study physician.

A blood sample is obtained immediately prior to and approximately 1 month after each injection of vaccine. All serum samples are assayed for antibody to the capsular polysaccharide of Haemophilus influenzae type b by radioimmunoassay. Selected samples may also be tested for bactericidal and opsonophagocytic activity immunoglobulin isotype and subclass IgG. Assays for opsonophagocytic activity are performed at the University of Alabama. All other assays may be performed by Merck Sharp & Dohme Research Laboratories and by (b) (4) (b) (4)

RESULTS:

Demographic information and individual pre and postimmunization antibody data for each vaccine recipient are presented in Tables 1 and 2.

1. Current status:

	No. Vaccinated Injection No.		
Vaccine Group	1	2	3
PRP-OMPC	14	13	--
PRP	18	13*	8*

*PRP-OMPC vaccine.

Two children (case no. (b) (6) received nonconjugated PRP vaccine prior to entry in the study. Four to 6 months after receiving PRP vaccine, they were enrolled in the study and received two injections of PRP-OMPC vaccine. Their results are not included in the summary statistics for either group.

RESULTS: (CONT.)

2. Serologic results:

Anti-PRP responses prior to each injection of vaccine and approximately 1 month after the last injection of vaccine are as follows:

Group	Time	% With Anti-PRP >0.15 mcg/ml	% With Anti-PRP >1.0 mcg/ml	GMT (mcg/ml)
PRP-OMPC	Pre	62 (8/13)	0 (0/13)	0.17
	Post 1	100 (13/13)	100 (13/13)	6.16
	Post 2	100 (13/13)	100 (13/13)	10.80
PRP	Pre	62 (8/13)	0 (0/13)	0.16
	Post	83 (10/13)	31 (4/13)	0.53
	Post PRP-OMPC 1	100 (8/8)	88 (7/8)	2.48
	Post PRP-OMPC 2	100 (7/7)	86 (6/7)	6.85

Antibody responses by lot are presented in Tables 3 to 5.

RESULTS: (CONT.)

4. Clinical results:

The incidence of selected injection site and systemic reactions occurring within 2 days after vaccination are as follows:

	% of Vaccinees with Reaction*				
	PRP-OMPC		PRP		
Type of Reaction	Inj. 1 n=14	Inj. 2 n=13	Inj. 1 n=16	Inj. 2** n=10	Inj. 3** n=8
Injection Site:					
Pain/soreness	57	77	6	30	38
Erythema >1 inch	14	8	0	0	0
Swelling >1 inch	7	39	0	0	0
Induration	0	0	0	0	0
Systemic:					
Irritability	29	23	13	20	0
Sleepiness/Lethargy Fatigue	36	31	6	20	13

* The increased reaction rates reported may be due to the disparity in reporting of complaints by the numerous individual physicians involved in the study.

** PRP-OMPC vaccine.

The frequencies of all clinical reactions and maximum temperatures occurring during the 5 days following each injection of vaccine are presented in Tables 6 to 8 by lot.

No serious or alarming reactions attributable to vaccine have been reported.

TABLE 1

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : GRANOFF,DAN
STUDY : 000601
VACCINE : HIB CONJUGATE
PATIENT CLASS: HIB POLYS VACCINE FAILURES

CASE	SEX	RACE	BIRTH	AGE DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA
(b) (6)	F	CAUC	(b) (6)	3Y -15	(b) (6)	001	PREBLEED				167		5
				0		011	INJ 1	CP241	15 MCG				
				62		011	BLEED 1				18140		>= 80
				62		021	INJ 2	CP241	15 MCG				
				111		021	BLEED 2				28448		>= 80
	M	CAUC		3Y -30		001	PREBLEED				249		
				0		011	INJ 1	CP241	15 MCG				
				70		011	BLEED 1				3427		
				70		021	INJ 2	CP241	15 MCG				
				119		021	BLEED 2				3476		
	F	CAUC		3Y 0		011	INJ 1	CP298	15 MCG				
				62		011	BLEED 1				17872		
	M	CAUC		4Y -80		001	PREBLEED				162		
				0		001	PREBLEED				346		
				0		011	INJ 1	CP298	37.5 MCG				
				84		011	BLEED 1				18455		
				84		021	INJ 2	CP298	15 MCG				
				115		021	BLEED 2				32324		
	M	CAUC		5Y -37		001	PREBLEED				< 125		< 5
				0		011	INJ 1	CP241	15 MCG				
				82		021	INJ 2	CP241	15 MCG				
				83		021	BLEED 1				7003		20
				122		021	BLEED 2				23440		80
	F	CAUC		4Y -13		001	PREBLEED				< 125		< 5
				0		011	INJ 1	CP241	15 MCG				
				62		011	BLEED 1				3190		< 5
				63		021	INJ 2	CP241	15 MCG				
				167		021	BLEED 2				5420		< 5
	F	CAUC		3Y -38		001	PREBLEED				309		5
				0		011	INJ 1	CP298	15 MCG				
				64		011	BLEED 1				1690		>= 80
				64		021	INJ 2	CP298	15 MCG				
				158		021	BLEED 2				9394		>= 80
	M	BLAC		3Y -42		001	PREBLEED				141		< 5

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : GRANOFF,DAN
STUDY : 000601
VACCINE : HIB CONJUGATE
PATIENT CLASS: HIB POLYS VACCINE FAILURES

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA
(b) (6)	M	BLAC	(b) (6)	3Y	0	(b) (6)	011	INJ 1	CP298	15 MCG				
					56		011	BLEED 1				3830		>= 80
					56		021	INJ 2	CP298	15 MCG				
					91		021	BLEED 2				8995		>= 80
	M	CAUC		3Y	-49		001	PREBLEED				333		
					0		011	INJ 1	CP298	15 MCG				
					69		011	BLEED 1				3749		
					69		021	INJ 2	CP298	15 MCG				
					110		021	BLEED 2				5023		
	M	CAUC		4Y	-33		001	PREBLEED				< 125		
					0		011	INJ 1	CP241	15 MCG				
					63		011	BLEED 1				15528		20
					63		021	INJ 2	CP241	15 MCG				
					130		021	BLEED 2				14178		20
	F	CAUC		3Y	-28		001	PREBLEED				297		< 5
					0		011	INJ 1	CP298	15 MCG				
					63		011	BLEED 1				4693		80
					63		021	INJ 2	CP298	15 MCG				
					99		021	BLEED 2				16550		20
	F	CAUC		3Y	-73		001	PREBLEED				161		< 5
					0		011	INJ 1	CP241	15 MCG				
					63		011	BLEED 1				8044		5
					63		021	INJ 2	CP241	15 MCG				
					97		021	BLEED 2				6389		20
	F	CAUC		3Y	-52		001	PREBLEED				125		< 5
					0		011	INJ 1	CP241	14 MCG				
					62		011	BLEED 1				19534		20
					62		021	INJ 2	CP241	14 MCG				
					95		021	BLEED 2				31305		>= 80
	F	CAUC		2Y	-57		001	PREBLEED				387		< 5
					0		011	INJ 1	CP298	39 MCG				
					71		011	BLEED 1				2566		< 5
					71		021	INJ 2	CP298	15 MCG				
					101		021	BLEED 2				3366		5

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : GRANOFF,DAN
STUDY : 000601
VACCINE : POLYSACCHARIDE VACCINE
PATIENT CLASS: HIB POLYS VACCINE FAILURES

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA
(b) (6)	M	BLAC	(b) (6)	4Y	0	(b) (6)	001	PREBLEED				175		< 5
					0		011	INJ 1	POLYS	25 MCG				
					47		011	BLEED 1				< 125		< 5
					83		021	INJ 2	CP298	15 MCG				
					150		021	BLEED 2				16071		20
					150		031	INJ 3	CP298	15 MCG				
					194		031	BLEED 3				22769		20
	M	AM I		4Y	-60		001	PREBLEED				146		
					0		011	INJ 1	POLYS	25 MCG				
					30		011	BLEED 1				3374		
	F	CAUC		3Y	0		001	PREBLEED				< 125		< 5
					0		011	INJ 1	POLYS	25 MCG				
					34		011	BLEED 1				570		< 5
					48		021	INJ 2	CP241	15 MCG				
					120		031	INJ 3	CP241	15 MCG				
					155		031	BLEED 2				5000		5
	M	BLAC		3Y	-28		001	PREBLEED				238		< 5
					0		011	INJ 1	POLYS	25 MCG				
					40		011	BLEED 1				647		
					75		021	INJ 2	CP298	15 MCG				
					140		021	BLEED 2				4051		80
	F	CAUC		3Y	-4		001	PREBLEED				126		< 5
					0		011	INJ 1	POLYS	25 MCG				
					30		011	BLEED 1				310		< 5
					46		021	INJ 2	CP298	15 MCG				
					114		021	BLEED 2				1585		< 5
					114		031	INJ 3	CP298	15 MCG				
					172		031	BLEED 3				9110		5
	F	CAUC		3Y	-25		001	PREBLEED				< 125		< 5
					0		011	INJ 1	POLYS	25 MCG				
					35		011	BLEED 1				294		< 5
					73		021	INJ 2	CP298	15 MCG				
					128		021	BLEED 2				2369		< 5
					134		031	INJ 3	CP298	15 MCG				
					163		031	BLEED 3				4357		< 5
	M	CAUC		3Y	-43		001	PREBLEED				384		

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : GRANOFF,DAN
STUDY : 000601
VACCINE : POLYSACCHARIDE VACCINE
PATIENT CLASS: HIB POLYS VACCINE FAILURES

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA
(b) (6)	M	CAUC	(b) (6)	3Y	0	(b) (6)	011	INJ 1	POLYS	25 MCG				
					30		011	BLEED 1				1633		
	M	CAUC		3Y	-94		001	PREBLEED				186		
					0		011	INJ 1	POLYS	25 MCG				
					33		011	BLEED 1				1290		
	M	CAUC		4Y	-46		001	PREBLEED				< 125		
					0		011	INJ 1	POLYS	25 MCG				
					78		021	INJ 2	CP298	15 MCG				
					148		021	BLEED 1				1560		
					148		031	INJ 3	POLYS	25 MCG				
	F	CAUC		3Y	-56		001	PREBLEED				377		< 5
					0		011	INJ 1	POLYS	25 MCG				
					30		011	BLEED 1				332		< 5
					58		021	INJ 2	CP241	15 MCG				
					93		021	BLEED 2			05/	2581		20
					93		031	INJ 3	CP241	15 MCG				
					141		031	BLEED 3			05/	23431		>= 80
	F	CAUC		4Y	-68		001	PREBLEED				388		
					0		011	INJ 1	POLYS	25 MCG				
					28		011	BLEED 1				8489		
	M	CAUC		3Y	-41		001	PREBLEED				202		< 5
					0		011	INJ 1	POLYS	25 MCG				
					32		011	BLEED 1				< 125		< 5
					53		021	INJ 2	CP298	15 MCG				
					115		021	BLEED 2				2647		< 5
					115		031	INJ 3	CP298	15 MCG				
					190		031	BLEED 3				7459		< 5
	F	HISP		3Y	0		011	INJ 1	POLYS	25 MCG				
					38		011	BLEED 1				< 250		
					96		021	INJ 2	CP298	15 MCG				
					174		021	BLEED 2				4040		
					180		031	INJ 3	CP298	15 MCG				
					217		031	BLEED 3				37374		
	M	CAUC		3Y	-27		001	PREBLEED				204		

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : GRANOFF,DAN
STUDY : 000601
VACCINE : POLYSACCHARIDE VACCINE
PATIENT CLASS: HIB POLYS VACCINE FAILURES

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT		LOT	DOSE	CODE/	RIA	CODE/	SBA
(b) (6)	M	CAUC	(b) (6)	3Y	0	(b) (6)	011	INJ	1	POLYS	25 MCG				
					53		011	BLEED	1				386		
					82		021	INJ	2	CP298	15 MCG				
					138		021	BLEED	2				545		
					138		031	INJ	3	CP298	15 MCG				
					167		031	BLEED	3				896		
	F	CAUC		3Y	0		011	INJ	1	POLYS	25 MCG				
	F	BLAC		2Y	0		011	INJ	1	POLYS	25 MCG				
					63		021	INJ	2	CP298	15 MCG				
					124		021	BLEED	1				2565		

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : GRANOFF,DAN
STUDY : 000601
VACCINE : POLYSACCHARIDE *
PATIENT CLASS: HIB POLYS VACCINE FAILURES

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ RIA	CODE/ IGG1
(b) (6)	F	CAUC	(b) (6)	4Y	0	(b) (6)	011	INJ 1	CP241	15 MCG		
					60		011	BLEED 1			2548	
					61		021	INJ 2	CP241	15 MCG		
					95		021	BLEED 2			5354	
	M	CAUC		3Y	-27		001	PREBLEED			316	< 600
					0		011	INJ 1	CP298	15 MCG		
					62		011	BLEED 1			1827	1729
					66		021	INJ 2	CP298	15 MCG		
					100		021	BLEED 2			13340	24138

* PRIOR TO ENTRY INTO THE STUDY

TABLE 2

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : GRANOFF,DAN
STUDY : 000601
VACCINE : HIB CONJUGATE
PATIENT CLASS: HIB POLYS VACCINE FAILURES

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/IGG	TOTAL	CODE/	IGGM	CODE/	IGG1	CODE/	IGG2
(b) (6)	F	CAUC	(b) (6)	3Y	-15	(b) (6)	001	PREBLEED				< 100		1197		< 600		< 250
					0		011	INJ 1	CP241	15 MCG								
					62		011	BLEED 1				7041		11555		3930		830
					62		021	INJ 2	CP241	15 MCG								
					111		021	BLEED 2				2838		9576		6169		1546
	M	CAUC		3Y	0		011	INJ 1	CP241	15 MCG								
					70		021	INJ 2	CP241	15 MCG								
	F	CAUC		3Y	0		011	INJ 1	CP298	15 MCG								
	M	CAUC		4Y	0		011	INJ 1	CP298	37.5 MCG								
					84		021	INJ 2	CP298	15 MCG								
	M	CAUC		5Y	-37		001	PREBLEED				< 100		< 100		< 600		< 250
					0		011	INJ 1	CP241	15 MCG								
					82		021	INJ 2	CP241	15 MCG								
					83		021	BLEED 1				529		514		4525		< 250
					122		021	BLEED 2				2601		1591		8765		292
	F	CAUC		4Y	-13		001	PREBLEED				< 100		193		< 600		< 250
					0		011	INJ 1	CP241	15 MCG								
					62		011	BLEED 1				418		6199		1808		< 250
					63		021	INJ 2	CP241	15 MCG								
					167		021	BLEED 2				930		3492		3290		< 250
	F	CAUC		3Y	-38		001	PREBLEED				< 100		478		< 600		< 250
					0		011	INJ 1	CP298	15 MCG								
					64		011	BLEED 1				358		886		1606		< 250
					64		021	INJ 2	CP298	15 MCG								
					158		021	BLEED 2				532		661		3199		< 250
	M	BLAC		3Y	-42		001	PREBLEED				< 100		< 100		< 600		< 250
					0		011	INJ 1	CP298	15 MCG								
					56		011	BLEED 1				659		2312		4791		265
					56		021	INJ 2	CP298	15 MCG								
					91		021	BLEED 2				958		564		6702		494
	M	CAUC		3Y	-49		001	PREBLEED								< 600		
					0		011	INJ 1	CP298	15 MCG								
					69		011	BLEED 1								1187		

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : GRANOFF,DAN
STUDY : 000601
VACCINE : HIB CONJUGATE
PATIENT CLASS: HIB POLYS VACCINE FAILURES

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/IGG	TOTAL	CODE/	IGGM	CODE/	IGG1	CODE/	IGG2
(b) (6)	M	CAUC	(b) (6)	3Y	69	(b) (6)	021	INJ 2	CP298	15 MCG								
					110		021	BLEED 2								2328		
	M	CAUC		4Y	-33		001	PREBLEED				< 100		< 100		< 600		
					0		011	INJ 1	CP241	15 MCG								
					63		011	BLEED 1			01/	QNS		12985	01/	QNS		
					63		021	INJ 2	CP241	15 MCG								
					130		021	BLEED 2				2273		2088		7846		
	F	CAUC		3Y	-28		001	PREBLEED				< 100		189		< 600		
					0		011	INJ 1	CP298	15 MCG								
					63		011	BLEED 1				905		3915		2581		
					63		021	INJ 2	CP298	15 MCG								
					99		021	BLEED 2				2482		2977		14647		
	F	CAUC		3Y	-73		001	PREBLEED				< 100		< 100		< 600		
					0		011	INJ 1	CP241	15 MCG								
					63		011	BLEED 1				2357		245		7886		
					63		021	INJ 2	CP241	15 MCG								
					97		021	BLEED 2				3072		185		5697		
	F	CAUC		3Y	-52		001	PREBLEED								< 600		
					0		011	INJ 1	CP241	14 MCG								
					62		011	BLEED 1								25014		
					62		021	INJ 2	CP241	14 MCG								
					95		021	BLEED 2								22316		
	F	CAUC		2Y	-57		001	PREBLEED				152		< 100		< 600		
					0		011	INJ 1	CP298	39 MCG								
					71		011	BLEED 1				388		160		1590		
					71		021	INJ 2	CP298	15 MCG								
					101		021	BLEED 2				2269		268		6776		

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : GRANOFF,DAN
STUDY : 000601
VACCINE : POLYSACCHARIDE VACCINE
PATIENT CLASS: HIB POLYS VACCINE FAILURES

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/IGG	TOTAL	CODE/	IGGM	CODE/	IGG1	CODE/	IGG2
(b) (6)	M	BLAC	(b) (6)	4Y	0	(b) (6)	001	PREBLEED				< 100		< 100		< 600		< 250
					0		011	INJ 1	POLYS	25 MCG								
					47		011	BLEED 1				< 100		< 100		< 600	01/	QNS
					83		021	INJ 2	CP298	15 MCG								
					150		021	BLEED 2				340		542		3761		< 250
					150		031	INJ 3	CP298	15 MCG								
					194		031	BLEED 3				1570		475		8067		330
	M	AM I		4Y	0		011	INJ 1	POLYS	25 MCG								
	F	CAUC		3Y	0		001	PREBLEED				< 100		126		< 600		
					0		011	INJ 1	POLYS	25 MCG								
					34		011	BLEED 1				203		< 100		604		
					48		021	INJ 2	CP241	15 MCG								
					120		031	INJ 3	CP241	15 MCG								
					155		031	BLEED 2				1525		776		3756		
	M	BLAC		3Y	-28		001	PREBLEED				< 100		< 100		< 600		
					0		011	INJ 1	POLYS	25 MCG								
					40		011	BLEED 1				< 100		452		< 600		
					75		021	INJ 2	CP298	15 MCG								
					140		021	BLEED 2				1159		304		2714		
	F	CAUC		3Y	-4		001	PREBLEED								< 600		
					0		011	INJ 1	POLYS	25 MCG								
					30		011	BLEED 1								< 600		
					46		021	INJ 2	CP298	15 MCG								
					114		021	BLEED 2								3080		
					114		031	INJ 3	CP298	15 MCG								
					172		031	BLEED 3								19396		
	F	CAUC		3Y	-25		001	PREBLEED				< 100		191		< 600		
					0		011	INJ 1	POLYS	25 MCG								
					35		011	BLEED 1				< 100		243		< 600		
					73		021	INJ 2	CP298	15 MCG								
					128		021	BLEED 2				3920		653		2902		
					134		031	INJ 3	CP298	15 MCG								
					163		031	BLEED 3				4361		603		2263		
	M	CAUC		3Y	0		011	INJ 1	POLYS	25 MCG								
	M	CAUC		3Y	0		011	INJ 1	POLYS	25 MCG								

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : GRANOFF,DAN
STUDY : 000601
VACCINE : POLYSACCHARIDE VACCINE
PATIENT CLASS: HIB POLYS VACCINE FAILURES

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT		LOT	DOSE	CODE/IGG	TOTAL	CODE/	IGGM	CODE/	IGG1	CODE/	IGG2
(b) (6)	M	CAUC	(b) (6)	4Y	0	(b) (6)	011	INJ	1	POLYS	25 MCG								
					78		021	INJ	2	CP298	15 MCG								
					148		031	INJ	3	POLYS	25 MCG								
	F	CAUC		3Y	-56		001	PREBLEED									< 600		
					0		011	INJ	1	POLYS	25 MCG								
					30		011	BLEED	1								< 600		
					58		021	INJ	2	CP241	15 MCG								
					93		021	BLEED	2								801		
					93		031	INJ	3	CP241	15 MCG								
					141		031	BLEED	3								14101		
	F	CAUC		4Y	0		011	INJ	1	POLYS	25 MCG								
	M	CAUC		3Y	-41		001	PREBLEED				< 100		< 100			< 600		
					0		011	INJ	1	POLYS	25 MCG								
					32		011	BLEED	1			< 100		106			< 600		
					53		021	INJ	2	CP298	15 MCG								
					115		021	BLEED	2			812		306			3245		
					115		031	INJ	3	CP298	15 MCG								
					190		031	BLEED	3			1009		317			5630		
	F	HISP		3Y	0		011	INJ	1	POLYS	25 MCG								
					38		011	BLEED	1							01/	QNS		
					96		021	INJ	2	CP298	15 MCG								
					174		021	BLEED	2								3443		
					180		031	INJ	3	CP298	15 MCG								
					217		031	BLEED	3								59334		
	M	CAUC		3Y	-27		001	PREBLEED									< 600		
					0		011	INJ	1	POLYS	25 MCG								
					53		011	BLEED	1							01/	QNS		
					82		021	INJ	2	CP298	15 MCG								
					138		021	BLEED	2								866		
					138		031	INJ	3	CP298	15 MCG								
					167		031	BLEED	3								1175		
	F	CAUC		3Y	0		011	INJ	1	POLYS	25 MCG								
	F	BLAC		2Y	0		011	INJ	1	POLYS	25 MCG								
					63		021	INJ	2	CP298	15 MCG								

TABLE 3

A N T I B O D Y R E S P O N S E S

INVESTIGATOR : GRANOFF,DAN
STUDY : 000601
VACCINE : HIB CONJUGATE
ASSAY : RIA
LOT NUMBER : CP241
POPULATION : HIB POLYS VACCINE FAILURES

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
12-71 MOS.	PRE INJ	43 (3/ 7)	0 (0/ 7)			0.111 (7)
	MONTHS 2/3	100 (7/ 7)	100 (7/ 7)	100 (7/ 7)	57.5	8.568 (7)
	MONTHS 3/5	100 (7/ 7)	100 (7/ 7)	100 (7/ 7)	80.4	11.990 (7)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 4

A N T I B O D Y R E S P O N S E S

INVESTIGATOR : GRANOFF,DAN
STUDY : 000601
VACCINE : HIB CONJUGATE
ASSAY : RIA
LOT NUMBER : CP298
POPULATION : HIB POLYS VACCINE FAILURES

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
12-71 MOS.	PRE INJ	83 (5/ 6)	0 (0/ 6)			0.289 (6)
	MONTHS 2/3	100 (6/ 6)	100 (6/ 6)	100 (6/ 6)	14.5	4.188 (6)
	MONTHS 3/5	100 (4/ 4)	100 (4/ 4)	100 (4/ 4)	35.7	9.155 (4)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 5

A N T I B O D Y R E S P O N S E S

INVESTIGATOR : GRANOFF,DAN
STUDY : 000601
VACCINE : POLYSACCHARIDE VACCINE
ASSAY : RIA
POPULATION : HIB POLYS VACCINE FAILURES

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	GMT MCG AB/ML (N) ALL VACCINEES	GMT MCG AB/ML (N) RESPONDERS (>2 FOLD RISE)	FOLD RISE MEAN	FOLD RISE % >2 FOLD
12 71 MOS.	PRE INJ	62 (8/ 13)	0 (0/ 13)	0.167 (13)			
	MONTHS 1/2	83 (10/ 12)	33 (4/ 12)	0.563 (12)	1.092 (8)	3.1	67 (8/ 12)
	MONTHS 3/5	100 (8/ 8)	88 (7/ 8)	2.478 (8)	2.478 (8)	13.5	100 (8/ 8)
	MONTHS 5/7	100 (7/ 7)	86 (6/ 7)	6.850 (7)	6.850 (7)	38.8	100 (7/ 7)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 6

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : GRANOFF,DAN
STUDY : 000601
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
POPULATION : HIB POLYS VACCINE FAILURES
AGE RANGE : 12-71 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	7	
VACCINEES WITH NO COMPLAINTS :	2	(28.6 %)
VACCINEES WITH COMPLAINTS :	5	(71.4 %)
VACCINEES WITH NO DATA :	0	

CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 7 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	5	71.4
PAIN/SORENESS, INJ. SITE	3	42.9
ERYTHEMA, INJ. SITE (<=1 IN.)	2	28.6
ERYTHEMA, INJ. SITE (>1 INCH)	2	28.6
STIFFNESS/TIGHTNESS, INJECTION SITE	1	14.3
SWELLING, INJ. SITE (<=1 IN.)	1	14.3
SYSTEMIC REACTIONS	4	57.1
FATIGUE	4	57.1
IRRITABILITY	3	42.9
WARM TO TOUCH	2	28.6
DIARRHEA	1	14.3
POLYDIPSIA	1	14.3
RASH	1	14.3
URTICARIA	1	14.3

TABLE 6 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : GRANOFF,DAN
STUDY : 000601
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
POPULATION : HIB POLYS VACCINE FAILURES
AGE RANGE : 12-71 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE	HIB CONJUGATE INJECTION: 2	
TOTAL VACCINEES	7	
VACCINEES WITH NO COMPLAINTS	2	(28.6 %)
VACCINEES WITH COMPLAINTS	5	(71.4 %)
VACCINEES WITH NO DATA	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 7 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	5	71.4
PAIN/SORENESS, INJ. SITE	5	71.4
ERYTHEMA, INJ. SITE (<=1 IN.)	3	42.9
SWELLING, INJ. SITE (>1 INCH)	3	42.9
ERYTHEMA, INJ. SITE (>1 INCH)	1	14.3
SWELLING, INJ. SITE (<=1 IN.)	1	14.3
SYSTEMIC REACTIONS	4	57.1
FATIGUE	3	42.9
IRRITABILITY	3	42.9
TEETHING	1	14.3
WARM TO TOUCH	1	14.3

TABLE 6 (cont.)

C L I N I C A L C O M P L A I N T S B Y F R E Q U E N C Y

INVESTIGATOR : GRANOFF,DAN
STUDY : 000601
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
POPULATION : HIB POLYS VACCINE FAILURES
AGE RANGE : 12-71 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES :	7	
VACCINEES WITH NO COMPLAINTS :	2	(28.6 %)
VACCINEES WITH COMPLAINTS :	5	(71.4 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 7 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	5	71.4
PAIN/SORENESS, INJ. SITE	5	71.4
SWELLING, INJ. SITE (<=1 IN.)	2	28.6
ERYTHEMA, INJ. SITE (<=1 IN.)	1	14.3
SWELLING, INJ. SITE (>1 INCH)	1	14.3
SYSTEMIC REACTIONS	3	42.9
COUGH	1	14.3
DIARRHEA	1	14.3
FATIGUE	1	14.3
IRRITABILITY	1	14.3
NAUSEA	1	14.3
VOMITING	1	14.3
WARM TO TOUCH	1	14.3
WHEEZING	1	14.3

TABLE 6 (cont.)

C L I N I C A L C O M P L A I N T S B Y F R E Q U E N C Y

INVESTIGATOR : GRANOFF,DAN
STUDY : 000601
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
POPULATION : HIB POLYS VACCINE FAILURES
AGE RANGE : 12-71 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 2	
TOTAL VACCINEES :	6	
VACCINEES WITH NO COMPLAINTS :	1	(16.7 %)
VACCINEES WITH COMPLAINTS :	5	(83.3 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 6 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	5	83.3
PAIN/SORENESS, INJ. SITE	5	83.3
SWELLING, INJ. SITE (>1 INCH)	2	33.3
SYSTEMIC REACTIONS	4	66.7
FATIGUE	1	16.7
HYPERHYDROSIS	1	16.7
IRRITABILITY	1	16.7
PROLONGED CRYING, >1/2 HR	1	16.7
RASH	1	16.7
WARM TO TOUCH	1	16.7

TABLE 6 (cont.)

C L I N I C A L C O M P L A I N T S B Y F R E Q U E N C Y

INVESTIGATOR : GRANOFF,DAN
STUDY : 000601
VACCINE : POLYSACCHARIDE VACCINE
LOT NUMBER : POLYS
POPULATION : HIB POLYS VACCINE FAILURES
AGE RANGE : 12-71 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE	HIB POLYSACCHARIDE(NON-M INJECTION: 1	
TOTAL VACCINEES	16	
VACCINEES WITH NO COMPLAINTS	10	(62.5 %)
VACCINEES WITH COMPLAINTS	6	(37.5 %)
VACCINEES WITH NO DATA	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 16 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	2	12.5
ERYTHEMA, INJ. SITE (<=1 IN.)	1	6.3
PAIN/SORENESS, INJ. SITE	1	6.3
REACTION, LOCAL	1	6.3
SYSTEMIC REACTIONS	5	31.3
IRRITABILITY	2	12.5
COMMON COLD	1	6.3
COOL TO TOUCH	1	6.3
ENURESIS	1	6.3
FATIGUE	1	6.3
GASTROINTESTINAL PAIN	1	6.3
HEADACHE	1	6.3
NAUSEA	1	6.3
VOMITING	1	6.3
WARM TO TOUCH	1	6.3
WHEEZING	1	6.3

TABLE 6 (cont.)

C L I N I C A L C O M P L A I N T S B Y F R E Q U E N C Y

INVESTIGATOR : GRANOFF,DAN
STUDY : 000601
VACCINE : POLYSACCHARIDE VACCINE
LOT NUMBER : CP241
POPULATION : HIB POLYS VACCINE FAILURES
AGE RANGE : 12-71 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 2	
TOTAL VACCINEES :	2	
VACCINEES WITH NO COMPLAINTS :	1	(50.0 %)
VACCINEES WITH COMPLAINTS :	1	(50.0 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 2 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	1	50.0
PAIN/SORENESS, INJ. SITE	1	50.0
SYSTEMIC REACTIONS	1	50.0
FATIGUE	1	50.0
GAIT ABNORMALITIES	1	50.0
IRRITABILITY	1	50.0

TABLE 6 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : GRANOFF,DAN
STUDY : 000601
VACCINE : POLYSACCHARIDE VACCINE
LOT NUMBER : CP241
POPULATION : HIB POLYS VACCINE FAILURES
AGE RANGE : 12-71 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 3	
TOTAL VACCINEES :	2	
VACCINEES WITH NO COMPLAINTS :	1	(50.0 %)
VACCINEES WITH COMPLAINTS :	1	(50.0 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 2 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	1	50.0
ERYTHEMA, INJ. SITE (<=1 IN.)	1	50.0
PAIN/SORENESS, INJ. SITE	1	50.0
STIFFNESS/TIGHTNESS, INJECTION SITE	1	50.0
SWELLING, INJ. SITE (<=1 IN.)	1	50.0
SYSTEMIC REACTIONS	1	50.0
CONTUSION	1	50.0
WARM TO TOUCH	1	50.0

TABLE 6 (cont.)

C L I N I C A L C O M P L A I N T S B Y F R E Q U E N C Y

INVESTIGATOR : GRANOFF,DAN
STUDY : 000601
VACCINE : POLYSACCHARIDE VACCINE
LOT NUMBER : CP298
POPULATION : HIB POLYS VACCINE FAILURES
AGE RANGE : 12-71 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 2	
TOTAL VACCINEES :	9	
VACCINEES WITH NO COMPLAINTS :	4	(50.0 %)
VACCINEES WITH COMPLAINTS :	4	(50.0 %)
VACCINEES WITH NO DATA :	1	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 8 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	3	37.5
ERYTHEMA, INJ. SITE (<=1 IN.)	2	25.0
PAIN/SORENESS, INJ. SITE	2	25.0
SWELLING, INJ. SITE (<=1 IN.)	2	25.0
REACTION, LOCAL	1	12.5
SYSTEMIC REACTIONS	2	25.0
ANOREXIA	1	12.5
FATIGUE	1	12.5
IRRITABILITY	1	12.5

TABLE 6 (cont.)

C L I N I C A L C O M P L A I N T S B Y F R E Q U E N C Y

INVESTIGATOR : GRANOFF,DAN
STUDY : 000601
VACCINE : POLYSACCHARIDE VACCINE
LOT NUMBER : CP298
POPULATION : HIB POLYS VACCINE FAILURES
AGE RANGE : 12-71 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 3	
TOTAL VACCINEES :	6	
VACCINEES WITH NO COMPLAINTS :	2	(33.3 %)
VACCINEES WITH COMPLAINTS :	4	(66.7 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 6 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	4	66.7
PAIN/SORENESS, INJ. SITE	2	33.3
ECCHYMOSIS, INJECTION SITE	1	16.7
ERYTHEMA, INJ. SITE (<=1 IN.)	1	16.7
SWELLING, INJ. SITE (<=1 IN.)	1	16.7
WARMTH, INJECTION SITE	1	16.7
SYSTEMIC REACTIONS	2	33.3
WARM TO TOUCH	2	33.3
FATIGUE	1	16.7
GAIT ABNORMALITIES	1	16.7

TABLE 6 (cont.)

C L I N I C A L C O M P L A I N T S B Y F R E Q U E N C Y

INVESTIGATOR : GRANOFF,DAN
STUDY : 000601
VACCINE : POLYSACCHARIDE VACCINE
LOT NUMBER : POLYS
POPULATION : HIB POLYS VACCINE FAILURES
AGE RANGE : 12-71 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB POLYSACCHARIDE(NON-M INJECTION: 3
TOTAL VACCINEES :	1
VACCINEES WITH NO COMPLAINTS :	0 (0.0 %)
VACCINEES WITH COMPLAINTS :	1 (100.0 %)
VACCINEES WITH NO DATA :	0

CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 1 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	0	0.0
SYSTEMIC REACTIONS	1	100.0
WARM TO TOUCH	1	100.0

TABLE 6 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : GRANOFF,DAN
STUDY : 000601
VACCINE : HIB CONJUGATE *
LOT NUMBER : CP241
POPULATION : HIB POLYS VACCINE FAILURES
AGE RANGE : 12-71 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES	1	
VACCINEES WITH NO COMPLAINTS	0	(0.0 %)
VACCINEES WITH COMPLAINTS	1	(100.0 %)
VACCINEES WITH NO DATA	0	

CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 1 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	1	100.0
PAIN/SORENESS, INJ. SITE	1	100.0
SYSTEMIC REACTIONS	1	100.0
GAIT ABNORMALITIES	1	100.0

* Case (b) (6). Received PRP vaccine prior to entry in the study.

TABLE 6 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : GRANOFF,DAN
STUDY : 000601
VACCINE : HIB CONJUGATE *
LOT NUMBER : CP241
POPULATION : HIB POLYS VACCINE FAILURES
AGE RANGE : 12-71 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 2	
TOTAL VACCINEES :	1	
VACCINEES WITH NO COMPLAINTS :	0	(0.0 %)
VACCINEES WITH COMPLAINTS :	1	(100.0 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 1 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	1	100.0
PAIN/SORENESS, INJ. SITE	1	100.0

* Case (b) (6). Received PRP vaccine prior to entry in the study.

TABLE 6 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : GRANOFF,DAN
STUDY : 000601
VACCINE : HIB CONJUGATE *
LOT NUMBER : CP298
POPULATION : HIB POLYS VACCINE FAILURES
AGE RANGE : 12-71 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES	1	
VACCINEES WITH NO COMPLAINTS	0	(0.0 %)
VACCINEES WITH COMPLAINTS	1	(100.0 %)
VACCINEES WITH NO DATA	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 1 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	1	100.0
ERYTHEMA, INJ. SITE (<=1 IN.)	1	100.0
PAIN/SORENESS, INJ. SITE	1	100.0
SWELLING, INJ. SITE (>1 INCH)	1	100.0
SYSTEMIC REACTIONS	1	100.0
WARM TO TOUCH	1	100.0

* Case (b) (6). Received PRP vaccine prior to entry into the study.

TABLE 6 (cont.)

C L I N I C A L C O M P L A I N T S B Y F R E Q U E N C Y

INVESTIGATOR : GRANOFF,DAN
STUDY : 000601
VACCINE : HIB CONJUGATE *
LOT NUMBER : CP298
POPULATION : HIB POLYS VACCINE FAILURES
AGE RANGE : 12-71 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 2	
TOTAL VACCINEES :	1	
VACCINEES WITH NO COMPLAINTS :	0	(0.0 %)
VACCINEES WITH COMPLAINTS :	1	(100.0 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 1 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	1	100.0
PAIN/SORENESS, INJ. SITE	1	100.0
SWELLING, INJ. SITE (<=1 IN.)	1	100.0

* Case # (b) (6). Received PRP vaccine prior to entry in the study.

TABLE 7

CLINICAL COMPLAINTS

INVESTIGATOR : GRANOFF,DAN
STUDY : 000601
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (7 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
LOCAL REACTIONS	4 (57.1%)	3 (42.9%)	2 (28.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		5 (71.4%)
ERYTHEMA, INJ. SITE (>1 INCH)	1 (14.3%)	2 (28.6%)	1 (14.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (28.6%)
ERYTHEMA, INJ. SITE (<=1 IN.)	1 (14.3%)	1 (14.3%)	1 (14.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (28.6%)
PAIN/SORENESS, INJ. SITE	3 (42.9%)	1 (14.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		3 (42.9%)
STIFFNESS/TIGHTNESS, INJECTION SI	1 (14.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (14.3%)
SWELLING, INJ. SITE (<=1 IN.)	0 (0.0%)	1 (14.3%)	1 (14.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (14.3%)
SYSTEMIC	3 (42.9%)	3 (42.9%)	2 (28.6%)	2 (28.6%)	2 (28.6%)	1 (14.3%)		4 (57.1%)
BODY AS A WHOLE/SITE UNSPEC.	2 (28.6%)	2 (28.6%)	2 (28.6%)	2 (28.6%)	1 (14.3%)	1 (14.3%)		4 (57.1%)
FATIGUE	2 (28.6%)	1 (14.3%)	2 (28.6%)	2 (28.6%)	1 (14.3%)	1 (14.3%)		4 (57.1%)
WARM TO TOUCH	1 (14.3%)	1 (14.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (28.6%)
DIGESTIVE SYSTEM	1 (14.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (14.3%)	0 (0.0%)		2 (28.6%)

TABLE 7 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : GRANOFF,DAN
STUDY : 000601
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (7 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		
DIARRHEA	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (14.3%)	0 (0.0%)		1 (14.3%)
POLYDIPSIA	1 (14.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (14.3%)
NERVOUS SYSTEM & PSYCHIATRIC	3 (42.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		3 (42.9%)
IRRITABILITY	3 (42.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		3 (42.9%)
SKIN & SKIN APPENDAGE	0 (0.0%)	1 (14.3%)	1 (14.3%)	0 (0.0%)	1 (14.3%)	1 (14.3%)		1 (14.3%)
RASH	0 (0.0%)	0 (0.0%)	1 (14.3%)	0 (0.0%)	1 (14.3%)	1 (14.3%)		1 (14.3%)
URTICARIA	0 (0.0%)	1 (14.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (14.3%)
VACCINEES WITH COMPLAINTS	5 (71.4%)	3 (42.9%)	2 (28.6%)	2 (28.6%)	2 (28.6%)	1 (14.3%)		5 (71.4%)
VACCINEES WITH NO COMPLAINTS	2 (28.6%)	4 (57.1%)	5 (71.4%)	5 (71.4%)	5 (71.4%)	6 (85.7%)		2 (28.6%)
TOTAL VACCINEES REPORTING	7	7	7	7	7	7		7
VACCINEES WITH NO DATA	0	0	0	0	0	0		0

TABLE 7 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : GRANOFF,DAN
STUDY : 000601
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (7 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		
LOCAL REACTIONS	5 (71.4%)	3 (42.9%)	2 (28.6%)	1 (14.3%)	1 (14.3%)	1 (14.3%)		5 (71.4%)
ERYTHEMA, INJ. SITE (>1 INCH)	0 (0.0%)	1 (14.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (14.3%)
ERYTHEMA, INJ. SITE (<=1 IN.)	2 (28.6%)	1 (14.3%)	1 (14.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		3 (42.9%)
PAIN/SORENESS, INJ. SITE	5 (71.4%)	3 (42.9%)	2 (28.6%)	1 (14.3%)	1 (14.3%)	0 (0.0%)		5 (71.4%)
SWELLING, INJ. SITE (>1 INCH)	2 (28.6%)	2 (28.6%)	1 (14.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		3 (42.9%)
SWELLING, INJ. SITE (<=1 IN.)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (14.3%)	1 (14.3%)	1 (14.3%)		1 (14.3%)
SYSTEMIC	3 (42.9%)	1 (14.3%)	1 (14.3%)	0 (0.0%)	0 (0.0%)	1 (14.3%)		4 (57.1%)
BODY AS A WHOLE/SITE UNSPEC.	3 (42.9%)	1 (14.3%)	1 (14.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		4 (57.1%)
FATIGUE	2 (28.6%)	1 (14.3%)	1 (14.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		3 (42.9%)
WARM TO TOUCH	1 (14.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (14.3%)
DIGESTIVE SYSTEM	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (14.3%)		1 (14.3%)

TABLE 7 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : GRANOFF,DAN
STUDY : 000601
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (7 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		
TEETHING	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (14.3%)		1 (14.3%)
NERVOUS SYSTEM & PSYCHIATRIC	0 (0.0%)	1 (14.3%)	1 (14.3%)	0 (0.0%)	0 (0.0%)	1 (14.3%)		3 (42.9%)
IRRITABILITY	0 (0.0%)	1 (14.3%)	1 (14.3%)	0 (0.0%)	0 (0.0%)	1 (14.3%)		3 (42.9%)
VACCINEES WITH COMPLAINTS	5 (71.4%)	3 (42.9%)	3 (42.9%)	1 (14.3%)	1 (14.3%)	2 (28.6%)		5 (71.4%)
VACCINEES WITH NO COMPLAINTS	2 (28.6%)	4 (57.1%)	4 (57.1%)	6 (85.7%)	6 (85.7%)	5 (71.4%)		2 (28.6%)
TOTAL VACCINEES REPORTING	7	7	7	7	7	7		7
VACCINEES WITH NO DATA	0	0	0	0	0	0		0

TABLE 7 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : GRANOFF,DAN
STUDY : 000601
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (7 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		
LOCAL REACTIONS	5 (71.4%)	4 (57.1%)	1 (14.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		5 (71.4%)
ERYTHEMA, INJ. SITE (<=1 IN.)	1 (14.3%)	1 (14.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (14.3%)
PAIN/SORENESS, INJ. SITE	5 (71.4%)	3 (42.9%)	1 (14.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		5 (71.4%)
SWELLING, INJ. SITE (>1 INCH)	1 (14.3%)	1 (14.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (14.3%)
SWELLING, INJ. SITE (<=1 IN.)	2 (28.6%)	1 (14.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (28.6%)
SYSTEMIC	2 (28.6%)	0 (0.0%)	0 (0.0%)	1 (14.3%)	1 (14.3%)	0 (0.0%)		3 (42.9%)
BODY AS A WHOLE/SITE UNSPEC.	2 (28.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (28.6%)
FATIGUE	1 (14.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (14.3%)
WARM TO TOUCH	1 (14.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (14.3%)
DIGESTIVE SYSTEM	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (14.3%)	0 (0.0%)	0 (0.0%)		1 (14.3%)
DIARRHEA	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (14.3%)	0 (0.0%)	0 (0.0%)		1 (14.3%)

TABLE 7 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : GRANOFF,DAN
STUDY : 000601
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (7 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		
NAUSEA	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (14.3%)	0 (0.0%)	0 (0.0%)		1 (14.3%)
VOMITING	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (14.3%)	0 (0.0%)	0 (0.0%)		1 (14.3%)
NERVOUS SYSTEM & PSYCHIATRIC	1 (14.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (14.3%)
IRRITABILITY	1 (14.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (14.3%)
RESPIRATORY SYSTEM	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (14.3%)	1 (14.3%)	0 (0.0%)		1 (14.3%)
COUGH	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (14.3%)	1 (14.3%)	0 (0.0%)		1 (14.3%)
WHEEZING	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (14.3%)	0 (0.0%)		1 (14.3%)
VACCINEES WITH COMPLAINTS	5 (71.4%)	4 (57.1%)	1 (14.3%)	1 (14.3%)	1 (14.3%)	0 (0.0%)		5 (71.4%)
VACCINEES WITH NO COMPLAINTS	2 (28.6%)	3 (42.9%)	6 (85.7%)	6 (85.7%)	6 (85.7%)	7 (100.0%)		2 (28.6%)
TOTAL VACCINEES REPORTING	7	7	7	7	7	7		7
VACCINEES WITH NO DATA	0	0	0	0	0	0		0

TABLE 7 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : GRANOFF,DAN
STUDY : 000601
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (6 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		
LOCAL REACTIONS	4 (80.0%)	3 (50.0%)	2 (33.3%)	1 (16.7%)	1 (16.7%)	1 (16.7%)		5 (83.3%)
PAIN/SORENESS, INJ. SITE	4 (80.0%)	3 (50.0%)	2 (33.3%)	1 (16.7%)	1 (16.7%)	0 (0.0%)		5 (83.3%)
SWELLING, INJ. SITE (>1 INCH)	1 (20.0%)	1 (16.7%)	1 (16.7%)	1 (16.7%)	1 (16.7%)	1 (16.7%)		2 (33.3%)
SYSTEMIC	3 (60.0%)	1 (16.7%)	1 (16.7%)	1 (16.7%)	0 (0.0%)	0 (0.0%)		4 (66.7%)
BODY AS A WHOLE/SITE UNSPEC.	2 (40.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (33.3%)
FATIGUE	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (16.7%)
WARM TO TOUCH	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (16.7%)
NERVOUS SYSTEM & PSYCHIATRIC	0 (0.0%)	1 (16.7%)	1 (16.7%)	1 (16.7%)	0 (0.0%)	0 (0.0%)		1 (16.7%)
IRRITABILITY	0 (0.0%)	1 (16.7%)	1 (16.7%)	1 (16.7%)	0 (0.0%)	0 (0.0%)		1 (16.7%)
PROLONGED CRYING, >1/2 HR	0 (0.0%)	1 (16.7%)	1 (16.7%)	1 (16.7%)	0 (0.0%)	0 (0.0%)		1 (16.7%)
SKIN & SKIN APPENDAGE	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (16.7%)

TABLE 7 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : GRANOFF,DAN
STUDY : 000601
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (6 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
HYPERHYDROSIS	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (16.7%)
RASH	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (16.7%)
VACCINEES WITH COMPLAINTS	4 (80.0%)	3 (50.0%)	2 (33.3%)	1 (16.7%)	1 (16.7%)	1 (16.7%)		5 (83.3%)
VACCINEES WITH NO COMPLAINTS	1 (20.0%)	3 (50.0%)	4 (66.7%)	5 (83.3%)	5 (83.3%)	5 (83.3%)		1 (16.7%)
TOTAL VACCINEES REPORTING	5	6	6	6	6	6		6
VACCINEES WITH NO DATA	1	0	0	0	0	0		0

TABLE 7 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : GRANOFF,DAN
STUDY : 000601
VACCINE : POLYSACCHARIDE VACCINE
LOT NUMBER : POLYS
AGE RANGE : 12-71 MOS.

VACCINE : HIB POLYSACCHARIDE(N	NUMBER OF VACCINEES (16 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		
LOCAL REACTIONS	2 (12.5%)	1 (6.3%)	1 (6.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (12.5%)
ERYTHEMA, INJ. SITE (<=1 IN.)	1 (6.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (6.3%)
PAIN/SORENESS, INJ. SITE	1 (6.3%)	1 (6.3%)	1 (6.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (6.3%)
REACTION, LOCAL	1 (6.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (6.3%)
SYSTEMIC	4 (25.0%)	3 (18.8%)	2 (12.5%)	2 (12.5%)	2 (12.5%)	2 (12.5%)		5 (31.3%)
BODY AS A WHOLE/SITE UNSPEC.	3 (18.8%)	2 (12.5%)	1 (6.3%)	1 (6.3%)	1 (6.3%)	1 (6.3%)		3 (18.8%)
COOL TO TOUCH	1 (6.3%)	1 (6.3%)	1 (6.3%)	1 (6.3%)	1 (6.3%)	1 (6.3%)		1 (6.3%)
FATIGUE	1 (6.3%)	1 (6.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (6.3%)
WARM TO TOUCH	1 (6.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (6.3%)
DIGESTIVE SYSTEM	0 (0.0%)	1 (6.3%)	0 (0.0%)	0 (0.0%)	1 (6.3%)	0 (0.0%)		2 (12.5%)
GASTROINTESTINAL PAIN	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (6.3%)	0 (0.0%)		1 (6.3%)

TABLE 7 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : GRANOFF,DAN
STUDY : 000601
VACCINE : POLYSACCHARIDE VACCINE
LOT NUMBER : POLYS
AGE RANGE : 12-71 MOS.

VACCINE : HIB POLYSACCHARIDE(N	NUMBER OF VACCINEES (16 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		
NAUSEA	0 (0.0%)	1 (6.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (6.3%)
VOMITING	0 (0.0%)	1 (6.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (6.3%)
NERVOUS SYSTEM & PSYCHIATRIC	2 (12.5%)	2 (12.5%)	0 (0.0%)	0 (0.0%)	1 (6.3%)	0 (0.0%)		3 (18.8%)
ENURESIS	1 (6.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (6.3%)
HEADACHE	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (6.3%)	0 (0.0%)		1 (6.3%)
IRRITABILITY	1 (6.3%)	2 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (12.5%)
RESPIRATORY SYSTEM	0 (0.0%)	1 (6.3%)	1 (6.3%)	1 (6.3%)	0 (0.0%)	1 (6.3%)		1 (6.3%)
COMMON COLD	0 (0.0%)	1 (6.3%)	1 (6.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (6.3%)
WHEEZING	0 (0.0%)	1 (6.3%)	1 (6.3%)	1 (6.3%)	0 (0.0%)	1 (6.3%)		1 (6.3%)
VACCINEES WITH COMPLAINTS	5 (31.3%)	3 (18.8%)	3 (18.8%)	2 (12.5%)	2 (12.5%)	2 (12.5%)		6 (37.5%)
VACCINEES WITH NO COMPLAINTS	11 (68.8%)	13 (81.3%)	13 (81.3%)	14 (87.5%)	14 (87.5%)	14 (87.5%)		10 (62.5%)
TOTAL VACCINEES REPORTING	16	16	16	16	16	16		16

01342

TABLE 7 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : GRANOFF,DAN
STUDY : 000601
VACCINE : POLYSACCHARIDE VACCINE
LOT NUMBER : POLYS
AGE RANGE : 12-71 MOS.

VACCINE : HIB POLYSACCHARIDE(N	NUMBER OF VACCINEES (16 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		**********
VACCINEES WITH NO DATA	0	0	0	0	0	0		0

01343

TABLE 7 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : GRANOFF,DAN
STUDY : 000601
VACCINE : POLYSACCHARIDE VACCINE
LOT NUMBER : CP241
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE — NUMBER OF VACCINEES (2 VACCINEES) - INJECTION: 2

CLINICAL COMPLAINTS	DAYS POST VACCINATION 0	1	2	3	4	5		NUMBER WITH COMPLAINTS
LOCAL REACTIONS	1 (50.0%)	1 (50.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (50.0%)
PAIN/SORENESS, INJ. SITE	1 (50.0%)	1 (50.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (50.0%)
SYSTEMIC	1 (50.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (50.0%)
BODY AS A WHOLE/SITE UNSPEC.	1 (50.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (50.0%)
FATIGUE	1 (50.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (50.0%)
NERVOUS SYSTEM & PSYCHIATRIC	1 (50.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (50.0%)
GAIT ABNORMALITIES	1 (50.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (50.0%)
IRRITABILITY	1 (50.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (50.0%)
VACCINEES WITH COMPLAINTS	1 (50.0%)	1 (50.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (50.0%)
VACCINEES WITH NO COMPLAINTS	1 (50.0%)	1 (50.0%)	2 (100.0%)	2 (100.0%)	2 (100.0%)	2 (100.0%)		1 (50.0%)
TOTAL VACCINEES REPORTING	2	2	2	2	2	2		2

TABLE 7 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : GRANOFF,DAN
STUDY : 000601
VACCINE : POLYSACCHARIDE VACCINE
LOT NUMBER : CP241
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (2 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
								**********
VACCINEES WITH NO DATA	0	0	0	0	0	0		0

TABLE 7 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : GRANOFF,DAN
STUDY : 000601
VACCINE : POLYSACCHARIDE VACCINE
LOT NUMBER : CP241
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (2 VACCINEES) - INJECTION: 3							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		
LOCAL REACTIONS	1 (50.0%)	1 (50.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (50.0%)
ERYTHEMA, INJ. SITE (<=1 IN.)	1 (50.0%)	1 (50.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (50.0%)
PAIN/SORENESS, INJ. SITE	1 (50.0%)	1 (50.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (50.0%)
STIFFNESS/TIGHTNESS, INJECTION SI	1 (50.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (50.0%)
SWELLING, INJ. SITE (<=1 IN.)	1 (50.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (50.0%)
SYSTEMIC	1 (50.0%)	1 (50.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (50.0%)
BODY AS A WHOLE/SITE UNSPEC.	1 (50.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (50.0%)
WARM TO TOUCH	1 (50.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (50.0%)
SKIN & SKIN APPENDAGE	0 (0.0%)	1 (50.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (50.0%)
CONTUSION	0 (0.0%)	1 (50.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (50.0%)
VACCINEES WITH COMPLAINTS	1 (50.0%)	1 (50.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (50.0%)

01346

TABLE 7 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : GRANOFF,DAN
STUDY : 000601
VACCINE : POLYSACCHARIDE VACCINE
LOT NUMBER : CP241
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (2 VACCINEES) - INJECTION: 3							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		**********
VACCINEES WITH NO COMPLAINTS	1 (50.0%)	1 (50.0%)	2 (100.0%)	2 (100.0%)	2 (100.0%)	2 (100.0%)		1 (50.0%)
TOTAL VACCINEES REPORTING	2	2	2	2	2	2		2
VACCINEES WITH NO DATA	0	0	0	0	0	0		0

TABLE 7 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : GRANOFF,DAN
STUDY : 000601
VACCINE : POLYSACCHARIDE VACCINE
LOT NUMBER : CP298
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE — NUMBER OF VACCINEES (9 VACCINEES) - INJECTION: 2

CLINICAL COMPLAINTS	DAYS POST VACCINATION 0	1	2	3	4	5		NUMBER WITH COMPLAINTS
LOCAL REACTIONS	2 (25.0%)	2 (25.0%)	2 (25.0%)	2 (25.0%)	2 (25.0%)	2 (25.0%)		3 (37.5%)
ERYTHEMA, INJ. SITE (<=1 IN.)	0 (0.0%)	1 (12.5%)	1 (12.5%)	1 (12.5%)	1 (12.5%)	0 (0.0%)		2 (25.0%)
PAIN/SORENESS, INJ. SITE	2 (25.0%)	1 (12.5%)	1 (12.5%)	1 (12.5%)	1 (12.5%)	1 (12.5%)		2 (25.0%)
REACTION, LOCAL	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (12.5%)	0 (0.0%)	0 (0.0%)		1 (12.5%)
SWELLING, INJ. SITE (<=1 IN.)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (25.0%)	1 (12.5%)	1 (12.5%)		2 (25.0%)
SYSTEMIC	2 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (25.0%)
BODY AS A WHOLE/SITE UNSPEC.	1 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (12.5%)
FATIGUE	1 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (12.5%)
DIGESTIVE SYSTEM	1 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (12.5%)
ANOREXIA	1 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (12.5%)
NERVOUS SYSTEM & PSYCHIATRIC	1 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (12.5%)

TABLE 7 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : GRANOFF,DAN
STUDY : 000601
VACCINE : POLYSACCHARIDE VACCINE
LOT NUMBER : CP298
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (9 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		
IRRITABILITY	1 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (12.5%)
VACCINEES WITH COMPLAINTS	3 (37.5%)	2 (25.0%)	2 (25.0%)	2 (25.0%)	2 (25.0%)	2 (25.0%)		4 (50.0%)
VACCINEES WITH NO COMPLAINTS	5 (62.5%)	6 (75.0%)	6 (75.0%)	6 (75.0%)	6 (75.0%)	6 (75.0%)		4 (50.0%)
TOTAL VACCINEES REPORTING	8	8	8	8	8	8		8
VACCINEES WITH NO DATA	1	1	1	1	1	1		1

TABLE 7 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : GRANOFF,DAN
STUDY : 000601
VACCINE : POLYSACCHARIDE VACCINE
LOT NUMBER : CP298
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE

	NUMBER OF VACCINEES (6 VACCINEES) - INJECTION: 3							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		
LOCAL REACTIONS	4 (66.7%)	3 (50.0%)	1 (16.7%)	1 (16.7%)	1 (16.7%)	1 (16.7%)		4 (66.7%)
ECCHYMOSIS, INJECTION SITE	1 (16.7%)	1 (16.7%)	1 (16.7%)	1 (16.7%)	1 (16.7%)	1 (16.7%)		1 (16.7%)
ERYTHEMA, INJ. SITE (<=1 IN.)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (16.7%)
PAIN/SORENESS, INJ. SITE	1 (16.7%)	2 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (33.3%)
SWELLING, INJ. SITE (<=1 IN.)	1 (16.7%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (16.7%)
WARMTH, INJECTION SITE	0 (0.0%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (16.7%)
SYSTEMIC	2 (33.3%)	2 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (33.3%)
BODY AS A WHOLE/SITE UNSPEC.	2 (33.3%)	2 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (33.3%)
FATIGUE	1 (16.7%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (16.7%)
WARM TO TOUCH	2 (33.3%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (33.3%)
NERVOUS SYSTEM & PSYCHIATRIC	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (16.7%)

TABLE 7 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : GRANOFF,DAN
STUDY : 000601
VACCINE : POLYSACCHARIDE VACCINE
LOT NUMBER : CP298
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (6 VACCINEES) - INJECTION: 3							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		
GAIT ABNORMALITIES	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (16.7%)
VACCINEES WITH COMPLAINTS	4 (66.7%)	3 (50.0%)	1 (16.7%)	1 (16.7%)	1 (16.7%)	1 (16.7%)		4 (66.7%)
VACCINEES WITH NO COMPLAINTS	2 (33.3%)	3 (50.0%)	5 (83.3%)	5 (83.3%)	5 (83.3%)	5 (83.3%)		2 (33.3%)
TOTAL VACCINEES REPORTING	6	6	6	6	6	6		6
VACCINEES WITH NO DATA	0	0	0	0	0	0		0

TABLE 7 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : GRANOFF,DAN
STUDY : 000601
VACCINE : POLYSACCHARIDE VACCINE
LOT NUMBER : POLYS
AGE RANGE : 12-71 MOS.

VACCINE : HIB POLYSACCHARIDE(N — NUMBER OF VACCINEES (1 VACCINEES) - INJECTION: 3

CLINICAL COMPLAINTS	DAYS POST VACCINATION 0	1	2	3	4	5		NUMBER WITH COMPLAINTS **********
SYSTEMIC	1 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (100.0%)
BODY AS A WHOLE/SITE UNSPEC.	1 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (100.0%)
WARM TO TOUCH	1 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (100.0%)
VACCINEES WITH COMPLAINTS	1 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (100.0%)
VACCINEES WITH NO COMPLAINTS	0 (0.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)		0 (0.0%)
TOTAL VACCINEES REPORTING	1	1	1	1	1	1		1
VACCINEES WITH NO DATA	0	0	0	0	0	0		0

TABLE 7 (cont.)
CLINICAL COMPLAINTS

INVESTIGATOR : GRANOFF,DAN
STUDY : 000601
VACCINE : HIB CONJUGATE *
LOT NUMBER : CP241
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (1 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		
LOCAL REACTIONS	1 (100.0%)	1 (100.0%)	1 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (100.0%)
PAIN/SORENESS, INJ. SITE	1 (100.0%)	1 (100.0%)	1 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (100.0%)
SYSTEMIC	1 (100.0%)	1 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (100.0%)
NERVOUS SYSTEM & PSYCHIATRIC	1 (100.0%)	1 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (100.0%)
GAIT ABNORMALITIES	1 (100.0%)	1 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (100.0%)
VACCINEES WITH COMPLAINTS	1 (100.0%)	1 (100.0%)	1 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (100.0%)
VACCINEES WITH NO COMPLAINTS	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)		0 (0.0%)
TOTAL VACCINEES REPORTING	1	1	1	1	1	1		1
VACCINEES WITH NO DATA	0	0	0	0	0	0		0

* Case # (b) (6). Received PRP vaccine prior to entry in the study.

TABLE 7 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : GRANOFF,DAN
STUDY : 000601
VACCINE : HIB CONJUGATE *
LOT NUMBER : CP241
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (1 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		
LOCAL REACTIONS	1 (100.0%)	1 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (100.0%)
PAIN/SORENESS, INJ. SITE	1 (100.0%)	1 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (100.0%)
VACCINEES WITH COMPLAINTS	1 (100.0%)	1 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (100.0%)
VACCINEES WITH NO COMPLAINTS	0 (0.0%)	0 (0.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)		0 (0.0%)
TOTAL VACCINEES REPORTING	1	1	1	1	1	1		1
VACCINEES WITH NO DATA	0	0	0	0	0	0		0

* Case #(b) (6). Received PRP vaccine prior to entry in the study.

TABLE 7 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : GRANOFF,DAN
STUDY : 000601
VACCINE : HIB CONJUGATE *
LOT NUMBER : CP298
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (1 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		
LOCAL REACTIONS	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	0 (0.0%)	0 (0.0%)		1 (100.0%)
ERYTHEMA, INJ. SITE (<=1 IN.)	1 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (100.0%)
PAIN/SORENESS, INJ. SITE	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	0 (0.0%)	0 (0.0%)		1 (100.0%)
SWELLING, INJ. SITE (>1 INCH)	1 (100.0%)	1 (100.0%)	1 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (100.0%)
SYSTEMIC	1 (100.0%)	1 (100.0%)	1 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (100.0%)
BODY AS A WHOLE/SITE UNSPEC.	1 (100.0%)	1 (100.0%)	1 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (100.0%)
WARM TO TOUCH	1 (100.0%)	1 (100.0%)	1 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (100.0%)
VACCINEES WITH COMPLAINTS	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	0 (0.0%)	0 (0.0%)		1 (100.0%)
VACCINEES WITH NO COMPLAINTS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (100.0%)	1 (100.0%)		0 (0.0%)
TOTAL VACCINEES REPORTING	1	1	1	1	1	1		1

* Case # (b) (6). Received PRP vaccine prior to entry in the study.

TABLE 7 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : GRANOFF,DAN
STUDY : 000601
VACCINE : HIB CONJUGATE *
LOT NUMBER : CP298
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (1 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		**********
VACCINEES WITH NO DATA	0	0	0	0	0	0		0

* Case (b) (6). Received PRP vaccine prior to entry in the study.

TABLE 7 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : GRANOFF,DAN
STUDY : 000601
VACCINE : HIB CONJUGATE *
LOT NUMBER : CP298
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (1 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		
LOCAL REACTIONS	1 (100.0%)	1 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (100.0%)
PAIN/SORENESS, INJ. SITE	1 (100.0%)	1 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (100.0%)
SWELLING, INJ. SITE (<=1 IN.)	1 (100.0%)	1 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (100.0%)
VACCINEES WITH COMPLAINTS	1 (100.0%)	1 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (100.0%)
VACCINEES WITH NO COMPLAINTS	0 (0.0%)	0 (0.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)		0 (0.0%)
TOTAL VACCINEES REPORTING	1	1	1	1	1	1		1
VACCINEES WITH NO DATA	0	0	0	0	0	0		0

* Case # (b) (6). Received PRP vaccine prior to entry in the study.

TABLE 8

MAXIMUM TEMPERATURES

INVESTIGATOR : GRANOFF,DAN
STUDY : 000601
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (7 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
< 99	1 (14.3%)	4 (57.1%)	4 (57.1%)	4 (57.1%)	3 (42.9%)	4 (57.1%)		1 (14.3%)
99 - 99.9	6 (85.7%)	3 (42.9%)	2 (28.6%)	3 (42.9%)	4 (57.1%)	3 (42.9%)		5 (71.4%)
100 - 100.9	0 (0.0%)	0 (0.0%)	1 (14.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (14.3%)
TEMPERATURE TAKEN	7 (100.0%)	7 (100.0%)	7 (100.0%)	7 (100.0%)	7 (100.0%)	7 (100.0%)		7 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)

TABLE 8 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : GRANOFF,DAN
STUDY : 000601
VACCINE : HIB CONJUGATE
LOT NUMBER : CP241
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (7 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
NORMAL	0 (0.0%)	0 (0.0%)	1 (14.3%)	1 (14.3%)	1 (14.3%)	1 (14.3%)		0 (0.0%)
< 99	5 (71.4%)	6 (85.7%)	5 (71.4%)	5 (71.4%)	4 (57.1%)	4 (57.1%)		3 (42.9%)
99 - 99.9	2 (28.6%)	1 (14.3%)	1 (14.3%)	1 (14.3%)	2 (28.6%)	2 (28.6%)		4 (57.1%)
TEMPERATURE TAKEN	7 (100.0%)	7 (100.0%)	7 (100.0%)	7 (100.0%)	7 (100.0%)	7 (100.0%)		7 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)

TABLE 8 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : GRANOFF,DAN
STUDY : 000601
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (7 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		MAX TEMP
< 99	5 (71.4%)	5 (71.4%)	4 (57.1%)	4 (57.1%)	4 (57.1%)	4 (66.7%)		4 (57.1%)
99 - 99.9	2 (28.6%)	1 (14.3%)	1 (14.3%)	2 (28.6%)	3 (42.9%)	1 (16.7%)		1 (14.3%)
100 - 100.9	0 (0.0%)	1 (14.3%)	1 (14.3%)	1 (14.3%)	0 (0.0%)	1 (16.7%)		1 (14.3%)
101 - 101.9	0 (0.0%)	0 (0.0%)	1 (14.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (14.3%)
TEMPERATURE TAKEN	7 (100.0%)	7 (100.0%)	7 (100.0%)	7 (100.0%)	7 (100.0%)	6 (85.7%)		7 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (14.3%)		0 (0.0%)

TABLE 8 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : GRANOFF,DAN
STUDY : 000601
VACCINE : HIB CONJUGATE
LOT NUMBER : CP298
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (6 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
NORMAL	1 (20.0%)	1 (16.7%)	1 (16.7%)	1 (16.7%)	1 (16.7%)	1 (16.7%)		1 (16.7%)
< 99	2 (40.0%)	0 (0.0%)	2 (33.3%)	3 (50.0%)	2 (33.3%)	2 (33.3%)		0 (0.0%)
99 - 99.9	1 (20.0%)	1 (16.7%)	3 (50.0%)	2 (33.3%)	2 (33.3%)	2 (33.3%)		1 (16.7%)
100 - 100.9	1 (20.0%)	4 (66.7%)	0 (0.0%)	0 (0.0%)	1 (16.7%)	1 (16.7%)		4 (66.7%)
TEMPERATURE TAKEN	5 (83.3%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)		6 (100.0%)
TEMPERATURE NOT TAKEN	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)

TABLE 8 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : GRANOFF,DAN
STUDY : 000601
VACCINE : POLYSACCHARIDE VACCINE
LOT NUMBER : POLYS
AGE RANGE : 12-71 MOS.

VACCINE : HIB POLYSACCHARIDE(N	NUMBER OF VACCINEES (16 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
NORMAL	8 (57.1%)	9 (56.3%)	9 (56.3%)	9 (56.3%)	8 (53.3%)	8 (53.3%)		8 (50.0%)
< 99	2 (14.3%)	3 (18.8%)	5 (31.3%)	3 (18.8%)	2 (13.3%)	6 (40.0%)		1 (6.3%)
99 - 99.9	4 (28.6%)	4 (25.0%)	1 (6.3%)	4 (25.0%)	5 (33.3%)	1 (6.7%)		6 (37.5%)
100 - 100.9	0 (0.0%)	0 (0.0%)	1 (6.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (6.3%)
TEMPERATURE TAKEN	14 (87.5%)	16 (100.0%)	16 (100.0%)	16 (100.0%)	15 (93.8%)	15 (93.8%)		16 (100.0%)
TEMPERATURE NOT TAKEN	2 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (6.3%)	1 (6.3%)		0 (0.0%)

TABLE 8 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : GRANOFF,DAN
STUDY : 000601
VACCINE : POLYSACCHARIDE VACCINE
LOT NUMBER : CP241
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE — NUMBER OF VACCINEES (2 VACCINEES) - INJECTION: 2

MAX TEMPERATURE (DEG F, ORAL)	DAYS POST VACCINATION 0	1	2	3	4	5		NUMBER WITH MAX TEMP
< 99	0 (0.0%)	1 (50.0%)	1 (50.0%)	1 (50.0%)	1 (50.0%)	1 (50.0%)		0 (0.0%)
99 - 99.9	2 (100.0%)	1 (50.0%)	0 (0.0%)	0 (0.0%)	1 (50.0%)	0 (0.0%)		1 (50.0%)
100 - 100.9	0 (0.0%)	0 (0.0%)	1 (50.0%)	1 (50.0%)	0 (0.0%)	1 (50.0%)		1 (50.0%)
TEMPERATURE TAKEN	2 (100.0%)	2 (100.0%)	2 (100.0%)	2 (100.0%)	2 (100.0%)	2 (100.0%)		2 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)

TABLE 8 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : GRANOFF,DAN
STUDY : 000601
VACCINE : POLYSACCHARIDE VACCINE
LOT NUMBER : CP241
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE

MAX TEMPERATURE (DEG F, ORAL)	NUMBER OF VACCINEES (2 VACCINEES) - INJECTION: 3 — DAYS POST VACCINATION 0	1	2	3	4	5		NUMBER WITH MAX TEMP
NORMAL	1 (50.0%)	1 (50.0%)	1 (50.0%)	1 (50.0%)	1 (50.0%)	1 (50.0%)		1 (50.0%)
< 99	1 (50.0%)	0 (0.0%)	1 (50.0%)	0 (0.0%)	0 (0.0%)	1 (50.0%)		0 (0.0%)
99 - 99.9	0 (0.0%)	1 (50.0%)	0 (0.0%)	1 (50.0%)	1 (50.0%)	0 (0.0%)		1 (50.0%)
TEMPERATURE TAKEN	2 (100.0%)	2 (100.0%)	2 (100.0%)	2 (100.0%)	2 (100.0%)	2 (100.0%)		2 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)

TABLE 8 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : GRANOFF,DAN
STUDY : 000601
VACCINE : POLYSACCHARIDE VACCINE
LOT NUMBER : CP298
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE

MAX TEMPERATURE (DEG F, ORAL)	NUMBER OF VACCINEES (9 VACCINEES) - INJECTION: 2 — DAYS POST VACCINATION							NUMBER WITH MAX TEMP
	0	1	2	3	4	5		
NORMAL	3 (37.5%)	4 (50.0%)	4 (50.0%)	4 (50.0%)	4 (50.0%)	4 (50.0%)		3 (37.5%)
< 99	4 (50.0%)	2 (25.0%)	3 (37.5%)	2 (25.0%)	2 (25.0%)	3 (37.5%)		2 (25.0%)
99 - 99.9	1 (12.5%)	2 (25.0%)	1 (12.5%)	2 (25.0%)	2 (25.0%)	1 (12.5%)		3 (37.5%)
TEMPERATURE TAKEN	8 (88.9%)	8 (88.9%)	8 (88.9%)	8 (88.9%)	8 (88.9%)	8 (88.9%)		8 (88.9%)
TEMPERATURE NOT TAKEN	1 (11.1%)	1 (11.1%)	1 (11.1%)	1 (11.1%)	1 (11.1%)	1 (11.1%)		1 (11.1%)

TABLE 8 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : GRANOFF,DAN
STUDY : 000601
VACCINE : POLYSACCHARIDE VACCINE
LOT NUMBER : CP298
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE

MAX TEMPERATURE (DEG F, ORAL)	NUMBER OF VACCINEES (6 VACCINEES) - INJECTION: 3 — DAYS POST VACCINATION							NUMBER WITH MAX TEMP
	0	1	2	3	4	5		
NORMAL	2 (33.3%)	2 (40.0%)	2 (40.0%)	3 (60.0%)	2 (40.0%)	2 (40.0%)		2 (33.3%)
< 99	3 (50.0%)	2 (40.0%)	3 (60.0%)	2 (40.0%)	3 (60.0%)	3 (60.0%)		2 (33.3%)
99 - 99.9	0 (0.0%)	1 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (16.7%)
FEVER	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (16.7%)
TEMPERATURE TAKEN	6 (100.0%)	5 (83.3%)	5 (83.3%)	5 (83.3%)	5 (83.3%)	5 (83.3%)		6 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	1 (16.7%)	1 (16.7%)	1 (16.7%)	1 (16.7%)	1 (16.7%)		0 (0.0%)

TABLE 8 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : GRANOFF,DAN
STUDY : 000601
VACCINE : POLYSACCHARIDE VACCINE
LOT NUMBER : POLYS
AGE RANGE : 12-71 MOS.

VACCINE : HIB POLYSACCHARIDE(N	NUMBER OF VACCINEES (1 VACCINEES) - INJECTION: 3							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
< 99	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)		1 (100.0%)
TEMPERATURE TAKEN	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)		1 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)

01367

TABLE 8 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : GRANOFF,DAN
STUDY : 000601
VACCINE : HIB CONJUGATE *
LOT NUMBER : CP241
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (1 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
< 99	1 (100.0%)	1 (100.0%)	1 (100.0%)	0 (0.0%)	1 (100.0%)	0 (0.0%)		0 (0.0%)
99 - 99.9	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (100.0%)		1 (100.0%)
TEMPERATURE TAKEN	1 (100.0%)	1 (100.0%)	1 (100.0%)	0 (0.0%)	1 (100.0%)	1 (100.0%)		1 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (100.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)

* Case (b) (6). Received PRP vaccine prior to entry in the study.

TABLE 8 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : GRANOFF,DAN
STUDY : 000601
VACCINE : HIB CONJUGATE *
LOT NUMBER : CP241
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (1 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
< 99	0 (0.0%)	1 (100.0%)	1 (100.0%)	0 (0.0%)	1 (100.0%)	1 (100.0%)		1 (100.0%)
TEMPERATURE TAKEN	0 (0.0%)	1 (100.0%)	1 (100.0%)	0 (0.0%)	1 (100.0%)	1 (100.0%)		1 (100.0%)
TEMPERATURE NOT TAKEN	1 (100.0%)	0 (0.0%)	0 (0.0%)	1 (100.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)

* Case # (b) (6). Received PRP vaccine prior to entry in the study.

01369

TABLE 8 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : GRANOFF,DAN
STUDY : 000601
VACCINE : HIB CONJUGATE *
LOT NUMBER : CP298
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE

MAX TEMPERATURE (DEG F, ORAL)	NUMBER OF VACCINEES (1 VACCINEES) - INJECTION: 1							NUMBER WITH MAX TEMP
	DAYS POST VACCINATION							
	0	1	2	3	4	5		
< 99	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)		0 (0.0%)
99 - 99.9	1 (100.0%)	1 (100.0%)	1 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (100.0%)
TEMPERATURE TAKEN	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)		1 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)

* Case # (b) (6). Received PRP vaccine prior to entry in the study.

TABLE 8 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : GRANOFF,DAN
STUDY : 000601
VACCINE : HIB CONJUGATE *
LOT NUMBER : CP298
AGE RANGE : 12-71 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (1 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		
< 99	0 (0.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)		0 (0.0%)
99 - 99.9	1 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (100.0%)
TEMPERATURE TAKEN	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)		1 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)

* Case # (b) (6). Received PRP vaccine prior to entry in the study.

Haemophilus b Conjugate Vaccine
(Neisseria meningitidis Outer Membrane Protein Complex)

COMPARATIVE STUDY OF POLYSACCHARIDE VACCINES

007-01 - Los Angeles, CA - Kwang Sik Kim, M.D.

Healthy children 18-60 months of age received a single 25 mcg dose of either b-Capsa I®, Hib IMUNE® or Hib Vax™. Eleven children 18-23 months of age and 52 children 24-60 months of age received b-Capsa I®. Prior to immunization, no children in the 8-23 month age group and 15% (6/41) in the 24-60 month age group had antibody titers >1.0 mcg/ml. The GMT prior to vaccination was 0.111 mcg/ml for the 8-23 month age group and 0.212 mcg/ml for the 24-60 month age group. One month following immunization 36% (4/11) in the 18-23 month age group and 66% (27/41) in the 24-60 month age group had antibody levels >1.0 mcg/ml. The GMT at that time was 0.512 mcg/ml and 4.032 mcg/ml respectively.

Forty-six children (five 18-23 months of age and forty-one 24-60 months of age) received Hib IMUNE®. Prior to immunization no children in the 18-23 month age group and 23% (9/39) in the 24-60 month age group had antibody titers >1.0 mcg/ml. The GMT prior to vaccination was 0.062 mcg/ml for the 8-23 month age group and 0.332 for the 24-60 month age group. One month following immunization 25% (1/4) in the 18-23 month age group and 54% (21/39) in the 24-60 month age group had antibody levels >1.0 mcg/ml. The GMT at that time was 1.194 mcg/ml and 2.714 mcg/ml respectively.

Ten children 18-23 months old and 41 children 24-60 months old received HibVax™. Thirteen percent (1/8) in the 18-23 month age group and 18% (6/34) in the older age group had antibody levels >1.0 mcg/ml prior to vaccination. The GMT prior to vaccination was 0.251 mcg/ml for the 8-23 month age group and 0.214 mcg/ml for the 24-60 month age group. One month following immunization 50% (4/8) in the 18-23 month age group and 62% (21/34) in the older group had antibody levels >1.0 mcg/ml. The GMT at that time was 1.436 mcg/ml and 2.553 mcg/ml respectively.

Serious adverse experiences were reported for one child who developed otitis media and a urinary tract infection 2 days following immunization with Hib Vax™. The investigator felt this experience was unrelated to use of the vaccine.

STUDY 007-01

PROGRAM: Haemophilus b Conjugate Vaccine (*Neisseria meningitidis* Outer Membrane Protein Complex), Study 007-01.

PURPOSE: To compare the safety and immunogenicity of licensed Haemophilus b polysaccharide vaccines in healthy children 18 months to 5 years of age.

VACCINE: Haemophilus b Polysaccharide Vaccine (PRP)

b-CAPSA® I Vaccine
Mead Johnson Nutritional Division
Lot M068BC
Lot 0878BD

HIB-IMUNE®
Lederle Laboratories
Lot 184-669
Lot 190-654

HibVAX™
Connaught Laboratories, Inc.
Lot 7D91043
Lot 7L91071

INVESTIGATOR: Kwang Sik Kim, M.D.
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SUB-INVESTIGATOR: Evan Steinberg, M.D.
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Robert Adler, M.D.
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Los Angeles, CA 90027

STUDY LOCATION: Children's Hospital of Los Angeles
4650 Sunset Boulevard
Los Angeles, CA 90027

Kaiser Foundation Hospital
1505 North Edgemont
Los Angeles, CA 90027

DATE STUDY INITIATED: October 19, 1987

DATE STUDY COMPLETED: In progress.

STUDY POPULATION: Healthy children 19 to 58 months of age are included in the study.

STUDY PROCEDURE: Children are randomly assigned to receive a single 0.5 ml (25 mcg polysaccharide) intramuscular injection of b-CAPSA®I, HIB-IMUNE®, or HibVAX™.

The parent or guardian is required to record the vaccine recipient's temperature and any reactions at the injection site or systemic complaints for 3 days after vaccination. Unexpected or serious reactions are to be reported immediately to the study physician. Serious adverse experiences in the 14 days following vaccination are required to be reported by the investigator.

Blood samples are obtained immediately prior to and approximately 1 month after vaccination. All serum samples are assayed for antibody to the capsular polysaccharide of Haemophilus influenzae type b by radioimmunoassay. Selected samples are also tested for bactericidal and opsonophagocytic activity, immunoglobulin isotype and subclass IgG. Assays for opsonophagocytic activity are performed at the University of Alabama. All other assays are performed at Merck Sharp & Dohme Research Laboratories.

RESULTS: Demographic information and individual pre and postimmunization antibody data for each vaccine recipient are presented in Tables 1 and 2.

1. Current status:

Lot	Age	No. Vaccinated
b-CAPSA®	18-23 mos.	11
	≥24 mos.	52
HIB-IMUNE®	18-23 mos.	5
	≥ 24 mos.	43
HibVAX™	18-23 mos.	26
	≥24 mos.	25

2. Serologic results:

Anti-PRP responses prior to and 1 month after vaccination are as follows:

Age (Months)	Vaccine	Time	% With Anti-PRP >0.15 mcg/ml	% With Anti-PRP >1.0 mcg/ml	GMT (mcg/ml) All Vaccinees
18-23	b-CAPSA®	Pre	45 (5/11)	0 (0/11)	0.11
		Post	82 (9/11)	36 (4/11)	0.51
	HIB-IMUNE®	Pre	0 (0/4)	0 (0/4)	0.06
		Post	100 (4/4)	25 (1/4)	1.19
	HibVAX™	Pre	63 (5/8)	13 (1/8)	0.25
		Post	88 (7/8)	50 (4/8)	1.44
≥ 24	b-CAPSA®	Pre	51 (21/41)	15 (6/41)	0.21
		Post	98 (40/41)	66 (27/41)	4.03
	HIB-IMUNE®	Pre	67 (26/39)	23 (9/39)	0.33
		Post	97 (38/39)	54 (21/39)	2.71
	HibVAX™	Pre	59 (20/34)	18 (6/34)	0.21
		Post	94 (32/34)	62 (21/34)	2.55

Antibody response summary statistics are presented in Tables 3-5.

RESULTS (CONT.)

4. Clinical results:

The incidence of selected injection site and systemic reactions occurring within 2 days after vaccination are as follows:

Type of Reaction	% of Vaccinees with Reaction b-CAPSA®	HIB-IMUNE®	HibVAX™
Injection Site:			
Pain/Soreness	10 (6/59)	15 (7/48)	12 (6/51)
Erythema >1 inch	0 (0/59)	2 (1/48)	0 (0/51)
Swelling >1 inch	0 (0/59)	0 (0/48)	0 (0/51)
Induration	0 (0/59)	2 (1/48)	0 (0/51)
Systemic:			
Irritability	7 (4/59)	19 (9/48)	14 (7/51)
Sleepiness/Lethargy/ Fatigue	10 (6/59)	15 (7/48)	12 (6/51)

The incidence of all clinical reactions and maximum temperatures occurring during the 5 days following each injection of b-CAPSA®, HIB-IMUNE®, or HibVAX™ are presented in Tables 6-8.

No serious or alarming reactions attributable to the vaccines have been reported. However, one adverse experience probably not related to vaccination was reportable as serious as it required hospitalization. A 23 month old male child with a medical history of underlying obstructive neuropathy was diagnosed as having otitis media and an *E. coli* urinary tract infection 2 days after receiving HibVAX™. The child was hospitalized 3 days later. He subsequently recovered and was discharged within 10 days.

TABLE 1

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : KIM, KWANG S.
STUDY : 000701
VACCINE : B-CAPSA
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	F	HISP	(b) (6)	2Y	0	(b) (6)	001	PREBLEED				130				
					0		011	INJ 1	068BC	25 MCG						
					34		011	BLEED 1				181				
	F	HISP		2Y	0		001	PREBLEED				293		< 5		
					0		011	INJ 1	068BC	25 MCG						
					34		011	BLEED 1				2208		< 5		
	F	BLAC		2Y	0		001	PREBLEED				143		< 5		51
					0		011	INJ 1	068BC	25 MCG						
					45		011	BLEED 1				1812		< 5		83
	F	CAUC		2Y	0		011	INJ 1	068BC	25 MCG						
	M	HISP		2Y	0		001	PREBLEED				192		< 5		32
					0		011	INJ 1	068BC	25 MCG						
					31		011	BLEED 1				4168		5		67
	M	CAUC		3Y	0		011	INJ 1	068BC	25 MCG						
	M	HISP		3Y	0		001	PREBLEED				147		< 5		23
					0		011	INJ 1	068BC	25 MCG						
					28		011	BLEED 1				2112		< 5		1
	M	HISP		2Y	0		001	PREBLEED				4609				
					0		011	INJ 1	068BC	25 MCG						
					47		011	BLEED 1				139901				
	M	CAUC		19M	0		001	PREBLEED				< 125				
					0		011	INJ 1	068BC	25 MCG						
					24		011	BLEED 1				125				
	M	HISP		2Y	0		011	INJ 1	068BC	25 MCG						
	M	BLAC		2Y	0		011	INJ 1	068BC	25 MCG						
	F	BLAC		2Y	0		011	INJ 1	068BC	25 MCG						
	F	CAUC		3Y	0		001	PREBLEED				< 125				
					0		011	INJ 1	068BC	25 MCG						
					39		011	BLEED 1				133				

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : KIM, KWANG S.
STUDY : 000701
VACCINE : B-CAPSA
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	HISP	(b) (6)	2Y	0	(b) (6)	001	PREBLEED				242		< 5		3
					0		011	INJ 1	068BC	25 MCG						
					34		011	BLEED 1				8412		20		93
	F	BLAC		2Y	0		001	PREBLEED				200				
					0		011	INJ 1	068BC	25 MCG						
					42		011	BLEED 1				895				
	F	HISP		24M	0		001	PREBLEED				< 125				
					0		011	INJ 1	068BC	25 MCG						
					31		011	BLEED 1				722				
	F	BLAC		3Y	0		011	INJ 1	068BC	25 MCG						
	F	BLAC		3Y	0		001	PREBLEED				155		< 5		41
					0		011	INJ 1	068BC	25 MCG						
					29		011	BLEED 1				28478		>= 80		95
	M	HISP		22M	-1		001	PREBLEED				< 125				
					0		011	INJ 1	068BC	25 MCG						
					34		011	BLEED 1				275				
	F	HISP		2Y	0		001	PREBLEED				593		< 5		0
					0		011	INJ 1	068BC	25 MCG						
					39		011	BLEED 1				2520		20		8
	M	BLAC		2Y	0		001	PREBLEED				362		< 5		1
					0		011	INJ 1	068BC	25 MCG						
					37		011	BLEED 1				21831		20		100
	F	HISP		24M	0		001	PREBLEED				< 125				
					0		011	INJ 1	068BC	25 MCG						
					24		011	BLEED 1				729				
	M	CAUC		23M	0		001	PREBLEED				194		< 5		0
					0		011	INJ 1	068BC	25 MCG						
					21		011	BLEED 1				7986		80		100
	M	BLAC		4Y	0		001	PREBLEED				305		< 5		0
					0		011	INJ 1	068BC	25 MCG						
					20		011	BLEED 1				195489		>= 80		37

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : KIM, KWANG S.
STUDY : 000701
VACCINE : B-CAPSA
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	HISP	(b) (6)	24M	0	(b) (6)	001	PREBLEED				1519				
					0		011	INJ 1	068BC	25 MCG						
					23		011	BLEED 1				9693				
	M	HISP		23M	0		001	PREBLEED				523		< 5		
					0		011	INJ 1	068BC	25 MCG						
					37		011	BLEED 1				2635		5		
	F	HISP		24M	0		001	PREBLEED				1726				
					0		011	INJ 1	068BC	25 MCG						
					27		011	BLEED 1				28205				
	F	BLAC		22M	0		001	PREBLEED				162				
					0		011	INJ 1	068BC	25 MCG						
					37		011	BLEED 1				< 250				
	M	HISP		2Y	0		011	INJ 1	068BC	25 MCG						
	F	BLAC		2Y	0		001	PREBLEED				< 125		< 5		
					0		011	INJ 1	068BC	25 MCG						
					50		011	BLEED 1				1632		5		
	F	HISP		3Y	0		001	PREBLEED				3155				
					0		011	INJ 1	068BC	25 MCG						
					30		011	BLEED 1				112827				
	M	HISP		2Y	0		001	PREBLEED				964				
					0		011	INJ 1	068BC	25 MCG						
					32		011	BLEED 1				6607				
	M	HISP		2Y	0		001	PREBLEED				< 125				
					0		011	INJ 1	068BC	25 MCG						
					22		011	BLEED 1				< 250				
	M	OTHE		23M	0		001	PREBLEED				211				
					0		011	INJ 1	068BC	25 MCG						
					42		011	BLEED 1				3462				
	F	HISP		3Y	0		001	PREBLEED				< 125		< 5		45
					0		011	INJ 1	068BC	25 MCG						
					28		011	BLEED 1				4213		>= 80		98

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : KIM, KWANG S.
STUDY : 000701
VACCINE : B-CAPSA
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	CAUC	(b) (6)	2Y	0	(b) (6)	001	PREBLEED				< 125				
					0		011	INJ 1	068BC	25 MCG						
					27		011	BLEED 1				449				
	F	BLAC		23M	0		001	PREBLEED				158				
					0		011	INJ 1	068BC	25 MCG						
					28		011	BLEED 1				< 250				
	F	CAUC		2Y	0		001	PREBLEED				< 125		< 5		0
					0		011	INJ 1	087BD	25 MCG						
					28		011	BLEED 1				53922		20		100
	M	HISP		24M	0		001	PREBLEED				< 125				
					0		011	INJ 1	068BC	25 MCG						
					25		011	BLEED 1				392				
	F	HISP		24M	0		001	PREBLEED				135		< 5		
					0		011	INJ 1	068BC	25 MCG						
					36		011	BLEED 1				16858		20		
	F	HISP		2Y	0		001	PREBLEED				106				
					0		011	INJ 1	068BC	25 MCG						
					36		011	BLEED 1				330				
	F	OTHE		2Y	0		001	PREBLEED				< 125		< 5		
					0		011	INJ 1	068BC	25 MCG						
					29		011	BLEED 1				20440		< 5		
	M	HISP		23M	0		001	PREBLEED				< 125				
					0		011	INJ 1	087BD	25 MCG						
					33		011	BLEED 1				< 250				
	M	HISP		3Y	0		001	PREBLEED				207				
					0		011	INJ 1	087BD	25 MCG						
					23		011	BLEED 1				61377				
	M	HISP		22M	0		001	PREBLEED				< 125				
					0		011	INJ 1	087BD	25 MCG						
					21		011	BLEED 1				< 250				
	M	HISP		2Y	0		001	PREBLEED				197		< 5		

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : KIM, KWANG S.
STUDY : 000701
VACCINE : B-CAPSA
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ RIA	CODE/ SBA	CODE/ OPSO
(b) (6)	M	HISP	(b) (6)	2Y	0	(b) (6)	011	INJ 1	087BD	25 MCG			
					29		011	BLEED 1			36966	>= 80	
	M	HISP		2Y	0		001	PREBLEED			< 125		
					0		011	INJ 1	087BD	25 MCG			
					21		011	BLEED 1			31524		
	F	CAUC		2Y	0		001	PREBLEED			2175		
					0		011	INJ 1	068BC	25 MCG			
					27		011	BLEED 1			6422		
	F	HISP		24M	0		001	PREBLEED			< 125		
					0		011	INJ 1	087BD	25 MCG			
					50		011	BLEED 1			186		
	M	HISP		2Y	0		001	PREBLEED			197		
					0		011	INJ 1	087BD	25 MCG			
					24		011	BLEED 1			551		
	F	OTHE		2Y	0		001	PREBLEED			< 125	< 5	
					0		011	INJ 1	087BD	25 MCG			
					28		011	BLEED 1			1303	< 5	
	F	CAUC		2Y	0		001	PREBLEED			< 125	< 5	
					0		011	INJ 1	087BD	25 MCG			
					29		011	BLEED 1			21927	20	
	M	BLAC		24M	0		001	PREBLEED			12307		
					0		011	INJ 1	087BD	25 MCG			
					29		011	BLEED 1			99898		
	M	OTHE		2Y	0		001	PREBLEED			< 125		
					0		011	INJ 1	087BD	25 MCG			
					24		011	BLEED 1			428		
	M	HISP		2Y	0		001	PREBLEED			< 125		
					0		011	INJ 1	087BD	25 MCG			
					49		011	BLEED 1			677		
	M	HISP		2Y	0		001	PREBLEED			264	< 5	
					0		011	INJ 1	087BD	25 MCG			

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : KIM, KWANG S.
STUDY : 000701
VACCINE : B-CAPSA
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	HISP	(b) (6)	2Y	24	(b) (6)	011	BLEED 1				40496		>= 80		
	F	HISP		3Y	0		001	PREBLEED				166				
					0		011	INJ 1	0878D	25 MCG						
					29		011	BLEED 1				37617				
	F	HISP		23M	0		001	PREBLEED				< 125		20		
					0		011	INJ 1	0878D	25 MCG						
					26		011	BLEED 1				16543		80		
	F	HISP		24M	0		001	PREBLEED				473				
					0		011	INJ 1	0878D	25 MCG						
					21		011	BLEED 1				214				
	M	CAUC		2Y	0		001	PREBLEED				133		< 5		
					0		011	INJ 1	0878D	25 MCG						
					25		011	BLEED 1				2010		< 5		
	M	BLAC		2Y	0		001	PREBLEED				345				
					0		011	INJ 1	0878D	25 MCG						
					27		011	BLEED 1				572				
	M	BLAC		23M	0		001	PREBLEED				< 125				
					0		011	INJ 1	0688C	25 MCG						
					36		011	BLEED 1				< 125				
	M	BLAC		24M	0		011	INJ 1	0688C	25 MCG						

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : KIM, KWANG S.
STUDY : 000701
VACCINE : HIB-IMUNE
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	HISP	(b) (6)	4Y	0	(b) (6)	001	PREBLEED				2875				
					0		011	INJ 1	90654	25 MCG						
					30		011	BLEED 1				39844				
	M	CAUC		21M	0		001	PREBLEED				< 125				
					0		011	INJ 1	90654	25 MCG						
					29		011	BLEED 1				418				
	M	BLAC		2Y	0		001	PREBLEED				< 125		< 5		
					0		011	INJ 1	90654	25 MCG						
					27		011	BLEED 1				1120		< 5		
	F	HISP		2Y	0		001	PREBLEED				298				
					0		011	INJ 1	90654	25 MCG						
					28		011	BLEED 1				363				
	F	CAUC		2Y	0		001	PREBLEED				182		< 5		
					0		011	INJ 1	90654	25 MCG						
					25		011	BLEED 1				57938		5		
	M	HISP		3Y	0		001	PREBLEED				1183				
					0		011	INJ 1	90654	25 MCG						
					26		011	BLEED 1				265192				
	M	HISP		24M	0		001	PREBLEED				173				
					0		011	INJ 1	90654	25 MCG						
					30		011	BLEED 1				63776				
	M	HISP		2Y	0		001	PREBLEED				125				
					0		011	INJ 1	90654	25 MCG						
					30		011	BLEED 1				287				
	F	HISP		2Y	0		001	PREBLEED				279		< 5		27
					0		011	INJ 1	90654	25 MCG						
					48		011	BLEED 1				1019		20		48
	F	HISP		2Y	0		001	PREBLEED				241				
					0		011	INJ 1	90654	25 MCG						
					34		D11	BLEED 1				333				
	M	BLAC		4Y	0		001	PREBLEED				4807				

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : KIM, KWANG S.
STUDY : 000701
VACCINE : HIB-IMUNE
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	BLAC	(b) (6)	4Y	0	(b) (6)	001	PREBLEED								
					45		011	BLEED 1				83530				
	F	CAUC		3Y	0		001	PREBLEED				3782				
					0		011	INJ 1	90654	25 MCG						
					28		011	BLEED 1				151818				
	F	HISP		3Y	0		001	PREBLEED				4363				
					0		011	INJ 1	90654	25 MCG						
					41		011	BLEED 1				126743				
	M	BLAC		24M	0		001	PREBLEED				< 125				
					0		011	INJ 1	90654	25 MCG						
					25		011	BLEED 1				< 125				
	M	OTHE		2Y	0		001	PREBLEED				422		< 5		18
					0		011	INJ 1	90654	25 MCG						
					44		011	BLEED 1				21105		20		100
	M	CAUC		2Y	0		001	PREBLEED				330				
					0		011	INJ 1	90854	25 MCG						
					29		011	BLEED 1				27799				
	M	CAUC		2Y	0		001	PREBLEED				1004				
					0		011	INJ 1	90654	25 MCG						
					26		011	BLEED 1				2717				
	F	HISP		2Y	0		001	PREBLEED			02/	258				
					0		011	INJ 1	90654	25 MCG						
					30		011	BLEED 1			02/	588				
	M	BLAC		23M	0		001	PREBLEED				< 125		< 5		2
					0		011	INJ 1	90654	25 MCG						
					29		011	BLEED 1				11278		< 5		99
	M	BLAC		2Y	0		001	PREBLEED				< 125				
					0		011	INJ 1	90654	25 MCG						
					39		011	BLEED 1				260				
	M	BLAC		2Y	0		001	PREBLEED				352				
					0		011	INJ 1	90654	25 MCG						

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : KIM, KWANG S.
STUDY : 000701
VACCINE : HIB-IMUNE
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ RIA	CODE/ SBA	CODE/ OPSO
(b) (6)	M	BLAC	(b) (6)	2Y	37	(b) (6)	011	BLEED 1			293		
	F	BLAC		2Y	0		011	INJ 1	90654	25 MCG			
	M	BLAC		24M	0		001	PREBLEED			553		
					0		011	INJ 1	90654	25 MCG			
					23		011	BLEED 1			< 250		
	M	HISP		2Y	0		001	PREBLEED			< 125		
					0		011	INJ 1	90654	25 MCG			
					25		011	BLEED 1			< 250		
	F	HISP		2Y	0		001	PREBLEED			< 125		
					0		011	INJ 1	90654	25 MCG			
					36		011	BLEED 1			< 250		
	M	HISP		3Y	0		001	PREBLEED			6731		
					0		011	INJ 1	90654	25 MCG			
					29		011	BLEED 1			37470		
	M	CAUC		2Y	0		001	PREBLEED			127	< 5	0
					0		011	INJ 1	90654	25 MCG			
					19		011	BLEED 1			13409	>= 80	100
	M	HISP		2Y	0		001	PREBLEED			238	< 5	0
					0		011	INJ 1	90654	25 MCG			
		.			21		011	BLEED 1			8629	>= 80	99
	M	OTHE		2Y	0		001	PREBLEED			< 125		
					0		011	INJ 1	06521	25 MCG			
					21		011	BLEED 1			628		
	M	OTHE		24M	0		001	PREBLEED			< 125	< 5	27
					0		011	INJ 1	84669	25 MCG			
					16		011	BLEED 1			11499	>= 80	100
	F	CAUC		23M	0		001	PREBLEED			< 125		
					0		011	INJ 1	90654	25 MCG			
					30		011	BLEED 1			579		
	M	HISP		2Y	0		001	PREBLEED			< 125	< 5	54

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : KIM, KWANG S.
STUDY : 000701
VACCINE : HIB-IMUNE
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ RIA	CODE/ SBA	CODE/ OPSO
(b) (6)	M	HISP	(b) (6)	2Y	0	(b) (6)	011	INJ 1	90654	25 MCG			
					30		011	BLEED 1			15229	5	90
	M	HISP		2Y	0		001	PREBLEED			66409		
					0		011	INJ 1	90654	25 MCG			
					46		011	BLEED 1			62887		
	M	OTHE		3Y	0		001	PREBLEED			< 125	< 5	40
					0		011	INJ 1	90654	25 MCG			
					22		011	BLEED 1			8024	20	99
	F	OTHE		2Y	0		001	PREBLEED			< 125		
					0		011	INJ 1	90654	25 MCG			
					22		011	BLEED 1			< 250		
	M	HISP		2Y	0		001	PREBLEED			335	5	67
					0		011	INJ 1	90654	25 MCG			
					27		011	BLEED 1			54770	>= 80	98
	M	HISP		2Y	0		001	PREBLEED			221		
					0		011	INJ 1	90654	25 MCG			
					42		011	BLEED 1			224		
	M	HISP		24M	0		001	PREBLEED			224		
					0		011	INJ 1	84669	25 MCG			
					28		011	BLEED 1			< 250		
	F	OTHE		2Y	0		001	PREBLEED			242		
					0		011	INJ 1	90654	25 MCG			
					34		011	BLEED 1			371		
	F	CAUC		2Y	0		001	PREBLEED			369	20	96
					0		011	INJ 1	90654	25 MCG			
					21		011	BLEED 1			14407	80	100
	M	HISP		24M	0		001	PREBLEED			< 125		
					0		011	INJ 1	90654	25 MCG			
					23		011	BLEED 1			401		
	M	BLAC		2Y	0		001	PREBLEED			< 125		
					0		011	INJ 1	90654	25 MCG			

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : KIM, KWANG S.
STUDY : 000701
VACCINE : HIB-IMUNE
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ RIA	CODE/ SBA	CODE/ OPSO
(b) (6)	M	BLAC	(b) (6)	2Y	21	(b) (6)	011	BLEED 1			684		
	M	OTHE		23M	0		011	INJ 1	90654	25 MCG			
	M	HISP		2Y	0		001	PREBLEED			< 125		
					0		011	INJ 1	90654	25 MCG			
					30		011	BLEED 1			511		
	F	HISP		3Y	0		001	PREBLEED			4143		
					0		011	INJ 1	90654	25 MCG			
					37		011	BLEED 1			5717		
	F	HISP		2Y	0		001	PREBLEED			614	< 5	0
					0		011	INJ 1	90654	25 MCG			
					21		011	BLEED 1			13816	20	100
	M	BLAC		2Y	0		001	PREBLEED			260		
					0		011	INJ 1	90654	25 MCG			
					28		011	BLEED 1			< 250		
	M	HISP		23M	0		001	PREBLEED			< 125		
					0		011	INJ 1	90654	25 MCG			
					49		011	BLEED 1			745		

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : KIM, KWANG S.
STUDY : 000701
VACCINE : HIB-VAX
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ RIA	CODE/ SBA	CODE/ OPSO
(b) (6)	F	HISP	(b) (6)	2Y	0	(b) (6)	001	PREBLEED			< 125	< 5	
					0		011	INJ 1	91043	25 MCG			
					30		011	BLEED 1			1113	< 5	
	F	HISP		22M	0		001	PREBLEED			305		
					0		011	INJ 1	91043	25 MCG			
					29		011	BLEED 1			317		
	M	HISP		2Y	0		001	PREBLEED			289	< 5	5
					0		011	INJ 1	91043	25 MCG			
					27		011	BLEED 1			29567	>= 80	95
	F	HISP		3Y	0		001	PREBLEED			3668		
					0		011	INJ 1	91043	25 MCG			
					41		011	BLEED 1			6557		
	F	HISP		3Y	0		001	PREBLEED			208		
					0		011	INJ 1	91043	25 MCG			
					25		011	BLEED 1			475		
	M	BLAC		2Y	0		001	PREBLEED			204	< 5	11
					0		011	INJ 1	91043	25 MCG			
					34		011	BLEED 1			3229	< 5	95
	M	HISP		3Y	0		001	PREBLEED			161	< 5	38
					0		011	INJ 1	91043	25 MCG			
					23		011	BLEED 1			18159	20	99
	F	HISP		3Y	0		001	PREBLEED			378	20	30
					0		011	INJ 1	91043	25 MCG			
					28		011	BLEED 1			2416	80	41
	M	BLAC		24M	0		001	PREBLEED			< 125		
					0		011	INJ 1	91043	25 MCG			
					45		011	BLEED 1			< 125		
	F	BLAC		4Y	0		001	PREBLEED			796		
					0		011	INJ 1	91043	25 MCG			
					23		011	BLEED 1			4924		
	F	HISP		24M	0		011	INJ 1	91043	25 MCG			

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : KIM, KWANG S.
STUDY : 000701
VACCINE : HIB-VAX
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ RIA	CODE/ SBA	CODE/ OPSO
(b) (6)	M	OTHE	(b) (6)	22M	0	(b) (6)	001	PREBLEED			2108		
					0		011	INJ 1	91043	25 MCG			
					41		011	BLEED 1			2332		
	F	HISP		2Y	0		011	INJ 1	91043	25 MCG			
	F	HISP		22M	0		001	PREBLEED			724	< 5	14
					0		011	INJ 1	91043	25 MCG			
					47		011	BLEED 1			1703	< 5	2
	F	CAUC		23M	0		001	PREBLEED			173	< 5	61
					0		011	INJ 1	91043	25 MCG			
					31		011	BLEED 1			166382	>= 80	100
	M	BLAC		23M	0		001	PREBLEED			< 125		
					0		011	INJ 1	91043	25 MCG			
					29		011	BLEED 1			< 125		
	F	BLAC		23M	0		011	INJ 1	91043	25 MCG			
	M	BLAC		2Y	0		011	INJ 1	91043	25 MCG			
	F	CAUC		2Y	0		001	PREBLEED			4049		
					0		011	INJ 1	91043	25 MCG			
					21		011	BLEED 1			4233		
	M	HISP		3Y	0		001	PREBLEED			878		
					0		011	INJ 1	91043	25 MCG			
					23		011	BLEED 1			21887		
	M	HISP		2Y	0		001	PREBLEED			< 125		
					0		011	INJ 1	91043	25 MCG			
					29		011	BLEED 1			396		
	F	CAUC		21M	0		001	PREBLEED			< 125		
					0		011	INJ 1	91043	25 MCG			
					20		011	BLEED 1			< 125		
	F	BLAC		2Y	0		001	PREBLEED			< 125	< 5	34
					0		011	INJ 1	91043	25 MCG			
					31		011	BLEED 1			18504	< 5	91

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : KIM, KWANG S.
STUDY : 000701
VACCINE : HIB-VAX
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	HISP	(b) (6)	23M	0	(b) (6)	001	PREBLEED				400		< 5		9
					0		011	INJ 1	91043	25 MCG						
					23		011	BLEED 1				17975		>= 80		100
	F	HISP		4Y	0		001	PREBLEED				< 125		< 5		3
					0		011	INJ 1	91043	25 MCG						
					20		011	BLEED 1				7867		>= 80		98
	F	HISP		2Y	0		001	PREBLEED				164				
					0		011	INJ 1	91043	25 MCG						
					28		011	BLEED 1				< 250				
	F	HISP		4Y	0		001	PREBLEED				1253				
					0		011	INJ 1	91043	25 MCG						
					46		011	BLEED 1				107878				
	F	BLAC		2Y	0		001	PREBLEED				215				
					0		011	INJ 1	91043	25 MCG						
					32		011	BLEED 1				363				
	M	OTHE		24M	0		001	PREBLEED				< 125				
					0		011	INJ 1	91043	25 MCG						
					32		011	BLEED 1				< 250				
	M	HISP		2Y	0		001	PREBLEED				< 125				
					0		011	INJ 1	91043	25 MCG						
					29		011	BLEED 1				696				
	M	HISP		24M	0		001	PREBLEED				215		< 5		9
					0		011	INJ 1	91043	25 MCG						
					28		011	BLEED 1				90998		20		75
	F	HISP		2Y	0		001	PREBLEED				138				
					0		011	INJ 1	91043	25 MCG						
					48		011	BLEED 1				15055				
	F	BLAC		2Y	0		001	PREBLEED				161		< 5		15
					0		011	INJ 1	91043	25 MCG						
					42		011	BLEED 1				18596		5		100
	M	BLAC		2Y	0		001	PREBLEED				< 125		< 5		

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : KIM, KWANG S.
STUDY : 000701
VACCINE : HIB-VAX
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	M	BLAC	(b) (6)	2Y	0	(b) (6)	011	INJ 1	91043	25 MCG						
					34		011	BLEED 1				30481		>= 80		
	M	HISP		2Y	0		001	PREBLEED				< 125				
					0		011	INJ 1	91043	25 MCG						
					29		011	BLEED 1				< 250				
	M	HISP		2Y	0		001	PREBLEED				< 125				
					0		011	INJ 1	91043	25 MCG						
					21		011	BLEED 1				311				
	M	HISP		3Y	-4		001	PREBLEED			02/	4179				
					0		011	INJ 1	91071	25 MCG						
					17		011	BLEED 1			02/	142624				
	M	HISP		21M	0		001	PREBLEED				125				
					0		011	INJ 1	91071	25 MCG						
					31		011	BLEED 1				174				
	F	BLAC		24M	0		001	PREBLEED				< 125				
					0		011	INJ 1	91071	25 MCG						
					21		011	BLEED 1				< 250				
	M	HISP		2Y	0		001	PREBLEED				325		< 5		
					0		011	INJ 1	91043	25 MCG						
					36		011	BLEED 1				203016		20		
	M	HISP		3Y	0		011	INJ 1	91043	25 MCG						
					26		011	BLEED 1				1092				
	M	OTHE		24M	0		001	PREBLEED				211				
					0		011	INJ 1	91043	25 MCG						
					22		011	BLEED 1				1113				
	M	HISP		24M	0		001	PREBLEED				227		< 5		
					0		011	INJ 1	91043	25 MCG						
					30		011	BLEED 1				2954		5		
	F	OTHE		23M	0		001	PREBLEED				< 125				
					0		011	INJ 1	91043	25 MCG						
					22		011	BLEED 1				442				

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : KIM, KWANG S.
STUDY : 000701
VACCINE : HIB-VAX
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	RIA	CODE/	SBA	CODE/	OPSO
(b) (6)	F	HISP	(b) (6)	2Y	0	(b) (6)	001	PREBLEED				1065				
					0		011	INJ 1	91071	25 MCG						
					42		011	BLEED 1				14159				
	M	HISP		2Y	0		001	PREBLEED				127				
					0		011	INJ 1	91071	25 MCG						
					32		011	BLEED 1				491				
	F	HISP		24M	0		001	PREBLEED				< 125				
					0		011	INJ 1	91071	25 MCG						
					50		011	BLEED 1				197				
	M	HISP		3Y	0		001	PREBLEED				1289				
					0		011	INJ 1	91071	25 MCG						
					42		011	BLEED 1				13551				
	M	CAUC		24M	0		001	PREBLEED				1034				
					0		011	INJ 1	91071	25 MCG						
					28		011	BLEED 1				12771				
	M	BLAC		2Y	0		001	PREBLEED				< 125				
					0		011	INJ 1	91071	25 MCG						
					28		011	BLEED 1				< 250				
	F	HISP		2Y	0		001	PREBLEED				< 125				
					0		011	INJ 1	91071	25 MCG						
					48		011	BLEED 1				142				

TABLE 2

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : KIM, KWANG S.
STUDY : 000701
VACCINE : B-CAPSA
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ IGGM	CODE/IGG TOTAL	CODE/ IGG1	CODE/ IGG2
(b) (6)	F	HISP	(b) (6)	2Y	0	(b) (6)	001	PREBLEED			< 100	< 100	< 600	
					0		011	INJ 1	068BC	25 MCG				
					34		011	BLEED 1			< 100	< 100	< 600	
	F	HISP		2Y	0		001	PREBLEED			196	< 100	< 600	< 250
					0		011	INJ 1	068BC	25 MCG				
					34		011	BLEED 1			409	1512	15962	< 250
	F	BLAC		2Y	0		001	PREBLEED			250	< 100	< 600	< 250
					0		011	INJ 1	068BC	25 MCG				
					45		011	BLEED 1			229	271	3095	< 250
	F	CAUC		2Y	0		011	INJ 1	068BC	25 MCG				
	M	HISP		2Y	0		001	PREBLEED			< 100	< 100	< 600	< 250
					0		011	INJ 1	068BC	25 MCG				
					31		011	BLEED 1			< 100	610	4460	< 250
	M	CAUC		3Y	0		011	INJ 1	068BC	25 MCG				
	M	HISP		3Y	0		001	PREBLEED			325	< 100	< 600	< 250
					0		011	INJ 1	068BC	25 MCG				
					28		011	BLEED 1			345	< 100	< 600	< 250
	M	HISP		2Y	0		011	INJ 1	068BC	25 MCG				
	M	CAUC		19M	0		011	INJ 1	068BC	25 MCG				
	M	HISP		2Y	0		011	INJ 1	068BC	25 MCG				
	M	BLAC		2Y	0		011	INJ 1	068BC	25 MCG				
	F	BLAC		2Y	0		011	INJ 1	068BC	25 MCG				
	F	CAUC		3Y	0		011	INJ 1	068BC	25 MCG				
	M	HISP		2Y	0		001	PREBLEED			329	< 100	< 600	< 250
					0		011	INJ 1	068BC	25 MCG				
					34		011	BLEED 1			289	909	5221	< 250
	F	BLAC		2Y	0		011	INJ 1	068BC	25 MCG				

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : KIM, KWANG S.
STUDY : 000701
VACCINE : B-CAPSA
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	IGGM	CODE/IGG	TOTAL	CODE/	IGG1	CODE/	IGG2
(b) (6)	F	HISP	(b) (6)	4M	0	(b) (6)	011	INJ 1	068BC	25 MCG								
	F	BLAC		3Y	0		011	INJ 1	068BC	25 MCG								
	F	BLAC		3Y	0		001	PREBLEED				260		< 100		< 600		< 250
					0		011	INJ 1	068BC	25 MCG								
					29		011	BLEED 1				1510		1556		18867		565
	M	HISP		2M	0		011	INJ 1	068BC	25 MCG								
	F	HISP		2Y	0		001	PREBLEED				185		< 100		< 600		< 250
					0		011	INJ 1	068BC	25 MCG								
					39		011	BLEED 1				381		1186		4948		583
	M	BLAC		2Y	0		001	PREBLEED				248		132		< 600		< 250
					0		011	INJ 1	068BC	25 MCG								
					37		011	BLEED 1				458		4012		10055		1481
	F	HISP		4M	0		011	INJ 1	068BC	25 MCG								
	M	CAUC		3M	0		001	PREBLEED				< 100		< 100		< 600		< 250
					0		011	INJ 1	068BC	25 MCG								
					21		011	BLEED 1				931		861		2574		477
	M	BLAC		4Y	0		001	PREBLEED				122		< 100		< 600		< 250
					0		011	INJ 1	068BC	25 MCG								
					20		011	BLEED 1				1114		19248		25701		3868
	M	HISP		4M	0		011	INJ 1	068BC	25 MCG								
	M	HISP		3M	0		001	PREBLEED				287		< 100		< 600		< 250
					0		011	INJ 1	068BC	25 MCG								
					37		011	BLEED 1				235		275		< 600		< 250
	F	HISP		4M	0		011	INJ 1	068BC	25 MCG								
	F	BLAC		2M	0		011	INJ 1	068BC	25 MCG								
	M	HISP		2Y	0		011	INJ 1	068BC	25 MCG								
	F	BLAC		2Y	0		001	PREBLEED				< 100		< 100		< 600		< 250

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : KIM, KWANG S.
STUDY : 000701
VACCINE : B-CAPSA
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ IGGM	CODE/IGG TOTAL	CODE/ IGG1	CODE/ IGG2
(b) (6)	F	BLAC	(b) (6)	2Y	0	(b) (6)	011	INJ 1	068BC	25 MCG				
					50		011	BLEED 1			1218	< 100	< 600	< 250
	F	HISP		3Y	0		011	INJ 1	068BC	25 MCG				
	M	HISP		2Y	0		011	INJ 1	068BC	25 MCG				
	M	HISP		2Y	0		011	INJ 1	068BC	25 MCG				
	M	OTHE		23M	0		011	INJ 1	068BC	25 MCG				
	F	HISP		3Y	0		001	PREBLEED			138	< 100	< 600	< 250
					0		011	INJ 1	068BC	25 MCG				
					28		011	BLEED 1			650	9374	2667	3264
	M	CAUC		2Y	0		011	INJ 1	068BC	25 MCG				
	F	BLAC		23M	0		011	INJ 1	068BC	25 MCG				
	F	CAUC		2Y	0		001	PREBLEED			204	< 100	< 600	< 250
					0		011	INJ 1	087BD	25 MCG				
					28		011	BLEED 1			785	12410	56913	1586
	M	HISP		24M	0		011	INJ 1	068BC	25 MCG				
	F	HISP		24M	0		001	PREBLEED			< 100	< 100	< 600	< 250
					0		011	INJ 1	068BC	25 MCG				
					36		011	BLEED 1			261	3998	5752	1171
	F	HISP		2Y	0		011	INJ 1	068BC	25 MCG				
	F	OTHE		2Y	0		001	PREBLEED			390	< 100	< 600	< 250
					0		011	INJ 1	068BC	25 MCG				
					29		011	BLEED 1			768	3265	15389	522
	M	HISP		23M	0		011	INJ 1	087BD	25 MCG				
	M	HISP		3Y	0		011	INJ 1	087BD	25 MCG				
	M	HISP		22M	0		011	INJ 1	087BD	25 MCG				
	M	HISP		2Y	0		001	PREBLEED					< 600	

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : KIM, KWANG S.
STUDY : 000701
VACCINE : B-CAPSA
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ IGGM	CODE/IGG	TOTAL CODE/ IGG1	CODE/ IGG2
(b) (6)	M	HISP	(b) (6)	2Y	0	(b) (6)	011	INJ 1	087BD	25 MCG				
					29		011	BLEED 1					45443	
	M	HISP		2Y	0		011	INJ 1	087BD	25 MCG				
	F	CAUC		2Y	0		011	INJ 1	068BC	25 MCG				
	F	HISP		24M	0		011	INJ 1	087BD	25 MCG				
	M	HISP		2Y	0		011	INJ 1	087BD	25 MCG				
	F	OTHE		2Y	0		001	PREBLEED			176	< 100	< 600	< 250
					0		011	INJ 1	087BD	25 MCG				
					28		011	BLEED 1			326	348	< 600	< 250
	F	CAUC		2Y	0		001	PREBLEED			350	< 100	< 600	< 250
					0		011	INJ 1	087BD	25 MCG				
					24		011	BLEED 1					12407	
					29		011	BLEED 2			697	5102		< 250
	M	BLAC		24M	0		011	INJ 1	087BD	25 MCG				
	M	OTHE		2Y	0		011	INJ 1	087BD	25 MCG				
	M	HISP		2Y	0		011	INJ 1	087BD	25 MCG				
	M	HISP		2Y	0		011	INJ 1	087BD	25 MCG				
	F	HISP		3Y	0		011	INJ 1	087BD	25 MCG				
	F	HISP		23M	0		011	INJ 1	087BD	25 MCG				
	F	HISP		24M	0		011	INJ 1	087BD	25 MCG				
	M	CAUC		2Y	0		001	PREBLEED			< 100	< 100		< 250
					0		011	INJ 1	087BD	25 MCG				
					25		011	BLEED 1			< 100	352		< 250
	M	BLAC		2Y	0		011	INJ 1	087BD	25 MCG				
	M	BLAC		23M	0		011	INJ 1	068BC	25 MCG				

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : KIM, KWANG S.
STUDY : 000701
VACCINE : B-CAPSA
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ IGGM	CODE/IGG	TOTAL	CODE/ IGG1	CODE/ IGG2
(b) (6)	M	BLAC	(b) (6)	24M	0	(b) (6)	011	INJ	1 0688C	25 MCG					

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : KIM, KWANG S.
STUDY : 000701
VACCINE : HIB-IMUNE
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/	IGGM	CODE/	IGG	TOTAL	CODE/	IGG1	CODE/	IGG2
(b) (6)	M	HISP	(b) (6)	4Y	0	(b) (6)	001	PREBLEED			01/	QNS		119			< 600		
					0		011	INJ 1	90654	25 MCG									
					30		011	BLEED 1			01/	QNS		3768			22358		
	M	CAUC		1M	0		001	PREBLEED				< 10D		< 100			< 600		
					0		011	INJ 1	90654	25 MCG									
					29		011	BLEED 1				< 100		< 100			615		
	M	BLAC		2Y	0		001	PREBLEED				< 100		< 100			< 600		< 250
					0		011	INJ 1	90654	25 MCG									
					27		011	BLEED 1				128		122			773		< 250
	F	HISP		2Y	0		001	PREBLEED				181		< 100			< 600		
					0		011	INJ 1	90654	25 MCG									
					28		011	BLEED 1				< 100		< 100			< 600		
	F	CAUC		2Y	0		001	PREBLEED				362		< 100			< 600		< 250
					0		011	INJ 1	90654	25 MCG									
					25		011	BLEED 1				623		1274			19939		< 250
	M	HISP		3Y	0		001	PREBLEED				425		483			1858		
					0		011	INJ 1	90654	25 MCG									
					26		011	BLEED 1				356		50565			88358		
	M	HISP		24M	0		001	PREBLEED									< 600		
					0		011	INJ 1	90654	25 MCG									
					30		011	BLEED 1									57959		
	M	HISP		2Y	0		011	INJ 1	90654	25 MCG									
	F	HISP		2Y	0		001	PREBLEED				585		< 100			< 600		< 250
					0		011	INJ 1	90654	25 MCG									
					48		011	BLEED 1				1370		611			5350		255
	F	HISP		2Y	0		011	INJ 1	90654	25 MCG									
	M	BLAC		4Y	0		011	INJ 1	90654	25 MCG									
	F	CAUC		3Y	0		011	INJ 1	90654	25 MCG									
	F	HISP		3Y	0		011	INJ 1	90654	25 MCG									

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : KIM, KWANG S.
STUDY : 000701
VACCINE : HIB-IMUNE
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ IGGM	CODE/IGG TOTAL	CODE/ IGG1	CODE/ IGG2
(b) (6)	M	BLAC	(b) (6)	24M	0	(b) (6)	011	INJ 1	90654	25 MCG				
	M	OTHE		2Y	0		001	PREBLEED			105	< 100	< 600	< 250
					0		011	INJ 1	90654	25 MCG				
					44		011	BLEED 1			716	3375	8869	1208
	M	CAUC		2Y	0		011	INJ 1	90654	25 MCG				
	M	CAUC		2Y	0		011	INJ 1	90654	25 MCG				
	F	HISP		2Y	0		011	INJ 1	90654	25 MCG				
	M	BLAC		23M	0		001	PREBLEED			200	< 100	< 600	< 250
					0		011	INJ 1	90654	25 MCG				
					29		011	BLEED 1			387	1118	12286	< 250
	M	BLAC		2Y	0		011	INJ 1	90654	25 MCG				
	M	BLAC		2Y	0		011	INJ 1	90654	25 MCG				
	F	BLAC		2Y	0		011	INJ 1	90654	25 MCG				
	M	BLAC		24M	0		011	INJ 1	90654	25 MCG				
	M	HISP		2Y	0		011	INJ 1	90654	25 MCG				
	F	HISP		2Y	0		011	INJ 1	90654	25 MCG				
	M	HISP		3Y	0		011	INJ 1	90654	25 MCG				
	M	CAUC		2Y	0		001	PREBLEED			351	< 100	< 600	< 250
					0		011	INJ 1	90654	25 MCG				
					19		011	BLEED 1			1005	2062	12717	374
	M	HISP		2Y	0		001	PREBLEED			753	< 100	< 600	< 250
					0		011	INJ 1	90654	25 MCG				
					21		011	BLEED 1			671	493	2591	476
	M	OTHE		2Y	0		011	INJ 1	06521	25 MCG				
	M	OTHE		24M	0		001	PREBLEED			1448	< 100	< 600	< 250

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : KIM, KWANG S.
STUDY : 000701
VACCINE : HIB-IMUNE
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ IGGM	CODE/IGG TOTAL	CODE/ IGG1	CODE/ IGG2
(b) (6)	M	OTHE	(b) (6)	24M	0	(b) (6)	011	INJ 1	84669	25 MCG				
					16		011	BLEED 1			2664	860	5530	< 250
	F	CAUC		23M	0		011	INJ 1	90654	25 MCG				
	M	HISP		2Y	0		001	PREBLEED			430	400	< 600	< 250
					0		011	INJ 1	90654	25 MCG				
					30		011	BLEED 1			1453	984	3937	< 250
	M	HISP		2Y	0		011	INJ 1	90654	25 MCG				
	M	OTHE		3Y	0		001	PREBLEED			728	< 100	< 600	< 250
					0		011	INJ 1	90654	25 MCG				
					22		011	BLEED 1			1026	338	4305	407
	F	OTHE		2Y	0		011	INJ 1	90654	25 MCG				
	M	HISP		2Y	0		001	PREBLEED			< 100	< 100	< 600	< 250
					0		011	INJ 1	90654	25 MCG				
					27		011	BLEED 1			489	8876	15960	2625
	M	HISP		2Y	0		011	INJ 1	90654	25 MCG				
	M	HISP		24M	0		011	INJ 1	84669	25 MCG				
	F	OTHE		2Y	0		011	INJ 1	90654	25 MCG				
	F	CAUC		2Y	0		001	PREBLEED			129	< 100	< 600	< 250
					0		011	INJ 1	90654	25 MCG				
					21		011	BLEED 1			2913	1445	7918	708
	M	HISP		24M	0		011	INJ 1	90654	25 MCG				
	M	BLAC		2Y	0		011	INJ 1	90654	25 MCG				
	M	OTHE		23M	0		011	INJ 1	90654	25 MCG				
	M	HISP		2Y	0		011	INJ 1	90654	25 MCG				
	F	HISP		3Y	0		011	INJ 1	90654	25 MCG				
	F	HISP		2Y	0		001	PREBLEED			1132	473	1040	< 250

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : KIM, KWANG S.
STUDY : 000701
VACCINE : HIB-IMUNE
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ IGGM	CODE/IGG TOTAL	CODE/ IGG1	CODE/ IGG2
(b) (6)	F	HISP	(b) (6)	2Y	0	(b) (6)	011	INJ	1	90654	25 MCG			
					21		011	BLEED	1					
											859	3445	14513	1085
	M	BLAC		2Y	0		011	INJ	1	90654	25 MCG			
	M	HISP		23M	0		011	INJ	1	90654	25 MCG			

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : KIM, KWANG S.
STUDY : 000701
VACCINE : HIB-VAX
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ IGGM	CODE/IGG	TOTAL CODE/ IGG1	CODE/ IGG2
(b) (6)	F	HISP	(b) (6)	2Y	0	(b) (6)	001	PREBLEED					< 600	< 250
					0		011	INJ 1	91043	25 MCG				
					30		011	BLEED 1					3356	< 250
	F	HISP		22M	0		001	PREBLEED			396	< 100	< 600	
					0		011	INJ 1	91043	25 MCG				
					29		011	BLEED 1			398	< 100	< 600	
	M	HISP		2Y	0		001	PREBLEED			< 100	< 100	< 600	< 250
					0		011	INJ 1	91043	25 MCG				
					27		011	BLEED 1			944	1044	14859	531
	F	HISP		3Y	0		001	PREBLEED			388	314	< 600	
					0		011	INJ 1	91043	25 MCG				
					41		011	BLEED 1			217	595	1121	
	F	HISP		3Y	0		001	PREBLEED			1284	< 100	< 600	
					0		011	INJ 1	91043	25 MCG				
					25		011	BLEED 1			1181	< 100	< 600	
	M	BLAC		2Y	0		001	PREBLEED			< 100	< 100	< 600	< 250
					0		011	INJ 1	91043	25 MCG				
					34		011	BLEED 1			100	278	3121	< 250
	M	HISP		3Y	0		001	PREBLEED			< 100	< 100	< 600	< 250
					0		011	INJ 1	91043	25 MCG				
					23		011	BLEED 1			150	1347	7807	540
	F	HISP		3Y	0		001	PREBLEED			617	< 100	< 600	< 250
					0		011	INJ 1	91043	25 MCG				
					28		011	BLEED 1			1709	297	632	< 250
	M	BLAC		24M	0		011	INJ 1	91043	25 MCG				
	F	BLAC		4Y	0		011	INJ 1	91043	25 MCG				
	F	HISP		24M	0		011	INJ 1	91043	25 MCG				
	M	OTHE		22M	0		011	INJ 1	91043	25 MCG				
	F	HISP		2Y	0		011	INJ 1	91043	25 MCG				

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : KIM, KWANG S.
STUDY : 000701
VACCINE : HIB-VAX
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ IGGM	CODE/IGG TOTAL	CODE/ IGG1	CODE/ IGG2
(b) (6)	F	HISP	(b) (6)	22M	0	(b) (6)	001	PREBLEED			1285	< 100	< 600	< 250
					0		011	INJ 1	91043	25 MCG				
					47		011	BLEED 1			1523	231	721	< 250
	F	CAUC		23M	0		001	PREBLEED			< 100	< 100	< 600	< 250
					0		011	INJ 1	91043	25 MCG				
					31		011	BLEED 1			567	34485	63294	1259
	M	BLAC		23M	0		011	INJ 1	91043	25 MCG				
	F	BLAC		23M	0		011	INJ 1	91043	25 MCG				
	M	BLAC		2Y	0		011	INJ 1	91043	25 MCG				
	F	CAUC		2Y	0		011	INJ 1	91043	25 MCG				
	M	HISP		3Y	0		011	INJ 1	91043	25 MCG				
	M	HISP		2Y	0		011	INJ 1	91043	25 MCG				
	F	CAUC		21M	0		011	INJ 1	91043	25 MCG				
	F	BLAC		2Y	0		001	PREBLEED			269	< 100	< 600	< 250
					0		011	INJ 1	91043	25 MCG				
					31		011	BLEED 1			370	1599	12431	855
	M	HISP		23M	0		001	PREBLEED			271	< 100	< 600	< 250
					0		011	INJ 1	91043	25 MCG				
					23		011	BLEED 1			1491	6188	28719	1064
	F	HISP		4Y	0		001	PREBLEED			316	< 100	< 600	< 250
					0		011	INJ 1	91043	25 MCG				
					20		011	BLEED 1			547	333	6622	< 250
	F	HISP		2Y	0		011	INJ 1	91043	25 MCG				
	F	HISP		4Y	0		011	INJ 1	91043	25 MCG				
	F	BLAC		2Y	0		011	INJ 1	91043	25 MCG				
	M	OTHE		24M	0		011	INJ 1	91043	25 MCG				

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : KIM, KWANG S.
STUDY : 000701
VACCINE : HIB-VAX
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ IGGM	CODE/IGG TOTAL	CODE/ IGG1	CODE/ IGG2
(b) (6)	M	HISP	(b) (6)	2Y	0	(b) (6)	011	INJ 1	91043	25 MCG				
	M	HISP		24M	0		001	PREBLEED			< 100	< 100	< 600	< 250
					0		011	INJ 1	91043	25 MCG				
					28		011	BLEED 1			< 100	5008	21091	1859
	F	HISP		2Y	0		011	INJ 1	91043	25 MCG				
	F	BLAC		2Y	0		001	PREBLEED			200	< 100	< 600	< 250
					0		011	INJ 1	91043	25 MCG				
					42		011	BLEED 1			460	2419	13105	1181
	M	BLAC		2Y	0		001	PREBLEED			640	< 100	< 600	< 250
					0		011	INJ 1	91043	25 MCG				
					34		011	BLEED 1			953	1570	18154	862
	M	HISP		2Y	0		011	INJ 1	91043	25 MCG				
	M	HISP		2Y	0		011	INJ 1	91043	25 MCG				
	M	HISP		3Y	0		011	INJ 1	91071	25 MCG				
	M	HISP		21M	0		011	INJ 1	91071	25 MCG				
	F	BLAC		24M	0		011	INJ 1	91071	25 MCG				
	M	HISP		2Y	0		001	PREBLEED					< 600	< 250
					0		011	INJ 1	91043	25 MCG				
					36		011	BLEED 1					4656	31801
	M	HISP		3Y	0		011	INJ 1	91043	25 MCG				
	M	OTHE		24M	0		011	INJ 1	91043	25 MCG				
	M	HISP		24M	0		001	PREBLEED			< 100	< 100	< 600	< 250
					0		011	INJ 1	91043	25 MCG				
					30		011	BLEED 1			254	442	< 600	323
	F	OTHE		23M	0		011	INJ 1	91043	25 MCG				
	F	HISP		2Y	0		011	INJ 1	91071	25 MCG				

TABLE 2 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : KIM, KWANG S.
STUDY : 000701
VACCINE : HIB-VAX
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	DAY	DATE	PHS	EVENT	LOT	DOSE	CODE/ IGGM	CODE/IGG TOTAL	CODE/ IGG1	CODE/ IGG2
(b) (6)	M	HISP	(b) (6)	2Y	0	(b) (6)	011	INJ	1 91071	25 MCG				
	F	HISP		24M	0		011	INJ	1 91071	25 MCG				
	M	HISP		3Y	0		011	INJ	1 91071	25 MCG				
	M	CAUC		24M	0		011	INJ	1 91071	25 MCG				
	M	BLAC		2Y	0		011	INJ	1 91071	25 MCG				
	F	HISP		2Y	0		011	INJ	1 91071	25 MCG				

TABLE 3

ANTIBODY RESPONSES

INVESTIGATOR : KIM, KWANG S.
STUDY : 000701
VACCINE : B-CAPSA
ASSAY : RIA
POPULATION : HEALTHY CHILDREN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
18-23 MOS.	PRE INJ	45 (5/ 11)	0 (0/ 11)			0.111 (11)
	1 MONTH	82 (9/ 11)	36 (4/ 11)	45 (5/ 11)	4.3	0.512 (11)
24-60 MOS.	PRE INJ	51 (21/ 41)	15 (6/ 41)			0.212 (41)
	1 MONTH	98 (40/ 41)	66 (27/ 41)	88 (36/ 41)	15.0	4.032 (41)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 4

ANTIBODY RESPONSES

INVESTIGATOR : KIM, KWANG S.
STUDY : 000701
VACCINE : HIB-IMUNE
ASSAY : RIA
POPULATION : HEALTHY CHILDREN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
18-23 MOS.	PRE INJ	0 (0/ 4)	0 (0/ 4)			0.062 (4)
	1 MONTH	100 (4/ 4)	25 (1/ 4)	100 (4/ 4)	9.6	1.194 (4)
24-60 MOS.	PRE INJ	67 (26/ 39)	23 (9/ 39)			0.332 (39)
	1 MONTH	97 (38/ 39)	54 (21/ 39)	64 (25/ 39)	7.5	2.714 (39)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 5

ANTIBODY RESPONSES

INVESTIGATOR : KIM, KWANG S.
STUDY : 000701
VACCINE : HIB-VAX
ASSAY : RIA
POPULATION : HEALTHY CHILDREN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
18-23 MOS.	PRE INJ	63 (5/ 8)	13 (1/ 8)			0.251 (8)
	1 MONTH	88 (7/ 8)	50 (4/ 8)	50 (4/ 8)	5.2	1.436 (8)
24-60 MOS.	PRE INJ	59 (20/ 34)	18 (6/ 34)			0.214 (34)
	1 MONTH	94 (32/ 34)	62 (21/ 34)	71 (24/ 34)	10.6	2.553 (34)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 6

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : KIM, KWANG S.
STUDY : 000701
VACCINE : B-CAPSA
POPULATION : HEALTHY CHILDREN
AGE RANGE : 18-60 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	B-CAPSA INJECTION: 1	
TOTAL VACCINEES :	63	
VACCINEES WITH NO COMPLAINTS :	46	(78.0 %)
VACCINEES WITH COMPLAINTS :	13	(22.0 %)
VACCINEES WITH NO DATA :	4	

CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 59 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	7	11.9
PAIN/SORENESS, INJ. SITE	7	11.9
ERYTHEMA, INJ. SITE (<=1 IN.)	1	1.7
SWELLING, INJ. SITE (<=1 IN.)	1	1.7
SYSTEMIC REACTIONS	11	18.6
FATIGUE	6	10.2
IRRITABILITY	4	6.8
WARM TO TOUCH	4	6.8
VOMITING	3	5.1
DIARRHEA	2	3.4
NAUSEA	2	3.4
FEVER	1	1.7
PROLONGED CRYING, >1/2 HR	1	1.7
RASH	1	1.7
UNUSUAL HIGH-PITCHED CRYING	1	1.7

TABLE 6

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : KIM, KWANG S.
STUDY : 000701
VACCINE : HIB-IMUNE
POPULATION : HEALTHY CHILDREN
AGE RANGE : 18-60 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB-IMUNE INJECTION: 1	
TOTAL VACCINEES :	48	
VACCINEES WITH NO COMPLAINTS :	31	(64.6 %)
VACCINEES WITH COMPLAINTS :	17	(35.4 %)
VACCINEES WITH NO DATA :	0	

CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 48 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	9	18.8
PAIN/SORENESS, INJ. SITE	7	14.6
SWELLING, INJ. SITE (<=1 IN.)	5	10.4
ERYTHEMA, INJ. SITE (<=1 IN.)	3	6.3
ERYTHEMA, INJ. SITE (>1 INCH)	1	2.1
INDURATION, INJECTION SITE	1	2.1
SYSTEMIC REACTIONS	14	29.2
IRRITABILITY	9	18.8
FATIGUE	7	14.6
WARM TO TOUCH	6	12.5
FEVER	5	10.4
DIARRHEA	3	6.3
PROLONGED CRYING, >1/2 HR	2	4.2
VOMITING	2	4.2
COMMON COLD	1	2.1
NASAL CONGESTION	1	2.1
NASAL DISCHARGE	1	2.1
NAUSEA	1	2.1
NERVOUSNESS	1	2.1
OTITIS MEDIA	1	2.1
RASH	1	2.1
UNUSUAL HIGH-PITCHED CRYING	1	2.1

TABLE 6

CLINICAL COMPLAINTS BY FREQUENCY

INVESTIGATOR : KIM, KWANG S.
STUDY : D00701
VACCINE : HIB-VAX
POPULATION : HEALTHY CHILDREN
AGE RANGE : 18-60 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB-VAX INJECTION: 1	
TOTAL VACCINEES :	51	
VACCINEES WITH NO COMPLAINTS :	36	(70.6 %)
VACCINEES WITH COMPLAINTS :	15	(29.4 %)
VACCINEES WITH NO DATA :	0	

CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 51 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	6	11.8
PAIN/SORENESS, INJ. SITE	6	11.8
ERYTHEMA, INJ. SITE (<=1 IN.)	2	3.9
SWELLING, INJ. SITE (<=1 IN.)	2	3.9
SYSTEMIC REACTIONS	15	29.4
IRRITABILITY	7	13.7
FATIGUE	6	11.8
WARM TO TOUCH	6	11.8
DIARRHEA	2	3.9
FEVER	2	3.9
NASAL CONGESTION	1	2.0
OTITIS MEDIA	1	2.0
PROLONGED CRYING, >1/2 HR	1	2.0
RASH	1	2.0
UNUSUAL HIGH-PITCHED CRYING	1	2.0
URINARY TRACT INFECTION, NOS	1	2.0
WHEEZING	1	2.0

TABLE 7

CLINICAL COMPLAINTS

INVESTIGATOR : KIM, KWANG S.
STUDY : 000701
VACCINE : B-CAPSA
AGE RANGE : 18-60 MOS.

CLINICAL COMPLAINTS	NUMBER OF VACCINEES (63 VACCINEES) - INJECTION 1							NUMBER WITH COMPLAINTS
	DAYS POST VACCINATION							
	0	1	2	3	4	5		
LOCAL REACTIONS	6 (10.0%)	2 (3.3%)	1 (1.7%)	0 (0.0%)	1 (50.0%)	0 (0.0%)		7 (11.7%)
ERYTHEMA, INJECTION SITE (1 INCH,	1 (1.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (1.7%)
PAIN/SORENESS, INJECTION SITE	6 (10.0%)	2 (3.3%)	1 (1.7%)	0 (0.0%)	1 (50.0%)	0 (0.0%)		7 (11.7%)
SWELLING, INJECTION SITE (1 INCH,	1 (1.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (1.7%)
SYSTEMIC	8 (13.3%)	2 (3.3%)	3 (5.0%)	3 (5.0%)	2 (100.0%)	2 (100.0%)		11 (18.3%)
BODY AS A WHOLE/SITE UNSPEC.	6 (10.0%)	0 (0.0%)	2 (3.3%)	1 (1.7%)	2 (100.0%)	1 (50.0%)		9 (15.0%)
FATIGUE	6 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		6 (10.0%)
FEVER	0 (0.0%)	0 (0.0%)	1 (1.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (1.7%)
WARM TO TOUCH	2 (3.3%)	0 (0.0%)	1 (1.7%)	1 (1.7%)	2 (100.0%)	1 (50.0%)		4 (6.7%)
DIGESTIVE SYSTEM	3 (5.0%)	1 (1.7%)	2 (3.3%)	3 (5.0%)	1 (50.0%)	0 (0.0%)		6 (10.0%)
DIARRHEA	1 (1.7%)	1 (1.7%)	0 (0.0%)	1 (1.7%)	1 (50.0%)	0 (0.0%)		2 (3.3%)

TABLE 7 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : KIM, KWANG S.
STUDY : 000701
VACCINE : B-CAPSA
AGE RANGE : 18-60 MOS.

CLINICAL COMPLAINTS	NUMBER OF VACCINEES (63 VACCINEES) - INJECTION 1							NUMBER WITH COMPLAINTS
	DAYS POST VACCINATION							
	0	1	2	3	4	5		
NAUSEA	1 (1.7%)	0 (0.0%)	2 (3.3%)	1 (1.7%)	0 (0.0%)	0 (0.0%)		2 (3.3%)
VOMITING	1 (1.7%)	0 (0.0%)	1 (1.7%)	1 (1.7%)	0 (0.0%)	0 (0.0%)		3 (5.0%)
NERVOUS SYSTEM & PSYCHIATRIC	5 (8.3%)	2 (3.3%)	2 (3.3%)	1 (1.7%)	1 (50.0%)	1 (50.0%)		6 (10.0%)
IRRITABILITY	3 (5.0%)	1 (1.7%)	1 (1.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		4 (6.7%)
PROLONGED CRYING, >1/2 HR	1 (1.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (1.7%)
UNUSUAL HIGH-PITCHED CRYING	1 (1.7%)	1 (1.7%)	1 (1.7%)	1 (1.7%)	1 (50.0%)	1 (50.0%)		1 (1.7%)
SKIN & SKIN APPENDAGE	1 (1.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (1.7%)
RASH	1 (1.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (1.7%)
VACCINEES WITH COMPLAINTS	10 (16.7%)	4 (6.7%)	3 (5.0%)	3 (5.0%)	2 (100.0%)	2 (100.0%)		13 (21.7%)
VACCINEES WITH NO COMPLAINTS	50 (83.3%)	56 (93.3%)	57 (95.0%)	57 (95.0%)	0 (0.0%)	0 (0.0%)		47 (78.3%)
TOTAL VACCINEES REPORTING	60	60	60	60	2	2		60

TABLE 7 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : KIM, KWANG S.
STUDY : 000701
VACCINE : B-CAPSA
AGE RANGE : 18-60 MOS.

CLINICAL COMPLAINTS	NUMBER OF VACCINEES (63 VACCINEES) - INJECTION 1							NUMBER WITH COMPLAINTS
	DAYS POST VACCINATION							
	0	1	2	3	4	5		**********
VACCINEES WITH NO DATA	3	3	3	3	61	61		3

TABLE 7 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : KIM, KWANG S.
STUDY : 000701
VACCINE : HIB-IMUNE
AGE RANGE : 18-60 MOS.

CLINICAL COMPLAINTS	NUMBER OF VACCINEES (48 VACCINEES) - INJECTION 1 — DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
	0	1	2	3	4	5		
LOCAL REACTIONS	10 (20.8%)	5 (10.4%)	3 (6.3%)	1 (2.1%)	0 (0.0%)	0 (0.0%)		10 (20.8%)
ERYTHEMA, INJECTION SITE (>1 INCH	1 (2.1%)	1 (2.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (2.1%)
ERYTHEMA, INJECTION SITE (1 INCH,	2 (4.2%)	2 (4.2%)	1 (2.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		3 (6.3%)
INDURATION, INJECTION SITE	1 (2.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (2.1%)
PAIN/SORENESS, INJECTION SITE	7 (14.6%)	4 (8.3%)	3 (6.3%)	1 (2.1%)	0 (0.0%)	0 (0.0%)		7 (14.6%)
SWELLING, INJECTION SITE (1 INCH,	6 (12.5%)	4 (8.3%)	1 (2.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		6 (12.5%)
SYSTEMIC	13 (27.1%)	9 (18.8%)	7 (14.6%)	6 (12.5%)	1 (50.0%)	0 (0.0%)		14 (29.2%)
BODY AS A WHOLE/SITE UNSPEC.	10 (20.8%)	7 (14.6%)	4 (8.3%)	3 (6.3%)	0 (0.0%)	0 (0.0%)		12 (25.0%)
FATIGUE	6 (12.5%)	2 (4.2%)	2 (4.2%)	1 (2.1%)	0 (0.0%)	0 (0.0%)		7 (14.6%)
FEVER	5 (10.4%)	3 (6.3%)	1 (2.1%)	1 (2.1%)	0 (0.0%)	0 (0.0%)		5 (10.4%)
WARM TO TOUCH	4 (8.3%)	5 (10.4%)	2 (4.2%)	2 (4.2%)	0 (0.0%)	0 (0.0%)		6 (12.5%)

TABLE 7 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : KIM, KWANG S.
STUDY : 000701
VACCINE : HIB-IMUNE
AGE RANGE : 18-60 MOS.

CLINICAL COMPLAINTS	NUMBER OF VACCINEES (48 VACCINEES) - INJECTION 1 — DAYS POST VACCINATION 0	1	2	3	4	5		NUMBER WITH COMPLAINTS
DIGESTIVE SYSTEM	2 (4.2%)	2 (4.2%)	2 (4.2%)	2 (4.2%)	0 (0.0%)	0 (0.0%)		3 (6.3%)
DIARRHEA	2 (4.2%)	2 (4.2%)	2 (4.2%)	1 (2.1%)	0 (0.0%)	0 (0.0%)		3 (6.3%)
NAUSEA	0 (0.0%)	1 (2.1%)	1 (2.1%)	1 (2.1%)	0 (0.0%)	0 (0.0%)		1 (2.1%)
VOMITING	1 (2.1%)	1 (2.1%)	1 (2.1%)	1 (2.1%)	0 (0.0%)	0 (0.0%)		2 (4.2%)
NERVOUS SYSTEM & PSYCHIATRIC	6 (12.5%)	5 (10.4%)	5 (10.4%)	4 (8.3%)	0 (0.0%)	0 (0.0%)		9 (18.8%)
IRRITABILITY	6 (12.5%)	5 (10.4%)	5 (10.4%)	3 (6.3%)	0 (0.0%)	0 (0.0%)		9 (18.8%)
NERVOUSNESS	1 (2.1%)	1 (2.1%)	1 (2.1%)	1 (2.1%)	0 (0.0%)	0 (0.0%)		1 (2.1%)
PROLONGED CRYING, >1/2 HR	2 (4.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (4.2%)
UNUSUAL HIGH-PITCHED CRYING	1 (2.1%)	1 (2.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (2.1%)
RESPIRATORY SYSTEM	1 (2.1%)	1 (2.1%)	1 (2.1%)	1 (2.1%)	0 (0.0%)	0 (0.0%)		1 (2.1%)
COMMON COLD	1 (2.1%)	1 (2.1%)	1 (2.1%)	1 (2.1%)	0 (0.0%)	0 (0.0%)		1 (2.1%)
NASAL CONGESTION	1 (2.1%)	1 (2.1%)	1 (2.1%)	1 (2.1%)	0 (0.0%)	0 (0.0%)		1 (2.1%)

TABLE 7 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : KIM, KWANG S.
STUDY : 000701
VACCINE : HIB-IMUNE
AGE RANGE : 18-60 MOS.

CLINICAL COMPLAINTS	NUMBER OF VACCINEES (48 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
	0	1	2	3	4	5		
NASAL DISCHARGE	1 (2.1%)	1 (2.1%)	1 (2.1%)	1 (2.1%)	0 (0.0%)	0 (0.0%)		1 (2.1%)
SKIN & SKIN APPENDAGE	0 (0.0%)	1 (2.1%)	1 (2.1%)	1 (2.1%)	0 (0.0%)	0 (0.0%)		1 (2.1%)
RASH	0 (0.0%)	1 (2.1%)	1 (2.1%)	1 (2.1%)	0 (0.0%)	0 (0.0%)		1 (2.1%)
SPECIAL SENSES	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (50.0%)	0 (0.0%)		1 (2.1%)
OTITIS MEDIA	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (50.0%)	0 (0.0%)		1 (2.1%)
VACCINEES WITH COMPLAINTS	16 (33.3%)	10 (20.8%)	7 (14.6%)	6 (12.5%)	1 (50.0%)	0 (0.0%)		17 (35.4%)
VACCINEES WITH NO COMPLAINTS	32 (66.7%)	38 (79.2%)	41 (85.4%)	42 (87.5%)	1 (50.0%)	0 (0.0%)		31 (64.6%)
TOTAL VACCINEES REPORTING	48	48	48	48	2	0		48
VACCINEES WITH NO DATA	0	0	0	0	46	48		0

TABLE 7 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : KIM, KWANG S.
STUDY : 000701
VACCINE : HIB-VAX
AGE RANGE : 18-60 MOS.

CLINICAL COMPLAINTS	NUMBER OF VACCINEES (51 VACCINEES) - INJECTION 1							NUMBER WITH COMPLAINTS
	DAYS POST VACCINATION							
	0	1	2	3	4	5		
LOCAL REACTIONS	6 (11.8%)	2 (3.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		6 (11.8%)
ERYTHEMA, INJECTION SITE (1 INCH,	2 (3.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (3.9%)
PAIN/SORENESS, INJECTION SITE	6 (11.8%)	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		6 (11.8%)
SWELLING, INJECTION SITE (1 INCH,	1 (2.0%)	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (3.9%)
SYSTEMIC	11 (21.6%)	5 (9.8%)	3 (5.9%)	3 (5.9%)	1 (25.0%)	1 (100.0%)		15 (29.4%)
BODY AS A WHOLE/SITE UNSPEC.	10 (19.6%)	2 (3.9%)	0 (0.0%)	1 (2.0%)	0 (0.0%)	0 (0.0%)		10 (19.6%)
FATIGUE	6 (11.8%)	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		6 (11.8%)
FEVER	2 (3.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (3.9%)
WARM TO TOUCH	6 (11.8%)	2 (3.9%)	0 (0.0%)	1 (2.0%)	0 (0.0%)	0 (0.0%)		6 (11.8%)
DIGESTIVE SYSTEM	1 (2.0%)	1 (2.0%)	1 (2.0%)	1 (2.0%)	0 (0.0%)	0 (0.0%)		2 (3.9%)
DIARRHEA	1 (2.0%)	1 (2.0%)	1 (2.0%)	1 (2.0%)	0 (0.0%)	0 (0.0%)		2 (3.9%)

TABLE 7 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : KIM, KWANG S.
STUDY : 000701
VACCINE : HIB-VAX
AGE RANGE : 18-60 MOS.

CLINICAL COMPLAINTS	NUMBER OF VACCINEES (51 VACCINEES) - INJECTION 1 — DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
	0	1	2	3	4	5		
NERVOUS SYSTEM & PSYCHIATRIC	4 (7.8%)	3 (5.9%)	2 (3.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		7 (13.7%)
IRRITABILITY	4 (7.8%)	3 (5.9%)	2 (3.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		7 (13.7%)
PROLONGED CRYING, >1/2 HR	0 (0.0%)	1 (2.0%)	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (2.0%)
UNUSUAL HIGH-PITCHED CRYING	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (2.0%)
RESPIRATORY SYSTEM	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.0%)	0 (0.0%)	0 (0.0%)		1 (2.0%)
NASAL CONGESTION	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.0%)	0 (0.0%)	0 (0.0%)		1 (2.0%)
WHEEZING	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.0%)	0 (0.0%)	0 (0.0%)		1 (2.0%)
SKIN & SKIN APPENDAGE	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.0%)	0 (0.0%)	0 (0.0%)		1 (2.0%)
RASH	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.0%)	0 (0.0%)	0 (0.0%)		1 (2.0%)
SPECIAL SENSES	0 (0.0%)	0 (0.0%)	1 (2.0%)	1 (2.0%)	1 (25.0%)	1 (100.0%)		1 (2.0%)
OTITIS MEDIA	0 (0.0%)	0 (0.0%)	1 (2.0%)	1 (2.0%)	1 (25.0%)	1 (100.0%)		1 (2.0%)
UROGENITAL SYSTEM	0 (0.0%)	0 (0.0%)	1 (2.0%)	1 (2.0%)	1 (25.0%)	1 (100.0%)		1 (2.0%)

TABLE 7 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : KIM, KWANG S.
STUDY : 000701
VACCINE : HIB-VAX
AGE RANGE : 18-60 MOS.

CLINICAL COMPLAINTS	NUMBER OF VACCINEES (51 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
	0	1	2	3	4	5		
URINARY TRACT INFECTION, NOS	0 (0.0%)	0 (0.0%)	1 (2.0%)	1 (2.0%)	1 (25.0%)	1 (100.0%)		1 (2.0%)
VACCINEES WITH COMPLAINTS	12 (23.5%)	5 (9.8%)	3 (5.9%)	3 (5.9%)	1 (25.0%)	1 (100.0%)		15 (29.4%)
VACCINEES WITH NO COMPLAINTS	39 (76.5%)	46 (90.2%)	48 (94.1%)	48 (94.1%)	3 (75.0%)	0 (0.0%)		36 (70.6%)
TOTAL VACCINEES REPORTING	51	51	51	51	4	1		51
VACCINEES WITH NO DATA	0	0	0	0	47	50		0

TABLE 8

MAXIMUM TEMPERATURES

INVESTIGATOR : KIM, KWANG S.
STUDY : 000701
VACCINE : B-CAPSA
AGE RANGE : 18-60 MOS.

MAX TEMPERATURE (DEG F, ORAL)	NUMBER OF VACCINEES (63 VACCINEES) - INJECTION 1							NUMBER WITH MAX TEMP
	DAYS POST VACCINATION							
	0	1	2	3	4	5		
NORMAL	25 (41.7%)	26 (44.1%)	26 (44.1%)	28 (46.7%)	0 (0.0%)	0 (0.0%)		24 (40.0%)
< 99	30 (50.0%)	27 (45.8%)	26 (44.1%)	30 (50.0%)	1 (50.0%)	2 (100.0%)		25 (41.7%)
99 - 99.9	3 (5.0%)	5 (8.5%)	4 (6.8%)	1 (1.7%)	1 (50.0%)	0 (0.0%)		7 (11.7%)
100 - 100.9	1 (1.7%)	1 (1.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)
101 - 101.9	1 (1.7%)	0 (0.0%)	1 (1.7%)	1 (1.7%)	0 (0.0%)	0 (0.0%)		2 (3.3%)
102 - 102.9	0 (0.0%)	0 (0.0%)	1 (1.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (1.7%)
FEVER	0 (0.0%)	0 (0.0%)	1 (1.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (1.7%)
TEMPERATURE TAKEN	60 (95.2%)	59 (93.7%)	59 (93.7%)	60 (95.2%)	2 (3.2%)	2 (3.2%)		60 (95.2%)
TEMPERATURE NOT TAKEN	3 (4.8%)	4 (6.3%)	4 (6.3%)	3 (4.8%)	61 (96.8%)	61 (96.8%)		3 (4.8%)

TABLE 8 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : KIM, KWANG S.
STUDY : 000701
VACCINE : HIB-IMUNE
AGE RANGE : 18-60 MOS.

MAX TEMPERATURE (DEG F, ORAL)	NUMBER OF VACCINEES (48 VACCINEES) - INJECTION 1							NUMBER WITH MAX TEMP
	DAYS POST VACCINATION							
	0	1	2	3	4	5		
NORMAL	16 (34.0%)	16 (34.0%)	17 (36.2%)	15 (31.9%)	0 (0.0%)	0 (0.0%)		12 (25.5%)
< 99	14 (29.8%)	19 (40.4%)	18 (38.3%)	24 (51.1%)	1 (100.0%)	0 (0.0%)		13 (27.7%)
99 - 99.9	8 (17.0%)	7 (14.9%)	6 (12.8%)	4 (8.5%)	0 (0.0%)	0 (0.0%)		9 (19.1%)
100 - 100.9	4 (8.5%)	2 (4.3%)	5 (10.6%)	2 (4.3%)	0 (0.0%)	0 (0.0%)		4 (8.5%)
101 - 101.9	3 (6.4%)	2 (4.3%)	0 (0.0%)	1 (2.1%)	0 (0.0%)	0 (0.0%)		5 (10.6%)
102 - 102.9	1 (2.1%)	0 (0.0%)	0 (0.0%)	1 (2.1%)	0 (0.0%)	0 (0.0%)		1 (2.1%)
103 - 103.9	0 (0.0%)	0 (0.0%)	1 (2.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (2.1%)
FEVER	1 (2.1%)	1 (2.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (4.3%)
TEMPERATURE TAKEN	47 (97.9%)	47 (97.9%)	47 (97.9%)	47 (97.9%)	1 (2.1%)	0 (0.0%)		47 (97.9%)
TEMPERATURE NOT TAKEN	1 (2.1%)	1 (2.1%)	1 (2.1%)	1 (2.1%)	47 (97.9%)	48 (100.0%)		1 (2.1%)

TABLE 8 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : KIM, KWANG S.
STUDY : 000701
VACCINE : HIB-VAX
AGE RANGE : 18-60 MOS.

MAX TEMPERATURE (DEG F, ORAL)	NUMBER OF VACCINEES (51 VACCINEES) - INJECTION 1							NUMBER WITH MAX TEMP
	DAYS POST VACCINATION							
	0	1	2	3	4	5		
NORMAL	21 (44.7%)	22 (44.0%)	22 (44.0%)	22 (44.0%)	0 (0.0%)	0 (0.0%)		21 (42.0%)
< 99	19 (40.4%)	22 (44.0%)	24 (48.0%)	24 (48.0%)	3 (100.0%)	0 (0.0%)		19 (38.0%)
99 - 99.9	2 (4.3%)	4 (8.0%)	3 (6.0%)	2 (4.0%)	0 (0.0%)	0 (0.0%)		4 (8.0%)
100 - 100.9	4 (8.5%)	2 (4.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		3 (6.0%)
101 - 101.9	1 (2.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (2.0%)
102 - 102.9	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.0%)	0 (0.0%)	0 (0.0%)		1 (2.0%)
103 - 103.9	0 (0.0%)	0 (0.0%)	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		0 (0.0%)
105 - 105.9	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.0%)	0 (0.0%)	0 (0.0%)		1 (2.0%)
TEMPERATURE TAKEN	47 (92.2%)	50 (98.0%)	50 (98.0%)	50 (98.0%)	3 (5.9%)	0 (0.0%)		50 (98.0%)
TEMPERATURE NOT TAKEN	4 (7.8%)	1 (2.0%)	1 (2.0%)	1 (2.0%)	48 (94.1%)	51 (100.0%)		1 (2.0%)

Twenty-eighth Interscience Conference
Antimicrobial Agents and Chemotherapy
23-26 October 1988 Los Angeles, CA

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A Comparative Study of the Safety, Tolerance and Immunogenicity of 3 Licensed *Haemophilus influenzae* Type B Capsular Polysaccharide (Hib-PRP) Vaccines in Children.

V.K.WONG*, R. ADLER, E.A. STEINBERG, and K.S.KIM. Childrens Hospital of Los Angeles, USC Schl of Med, and Kaiser Found. Hosp. Los Angeles, L.A. CA.

The efficacy of Hib-PRP vaccines in the United States has been shown to be unpredictable. We undertook a prospective randomized study to evaluate the safety, tolerance and immunogenicity of the Lederle(n=46), Connaught (n=46)and Praxis(n=55) Hib-PRP vaccines in children 18-24 mos(n=14) and 24-58 mos(n=133) of age. Total serum anti-PRP antibody (Ab) levels were measured by RIA before and 1 month following vaccination(vac). Mild systemic or local reactions were observed in 24% of the vac recipients with all 3 vaccines being tolerated equally well. Pre- and post-vac anti-PRP Ab ranged from <0.125-66.4 µg/ml and <0.125-265 µg/ml, respectively. Overall, 58% of the children had post-vac anti-PRP Ab≥1.0 µg/ml. There was no significant difference in Ab response by age or vaccine group. However, patients with pre-vac Ab ≥0.15 µg/ml were more likely to have post-vac Ab ≥1.0 µg/ml (75% vs 33% for those with pre-vac Ab <0.15 µg/ml, p<0.0001). Hib-PRP vac in children in the Los Angeles area was well tolerated but only half of the patients had anti-PRP Ab >1.0 µg/ml after vac. The low rate of Ab response especially in children with pre-vac anti-PRP Ab <0.15 µg/ml was apparent in all 3 of the vaccines studied. Alternative methods to prevent invasive Hib disease in children is warranted.

STUDY 822

Haemophilus b Conjugate Vaccine
(Neisseria meningitidis Outer Membrane Protein Complex)

CLINICAL STUDIES WITH EARLY LOTS

Study 001-01 (822) - Philadelphia, PA - Dr. R. Weibel

Healthy children 2-71 months of age and healthy adults were entered in this study. Six adults received one 20 mcg dose of vaccine (Lot 984/C-K731) reconstituted in saline. Three of these 6 (50%) had antibody titers >1.0 mcg/ml prior to vaccination. The prevaccination GMT was 1.975 mcg/ml. One month following vaccination 100% (6/6) had antibody levels >1.0 mcg/ml. The GMT for all vaccinees at that time was 27.176 mcg/ml.

Eight children 12-71 months of age received a single 10 mcg (n=5) or 20 mcg (n=3) dose of vaccine (Lot 984/C-K731) reconstituted in saline. Antibody levels were measured in 7 of the 8 vaccinees and the data were combined for both doses due to the small number of vaccinees. One of seven (14%) had an antibody titer >1.0 mcg/ml prior to vaccination. The GMT was 0.172 mcg/ml. One month following vaccination 71% (5/7) had antibody titers >1.0 mcg/ml. The GMT for these 7 vaccinees at that time was 4.712 mcg/ml.

Thirteen children 2-11 months of age received either one 10 mcg dose (n=7) or two 10 mcg doses (n=6) of vaccine (Lot 984/C-K731) reconstituted in saline at 0, 2 or 3 months. The data were combined due to the small number of vaccinees. The prevaccination GMT was 0.073 mcg/ml. One month following the first dose 38% (5/13) had antibody levels >1.0 mcg/ml. One to two months following the second dose 100% (5/5) had antibody levels >1 mcg/ml. The GMT was 0.722 mcg/ml at one month following the first dose and 6.114 mcg/ml one to two months following the second dose.

Ten children 2-6 months of age received two 6 mcg (n=7) or 10 mcg (n=3) doses of vaccine (Lot 1002/C-L466) reconstituted in saline at 0 and 2 weeks. The data for both dosage regimens were combined due to the small number of vaccinees. An additional child received only one 6 mcg dose. Thirteen percent (1/8) had an antibody titer >1.0 mcg/ml prior to vaccination. The GMT was 0.225 mcg/ml. Six weeks after the second injection 38% (3/8) had antibody >1.0 mcg/ml. The GMT at six weeks was 0.586 mcg/ml for these 8 vaccinees.

No serious adverse experiences were reported in this study.

Study 002-70 (870) - Huntington WV - Dr. E. Anderson

Healthy children 2-6 months of age were entered in this study and received two injections of vaccine at 0 and 1 month. Fourteen children received two 10 mcg doses of vaccine (Lot 1002/C-L466) reconstituted in saline. One additional child received only one dose. The prevaccination GMT was 0.105 mcg/ml. One month after the second injection, 92% (12/13) had developed antibody titers >1.0 mcg/ml. The GMT for the 13 vaccinees at that time was 2.284 mcg/ml. Another group of 12 children received two 13 mcg doses of vaccine (Lot 1018/C-M679) reconstituted in alum. Two additional children received only one dose. Two children had antibody titers >1.0 mcg/ml prior to vaccination. The GMT was 0.214 mcg/ml. One month after the second injection 42% (5/12) had antibody >1.0 mcg/ml. The GMT for the 12 vaccinees at that time was 0.903 mcg/ml.

No serious adverse experiences were reported in this study.

Study 003-73 (873) - St. Louis, MO - Dr. D. Granoff

Healthy children 2-17 months of age and healthy adults were entered in this study. Six adults received one 7 mcg dose of vaccine (Lot 1003/C-L680) reconstituted in alum. Four of these 6 (67%) had antibody titers >1.0 mcg/ml prior to vaccination. The GMT was 0.915 mcg/ml. One month following vaccination 100% (6/6) had antibody levels >1.0 mcg/ml. The GMT for all vaccinees at that time was 44.240 mcg/ml.

Eight children 2-11 months of age and 3 children 12-17 months of age received two 7 mcg doses of vaccine (Lot 1003/C-L680) reconstituted in saline one month apart. Two additional children (2-11 months) received only one dose. The prevaccination GMT was 0.207 mcg/ml for the 2-11 month age group and 0.063 mcg/ml for the 12-17 month age group. One month after the first dose 29% (2/7) of the 2-11 month age group and 100% (2/2) of the 12-17 month age group had developed antibody titers >1.0 mcg/ml. One month after the second injection, 71% (5/7) of the 2-11 month age group had antibody titers >1.0 mcg/ml. The GMT was 1.018 mcg/ml after one dose and 1.594 mcg/ml after two doses for the 2-11 month age group and 13.920 mcg/ml for the 12-17 month age group. Three children received a booster dose at one year of Lot 1018/C-M679 (6 mcg) as a third dose. Six children received a booster dose of polysaccharide vaccine (25 mcg) at one year as a third injection, while 2 children received a booster dose of polysaccharide vaccine at one year as a second dose. All children showed a greater than 2-fold rise in antibody titer following the booster dose.

Twenty-nine children 2-11 months of age and 10 children 12-17 months of age received one 7 mcg dose of vaccine (Lot 1003/C-L680) reconstituted in alum. Twenty-four children (2-11 months) and 2 children (12-17 months) received a second dose one month later. The prevaccination GMT was 0.104 mcg/ml for the 2-11 month age group and 0.102 mcg/ml for the 12-17 month age group. After one dose 44% (12/27) of the 2-11 month age group and 89% (8/9) of the 12-17 month age group had antibody titers >1.0 mcg/ml. After two doses 63% (15/24) of the 2-11 month old children had developed titers of >1.0 mcg/ml. The GMT was 0.866 mcg/ml after one dose and 1.272 mcg/ml after two doses for the 2-11 month age group and 3.092 mcg/ml at one month for the 12-17 month age group. Six children received a booster dose at one year of Lot 1018/C-M679 (6 mcg) as a third dose. One additional child received a dose of this same lot as a second dose at one year. Seventeen children received a booster dose of polysaccharide vaccine (25 mcg) at one year as a third dose. Five children received a booster dose of polysaccharide vaccine (25 mcg) at one year as a second dose. All children showed a greater than 2-fold rise in antibody titer following the booster dose.

Twenty-five children 2-6 months of age received two 13 mcg doses of vaccine (Lot 1018/C-M679) reconstituted in alum one month apart. Three additional children received only the first dose. The prevaccination GMT was 0.102 mcg/ml. After one dose and two doses, respectively, 38% (5/13) and 50% (6/12) had antibody titers >1.0 mcg/ml. The GMT was 0.778 mcg/ml after one dose and 1.216 mcg/ml after 2 doses. Twenty-six children received two 13 mcg doses of vaccine (Lot 1018/C-M679) reconstituted in alum two months apart. The prevaccination GMT was 0.088 mcg/ml. Antibody titers of >1.0 mcg/ml were developed by 43% (9/21) and 87% (20/23) after the first and second doses, respectively. The GMT was 1.001 mcg/ml after the first dose and 3.550 mcg/ml after the second dose.

Fifty-three black children were entered into the study to receive a 6 mcg dose of vaccine (Lot 1018/ C-M679) followed by polysaccharide vaccine (25 mcg) as a booster dose 6 months to 1 year later. However, only 32 children completed the two dose regimen. Sixteen children 2-11 months of age and 16 children 12-17 months of age received both doses. Prior to the booster dose 29% (2/7) of the 2-11 month age group and 57% (4/7) of the 12-17 month age group had antibody titers >1.0 mcg/ml. The prebooster GMT was 0.858 mcg/ml for the 2-11 month age group and 1.671 mcg/ml for the 12-17 month age group. Following the booster dose 100% in both age groups (14/14) had antibody titers >1.0 mcg/ml. The GMT was 117.9 mcg/ml for the 2-11 month age group and 147.9 mcg/ml for the 12-17 month age group following the booster dose.

An additional three children 2-11 months of age received a single 18 mcg dose of vaccine (Lot 1018/ C-M679) reconstituted in alum. Serology data are not available for these vaccinees.

Serious adverse experiences were reported for three patients. Three days postvaccination, a 7 month old child developed fever and rash, presumed to be due to a viral syndrome. The investigator felt that these experiences were unrelated to use of the vaccine. One child experienced excessive crying which the investigator felt was related to use of the vaccine. A third child who received vaccine reconstituted in saline experienced leg swelling, erythema, fever, anorexia and lethargy. The investigator felt these experiences were probably related to use of the vaccine.

Program: Haemophilus b Conjugate Vaccine (Neisseria meningitidis Outer Membrane Protein Complex), Study #822

Purpose: To evaluate antibody and clinical responses among healthy adults and children, 2 months to 5 years of age, to Haemophilus influenzae type b capsular polysaccharide or conjugate vaccine.

Vaccine: Haemophilus influenzae type b capsular polysaccharide vaccine
Lot 956/C-K074 - (b) (4) mcg capsular polysaccharide/ml

Haemophilus b Conjugate Vaccine (Neisseria meningitidis Outer Membrane Protein Complex)
Lot 941/C-J767* - (b) (4) mcg capsular polysaccharide/ml
(b) (4) mcg meningococcal protein/ml

Haemophilus b Conjugate Vaccine (Neisseria meningitidis Outer Membrane Protein Complex)
Lot 984/C-K731 - (b) (4) mcg capsular polysaccharide/ml
(b) (4) mcg meningococcal protein/ml
Lot 1002/C-L466 - (b) (4) mcg capsular polysaccharide/ml
(b) (4) mcg meningococcal protein/ml

Diluent

Saline diluent
Lot (b) (4)

Investigator: Robert Weibel, M.D.
Director, Division of Preventive Medicine
Joseph Stokes, Jr. Research Institute
Children's Hospital of Philadelphia
34th Street and Civic Center Boulevard
Philadelphia, PA 19104

Sub-Investigator: Alfred J. Carlson, Jr., M.D.
420 Township Line Road
Havertown, PA 19083

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* Conjugate vaccine prepared by a different process and (b) (4) exhibited by the subsequent lots.

Study Location: Pediatric Medical Associates
420 Township Line Road
Havertown, PA 19083

The Office of
George A. Starkweather, M.D.
1001 Pennsylvania Avenue
Havertown, PA 19083

Date Study Started: March 1, 1984

Date Study Completed: February 7, 1985

Study Population: A total of 61 healthy adults and children (31 males and 30 females) were included in the study.

Vaccinees receiving Lot 956/C-K074 or Lot 941/C-J767 are excluded from this summary. Lot 956/C-K074 is a polysaccharide vaccine and Lot 941/C-J767 is a conjugate vaccine prepared by a different process and (b) (4) exhibited in the subsequent lots of vaccine.

Study Procedure: Adults received a single 0.5 ml (20 mcg polysaccharide) subcutaneous injection of Lot 984/C-K731 reconstituted in saline.

Children 12 months to 5 years of age received a single 0.5 ml (10 or 20 mcg polysaccharide) subcutaneous injection of Lot 984/C-K731 reconstituted in saline. Infants 2 to 11 months of age received a single 0.5 ml (10 mcg polysaccharide) subcutaneous injection of Lot 984/C-K731 reconstituted in saline. Those children who did not respond to a single injection of Lot 984/C-K731 with antibody levels of >1.0 mcg Ab/ml by radioimmunoassay, received a second dose of Lot 984/C-K731 approximately 2 to 3 months later.

Infants 2 to 6 months of age, received two 0.3 ml (6 mcg polysaccharide) or two 0.5 ml (10 mcg polysaccharide) subcutaneous injections of Lot 1002/C-L466 reconstituted in saline.

Infants 2 to 6 months of age, received two 0.3 ml (6 mcg polysaccharide) or two 0.5 ml (10 mcg polysaccharide) subcutaneous injections of Lot 1002/C-L466 reconstituted in saline.

The parent, guardian or vaccine recipient was asked to record vaccinee's temperature and any systemic injection site reactions for 10 days after each injection of vaccine. Unexpected or serious reactions were to be reported immediately to the study physician.

A blood sample was obtained immediately before and 1 month after each vaccination. Children receiving Lot 1002/C-L466 were bled prior to the first vaccination and 1 month after the second vaccination only.

All serum samples were assayed for antibody to H. influenzae type b capsular polysaccharide by radioimmunoassay (RIA) and serum bactericidal assay (SBA).

Results:

Demographic information and individual pre and postvaccination antibody data for each vaccine enrolled in the study are reported in Table 1.

1. Number Vaccinated:

Lot	Age	Injection No. 1	Injection No. 2
984/C-K731	2-11 Mo.	13	6
	12-71 Mo.	8	2
	Adults	6	-
1002/C-L466	2-11 Mo.	11	10

2. Serologic Results:

Antibody responses (RIA) prior to and after vaccination are as follows:

Lot	Age	Dose (mcg)	Time	% With Anti-PRP >.15 mcg Ab/ml	% With Anti-PRP >1.0 mcg Ab/ml	GMT (mcg Ab/ml) All Vaccinees
984/C-K731	2-11 Mo.	10	Pre	15 (2/13)	0 (0/13)	0.07
			1 Mo.	85 (11/13)	38 (5/13)	0.72
	12-71 Mo.	10	Pre	43 (3/7)	14 (1/7)	0.17
		or	1 Mo.	86 (6/7)	71 (5/7)	>4.71
		20				
	Adults	20	Pre	100 (6/6)	50 (3/6)	1.98
			1 Mo.	100 (6/6)	100 (6/6)	>27.18
1002/C-L466	2-6 Mo.	6	Pre	63 (5/8)	13 (1/8)	0.23
		or	6 Wks.	100 (8/8)	38 (3/8)	0.59
		10				

Antibody responses (by lot per age group) prior to vaccination through 4 months postvaccination are included in Tables 2-5.

3. Clinical Results:

The frequencies of reactions during the 10 days following vaccination are as follows:

Type of Reaction	Lot	Dose	Age	% Frequency
Injection Site	984/C-K731	10 mcg	2-11 Mo.	85 (11/13)
		10 or 20 mcg	12-71 Mo.	100 (8/8)
		20 mcg	Adults	67 (4/6)
	1002/C-L466	6 or 10 mcg	2-6 Mo.	90 (9/10)
Systemic	984/C-K731	10 mcg	2-11 Mo.	54 (7/13)
		10 or 20 mcg	12-71 Mo.	50 (4/8)
		20 mcg	Adults	50 (3/6)
	1002/C-L466	6 or 10 mcg	2-6 Mo.	80 (8/10)

Reaction frequencies and maximum temperatures recorded during the 10 days following each injection of vaccination are reported in Tables 6-8.

No serious or alarming reactions attributable to the vaccine were reported.

TABLE 1

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : HEIBEL, ROBERT E.
STUDY : 082201
VACCINE : HIB CONJUGATE - SALINE
REGIMEN : 01
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE GROUP	DAY	DATE	PHASSQ	EVENT	LOT	DOSE	CODE	RIA	SBA
(b) (6)	F		(b) (6)	5Y 03	0	(b) (6)	001	PREBLEED				< 125	< 2
					0		011	INJ 1	CK731	20 MCG			
					26		011	BLEED 1				>= 160000	>= 4096
	M			5Y 03	0		001	PREBLEED				1876	256
					0		011	INJ 1	CK731	20 MCG			
					26		011	BLEED 1				>= 42794	2048
	F			5Y 03	0		001	PREBLEED				370	32
					0		011	INJ 1	CK731	20 MCG			
					35		011	BLEED 1				21446	>= 4096
	F			22M 03	0		001	PREBLEED				< 125	< 2
					0		011	INJ 1	CK731	10 MCG			
					28		011	BLEED 1				>= 11217	512
	M			19M 03	0		001	PREBLEED				150	< 2
					0		011	INJ 1	CK731	10 MCG			
					28		011	BLEED 1				2544	256
	M			13M 06	0		001	PREBLEED				235	< 2
					0		011	INJ 1	CK731	10 MCG			
					76		011	BLEED 1				779	64
					98		021	INJ 2	CK731	10 MCG			
					126		021	BLEED 2				>= 80000	
	F			14M 06	0		001	PREBLEED				< 100	< 2
					0		011	INJ 1	CK731	10 MCG			
					35		011	BLEED 1				< 100	< 2
					105		021	INJ 2	CK731	10 MCG			
					140		021	BLEED 2				1003	16
	M			15M 06	0		001	PREBLEED				176	< 2
					0		011	INJ 1	CK731	10 MCG			
					35		011	BLEED 1				197	512

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : HEIBEL, ROBERT E.
STUDY : 082201
VACCINE : HIB CONJUGATE - SALINE
REGIMEN : 01
PATIENT CLASS: HEALTHY ADULTS

CASE	SEX	RACE	BIRTH	AGE GROUP	DAY	DATE	PHASSQ	EVENT	LOT	DOSE	CODE	RIA	SBA
(b) (6)	M		(b) (6)	54Y 10	0	(b) (6)	001	PREBLEED				3822	16
					0		011	INJ 1	CK731	20 MCG			
					28		011	BLEED 1				34636	1024
	F			35Y 10	0		001	PREBLEED				304	128
					0		011	INJ 1	CK731	20 MCG			
					28		011	BLEED 1				35032	2048
	F			43Y 10	0		001	PREBLEED				316	32
					0		011	INJ 1	CK731	20 MCG			
					28		011	BLEED 1				1153	128
	M			60Y 10	0		001	PREBLEED				659	32
					0		011	INJ 1	CK731	20 MCG			
					31		011	BLEED 1				11247	2048
	F			21Y 10	0		001	PREBLEED				20924	128
					0		011	INJ 1	CK731	20 MCG			
					27		011	BLEED 1				>= 160000	256
	M			60Y 10	0		001	PREBLEED				11710	128
					0		011	INJ 1	CK731	20 MCG			
					27		011	BLEED 1				>= 160000	1024

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : HEIBEL, ROBERT E.
STUDY : 082201
VACCINE : HIB CONJUGATE - SALINE
REGIMEN : 02
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE GROUP	DAY	DATE	PHASSQ	EVENT	LOT	DOSE	CODE	RIA	SBA
(b) (6)	F		(b) (6)	3M 07	0	(b) (6)	001	PREBLEED				119	< 2
					0		011	INJ 1	CK731	10 MCG			
					29		011	BLEED 1				183	< 2
					57		021	INJ 2	CK731	10 MCG			
					86		021	BLEED 2				4135	32
	F			8M 06	0		001	PREBLEED				< 100	< 2
					0		011	INJ 1	CK731	10 MCG			
					29		011	BLEED 1				986	32
					57		021	INJ 2	CK731	10 MCG			
					107		021	BLEED 2				8278	16
	F			6M 07	0		001	PREBLEED				< 100	< 2
					0		011	INJ 1	CK731	10 MCG			
					30		011	BLEED 1				309	< 2
					57		021	INJ 2	CK731	10 MCG			
					154		021	BLEED 2				3090	4

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : HEIBEL, ROBERT E.
STUDY : 082201
VACCINE : HIB CONJUGATE - SALINE
REGIMEN : 04
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE GROUP	DAY	DATE	PHASSQ	EVENT	LOT	DOSE	CODE	RIA	SBA
(b) (6)	F		(b) (6)	9M 06	0	(b) (6)	001	PREBLEED				< 125	< 2
					0		011	INJ 1	CK731	10 MCG			
					28		011	BLEED 1				1908	128
	M			11M 06	0		001	PREBLEED				151	< 2
					0		011	INJ 1	CK731	10 MCG			
					28		011	BLEED 1				7599	256
	M			9M 06	0		001	PREBLEED				< 100	< 2
					0		011	INJ 1	CK731	10 MCG			
					28		011	BLEED 1				7917	512
	M			9M 06	0		001	PREBLEED			01	< 100	
					0		011	INJ 1	CK731	10 MCG			
					28		011	BLEED 1				1006	8
	F			6M 07	0		001	PREBLEED				< 100	< 2
					0		011	INJ 1	CK731	10 MCG			
					29		011	BLEED 1				906	32
	F			10M 06	0		001	PREBLEED				182	< 2
					0		011	INJ 1	CK731	10 MCG			
					29		011	BLEED 1				2019	128
	M			3M 07	0		001	PREBLEED				< 100	< 2
					0		011	INJ 1	CK731	10 MCG			
					37		011	BLEED 1				176	< 2

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : HEIBEL, ROBERT E.
STUDY : 082201
VACCINE : HIB CONJUGATE - SALINE
REGIMEN : 05
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE GROUP	DAY	DATE	PHASSQ	EVENT	LOT	DOSE	CODE	RIA	SBA
(b) (6)	M		(b) (6)	4M 08	0	(b) (6)	001	PREBLEED				< 125	< 2
					0		011	INJ 1	CL466	6 MCG			
					14		021	INJ 2	CL466	6 MCG			
					42		021	BLEED 1				1004	4
	F			2M 08	0		001	PREBLEED				917	< 2
					0		011	INJ 1	CL466	6 MCG			
					19		021	INJ 2	CL466	6 MCG			
					42		021	BLEED 1				501	< 2
	F			5M 08	0		011	INJ 1	CL466	6 MCG			
	F			3M 08	0		001	PREBLEED				220	< 2
					0		011	INJ 1	CL466	6 MCG			
					14		021	INJ 2	CL466	6 MCG			
					42		021	BLEED 1				210	< 2
	M			3M 08	0		001	PREBLEED				< 125	< 2
					0		011	INJ 1	CL466	6 MCG			
					14		021	INJ 2	CL466	6 MCG			
					42		021	BLEED 1				1215	2
	F			2M 08	0		001	PREBLEED				140	< 2
					0		011	INJ 1	CL466	6 MCG			
					14		021	INJ 2	CL466	6 MCG			
					42		021	BLEED 1				289	8
	M			4M 08	0		001	PREBLEED				275	< 2
					0		011	INJ 1	CL466	6 MCG			
					15		021	INJ 2	CL466	6 MCG			
					42		021	BLEED 1				5355	64
	F			3M 08	0		001	PREBLEED			01	179	< 2
					0		011	INJ 1	CL466	6 MCG			
					14		021	INJ 2	CL466	6 MCG			
					60		021	BLEED 1				193	8
	M			5M 09	0		001	PREBLEED				< 125	< 2
					0		011	INJ 1	CL466	10 MCG			
					14		021	INJ 2	CL466	10 MCG			

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : HEIBEL, ROBERT E.
STUDY : 082201
VACCINE : HIB CONJUGATE - SALINE
REGIMEN : 05
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE GROUP	DAY	DATE	PHASSQ	EVENT	LOT	DOSE	CODE	RIA	SBA
(b) (6)	M		(b) (6)	5M 09	84	(b) (6)	021	BLEED 1				3742	32
	F			4M 09	0		001	PREBLEED				1199	< 2
					0		011	INJ 1	CL466	10 MCG			
					14		021	INJ 2	CL466	10 MCG			
					57		021	BLEED 1				361	< 2
	M			3M 09	0		001	PREBLEED				< 125	< 2
					0		011	INJ 1	CL466	10 MCG			
					14		021	INJ 2	CL466	10 MCG			
					84		021	BLEED 1				678	4

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : MEIBEL, ROBERT E.
STUDY : 082201
VACCINE : HIB CONJUGATE - SALINE
REGIMEN : 06
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE	GROUP	DAY	DATE	PHASSQ	EVENT	LOT	DOSE	CODE	RIA	SBA
(b) (6)	M		(b) (6)	7M	07	0	(b) (6)	001	PREBLEED				< 100	< 2
						0		011	INJ 1	CK731	10	MCG		
						28		011	BLEED 1				889	
						84		021	INJ 2	CK731	10	MCG		
						112		021	BLEED 2				36337	128
	M			6M	07	0		001	PREBLEED				< 100	< 2
						0		011	INJ 1	CK731	10	MCG		
						30		011	BLEED 1				125	32
						86		021	INJ 2	CK731	10	MCG		
						120		021	BLEED 2				3391	64
	F			5M	07	0		001	PREBLEED				< 100	< 2
						0		011	INJ 1	CK731	10	MCG		
						29		011	BLEED 1				< 100	4
						86		021	INJ 2	CK731	10	MCG		
						114		021	BLEED 2				2026	64

TABLE 2

ANTIBODY RESPONSES
VACCINE CONTAINS 10 OR 20 MCG PRP

INVESTIGATOR : WEIBEL, ROBERT E.
STUDY : 082201
VACCINE : HIB CONJUGATE - SALINE
ASSAY : RIA
LOT NUMBER : CK731
POPULATION : HEALTHY CHILDREN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
12-71 MOS.	PRE INJ	43 (3/ 7)	14 (1/ 7)			0.172 (7)
	1 MONTH	86 (6/ 7)	71 (5/ 7)	71 (5/ 7)	> 22.5	> 4.712 (7)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE,
AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 3

ANTIBODY RESPONSES

INVESTIGATOR : WEIBEL, ROBERT E.
STUDY : 082201
VACCINE : HIB CONJUGATE - SALINE
ASSAY : RIA
LOT NUMBER : CK731
DOSE : 20 MCG
POPULATION : HEALTHY ADULTS

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
20 TO 5 YRS.	PRE INJ	100 (6/ 6)	50 (3/ 6)			1.975 (6)
	1 MONTH	100 (6/ 6)	100 (6/ 6)	100 (6/ 6)	> 13.8	> 27.176 (6)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 4

A N T I B O D Y R E S P O N S E S
ADMINISTERED AS ONE INJECTION OR TWO INJECTIONS
TWO TO THREE MONTHS APART

INVESTIGATOR : WEIBEL, ROBERT E.
STUDY : 082201
VACCINE : HIB CONJUGATE - SALINE
ASSAY : RIA
LOT NUMBER : CK731
DOSE : 10 MCG
POPULATION : HEALTHY CHILDREN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
2-11 MOS.	PRE INJ	15 (2/ 13)	0 (0/ 13)			0.073 (13)
	1 MONTH	85 (11/ 13)	38 (5/ 13)	69 (9/ 13)	5.8	0.722 (13)
	3/4 MONTH	100 (5/ 5)	100 (5/ 5)	100 (5/ 5)	48.9	6.114 (5)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 5

ANTIBODY RESPONSES
CONTAINING 6 OR 10 MCP PRP
ADMINISTERED AS TWO INJECTIONS TWO WEEKS APART

INVESTIGATOR : WEIBEL, ROBERT E.
STUDY : 082201
VACCINE : HIB CONJUGATE - SALINE
ASSAY : RIA
LOT NUMBER : CL466
POPULATION : HEALTHY CHILDREN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
2- 6 MOS.	PRE INJ	63 (5/ 8)	13 (1/ 8)			0.225 (8)
	6 WEEKS	100 (8/ 8)	38 (3/ 8)	50 (4/ 8)	2.2	0.586 (8)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 6 (cont.)

FREQUENCY OF CLINICAL COMPLAINTS FOLLOWING VACCINATION WITH HIB VACCINE
VACCINE CONTAINING 10 OR 20 MCG PRP

INVESTIGATOR : WEIBEL, ROBERT E.
STUDY : 082201
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CK731
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

	DOSE NUMBER: 1	
	TOTAL VACCINEES : 8 TOTAL VACCINEES PRESENTING DATA: 8	
CLINICAL COMPLAINTS	NUMBER OF VACCINEES	PERCENT
VOMITING	1	12.5
VACCINEES WITH COMPLAINTS:	8	100.0
VACCINEES WITH NO COMPLAINTS:	0	0.0
VACCINEES WITH NO DATA:	0	

TABLE 6 (cont.)

FREQUENCY OF CLINICAL COMPLAINTS FOLLOWING VACCINATION WITH HIB VACCINE
VACCINE CONTAINING 10 OR 20 MCG PRP

INVESTIGATOR : WEIBEL, ROBERT E.
STUDY : 082201
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CK731
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

DOSE NUMBER: 2

TOTAL VACCINEES : 2
TOTAL VACCINEES PRESENTING DATA: 2

CLINICAL COMPLAINTS	NUMBER OF VACCINEES	PERCENT
REACTION,LOCAL (INJECT SITE)	2	100.0
ERYTHEMA, INJECTION SITE	1	50.0
ERYTHEMA, INJECTION SITE (>1 INCH)	1	50.0
SWELLING, INJECTION SITE (>1 INCH)	1	50.0
SYSTEMIC	0	0.0
VACCINEES WITH COMPLAINTS:	2	100.0
VACCINEES WITH NO COMPLAINTS:	0	0.0
VACCINEES WITH NO DATA:	0	

TABLE 6 (cont.)

FREQUENCY OF CLINICAL COMPLAINTS FOLLOWING VACCINATION WITH HIB VACCINE

INVESTIGATOR : WEIBEL, ROBERT E.
STUDY : 082201
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CK731
DOSE : 20 MCG
PATIENT CLASS: HEALTHY ADULTS
AGE RANGE : 20-75 YRS.

	DOSE NUMBER: 1 TOTAL VACCINEES : 6 TOTAL VACCINEES PRESENTING DATA: 6	
CLINICAL COMPLAINTS	NUMBER OF VACCINEES	PERCENT
REACTION,LOCAL (INJECT SITE)	4	66.7
PAIN/SORENESS, INJECTION SITE	3	50.0
ECCHYMOSIS, INJECTION SITE	2	33.3
ERYTHEMA, INJECTION SITE	2	33.3
INDURATION, INJECTION SITE	2	33.3
ERYTHEMA, INJECTION SITE (>1 INCH)	1	16.7
INFLAMMATION, INJECTION SITE	1	16.7
SWELLING, INJECTION SITE	1	16.7
SYSTEMIC	3	50.0
DIARRHEA	2	33.3
CHILLS	1	16.7
COUGH	1	16.7
EYE PAIN	1	16.7
EYE SWELLING	1	16.7
FATIGUE	1	16.7
HEADACHE	1	16.7

TABLE 6 (cont.)

FREQUENCY OF CLINICAL COMPLAINTS FOLLOWING VACCINATION WITH HIB VACCINE

INVESTIGATOR : MEIBEL, ROBERT E.
STUDY : 082201
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CK731
DOSE : 20 MCG
PATIENT CLASS: HEALTHY ADULTS
AGE RANGE : 20-75 YRS.

	DOSE NUMBER: 1	
	TOTAL VACCINEES : 6 TOTAL VACCINEES PRESENTING DATA: 6	
CLINICAL COMPLAINTS	NUMBER OF VACCINEES	PERCENT
LYMPHADENITIS	1	16.7
MALAISE	1	16.7
VACCINEES WITH COMPLAINTS:	4	66.7
VACCINEES WITH NO COMPLAINTS:	2	33.3
VACCINEES WITH NO DATA:	0	

TABLE 6 (cont.)

FREQUENCY OF CLINICAL COMPLAINTS FOLLOWING VACCINATION WITH HIB VACCINE
ADMINISTERED AS ONE INJECTION OR TWO INJECTIONS
TWO TO THREE MONTHS APART

INVESTIGATOR : WEIBEL, ROBERT E.
STUDY : 082201
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CK731
DOSE : 10 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2-11 MOS.

	DOSE NUMBER: 1 TOTAL VACCINEES : 13 TOTAL VACCINEES PRESENTING DATA: 13	
CLINICAL COMPLAINTS	NUMBER OF VACCINEES	PERCENT
REACTION,LOCAL (INJECT SITE)	11	84.6
ERYTHEMA, INJECTION SITE	8	61.5
ECCHYMOSIS, INJECTION SITE	3	23.1
PAIN/SORENESS, INJECTION SITE	3	23.1
SWELLING, INJECTION SITE	3	23.1
INFLAMMATION, INJECTION SITE	1	7.7
SYSTEMIC	7	53.8
IRRITABILITY	7	53.8
ANOREXIA	1	7.7
ASTHENIA	1	7.7
CONJUNCTIVITIS	1	7.7
DIARRHEA	1	7.7
EAR INFECTION, NOS	1	7.7
ENDOPHTHALMITIS	1	7.7
EYE DISCHARGE	1	7.7

TABLE 6 (cont.)

FREQUENCY OF CLINICAL COMPLAINTS FOLLOWING VACCINATION WITH HIB VACCINE
ADMINISTERED AS ONE INJECTION OR TWO INJECTIONS
TWO TO THREE MONTHS APART

INVESTIGATOR : HEIBEL, ROBERT E.
STUDY : 082201
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CK731
DOSE : 10 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2-11 MOS.

	DOSE NUMBER: 1 TOTAL VACCINEES : 13 TOTAL VACCINEES PRESENTING DATA: 13	
CLINICAL COMPLAINTS	NUMBER OF VACCINEES	PERCENT
FATIGUE	1	7.7
HYPERSOMNIA	1	7.7
NASAL CONGESTION	1	7.7
NASAL DISCHARGE	1	7.7
POLYDIPSIA	1	7.7
SKIN INFLAMMATION	1	7.7
VACCINEES WITH COMPLAINTS:	13	100.0
VACCINEES WITH NO COMPLAINTS:	0	0.0
VACCINEES WITH NO DATA:	0	

TABLE 6 (cont.)

FREQUENCY OF CLINICAL COMPLAINTS FOLLOWING VACCINATION WITH HIB VACCINE
ADMINISTERED AS ONE INJECTION OR TWO INJECTIONS
TWO TO THREE MONTHS APART

INVESTIGATOR : HEIBEL, ROBERT E.
STUDY : 082201
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CK731
DOSE : 10 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2-11 MOS.

	DOSE NUMBER: 2 TOTAL VACCINEES : 6 TOTAL VACCINEES PRESENTING DATA: 6	
CLINICAL COMPLAINTS	NUMBER OF VACCINEES	PERCENT
REACTION,LOCAL (INJECT SITE)	4	66.7
PAIN/SORENESS, INJECTION SITE	3	50.0
ERYTHEMA, INJECTION SITE	1	16.7
ERYTHEMA, INJECTION SITE (1 INCH, LESS THAN)	1	16.7
SYSTEMIC	2	33.3
IRRITABILITY	2	33.3
HARM TO TOUCH	1	16.7
VACCINEES WITH COMPLAINTS:	4	66.7
VACCINEES WITH NO COMPLAINTS:	2	33.3
VACCINEES WITH NO DATA:	0	

TABLE 6 (cont.)

FREQUENCY OF CLINICAL COMPLAINTS FOLLOWING VACCINATION WITH HIB VACCINE
CONTAINING 6 OR 10 MCG PRP
ADMINISTERED AS TWO INJECTIONS TWO WEEKS APART

INVESTIGATOR : WEIBEL, ROBERT E.
STUDY : 082201
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CL466
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2- 6 MOS.

DOSE NUMBER: 1

TOTAL VACCINEES : 11
TOTAL VACCINEES PRESENTING DATA: 10

CLINICAL COMPLAINTS	NUMBER OF VACCINEES	PERCENT
REACTION,LOCAL (INJECT SITE)	7	70.0
ERYTHEMA, INJECTION SITE	6	60.0
INDURATION, INJECTION SITE	4	40.0
PAIN/SORENESS, INJECTION SITE	4	40.0
ECCHYMOSIS, INJECTION SITE	2	20.0
SWELLING, INJECTION SITE	2	20.0
WARMTH, INJECTION SITE	2	20.0
SYSTEMIC	7	70.0
IRRITABILITY	7	70.0
COMMON COLD	1	10.0
CRYING, EXCESSIVE	1	10.0
INSOMNIA	1	10.0
OTITIS MEDIA	1	10.0
VACCINEES WITH COMPLAINTS:	9	90.0
VACCINEES WITH NO COMPLAINTS:	1	10.0
VACCINEES WITH NO DATA:	1	

TABLE 6 (cont.)

FREQUENCY OF CLINICAL COMPLAINTS FOLLOWING VACCINATION WITH HIB VACCINE
CONTAINING 6 OR 10 MCG PRP
ADMINISTERED AS TWO INJECTIONS TWO WEEKS APART

INVESTIGATOR : WEIBEL, ROBERT E.
STUDY : 082201
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CL466
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2- 6 MOS.

	DOSE NUMBER: 2 TOTAL VACCINEES : 10 TOTAL VACCINEES PRESENTING DATA: 10	
CLINICAL COMPLAINTS	NUMBER OF VACCINEES	PERCENT
REACTION,LOCAL (INJECT SITE)	5	50.0
INDURATION, INJECTION SITE	3	30.0
ECCHYMOSIS, INJECTION SITE	2	20.0
SWELLING, INJECTION SITE	2	20.0
ERYTHEMA, INJECTION SITE	1	10.0
INFLAMMATION, INJECTION SITE	1	10.0
PAIN/SORENESS, INJECTION SITE	1	10.0
SYSTEMIC	5	50.0
IRRITABILITY	5	50.0
NASAL DISCHARGE	3	30.0
OTITIS MEDIA	1	10.0
VACCINEES WITH COMPLAINTS:	5	50.0
VACCINEES WITH NO COMPLAINTS:	5	50.0
VACCINEES WITH NO DATA:	0	

TABLE 6

FREQUENCY OF CLINICAL COMPLAINTS FOLLOWING VACCINATION WITH HIB VACCINE
VACCINE CONTAINING 10 OR 20 MCG PRP

INVESTIGATOR : WEIBEL, ROBERT E.
STUDY : 082201
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CK731
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

DOSE NUMBER: 1

TOTAL VACCINEES : 8
TOTAL VACCINEES PRESENTING DATA: 8

CLINICAL COMPLAINTS	NUMBER OF VACCINEES	PERCENT
REACTION,LOCAL (INJECT SITE)	8	100.0
ERYTHEMA, INJECTION SITE	6	75.0
PAIN/SORENESS, INJECTION SITE	4	50.0
SWELLING, INJECTION SITE	2	25.0
INDURATION, INJECTION SITE	1	12.5
SYSTEMIC	4	50.0
ANOREXIA	1	12.5
APATHY	1	12.5
COUGH	1	12.5
DIARRHEA	1	12.5
INFECTIOUS GASTROENTERITIS	1	12.5
IRRITABILITY	1	12.5
NERVOUSNESS	1	12.5
OTALGIA	1	12.5
PHARYNGEAL PAIN	1	12.5
TONSILLITIS	1	12.5

TABLE 7

PATIENT COUNT CLINICAL COMPLAINTS
VACCINE CONTAINING 10 OR 20 MCG PRP

INVESTIGATOR : HEIBEL, ROBERT E.
STUDY : 082201
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CK731
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

CLINICAL COMPLAINTS	NUMBER OF VACCINEES (8 VACCINEES) - INJECTION 1						
	DAYS POST VACCINATION						
	0	1	2	3	4	5	6
LOCAL REACTIONS	7 (87.5%)	4 (50.0%)	1 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
ERYTHEMA, INJECTION SITE	4 (50.0%)	3 (37.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
INDURATION, INJECTION SITE	0 (0.0%)	1 (12.5%)	1 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
PAIN/SORENESS, INJECTION SITE	3 (37.5%)	3 (37.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
SWELLING, INJECTION SITE	1 (12.5%)	1 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
SYSTEMIC	3 (37.5%)	1 (12.5%)	1 (12.5%)	1 (12.5%)	1 (12.5%)	2 (25.0%)	2 (25.0%)
DIGESTIVE SYSTEM	1 (12.5%)	0 (0.0%)	1 (12.5%)	0 (0.0%)	0 (0.0%)	1 (12.5%)	1 (12.5%)
ANOREXIA	1 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
DIARRHEA	1 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
INFECTIOUS GASTROENTERITIS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (12.5%)	1 (12.5%)
VOMITING	0 (0.0%)	0 (0.0%)	1 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
NERVOUS SYSTEM & PSYCHIATRIC	3 (37.5%)	1 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

TABLE 7 (cont.)

PATIENT COUNT CLINICAL COMPLAINTS
VACCINE CONTAINING 10 OR 20 MCG PRP

INVESTIGATOR : HEIBEL, ROBERT E.
STUDY : 082201
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CK731
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

CLINICAL COMPLAINTS	NUMBER OF VACCINEES (8 VACCINEES) - INJECTION 1							NUMBER WITH COMPLAINTS
	DAYS POST VACCINATION							
	7	8	9	10				
LOCAL REACTIONS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				8 (100.0%)
ERYTHEMA, INJECTION SITE	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				6 (75.0%)
INDURATION, INJECTION SITE	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (12.5%)
PAIN/SORENESS, INJECTION SITE	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				4 (50.0%)
SWELLING, INJECTION SITE	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				2 (25.0%)
SYSTEMIC	2 (25.0%)	1 (12.5%)	1 (12.5%)	1 (12.5%)				4 (50.0%)
DIGESTIVE SYSTEM	1 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				3 (37.5%)
ANOREXIA	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (12.5%)
DIARRHEA	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (12.5%)
INFECTIOUS GASTROENTERITIS	1 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (12.5%)
VOMITING	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (12.5%)
NERVOUS SYSTEM & PSYCHIATRIC	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				3 (37.5%)

TABLE 7 (cont.)

PATIENT COUNT CLINICAL COMPLAINTS
VACCINE CONTAINING 10 OR 20 MCG PRP

INVESTIGATOR : HEIBEL, ROBERT E.
STUDY : 082201
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CK731
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

CLINICAL COMPLAINTS	NUMBER OF VACCINEES (8 VACCINEES) - INJECTION 1						
	DAYS POST VACCINATION						
	0	1	2	3	4	5	6
APATHY	1 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
IRRITABILITY	1 (12.5%)	1 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
NERVOUSNESS	1 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
RESPIRATORY SYSTEM	0 (0.0%)	0 (0.0%)	1 (12.5%)	1 (12.5%)	1 (12.5%)	1 (12.5%)	1 (12.5%)
COUGH	0 (0.0%)	0 (0.0%)	1 (12.5%)	1 (12.5%)	1 (12.5%)	1 (12.5%)	1 (12.5%)
PHARYNGEAL PAIN	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
TONSILLITIS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (12.5%)	1 (12.5%)	1 (12.5%)
SPECIAL SENSES	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
OTALGIA	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
VACCINEES WITH COMPLAINTS	7 (87.5%)	4 (50.0%)	2 (25.0%)	1 (12.5%)	1 (12.5%)	2 (25.0%)	2 (25.0%)
VACCINEES WITH NO COMPLAINTS	1 (12.5%)	4 (50.0%)	6 (75.0%)	7 (87.5%)	7 (87.5%)	6 (75.0%)	6 (75.0%)
TOTAL VACCINEES REPORTING	8	8	8	8	8	8	8

TABLE 7 (cont.)

PATIENT COUNT CLINICAL COMPLAINTS
VACCINE CONTAINING 10 OR 20 MCG PRP

INVESTIGATOR : HEIBEL, ROBERT E.
STUDY : 082201
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CK731
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

CLINICAL COMPLAINTS	NUMBER OF VACCINEES (8 VACCINEES) - INJECTION 1							NUMBER WITH COMPLAINTS
	DAYS POST VACCINATION							
	7	8	9	10				
APATHY	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (12.5%)
IRRITABILITY	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (12.5%)
NERVOUSNESS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (12.5%)
RESPIRATORY SYSTEM	1 (12.5%)	1 (12.5%)	1 (12.5%)	1 (12.5%)				1 (12.5%)
COUGH	1 (12.5%)	1 (12.5%)	1 (12.5%)	1 (12.5%)				1 (12.5%)
PHARYNGEAL PAIN	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (12.5%)
TONSILLITIS	1 (12.5%)	1 (12.5%)	1 (12.5%)	1 (12.5%)				1 (12.5%)
SPECIAL SENSES	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (12.5%)
OTALGIA	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (12.5%)
VACCINEES WITH COMPLAINTS	2 (25.0%)	1 (12.5%)	1 (12.5%)	1 (12.5%)				8 (100.0%)
VACCINEES WITH NO COMPLAINTS	6 (75.0%)	7 (87.5%)	7 (87.5%)	7 (87.5%)				0 (0.0%)
TOTAL VACCINEES REPORTING	8	8	8	8				8

TABLE 7 (cont.)

PATIENT COUNT CLINICAL COMPLAINTS
VACCINE CONTAINING 10 OR 20 MCG PRP

INVESTIGATOR : WEIBEL, ROBERT E.
STUDY : 082201
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CK731
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

	NUMBER OF VACCINEES (8 VACCINEES) - INJECTION 1						
	DAYS POST VACCINATION						
CLINICAL COMPLAINTS	0	1	2	3	4	5	6
VACCINEES WITH NO DATA	0	0	0	0	0	0	0

TABLE 7 (cont.)

PATIENT COUNT CLINICAL COMPLAINTS
VACCINE CONTAINING 10 OR 20 MCG PRP

INVESTIGATOR : MEIBEL, ROBERT E.
STUDY : 082201
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CK731
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

	NUMBER OF VACCINEES (0 VACCINEES) - INJECTION 1						
	DAYS POST VACCINATION						NUMBER
CLINICAL COMPLAINTS	7	8	9	10			WITH COMPLAINTS
VACCINEES WITH NO DATA	0	0	0	0			0

TABLE 7 (cont.)

PATIENT COUNT CLINICAL COMPLAINTS
VACCINE CONTAINING 10 OR 20 MCG PRP

INVESTIGATOR : MEIBEL, ROBERT E.
STUDY : 082201
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CK731
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

CLINICAL COMPLAINTS	NUMBER OF VACCINEES (2 VACCINEES) - INJECTION 2						
	DAYS POST VACCINATION						
	0	1	2	3	4	5	6
LOCAL REACTIONS	1 (50.0%)	2 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
ERYTHEMA, INJECTION SITE	0 (0.0%)	1 (50.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
ERYTHEMA, INJECTION SITE (>1 INCH	1 (50.0%)	1 (50.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
SWELLING, INJECTION SITE (>1 INCH	1 (50.0%)	1 (50.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
VACCINEES WITH COMPLAINTS	1 (50.0%)	2 (100.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
VACCINEES WITH NO COMPLAINTS	1 (50.0%)	0 (0.0%)	2 (100.0%)	2 (100.0%)	2 (100.0%)	2 (100.0%)	2 (100.0%)
TOTAL VACCINEES REPORTING	2	2	2	2	2	2	2
VACCINEES WITH NO DATA	0	0	0	0	0	0	0

TABLE 7 (cont.)

PATIENT COUNT CLINICAL COMPLAINTS
VACCINE CONTAINING 10 OR 20 MCG PRP

INVESTIGATOR : WEIBEL, ROBERT E.
STUDY : 082201
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CK731
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

CLINICAL COMPLAINTS	NUMBER OF VACCINEES (2 VACCINEES) - INJECTION 2							NUMBER WITH COMPLAINTS
	DAYS POST VACCINATION							
	7	8	9	10				
LOCAL REACTIONS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				2 (100.0%)
ERYTHEMA, INJECTION SITE	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (50.0%)
ERYTHEMA, INJECTION SITE (>1 INCH	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (50.0%)
SWELLING, INJECTION SITE (>1 INCH	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (50.0%)
VACCINEES WITH COMPLAINTS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				2 (100.0%)
VACCINEES WITH NO COMPLAINTS	2 (100.0%)	2 (100.0%)	2 (100.0%)	2 (100.0%)				0 (0.0%)
TOTAL VACCINEES REPORTING	2	2	2	2				2
VACCINEES WITH NO DATA	0	0	0	0				0

TABLE 7 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : WEIBEL, ROBERT E.
STUDY : 082201
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CK731
DOSE : 20 MCG
PATIENT CLASS: HEALTHY ADULTS
AGE RANGE : 20-75 YRS.

CLINICAL COMPLAINTS	NUMBER OF VACCINEES (6 VACCINEES) - INJECTION 1						
	DAYS POST VACCINATION						
	0	1	2	3	4	5	6
LOCAL REACTIONS	4 (66.7%)	4 (66.7%)	2 (33.3%)	2 (33.3%)	2 (33.3%)	1 (16.7%)	1 (16.7%)
ECCHYMOSIS, INJECTION SITE	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (33.3%)	0 (0.0%)	0 (0.0%)
ERYTHEMA, INJECTION SITE	2 (33.3%)	2 (33.3%)	2 (33.3%)	2 (33.3%)	1 (16.7%)	0 (0.0%)	1 (16.7%)
ERYTHEMA, INJECTION SITE (>1 INCH	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)	0 (0.0%)
INDURATION, INJECTION SITE	2 (33.3%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
INFLAMMATION, INJECTION SITE	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)	0 (0.0%)	0 (0.0%)
PAIN/SORENESS, INJECTION SITE	3 (50.0%)	2 (33.3%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
SWELLING, INJECTION SITE	1 (16.7%)	1 (16.7%)	1 (16.7%)	1 (16.7%)	1 (16.7%)	1 (16.7%)	1 (16.7%)
SYSTEMIC	3 (50.0%)	2 (33.3%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
BODY AS A WHOLE/SITE UNSPEC.	2 (33.3%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
CHILLS	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
FATIGUE	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

TABLE 7 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : HEIBEL, ROBERT E.
STUDY : 082201
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CK731
DOSE : 20 MCG
PATIENT CLASS: HEALTHY ADULTS
AGE RANGE : 20-75 YRS.

CLINICAL COMPLAINTS	NUMBER OF VACCINEES (6 VACCINEES) - INJECTION 1 DAYS POST VACCINATION 7	8	9	10				NUMBER WITH COMPLAINTS
LOCAL REACTIONS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				4 (66.7%)
ECCHYMOSIS, INJECTION SITE	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				2 (33.3%)
ERYTHEMA, INJECTION SITE	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				2 (33.3%)
ERYTHEMA, INJECTION SITE (>1 INCH	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (16.7%)
INDURATION, INJECTION SITE	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				2 (33.3%)
INFLAMMATION, INJECTION SITE	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (16.7%)
PAIN/SORENESS, INJECTION SITE	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				3 (50.0%)
SWELLING, INJECTION SITE	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (16.7%)
SYSTEMIC	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				3 (50.0%)
BODY AS A WHOLE/SITE UNSPEC.	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				2 (33.3%)
CHILLS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (16.7%)
FATIGUE	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (16.7%)

TABLE 7 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : NEIBEL, ROBERT E.
STUDY : 082201
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CK731
DOSE : 20 MCG
PATIENT CLASS: HEALTHY ADULTS
AGE RANGE : 20-75 YRS.

CLINICAL COMPLAINTS	NUMBER OF VACCINEES (6 VACCINEES) - INJECTION 1						
	DAYS POST VACCINATION						
	0	1	2	3	4	5	6
MALAISE	0 (0.0%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
DIGESTIVE SYSTEM	2 (33.3%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
DIARRHEA	2 (33.3%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
HEMIC & LYMPHATIC SYSTEM	1 (16.7%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
LYMPHADENITIS	1 (16.7%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
NERVOUS SYSTEM & PSYCHIATRIC	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
HEADACHE	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
RESPIRATORY SYSTEM	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
COUGH	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
SPECIAL SENSES	0 (0.0%)	1 (16.7%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
EYE PAIN	0 (0.0%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
EYE SHELLING	0 (0.0%)	0 (0.0%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

TABLE 7 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : MEIBEL, ROBERT E.
STUDY : 082201
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CK731
DOSE : 20 MCG
PATIENT CLASS: HEALTHY ADULTS
AGE RANGE : 20-75 YRS.

CLINICAL COMPLAINTS	NUMBER OF VACCINEES (6 VACCINEES) - INJECTION 1							NUMBER WITH COMPLAINTS
	DAYS POST VACCINATION							
	7	8	9	10				
MALAISE	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (16.7%)
DIGESTIVE SYSTEM	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				2 (33.3%)
DIARRHEA	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				2 (33.3%)
HEMIC & LYMPHATIC SYSTEM	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (16.7%)
LYMPHADENITIS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (16.7%)
NERVOUS SYSTEM & PSYCHIATRIC	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (16.7%)
HEADACHE	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (16.7%)
RESPIRATORY SYSTEM	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (16.7%)
COUGH	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (16.7%)
SPECIAL SENSES	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (16.7%)
EYE PAIN	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (16.7%)
EYE SMELLING	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (16.7%)

TABLE 7 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : HEIBEL, ROBERT E.
STUDY : 082201
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CK731
DOSE : 20 MCG
PATIENT CLASS: HEALTHY ADULTS
AGE RANGE : 20-75 YRS.

	NUMBER OF VACCINEES (6 VACCINEES) - INJECTION 1						
	DAYS POST VACCINATION						
CLINICAL COMPLAINTS	0	1	2	3	4	5	6
VACCINEES WITH COMPLAINTS	4 (66.7%)	4 (66.7%)	2 (33.3%)	2 (33.3%)	2 (33.3%)	1 (16.7%)	1 (16.7%)
VACCINEES WITH NO COMPLAINTS	2 (33.3%)	2 (33.3%)	4 (66.7%)	4 (66.7%)	4 (66.7%)	5 (83.3%)	5 (83.3%)
TOTAL VACCINEES REPORTING	6	6	6	6	6	6	6
VACCINEES WITH NO DATA	0	0	0	0	0	0	0

TABLE 7 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : HEIBEL, ROBERT E.
STUDY : 082201
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CK731
DOSE : 20 MCG
PATIENT CLASS: HEALTHY ADULTS
AGE RANGE : 20-75 YRS.

CLINICAL COMPLAINTS	NUMBER OF VACCINEES (6 VACCINEES) - INJECTION 1						DAYS POST VACCINATION	NUMBER WITH COMPLAINTS
	7	8	9	10				
VACCINEES WITH COMPLAINTS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				4 (66.7%)
VACCINEES WITH NO COMPLAINTS	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)				2 (33.3%)
TOTAL VACCINEES REPORTING	6	6	6	6				6
VACCINEES WITH NO DATA	0	0	0	0				0

TABLE 7 (cont.)

PATIENT COUNT CLINICAL COMPLAINTS
ADMINISTERED AS ONE INJECTION OR TWO INJECTIONS
TWO TO THREE MONTHS APART

INVESTIGATOR : HEIBEL, ROBERT E.
STUDY : 082201
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CK731
DOSE : 10 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2-11 MOS.

CLINICAL COMPLAINTS	NUMBER OF VACCINEES (13 VACCINEES) - INJECTION 1 — DAYS POST VACCINATION						
	0	1	2	3	4	5	6
LOCAL REACTIONS	8 (61.5%)	8 (61.5%)	4 (30.8%)	1 (7.7%)	1 (7.7%)	1 (7.7%)	0 (0.0%)
ECCHYMOSIS, INJECTION SITE	0 (0.0%)	1 (7.7%)	2 (15.4%)	1 (7.7%)	1 (7.7%)	1 (7.7%)	0 (0.0%)
ERYTHEMA, INJECTION SITE	6 (46.2%)	5 (38.5%)	1 (7.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
INFLAMMATION, INJECTION SITE	1 (7.7%)	1 (7.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
PAIN/SORENESS, INJECTION SITE	3 (23.1%)	2 (15.4%)	1 (7.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
SWELLING, INJECTION SITE	2 (15.4%)	3 (23.1%)	1 (7.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
SYSTEMIC	6 (46.2%)	4 (30.8%)	0 (0.0%)	0 (0.0%)	1 (7.7%)	0 (0.0%)	0 (0.0%)
BODY AS A WHOLE/SITE UNSPEC.	1 (7.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.7%)	0 (0.0%)	0 (0.0%)
ASTHENIA	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.7%)	0 (0.0%)	0 (0.0%)
FATIGUE	1 (7.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
DIGESTIVE SYSTEM	0 (0.0%)	1 (7.7%)	0 (0.0%)	0 (0.0%)	1 (7.7%)	0 (0.0%)	0 (0.0%)
ANOREXIA	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

TABLE 7 (cont.)

PATIENT COUNT CLINICAL COMPLAINTS
ADMINISTERED AS ONE INJECTION OR TWO INJECTIONS
TWO TO THREE MONTHS APART

INVESTIGATOR : NEIBEL, ROBERT E.
STUDY : 082201
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CK731
DOSE : 10 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2-11 MOS.

CLINICAL COMPLAINTS	NUMBER OF VACCINEES (13 VACCINEES) - INJECTION 1 — DAYS POST VACCINATION 7	8	9	10	NUMBER WITH COMPLAINTS
LOCAL REACTIONS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	11 (84.6%)
ECCHYMOSIS, INJECTION SITE	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (23.1%)
ERYTHEMA, INJECTION SITE	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	8 (61.5%)
INFLAMMATION, INJECTION SITE	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.7%)
PAIN/SORENESS, INJECTION SITE	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (23.1%)
SWELLING, INJECTION SITE	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (23.1%)
SYSTEMIC	1 (7.7%)	3 (23.1%)	3 (23.1%)	2 (15.4%)	7 (53.8%)
BODY AS A WHOLE/SITE UNSPEC.	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (15.4%)
ASTHENIA	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.7%)
FATIGUE	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.7%)
DIGESTIVE SYSTEM	1 (7.7%)	0 (0.0%)	1 (7.7%)	0 (0.0%)	2 (15.4%)
ANOREXIA	1 (7.7%)	0 (0.0%)	1 (7.7%)	0 (0.0%)	1 (7.7%)

TABLE 7 (cont.)

PATIENT COUNT CLINICAL COMPLAINTS
ADMINISTERED AS ONE INJECTION OR TWO INJECTIONS
TWO TO THREE MONTHS APART

INVESTIGATOR : HEIBEL, ROBERT E.
STUDY : 082201
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CK731
DOSE : 10 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2-11 MOS.

CLINICAL COMPLAINTS	NUMBER OF VACCINEES (13 VACCINEES) - INJECTION 1						
	DAYS POST VACCINATION						
	0	1	2	3	4	5	6
DIARRHEA	0 (0.0%)	1 (7.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
POLYDIPSIA	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.7%)	0 (0.0%)	0 (0.0%)
NERVOUS SYSTEM & PSYCHIATRIC	5 (38.5%)	2 (15.4%)	0 (0.0%)	0 (0.0%)	1 (7.7%)	0 (0.0%)	0 (0.0%)
HYPERSOMNIA	1 (7.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
IRRITABILITY	4 (30.8%)	2 (15.4%)	0 (0.0%)	0 (0.0%)	1 (7.7%)	0 (0.0%)	0 (0.0%)
RESPIRATORY SYSTEM	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
NASAL CONGESTION	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
NASAL DISCHARGE	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
SKIN & SKIN APPENDAGE	1 (7.7%)	1 (7.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
SKIN INFLAMMATION	1 (7.7%)	1 (7.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
SPECIAL SENSES	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
CONJUNCTIVITIS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

TABLE 7 (cont.)

PATIENT COUNT CLINICAL COMPLAINTS
ADMINISTERED AS ONE INJECTION OR TWO INJECTIONS
TWO TO THREE MONTHS APART

INVESTIGATOR : HEIBEL, ROBERT E.
STUDY : 082201
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CK731
DOSE : 10 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2-11 MOS.

CLINICAL COMPLAINTS	NUMBER OF VACCINEES (13 VACCINEES) - INJECTION 1 — DAYS POST VACCINATION 7	8	9	10	NUMBER WITH COMPLAINTS
DIARRHEA	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.7%)
POLYDIPSIA	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.7%)
NERVOUS SYSTEM & PSYCHIATRIC	1 (7.7%)	3 (23.1%)	2 (15.4%)	1 (7.7%)	7 (53.8%)
HYPERSOMNIA	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.7%)
IRRITABILITY	1 (7.7%)	3 (23.1%)	2 (15.4%)	1 (7.7%)	7 (53.8%)
RESPIRATORY SYSTEM	0 (0.0%)	1 (7.7%)	1 (7.7%)	1 (7.7%)	2 (15.4%)
NASAL CONGESTION	0 (0.0%)	1 (7.7%)	1 (7.7%)	0 (0.0%)	1 (7.7%)
NASAL DISCHARGE	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.7%)	1 (7.7%)
SKIN & SKIN APPENDAGE	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.7%)
SKIN INFLAMMATION	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.7%)
SPECIAL SENSES	0 (0.0%)	1 (7.7%)	0 (0.0%)	2 (15.4%)	2 (15.4%)
CONJUNCTIVITIS	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.7%)	1 (7.7%)

TABLE 7 (cont.)

PATIENT COUNT CLINICAL COMPLAINTS
ADMINISTERED AS ONE INJECTION OR TWO INJECTIONS
TWO TO THREE MONTHS APART

INVESTIGATOR : HEIBEL, ROBERT E.
STUDY : 082201
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CK731
DOSE : 10 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2-11 MOS.

CLINICAL COMPLAINTS	NUMBER OF VACCINEES (13 VACCINEES) - INJECTION 1 DAYS POST VACCINATION						
	0	1	2	3	4	5	6
EAR INFECTION, NOS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
ENDOPHTHALMITIS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
EYE DISCHARGE	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
VACCINEES WITH COMPLAINTS	11 (84.6%)	10 (76.9%)	4 (30.8%)	1 (7.7%)	2 (15.4%)	1 (7.7%)	0 (0.0%)
VACCINEES WITH NO COMPLAINTS	2 (15.4%)	3 (23.1%)	9 (69.2%)	12 (92.3%)	11 (84.6%)	12 (92.3%)	13 (100.0%)
TOTAL VACCINEES REPORTING	13	13	13	13	13	13	13
VACCINEES WITH NO DATA	0	0	0	0	0	0	0

TABLE 7 (cont.)

PATIENT COUNT CLINICAL COMPLAINTS
ADMINISTERED AS ONE INJECTION OR TWO INJECTIONS
TWO TO THREE MONTHS APART

INVESTIGATOR : HEIBEL, ROBERT E.
STUDY : 082201
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CK731
DOSE : 10 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2-11 MOS.

CLINICAL COMPLAINTS	NUMBER OF VACCINEES (13 VACCINEES) - INJECTION 1 — DAYS POST VACCINATION 7	8	9	10			NUMBER WITH COMPLAINTS
EAR INFECTION, NOS	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.7%)			1 (7.7%)
ENDOPHTHALMITIS	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.7%)			1 (7.7%)
EYE DISCHARGE	0 (0.0%)	1 (7.7%)	0 (0.0%)	0 (0.0%)			1 (7.7%)
VACCINEES WITH COMPLAINTS	1 (7.7%)	3 (23.1%)	3 (23.1%)	2 (15.4%)			13 (100.0%)
VACCINEES WITH NO COMPLAINTS	12 (92.3%)	10 (76.9%)	10 (76.9%)	11 (84.6%)			0 (0.0%)
TOTAL VACCINEES REPORTING	13	13	13	13			13
VACCINEES WITH NO DATA	0	0	0	0			0

TABLE 7 (cont.)

PATIENT COUNT CLINICAL COMPLAINTS
ADMINISTERED AS ONE INJECTION OR TWO INJECTIONS
TWO TO THREE MONTHS APART

INVESTIGATOR : MEIBEL, ROBERT E.
STUDY : 082201
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CK731
DOSE : 10 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2-11 MOS.

CLINICAL COMPLAINTS	NUMBER OF VACCINEES (6 VACCINEES) - INJECTION 2						
	DAYS POST VACCINATION						
	0	1	2	3	4	5	6
LOCAL REACTIONS	3 (50.0%)	2 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
ERYTHEMA, INJECTION SITE	0 (0.0%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
ERYTHEMA, INJECTION SITE (1 INCH, LESS THAN)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
PAIN/SORENESS, INJECTION SITE	3 (50.0%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
SYSTEMIC	2 (33.3%)	0 (0.0%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
BODY AS A WHOLE/SITE UNSPEC.	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
HARM TO TOUCH	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
NERVOUS SYSTEM & PSYCHIATRIC	2 (33.3%)	0 (0.0%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
IRRITABILITY	2 (33.3%)	0 (0.0%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
VACCINEES WITH COMPLAINTS	3 (50.0%)	2 (33.3%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
VACCINEES WITH NO COMPLAINTS	3 (50.0%)	4 (66.7%)	5 (83.3%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
TOTAL VACCINEES REPORTING	6	6	6	6	6	6	6

TABLE 7 (cont.)

PATIENT COUNT CLINICAL COMPLAINTS
ADMINISTERED AS ONE INJECTION OR TWO INJECTIONS
TWO TO THREE MONTHS APART

INVESTIGATOR : NEIBEL, ROBERT E.
STUDY : 082201
VACCINE : NIB CONJUGATE - SALINE
LOT NUMBER : CK731
DOSE : 10 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2-11 MOS.

CLINICAL COMPLAINTS	NUMBER OF VACCINEES (6 VACCINEES) - INJECTION 2							NUMBER WITH COMPLAINTS
	DAYS POST VACCINATION							
	7	8	9	10				
LOCAL REACTIONS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				4 (66.7%)
ERYTHEMA, INJECTION SITE	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (16.7%)
ERYTHEMA, INJECTION SITE (1 INCH, LESS THAN)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (16.7%)
PAIN/SORENESS, INJECTION SITE	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				3 (50.0%)
SYSTEMIC	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				2 (33.3%)
BODY AS A WHOLE/SITE UNSPEC.	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (16.7%)
HARM TO TOUCH	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (16.7%)
NERVOUS SYSTEM & PSYCHIATRIC	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				2 (33.3%)
IRRITABILITY	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				2 (33.3%)
VACCINEES WITH COMPLAINTS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				4 (66.7%)
VACCINEES WITH NO COMPLAINTS	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)				2 (33.3%)
TOTAL VACCINEES REPORTING	6	6	6	6				6

TABLE 7 (cont.)

PATIENT COUNT CLINICAL COMPLAINTS
ADMINISTERED AS ONE INJECTION OR TWO INJECTIONS
TWO TO THREE MONTHS APART

INVESTIGATOR : HEIBEL, ROBERT E.
STUDY : 082201
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CK731
DOSE : 10 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2-11 MOS.

CLINICAL COMPLAINTS	NUMBER OF VACCINEES (6 VACCINEES) - INJECTION 2						
	DAYS POST VACCINATION						
	0	1	2	3	4	5	6
VACCINEES WITH NO DATA	0	0	0	0	0	0	0

TABLE 7 (cont.)

PATIENT COUNT CLINICAL COMPLAINTS
ADMINISTERED AS ONE INJECTION OR TWO INJECTIONS
TWO TO THREE MONTHS APART

INVESTIGATOR : WEIBEL, ROBERT E.
STUDY : 082201
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CK731
DOSE : 10 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2-11 MOS.

CLINICAL COMPLAINTS	NUMBER OF VACCINEES (6 VACCINEES) - INJECTION 2						NUMBER WITH COMPLAINTS
	DAYS POST VACCINATION						
	7	8	9	10			
VACCINEES WITH NO DATA	0	0	0	0			0

TABLE 7 (cont.)

PATIENT COUNT CLINICAL COMPLAINTS
CONTAINING 6 OR 10 MCG PRP
ADMINISTERED AS TWO INJECTIONS TWO WEEKS APART

INVESTIGATOR : WEIBEL, ROBERT E.
STUDY : 082201
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CL466
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2- 6 MOS.

	NUMBER OF VACCINEES (11 VACCINEES) - INJECTION 1						
	DAYS POST VACCINATION						
CLINICAL COMPLAINTS	0	1	2	3	4	5	6
LOCAL REACTIONS	4 (40.0%)	5 (50.0%)	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
ECCHYMOSIS, INJECTION SITE	1 (10.0%)	2 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
ERYTHEMA, INJECTION SITE	4 (40.0%)	2 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
INDURATION, INJECTION SITE	3 (30.0%)	2 (20.0%)	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
PAIN/SORENESS, INJECTION SITE	3 (30.0%)	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
SWELLING, INJECTION SITE	2 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
WARMTH, INJECTION SITE	2 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
SYSTEMIC	6 (60.0%)	4 (40.0%)	0 (0.0%)	0 (0.0%)	1 (10.0%)	1 (10.0%)	0 (0.0%)
NERVOUS SYSTEM & PSYCHIATRIC	6 (60.0%)	4 (40.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
CRYING, EXCESSIVE	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
INSOMNIA	1 (10.0%)	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
IRRITABILITY	6 (60.0%)	4 (40.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

TABLE 7 (cont.)

PATIENT COUNT CLINICAL COMPLAINTS
CONTAINING 6 OR 10 MCG PRP
ADMINISTERED AS TWO INJECTIONS TWO WEEKS APART

INVESTIGATOR : WEIBEL, ROBERT E.
STUDY : 082201
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CL466
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2- 6 MOS.

CLINICAL COMPLAINTS	NUMBER OF VACCINEES (11 VACCINEES) - INJECTION 1							NUMBER WITH COMPLAINTS
	DAYS POST VACCINATION							
	7	8	9	10				
LOCAL REACTIONS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				7 (70.0%)
ECCHYMOSIS, INJECTION SITE	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				2 (20.0%)
ERYTHEMA, INJECTION SITE	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				6 (60.0%)
INDURATION, INJECTION SITE	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				4 (40.0%)
PAIN/SORENESS, INJECTION SITE	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				4 (40.0%)
SWELLING, INJECTION SITE	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				2 (20.0%)
WARMTH, INJECTION SITE	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				2 (20.0%)
SYSTEMIC	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				7 (70.0%)
NERVOUS SYSTEM & PSYCHIATRIC	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				7 (70.0%)
CRYING, EXCESSIVE	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (10.0%)
INSOMNIA	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (10.0%)
IRRITABILITY	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				7 (70.0%)

TABLE 7 (cont.)

PATIENT COUNT CLINICAL COMPLAINTS
CONTAINING 6 OR 10 MCG PRP
ADMINISTERED AS TWO INJECTIONS TWO WEEKS APART

INVESTIGATOR : MEIBEL, ROBERT E.
STUDY : 082201
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CL466
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2- 6 MOS.

CLINICAL COMPLAINTS	NUMBER OF VACCINEES (11 VACCINEES) - INJECTION 1						
	DAYS POST VACCINATION						
	0	1	2	3	4	5	6
RESPIRATORY SYSTEM	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (10.0%)	0 (0.0%)	0 (0.0%)
COMMON COLD	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (10.0%)	0 (0.0%)	0 (0.0%)
SPECIAL SENSES	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (10.0%)	1 (10.0%)	0 (0.0%)
OTITIS MEDIA	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (10.0%)	1 (10.0%)	0 (0.0%)
VACCINEES WITH COMPLAINTS	8 (80.0%)	7 (70.0%)	1 (10.0%)	0 (0.0%)	1 (10.0%)	1 (10.0%)	0 (0.0%)
VACCINEES WITH NO COMPLAINTS	2 (20.0%)	3 (30.0%)	9 (90.0%)	10 (100.0%)	9 (90.0%)	9 (90.0%)	10 (100.0%)
TOTAL VACCINEES REPORTING	10	10	10	10	10	10	10
VACCINEES WITH NO DATA	1	1	1	1	1	1	1

TABLE 7 (cont.)

PATIENT COUNT CLINICAL COMPLAINTS
CONTAINING 6 OR 10 MCG PRP
ADMINISTERED AS TWO INJECTIONS TWO WEEKS APART

INVESTIGATOR : WEIBEL, ROBERT E.
STUDY : 082201
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CL466
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2- 6 MOS.

CLINICAL COMPLAINTS	NUMBER OF VACCINEES (11 VACCINEES) - INJECTION 1							NUMBER WITH COMPLAINTS
	DAYS POST VACCINATION							
	7	8	9	10				
RESPIRATORY SYSTEM	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (10.0%)
COMMON COLD	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (10.0%)
SPECIAL SENSES	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (10.0%)
OTITIS MEDIA	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (10.0%)
VACCINEES WITH COMPLAINTS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				9 (90.0%)
VACCINEES WITH NO COMPLAINTS	10 (100.0%)	10 (100.0%)	10 (100.0%)	10 (100.0%)				1 (10.0%)
TOTAL VACCINEES REPORTING	10	10	10	10				10
VACCINEES WITH NO DATA	1	1	1	1				1

TABLE 7 (cont.)

PATIENT COUNT CLINICAL COMPLAINTS
CONTAINING 6 OR 10 MCG PRP
ADMINISTERED AS TWO INJECTIONS TWO WEEKS APART

INVESTIGATOR : WEIBEL, ROBERT E.
STUDY : 082201
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CL466
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2- 6 MOS.

CLINICAL COMPLAINTS	NUMBER OF VACCINEES (10 VACCINEES) - INJECTION 2						
	DAYS POST VACCINATION						
	0	1	2	3	4	5	6
LOCAL REACTIONS	5 (50.0%)	3 (30.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
ECCHYMOSIS, INJECTION SITE	1 (10.0%)	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
ERYTHEMA, INJECTION SITE	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
INDURATION, INJECTION SITE	2 (20.0%)	2 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
INFLAMMATION, INJECTION SITE	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
PAIN/SORENESS, INJECTION SITE	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
SWELLING, INJECTION SITE	2 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
SYSTEMIC	5 (50.0%)	2 (20.0%)	0 (0.0%)	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
NERVOUS SYSTEM & PSYCHIATRIC	5 (50.0%)	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
IRRITABILITY	5 (50.0%)	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
RESPIRATORY SYSTEM	0 (0.0%)	1 (10.0%)	0 (0.0%)	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
NASAL DISCHARGE	0 (0.0%)	1 (10.0%)	0 (0.0%)	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

TABLE 7 (cont.)

PATIENT COUNT CLINICAL COMPLAINTS
CONTAINING 6 OR 10 MCG PRP
ADMINISTERED AS TWO INJECTIONS TWO WEEKS APART

INVESTIGATOR : WEIBEL, ROBERT E.
STUDY : 082201
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CL466
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2- 6 MOS.

CLINICAL COMPLAINTS	NUMBER OF VACCINEES (10 VACCINEES) - INJECTION 2 — DAYS POST VACCINATION 7	8	9	10				NUMBER WITH COMPLAINTS
LOCAL REACTIONS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				5 (50.0%)
ECCHYMOSIS, INJECTION SITE	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				2 (20.0%)
ERYTHEMA, INJECTION SITE	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (10.0%)
INDURATION, INJECTION SITE	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				3 (30.0%)
INFLAMMATION, INJECTION SITE	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (10.0%)
PAIN/SORENESS, INJECTION SITE	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (10.0%)
SWELLING, INJECTION SITE	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				2 (20.0%)
SYSTEMIC	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (10.0%)				5 (50.0%)
NERVOUS SYSTEM & PSYCHIATRIC	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				5 (50.0%)
IRRITABILITY	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				5 (50.0%)
RESPIRATORY SYSTEM	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (10.0%)				3 (30.0%)
NASAL DISCHARGE	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (10.0%)				3 (30.0%)

TABLE 7 (cont.)

PATIENT COUNT CLINICAL COMPLAINTS
CONTAINING 6 OR 10 MCG PRP
ADMINISTERED AS TWO INJECTIONS TWO WEEKS APART

INVESTIGATOR : MEIBEL, ROBERT E.
STUDY : 082201
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CL466
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2- 6 MOS.

CLINICAL COMPLAINTS	NUMBER OF VACCINEES (10 VACCINEES) - INJECTION 2						
	DAYS POST VACCINATION						
	0	1	2	3	4	5	6
SPECIAL SENSES	0 (0.0%)	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
OTITIS MEDIA	0 (0.0%)	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
VACCINEES WITH COMPLAINTS	5 (50.0%)	3 (30.0%)	0 (0.0%)	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
VACCINEES WITH NO COMPLAINTS	5 (50.0%)	7 (70.0%)	10 (100.0%)	9 (90.0%)	10 (100.0%)	10 (100.0%)	10 (100.0%)
TOTAL VACCINEES REPORTING	10	10	10	10	10	10	10
VACCINEES WITH NO DATA	0	0	0	0	0	0	0

TABLE 7 (cont.)

PATIENT COUNT CLINICAL COMPLAINTS
CONTAINING 6 OR 10 MCG PRP
ADMINISTERED AS TWO INJECTIONS TWO WEEKS APART

INVESTIGATOR : WEIBEL, ROBERT E.
STUDY : 082201
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CL466
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2- 6 MOS.

CLINICAL COMPLAINTS	NUMBER OF VACCINEES (10 VACCINEES) - INJECTION 2 — DAYS POST VACCINATION 7	8	9	10				NUMBER WITH COMPLAINTS
SPECIAL SENSES	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (10.0%)
OTITIS MEDIA	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (10.0%)
VACCINEES WITH COMPLAINTS	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (10.0%)				5 (50.0%)
VACCINEES WITH NO COMPLAINTS	10 (100.0%)	10 (100.0%)	10 (100.0%)	9 (90.0%)				5 (50.0%)
TOTAL VACCINEES REPORTING	10	10	10	10				10
VACCINEES WITH NO DATA	0	0	0	0				0

TABLE 8

PATIENT COUNT MAXIMUM TEMPERATURES
VACCINE CONTAINING 10 OR 20 MCG PRP

INVESTIGATOR : NEIBEL, ROBERT E.
STUDY : 082201
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CK731
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

MAX TEMPERATURE (DEG F, ORAL)	NUMBER OF VACCINEES (8 VACCINEES) - INJECTION 1						
	DAYS POST VACCINATION						
	0	1	2	3	4	5	6
NORMAL	1 (12.5%)	1 (14.3%)	1 (14.3%)	2 (28.6%)	2 (28.6%)	2 (28.6%)	2 (28.6%)
< 99	3 (37.5%)	2 (28.6%)	4 (57.1%)	4 (57.1%)	3 (42.9%)	4 (57.1%)	4 (57.1%)
99 - 99.9	3 (37.5%)	4 (57.1%)	2 (28.6%)	1 (14.3%)	2 (28.6%)	1 (14.3%)	1 (14.3%)
100 - 100.9	1 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
TEMPERATURE TAKEN	8 (100.0%)	7 (87.5%)	7 (87.5%)	7 (87.5%)	7 (87.5%)	7 (87.5%)	7 (87.5%)
TEMPERATURE NOT TAKEN	0 (0.0%)	1 (12.5%)	1 (12.5%)	1 (12.5%)	1 (12.5%)	1 (12.5%)	1 (12.5%)

TABLE 8 (cont.)

PATIENT COUNT MAXIMUM TEMPERATURES
VACCINE CONTAINING 10 OR 20 MCG PRP

INVESTIGATOR : HEIBEL, ROBERT E.
STUDY : 082201
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CK731
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

MAX TEMPERATURE (DEG F, ORAL)	NUMBER OF VACCINEES (8 VACCINEES) - INJECTION 1							NUMBER WITH MAX TEMP
	DAYS POST VACCINATION							
	7	8	9	10				
NORMAL	2 (28.6%)	2 (28.6%)	2 (33.3%)	2 (33.3%)				1 (12.5%)
< 99	4 (57.1%)	5 (71.4%)	4 (66.7%)	3 (50.0%)				1 (12.5%)
99 - 99.9	1 (14.3%)	0 (0.0%)	0 (0.0%)	1 (16.7%)				5 (62.5%)
100 - 100.9	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (12.5%)
TEMPERATURE TAKEN	7 (87.5%)	7 (87.5%)	6 (75.0%)	6 (75.0%)				8 (100.0%)
TEMPERATURE NOT TAKEN	1 (12.5%)	1 (12.5%)	2 (25.0%)	2 (25.0%)				0 (0.0%)

TABLE 8 (cont.)

PATIENT COUNT MAXIMUM TEMPERATURES
VACCINE CONTAINING 10 OR 20 MCG PRP

INVESTIGATOR : MEIBEL, ROBERT E.
STUDY : 082201
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CK731
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

	NUMBER OF VACCINEES (2 VACCINEES) - INJECTION 2						
	DAYS POST VACCINATION						
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5	6
NORMAL	1 (50.0%)	1 (50.0%)	1 (50.0%)	1 (50.0%)	1 (50.0%)	1 (50.0%)	1 (50.0%)
< 99	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (50.0%)	1 (50.0%)	1 (50.0%)	0 (0.0%)
99 - 99.9	0 (0.0%)	0 (0.0%)	1 (50.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (50.0%)
100 - 100.9	0 (0.0%)	1 (50.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
104 - 104.9	1 (50.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
TEMPERATURE TAKEN	2 (100.0%)	2 (100.0%)	2 (100.0%)	2 (100.0%)	2 (100.0%)	2 (100.0%)	2 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

TABLE 8 (cont.)

PATIENT COUNT MAXIMUM TEMPERATURES
VACCINE CONTAINING 10 OR 20 MCG PRP

INVESTIGATOR : MEIBEL, ROBERT E.
STUDY : 082201
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CK731
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.

MAX TEMPERATURE (DEG F, ORAL)	NUMBER OF VACCINEES (2 VACCINEES) - INJECTION 2							NUMBER WITH MAX TEMP
	DAYS POST VACCINATION							
	7	8	9	10				
NORMAL	1 (50.0%)	1 (50.0%)	1 (50.0%)	1 (50.0%)				1 (50.0%)
< 99	1 (50.0%)	1 (50.0%)	0 (0.0%)	1 (50.0%)				0 (0.0%)
99 - 99.9	0 (0.0%)	0 (0.0%)	1 (50.0%)	0 (0.0%)				0 (0.0%)
100 - 100.9	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				0 (0.0%)
104 - 104.9	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (50.0%)
TEMPERATURE TAKEN	2 (100.0%)	2 (100.0%)	2 (100.0%)	2 (100.0%)				2 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				0 (0.0%)

TABLE 8 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : NEIBEL, ROBERT E.
STUDY : 082201
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CK731
DOSE : 20 MCG
PATIENT CLASS: HEALTHY ADULTS
AGE RANGE : 20-75 YRS.

MAX TEMPERATURE (DEG F, ORAL)	NUMBER OF VACCINEES (6 VACCINEES) - INJECTION 1						
	DAYS POST VACCINATION						
	0	1	2	3	4	5	6
NORMAL	1 (16.7%)	1 (16.7%)	1 (16.7%)	1 (16.7%)	1 (16.7%)	1 (16.7%)	1 (16.7%)
< 99	4 (66.7%)	4 (66.7%)	4 (66.7%)	4 (66.7%)	5 (83.3%)	5 (83.3%)	5 (83.3%)
99 - 99.9	1 (16.7%)	0 (0.0%)	1 (16.7%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
100 - 100.9	0 (0.0%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
TEMPERATURE TAKEN	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

TABLE 8 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : MEIBEL, ROBERT E.
STUDY : 082201
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CK731
DOSE : 20 MCG
PATIENT CLASS: HEALTHY ADULTS
AGE RANGE : 20-75 YRS.

MAX TEMPERATURE (DEG F, ORAL)	NUMBER OF VACCINEES (6 VACCINEES) - INJECTION 1							NUMBER WITH MAX TEMP
	DAYS POST VACCINATION							
	7	8	9	10				
NORMAL	1 (16.7%)	1 (16.7%)	1 (16.7%)	1 (16.7%)				1 (16.7%)
< 99	5 (83.3%)	5 (83.3%)	5 (83.3%)	5 (83.3%)				4 (66.7%)
99 - 99.9	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				0 (0.0%)
100 - 100.9	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (16.7%)
TEMPERATURE TAKEN	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)				6 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				0 (0.0%)

TABLE 8 (cont.)

PATIENT COUNT MAXIMUM TEMPERATURES
ADMINISTERED AS ONE INJECTION OR TWO INJECTIONS
TWO TO THREE MONTHS APART

INVESTIGATOR : HEIBEL, ROBERT E.
STUDY : 082201
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CK731
DOSE : 10 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2-11 MOS.

MAX TEMPERATURE (DEG F, ORAL)	NUMBER OF VACCINEES (13 VACCINEES) - INJECTION 1						
	DAYS POST VACCINATION						
	0	1	2	3	4	5	6
NORMAL	2 (15.4%)	2 (15.4%)	2 (15.4%)	2 (15.4%)	2 (18.2%)	2 (16.7%)	2 (15.4%)
< 99	5 (38.5%)	5 (38.5%)	9 (69.2%)	9 (69.2%)	7 (63.6%)	9 (75.0%)	9 (69.2%)
99 - 99.9	2 (15.4%)	4 (30.8%)	2 (15.4%)	2 (15.4%)	1 (9.1%)	1 (8.3%)	2 (15.4%)
100 - 100.9	3 (23.1%)	2 (15.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
101 - 101.9	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (9.1%)	0 (0.0%)	0 (0.0%)
103 - 103.9	1 (7.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
TEMPERATURE TAKEN	13 (100.0%)	13 (100.0%)	13 (100.0%)	13 (100.0%)	11 (84.6%)	12 (92.3%)	13 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (15.4%)	1 (7.7%)	0 (0.0%)

TABLE 8 (cont.)

PATIENT COUNT MAXIMUM TEMPERATURES
ADMINISTERED AS ONE INJECTION OR TWO INJECTIONS
TWO TO THREE MONTHS APART

INVESTIGATOR : WEIBEL, ROBERT E.
STUDY : 082201
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CK731
DOSE : 10 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2-11 MOS.

MAX TEMPERATURE (DEG F, ORAL)	NUMBER OF VACCINEES (13 VACCINEES) - INJECTION 1							NUMBER WITH MAX TEMP
	DAYS POST VACCINATION							
	7	8	9	10				
NORMAL	2 (16.7%)	2 (15.4%)	2 (15.4%)	2 (18.2%)				2 (15.4%)
< 99	7 (58.3%)	10 (76.9%)	7 (53.8%)	6 (54.5%)				2 (15.4%)
99 - 99.9	3 (25.0%)	1 (7.7%)	4 (30.8%)	2 (18.2%)				4 (30.8%)
100 - 100.9	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (9.1%)				3 (23.1%)
101 - 101.9	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (7.7%)
103 - 103.9	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (7.7%)
TEMPERATURE TAKEN	12 (92.3%)	13 (100.0%)	13 (100.0%)	11 (84.6%)				13 (100.0%)
TEMPERATURE NOT TAKEN	1 (7.7%)	0 (0.0%)	0 (0.0%)	2 (15.4%)				0 (0.0%)

TABLE 8 (cont.)

PATIENT COUNT MAXIMUM TEMPERATURES
ADMINISTERED AS ONE INJECTION OR TWO INJECTIONS
TWO TO THREE MONTHS APART

INVESTIGATOR : MEIBEL, ROBERT E.
STUDY : 082201
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CK731
DOSE : 10 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2-11 MOS.

MAX TEMPERATURE (DEG F, ORAL)	NUMBER OF VACCINEES (6 VACCINEES) - INJECTION 2						
	DAYS POST VACCINATION						
	0	1	2	3	4	5	6
NORMAL	3 (50.0%)	3 (50.0%)	3 (50.0%)	3 (50.0%)	3 (50.0%)	3 (50.0%)	3 (50.0%)
< 99	2 (33.3%)	3 (50.0%)	2 (33.3%)	3 (50.0%)	3 (50.0%)	3 (50.0%)	2 (33.3%)
99 - 99.9	0 (0.0%)	0 (0.0%)	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (16.7%)
100 - 100.9	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
TEMPERATURE TAKEN	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)	6 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

TABLE 8 (cont.)

PATIENT COUNT MAXIMUM TEMPERATURES
ADMINISTERED AS ONE INJECTION OR TWO INJECTIONS
TWO TO THREE MONTHS APART

INVESTIGATOR : MEIBEL, ROBERT E.
STUDY : 082201
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CK731
DOSE : 10 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2-11 MOS.

MAX TEMPERATURE (DEG F, ORAL)	NUMBER OF VACCINEES (6 VACCINEES) - INJECTION 2							NUMBER WITH MAX TEMP
	DAYS POST VACCINATION							
	7	8	9	10				
NORMAL	3 (60.0%)	3 (50.0%)	3 (50.0%)	3 (50.0%)				3 (50.0%)
< 99	2 (40.0%)	3 (50.0%)	3 (50.0%)	3 (50.0%)				1 (16.7%)
99 - 99.9	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (16.7%)
100 - 100.9	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (16.7%)
TEMPERATURE TAKEN	5 (83.3%)	6 (100.0%)	6 (100.0%)	6 (100.0%)				6 (100.0%)
TEMPERATURE NOT TAKEN	1 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				0 (0.0%)

TABLE 8 (cont.)

PATIENT COUNT MAXIMUM TEMPERATURES
CONTAINING 6 OR 10 MCG PRP
ADMINISTERED AS TWO INJECTIONS TWO WEEKS APART

INVESTIGATOR : MEIBEL, ROBERT E.
STUDY : 082201
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CL466
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2- 6 MOS.

MAX TEMPERATURE (DEG F, ORAL)	NUMBER OF VACCINEES (11 VACCINEES) - INJECTION 1						
	DAYS POST VACCINATION						
	0	1	2	3	4	5	6
NORMAL	1 (10.0%)	1 (10.0%)	1 (10.0%)	1 (10.0%)	1 (10.0%)	1 (10.0%)	1 (10.0%)
< 99	5 (50.0%)	6 (60.0%)	8 (80.0%)	9 (90.0%)	6 (60.0%)	7 (70.0%)	8 (80.0%)
99 - 99.9	3 (30.0%)	3 (30.0%)	1 (10.0%)	0 (0.0%)	3 (30.0%)	2 (20.0%)	1 (10.0%)
100 - 100.9	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
TEMPERATURE TAKEN	10 (90.9%)	10 (90.9%)	10 (90.9%)	10 (90.9%)	10 (90.9%)	10 (90.9%)	10 (90.9%)
TEMPERATURE NOT TAKEN	1 (9.1%)	1 (9.1%)	1 (9.1%)	1 (9.1%)	1 (9.1%)	1 (9.1%)	1 (9.1%)

TABLE 8 (cont.)

PATIENT COUNT MAXIMUM TEMPERATURES
CONTAINING 6 OR 10 MCG PRP
ADMINISTERED AS TWO INJECTIONS TWO WEEKS APART

INVESTIGATOR : WEIBEL, ROBERT E.
STUDY : 082201
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CL466
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2- 6 MOS.

MAX TEMPERATURE (DEG F, ORAL)	NUMBER OF VACCINEES (11 VACCINEES) - INJECTION 1							NUMBER WITH MAX TEMP
	DAYS POST VACCINATION							
	7	8	9	10				
NORMAL	1 (10.0%)	1 (10.0%)	1 (10.0%)	1 (10.0%)				1 (10.0%)
< 99	8 (80.0%)	9 (90.0%)	9 (90.0%)	9 (90.0%)				4 (40.0%)
99 - 99.9	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				4 (40.0%)
100 - 100.9	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (10.0%)
TEMPERATURE TAKEN	10 (90.9%)	10 (90.9%)	10 (90.9%)	10 (90.9%)				10 (90.9%)
TEMPERATURE NOT TAKEN	1 (9.1%)	1 (9.1%)	1 (9.1%)	1 (9.1%)				1 (9.1%)

TABLE 8 (cont.)

PATIENT COUNT MAXIMUM TEMPERATURES
CONTAINING 6 OR 10 MCG PRP
ADMINISTERED AS TWO INJECTIONS TWO WEEKS APART

INVESTIGATOR : HEIBEL, ROBERT E.
STUDY : 082201
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CL466
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2- 6 MOS.

MAX TEMPERATURE (DEG F, ORAL)	NUMBER OF VACCINEES (10 VACCINEES) - INJECTION 2						
	DAYS POST VACCINATION						
	0	1	2	3	4	5	6
NORMAL	1 (10.0%)	2 (20.0%)	2 (20.0%)	2 (20.0%)	2 (20.0%)	2 (20.0%)	2 (20.0%)
< 99	6 (60.0%)	5 (50.0%)	7 (70.0%)	7 (70.0%)	6 (60.0%)	6 (60.0%)	7 (70.0%)
99 - 99.9	2 (20.0%)	2 (20.0%)	1 (10.0%)	1 (10.0%)	2 (20.0%)	2 (20.0%)	1 (10.0%)
100 - 100.9	1 (10.0%)	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
TEMPERATURE TAKEN	10 (100.0%)	10 (100.0%)	10 (100.0%)	10 (100.0%)	10 (100.0%)	10 (100.0%)	10 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

TABLE 8 (cont.)

PATIENT COUNT MAXIMUM TEMPERATURES
CONTAINING 6 OR 10 MCG PRP
ADMINISTERED AS TWO INJECTIONS TWO WEEKS APART

INVESTIGATOR : HEIBEL, ROBERT E.
STUDY : 082201
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CL466
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2- 6 MOS.

MAX TEMPERATURE (DEG F, ORAL)	NUMBER OF VACCINEES (10 VACCINEES) - INJECTION 2							NUMBER WITH MAX TEMP
	DAYS POST VACCINATION							
	7	8	9	10				
NORMAL	2 (20.0%)	2 (20.0%)	2 (20.0%)	2 (20.0%)				1 (10.0%)
< 99	7 (70.0%)	8 (80.0%)	8 (80.0%)	8 (80.0%)				5 (50.0%)
99 - 99.9	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				2 (20.0%)
100 - 100.9	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				2 (20.0%)
TEMPERATURE TAKEN	10 (100.0%)	10 (100.0%)	10 (100.0%)	10 (100.0%)				10 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				0 (0.0%)

STUDY 870

PROGRAM: Haemophilus b Conjugate Vaccine (Neisseria meningitidis Outer Membrane Protein Complex), Study #870

PURPOSE: To evaluate safety and immunogenicity in healthy infants 2 to 6 months of age of Haemophilus b Conjugate Vaccine (Neisseria meningitidis Outer Membrane Protein Complex) reconstituted in saline or aluminum hydroxide diluent.

VACCINE: Haemophilus b Conjugate Vaccine (Neisseria meningitidis Outer Membrane Protein Complex)
Lot 1002/C-L466 - (b) (4) mcg polysaccharide/ml
(b) (4) mcg meningococcal protein/ml
Lot 1018/C-M679 - (b) (4) mcg polysaccharide/ml
(b) (4) mcg meningococcal protein/ml

Diluent

Saline diluent
Lot (b) (4)

Aluminum hydroxide diluent
Lot (b) (4)

INVESTIGATOR: Edwin L. Anderson, M.D.
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SUB-INVESTIGATOR: Robert B. Belshe, M.D.
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STUDY LOCATION: John Marshall Medical Services
Marshall University
Huntington, West Virginia 25701

DATE STUDY INITIATED: November 2, 1984

DATE STUDY COMPLETED: January 14, 1988

STUDY POPULATION: A total of 29 healthy infants (12 male and 17 female) 2 to 6 months of age were included in the study.

STUDY PROCEDURE: Healthy infants 2 to 6 months of age received two 0.5 ml (10 mcg polysaccharide) intramuscular injections of vaccine reconstituted in saline or two 0.65 ml (13 mcg polysaccharide) intramuscular injections of vaccine reconstituted in alumuminum hydroxide, one month apart.

Parents or guardians were required to record the vaccinee's temperature and any systemic or injection site reactions for 5 days after each injection of vaccine. Unexpected or serious reactions were to be reported immediately to the study physician.

A blood sample was obtained immediately before the first injection and 4 weeks after the second injection. Additional blood samples were obtained 6-12 months and 18-24 months after the second injection of vaccine.

All serum samples were assayed for antibody to H. influenzae type b capsular polysaccharide by radioimmunoassay (RIA). Selected samples are also tested for serum bactericidal activity.

RESULTS: Demographic information and individual pre and post vaccination antibody data for each vaccinee enrolled in the study is reported in Table 1.

1. Number Vaccinated:

Lot	Formulation	Injection No. 1	Injection No. 2
1002/C-L466	Saline	15	14
1018/C-M679	Alum	14	12

2. Serologic Results:

Antibody responses (RIA) prior to vaccination and 1 month after the second injection are as follows:

Lot	Formulation	Dose (mcg)	Time	% With Anti-PRP >.15 mcg Ab/ml	% With Anti-PRP >1.0 mcg Ab/ml	GMT (mcg Ab/ml) All Vaccinees
1002/C-L466	Saline	10	Pre	31 (4/13)	0 (0/13)	0.11
			2 Mos.	100 (13/13)	92 (12/13)	2.28
1018/C-M679	Alum	13	Pre	58 (7/12)	17 (2/12)	0.21
			2 Mos.	100 (12/12)	42 (5/12)	0.90

Antibody responses (by lot) prior to vaccination through 24 months are included in Tables 2 and 3.

3. Clinical Results:

The frequencies of reactions during the 5 days following vaccination are as follows:

Type of Reaction	Lot	Formulation	% Frequency Injection 1	% Frequency Injection 2
Injection Site	1002/C-L466	Saline	20 (3/15)	50 (7/14)
	1018/C-M679	Alum	21 (3/14)	17 (2/12)
Systemic	1002/C-L466	Saline	67 (10/15)	43 (6/14)
	1018/C-M679	Alum	29 (4/14)	42 (5/12)

Reaction frequencies and maximum temperatures reported during the five days following each injection of vaccine are reported in Tables 4-6.

No serious or alarming reactions attributable to vaccine were reported.

TABLE 1

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : ANDERSON, EDWIN
STUDY : 087001
VACCINE : HIB CONJUGATE - SALINE
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE GROUP	DAY	DATE	PHASSQ	EVENT	LOT	DOSE	CODE	RIA	SBA
(b) (6)	F		(b) (6)	2M	0	(b) (6)	001	PREBLEED				467	QNS
					0		011	INJ 1	CL466	10 MCG			
					26		021	INJ 2	CL466	10 MCG			
					55		021	BLEED 1				1769	16
	F			2M	0		001	PREBLEED				246	< 2
					0		011	INJ 1	CL466	10 MCG			
					28		021	INJ 2	CL466	10 MCG			
					62		021	BLEED 1				2037	16
					279		071	BLEED 2				3671	
					629		071	BLEED 3				1611	
	F			2M	0		001	PREBLEED				< 62	
					0		011	INJ 1	CL466	10 MCG			
					33		021	INJ 2	CL466	10 MCG			
					63		021	BLEED 1				2411	
					219		071	BLEED 2				81	
	F			2M	0		001	PREBLEED				< 125	
					0		011	INJ 1	CL466	10 MCG			
					28		021	INJ 2	CL466	10 MCG			
					56		021	BLEED 1				1591	
					471		021	BLEED 2				216	
	F			2M	0		001	PREBLEED				< 125	
					0		011	INJ 1	CL466	10 MCG			
					28		021	INJ 2	CL466	10 MCG			
					56		021	BLEED 1				2863	
					471		021	BLEED 2				< 125	
	M			2M	0		001	PREBLEED				186	< 2
					0		011	INJ 1	CL466	10 MCG			
					35		D21	INJ 2	CL466	10 MCG			
					63		021	BLEED 1				5236	16
					372		021	BLEED 2				542	
					694		021	BLEED 3				494	
	M			2M	0		001	PREBLEED				< 62	
					0		011	INJ 1	CL466	10 MCG			
					29		021	INJ 2	CL466	10 MCG			
					57		021	BLEED 1				629	

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : ANDERSON, EDWIN
STUDY : 087001
VACCINE : HIB CONJUGATE - SALINE
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE GROUP	DAY	DATE	PHASSQ	EVENT	LOT	DOSE	CODE	RIA	SBA
(b) (6)	M		(b) (6)	2M	202	(b) (6)	071	BLEED 2				254	
	F			3M	0		001	PREBLEED				< 62	< 2
					0		011	INJ 1	CL466	10 MCG			
					36		021	INJ 2	CL466	10 MCG			
					75		021	BLEED 1				1537	< 2
					303		071	BLEED 2				591	
					513		071	BLEED 3				141	
	F			3M	0		001	PREBLEED				< 125	
					0		011	INJ 1	CL466	10 MCG			
					33		021	INJ 2	CL466	10 MCG			
					61		021	BLEED 1				2465	
	F			2M	0		001	PREBLEED				< 125	
					0		011	INJ 1	CL466	10 MCG			
					32		011	BLEED 1				6992	
	F			4M	0		001	PREBLEED				< 125	QNS
					0		011	INJ 1	CL466	10 MCG			
					34		021	INJ 2	CL466	10 MCG			
					56		021	BLEED 1				3607	8
	F			4M	0		001	PREBLEED				< 62	< 2
					0		011	INJ 1	CL466	10 MCG			
					27		021	INJ 2	CL466	10 MCG			
					54		021	BLEED 1			01	2375	16
					656		071	BLEED 2				310	
					656		091	INJ 3	POLYS	25 MCG			
					698		091	BLEED 3				10843	
	F			4M	0		001	PREBLEED				< 125	
					0		011	INJ 1	CL466	10 MCG			
					62		021	INJ 2	CL466	10 MCG			
					97		021	BLEED 1			05	3274	
					891		021	BLEED 2			05	216	
	F			5M	0		001	PREBLEED				142	< 2
					0		011	INJ 1	CL466	10 MCG			
					28		021	INJ 2	CL466	10 MCG			
					63		021	BLEED 1				2425	8

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : ANDERSON, EDWIN
STUDY : 087001
VACCINE : HIB CONJUGATE - SALINE
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE GROUP	DAY	DATE	PHASSQ	EVENT	LOT	DOSE	CODE	RIA	SBA
(b) (6)	F		(b) (6)	5M	381	(b) (6)	071	BLEED 2				582	
					668		091	INJ 3	POLYS	25 MCG			
					819		091	BLEED 3				15924	
	M			6M	0		001	PREBLEED				253	< 2
					0		011	INJ 1	CL466	10 MCG			
					28		021	INJ 2	CL466	10 MCG			
					63		021	BLEED 1				4487	32
					381		071	BLEED 2				956	
					668		091	INJ 3	POLYS	25 MCG			
					819		091	BLEED 3				29125	

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : ANDERSON, EDWIN
STUDY : 087001
VACCINE : HIB CONJUGATE - ALUM
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE GROUP	DAY	DATE	PHASSQ	EVENT		LOT	DOSE	CODE	RIA	SBA
(b) (6)	M		(b) (6)	6M	0	(b) (6)	001	PREBLEED					< 125	
					0		011	INJ	1	CM679	13 MCG			
					22		021	INJ	2	CM679	13 MCG			
					50		021	BLEED	1				1574	
	F			5M	0		001	PREBLEED					< 125	
					0		011	INJ	1	CM679	13 MCG			
					26		021	INJ	2	CM679	13 MCG			
					54		021	BLEED	1				990	
					743		071	BLEED	2			06	> 5000	
	F			5M	-7		001	PREBLEED					306	
					0		011	INJ	1	CM679	13 MCG			
					28		021	INJ	2	CM679	13 MCG			
					56		021	BLEED	1				186	
					144		021	BLEED	2				142	
					487		071	BLEED	3			06	3140	
	M			4M	0		001	PREBLEED					190	
					0		011	INJ	1	CM679	13 MCG			
					32		021	INJ	2	CM679	13 MCG			
					60		021	BLEED	1				19602	
					476		071	BLEED	2				8943	
	M			3M	0		001	PREBLEED					< 125	
					0		011	INJ	1	CM679	13 MCG			
					33		021	INJ	2	CM679	13 MCG			
					61		021	BLEED	1				1670	
	M			2M	0		001	PREBLEED					3172	
					0		011	INJ	1	CM679	13 MCG			
					34		021	INJ	2	CM679	13 MCG			
					62		021	BLEED	1				3067	
	F			2M	0		001	PREBLEED					263	
					0		011	INJ	1	CM679	13 MCG			
					28		021	INJ	2	CM679	13 MCG			
					56		021	BLEED	1				214	
					136		071	BLEED	2			06	4029	
					448		071	BLEED	3			06	2438	
	M			2M	0		001	PREBLEED					372	

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : ANDERSON, EDWIN
STUDY : 087001
VACCINE : HIB CONJUGATE - ALUM
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE GROUP	DAY	DATE	PHASSQ	EVENT	LOT	DOSE	CODE	RIA	SBA
(b) (6)	M		(b) (6)	2M	0	(b) (6)	011	INJ 1	CM679	13 MCG			
					35		021	INJ 2	CM679	13 MCG			
					63		021	BLEED 1				4421	
	M			2M	0		001	PREBLEED				< 125	
					0		011	INJ 1	CM679	13 MCG			
					26		021	INJ 2	CM679	13 MCG			
					54		021	BLEED 1				361	
	M			2M	0		001	PREBLEED				< 125	
					0		011	INJ 1	CM679	13 MCG			
					28		021	INJ 2	CM679	13 MCG			
					57		021	BLEED 1				188	
					293		071	BLEED 2				149	
	M			2M	0		001	PREBLEED				154	
					0		011	INJ 1	CM679	13 MCG.			
					66		011	BLEED 1				748	
	F			2M	0		001	PREBLEED				< 125	
					0		011	INJ 1	CM679	13 MCG			
					50		011	BLEED 1				306	
	F			2M	0		001	PREBLEED				232	
					0		011	INJ 1	CM679	13 MCG			
					28		021	INJ 2	CM679	13 MCG			
					57		021	BLEED 1				290	
					215		071	BLEED 2				730	
					334		071	BLEED 3				315	
	M			3M	0		001	PREBLEED				2293	
					0		011	INJ 1	CM679	13 MCG			
					29		021	INJ 2	CM679	13 MCG			
					58		021	BLEED 1				544	
					345		071	BLEED 2				< 125	

TABLE 2

A N T I B O D Y R E S P O N S E S
ADMINISTERED AS TWO INJECTIONS ONE MONTH APART

INVESTIGATOR : ANDERSON, EDWIN
STUDY : 087001
VACCINE : HIB CONJUGATE - SALINE
ASSAY : RIA
LOT NUMBER : CL466
DOSE : 10 MCG
POPULATION : HEALTHY CHILDREN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
2- 6 MOS.	PRE INJ	31 (4/ 13)	0 (0/ 13)			0.105 (13)
	2 MONTHS	100 (13/ 13)	92 (12/ 13)	100 (13/ 13)	14.3	2.284 (13)
	6/12 MONTHS	80 (4/ 5)	20 (1/ 5)	80 (4/ 5)	3.3	0.451 (5)
	13/23 MONTHS	75 (6/ 8)	13 (1/ 8)	63 (5/ 8)	2.5	0.357 (8)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 3

A N T I B O D Y R E S P O N S E S
ADMINISTERED AS TWO INJECTIONS ONE MONTH APART

INVESTIGATOR : ANDERSON, EDWIN
STUDY : 087001
VACCINE : HIB CONJUGATE - ALUM
ASSAY : RIA
LOT NUMBER : CM679
DOSE : 13 MCG
POPULATION : HEALTHY CHILDREN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
2- 6 MOS.	PRE INJ	58 (7/ 12)	17 (2/ 12)			0.214 (12)
	2 MONTHS	100 (12/ 12)	42 (5/ 12)	50 (6/ 12)	3.2	0.903 (12)
	6/12 MONTHS	33 (1/ 3)	0 (0/ 3)	0 (0/ 3)	0.4	0.143 (3)
	13/23 MONTHS	100 (1/ 1)	100 (1/ 1)	100 (1/ 1)	47.1	8.943 (1)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 4

CLINICAL COMPLAINTS BY FREQUENCY
ADMINISTERED AS TWO INJECTINS ONE MONTH APART

INVESTIGATOR : ANDERSON, EDWIN
STUDY : 087001
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CL466
DOSE : 10 MCG
POPULATION : HEALTHY CHILDREN
AGE RANGE : 2- 6 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE - SALINE INJECTION: 1	
TOTAL VACCINEES :	15	
VACCINEES WITH NO COMPLAINTS :	5	(33.3 %)
VACCINEES WITH COMPLAINTS :	10	(66.7 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 15 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	3	20.0
PAIN/SORENESS, INJ. SITE	2	13.3
ERYTHEMA, INJECTION SITE	1	6.7
SYSTEMIC REACTIONS	10	66.7
IRRITABILITY	10	66.7
NASAL DISCHARGE	2	13.3
PROLONGED CRYING, >1/2 HR	2	13.3
CERUMEN IMPACTION	1	6.7
COUGH	1	6.7
CRYING	1	6.7
RASH	1	6.7
SINUSITIS, CHRONIC	1	6.7
TEETHING	1	6.7

TABLE 4 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY
ADMINISTERED AS TWO INJECTINS ONE MONTH APART

INVESTIGATOR : ANDERSON, EDWIN
STUDY : 087001
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CL466
DOSE : 10 MCG
POPULATION : HEALTHY CHILDREN
AGE RANGE : 2- 6 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE - SALINE INJECTION: 2	
TOTAL VACCINEES :	14	
VACCINEES WITH NO COMPLAINTS :	4	(28.6 %)
VACCINEES WITH COMPLAINTS :	10	(71.4 %)
VACCINEES WITH NO DATA :	0	

CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 14 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	7	50.0
INDURATION, INJECTION SITE	2	14.3
PAIN/SORENESS, INJ. SITE	2	14.3
ECCHYMOSIS, INJECTION SITE	1	7.1
ERYTHEMA, INJ. SITE (<=1 IN.)	1	7.1
ERYTHEMA, INJ. SITE (>1 INCH)	1	7.1
ERYTHEMA, INJECTION SITE	1	7.1
SYSTEMIC REACTIONS	6	42.9
IRRITABILITY	5	35.7
PROLONGED CRYING, >1/2 HR	1	7.1

TABLE 4 (cont.)

C L I N I C A L C O M P L A I N T S B Y F R E Q U E N C Y
ADMINISTERED AS TWO INJECTINS ONE MONTH APART

INVESTIGATOR : ANDERSON, EDWIN
STUDY : 087001
VACCINE : HIB CONJUGATE - ALUM
LOT NUMBER : CM679
DOSE : 13 MCG
POPULATION : HEALTHY CHILDREN
AGE RANGE : 2- 6 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE	HIB CONJUGATE INJECTION: 1	
TOTAL VACCINEES	14	
VACCINEES WITH NO COMPLAINTS	7	(50.0 %)
VACCINEES WITH COMPLAINTS	7	(50.0 %)
VACCINEES WITH NO DATA	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 14 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	3	21.4
ERYTHEMA, INJ. SITE (<=1 IN.)	1	7.1
ERYTHEMA, INJ. SITE (>1 INCH)	1	7.1
INDURATION, INJECTION SITE	1	7.1
INFLAMMATION, INJ. SITE	1	7.1
SYSTEMIC REACTIONS	4	28.6
IRRITABILITY	2	14.3
COUGH	1	7.1
NASAL DISCHARGE	1	7.1
VOMITING	1	7.1

TABLE 4 (cont.)

CLINICAL COMPLAINTS BY FREQUENCY
ADMINISTERED AS TWO INJECTINS ONE MONTH APART

INVESTIGATOR : ANDERSON, EDWIN
STUDY : 087001
VACCINE : HIB CONJUGATE - ALUM
LOT NUMBER : CM679
DOSE : 13 MCG
POPULATION : HEALTHY CHILDREN
AGE RANGE : 2- 6 MOS.
DAYS OF FOLLOWUP : DAYS 0 TO 5

VACCINE :	HIB CONJUGATE INJECTION: 2	
TOTAL VACCINEES :	12	
VACCINEES WITH NO COMPLAINTS :	6	(50.0 %)
VACCINEES WITH COMPLAINTS :	6	(50.0 %)
VACCINEES WITH NO DATA :	0	
CLINICAL COMPLAINTS	NO. OF VACCINEES WITH CLINICAL COMP.	% BASED ON 12 VACCINEES
LOCAL REACTIONS (INJECTION SITE)	2	16.7
INDURATION, INJECTION SITE	2	16.7
ERYTHEMA, INJ. SITE (<=1 IN.)	1	8.3
SYSTEMIC REACTIONS	5	41.7
IRRITABILITY	4	33.3
COUGH	2	16.7
NASAL DISCHARGE	1	8.3

TABLE 5

PATIENT COUNT CLINICAL COMPLAINTS
ADMINISTERED AS TWO INJECTIONS ONE MONTH APART

INVESTIGATOR : ANDERSON, EDWIN
STUDY : 087001
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CL466
DOSE : 10 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2- 6 MOS.

VACCINE : HIB CONJUGATE - SALI	NUMBER OF VACCINEES (15 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		
LOCAL REACTIONS	2 (14.3%)	1 (6.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		3 (20.0%)
ERYTHEMA, INJECTION SITE	1 (7.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (6.7%)
PAIN/SORENESS, INJ. SITE	1 (7.1%)	1 (6.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (13.3%)
SYSTEMIC	8 (57.1%)	5 (33.3%)	3 (20.0%)	4 (26.7%)	0 (0.0%)	0 (0.0%)		10 (66.7%)
DIGESTIVE SYSTEM	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (6.7%)	0 (0.0%)	0 (0.0%)		1 (6.7%)
TEETHING	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (6.7%)	0 (0.0%)	0 (0.0%)		1 (6.7%)
NERVOUS SYSTEM & PSYCHIATRIC	8 (57.1%)	4 (26.7%)	2 (13.3%)	1 (6.7%)	0 (0.0%)	0 (0.0%)		10 (66.7%)
CRYING	0 (0.0%)	1 (6.7%)	1 (6.7%)	1 (6.7%)	0 (0.0%)	0 (0.0%)		1 (6.7%)
IRRITABILITY	8 (57.1%)	4 (26.7%)	2 (13.3%)	1 (6.7%)	0 (0.0%)	0 (0.0%)		10 (66.7%)
PROLONGED CRYING, >1/2 HR	2 (14.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (13.3%)
RESPIRATORY SYSTEM	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (13.3%)	0 (0.0%)	0 (0.0%)		2 (13.3%)

TABLE 5 (cont.)

PATIENT COUNT CLINICAL COMPLAINTS
ADMINISTERED AS TWO INJECTIONS ONE MONTH APART

INVESTIGATOR : ANDERSON, EDWIN
STUDY : 087001
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CL466
DOSE : 10 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2- 6 MOS.

VACCINE : HIB CONJUGATE - SALI	NUMBER OF VACCINEES (15 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		
COUGH	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (6.7%)	0 (0.0%)	0 (0.0%)		1 (6.7%)
NASAL DISCHARGE	0 (0.0%)	0 (0.0%)	0 (0.0%)	2 (13.3%)	0 (0.0%)	0 (0.0%)		2 (13.3%)
SINUSITIS, CHRONIC	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (6.7%)	0 (0.0%)	0 (0.0%)		1 (6.7%)
SKIN & SKIN APPENDAGE	0 (0.0%)	1 (6.7%)	1 (6.7%)	1 (6.7%)	0 (0.0%)	0 (0.0%)		1 (6.7%)
RASH	0 (0.0%)	1 (6.7%)	1 (6.7%)	1 (6.7%)	0 (0.0%)	0 (0.0%)		1 (6.7%)
SPECIAL SENSES	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (6.7%)	0 (0.0%)	0 (0.0%)		1 (6.7%)
CERUMEN IMPACTION	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (6.7%)	0 (0.0%)	0 (0.0%)		1 (6.7%)
VACCINEES WITH COMPLAINTS	8 (57.1%)	5 (33.3%)	3 (20.0%)	4 (26.7%)	0 (0.0%)	0 (0.0%)		10 (66.7%)
VACCINEES WITH NO COMPLAINTS	6 (42.9%)	10 (66.7%)	12 (80.0%)	11 (73.3%)	3 (100.0%)	2 (100.0%)		5 (33.3%)
TOTAL VACCINEES REPORTING	14	15	15	15	3	2		15
VACCINEES WITH NO DATA	1	0	0	0	12	13		0

TABLE 5 (cont.)

PATIENT COUNT CLINICAL COMPLAINTS
ADMINISTERED AS TWO INJECTIONS ONE MONTH APART

INVESTIGATOR : ANDERSON, EDWIN
STUDY : 087001
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CL466
DOSE : 10 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2- 6 MOS.

VACCINE : HIB CONJUGATE - SALI	NUMBER OF VACCINEES (14 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
LOCAL REACTIONS	4 (28.6%)	5 (35.7%)	1 (7.1%)	1 (7.1%)	1 (50.0%)	1 (50.0%)		7 (50.0%)
ECCHYMOSIS, INJECTION SITE	0 (0.0%)	0 (0.0%)	1 (7.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (7.1%)
ERYTHEMA, INJECTION SITE	0 (0.0%)	1 (7.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (7.1%)
ERYTHEMA, INJ. SITE (>1 INCH)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (7.1%)	1 (50.0%)	1 (50.0%)		1 (7.1%)
ERYTHEMA, INJ. SITE (<=1 IN.)	1 (7.1%)	1 (7.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (7.1%)
INDURATION, INJECTION SITE	1 (7.1%)	2 (14.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (14.3%)
PAIN/SORENESS, INJ. SITE	2 (14.3%)	1 (7.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (14.3%)
SYSTEMIC	5 (35.7%)	1 (7.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		6 (42.9%)
NERVOUS SYSTEM & PSYCHIATRIC	5 (35.7%)	1 (7.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		6 (42.9%)
IRRITABILITY	4 (28.6%)	1 (7.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		5 (35.7%)
PROLONGED CRYING, >1/2 HR	1 (7.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (7.1%)

TABLE 5 (cont.)

PATIENT COUNT CLINICAL COMPLAINTS
ADMINISTERED AS TWO INJECTIONS ONE MONTH APART

INVESTIGATOR : ANDERSON, EDWIN
STUDY : 087001
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CL466
DOSE : 10 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2- 6 MOS.

VACCINE : HIB CONJUGATE - SALI	NUMBER OF VACCINEES (14 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		**********
VACCINEES WITH COMPLAINTS	7 (50.0%)	6 (42.9%)	1 (7.1%)	1 (7.1%)	1 (50.0%)	1 (50.0%)		10 (71.4%)
VACCINEES WITH NO COMPLAINTS	7 (50.0%)	8 (57.1%)	13 (92.9%)	13 (92.9%)	1 (50.0%)	1 (50.0%)		4 (28.6%)
TOTAL VACCINEES REPORTING	14	14	14	14	2	2		14
VACCINEES WITH NO DATA	0	0	0	0	12	12		0

TABLE 5 (cont.)

PATIENT COUNT CLINICAL COMPLAINTS
ADMINISTERED AS TWO INJECTIONS ONE MONTH APART

INVESTIGATOR : ANDERSON, EDWIN
STUDY : 087001
VACCINE : HIB CONJUGATE - ALUM
LOT NUMBER : CM679
DOSE : 13 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2- 6 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (14 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
LOCAL REACTIONS	2 (14.3%)	2 (14.3%)	1 (7.1%)	1 (7.1%)	0 (0.0%)	0 (0.0%)		3 (21.4%)
ERYTHEMA, INJ. SITE (>1 INCH)	1 (7.1%)	1 (7.1%)	1 (7.1%)	1 (7.1%)	0 (0.0%)	0 (0.0%)		1 (7.1%)
ERYTHEMA, INJ. SITE (<=1 IN.)	0 (0.0%)	1 (7.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (7.1%)
INDURATION, INJECTION SITE	1 (7.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (7.1%)
INFLAMMATION, INJ. SITE	1 (7.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (7.1%)
SYSTEMIC	2 (14.3%)	1 (7.1%)	2 (14.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		4 (28.6%)
DIGESTIVE SYSTEM	0 (0.0%)	1 (7.1%)	1 (7.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (7.1%)
VOMITING	0 (0.0%)	1 (7.1%)	1 (7.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (7.1%)
NERVOUS SYSTEM & PSYCHIATRIC	1 (7.1%)	0 (0.0%)	1 (7.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (14.3%)
IRRITABILITY	1 (7.1%)	0 (0.0%)	1 (7.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (14.3%)
RESPIRATORY SYSTEM	1 (7.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (7.1%)

TABLE 5 (cont.)

PATIENT COUNT CLINICAL COMPLAINTS
ADMINISTERED AS TWO INJECTIONS ONE MONTH APART

INVESTIGATOR : ANDERSON, EDWIN
STUDY : 087001
VACCINE : HIB CONJUGATE - ALUM
LOT NUMBER : CM679
DOSE : 13 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2- 6 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (14 VACCINEES) - INJECTION: 1							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		
COUGH	1 (7.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (7.1%)
NASAL DISCHARGE	1 (7.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (7.1%)
VACCINEES WITH COMPLAINTS	4 (28.6%)	3 (21.4%)	3 (21.4%)	1 (7.1%)	0 (0.0%)	0 (0.0%)		7 (50.0%)
VACCINEES WITH NO COMPLAINTS	10 (71.4%)	11 (78.6%)	11 (78.6%)	13 (92.9%)	2 (100.0%)	1 (100.0%)		7 (50.0%)
TOTAL VACCINEES REPORTING	14	14	14	14	2	1		14
VACCINEES WITH NO DATA	0	0	0	0	12	13		0

TABLE 5 (cont.)

PATIENT COUNT CLINICAL COMPLAINTS
ADMINISTERED AS TWO INJECTIONS ONE MONTH APART

INVESTIGATOR : ANDERSON, EDWIN
STUDY : 087001
VACCINE : HIB CONJUGATE - ALUM
LOT NUMBER : CM679
DOSE : 13 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2- 6 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (12 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3	4	5		
LOCAL REACTIONS	2 (16.7%)	2 (16.7%)	1 (8.3%)	1 (8.3%)	0 (0.0%)	0 (0.0%)		2 (16.7%)
ERYTHEMA, INJ. SITE (<=1 IN.)	1 (8.3%)	1 (8.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (8.3%)
INDURATION, INJECTION SITE	1 (8.3%)	1 (8.3%)	1 (8.3%)	1 (8.3%)	0 (0.0%)	0 (0.0%)		2 (16.7%)
SYSTEMIC	2 (16.7%)	1 (8.3%)	3 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		5 (41.7%)
NERVOUS SYSTEM & PSYCHIATRIC	2 (16.7%)	0 (0.0%)	2 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		4 (33.3%)
IRRITABILITY	2 (16.7%)	0 (0.0%)	2 (16.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		4 (33.3%)
RESPIRATORY SYSTEM	0 (0.0%)	1 (8.3%)	1 (8.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (16.7%)
COUGH	0 (0.0%)	1 (8.3%)	1 (8.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		2 (16.7%)
NASAL DISCHARGE	0 (0.0%)	1 (8.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (8.3%)
VACCINEES WITH COMPLAINTS	4 (33.3%)	3 (25.0%)	3 (25.0%)	1 (8.3%)	0 (0.0%)	0 (0.0%)		6 (50.0%)
VACCINEES WITH NO COMPLAINTS	8 (66.7%)	9 (75.0%)	9 (75.0%)	11 (91.7%)	0 (0.0%)	0 (0.0%)		6 (50.0%)

TABLE 5 (cont.)

PATIENT COUNT CLINICAL COMPLAINTS
ADMINISTERED AS TWO INJECTIONS ONE MONTH APART

INVESTIGATOR : ANDERSON, EDWIN
STUDY : 087001
VACCINE : HIB CONJUGATE - ALUM
LOT NUMBER : CM679
DOSE : 13 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2- 6 MOS.

VACCINE : HIB CONJUGATE	NUMBER OF VACCINEES (12 VACCINEES) - INJECTION: 2							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3	4	5		COMPLAINTS
TOTAL VACCINEES REPORTING	12	12	12	12	0	0		12
VACCINEES WITH NO DATA	0	0	0	0	12	12		0

TABLE 6

PATIENT COUNT MAXIMUM TEMPERATURES
ADMINISTERED AS TWO INJECTIONS ONE MONTH APART

INVESTIGATOR : ANDERSON, EDWIN
STUDY : 087001
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CL466
DOSE : 10 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2- 6 MOS.

MAX TEMPERATURE (DEG F, ORAL)	NUMBER OF VACCINEES (15 VACCINEES) - INJECTION 1							NUMBER WITH MAX TEMP
	DAYS POST VACCINATION							
	0	1	2	3	4	5		
< 99	9 (60.0%)	12 (80.0%)	12 (80.0%)	15 (100.0%)	10 (83.3%)	8 (80.0%)		4 (26.7%)
99 - 99.9	6 (40.0%)	3 (20.0%)	1 (6.7%)	0 (0.0%)	2 (16.7%)	2 (20.0%)		9 (60.0%)
100 - 100.9	0 (0.0%)	0 (0.0%)	1 (6.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (6.7%)
101 - 101.9	0 (0.0%)	0 (0.0%)	1 (6.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (6.7%)
TEMPERATURE TAKEN	15 (100.0%)	15 (100.0%)	15 (100.0%)	15 (100.0%)	12 (80.0%)	10 (66.7%)		15 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	3 (20.0%)	5 (33.3%)		0 (0.0%)

TABLE 6 (cont.)

PATIENT COUNT MAXIMUM TEMPERATURES
ADMINISTERED AS TWO INJECTIONS ONE MONTH APART

INVESTIGATOR : ANDERSON, EDWIN
STUDY : 087001
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CL466
DOSE : 10 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2- 6 MOS.

MAX TEMPERATURE (DEG F, ORAL)	NUMBER OF VACCINEES (14 VACCINEES) - INJECTION 2							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
	0	1	2	3	4	5		
< 99	12 (85.7%)	12 (85.7%)	12 (85.7%)	10 (71.4%)	8 (88.9%)	8 (100.0%)		7 (50.0%)
99 - 99.9	2 (14.3%)	1 (7.1%)	2 (14.3%)	4 (28.6%)	1 (11.1%)	0 (0.0%)		6 (42.9%)
100 - 100.9	0 (0.0%)	1 (7.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)		1 (7.1%)
TEMPERATURE TAKEN	14 (100.0%)	14 (100.0%)	14 (100.0%)	14 (100.0%)	9 (64.3%)	8 (57.1%)		14 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	5 (35.7%)	6 (42.9%)		0 (0.0%)

TABLE 6 (cont.)

PATIENT COUNT MAXIMUM TEMPERATURES
ADMINISTERED AS TWO INJECTIONS ONE MONTH APART

INVESTIGATOR : ANDERSON, EDWIN
STUDY : 087001
VACCINE : HIB CONJUGATE - ALUM
LOT NUMBER : CM679
DOSE : 13 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2- 6 MOS.

	NUMBER OF VACCINEES (14 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3	4	5		WITH MAX TEMP
< 99	11 (84.6%)	10 (71.4%)	10 (71.4%)	13 (92.9%)	3 (100.0%)	3 (100.0%)		7 (50.0%)
99 - 99.9	2 (15.4%)	4 (28.6%)	4 (28.6%)	1 (7.1%)	0 (0.0%)	0 (0.0%)		7 (50.0%)
TEMPERATURE TAKEN	13 (92.9%)	14 (100.0%)	14 (100.0%)	14 (100.0%)	3 (21.4%)	3 (21.4%)		14 (100.0%)
TEMPERATURE NOT TAKEN	1 (7.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	11 (78.6%)	11 (78.6%)		0 (0.0%)

TABLE 6 (cont.)

PATIENT COUNT MAXIMUM TEMPERATURES
ADMINISTERED AS TWO INJECTIONS ONE MONTH APART

INVESTIGATOR : ANDERSON, EDWIN
STUDY : 087001
VACCINE : HIB CONJUGATE - ALUM
LOT NUMBER : CM679
DOSE : 13 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2- 6 MOS.

MAX TEMPERATURE (DEG F, ORAL)	NUMBER OF VACCINEES (12 VACCINEES) - INJECTION 2							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
	0	1	2	3	4	5		
< 99	10 (83.3%)	6 (50.0%)	9 (75.0%)	11 (91.7%)	3 (100.0%)	3 (100.0%)		5 (41.7%)
99 - 99.9	2 (16.7%)	6 (50.0%)	3 (25.0%)	1 (8.3%)	0 (0.0%)	0 (0.0%)		7 (58.3%)
TEMPERATURE TAKEN	12 (100.0%)	12 (100.0%)	12 (100.0%)	12 (100.0%)	3 (25.0%)	3 (25.0%)		12 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	9 (75.0%)	9 (75.0%)		0 (0.0%)

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IMMUNOGENICITY IN INFANTS OF HAEMOPHILUS INFLUENZAE TYPE B POLYSACCHARIDE IN A CONJUGATE VACCINE WITH NEISSERIA MENINGITIDIS OUTER-MEMBRANE PROTEIN

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Summary 63 children, aged 2–17 months, were given a new conjugate vaccine composed of the capsular polysaccharide of *Haemophilus influenzae* type b linked to a *Neisseria meningitidis* outer-membrane protein. Subjects under 7 months received two injections separated by 1 month, and older subjects received either one or two injections. There were no systemic reactions to this vaccine when it was given with aluminium hydroxide. A single injection of vaccine was highly immunogenic; the geometric mean serum anticapsular antibody concentrations before immunisation and 1 month later were 0·35 μg/ml and 0·98 μg/ml for babies of 2–3 months, 0·12 μg/ml and 1·85 μg/ml for those of 4–6 months, and 0·15 μg/ml and 4·1 μg/ml for those of 8–17 months ($p \leq 0.003$ for each age group). After a second injection of vaccine, 80% and 76% of infants of 2–3 and 4–6 months, respectively, had antibody concentrations > 1·0 μg/ml. Most subjects showed evidence of IgG responses as measured by enzyme-linked immunosorbent assay. 6–12 months after immunisation, serum antibody levels had fallen ($p < 0.05$) but they remained higher than those of unimmunised controls ($p < 0.001$).

Introduction

SERUM antibodies against the capsular polysaccharide of *Haemophilus influenzae* type b confer protection against invasive *H influenzae* type b disease.[1,2] In a field study in Finland, a capsular polysaccharide vaccine was protective in children older than 18–23 months,[2,3] but not in younger children. To date, the most successful approach to enhance the immunogenicity of the *H influenzae* type b polysaccharide is based on the hapten-carrier concept.[4] In animals[5] and in human beings[6] the immune response to the polysaccharide can be enhanced by covalently coupling it to a protein. In contrast to the plain polysaccharide vaccine, *H influenzae* type b conjugate vaccines elicit booster responses of antibody against capsular polysaccharide.[5,7] Several prototype conjugate vaccines have been reported to be immunogenic in infants as young as 6–7 months. However, the responses of infants younger than 6 months to one or two injections of vaccine have been meagre.[8,9] Infants in this age group account for approximately 20% of cases of *H influenzae* type b meningitis in the continental United States[10] and for approximately 35–50% of cases in Eskimos in Alaska.[11,12]

A conjugate vaccine composed of the *H influenzae* type b polysaccharide and an outer-membrane protein of *Neisseria meningitidis* group B was prepared at Merck Sharp and Dohme Research Laboratories, West Point, Pennsylvania. Both the coupling method and the protein carrier were different from those used to construct other experimental conjugate vaccines. The purpose of our study was to determine the safety and immunogenicity of this vaccine in children aged 2–17 months. Preliminary data from animal studies suggested that the vaccine was more immunogenic when administered with aluminium hydroxide than with saline alone. Therefore, we also compared the clinical and serological responses to the vaccine reconstituted with and without aluminium hydroxide.

Patients and Methods

Vaccine

The conjugate vaccine consists of the *H influenzae* type b capsular polysaccharide (molecular weight approximately 500 Kd by gel filtration on 'CL-4B Sepharose') covalently coupled to a meningococcal outer-membrane protein. Preparation and characterisation of the conjugate have been described elsewhere.[13] In brief, the solvent dimethylformamide and a column of tetra-n-butyl-ammonium-'Dowex-50' were used to form a soluble polysaccharide-$(butyl)_4$ ammonium salt; the polysaccharide was then sequentially activated by carbonyl di-imidazole and 1,4-butane diamine; the resulting pendant aminoalkyl groups were then bromoacetylated. A 40 Kd outer-membrane protein[14] was purified from group B *N meningitidis* (strain B-11, from Dr M. Artenstein,

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Walter Reed Army Institute of Research, Washington, DC[15]). The protein was independently activated with the introduction of pendant thiol groups by acylation with N-acetyl-homocysteine thiolactone. The activated polysaccharide and outer-membrane protein then reacted together to give a covalent conjugate containing a thioether linkage. This linkage is resistant to acid hydrolysis, so a novel aminoacid (S-carboxymethyl homocysteine) is produced by acid hydrolysis. Therefore, formation of the predicted thioether linkage was monitored by the S-carboxymethyl homocysteine content of the acid hydrolysis digest of the vaccine.

Two lots of vaccine were tested. A 0·5 ml dose of vaccine from lot 1 (1003/C-L680) contained 7 μg polysaccharide and 43 μg outer-membrane protein; the same volume of vaccine from lot 2 (1002/C-L466) contained 10 μg polysaccharide and 62 μg outer-membrane protein. The vaccine passed all safety and toxicity tests in animals. The endotoxin content of both vaccines was 1–6 μg/ml by Limulus lysate assay. Lot 1 was also assayed for glucosamine;[16] it was estimated to contain 0·25 μg/ml lipopolysaccharide. Both lots of vaccine were provided lyophilised and were stored at or below −40°C. After rehydration the vaccine was used within 1–4 h. The diluents used contained either sodium chloride or aluminium hydroxide; the same diluent was used for all injections in a particular subject.

Design

The study subjects were: 6 healthy adult volunteers from the staff of Washington University; 52 healthy children, 2–17 months old, recruited from private practices of paediatricians in St Louis or Batavia; and 11 healthy children, 2–6 months old, from private practices in Huntington, West Virginia. Of the 63 children, 32 were male and 31 female, 60 white and 3 black. No subject had a history of *H influenzae* type b disease. Informed consent was obtained from the adults and from one or both parents of the children. The protocol was approved by the IND Branch of the National Center for Drugs and Biologics (under BB-IND-1966) and local ethical committees.

Subjects were not enrolled if there was any indication of previous substantial adverse reactions to vaccines or an underlying immunodeficiency. Other reasons for exclusion were diphtheria-typhoid-pertussis vaccination in the preceding 10 days and a febrile illness (> 37·9°C) in the preceding 1–3 days.

To verify the safety of lot 1, 6 adults were given 0·5 ml vaccine with aluminium hydroxide by deep intramuscular injection into the deltoid muscle; no substantial reactions occurred. The first phase of the study in children was designed to compare the safety and immunogenicity of the same lot of vaccine given with either aluminium hydroxide or saline. 26 children (2–17 months) were randomly assigned to receive vaccine with either aluminium hydroxide or saline. Two injections of 0·5 ml were given 4 weeks apart by deep intramuscular injection into the quadriceps femoris. The second injection was not given if a substantial adverse reaction occurred after the first. After completion of this phase, it was apparent that side-effects were more common after saline injections than after aluminium hydroxide injections ($p < 0·001$). Therefore, only vaccine with aluminium hydroxide was used to immunise 26 other children. Also, because one injection of the vaccine was found to be highly immunogenic in most older children, only one injection was given routinely to children older than 8 months.

11 infants (2–6 months from West Virginia) were immunised with lot 2 by the same protocol, except that the dose was 10 μg capsular polysaccharide instead of 7 μg, and all children received vaccine suspended in saline.

Clinical Observations

At enrolment, a brief medical and immunisation history was taken. Before each injection the temperature, heart rate, respiratory rate, and weight were recorded. The child was observed for evidence of an immediate reaction for 15 min after the injection. A reporting card was given to the parents, who were instructed to record the child's axillary temperature and any local or systemic reactions, 4 h, 24 h, 48 h, and 72 h after the injection. In addition, all parents were contacted 24 h after the injection to ensure that any adverse reactions during that period were reported. Systemic reaction was defined as fever (temperature > 38°C during the 72 h after immunisation) or persistent crying for more than 1 h. Local reactions were swelling or redness at the injection site ≥ 1·5 cm or pain in the leg associated with reduced use of the leg.

Serology

Serum samples were obtained before vaccination and 1 month after the first and second injections (when applicable). In West Virginia, serum samples were obtained before immunisation and 1 month after the second injection. All samples were assayed at Washington University and at Merck Sharp and Dohme Research Laboratories. The results from the two laboratories were highly correlated ($r = 0·9$) and only the data from Washington University are reported. Total serum antibody against capsular polysaccharide was measured by the radioantigen binding assay of Kuo et al,[17] except that iodine-125 rather than tritium[6,18] was used to label the antigen. IgG antibody against capsular polysaccharide was measured by enzyme-linked immunosorbent assay (ELISA) with the type b polysaccharide coupled to poly-L-lysine as the antigen on the plate.[18] IgG antibody concentrations were determined by comparing the titration curve of the test serum samples with that obtained with the US Bureau of Biologics *H influenzae* type b immune reference pool. Undiluted, this reference pool was found to have an IgG antibody concentration of 62 μg/ml. All serum samples were tested at dilutions of 1/100 or greater, and all samples from each subject were assayed together. The sensitivity of the assay was approximately 0·4 μg/ml.

Statistics

Student's *t* test was used to compare the geometric mean concentrations of serum antibody between groups given vaccine in aluminium hydroxide and vaccine in saline. A *t* test (one-tailed) was used to compare the geometric mean antibody concentrations before and after immunisation within a group. Analysis of response was done on logarithmically transformed data. A chi-square test was used to compare the rates of adverse reactions in the different groups.

Results

All 6 adults given vaccine with aluminium hydroxide experienced only mild pain and tenderness at the injection site. These reactions were greatest 4 h after vaccination and resolved gradually within 48 h. 111 doses of vaccine (46 saline, 65 aluminium hydroxide) were given to 63 children (24 saline, 39 aluminium hydroxide). The frequency of systemic or local reactions was not related to the age of the subjects, the number of injections, the vaccine lot, or the dose. Therefore, the rates of reaction in all children were combined. 10 (22%) injections of vaccine in saline but none of vaccine with aluminium hydroxide were associated with possible adverse systemic reactions ($p < 0·001$)—fever (38·2°–40°C) in 8 children and persistent crying for 1–4 h in 2 children. The children were also irritable and 3 had varying degrees of local reaction. In 6 of the 10 children, the systemic reactions were noted within 4 h of vaccine administration and resolved by approximately 24 h. In the other 4 fever began 48 h after injection, without local reactions. 2 of these children had evidence of otitis media at the time of the fever.

Local reactions occurred after 9 injections (8%); 7 (15%) were associated with vaccine in saline and 2 (3%) with vaccine in aluminium hydroxide ($p = 0·02$). The 2 reactions to vaccine in aluminium hydroxide were very slight (1·5–3·0 cm of erythema or swelling associated with pain or tenderness), whereas 2 of the 7 reactions to vaccine in saline were more severe (erythema, pain, and swelling in a wide area of the thigh above and below the injection site).

The antibody responses did not differ significantly with

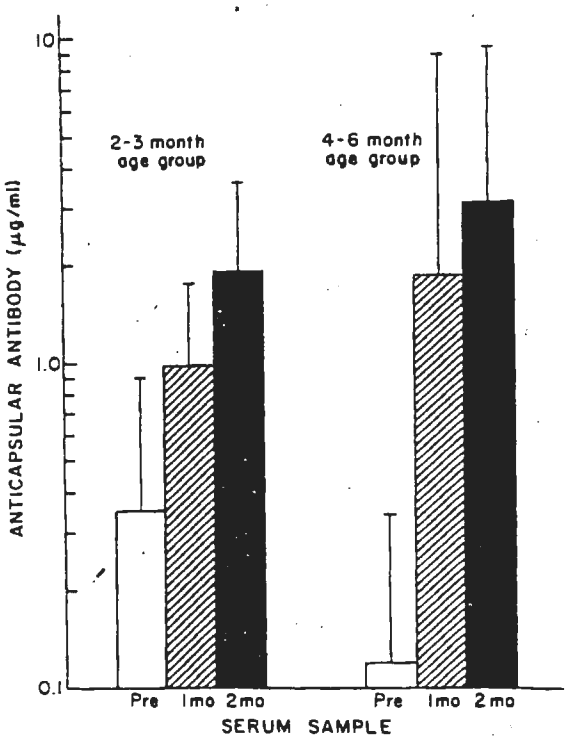

Fig 1—Geometric mean (SD) serum anticapsular-polysaccharide antibody levels in 17 infants aged 2–3 months and 21 infants aged 4–6 months at initial injection.

vaccine lot or dose or the diluent used so the results were combined. Subjects aged 8–17 months had high antibody responses to one injection of the vaccine. The geometric mean serum antibody concentrations before immunisation and 1 month later were 0·15 μg/ml and 4·1 μg/ml ($p < 0·001$). 84% of the 25 subjects had postimmunisation levels of antibody against capsular polysaccharide > 1·0 μg/ml. In a previous study with the plain polysaccharide vaccine[19,20] this postimmunisation level correlated with protection.

Fig 1 summarises the antibody responses of the 38 infants, aged 2–6 months, who were immunised routinely with two injections of conjugate vaccine, separated by a month. In this age group, a single injection was also immunogenic. In infants aged 2–3 months at first injection there were significant rises in antibody levels after both first (from 0·35 μg/ml to 0·98 μg/ml; $p = 0·003$) and second (to 1·9 μg/ml; $p = 0·005$) injections. In infants aged 4–6 months the rise in antibody level after the first injection was significant (from 0·12 μg/ml to 1·85 μg/ml; $p < 0·001$) but the rise after the second injection (to 3·1 μg/ml) was not significant. There were no significant differences between the age groups in the antibody levels achieved. After two injections, 80% of subjects immunised at 2–3 months and 76% of those immunised at 4–6 months had serum antibody concentrations > 1·0 μg/ml.

The radioantigen binding assay measures all antibody (IgM, IgG, and IgA) against the capsular polysaccharide. We were interested to see whether the immunised subjects showed specific IgG responses, since in vitro in the presence of complement, IgG antibody against capsular polysaccharide is more opsonic than IgM.[21,22] IgG antibody also persists longer in serum than IgM and, therefore, is likely to confer longer-lasting protection. Infants 2–3 and 4–6 months of age showed significant ($p < 0·01$) increases in

IgG ANTICAPSULAR ANTIBODY RESPONSES OF IMMUNISED CHILDREN BY ELISA

Age	No tested	Geometric mean (μg/ml)		% with ≥ two-fold rise
		Before immunisation	1 mo after second injection	
2–3 mo	15	<0·4	0·88	54
4–6 mo	21	<0·4	2·08	76

IgG antibody 1 month after the second injection (table). The geometric mean postimmunisation antibody level was significantly higher in the 4–6-month-olds than in the younger babies ($p = 0·02$). 54% of the younger babies and 76% of the older ones showed greater than two-fold increases in antibody. However, this is a minimum estimate of response, particularly in the younger age group. For example, 3 infants had high antibody levels before immunisation (reflecting maternal antibody). The antibody levels in these infants increased after immunisation but did not show a two-fold rise. (In the absence of immunisation, the levels would probably have declined.)

To date, serum samples have been obtained 6–12 months (mean ± SD = 7·3 ± 1·8) after the last injection of vaccine from 31 children. The antibody concentrations in these samples are shown in fig 2. The geometric means of the serum antibody levels declined significantly during the follow-up period ($p < 0·05$), from 1·8 μg/ml to 0·8 μg/ml in infants immunised at 2–6 months and from 4·9 μg/ml to 1·0 μg/ml in those immunised at 8–17 months. Nevertheless,

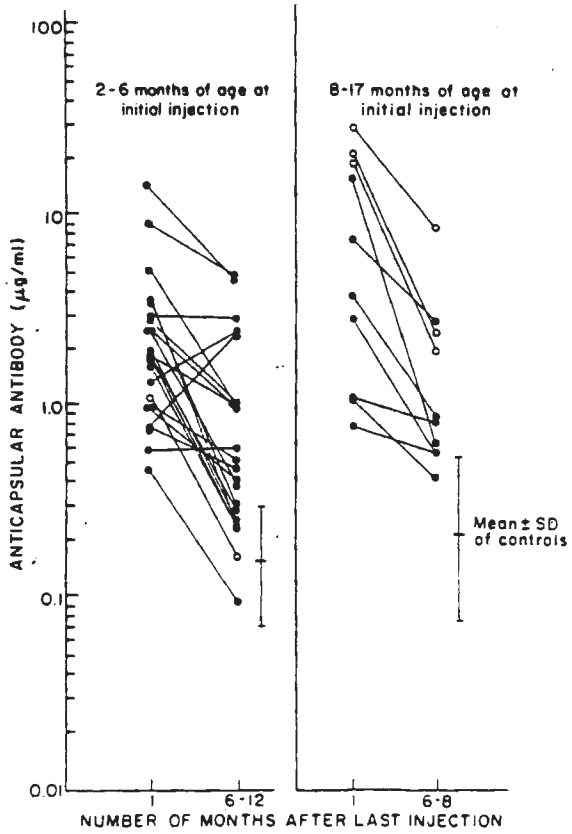

Fig 2—Serum anticapsular-polysaccharide antibody concentrations 6–12 months after immunisation.

○ = one injection only; ● = two injections 4 weeks apart.

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the levels at follow-up were significantly higher than those of 67 unimmunised children[23] of comparable age ($p \leq 0.001$).

Discussion

This conjugate vaccine, when administered with aluminium hydroxide, was well tolerated in both adults and infants. No systemic reactions were observed and slight local reactions occurred with only 3% of injections. In contrast, when the vaccine was given in saline alone reactions, both systemic and local, were frequent. The lower reaction rate with aluminium hydroxide may result from slower systemic release of vaccine adsorbed to aluminium hydroxide.

The vaccine was highly immunogenic, even in infants of 2–6 months. After one injection, the geometric mean increase in antibody concentration in infants of 2–6 months was 7·2 fold ($p < 0.001$), and two-thirds of subjects showed serum antibody levels > 1 μg/ml. In contrast, in previous trials with other *H influenzae* type b conjugate vaccines, infants of this age showed either a fall or no significant rise in total serum antibody levels after one or two injections of vaccine.[8,9] It is unlikely that the different results reflect differences in the assays between laboratories. Our results are based on two different assays and comparable results were obtained independently with the same samples at Merck Sharp and Dohme Laboratories. The greater antibody responses of the infants in our study may relate to the vaccine's carrier protein, a group-B meningococcal outer-membrane protein containing a small amount of endotoxin, or to the novel method used for coupling the polysaccharide to the protein.

The presence of high levels of maternal antibody in very young infants did not prevent a strong response to the vaccine. However, in babies aged 2–3 months there was a trend towards an inverse correlation between antibody levels before and after immunisation ($r = -0.47$, $p = 0.08$). There were no significant differences in the responses of infants immunised with two different lots of vaccine at slightly different doses (postimmunisation geometric means of 2·4 μg/ml and 2·8 μg/ml in infants immunised at 2–6 months of age in St Louis and West Virginia, respectively). We have also tested a third lot of vaccine in approximately 80 subjects (2–17 months) and have observed comparable immunogenicity and low reactivity (unpublished).

Much evidence indicates that serum antibody against the capsular polysaccharide protects against invasive *H influenzae* type b disease.[2,3] However, the precise level of antibody required to confer protection is not known. Previous estimates of 0·15 μg/ml of antibody after immunisation are probably too low and a concentration as high as 1·0 μg/ml may be required.[19,20] Furthermore, the contributions of other immunological mechanisms to protection of infants are not well understood. These questions are particularly relevant for the children who show a fall in serum antibody levels in the 6–12 months after immunisation (fig 2). A study with another *H influenzae* type b conjugate vaccine showed that children primed with conjugate vaccine had higher responses to a subsequent injection of conventional *H influenzae* polysaccharide vaccine than children who had not received conjugate vaccine.[9] We have made similar observations in children primed with the polysaccharide/outer-membrane-protein vaccine (unpublished). Thus, some immunised children may remain protected against disease, even in the face of declining serum antibodies, as a result of immunological priming.

Preliminary data indicate that the antibody produced by immunisation of our subjects with the polysaccharide/outer-membrane-protein conjugate vaccine activates complement-mediated bactericidal activity in vitro and confers protection against bacteraemia in infant rats (unpublished, Merck Sharp and Dohme Research Laboratories). These data suggest that the antibody elicited by the vaccine is biologically active and that the antigenic activity of the polysaccharide was preserved during coupling to the protein.

We thank Kathleen McCollough and Judy Adams, RN, for technical assistance and Dr K. Lynn Cates, University of Connecticut School of Medicine, for helpful comments. This work was supported by Merck Sharp and Dohme Research Laboratories and by US Public Health Service grants RO1 AI 17962 and National Research Service Award T32 AI 07172, from the National Institute of Allergy and Infectious Diseases, and RR-36, from the General Clinical Research Center Branch, National Institutes of Health.

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REFERENCES

1. Anderson P, Johnston RB Jr, Smith DH. Human serum activities against *Haemophilus influenzae* type b. *J Clin Invest* 1972; 51: 31–38.
2. Peltola H, Käyhty H, Sivonen A, Mäkelä PH. *Haemophilus influenzae* type b capsular polysaccharide vaccine in children: a double-blind field study of 100,000 vaccinees 3 months to 5 years of age in Finland. *Pediatrics* 1977; 60: 730–37.
3. Peltola H, Käyhty H, Virtanen, M, Mäkelä PH. Prevention of *Haemophilus influenzae* type b bacteremic infections with the capsular polysaccharide vaccine. *N Engl J Med* 1984; 310: 1561–66.
4. Goebel WF, Avery OT. Chemo-immunological studies on conjugated carbohydrate-proteins. I. The synthesis of p-aminophenol β-glucoside, p-aminophenol β-galactoside, and their coupling with serum globulin. *J Exp Med* 1929; 50: 521–31.
5. Schneerson R, Barrera O, Sutton A, Robbins JB. Preparation, characterization, and immunogenicity of *Haemophilus influenzae* type b polysaccharide-protein conjugates. *J Exp Med* 1980; 152: 361–76.
6. Granoff DM, Boies EG, Munson RS Jr. Immunogenicity of *Haemophilus influenzae* type b polysaccharide-diphtheria toxoid conjugate vaccine in adults. *J Pediatr* 1984; 105: 22–27.
7. Lepow ML, Samuelson JS, Gordon LK. Safety and immunogenicity of *Haemophilus influenzae* type b-polysaccharide diphtheria toxoid conjugate vaccine in infants 9 to 15 months of age. *J Pediatr* 1985; 106: 185–89.
8. Eskola J, Käyhty H, Peltola H, et al. Antibody levels achieved in infants by course of *Haemophilus influenzae* type b polysaccharide, diphtheria toxoid conjugate vaccine. *Lancet* 1985; i: 1184–86.
9. Anderson P, Pichichero ME, Insel RA. Immunization of two-month-old infants with protein-coupled oligosaccharides derived from the capsule of *Haemophilus influenzae* type b. *J Pediatr* 1985; 107: 346–51.
10. Schlech WF III, Ward JI, Band JD, Hightower A, Fraser DW, Broome CV. Bacterial meningitis in the United States, 1978 through 1981. The national bacterial meningitis surveillance study. *JAMA* 1985; 253: 1749–54.
11. Gilsdorf JR. Bacterial meningitis in southwestern Alaska. *Am J Epidemiol* 1977; 106: 388–91.
12. Ward JI, Lum MKW, Hall DB, Silimperi DR, Bender TR. Invasive *Haemophilus influenzae* type b disease in Alaska: background epidemiology for a vaccine efficacy trial. *J Infect Dis* 1986; 153: 17–26.
13. Marburg S, Jorn D, Tolman RL, et al. Bimolecular chemistry of macromolecules: synthesis of bacterial polysaccharide conjugates with *N. meningitidis* membrane protein. *J Am Chem Soc* (in press).
14. Helting TB, Guthöhrlein G, Blacklolb F, Ronnenberger H. Serotype determinant protein of *Neisseria meningitidis*. *Acta Path Microbiol Scand* 1981; 89: 69–78.
15. Goldschneider I, Gotschlich EC, Artenstein MS. Human immunity to the meningococcus. I. The role of humoral antibodies. *J Exp Med* 1969; 129: 1307–26.
16. Dixit VM, Grant GA, Santoro SA, Frazier WA. Isolation and characterization of a heparin-binding domain from the amino terminus of a platelet thrombospondin. *J Biol Chem* 1984; 259: 10100–05.
17. Kuo JS-C, Monji N, Schwalbe RS, McCoy DW. A radioactive antigen- binding assay for the measurement of antibody to *Haemophilus influenzae* type b capsular polysaccharide. *J Immunol Method* 1981; 43: 35–47.
18. Granoff DM, Shackelford PG, Pandey JP, Boies EG. Antibody responses to *Haemophilus influenzae* type b polysaccharide vaccine in relation to the Km(1; and G,m(23) immunoglobulin allotypes. *J Infect Dis* (in press).
19. Käyhty H, Peltola H, Karanko V, Mäkelä PH. The protective level of serum antibodies to the capsular polysaccharide of *Haemophilus influenzae* type b. *J Infect Dis* 1983; 147: 1100.
20. Anderson P. The protective level of serum antibodies to the capsular polysaccharide of *Haemophilus influenzae* type b. *J Infect Dis* 1984; 149: 1034.
21. Cates KL. Serum opsonic activity for *Haemophilus influenzae* type b in infants immunized with polysaccharide-protein conjugate vaccines. *J Infect Dis* 1985; 152: 1076–77.
22. Schreiber JR, Barrus V, Cates KL, Siber GR. Functional characterization of human IgG, IgM, and IgA antibody directed to the capsule of *Haemophilus influenzae* type b. *J Infect Dis* 1986; 153: 8–16.
23. Granoff DM, Munson RS Jr. Prospects for prevention of *Haemophilus influenzae* type b disease by immunization. *J Infect Dis* 1986; 153: 448–61.

PROGRAM: Haemophilus b Conjugate Vaccine (Neisseria meningitidis Outer Membrane Protein Complex), Study #873

PURPOSE: To evaluate the safety and immunogenicity Haemophilus b Conjugate Vaccine (Neisseria meningitidis Outer Membrane Protein Complex) in healthy children 2 months to 5 years of age.

VACCINE: Haemophilus b Conjugate Vaccine (Neisseria meningitidis Outer Membrane Protein Complex)*

Lot 1003/C-L680 - (b) (4) mcg polysaccharide/ml
(b) (4) mcg meningococcal protein/ml

Lot 1018/C-M679 - (b) (4) mcg polysaccharide/ml
(b) (4) mcg meningococcal protein/ml

Licensed Haemophilus b Polysaccharide Vaccine (PRP) - 25 mcg polysaccharide/0.5 ml.

Diluent

Saline diluent
Lot (b) (4)

Aluminum hydroxide diluent
Lot
Lot (b) (4)

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Menachem S. Einhorn, M.D.
Geoffrey A. Weinberg, M.D.

STUDY LOCATION: St. Louis Children's Hospital and Medical Care Group
St. Louis, Missouri

Aurora Pediatric Group
Aurora, Illinois

*PRP-OMPC

DATE STUDY STARTED: November 13, 1984

DATE STUDY COMPLETED: March 31, 1987

STUDY POPULATION: A total of 168 healthy adults and children (97 male and 71 female) were included in the study.

STUDY PROCEDURE: Adults (n=6) received a single 0.5 ml (7 mcg polysaccharide) intramuscular injection of Lot 1003/C-L680 reconstituted in aluminum hydroxide.

Children 2 to 16 months of age, received two 0.5 ml (7 mcg polysaccharide) intramuscular injections of Lot 1003/C-L680 reconstituted in either saline (n=13) or aluminum hydroxide (n=39), one month apart.

Children 2 to 6 months of age, received two 0.65 ml (13 mcg polysaccharide) intramuscular injections of Lot 1018/C-M679 reconstituted in aluminum hydroxide, either one (n=27) or two (n=27) months apart.

Children (n=53), 2 to 17 months of age, received a single 0.3 ml (6 mcg polysaccharide) intramuscular injections of Lot 1018/C-M679 reconstituted in aluminum hydroxide.

Children (n=3), 2 to 11 months of age, received a single 0.9 ml (18 mcg polysaccharide) intramuscular injection of Lot 1018/C-M679 reconstituted in aluminum hydroxide.

Children were randomly assigned to receive a booster dose of PRP-OMPC (n=10) or PRP (n=62) vaccine as a second or third injection, to evaluate the effect of a booster dose following priming with PRP-OMPC vaccine.

The parent, guardian or vaccine recipient was asked to record the vaccinee's temperature and any systemic or injection site reactions for 3 days after each injection of vaccine. Unexpected or serious reactions were to be reported immediately to the study physician.

Blood samples were obtained pre and postvaccination and at other intervals for each of the different groups of individuals receiving vaccine.

STUDY PROCEDURE (CONT.)

All serum samples were assayed for antibody H. influenzae type b capsular polysaccharide by radioimmunoassay (RIA). Some samples were also tested for serum bactericidal activity (SBA).

RESULTS:

Demographic information and individual pre and post vaccination antibody data for each vaccinee enrolled in the study is reported in Table 1.

1. Number Vaccinated:

				Injection No.			
						Booster	
Age	Lot	Formulation	Dose	1	2	Conj.	Polys.
2-11 mo.	1003/C-L680	Saline	7 mcg	10	8	3	7
	1003/C-L680	Alum	7 mcg	29	24	6	18
	1018/C-M679	Alum	13 mcg	54	51	—	—
	1018/C-M679	Alum	6 mcg	25	—	—	16
	1018/C-M679	Alum	18 mcg	3	—	—	—
12-71 mo.	1003/C-L680	Saline	7 mcg	3	3	—	1
	1003/C-L680	Alum	7 mcg	10	2	1	4
	1018/C-M679	Alum	6 mcg	28	—	—	16
Adults	1003/C-L680	Alum	7 mcg	6	—	—	—

RESULTS (CONT.): 2. Serologic Results:

Age	Lot	Formulation	Dose (mcg)	Time	% With Anti-PRP >.15 mcg Ab/ml	% With Anti-PRP >1.0 mcg Ab/ml	GMT (mcg Ab/ml) All Vaccinees
2-11 mo.	1003/C-L680	Saline	7	Pre	60 (6/10)	0 (0/10)	0.21
				2 mo.	100 (7/7)	71 (5/7)	1.59
	1003/C-L680	Alum	7	Pre	28 (8/29)	0 (0/29)	0.10
				2 mo.	100 (24/24)	63 (15/24)	1.27
	1018/C-M679	Alum	13*	Pre	31 (4/13)	0 (0/13)	0.10
				2 mo	100 (12/12)	50 (6/12)	1.22
	1018/C-M679	Alum	13**	Pre	22 (5/23)	0 (0/23)	0.09
				3 mo	100 (23/23)	87 (20/23)	3.55
12-71 mo.	1003/C-L680	Saline	7	Pre	0 (0/2)	0 (0/2)	0.06
				1 mo	100 (2/2)	100 (2/2)	13.92
	1003/C-L680	Alum	7	Pre	33 (3/9)	0 (0/9)	0.10
				1 mo	100 (9/9)	89 (8/9)	3.09
Adults	1003/C-L680	Alum	7	Pre	67 (4/6)	67 (4/6)	0.92
				1 mo	100 (6/6)	100 (6/6)	>44.24

*2 injections 1 month apart.
**2 injections 2 months apart.

Antibody responses (by lot per age group) are included in Tables 2-6. Antibody responses following booster injections of either PRP-OMPC or PRP vaccine are included in Tables 7-10.

RESULTS (CONT.): 3. Clinical Results:

The frequencies of complaints and temperatures >38.3°C (101°F) during the 3 days following vaccination are as follows:

Subject Group	Inj.	Percent with at least one: Local Complaints	Systemic Complaints	Temp.[>38.3°C (101°F)]
Lot 1003/C-L680 in saline Dose: 7 mcg Age: 2-71 mo.	1	8/13 (61.5%)	5/13 (38.5%)	1/13 (7.7%)
	2	7/11 (63.6%)	8/11 (72.7%)	4/11 (36.4%)
Lot 1003/C-L680 in alum Dose: 7 mcg Age: 2-71 mo.	1	23/39 (59.0%)	13/29 (33.3%)	0/39 (0.0%)
	2	10/26 (38.5%)	5/26 (19.2%)	0/25 (0.0%)
Lot 1003/C-L680 in alum Dose: 7 mcg Age: Adults	1	6/6 (100%)	0/6 (0.0%)	0/5 (0.0%)
Lot 1018/C-M679 in alum Dose: 13 mcg Interval: one month Age: 2-11 mo.	1	9/25 (36.0%)	6/25 (24.0%)	1/26 (3.8%)
	2	4/24 (16.7%)	7/24 (29.2%)	1/23 (4.3%)
Lot 1018/C-M679 in alum Dose: 13 mcg Interval: two months Age: 2-11 mo.	1	10/27 (37.0%)	13/27 (48.1%)	4/27 (14.8%)
	2	7/24 (29.2%)	6/24 (25.0%)	2/25 (8.0%)
Lot 1018/C-M679 in alum Dose: 6 mcg Age: 2-71 mo.	1	2/52 (3.8%)	11/52 (21.2%)	1/52 (1.9%)
Lot 1018/C-M679 in alum Dose: 18 mcg Age: 2-11 mo.	1	2/3 (66.7%)	1/3 (33.3%)	1/2 (50.0%)
Subjects with a booster injection	Conj	3/10 (30.0%)	3/10 (30.0%)	3/9 (33.3%)
	Polys	3/39 (7.7%)	2/39 (5.1%)	0/37 (0.0%)

RESULTS (CONT.): Reaction frequencies and maximum temperatures recorded during the three days following each injection of vaccine are reported in Tables 11-13.

Three serious adverse events occurred within the study.

1) Vaccine: Lot 1003/C-L680 saline
Dose: 7 mcg

A 10-month old infant developed a temperature of 38.9°C, four hours after receiving the second dose of vaccine. Swelling and erythema were present over the anterior thigh surrounding the injection site and extending from above the knee to the groin. Hospitalization was not required and subject recovered. The investigator assessed this event as probably related to the vaccine.

2) Vaccine: Lot 1018/C-M679 in alum
Dose: 18 mcg

A 7-month old infant developed a temperature of 38.9°C with erythema and tenderness at the injection site, two days after receiving the vaccine. A faint rash was present on the face, neck, upper torso and upper extremities. Hospitalization was not required. Fever and rash resolved. The investigator assessed this event as possibly related to the vaccine.

3) Vaccine: Lot 1018/C-M679 in alum
Dose: 18 mcg

A 5-month old infant began high-pitched screaming approximately 4 hours after vaccination. He was unconsolable for 2 hours. Next day, he awoke screaming and was unconsolable for 10 hours. He cried for 3 hours that evening. At 48 hours, he was alert and well. Hospitalization was not required. The investigator assessed this event as definitely related to the vaccine.

For children who received a booster dose of conjugate vaccine, there were no serious or alarming reactions reported.

RESULTS (CONT.): 4) Statistical Analysis

Natural log antibody titers of infants who received two 13 mcg doses of Lot 1018/C-M679 in alum at either one or two month intervals were compared adjusting for age (after no significant interaction between age and regimen was found). There was no significant difference in antibody titers prior to the first injection or at the time of the second injection. However, approximately one month after the second injection, anti-PRP titers were higher for those vaccinees whose injections were given two months apart rather than one month apart ($p=.05$ for vaccinees with baseline serology, $p = .02$ for all vaccinees).

Comparison of doses was restricted to 2-11 month old infants who received two injections of Lot 1003/C-L680 (7 mcg in alum) one month apart and those who received Lot 1018/C-M679 (13 mcg in alum) one month apart. There was no significant difference in antibody titers between the two dose groups prior to the first or second injection or approximately one month after the second injection. Assuming that a difference in lots did not mask a difference in doses, dose did not seem to be a factor in the levels of anti-PRP developed.

Due to the lack of data and imbalance in sample sizes, no formal comparison could be made between vaccine reconstituted in saline or aluminum hydroxide, and between booster injection data.

TABLE 1

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE - SALINE
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE GROUP	DAY	DATE	PHASSQ	EVENT	LOT	DOSE	CODE	RIA	SBA
(b) (6)	F		(b) (6)	16M	0	(b) (6)	001	PREBLEED				< 62	< 2
					0		011	INJ 1	CL680	7 MCG			
					28		011	BLEED 1				24645	256
					28		021	INJ 2	CL680	7 MCG			
					56		021	BLEED 2				11243	64
	M			10M	0		001	PREBLEED				178	< 2
					0		011	INJ 1	CL680	7 MCG			
					28		011	BLEED 1				695	16
					28		021	INJ 2	CL680	7 MCG			
					56		021	BLEED 2				1090	8
					224		021	BLEED 3				529	
					413		021	BLEED 4				183	
					415		091	INJ 3	POLYS	25 MCG			
					441		091	BLEED 5				>= 7000	
	F			16M	0		001	PREBLEED				< 62	< 2
					0		011	INJ 1	CL680	7 MCG			
					28		011	BLEED 1				7862	64
					28		021	INJ 2	CL680	7 MCG			
					56		021	BLEED 2				10113	32
	F			5M	-6		001	PREBLEED				593	< 2
					0		011	INJ 1	CL680	7 MCG			
					22		021	INJ 2	CL680	7 MCG			
					50		021	BLEED 1				1420	8
					218		021	BLEED 2				245	
					407		021	BLEED 3				252	
					407		091	INJ 3	POLYS	25 MCG			
					435		091	BLEED 4				5341	
	M			16M	0		001	PREBLEED				< 62	< 2
					0		011	INJ 1	CL680	7 MCG			
					33		021	INJ 2	CL680	7 MCG			
					56		021	BLEED 1				2734	
					224		021	BLEED 2				463	>= 64
					413		021	BLEED 3				367	
					413		091	INJ 3	POLYS	25 MCG			
					441		091	BLEED 4				5784	
	F			9M	0		001	PREBLEED				117	< 2

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE - SALINE
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE GROUP	DAY	DATE	PHASSQ	EVENT		LOT	DOSE	CODE	RIA	SBA
(b) (6)	F		(b) (6)	9M	0	(b) (6)	011	INJ	1	CL680	7	MCG		
					28		011	BLEED	1				6928	128
					28		021	INJ	2	CL680	7	MCG		
					56		021	BLEED	2				7090	512
					224		021	BLEED	3				3026	
					413		021	BLEED	4				1184	
					413		091	INJ	3	POLYS	25	MCG		
					441		091	BLEED	5				>= 7000	
	M			5M	0		001	PREBLEED					< 62	
					0		011	INJ	1	CL680	7	MCG		
					28		011	BLEED	1				4845	
					28		021	INJ	2	CL680	7	MCG		
					56		021	BLEED	2				5072	
					256		021	BLEED	3				>= 2200	
					483		021	BLEED	4				2084	
					483		091	INJ	3	CM679	6	MCG		
					516		091	BLEED	5				48334	
	M			4M	0		001	PREBLEED					< 62	< 2
					0		011	INJ	1	CL680	7	MCG		
					28		021	INJ	2	CL680	7	MCG		
					56		021	BLEED	1				2651	32
					301		021	BLEED	2				217	
					413		021	BLEED	3				197	
					413		091	INJ	3	CM679	6	MCG		
					441		091	BLEED	4				11937	
	F			2M	0		001	PREBLEED					537	
					0		011	INJ	1	CL680	7	MCG		
					32		011	BLEED	1				179	
					32		021	INJ	2	CL680	7	MCG		
					56		021	BLEED	2				571	
					260		021	BLEED	3				348	
					370		021	BLEED	4				150	
					370		091	INJ	3	POLYS	25	MCG		
					400		091	BLEED	5				5749	
	F			10M	0		001	PREBLEED					149	8
					0		011	INJ	1	CL680	7	MCG		
					28		011	BLEED	1				521	

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE - SALINE
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE GROUP	DAY	DATE	PHASSQ	EVENT		LOT	DOSE	CODE	RIA	SBA
(b) (6)	F		(b) (6)	10M	40	(b) (6)	021	INJ	2	CL680	7 MCG			
					56		021	BLEED	2				5744	512
					385		021	BLEED	3				266	
					385		091	INJ	3	POLYS	25 MCG			
					422		091	BLEED	4				47826	
	M			2M	0		001	PREBLEED					563	
					0		011	INJ	1	CL680	7 MCG			
					28		011	BLEED	1			D1	QNS	
					28		021	INJ	2	CL680	7 MCG			
					56		021	BLEED	2				310	
					245		021	BLEED	3				775	
					357		021	BLEED	4				486	
					357		091	INJ	3	CM679	6 MCG			
					385		091	BLEED	5				8541	
	M			2M	0		001	PREBLEED					515	
					0		011	INJ	1	CL680	7 MCG			
					28		011	BLEED	1				813	
					217		011	BLEED	2				182	
					357		011	BLEED	3				328	
					357		091	INJ	2	POLYS	25 MCG			
					385		091	BLEED	4				3861	
	M			2M	-2		001	PREBLEED					237	
					0		011	INJ	1	CL680	7 MCG			
					26		011	BLEED	1				642	
					355		011	BLEED	2				309	
					355		091	INJ	2	POLYS	25 MCG			
					383		091	BLEED	3				90703	

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE - ALUM
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE GROUP	DAY	DATE	PHASSQ	EVENT	LOT	DOSE	CODE	RIA	SBA
(b) (6)	M		(b) (6)	8M	0	(b) (6)	001	PREBLEED				< 62	< 2
					0		011	INJ 1	CL680	7	MCG		
					28		011	BLEED 1				765	4
					28		021	INJ 2	CL680	7	MCG		
					56		021	BLEED 2				470	< 2
					224		021	BLEED 3				265	
					413		021	BLEED 4				234	
					413		091	INJ 3	POLYS	25	MCG		
					441		091	BLEED 5				2567	
	M			3M	0		001	PREBLEED				< 62	< 2
					0		011	INJ 1	CL680	7	MCG		
					28		011	BLEED 1				625	< 2
					28		021	INJ 2	CL680	7	MCG		
					56		021	BLEED 2				2093	16
					224		021	BLEED 3				3085	
					441		021	BLEED 4				4211	
					441		091	INJ 3	POLYS	25	MCG		
					469		091	BLEED 5				>= 63138	
	F			13M	0		001	PREBLEED				279	< 2
					0		011	INJ 1	CL680	7	MCG		
					26		011	BLEED 1				19379	64
					182		011	BLEED 2				6050	
	M			13M	0		001	PREBLEED				< 62	< 2
					0		011	INJ 1	CL680	7	MCG		
					28		021	INJ 2	CL680	7	MCG		
					56		021	BLEED 1				17134	64
	F			16M	0		001	PREBLEED				213	< 2
					0		011	INJ 1	CL680	7	MCG		
					26		011	BLEED 1				13031	128
					218		011	BLEED 2					
					461		011	BLEED 3				587	
					461		091	INJ 2	CM679	6	MCG		
					489		091	BLEED 4				44168	
	F			11M	0		001	PREBLEED				< 62	>= 64
					0		011	INJ 1	CL680	7	MCG		
					26		011	BLEED 1				19166	32

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE -ALUM
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE GROUP	DAY	DATE	PHASSQ	EVENT	LOT	DOSE	CODE	RIA	SBA
(b) (6)	F		(b) (6)	11M	182	(b) (6)	011	BLEED	2			2190	
	M			5M	0		001	PREBLEED				< 62	< 2
					0		011	INJ	1 CL680	7 MCG			
					28		021	INJ	2 CL680	7 MCG			
					56		021	BLEED	1			225	< 2
					385		021	BLEED	2			193	
					385		091	INJ	3 POLYS	25 MCG			
					413		091	BLEED	3			>= 7000	
	M			2M	0		001	PREBLEED				87	
					0		011	INJ	1 CL680	7 MCG			
					28		011	BLEED	1			751	
					28		021	INJ	2 CL680	7 MCG			
					56		021	BLEED	2			1509	
					245		021	BLEED	3			1178	
					357		021	BLEED	4			1099	
					357		091	INJ	3 POLYS	25 MCG			
					385		091	BLEED	5			173272	
	M			5M	0		001	PREBLEED				< 62	< 2
					0		011	INJ	1 CL680	7 MCG			
					28		011	BLEED	1			727	2
					28		021	INJ	2 CL680	7 MCG			
					56		021	BLEED	2			1157	2
					301		021	BLEED	3			165	
					385		021	BLEED	4			115	
					385		091	INJ	3 POLYS	25 MCG			
					413		091	BLEED	5			2915	
	M			9M	0		001	PREBLEED				< 62	< 2
					0		011	INJ	1 CL680	7 MCG			
					27		011	BLEED	1			199	8
					34		021	INJ	2 CL680	7 MCG			
					62		021	BLEED	2			1235	
					287		021	BLEED	3			720	
					448		021	BLEED	4			452	
					448		091	INJ	3 CM679	6 MCG			
					478		091	BLEED	5			49004	
	M			4M	0		001	PREBLEED				< 62	

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE - ALUM
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE GROUP	DAY	DATE	PHASSQ	EVENT	LOT	DOSE	CODE	RIA	SBA
(b) (6)	M		(b) (6)	4M	0	(b) (6)	011	INJ 1	CL680	7 MCG			
					28		011	BLEED 1				188	
					28		021	INJ 2	CL680	7 MCG			
					56		021	BLEED 2				282	
					301		021	BLEED 3				213	
					357		021	BLEED 4				198	
					357		091	INJ 3	POLYS	25 MCG			
					391		091	BLEED 5				3302	
	M			3M	0		001	PREBLEED				< 62	
					0		011	INJ 1	CL680	7 MCG			
					32		011	BLEED 1				67	
					32		021	INJ 2	CL680	7 MCG			
					56		021	BLEED 2				999	
					245		021	BLEED 3				2171	
					357		021	BLEED 4				1585	
					357		091	INJ 3	CM679	6 MCG			
					397		091	BLEED 5				155538	
	M			2M	0		001	PREBLEED				564	
					0		011	INJ 1	CL680	7 MCG			
					28		011	BLEED 1				1094	
					28		021	INJ 2	CL680	7 MCG			
					56		021	BLEED 2				1281	
					217		021	BLEED 3				>= 2200	
					357		021	BLEED 4				3879	
					357		091	INJ 3	CM679	6 MCG			
					385		091	BLEED 5				>= 173272	
	F			4M	0		001	PREBLEED				94	
					0		011	INJ 1	CL680	7 MCG			
					28		011	BLEED 1			01	5333	
					28		021	INJ 2	CL680	7 MCG			
					64		021	BLEED 2				4623	
					222		021	BLEED 3				>= 2200	
					420		021	BLEED 4				31287	
					420		091	INJ 3	CM679	6 MCG			
					452		091	BLEED 5				>= 173272	
	F			3M	0		001	PREBLEED			01	< 250	
					0		011	INJ 1	CL680	7 MCG			

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE - ALUM
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE GROUP	DAY	DATE	PHASSQ	EVENT	LOT	DOSE	CODE	RIA	SBA
(b) (6)	F		(b) (6)	3M	28	(b) (6)	011	BLEED 1				1085	
					28		021	INJ 2	CL680	7	MCG		
					56		021	BLEED 2				1968	
					217		021	BLEED 3				802	
					395		021	BLEED 4				260	
					395		091	INJ 3	POLYS	25	MCG		
					420		091	BLEED 5				8819	
	M			4M	0		001	PREBLEED				< 125	
					0		011	INJ 1	CL680	7	MCG		
					28		011	BLEED 1				679	
					28		021	INJ 2	CL680	7	MCG		
					56		021	BLEED 2				1060	
					217		021	BLEED 3				218	
					392		021	BLEED 4				161	
					392		091	INJ 3	CM679	6	MCG		
					420		091	BLEED 5				34866	
	M			5M	0		001	PREBLEED				< 125	
					0		011	INJ 1	CL680	7	MCG		
					28		011	BLEED 1				2999	
					28		021	INJ 2	CL680	7	MCG		
					56		021	BLEED 2				3495	
					397		021	BLEED 3				5600	
					397		091	INJ 3	POLYS	25	MCG		
					420		091	BLEED 4				>= 173272	
	F			9M	0		001	PREBLEED				< 125	
					0		011	INJ 1	CL680	7	MCG		
					28		011	BLEED 1				< 125	
					33		021	INJ 2	CL680	7	MCG		
					56		021	BLEED 2				705	
					217		021	BLEED 3				348	
	M			3M	0		001	PREBLEED				430	
					0		011	INJ 1	CL680	7	MCG		
					31		011	BLEED 1				419	
					31		021	INJ 2	CL680	7	MCG		
					59		021	BLEED 2				176	
					245		021	BLEED 3				347	
					426		021	BLEED 4				283	

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE - ALUM
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE GROUP	DAY	DATE	PHASSQ	EVENT		LOT	DOSE	CODE	RIA	SBA
(b) (6)	M		(b) (6)	3M	430	(b) (6)	091	INJ	3	POLYS	25 MCG			
	M			6M	0		001	PREBLEED					340	
					0		011	INJ	1	CL680	7 MCG			
					30		011	BLEED	1				212	
					30		021	INJ	2	CL680	7 MCG			
					67		021	BLEED	2				163	
					225		021	BLEED	3				356	
					442		021	BLEED	4				264	
					442		091	INJ	3	POLYS	25 MCG			
					471		091	BLEED	5				8747	
	M			6M	0		001	PREBLEED					544	
					0		011	INJ	1	CL680	7 MCG			
					28		021	INJ	2	CL680	7 MCG			
					56		021	BLEED	1				2298	
					406		091	INJ	3	POLYS	25 MCG			
					437		091	BLEED	2				128640	
	M			12M	0		001	PREBLEED				01	< 125	
					0		011	INJ	1	CL680	7 MCG			
					27		011	BLEED	1			01	1353	
					228		011	BLEED	2				261	
					405		091	INJ	2	POLYS	25 MCG			
	F			10M	0		001	PREBLEED					146	
					0		011	INJ	1	CL680	7 MCG			
					28		011	BLEED	1				1704	
					234		011	BLEED	2				163	
					412		011	BLEED	3				< 125	
					412		091	INJ	2	POLYS	25 MCG			
					437		091	BLEED	4				7419	
	M			5M	0		001	PREBLEED					< 125	
					0		011	INJ	1	CL680	7 MCG			
					27		011	BLEED	1				1682	
					27		021	INJ	2	CL680	7 MCG			
					61		021	BLEED	2				9807	
					258		021	BLEED	3				8221	
					397		021	BLEED	4				8583	
					397		091	INJ	3	POLYS	25 MCG			

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE - ALUM
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE GROUP	DAY	DATE	PHASSQ	EVENT	LOT	DOSE	CODE	RIA	SBA
(b) (6)	M		(b) (6)	5M	425	(b) (6)	091	BLEED 5				675330	
	F			4M	0		001	PREBLEED				333	
					0		011	INJ 1	CL680	7 MCG			
					28		011	BLEED 1				951	
					28		021	INJ 2	CL680	7 MCG			
					56		021	BLEED 2				1920	
					245		021	BLEED 3				487	
					364		021	BLEED 4				518	
					364		091	INJ 3	CM679	6 MCG			
					392		091	BLEED 5				42122	
	F			14M	0		001	PREBLEED				< 125	
					0		011	INJ 1	CL680	7 MCG			
					28		011	BLEED 1				2627	
					210		011	BLEED 2				564	
	M			12M	0		001	PREBLEED				< 125	
					0		011	INJ 1	CL680	7 MCG			
					35		011	BLEED 1				8392	
					210		011	BLEED 2				>= 2200	
					394		011	BLEED 3				3528	
					394		091	INJ 2	POLYS	25 MCG			
					429		091	BLEED 4				93120	
	F			9M	0		001	PREBLEED				< 125	
					0		011	INJ 1	CL680	7 MCG			
					35		011	BLEED 1				413	
	M			11M	0		001	PREBLEED				< 125	
					0		011	INJ 1	CL680	7 MCG			
					28		011	BLEED 1				576	
					223		011	BLEED 2				621	
					403		011	BLEED 3				345	
					403		091	INJ 2	POLYS	25 MCG			
					435		091	BLEED 4				132800	
	F			5M	0		001	PREBLEED				276	
					0		011	INJ 1	CL680	7 MCG			
					30		011	BLEED 1				13911	
					30		021	INJ 2	CL680	7 MCG			

TABLE 1 (cont.)
DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE - ALUM
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE GROUP	DAY	DATE	PHASSQ	EVENT	LOT	DOSE	CODE	RIA	SBA
(b) (6)	F		(b) (6)	5M	56	(b) (6)	021	BLEED	2			19187	
					424		021	BLEED	3			85917	
					424		091	INJ	3	POLYS	25 MCG		
					459		091	BLEED	4			> 675330	
	F			13M	0		001	PREBLEED				< 125	
					0		011	INJ	1	CL680	7 MCG		
					30		011	BLEED	1			1968	
					218		011	BLEED	2			1343	
					409		011	BLEED	3			14055	
					409		091	INJ	2	POLYS	25 MCG		
					437		091	BLEED	4			123200	
	M			13M	-1		001	PREBLEED				< 125	
					0		011	INJ	1	CL680	7 MCG		
					29		011	BLEED	1			5089	
					190		011	BLEED	2			393	
	M			10M	-1		001	PREBLEED				< 125	
					0		011	INJ	1	CL680	7 MCG		
					30		011	BLEED	1			1615	
					183		011	BLEED	2			320	
	F			6M	-4		001	PREBLEED				< 125	
					0		011	INJ	1	CL680	7 MCG		
					27		011	BLEED	1			< 125	
					27		021	INJ	2	CL680	7 MCG		
					58		021	BLEED	2			459	
					246		021	BLEED	3			638	
					413		091	INJ	3	POLYS	25 MCG		
					442		091	BLEED	4			11162	
	M			4M	0		001	PREBLEED				< 125	
					0		011	INJ	1	CL680	7 MCG		
					24		011	BLEED	1			1271	
					24		021	INJ	2	CL680	7 MCG		
					55		021	BLEED	2			575	
					242		071	BLEED	3			580	
					399		091	INJ	3	POLYS	25 MCG		
	M			2M	-1		001	PREBLEED				466	

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE- ALUM
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE GROUP	DAY	DATE	PHASSQ	EVENT	LOT	DOSE	CODE	RIA	SBA
(b) (6)	M		(b) (6)	2M	0	(b) (6)	011	INJ 1	CL680	7 MCG			
					29		011	BLEED 1				1405	
					29		021	INJ 2	CL680	7 MCG			
					61		021	BLEED 2				1857	
					249		021	BLEED 3				195	
					406		091	INJ 3	POLYS	25 MCG			
					438		091	BLEED 4				66835	
	F			8M	-1		001	PREBLEED				< 125	
					0		011	INJ 1	CL680	7 MCG			
					31		011	BLEED 1				15288	
					31		021	INJ 2	CL680	7 MCG			
					64		021	BLEED 2				6707	
	M			16M	0		001	PREBLEED			01	< 125	
					0		011	INJ 1	CL680	7 MCG			
					31		011	BLEED 1				321	
					34		021	INJ 2	CL680	7 MCG			
					63		021	BLEED 2				1617	
					374		021	BLEED 3				1003	
					374		091	INJ 3	POLYS	25 MCG			
					411		091	BLEED 4				74706	
	F			16M	0		001	PREBLEED				345	
					0		011	INJ 1	CL680	7 MCG			
					29		011	BLEED 1				1067	
	F			3M	0		001	PREBLEED				< 62.5	
					0		011	INJ 1	CM679	13 MCG			
					28		011	BLEED 1				250	
					28		021	INJ 2	CM679	13 MCG			
					67		021	BLEED 2				651	
	F			5M	0		001	PREBLEED				< 62.5	
					0		011	INJ 1	CM679	13 MCG			
					56		011	BLEED 1				164	
					56		021	INJ 2	CM679	13 MCG			
					84		021	BLEED 2				1574	
	M			1M	0		001	PREBLEED				113	
					0		011	INJ 1	CM679	13 MCG			

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE - ALUM
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE GROUP	DAY	DATE	PHASSQ	EVENT	LOT	DOSE	CODE	RIA	SBA
(b) (6)	M		(b) (6)	1M	28	(b) (6)	011	BLEED 1				1080	
					28		021	INJ 2	CM679	13 MCG			
					57		021	BLEED 2				1462	
	F			3M	0		001	PREBLEED				< 62.5	
					0		011	INJ 1	CM679	13 MCG			
					56		011	BLEED 1				443	
					56		021	INJ 2	CM679	13 MCG			
					84		021	BLEED 2				2547	
	M			2M	0		001	PREBLEED				< 125	
					0		011	INJ 1	CM679	13 MCG			
					28		021	INJ 2	CM679	13 MCG			
					121		021	BLEED 1				701	
	F			3M	0		001	PREBLEED				88	
					0		011	INJ 1	CM679	13 MCG			
					56		011	BLEED 1				432	
					56		021	INJ 2	CM679	13 MCG			
					84		021	BLEED 2				2555	
	M			3M	0		001	PREBLEED				448	
					0		011	INJ 1	CM679	13 MCG			
					28		011	BLEED 1				727	
					28		021	INJ 2	CM679	13 MCG			
					56		021	BLEED 2				2174	
	M			6M	0		001	PREBLEED				< 125	
					0		011	INJ 1	CM679	13 MCG			
					56		011	BLEED 1				4353	
					56		021	INJ 2	CM679	13 MCG			
					103		021	BLEED 2				6134	
	M			3M	0		011	INJ 1	CM679	13 MCG			
					28		021	INJ 2	CM679	13 MCG			
	F			6M	0		001	PREBLEED			01	QNS	
					0		011	INJ 1	CM679	13 MCG			
					68		011	BLEED 1				14256	
					68		021	INJ 2	CM679	13 MCG			
					96		021	BLEED 2				21253	

TAPLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE - ALUM
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE GROUP	DAY	DATE	PHASSQ	EVENT		LOT	DOSE	CODE	RIA	SBA
(b) (6)	M		(b) (6)	2M	0	(b) (6)	001	PREBLEED				01	QNS	
					0		011	INJ	1	CM679	13 MCG			
					28		011	BLEED	1			01	QNS	
					28		021	INJ	2	CM679	13 MCG			
					57		021	BLEED	2				3973	
	F			6M	0		001	PREBLEED					< 125	
					0		011	INJ	1	CM679	13 MCG			
					56		011	BLEED	1			01	QNS	
					59		021	INJ	2	CM679	13 MCG			
					84		021	BLEED	2				5375	
	M			4M	0		001	PREBLEED				01	QNS	
					0		011	INJ	1	CM679	13 MCG			
					32		011	BLEED	1				455	
					32		021	INJ	2	CM679	13 MCG			
					68		021	BLEED	2				2126	
	M			6M	0		001	PREBLEED					< 125	
					0		011	INJ	1	CM679	13 MCG			
					59		011	BLEED	1				2977	
					59		021	INJ	2	CM679	13 MCG			
					94		021	BLEED	2				9101	
	M			5M	0		001	PREBLEED					< 125	
					0		011	INJ	1	CM679	13 MCG			
					28		011	BLEED	1				4282	
					28		021	INJ	2	CM679	13 MCG			
					63		021	BLEED	2				19215	
	M			6M	0		001	PREBLEED					< 125	
					0		011	INJ	1	CM679	13 MCG			
					56		011	BLEED	1				9174	
					56		021	INJ	2	CM679	13 MCG			
					84		021	BLEED	2				19634	
	F			2M	0		001	PREBLEED				01	QNS	
					0		011	INJ	1	CM679	13 MCG			
					32		011	BLEED	1			01	QNS	
					32		021	INJ	2	CM679	13 MCG			
					60		021	BLEED	2				884	

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE - ALUM
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE GROUP	DAY	DATE	PHASSQ	EVENT	LOT	DOSE	CODE	RIA	SBA
(b) (6)	M		(b) (6)	4M	0	(b) (6)	001	PREBLEED				< 125	
					0		011	INJ 1	CM679	13	MCG		
					63		011	BLEED 1				312	
					63		021	INJ 2	CM679	13	MCG		
					93		021	BLEED 2				3992	
	M			2M	0		001	PREBLEED				149	
					0		011	INJ 1	CM679	13	MCG		
					28		011	BLEED 1				179	
					28		021	INJ 2	CM679	13	MCG		
					56		021	BLEED 2				469	
	M			4M	0		001	PREBLEED				< 125	
					0		011	INJ 1	CM679	13	MCG		
					63		011	BLEED 1				1503	
					63		021	INJ 2	CM679	13	MCG		
					103		021	BLEED 2				1964	
	M			6M	0		001	PREBLEED				< 125	
					0		011	INJ 1	CM679	13	MCG		
					28		011	BLEED 1				962	
					28		021	INJ 2	CM679	13	MCG		
					56		021	BLEED 2				704	
	F			6M	0		001	PREBLEED				< 125	
					0		011	INJ 1	CM679	13	MCG		
					56		011	BLEED 1				891	
					56		021	INJ 2	CM679	13	MCG		
					90		021	BLEED 2				1303	
	F			2M	0		001	PREBLEED				< 125	
					0		011	INJ 1	CM679	13	MCG		
					28		011	BLEED 1				273	
					28		021	INJ 2	CM679	13	MCG		
					56		021	BLEED 2				413	
	M			3M	0		011	INJ 1	CM679	13	MCG		
	M			5M	0		001	PREBLEED				177	
					0		011	INJ 1	CM679	13	MCG		
					28		011	BLEED 1				1438	

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE - ALUM
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE GROUP	DAY	DATE	PHASSQ	EVENT	LOT	DOSE	CODE	RIA	SBA
(b) (6)	M		(b) (6)	5M	28	(b) (6)	021	INJ 2	CM679	13 MCG			
					53		021	BLEED 2				2846	
	M			2M	0		001	PREBLEED			01	QNS	
					0		011	INJ 1	CM679	13 MCG			
					53		011	BLEED 1			01	QNS	
					53		021	INJ 2	CM679	13 MCG			
					91		021	BLEED 2				3160	
	M			2M	0		001	PREBLEED			01	QNS	
					0		011	INJ 1	CM679	13 MCG			
					28		011	BLEED 1				961	
					28		021	INJ 2	CM679	13 MCG			
					56		021	BLEED 2			01	851	
	M			4M	0		001	PREBLEED				< 125	
					0		011	INJ 1	CM679	13 MCG			
					56		011	BLEED 1			01	2425	
					56		021	INJ 2	CM679	13 MCG			
					91		021	BLEED 2				16440	
	F			5M	0		001	PREBLEED			01	QNS	
					0		011	INJ 1	CM679	13 MCG			
					28		011	BLEED 1				306	
					28		021	INJ 2	CM679	13 MCG			
					56		021	BLEED 2			01	475	
	F			5M	-4		001	PREBLEED				237	
					0		011	INJ 1	CM679	13 MCG			
					52		011	BLEED 1				275	
					52		021	INJ 2	CM679	13 MCG			
					77		021	BLEED 2				581	
	M			2M	0		001	PREBLEED			01	QNS	
					0		011	INJ 1	CM679	13 MCG			
					28		011	BLEED 1				515	
					28		021	INJ 2	CM679	13 MCG			
					56		021	BLEED 2				1151	
	F			2M	0		001	PREBLEED				< 125	
					0		011	INJ 1	CM679	13 MCG			

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE - ALUM
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE GROUP	DAY	DATE	PHASSQ	EVENT	LOT	DOSE	CODE	RIA	SBA
(b) (6)	F		(b) (6)	2M	56	(b) (6)	011	BLEED 1				754	
					56		021	INJ 2	CM679	13 MCG			
					91		021	BLEED 2				1005	
	F			6M	0		001	PREBLEED				< 125	
					0		011	INJ 1	CM679	13 MCG			
					28		011	BLEED 1				610	
					28		021	INJ 2	CM679	13 MCG			
					58		021	BLEED 2				1340	
	F			2M	0		001	PREBLEED				< 125	
					0		011	INJ 1	CM679	13 MCG			
					68		011	BLEED 1				832	
					68		021	INJ 2	CM679	13 MCG			
					119		021	BLEED 2				23799	
	F			2M	0		001	PREBLEED				< 125	
					0		011	INJ 1	CM679	13 MCG			
					40		011	BLEED 1				4179	
					40		021	INJ 2	CM679	13 MCG			
					103		021	BLEED 2				5296	
	M			2M	0		001	PREBLEED				164	
					0		011	INJ 1	CM679	13 MCG			
					56		011	BLEED 1				11798	
					56		021	INJ 2	CM679	13 MCG			
					91		021	BLEED 2				22281	
	M			2M	0		001	PREBLEED			01	QNS	
					0		011	INJ 1	CM679	13 MCG			
					28		011	BLEED 1			01	901	
					28		021	INJ 2	CM679	13 MCG			
					57		021	BLEED 2				1473	
	M			4M	0		001	PREBLEED				< 125	
					0		011	INJ 1	CM679	13 MCG			
					56		011	BLEED 1			01	>= 3976	
					56		021	INJ 2	CM679	13 MCG			
					89		021	BLEED 2				5748	
	M			5M	0		001	PREBLEED				< 125	

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : GRANOFF, DAN
STUDY : D87301
VACCINE : HIB CONJUGATE - ALUM
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE GROUP	DAY	DATE	PHASSQ	EVENT		LOT	DOSE	CODE	RIA	SBA
(b) (6)	M		(b) (6)	5M	0	(b) (6)	011	INJ	1	CM679	13 MCG			
					32		011	BLEED	1				587	
					32		021	INJ	2	CM679	13 MCG			
					60		021	BLEED	2			01	1333	
	M			6M	0		001	PREBLEED					< 125	
					0		011	INJ	1	CM679	13 MCG			
					57		011	BLEED	1				162	
					57		021	INJ	2	CM679	13 MCG			
					85		021	BLEED	2			01	2102	
	M			4M	0		001	PREBLEED					< 125	
					0		011	INJ	1	CM679	13 MCG			
					28		011	BLEED	1				333	
					28		021	INJ	2	CM679	13 MCG			
					55		021	BLEED	2				504	
	M			4M	0		001	PREBLEED					144	
					0		011	INJ	1	CM679	13 MCG			
					60		011	BLEED	1				536	
					60		021	INJ	2	CM679	13 MCG			
					100		021	BLEED	2				791	
	F			2M	0		001	PREBLEED				01	QNS	
					0		011	INJ	1	CM679	13 MCG			
					30		011	BLEED	1				3551	
					30		021	INJ	2	CM679	13 MCG			
					56		021	BLEED	2				3372	
	M			2M	0		001	PREBLEED					786	
					0		011	INJ	1	CM679	13 MCG			
					61		011	BLEED	1				1034	
					61		021	INJ	2	CM679	13 MCG			
					90		021	BLEED	2				1658	
	F			2M	0		001	PREBLEED					257	
					0		011	INJ	1	CM679	13 MCG			
					28		011	BLEED	1				1161	
					33		021	INJ	2	CM679	13 MCG			
					63		021	BLEED	2				284	
	M			2M	0		001	PREBLEED					167	

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE - ALUM
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE GROUP	DAY	DATE	PHASSQ	EVENT	LOT	DOSE	CODE	RIA	SBA
(b) (6)	M		(b) (6)	2M	0	(b) (6)	011	INJ 1	CM679	13 MCG			
					68		021	INJ 2	CM679	13 MCG			
					94		021	BLEED 1				9786	
	M			2M	0		011	INJ 1	CM679	13 MCG			
					22		011	BLEED 1				< 125	
					28		021	INJ 2	CM679	13 MCG			
					91		021	BLEED 2				< 125	
	M			3M	0		001	PREBLEED				< 125	
					0		011	INJ 1	CM679	13 MCG			
					66		011	BLEED 1				296	
					66		021	INJ 2	CM679	13 MCG			
					92		021	BLEED 2				553	
	F			4M	0		001	PREBLEED				179	
					0		011	INJ 1	CM679	13 MCG			
					28		011	BLEED 1				1254	
					28		021	INJ 2	CM679	13 MCG			
					63		021	BLEED 2				3886	
	M			6M	0		001	PREBLEED				< 125	
					0		011	INJ 1	CM679	13 MCG			
					63		011	BLEED 1				579	
					63		021	INJ 2	CM679	13 MCG			
					91		021	BLEED 2				3939	
	F			6M	0		011	INJ 1	CM679	13 MCG			
	F			5M	0		001	PREBLEED				187	
					0		011	INJ 1	CM679	13 MCG			
					54		011	BLEED 1				2182	
					54		021	INJ 2	CM679	13 MCG			
					91		021	BLEED 2				4262	
	F			3M	0		011	INJ 1	CM679	13 MCG			
	M			5M	0		001	PREBLEED			01	QNS	
					0		011	INJ 1	CM679	13 MCG			
					58		011	BLEED 1				3080	
					58		021	INJ 2	CM679	13 MCG			

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE - ALUM
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE GROUP	DAY	DATE	PHASSQ	EVENT		LOT	DOSE	CODE	RIA	SBA
(b) (6)	M		(b) (6)	5M	84	(b) (6)	021	BLEED	2				7577	
	M	BLAC		13M	0		011	INJ	1	CM679	6	MCG		
					31		011	BLEED	1				6210	
	M	BLAC		7M	0		011	INJ	1	CM679	6	MCG		
					30		011	BLEED	1				7453	
	F	BLAC		12M	0		011	INJ	1	CM679	6	MCG		
					28		011	BLEED	1				644	
					206		091	INJ	2	POLYS	25	MCG		
					241		091	BLEED	2				128047	
	F	BLAC		11M	0		011	INJ	1	CM679	6	MCG		
					31		011	BLEED	1				4650	
					189		071	BLEED	2				1161	
					189		091	INJ	2	POLYS	25	MCG		
	F	BLAC		8M	0		011	INJ	1	CM679	6	MCG		
	M	BLAC		12M	0		011	INJ	1	CM679	6	MCG		
					33		011	BLEED	1				10488	
					195		071	BLEED	2				4643	
					195		091	INJ	2	POLYS	25	MCG		
					235		091	BLEED	3				223559	
	M	BLAC		11M	0		011	INJ	1	CM679	6	MCG		
					32		011	BLEED	1				5879	
					182		071	BLEED	2				2571	
					182		091	INJ	2	POLYS	25	MCG		
					223		091	BLEED	3				275669	
	F	BLAC		15M	0		011	INJ	1	CM679	6	MCG		
	M	BLAC		12M	0		011	INJ	1	CM679	6	MCG		
					29		011	BLEED	1				7037	
					325		071	BLEED	2				1337	
					325		091	INJ	2	POLYS	25	MCG		
					358		091	BLEED	3				72381	
	F	BLAC		17M	0		011	INJ	1	CM679	6	MCG		

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE - ALUM
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE GROUP	DAY	DATE	PHASSQ	EVENT	LOT	DOSE	CODE	RIA	SBA
(b) (6)	F	BLAC	(b) (6)	17M	29	(b) (6)	011	BLEED	1			29690	
	M	BLAC		13M	0		011	INJ	1	CM679	6 MCG		
					36		011	BLEED	1			10126	
	F	BLAC		12M	0		011	INJ	1	CM679	6 MCG		
					27		011	BLEED	1			5056	
					195		071	BLEED	2			5162	
					195		091	INJ	2	POLYS	25 MCG		
					245		091	BLEED	3			342511	
	F	BLAC		12M	0		011	INJ	1	CM679	6 MCG		
					340		071	BLEED	1			296	
					340		091	INJ	2	POLYS	25 MCG		
	F	BLAC		15M	0		011	INJ	1	CM679	6 MCG		
					42		011	BLEED	1			712	
	M	BLAC		9M	0		011	INJ	1	CM679	6 MCG		
					37		011	BLEED	1			4435	
	F	BLAC		15M	0		011	INJ	1	CM679	6 MCG		
					38		011	BLEED	1			570	
					334		071	BLEED	2			293	
					334		091	INJ	2	POLYS	25 MCG		
					369		091	BLEED	3			21377	
	F	BLAC		7M	0		011	INJ	1	CM679	6 MCG		
					28		011	BLEED	1			3850	
	F	BLAC		7M	0		011	INJ	1	CM679	6 MCG		
					28		011	BLEED	1			1115	
	F	BLAC		10M	0		011	INJ	1	CM679	6 MCG		
					41		011	BLEED	1			9007	
					218		071	BLEED	2			14829	
					218		091	INJ	2	POLYS	25 MCG		
	M	BLAC		17M	0		011	INJ	1	CM679	6 MCG		
	F	BLAC		15M	0		011	INJ	1	CM679	6 MCG		

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE - ALUM
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE GROUP	DAY	DATE	PHASSQ	EVENT	LOT	DOSE	CODE	RIA	SBA
(b) (6)	F	BLAC	(b) (6)	15M	35	(b) (6)	011	BLEED	1			27321	
					224		071	BLEED	2			7788	
					224		091	INJ	2	POLYS	25 MCG		
					252		091	BLEED	3			488977	
	M	BLAC		8M	0		011	INJ	1	CM679	6 MCG		
					32		011	BLEED	1			1094	
					257		071	BLEED	2			865	
					257		091	INJ	2	POLYS	25 MCG		
					300		091	BLEED	3			64156	
	F	BLAC		8M	0		011	INJ	1	CM679	6 MCG		
	M	BLAC		17M	0		011	INJ	1	CM679	6 MCG		
					35		011	BLEED	1			8215	
	M	BLAC		13M	0		011	INJ	1	CM679	6 MCG		
					33		011	BLEED	1			1942	
					242		071	BLEED	2			4417	
					242		091	INJ	2	POLYS	25 MCG		
					323		091	BLEED	3			75934	
	F	BLAC		17M	0		011	INJ	1	CM679	6 MCG		
					29		011	BLEED	1			12272	
					187		071	BLEED	2			558	
					187		091	INJ	2	POLYS	25 MCG		
					229		091	BLEED	3			170765	
	F	BLAC		17M	0		011	INJ	1	CM679	6 MCG		
					33		011	BLEED	1			9179	
	F	BLAC		10M	0		011	INJ	1	CM679	6 MCG		
					28		011	BLEED	1			1202	
					246		071	BLEED	2			1706	
					246		091	INJ	2	POLYS	25 MCG		
					274		091	BLEED	3			196045	
	M	BLAC		8M	0		011	INJ	1	CM679	6 MCG		
					326		071	BLEED	1			714	
					326		091	INJ	2	POLYS	25 MCG		
					356		091	BLEED	2			96317	

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE - ALUM
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE GROUP	DAY	DATE	PHASSQ	EVENT		LOT	DOSE	CODE	RIA	SBA
(b) (6)	F	BLAC	(b) (6)	15M	0	(b) (6)	011	INJ	1	CM679	6	MCG		
					39		011	BLEED	1				9834	
					259		071	BLEED	2				2673	
					259		091	INJ	2	POLYS	25	MCG		
	F	BLAC		9M	0		011	INJ	1	CM679	6	MCG		
	F	BLAC		12M	0		011	INJ	1	CM679	6	MCG		
					46		011	BLEED	1				2602	
					343		071	BLEED	2				390	
					343		091	INJ	2	POLYS	25	MCG		
	F	BLAC		14M	0		011	INJ	1	CM679	6	MCG		
					34		011	BLEED	1				7341	
					262		071	BLEED	2				3010	
					301		091	INJ	2	POLYS	25	MCG		
					335		091	BLEED	3				271073	
	F	BLAC		15M	0		011	INJ	1	CM679	6	MCG		
					33		011	BLEED	1				2512	
					316		071	BLEED	2				5417	
					316		091	INJ	2	POLYS	25	MCG		
					349		091	BLEED	3				530962	
	M	BLAC		15M	0		011	INJ	1	CM679	6	MCG		
					38		011	BLEED	1				1887	
	M	BLAC		15M	0		011	INJ	1	CM679	6	MCG		
					28		011	BLEED	1				74413	
	M	BLAC		7M	0		011	INJ	1	CM679	6	MCG		
					299		091	INJ	2	POLYS	25	MCG		
	F	BLAC		12M	0		011	INJ	1	CM679	6	MCG		
					36		011	BLEED	1				11041	
	F	BLAC		7M	0		011	INJ	1	CM679	6	MCG		
					42		011	BLEED	1				1108	
					233		071	BLEED	2				2528	
					233		091	INJ	2	POLYS	25	MCG		
					302		091	BLEED	3				5072	

TABLE 1 (cont.)
DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE - ALUM
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE GROUP	DAY	DATE	PHASSQ	EVENT	LOT	DOSE	CODE	RIA	SBA
(b) (6)	M	BLAC	(b) (6)	11M	0	(b) (6)	011	INJ 1	CM679	6	MCG		
					38		011	BLEED 1				5225	
					308		071	BLEED 2				583	
					308		091	INJ 2	POLYS	25	MCG		
					336		091	BLEED 3				150939	
	M	BLAC		8M	0		011	INJ 1	CM679	6	MCG		
					212		071	BLEED 1				< 125	
					212		091	INJ 2	POLYS	25	MCG		
	M	BLAC		7M	0		011	INJ 1	CM679	6	MCG		
					36		011	BLEED 1				430	
					232		091	INJ 2	POLYS	25	MCG		
					287		091	BLEED 2				29778	
	M	BLAC		16M	0		011	INJ 1	CM679	6	MCG		
					34		011	BLEED 1				554	
					184		071	BLEED 2				398	
					188		091	INJ 2	POLYS	25	MCG		
	M	BLAC		13M	0		011	INJ 1	CM679	6	MCG		
					28		011	BLEED 1				230	
					196		071	BLEED 2				848	
					196		091	INJ 2	POLYS	25	MCG		
					224		091	BLEED 3				101161	
	F	BLAC		13M	0		011	INJ 1	CM679	6	MCG		
					32		011	BLEED 1				721	
					267		071	BLEED 2				< 125	
					267		091	INJ 2	POLYS	25	MCG		
					323		091	BLEED 3				14664	
	M	BLAC		8M	0		011	INJ 1	CM679	6	MCG		
					34		011	BLEED 1				1393	
					194		071	BLEED 2				718	
					194		091	INJ 2	POLYS	25	MCG		
					222		091	BLEED 3				102589	
	M	BLAC		11M	0		011	INJ 1	CM679	6	MCG		
					28		011	BLEED 1				626	
	M	BLAC		7M	0		011	INJ 1	CM679	6	MCG		

TABLE 1 (cont.)
DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE - ALUM
PATIENT CLASS: HEALTHY CHILDREN

CASE	SEX	RACE	BIRTH	AGE GROUP	DAY	DATE	PHASSQ	EVENT	LOT	DOSE	CODE	RIA	SBA
(b) (6)	M	BLAC	(b) (6)	7M	29	(b) (6)	011	BLEED	1			792	
					180		091	INJ	2	POLYS	25 MCG		
					250		091	BLEED	2			10113	
	M	BLAC		8M	0		011	INJ	1	CM679	6 MCG		
					250		071	BLEED	1			361	
					250		091	INJ	2	POLYS	25 MCG		
	M	BLAC		13M	0		011	INJ	1	CM679	6 MCG		
					28		011	BLEED	1			4973	
	M	BLAC		9M	0		011	INJ	1	CM679	6 MCG		
					182		071	BLEED	1			302	
					182		091	INJ	2	POLYS	25 MCG		
					210		091	BLEED	2			61508	
	F	BLAC		11M	0		011	INJ	1	CM679	6 MCG		
					28		011	BLEED	1			1716	
	M	BLAC		9M	0		011	INJ	1	CM679	6 MCG		
					30		011	BLEED	1			12303	
					184		071	BLEED	2			1652	
					184		091	INJ	2	POLYS	25 MCG		
	F	BLAC		7M	0		011	INJ	1	CM679	18 MCG		
					5		011	BLEED	1			< 125	
					15		011	BLEED	2			529	
					28		011	BLEED	3			604	
	M	BLAC		7M	0		011	INJ	1	CM679	18 MCG		
					27		011	BLEED	1			351	
	M	BLAC		5M	0		011	INJ	1	CM679	18 MCG		
					30		011	BLEED	1			623	

TABLE 1 (cont.)

DEMOGRAPHICS / EVENTS LISTING

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE - ALUM
PATIENT CLASS: HEALTHY ADULTS

CASE	SEX	RACE	BIRTH	AGE GROUP	DAY	DATE	PHASSQ	EVENT	LOT	DOSE	CODE	RIA	SBA
(b) (6)	M		(b) (6)	26Y	0	(b) (6)	001	PREBLEED				1019	
					0		011	INJ 1	CL680	7 MCG			
					28		011	BLEED 1				>= 100000	
					192		011	BLEED 2				54855	
	M			23Y	0		001	PREBLEED				2296	
					0		011	INJ 1	CL680	7 MCG			
					28		011	BLEED 1				66140	
					192		021	BLEED 2				76322	
	F			43Y	0		001	PREBLEED				1227	
					0		011	INJ 1	CL680	7 MCG			
					28		011	BLEED 1				18197	
	F			23Y	0		001	PREBLEED				23375	
					0		011	INJ 1	CL680	7 MCG			
					28		011	BLEED 1				56344	
					192		011	BLEED 2				35500	
	M			33Y	0		001	PREBLEED				118	
					0		011	INJ 1	CL680	7 MCG			
					28		011	BLEED 1				78842	
					192		011	BLEED 2				15101	
	M			26Y	0		001	PREBLEED				140	
					0		011	INJ 1	CL680	7 MCG			
					28		011	BLEED 1				14022	
					192		011	BLEED 2				4452	

TABLE 2

ANTIBODY RESPONSES

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE
ASSAY : RIA
LOT NUMBER : CL680
DOSE : 7 MCG
POPULATION : HEALTHY ADULTS

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
20-45 YRS.	PRE INJ	67 (4/ 6)	67 (4/ 6)			0.915 (6)
	1 MONTH	100 (6/ 6)	100 (6/ 6)	100 (6/ 6)	> 43.1	> 44.240 (6)
	6 MONTHS	100 (5/ 5)	100 (5/ 5)	80 (4/ 5)	25.3	25.115 (5)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 3

ANTIBODY RESPONSES

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE - SALINE
ASSAY : RIA
LOT NUMBER : CL680
DOSE : 7 MCG
POPULATION : HEALTHY CHILDREN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
2-11 MOS.	PRE INJ	60 (6/ 10)	0 (0/ 10)			0.207 (10)
	MONTH 1	100 (7/ 7)	29 (2/ 7)	71 (5/ 7)	4.6	1.018 (7)
	MONTH 2	100 (7/ 7)	71 (5/ 7)	71 (5/ 7)	6.4	1.594 (7)
	MONTHS 7/10	100 (7/ 7)	29 (2/ 7)	43 (3/ 7)	> 2.6	> 0.653 (7)
	MONTHS 12/16	88 (7/ 8)	25 (2/ 8)	25 (2/ 8)	1.6	0.380 (8)
12-71 MOS.	PRE INJ	0 (0/ 2)	0 (0/ 2)			0.063 (2)
	MONTH 1	100 (2/ 2)	100 (2/ 2)	100 (2/ 2)	111.4	13.920 (2)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 4

ANTIBODY RESPONSES

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE
ASSAY : RIA
LOT NUMBER : CL680
DOSE : 7 MCG
POPULATION : HEALTHY CHILDREN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
2 11 MOS.	PRE INJ	28 (8/ 29)	0 (0/ 29)			0.104 (29)
	MONTH 1	89 (24/ 27)	44 (12/ 27)	70 (19/ 27)	5.6	0.866 (27)
	MONTH 2	100 (24/ 24)	63 (15/ 24)	88 (21/ 24)	7.0	1.272 (24)
	MONTHS 7/10	100 (19/ 19)	32 (6/ 19)	63 (12/ 19)	> 3.8	> 0.674 (19)
	MONTHS 12/16	94 (17/ 18)	44 (8/ 18)	50 (9/ 18)	6.0	1.023 (18)
12-71 MOS.	PRE INJ	33 (3/ 9)	0 (0/ 9)			0.102 (9)
	MONTH 1	100 (9/ 9)	89 (8/ 9)	100 (9/ 9)	19.0	3.092 (9)
	MONTHS 6/10	100 (6/ 6)	50 (3/ 6)	100 (6/ 6)	> 7.0	> 1.006 (6)
	MONTHS 12/16	100 (3/ 3)	67 (2/ 3)	100 (3/ 3)	20.6	3.076 (3)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 5

A N T I B O D Y R E S P O N S E S
ADMINISTERED AS TWO INJECTIONS ONE MONTH APART

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE
ASSAY : RIA
LOT NUMBER : CM679
DOSE : 13 MCG
POPULATION : HEALTHY CHILDREN
RACE : UNKNOWN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
2 - 6 MOS.	PRE INJ	31 (4/ 13)	0 (0/ 13)			0.102 (13)
	MONTH 1	100 (13/ 13)	38 (5/ 13)	77 (10/ 13)	5.0	0.778 (13)
	MONTH 2	100 (12/ 12)	50 (6/ 12)	92 (11/ 12)	7.7	1.216 (12)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 6

A N T I B O D Y R E S P O N S E S
ADMINISTERED AS TWO INJECTIONS TWO MONTHS APART

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE
ASSAY : RIA
LOT NUMBER : CM679
DOSE : 13 MCG
POPULATION : HEALTHY CHILDREN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
2- 6 MOS.	PRE VAC	22 (5/ 23)	0 (0/ 23)			0.088 (23)
	2 MONTHS	100 (21/ 21)	43 (9/ 21)	81 (17/ 21)	> 6.8	> 1.001 (21)
	3 MONTHS	100 (23/ 23)	87 (20/ 23)	100 (23/ 23)	24.3	3.550 (23)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 7

ANTIBODY RESPONSES

BOOSTER AS A SECOND INJECTION

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : COMBINED
ASSAY : RIA
LOT NUMBER : POLYS
POPULATION : HEALTHY CHILDREN
RACE : BLACK

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
2-11 MOS.	PRE BOOST	100 (7/ 7)	29 (2/ 7)			0.858 (7)
	POST BOOST	100 (7/ 7)	100 (7/ 7)	100 (7/ 7)	137.5	117.975 (7)
12-71 MOS.	PRE BOOST	100 (7/ 7)	57 (4/ 7)			1.671 (7)
	POST BOOST	100 (7/ 7)	100 (7/ 7)	100 (7/ 7)	88.6	147.946 (7)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 8

ANTIBODY RESPONSES
BOOSTER AS A SECOND INJECTION

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : COMBINED
ASSAY : RIA
LOT NUMBER : POLYS
POPULATION : HEALTHY CHILDREN
RACE : UNKNOWN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
2-11 MOS.	PRE BOOST	75 (3/ 4)	0 (0/ 4)			0.216 (4)
	POST BOOST	100 (4/ 4)	100 (4/ 4)	100 (4/ 4)	94.3	24.236 (4)
12-71 MOS.	PRE BOOST	100 (2/ 2)	100 (2/ 2)			7.042 (2)
	POST BOOST	100 (2/ 2)	100 (2/ 2)	100 (2/ 2)	15.2	107.109 (2)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 9

ANTIBODY RESPONSES
BOOSTER AS A THIRD INJECTION

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : COMBINED
ASSAY : RIA
LOT NUMBER : POLYS
POPULATION : HEALTHY CHILDREN
RACE : UNKNOWN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
2 - 11 MOS.	PRE BOOST	88 (14/ 16)	38 (6/ 16)			0.669 (16)
	POST BOOST	100 (16/ 16)	100 (16/ 16)	100 (16/ 16)	> 29.1	> 20.297 (16)
12 - 71 MOS.	PRE BOOST	100 (2/ 2)	50 (1/ 2)			0.607 (2)
	POST BOOST	100 (2/ 2)	100 (2/ 2)	100 (2/ 2)	34.3	20.787 (2)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 10

ANTIBODY RESPONSES

BOOSTER AS A THIRD INJECTION

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : COMBINED
ASSAY : RIA
LOT NUMBER : CM679
POPULATION : HEALTHY CHILDREN
RACE : UNKNOWN

AGE	TIME (MONTHS)	% WITH ANTI-PRP >.15 MCG AB/ML	% WITH ANTI-PRP >1.0 MCG AB/ML	FOLD RISE % >2 FOLD	FOLD RISE MEAN	GMT MCG AB/ML (N) ALL VACCINEES
2-11 MOS.	PRE BOOST	100 (9/ 9)	44 (4/ 9)			1.042 (9)
	POST BOOST	100 (9/ 9)	100 (9/ 9)	100 (9/ 9)	> 47.1	> 49.092 (9)

FOOTNOTE(S):
IF A TITER IS REPORTED AS <.125, THEN .125 IS USED TO CALCULATE THE MEAN FOLD RISE, AND .063 IS USED TO CALCULATE THE GEOMETRIC MEAN TITER.

TABLE 11

FREQUENCY OF CLINICAL COMPLAINTS FOLLOWING VACCINATION WITH HIB VACCINE

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE
LOT NUMBER : CL680
DOSE : 7 MCG
PATIENT CLASS: HEALTHY ADULTS
AGE RANGE : 20-45 YRS.
RACE : UNKNOWN

	DOSE NUMBER: 1 TOTAL VACCINEES : 6 TOTAL VACCINEES PRESENTING DATA: 6	
CLINICAL COMPLAINTS	NUMBER OF VACCINEES	PERCENT
REACTION,LOCAL (INJECT SITE)	6	100.0
PAIN/SORENESS, INJECTION SITE	6	100.0
SYSTEMIC	0	0.0
VACCINEES WITH COMPLAINTS:	6	100.0
VACCINEES WITH NO COMPLAINTS:	0	0.0
VACCINEES WITH NO DATA:	0	

TABLE 11 (cont.)

FREQUENCY OF CLINICAL COMPLAINTS FOLLOWING VACCINATION WITH HIB VACCINE

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CL680
DOSE : 7 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2-11 MOS.
RACE : UNKNOWN

DOSE NUMBER: 1

TOTAL VACCINEES : 10
TOTAL VACCINEES PRESENTING DATA: 10

CLINICAL COMPLAINTS	NUMBER OF VACCINEES	PERCENT
REACTION,LOCAL (INJECT SITE)	6	60.0
ERYTHEMA, INJECTION SITE (1 INCH, LESS THAN)	3	30.0
SWELLING, INJECTION SITE (1 INCH, LESS THAN)	2	20.0
ERYTHEMA, INJECTION SITE	1	10.0
INDURATION, INJECTION SITE	1	10.0
STIFFNESS/TIGHTNESS, INJECTION	1	10.0
SWELLING, INJECTION SITE (>1 INCH)	1	10.0
SYSTEMIC	3	30.0
IRRITABILITY	2	20.0
ANOREXIA	1	10.0
CRYING, EXCESSIVE	1	10.0
NERVOUSNESS	1	10.0
SOMNOLENCE	1	10.0
VACCINEES WITH COMPLAINTS:	7	70.0
VACCINEES WITH NO COMPLAINTS:	3	30.0
VACCINEES WITH NO DATA:	0	

TABLE 11 (cont.)

FREQUENCY OF CLINICAL COMPLAINTS FOLLOWING VACCINATION WITH HIB VACCINE

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CL680
DOSE : 7 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2-11 MOS.
RACE : UNKNOWN

DOSE NUMBER: 2

TOTAL VACCINEES : 8
TOTAL VACCINEES PRESENTING DATA: 8

CLINICAL COMPLAINTS	NUMBER OF VACCINEES	PERCENT
REACTION,LOCAL (INJECT SITE)	6	75.0
ERYTHEMA, INJECTION SITE (1 INCH, LESS THAN)	2	25.0
PAIN/SORENESS, INJECTION SITE	2	25.0
SWELLING, INJECTION SITE (>1 INCH)	2	25.0
ERYTHEMA, INJECTION SITE (>1 INCH)	1	12.5
SWELLING, INJECTION SITE (1 INCH, LESS THAN)	1	12.5
WARMTH, INJECTION SITE	1	12.5
SYSTEMIC	6	75.0
IRRITABILITY	4	50.0
OTITIS MEDIA	2	25.0
ANOREXIA	1	12.5
VACCINEES WITH COMPLAINTS:	7	87.5
VACCINEES WITH NO COMPLAINTS:	1	12.5
VACCINEES WITH NO DATA:	0	

TABLE 11 (cont.)

FREQUENCY OF CLINICAL COMPLAINTS FOLLOWING VACCINATION WITH HIB VACCINE

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CL680
DOSE : 7 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.
RACE : UNKNOWN

	DOSE NUMBER: 1 TOTAL VACCINEES : 3 TOTAL VACCINEES PRESENTING DATA: 3	
CLINICAL COMPLAINTS	NUMBER OF VACCINEES	PERCENT
REACTION,LOCAL (INJECT SITE)	2	66.7
ERYTHEMA, INJECTION SITE	1	33.3
PAIN/SORENESS, INJECTION SITE	1	33.3
SYSTEMIC	2	66.7
ANOREXIA	1	33.3
COMMON COLD	1	33.3
IRRITABILITY	1	33.3
VACCINEES WITH COMPLAINTS:	3	100.0
VACCINEES WITH NO COMPLAINTS:	0	0.0
VACCINEES WITH NO DATA:	0	

TABLE 11 (cont.)

FREQUENCY OF CLINICAL COMPLAINTS FOLLOWING VACCINATION WITH HIB VACCINE

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CL680
DOSE : 7 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.
RACE : UNKNOWN

	DOSE NUMBER: 2 TOTAL VACCINEES : 3 TOTAL VACCINEES PRESENTING DATA: 3	
CLINICAL COMPLAINTS	NUMBER OF VACCINEES	PERCENT
REACTION,LOCAL (INJECT SITE)	1	33.3
PAIN/SORENESS, INJECTION SITE	1	33.3
SYSTEMIC	2	66.7
IRRITABILITY	1	33.3
WARM SENSATION	1	33.3
VACCINEES WITH COMPLAINTS:	2	66.7
VACCINEES WITH NO COMPLAINTS:	1	33.3
VACCINEES WITH NO DATA:	0	

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TABLE 11 (cont.)

FREQUENCY OF CLINICAL COMPLAINTS FOLLOWING VACCINATION WITH HIB VACCINE

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE
LOT NUMBER : CL680
DOSE : 7 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2-11 MOS.
RACE : UNKNOWN

DOSE NUMBER: 1

TOTAL VACCINEES : 29
TOTAL VACCINEES PRESENTING DATA: 29

CLINICAL COMPLAINTS	NUMBER OF VACCINEES	PERCENT
REACTION,LOCAL (INJECT SITE)	19	65.5
ERYTHEMA, INJECTION SITE (1 INCH, LESS THAN)	12	41.4
PAIN/SORENESS, INJECTION SITE	5	17.2
ERYTHEMA, INJECTION SITE	4	13.8
INDURATION, INJECTION SITE	3	10.3
WARMTH, INJECTION SITE	2	6.9
ECCHYMOSIS, INJECTION SITE	1	3.4
SWELLING, INJECTION SITE	1	3.4
SYSTEMIC	11	37.9
IRRITABILITY	8	27.6
COMMON COLD	1	3.4
INSOMNIA	1	3.4
NASAL DISCHARGE	1	3.4
RASH	1	3.4
SOMNOLENCE	1	3.4
VACCINEES WITH COMPLAINTS:	21	72.4

TABLE 11 (cont.)

FREQUENCY OF CLINICAL COMPLAINTS FOLLOWING VACCINATION WITH HIB VACCINE

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE
LOT NUMBER : CL680
DOSE : 7 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2-11 MOS.
RACE : UNKNOWN

	DOSE NUMBER: 1	
	TOTAL VACCINEES : 29 TOTAL VACCINEES PRESENTING DATA: 29	
CLINICAL COMPLAINTS	NUMBER OF VACCINEES	PERCENT
VACCINEES WITH NO COMPLAINTS:	8	27.6
VACCINEES WITH NO DATA:	0	

TABLE 11 (cont.)

FREQUENCY OF CLINICAL COMPLAINTS FOLLOWING VACCINATION WITH HIB VACCINE

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE
LOT NUMBER : CL680
DOSE : 7 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2-11 MOS.
RACE : UNKNOWN

DOSE NUMBER: 2

TOTAL VACCINEES : 24
TOTAL VACCINEES PRESENTING DATA: 24

CLINICAL COMPLAINTS	NUMBER OF VACCINEES	PERCENT
REACTION,LOCAL (INJECT SITE)	9	37.5
ERYTHEMA, INJECTION SITE	3	12.5
ERYTHEMA, INJECTION SITE (1 INCH, LESS THAN)	2	8.3
INDURATION, INJECTION SITE	2	8.3
PAIN/SORENESS, INJECTION SITE	2	8.3
ECCHYMOSIS, INJECTION SITE	1	4.2
SYSTEMIC	5	20.8
IRRITABILITY	4	16.7
INSOMNIA	1	4.2
NASAL DISCHARGE	1	4.2
VACCINEES WITH COMPLAINTS:	12	50.0
VACCINEES WITH NO COMPLAINTS:	12	50.0
VACCINEES WITH NO DATA:	0	

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TABLE 11 (cont.)

FREQUENCY OF CLINICAL COMPLAINTS FOLLOWING VACCINATION WITH HIB VACCINE

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE
LOT NUMBER : CL680
DOSE : 7 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.
RACE : UNKNOWN

	DOSE NUMBER: 1 TOTAL VACCINEES : 10 TOTAL VACCINEES PRESENTING DATA: 10	
CLINICAL COMPLAINTS	NUMBER OF VACCINEES	PERCENT
REACTION,LOCAL (INJECT SITE)	4	40.0
ERYTHEMA, INJECTION SITE (1 INCH, LESS THAN)	2	20.0
ERYTHEMA, INJECTION SITE	1	10.0
INDURATION, INJECTION SITE	1	10.0
PAIN/SORENESS, INJECTION SITE	1	10.0
SYSTEMIC	2	20.0
IRRITABILITY	2	20.0
VACCINEES WITH COMPLAINTS:	5	50.0
VACCINEES WITH NO COMPLAINTS:	5	50.0
VACCINEES WITH NO DATA:	0	

TABLE 11 (cont.)

FREQUENCY OF CLINICAL COMPLAINTS FOLLOWING VACCINATION WITH HIB VACCINE

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE
LOT NUMBER : CL680
DOSE : 7 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.
RACE : UNKNOWN

	DOSE NUMBER: 2	
	TOTAL VACCINEES : 2 TOTAL VACCINEES PRESENTING DATA: 2	
CLINICAL COMPLAINTS	NUMBER OF VACCINEES	PERCENT
REACTION,LOCAL (INJECT SITE)	1	50.0
INDURATION, INJECTION SITE	1	50.0
SWELLING, INJECTION SITE (>1 INCH)	1	50.0
SYSTEMIC	0	0.0
VACCINEES WITH COMPLAINTS:	1	50.0
VACCINEES WITH NO COMPLAINTS:	1	50.0
VACCINEES WITH NO DATA:	0	

TABLE 11 (cont.)

FREQUENCY OF CLINICAL COMPLAINTS FOLLOWING VACCINATION WITH HIB VACCINE

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE
LOT NUMBER : CM679
DOSE : 13 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2-11 MOS.
RACE : UNKNOWN

	DOSE NUMBER: 1 TOTAL VACCINEES : 53 TOTAL VACCINEES PRESENTING DATA: 52	
CLINICAL COMPLAINTS	NUMBER OF VACCINEES	PERCENT
REACTION,LOCAL (INJECT SITE)	19	36.5
ERYTHEMA, INJECTION SITE	8	15.4
INDURATION, INJECTION SITE	5	9.6
PAIN/SORENESS, INJECTION SITE	4	7.7
ERYTHEMA, INJECTION SITE (1 INCH, LESS THAN)	3	5.8
ECCHYMOSIS, INJECTION SITE	2	3.8
ERYTHEMA, INJECTION SITE (>1 INCH)	2	3.8
WARMTH, INJECTION SITE	1	1.9
SYSTEMIC	19	36.5
IRRITABILITY	9	17.3
ANOREXIA	5	9.6
SOMNOLENCE	3	5.8
NASAL CONGESTION	2	3.8
NASAL DISCHARGE	2	3.8
CRYING	1	1.9
DIARRHEA	1	1.9

TABLE 11 (cont.)

FREQUENCY OF CLINICAL COMPLAINTS FOLLOWING VACCINATION WITH HIB VACCINE

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE
LOT NUMBER : CM679
DOSE : 13 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2-11 MOS.
RACE : UNKNOWN

	DOSE NUMBER: 1	
	TOTAL VACCINEES : 53 TOTAL VACCINEES PRESENTING DATA: 52	
CLINICAL COMPLAINTS	NUMBER OF VACCINEES	PERCENT
NAUSEA	1	1.9
NERVOUSNESS	1	1.9
OTITIS MEDIA	1	1.9
SLEEP DISORDERS	1	1.9
VACCINEES WITH COMPLAINTS:	34	65.4
VACCINEES WITH NO COMPLAINTS:	18	34.6
VACCINEES WITH NO DATA:	1	

TABLE 11 (cont.)

FREQUENCY OF CLINICAL COMPLAINTS FOLLOWING VACCINATION WITH HIB VACCINE

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE
LOT NUMBER : CM679
DOSE : 13 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2-11 MOS.
RACE : UNKNOWN

DOSE NUMBER: 2

TOTAL VACCINEES : 50
TOTAL VACCINEES PRESENTING DATA: 48

CLINICAL COMPLAINTS	NUMBER OF VACCINEES	PERCENT
REACTION,LOCAL (INJECT SITE)	11	22.9
ERYTHEMA, INJECTION SITE	6	12.5
INDURATION, INJECTION SITE	3	6.3
ECCHYMOSIS, INJECTION SITE	2	4.2
ERYTHEMA, INJECTION SITE (>1 INCH)	1	2.1
ERYTHEMA, INJECTION SITE (1 INCH, LESS THAN)	1	2.1
RASH, INJECTION SITE	1	2.1
SYSTEMIC	13	27.1
IRRITABILITY	9	18.8
CRYING	2	4.2
SOMNOLENCE	2	4.2
ANOREXIA	1	2.1
COUGH	1	2.1
NASAL DISCHARGE	1	2.1
OTITIS MEDIA	1	2.1
PERISTALSIS INCREASE	1	2.1

TABLE 11 (cont.)

FREQUENCY OF CLINICAL COMPLAINTS FOLLOWING VACCINATION WITH HIB VACCINE

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE
LOT NUMBER : CM679
DOSE : 13 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2-11 MOS.
RACE : UNKNOWN

	DOSE NUMBER: 2	
	TOTAL VACCINEES : 50 TOTAL VACCINEES PRESENTING DATA: 48	
CLINICAL COMPLAINTS	NUMBER OF VACCINEES	PERCENT
VOMITING	1	2.1
VACCINEES WITH COMPLAINTS:	21	43.8
VACCINEES WITH NO COMPLAINTS:	27	56.3
VACCINEES WITH NO DATA:	2	

TABLE 11 (cont.)

FREQUENCY OF CLINICAL COMPLAINTS FOLLOWING VACCINATION WITH HIB VACCINE

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE
LOT NUMBER : CM679
DOSE : 6 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2-11 MOS.
RACE : BLACK

	DOSE NUMBER: 1 TOTAL VACCINEES : 25 TOTAL VACCINEES PRESENTING DATA: 24	
CLINICAL COMPLAINTS	NUMBER OF VACCINEES	PERCENT
REACTION,LOCAL (INJECT SITE)	1	4.2
INDURATION, INJECTION SITE	1	4.2
SYSTEMIC	6	25.0
IRRITABILITY	3	12.5
ANOREXIA	2	8.3
FATIGUE	1	4.2
FEVER	1	4.2
TEETHING	1	4.2
VOMITING	1	4.2
VACCINEES WITH COMPLAINTS:	6	25.0
VACCINEES WITH NO COMPLAINTS:	18	75.0
VACCINEES WITH NO DATA:	1	

TABLE 11 (cont.)

FREQUENCY OF CLINICAL COMPLAINTS FOLLOWING VACCINATION WITH HIB VACCINE

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE
LOT NUMBER : CM679
DOSE : 6 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.
RACE : BLACK

DOSE NUMBER: 1

TOTAL VACCINEES : 28
TOTAL VACCINEES PRESENTING DATA: 28

CLINICAL COMPLAINTS	NUMBER OF VACCINEES	PERCENT
REACTION,LOCAL (INJECT SITE)	1	3.6
PAIN/SORENESS, INJECTION SITE	1	3.6
SYSTEMIC	5	17.9
CRYING, EXCESSIVE	2	7.1
IRRITABILITY	2	7.1
ANOREXIA	1	3.6
FATIGUE	1	3.6
NASAL DISCHARGE	1	3.6
VACCINEES WITH COMPLAINTS:	6	21.4
VACCINEES WITH NO COMPLAINTS:	22	78.6
VACCINEES WITH NO DATA:	0	

TABLE 11 (cont.)

FREQUENCY OF CLINICAL COMPLAINTS FOLLOWING VACCINATION WITH HIB VACCINE

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE
LOT NUMBER : CM679
DOSE : 18 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2-11 MOS.
RACE : BLACK

DOSE NUMBER: 1

TOTAL VACCINEES : 3
TOTAL VACCINEES PRESENTING DATA: 3

CLINICAL COMPLAINTS	NUMBER OF VACCINEES	PERCENT
REACTION,LOCAL (INJECT SITE)	2	66.7
INDURATION, INJECTION SITE	2	66.7
SWELLING, INJECTION SITE (1 INCH, LESS THAN)	1	33.3
SYSTEMIC	1	33.3
ANOREXIA	1	33.3
CRYING, EXCESSIVE	1	33.3
IRRITABILITY	1	33.3
VACCINEES WITH COMPLAINTS:	3	100.0
VACCINEES WITH NO COMPLAINTS:	0	0.0
VACCINEES WITH NO DATA:	0	

FREQUENCY OF CLINICAL COMPLAINTS FOLLOWING BOOSTER VACCINATION

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : COMBINE
LOT NUMBER : CM679 AS BOOSTER INJ.
DOSE : 6 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2-11 MOS.
RACE : UNKNOWN

DOSE NUMBER: COMBINED

TOTAL VACCINEES : 9
TOTAL VACCINEES PRESENTING DATA: 9

CLINICAL COMPLAINTS	NUMBER OF VACCINEES	PERCENT
REACTION,LOCAL (INJECT SITE)	3	33.3
ERYTHEMA, INJECTION SITE (1 INCH,LESS THAN)	2	22.2
PAIN/SORENESS, INJECTION SITE	1	11.1
SYSTEMIC	3	33.3
IRRITABILITY	3	33.3
OTITIS MEDIA	2	22.2
ANOREXIA	1	11.1
NASAL DISCHARGE	1	11.1
UPPER RESPIRATORY INFECTION, NOS	1	11.1
VACCINEES WITH COMPLAINTS:	4	44.4
VACCINEES WITH NO COMPLAINTS:	5	55.6
VACCINEES WITH NO DATA:	0	

TABLE 11 (cont.)

FREQUENCY OF CLINICAL COMPLAINTS FOLLOWING BOOSTER VACCINATION

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : COMBINE
LOT NUMBER : CM679
DOSE : 6 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.
RACE : UNKNOWN

DOSE NUMBER: COMBINED

TOTAL VACCINEES : 1
TOTAL VACCINEES PRESENTING DATA: 1

CLINICAL COMPLAINTS	NUMBER OF VACCINEES	PERCENT
REACTION,LOCAL (INJECT SITE)	0	0.0
SYSTEMIC	0	0.0
VACCINEES WITH COMPLAINTS:	0	0.0
VACCINEES WITH NO COMPLAINTS:	1	100.0
VACCINEES WITH NO DATA:	0	

TABLE 11 (cont.)

FREQUENCY OF CLINICAL COMPLAINTS FOLLOWING BOOSTER VACCINATION

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : COMBINE
LOT NUMBER : POLYS
DOSE : 25 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2-11 MOS.
RACE : BLACK

	DOSE NUMBER: COMBINED TOTAL VACCINEES : 16 TOTAL VACCINEES PRESENTING DATA: 4	
CLINICAL COMPLAINTS	NUMBER OF VACCINEES	PERCENT
REACTION,LOCAL (INJECT SITE)	0	0.0
SYSTEMIC	1	25.0
FATIGUE	1	25.0
IRRITABILITY	1	25.0
VACCINEES WITH COMPLAINTS:	1	25.0
VACCINEES WITH NO COMPLAINTS:	3	75.0
VACCINEES WITH NO DATA:	12	

TABLE 11 (cont.)

FREQUENCY OF CLINICAL COMPLAINTS FOLLOWING BOOSTER VACCINATION

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : COMBINE
LOT NUMBER : POLYS
DOSE : 25 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2-11 MOS.
RACE : UNKNOWN

DOSE NUMBER: COMBINED

TOTAL VACCINEES : 25
TOTAL VACCINEES PRESENTING DATA: 24

CLINICAL COMPLAINTS	NUMBER OF VACCINEES	PERCENT
REACTION,LOCAL (INJECT SITE)	3	12.5
ERYTHEMA, INJECTION SITE (1 INCH, LESS THAN)	2	8.3
ERYTHEMA, INJECTION SITE (>1 INCH)	1	4.2
SYSTEMIC	1	4.2
FATIGUE	1	4.2
IRRITABILITY	1	4.2
VACCINEES WITH COMPLAINTS:	4	16.7
VACCINEES WITH NO COMPLAINTS:	20	83.3
VACCINEES WITH NO DATA:	1	

TABLE 11 (cont.)

FREQUENCY OF CLINICAL COMPLAINTS FOLLOWING BOOSTER VACCINATION

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : COMBINE
LOT NUMBER : POLYS
DOSE : 25 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.
RACE : BLACK

	DOSE NUMBER: COMBINED TOTAL VACCINEES : 16 TOTAL VACCINEES PRESENTING DATA: 7	
CLINICAL COMPLAINTS	NUMBER OF VACCINEES	PERCENT
REACTION,LOCAL (INJECT SITE)	0	0.0
SYSTEMIC	1	14.3
CRYING, EXCESSIVE	1	14.3
FATIGUE	1	14.3
HYPERKINESIA	1	14.3
IRRITABILITY	1	14.3
NERVOUSNESS	1	14.3
VACCINEES WITH COMPLAINTS:	1	14.3
VACCINEES WITH NO COMPLAINTS:	6	85.7
VACCINEES WITH NO DATA:	9	

TABLE 11 (cont.)

FREQUENCY OF CLINICAL COMPLAINTS FOLLOWING BOOSTER VACCINATION

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : COMBINE
LOT NUMBER : POLYS
DOSE : 25 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.
RACE : UNKNOWN

	DOSE NUMBER: COMBINED TOTAL VACCINEES : 5 TOTAL VACCINEES PRESENTING DATA: 4	
CLINICAL COMPLAINTS	NUMBER OF VACCINEES	PERCENT
REACTION,LOCAL (INJECT SITE)	0	0.0
SYSTEMIC	0	0.0
VACCINEES WITH COMPLAINTS:	0	0.0
VACCINEES WITH NO COMPLAINTS:	4	100.0
VACCINEES WITH NO DATA:	1	

TABLE 12

CLINICAL COMPLAINTS

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE
LOT NUMBER : CL680
DOSE : 7 MCG
PATIENT CLASS: HEALTHY ADULTS
AGE RANGE : 20-45 YRS.
RACE : UNKNOWN

CLINICAL COMPLAINTS	NUMBER OF VACCINEES (6 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
	0	1	2	3				
LOCAL REACTIONS	4 (66.7%)	6 (100.0%)	6 (100.0%)	0 (0.0%)				6 (100.0%)
PAIN/SORENESS, INJECTION SITE	4 (66.7%)	6 (100.0%)	6 (100.0%)	0 (0.0%)				6 (100.0%)
VACCINEES WITH COMPLAINTS	4 (66.7%)	6 (100.0%)	6 (100.0%)	0 (0.0%)				6 (100.0%)
VACCINEES WITH NO COMPLAINTS	2 (33.3%)	0 (0.0%)	0 (0.0%)	6 (100.0%)				0 (0.0%)
TOTAL VACCINEES REPORTING	6	6	6	6				6
VACCINEES WITH NO DATA	0	0	0	0				0

TABLE 12 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CL680
DOSE : 7 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2-11 MOS.
RACE : UNKNOWN

CLINICAL COMPLAINTS	NUMBER OF VACCINEES (10 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
	0	1	2	3				
LOCAL REACTIONS	3 (30.0%)	6 (60.0%)	2 (20.0%)	1 (10.0%)				6 (60.0%)
ERYTHEMA, INJECTION SITE	0 (0.0%)	1 (10.0%)	0 (0.0%)	0 (0.0%)				1 (10.0%)
ERYTHEMA, INJECTION SITE (1 INCH, <)	0 (0.0%)	3 (30.0%)	1 (10.0%)	0 (0.0%)				3 (30.0%)
INDURATION, INJECTION SITE	1 (10.0%)	1 (10.0%)	0 (0.0%)	0 (0.0%)				1 (10.0%)
STIFFNESS/TIGHTNESS, INJECTION SI	1 (10.0%)	1 (10.0%)	1 (10.0%)	1 (10.0%)				1 (10.0%)
SWELLING, INJECTION SITE (>1 INCH	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (10.0%)
SWELLING, INJECTION SITE (1 INCH, <)	2 (20.0%)	1 (10.0%)	1 (10.0%)	1 (10.0%)				2 (20.0%)
SYSTEMIC	3 (30.0%)	2 (20.0%)	1 (10.0%)	1 (10.0%)				3 (30.0%)
DIGESTIVE SYSTEM	1 (10.0%)	1 (10.0%)	1 (10.0%)	1 (10.0%)				1 (10.0%)
ANOREXIA	1 (10.0%)	1 (10.0%)	1 (10.0%)	1 (10.0%)				1 (10.0%)
NERVOUS SYSTEM & PSYCHIATRIC	3 (30.0%)	2 (20.0%)	1 (10.0%)	0 (0.0%)				3 (30.0%)
CRYING, EXCESSIVE	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (10.0%)

TABLE 12 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CL680
DOSE : 7 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2-11 MOS.
RACE : UNKNOWN

	NUMBER OF VACCINEES (10 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER
CLINICAL COMPLAINTS	0	1	2	3				WITH COMPLAINTS
IRRITABILITY	1 (10.0%)	1 (10.0%)	1 (10.0%)	0 (0.0%)				2 (20.0%)
NERVOUSNESS	1 (10.0%)	1 (10.0%)	0 (0.0%)	0 (0.0%)				1 (10.0%)
SOMNOLENCE	1 (10.0%)	1 (10.0%)	1 (10.0%)	0 (0.0%)				1 (10.0%)
VACCINEES WITH COMPLAINTS	4 (40.0%)	7 (70.0%)	2 (20.0%)	2 (20.0%)				7 (70.0%)
VACCINEES WITH NO COMPLAINTS	6 (60.0%)	3 (30.0%)	8 (80.0%)	8 (80.0%)				3 (30.0%)
TOTAL VACCINEES REPORTING	10	10	10	10				10
VACCINEES WITH NO DATA	0	0	0	0				0

TABLE 12 (cont.)
CLINICAL COMPLAINTS

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CL680
DOSE : 7 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2-11 MOS.
RACE : UNKNOWN

	NUMBER OF VACCINEES (8 VACCINEES) - INJECTION 2							
	DAYS POST VACCINATION							NUMBER
CLINICAL COMPLAINTS	0	1	2	3				WITH COMPLAINTS
LOCAL REACTIONS	6 (75.0%)	2 (25.0%)	0 (0.0%)	0 (0.0%)				6 (75.0%)
ERYTHEMA, INJECTION SITE (>1 INCH	1 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (12.5%)
ERYTHEMA, INJECTION SITE (1 INCH, <)	2 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				2 (25.0%)
PAIN/SORENESS, INJECTION SITE	2 (25.0%)	1 (12.5%)	0 (0.0%)	0 (0.0%)				2 (25.0%)
SWELLING, INJECTION SITE (>1 INCH	2 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				2 (25.0%)
SWELLING, INJECTION SITE (1 INCH, <)	1 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (12.5%)
WARMTH, INJECTION SITE	0 (0.0%)	1 (12.5%)	0 (0.0%)	0 (0.0%)				1 (12.5%)
SYSTEMIC	5 (62.5%)	2 (25.0%)	2 (25.0%)	2 (25.0%)				6 (75.0%)
DIGESTIVE SYSTEM	1 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (12.5%)
ANOREXIA	1 (12.5%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (12.5%)
NERVOUS SYSTEM & PSYCHIATRIC	4 (50.0%)	1 (12.5%)	1 (12.5%)	1 (12.5%)				4 (50.0%)
IRRITABILITY	4 (50.0%)	1 (12.5%)	1 (12.5%)	1 (12.5%)				4 (50.0%)

TABLE 12 (cont.)
CLINICAL COMPLAINTS

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CL680
DOSE : 7 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2-11 MOS.
RACE : UNKNOWN

	NUMBER OF VACCINEES (8 VACCINEES) - INJECTION 2							
	DAYS POST VACCINATION							NUMBER
CLINICAL COMPLAINTS	0	1	2	3				WITH COMPLAINTS
SPECIAL SENSES	0 (0.0%)	1 (12.5%)	2 (25.0%)	2 (25.0%)				2 (25.0%)
OTITIS MEDIA	0 (0.0%)	1 (12.5%)	2 (25.0%)	2 (25.0%)				2 (25.0%)
VACCINEES WITH COMPLAINTS	6 (75.0%)	4 (50.0%)	2 (25.0%)	2 (25.0%)				7 (87.5%)
VACCINEES WITH NO COMPLAINTS	2 (25.0%)	4 (50.0%)	6 (75.0%)	6 (75.0%)				1 (12.5%)
TOTAL VACCINEES REPORTING	8	8	8	8				8
VACCINEES WITH NO DATA	0	0	0	0				0

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TABLE 12 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CL680
DOSE : 7 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.
RACE : UNKNOWN

CLINICAL COMPLAINTS	NUMBER OF VACCINEES (3 VACCINEES) - INJECTION 1							NUMBER WITH COMPLAINTS
	DAYS POST VACCINATION							
	0	1	2	3				
LOCAL REACTIONS	2 (66.7%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				2 (66.7%)
ERYTHEMA, INJECTION SITE	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (33.3%)
PAIN/SORENESS, INJECTION SITE	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (33.3%)
SYSTEMIC	2 (66.7%)	2 (66.7%)	0 (0.0%)	0 (0.0%)				2 (66.7%)
DIGESTIVE SYSTEM	1 (33.3%)	1 (33.3%)	0 (0.0%)	0 (0.0%)				1 (33.3%)
ANOREXIA	1 (33.3%)	1 (33.3%)	0 (0.0%)	0 (0.0%)				1 (33.3%)
NERVOUS SYSTEM & PSYCHIATRIC	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (33.3%)
IRRITABILITY	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (33.3%)
RESPIRATORY SYSTEM	1 (33.3%)	1 (33.3%)	0 (0.0%)	0 (0.0%)				1 (33.3%)
COMMON COLD	1 (33.3%)	1 (33.3%)	0 (0.0%)	0 (0.0%)				1 (33.3%)
VACCINEES WITH COMPLAINTS	3 (100.0%)	2 (66.7%)	0 (0.0%)	0 (0.0%)				3 (100.0%)
VACCINEES WITH NO COMPLAINTS	0 (0.0%)	1 (33.3%)	3 (100.0%)	3 (100.0%)				0 (0.0%)

TABLE 12 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CL680
DOSE : 7 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.
RACE : UNKNOWN

CLINICAL COMPLAINTS	NUMBER OF VACCINEES (3 VACCINEES) - INJECTION 1										NUMBER WITH COMPLAINTS
	DAYS POST VACCINATION										
	0	1	2	3							**********
TOTAL VACCINEES REPORTING	3	3	3	3							3
VACCINEES WITH NO DATA	0	0	0	0							0

TABLE 12 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CL680
DOSE : 7 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.
RACE : UNKNOWN

	NUMBER OF VACCINEES (3 VACCINEES) - INJECTION 2							
	DAYS POST VACCINATION							NUMBER
CLINICAL COMPLAINTS	0	1	2	3				WITH COMPLAINTS
LOCAL REACTIONS	1 (33.3%)	1 (33.3%)	0 (0.0%)	0 (0.0%)				1 (33.3%)
PAIN/SORENESS, INJECTION SITE	1 (33.3%)	1 (33.3%)	0 (0.0%)	0 (0.0%)				1 (33.3%)
SYSTEMIC	2 (66.7%)	1 (33.3%)	0 (0.0%)	0 (0.0%)				2 (66.7%)
BODY AS A WHOLE/SITE UNSPEC.	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (33.3%)
WARM SENSATION	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (33.3%)
NERVOUS SYSTEM & PSYCHIATRIC	1 (33.3%)	1 (33.3%)	0 (0.0%)	0 (0.0%)				1 (33.3%)
IRRITABILITY	1 (33.3%)	1 (33.3%)	0 (0.0%)	0 (0.0%)				1 (33.3%)
VACCINEES WITH COMPLAINTS	2 (66.7%)	1 (33.3%)	0 (0.0%)	0 (0.0%)				2 (66.7%)
VACCINEES WITH NO COMPLAINTS	1 (33.3%)	2 (66.7%)	3 (100.0%)	3 (100.0%)				1 (33.3%)
TOTAL VACCINEES REPORTING	3	3	3	3				3
VACCINEES WITH NO DATA	0	0	0	0				0

TABLE 12 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE
LOT NUMBER : CL680
DOSE : 7 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2-11 MOS.
RACE : UNKNOWN

CLINICAL COMPLAINTS	NUMBER OF VACCINEES (29 VACCINEES) - INJECTION 1							NUMBER WITH COMPLAINTS
	DAYS POST VACCINATION							
	0	1	2	3				
LOCAL REACTIONS	13 (44.8%)	11 (37.9%)	3 (10.3%)	2 (6.9%)				19 (65.5%)
ECCHYMOSIS, INJECTION SITE	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (3.4%)
ERYTHEMA, INJECTION SITE	2 (6.9%)	3 (10.3%)	1 (3.4%)	0 (0.0%)				4 (13.8%)
ERYTHEMA, INJECTION SITE (1 INCH, <)	7 (24.1%)	4 (13.8%)	2 (6.9%)	1 (3.4%)				12 (41.4%)
INDURATION, INJECTION SITE	0 (0.0%)	2 (6.9%)	0 (0.0%)	1 (3.4%)				3 (10.3%)
PAIN/SORENESS, INJECTION SITE	3 (10.3%)	3 (10.3%)	0 (0.0%)	0 (0.0%)				5 (17.2%)
SWELLING, INJECTION SITE	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (3.4%)
WARMTH, INJECTION SITE	2 (6.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				2 (6.9%)
SYSTEMIC	9 (31.0%)	3 (10.3%)	1 (3.4%)	0 (0.0%)				11 (37.9%)
NERVOUS SYSTEM & PSYCHIATRIC	8 (27.6%)	2 (6.9%)	0 (0.0%)	0 (0.0%)				10 (34.5%)
INSOMNIA	0 (0.0%)	1 (3.4%)	0 (0.0%)	0 (0.0%)				1 (3.4%)
IRRITABILITY	7 (24.1%)	1 (3.4%)	0 (0.0%)	0 (0.0%)				8 (27.6%)

TABLE 12 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE
LOT NUMBER : CL680
DOSE : 7 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2-11 MOS.
RACE : UNKNOWN

	NUMBER OF VACCINEES (29 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER
CLINICAL COMPLAINTS	0	1	2	3				WITH COMPLAINTS
SOMNOLENCE	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (3.4%)
RESPIRATORY SYSTEM	0 (0.0%)	1 (3.4%)	1 (3.4%)	0 (0.0%)				1 (3.4%)
COMMON COLD	0 (0.0%)	1 (3.4%)	0 (0.0%)	0 (0.0%)				1 (3.4%)
NASAL DISCHARGE	0 (0.0%)	0 (0.0%)	1 (3.4%)	0 (0.0%)				1 (3.4%)
SKIN & SKIN APPENDAGE	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (3.4%)
RASH	1 (3.4%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (3.4%)
VACCINEES WITH COMPLAINTS	16 (55.2%)	12 (41.4%)	4 (13.8%)	2 (6.9%)				21 (72.4%)
VACCINEES WITH NO COMPLAINTS	13 (44.8%)	17 (58.6%)	25 (86.2%)	27 (93.1%)				8 (27.6%)
TOTAL VACCINEES REPORTING	29	29	29	29				29
VACCINEES WITH NO DATA	0	0	0	0				0

TABLE 12 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE
LOT NUMBER : CL680
DOSE : 7 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2-11 MOS.
RACE : UNKNOWN

CLINICAL COMPLAINTS	NUMBER OF VACCINEES (24 VACCINEES) - INJECTION 2							NUMBER WITH COMPLAINTS
	DAYS POST VACCINATION							
	0	1	2	3				
LOCAL REACTIONS	6 (25.0%)	5 (20.8%)	1 (4.5%)	0 (0.0%)				9 (37.5%)
ECCHYMOSIS, INJECTION SITE	1 (4.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (4.2%)
ERYTHEMA, INJECTION SITE	1 (4.2%)	3 (12.5%)	0 (0.0%)	0 (0.0%)				3 (12.5%)
ERYTHEMA, INJECTION SITE (1 INCH, <)	1 (4.2%)	1 (4.2%)	0 (0.0%)	0 (0.0%)				2 (8.3%)
INDURATION, INJECTION SITE	2 (8.3%)	1 (4.2%)	1 (4.5%)	0 (0.0%)				2 (8.3%)
PAIN/SORENESS, INJECTION SITE	2 (8.3%)	1 (4.2%)	0 (0.0%)	0 (0.0%)				2 (8.3%)
SYSTEMIC	2 (8.3%)	1 (4.2%)	3 (13.6%)	0 (0.0%)				5 (20.8%)
NERVOUS SYSTEM & PSYCHIATRIC	2 (8.3%)	1 (4.2%)	3 (13.6%)	0 (0.0%)				5 (20.8%)
INSOMNIA	0 (0.0%)	0 (0.0%)	1 (4.5%)	0 (0.0%)				1 (4.2%)
IRRITABILITY	2 (8.3%)	1 (4.2%)	2 (9.1%)	0 (0.0%)				4 (16.7%)
RESPIRATORY SYSTEM	0 (0.0%)	0 (0.0%)	1 (4.5%)	0 (0.0%)				1 (4.2%)
NASAL DISCHARGE	0 (0.0%)	0 (0.0%)	1 (4.5%)	0 (0.0%)				1 (4.2%)

TABLE 12 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE
LOT NUMBER : CL680
DOSE : 7 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2-11 MOS.
RACE : UNKNOWN

	NUMBER OF VACCINEES (24 VACCINEES) - INJECTION 2						
	DAYS POST VACCINATION						NUMBER
CLINICAL COMPLAINTS	0	1	2	3			WITH COMPLAINTS
VACCINEES WITH COMPLAINTS	8 (33.3%)	6 (25.0%)	4 (18.2%)	0 (0.0%)			12 (50.0%)
VACCINEES WITH NO COMPLAINTS	16 (66.7%)	18 (75.0%)	18 (81.8%)	22 (100.0%)			12 (50.0%)
TOTAL VACCINEES REPORTING	24	24	22	22			24
VACCINEES WITH NO DATA	0	0	2	2			0

TABLE 12 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE
LOT NUMBER : CL680
DOSE : 7 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.
RACE : UNKNOWN

CLINICAL COMPLAINTS	NUMBER OF VACCINEES (10 VACCINEES) - INJECTION 1							NUMBER WITH COMPLAINTS
	DAYS POST VACCINATION							
	0	1	2	3				
LOCAL REACTIONS	2 (20.0%)	3 (30.0%)	1 (10.0%)	0 (0.0%)				4 (40.0%)
ERYTHEMA, INJECTION SITE	1 (10.0%)	1 (10.0%)	0 (0.0%)	0 (0.0%)				1 (10.0%)
ERYTHEMA, INJECTION SITE (1 INCH, <)	1 (10.0%)	1 (10.0%)	0 (0.0%)	0 (0.0%)				2 (20.0%)
INDURATION, INJECTION SITE	0 (0.0%)	0 (0.0%)	1 (10.0%)	0 (0.0%)				1 (10.0%)
PAIN/SORENESS, INJECTION SITE	0 (0.0%)	1 (10.0%)	0 (0.0%)	0 (0.0%)				1 (10.0%)
SYSTEMIC	2 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				2 (20.0%)
NERVOUS SYSTEM & PSYCHIATRIC	2 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				2 (20.0%)
IRRITABILITY	2 (20.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				2 (20.0%)
VACCINEES WITH COMPLAINTS	4 (40.0%)	3 (30.0%)	1 (10.0%)	0 (0.0%)				5 (50.0%)
VACCINEES WITH NO COMPLAINTS	6 (60.0%)	7 (70.0%)	9 (90.0%)	10 (100.0%)				5 (50.0%)
TOTAL VACCINEES REPORTING	10	10	10	10				10

TABLE 12 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE
LOT NUMBER : CL680
DOSE : 7 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.
RACE : UNKNOWN

	NUMBER OF VACCINEES (10 VACCINEES) - INJECTION 1						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3			COMPLAINTS
VACCINEES WITH NO DATA	0	0	0	0			0

TABLE 12 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE
LOT NUMBER : CL680
DOSE : 7 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.
RACE : UNKNOWN

	NUMBER OF VACCINEES (2 VACCINEES) - INJECTION 2							
	DAYS POST VACCINATION							NUMBER
CLINICAL COMPLAINTS	0	1	2	3				WITH COMPLAINTS
LOCAL REACTIONS	0 (0.0%)	1 (50.0%)	1 (50.0%)	0 (0.0%)				1 (50.0%)
INDURATION, INJECTION SITE	0 (0.0%)	1 (50.0%)	1 (50.0%)	0 (0.0%)				1 (50.0%)
SWELLING, INJECTION SITE (>1 INCH	0 (0.0%)	1 (50.0%)	0 (0.0%)	0 (0.0%)				1 (50.0%)
VACCINEES WITH COMPLAINTS	0 (0.0%)	1 (50.0%)	1 (50.0%)	0 (0.0%)				1 (50.0%)
VACCINEES WITH NO COMPLAINTS	2 (100.0%)	1 (50.0%)	1 (50.0%)	2 (100.0%)				1 (50.0%)
TOTAL VACCINEES REPORTING	2	2	2	2				2
VACCINEES WITH NO DATA	0	0	0	0				0

TABLE 12 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE
LOT NUMBER : CM679
DOSE : 13 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2-11 MOS.
RACE : UNKNOWN

CLINICAL COMPLAINTS	NUMBER OF VACCINEES (53 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
	0	1	2	3				
LOCAL REACTIONS	9 (17.3%)	15 (28.8%)	6 (11.8%)	5 (9.8%)				19 (36.5%)
ECCHYMOSIS, INJECTION SITE	1 (1.9%)	1 (1.9%)	0 (0.0%)	0 (0.0%)				2 (3.8%)
ERYTHEMA, INJECTION SITE	3 (5.8%)	6 (11.5%)	2 (3.9%)	2 (3.9%)				8 (15.4%)
ERYTHEMA, INJECTION SITE (>1 INCH	2 (3.8%)	2 (3.8%)	2 (3.9%)	1 (2.0%)				2 (3.8%)
ERYTHEMA, INJECTION SITE (1 INCH, <)	1 (1.9%)	3 (5.8%)	1 (2.0%)	0 (0.0%)				3 (5.8%)
INDURATION, INJECTION SITE	2 (3.8%)	3 (5.8%)	2 (3.9%)	3 (5.9%)				5 (9.6%)
PAIN/SORENESS, INJECTION SITE	3 (5.8%)	2 (3.8%)	1 (2.0%)	1 (2.0%)				4 (7.7%)
WARMTH, INJECTION SITE	1 (1.9%)	1 (1.9%)	1 (2.0%)	0 (0.0%)				1 (1.9%)
SYSTEMIC	14 (26.9%)	10 (19.2%)	5 (9.8%)	4 (7.8%)				19 (36.5%)
DIGESTIVE SYSTEM	2 (3.8%)	4 (7.7%)	0 (0.0%)	0 (0.0%)				6 (11.5%)
ANOREXIA	2 (3.8%)	3 (5.8%)	0 (0.0%)	0 (0.0%)				5 (9.6%)
DIARRHEA	0 (0.0%)	1 (1.9%)	0 (0.0%)	0 (0.0%)				1 (1.9%)

TABLE 12 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE
LOT NUMBER : CM679
DOSE : 13 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2-11 MOS.
RACE : UNKNOWN

	NUMBER OF VACCINEES (53 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
CLINICAL COMPLAINTS	0	1	2	3				
NAUSEA	0 (0.0%)	1 (1.9%)	0 (0.0%)	0 (0.0%)				1 (1.9%)
NERVOUS SYSTEM & PSYCHIATRIC	10 (19.2%)	5 (9.6%)	1 (2.0%)	2 (3.9%)				13 (25.0%)
CRYING	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.0%)				1 (1.9%)
IRRITABILITY	6 (11.5%)	3 (5.8%)	0 (0.0%)	1 (2.0%)				9 (17.3%)
NERVOUSNESS	1 (1.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (1.9%)
SLEEP DISORDERS	0 (0.0%)	1 (1.9%)	0 (0.0%)	0 (0.0%)				1 (1.9%)
SOMNOLENCE	3 (5.8%)	1 (1.9%)	1 (2.0%)	1 (2.0%)				3 (5.8%)
RESPIRATORY SYSTEM	1 (1.9%)	3 (5.8%)	3 (5.9%)	1 (2.0%)				3 (5.8%)
NASAL CONGESTION	1 (1.9%)	2 (3.8%)	1 (2.0%)	0 (0.0%)				2 (3.8%)
NASAL DISCHARGE	0 (0.0%)	1 (1.9%)	2 (3.9%)	1 (2.0%)				2 (3.8%)
SPECIAL SENSES	1 (1.9%)	1 (1.9%)	1 (2.0%)	1 (2.0%)				1 (1.9%)
OTITIS MEDIA	1 (1.9%)	1 (1.9%)	1 (2.0%)	1 (2.0%)				1 (1.9%)

TABLE 12 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE
LOT NUMBER : CM679
DOSE : 13 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2-11 MOS.
RACE : UNKNOWN

	NUMBER OF VACCINEES (53 VACCINEES) - INJECTION 1						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3			COMPLAINTS
VACCINEES WITH COMPLAINTS	23 (44.2%)	23 (44.2%)	11 (21.6%)	9 (17.6%)			34 (65.4%)
VACCINEES WITH NO COMPLAINTS	29 (55.8%)	29 (55.8%)	40 (78.4%)	42 (82.4%)			18 (34.6%)
TOTAL VACCINEES REPORTING	52	52	51	51			52
VACCINEES WITH NO DATA	1	1	2	2			1

TABLE 12 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE
LOT NUMBER : CM679
DOSE : 13 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2-11 MOS.
RACE : UNKNOWN

CLINICAL COMPLAINTS	NUMBER OF VACCINEES (50 VACCINEES) - INJECTION 2							NUMBER WITH COMPLAINTS
	DAYS POST VACCINATION							
	0	1	2	3				
LOCAL REACTIONS	4 (8.3%)	8 (16.7%)	2 (4.2%)	3 (6.3%)				11 (22.9%)
ECCHYMOSIS, INJECTION SITE	0 (0.0%)	1 (2.1%)	0 (0.0%)	1 (2.1%)				2 (4.2%)
ERYTHEMA, INJECTION SITE	3 (6.3%)	3 (6.3%)	0 (0.0%)	0 (0.0%)				6 (12.5%)
ERYTHEMA, INJECTION SITE (>1 INCH	0 (0.0%)	1 (2.1%)	0 (0.0%)	0 (0.0%)				1 (2.1%)
ERYTHEMA, INJECTION SITE (1 INCH, <)	1 (2.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (2.1%)
INDURATION, INJECTION SITE	1 (2.1%)	3 (6.3%)	2 (4.2%)	2 (4.2%)				3 (6.3%)
RASH, INJECTION SITE	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.1%)				1 (2.1%)
SYSTEMIC	7 (14.6%)	7 (14.6%)	5 (10.4%)	1 (2.1%)				13 (27.1%)
DIGESTIVE SYSTEM	2 (4.2%)	0 (0.0%)	1 (2.1%)	0 (0.0%)				3 (6.3%)
ANOREXIA	1 (2.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (2.1%)
PERISTALSIS INCREASE	0 (0.0%)	0 (0.0%)	1 (2.1%)	0 (0.0%)				1 (2.1%)
VOMITING	1 (2.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (2.1%)

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE
LOT NUMBER : CM679
DOSE : 13 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2-11 MOS.
RACE : UNKNOWN

CLINICAL COMPLAINTS	NUMBER OF VACCINEES (50 VACCINEES) - INJECTION 2							
	DAYS POST VACCINATION							NUMBER WITH COMPLAINTS
	0	1	2	3				
NERVOUS SYSTEM & PSYCHIATRIC	5 (10.4%)	5 (10.4%)	3 (6.3%)	0 (0.0%)				10 (20.8%)
CRYING	1 (2.1%)	1 (2.1%)	0 (0.0%)	0 (0.0%)				2 (4.2%)
IRRITABILITY	3 (6.3%)	4 (8.3%)	3 (6.3%)	0 (0.0%)				9 (18.8%)
SOMNOLENCE	1 (2.1%)	1 (2.1%)	0 (0.0%)	0 (0.0%)				2 (4.2%)
RESPIRATORY SYSTEM	0 (0.0%)	1 (2.1%)	0 (0.0%)	0 (0.0%)				1 (2.1%)
COUGH	0 (0.0%)	1 (2.1%)	0 (0.0%)	0 (0.0%)				1 (2.1%)
NASAL DISCHARGE	0 (0.0%)	1 (2.1%)	0 (0.0%)	0 (0.0%)				1 (2.1%)
SPECIAL SENSES	1 (2.1%)	1 (2.1%)	1 (2.1%)	1 (2.1%)				1 (2.1%)
OTITIS MEDIA	1 (2.1%)	1 (2.1%)	1 (2.1%)	1 (2.1%)				1 (2.1%)
VACCINEES WITH COMPLAINTS	11 (22.9%)	15 (31.3%)	7 (14.6%)	4 (8.3%)				21 (43.8%)
VACCINEES WITH NO COMPLAINTS	37 (77.1%)	33 (68.8%)	41 (85.4%)	44 (91.7%)				27 (56.3%)
TOTAL VACCINEES REPORTING	48	48	48	48				48

TABLE 12 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE
LOT NUMBER : CM679
DOSE : 13 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2-11 MOS.
RACE : UNKNOWN

	NUMBER OF VACCINEES (50 VACCINEES) - INJECTION 2						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3			COMPLAINTS
							**********
VACCINEES WITH NO DATA	2	2	2	2			2

TABLE 12 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE
LOT NUMBER : CM679
DOSE : 6 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2-11 MOS.
RACE : BLACK

CLINICAL COMPLAINTS	NUMBER OF VACCINEES (25 VACCINEES) - INJECTION 1 — DAYS POST VACCINATION 0	1	2	3				NUMBER WITH COMPLAINTS
LOCAL REACTIONS	0 (0.0%)	1 (4.3%)	0 (0.0%)	0 (0.0%)				1 (4.2%)
INDURATION, INJECTION SITE	0 (0.0%)	1 (4.3%)	0 (0.0%)	0 (0.0%)				1 (4.2%)
SYSTEMIC	3 (12.5%)	4 (17.4%)	4 (22.2%)	1 (5.6%)				6 (25.0%)
BODY AS A WHOLE/SITE UNSPEC.	1 (4.2%)	1 (4.3%)	2 (11.1%)	0 (0.0%)				2 (8.3%)
FATIGUE	1 (4.2%)	1 (4.3%)	1 (5.6%)	0 (0.0%)				1 (4.2%)
FEVER	0 (0.0%)	0 (0.0%)	1 (5.6%)	0 (0.0%)				1 (4.2%)
DIGESTIVE SYSTEM	2 (8.3%)	2 (8.7%)	2 (11.1%)	0 (0.0%)				3 (12.5%)
ANOREXIA	2 (8.3%)	1 (4.3%)	0 (0.0%)	0 (0.0%)				2 (8.3%)
TEETHING	0 (0.0%)	0 (0.0%)	1 (5.6%)	0 (0.0%)				1 (4.2%)
VOMITING	1 (4.2%)	1 (4.3%)	1 (5.6%)	0 (0.0%)				1 (4.2%)
NERVOUS SYSTEM & PSYCHIATRIC	0 (0.0%)	1 (4.3%)	1 (5.6%)	1 (5.6%)				3 (12.5%)
IRRITABILITY	0 (0.0%)	1 (4.3%)	1 (5.6%)	1 (5.6%)				3 (12.5%)

TABLE 12 (cont.)
CLINICAL COMPLAINTS

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE
LOT NUMBER : CM679
DOSE : 6 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2-11 MOS.
RACE : BLACK

	NUMBER OF VACCINEES (25 VACCINEES) - INJECTION 1					
	DAYS POST VACCINATION					NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3		COMPLAINTS
VACCINEES WITH COMPLAINTS	3 (12.5%)	4 (17.4%)	4 (22.2%)	1 (5.6%)		6 (25.0%)
VACCINEES WITH NO COMPLAINTS	21 (87.5%)	19 (82.6%)	14 (77.8%)	17 (94.4%)		18 (75.0%)
TOTAL VACCINEES REPORTING	24	23	18	18		24
VACCINEES WITH NO DATA	1	2	7	7		1

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE
LOT NUMBER : CM679
DOSE : 6 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.
RACE : BLACK

	NUMBER OF VACCINEES (28 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3				COMPLAINTS
LOCAL REACTIONS	1 (3.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (3.6%)
PAIN/SORENESS, INJECTION SITE	1 (3.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (3.6%)
SYSTEMIC	4 (14.3%)	3 (10.7%)	3 (13.6%)	3 (15.8%)				5 (17.9%)
BODY AS A WHOLE/SITE UNSPEC.	0 (0.0%)	1 (3.6%)	0 (0.0%)	0 (0.0%)				1 (3.6%)
FATIGUE	0 (0.0%)	1 (3.6%)	0 (0.0%)	0 (0.0%)				1 (3.6%)
DIGESTIVE SYSTEM	0 (0.0%)	0 (0.0%)	1 (4.5%)	1 (5.3%)				1 (3.6%)
ANOREXIA	0 (0.0%)	0 (0.0%)	1 (4.5%)	1 (5.3%)				1 (3.6%)
NERVOUS SYSTEM & PSYCHIATRIC	3 (10.7%)	2 (7.1%)	2 (9.1%)	2 (10.5%)				4 (14.3%)
CRYING, EXCESSIVE	1 (3.6%)	1 (3.6%)	1 (4.5%)	1 (5.3%)				2 (7.1%)
IRRITABILITY	2 (7.1%)	1 (3.6%)	1 (4.5%)	1 (5.3%)				2 (7.1%)
RESPIRATORY SYSTEM	1 (3.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (3.6%)
NASAL DISCHARGE	1 (3.6%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (3.6%)

TABLE 11 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE
LOT NUMBER : CM679
DOSE : 6 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.
RACE : BLACK

CLINICAL COMPLAINTS	NUMBER OF VACCINEES (28 VACCINEES) - INJECTION 1						
	DAYS POST VACCINATION						NUMBER WITH COMPLAINTS
	0	1	2	3			
VACCINEES WITH COMPLAINTS	5 (17.9%)	3 (10.7%)	3 (13.6%)	3 (15.8%)			6 (21.4%)
VACCINEES WITH NO COMPLAINTS	23 (82.1%)	25 (89.3%)	19 (86.4%)	16 (84.2%)			22 (78.6%)
TOTAL VACCINEES REPORTING	28	28	22	19			28
VACCINEES WITH NO DATA	0	0	6	9			0

TABLE 12 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE
LOT NUMBER : CM679
DOSE : 18 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2-11 MOS.
RACE : BLACK

CLINICAL COMPLAINTS	NUMBER OF VACCINEES (3 VACCINEES) - INJECTION 1							NUMBER WITH COMPLAINTS
	DAYS POST VACCINATION							
	0	1	2	3				
LOCAL REACTIONS	0 (0.0%)	1 (33.3%)	1 (100.0%)	1 (100.0%)				2 (66.7%)
INDURATION, INJECTION SITE	0 (0.0%)	1 (33.3%)	1 (100.0%)	1 (100.0%)				2 (66.7%)
SWELLING, INJECTION SITE (1 INCH, <)	0 (0.0%)	0 (0.0%)	1 (100.0%)	1 (100.0%)				1 (33.3%)
SYSTEMIC	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)				1 (33.3%)
DIGESTIVE SYSTEM	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)				1 (33.3%)
ANOREXIA	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)				1 (33.3%)
NERVOUS SYSTEM & PSYCHIATRIC	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)				1 (33.3%)
CRYING, EXCESSIVE	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)				1 (33.3%)
IRRITABILITY	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)				1 (33.3%)
VACCINEES WITH COMPLAINTS	0 (0.0%)	2 (66.7%)	1 (100.0%)	1 (100.0%)				3 (100.0%)
VACCINEES WITH NO COMPLAINTS	1 (100.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)				0 (0.0%)
TOTAL VACCINEES REPORTING	1	3	1	1				3

TABLE 12 (cont.)

CLINICAL COMPLAINTS

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE
LOT NUMBER : CM679
DOSE : 18 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2-11 MOS.
RACE : BLACK

	NUMBER OF VACCINEES (3 VACCINEES) - INJECTION 1						
	DAYS POST VACCINATION						NUMBER WITH
CLINICAL COMPLAINTS	0	1	2	3			COMPLAINTS
VACCINEES WITH NO DATA	2	0	2	2			0

CLINICAL COMPLAINTS

BOOSTER VACCINATION

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : COMBINE
LOT NUMBER : CM679
DOSE : 6 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2-11 MOS.
RACE : UNKNOWN

CLINICAL COMPLAINTS	NUMBER OF VACCINEES (9 VACCINEES) - INJECTION OVERALL							NUMBER WITH COMPLAINTS
	DAYS POST VACCINATION							
	0	1	2	3				
LOCAL REACTIONS	2 (22.2%)	2 (22.2%)	1 (11.1%)	0 (0.0%)				3 (33.3%)
ERYTHEMA, INJECTION SITE (1 INCH, <)	1 (11.1%)	2 (22.2%)	1 (11.1%)	0 (0.0%)				2 (22.2%)
PAIN/SORENESS, INJECTION SITE	1 (11.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (11.1%)
SYSTEMIC	3 (33.3%)	2 (22.2%)	3 (33.3%)	0 (0.0%)				3 (33.3%)
DIGESTIVE SYSTEM	1 (11.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (11.1%)
ANOREXIA	1 (11.1%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (11.1%)
NERVOUS SYSTEM & PSYCHIATRIC	3 (33.3%)	2 (22.2%)	0 (0.0%)	0 (0.0%)				3 (33.3%)
IRRITABILITY	3 (33.3%)	2 (22.2%)	0 (0.0%)	0 (0.0%)				3 (33.3%)
RESPIRATORY SYSTEM	0 (0.0%)	1 (11.1%)	1 (11.1%)	0 (0.0%)				2 (22.2%)
NASAL DISCHARGE	0 (0.0%)	1 (11.1%)	0 (0.0%)	0 (0.0%)				1 (11.1%)
UPPER RESPIRATORY INFECTION, NOS	0 (0.0%)	0 (0.0%)	1 (11.1%)	0 (0.0%)				1 (11.1%)

TABLE 12 (cont.)

CLINICAL COMPLAINTS
BOOSTER VACCINATION

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : COMBINE
LOT NUMBER : CM679
DOSE : 6 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2-11 MOS.
RACE : UNKNOWN

CLINICAL COMPLAINTS	NUMBER OF VACCINEES (9 VACCINEES) - INJECTION OVERALL							NUMBER WITH COMPLAINTS
	DAYS POST VACCINATION							
	0	1	2	3				
SPECIAL SENSES	0 (0.0%)	0 (0.0%)	2 (22.2%)	0 (0.0%)				2 (22.2%)
OTITIS MEDIA	0 (0.0%)	0 (0.0%)	2 (22.2%)	0 (0.0%)				2 (22.2%)
VACCINEES WITH COMPLAINTS	3 (33.3%)	4 (44.4%)	3 (33.3%)	0 (0.0%)				4 (44.4%)
VACCINEES WITH NO COMPLAINTS	6 (66.7%)	5 (55.6%)	6 (66.7%)	9 (100.0%)				5 (55.6%)
TOTAL VACCINEES REPORTING	9	9	9	9				9
VACCINEES WITH NO DATA	0	0	0	0				0

TABLE 12 (cont.)

CLINICAL COMPLAINTS

BOOSTER VACCINATION

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : COMBINE
LOT NUMBER : CM679
DOSE : 6 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.
RACE : UNKNOWN

CLINICAL COMPLAINTS	NUMBER OF VACCINEES (1 VACCINEES) - INJECTION OVERALL						NUMBER WITH COMPLAINTS
	DAYS POST VACCINATION						
	0	1	2	3			**********
VACCINEES WITH COMPLAINTS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)			0 (0.0%)
VACCINEES WITH NO COMPLAINTS	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)			1 (100.0%)
TOTAL VACCINEES REPORTING	1	1	1	1			1
VACCINEES WITH NO DATA	0	0	0	0			0

TABLE 12 (cont.)

CLINICAL COMPLAINTS

BOOSTER VACCINATION

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : COMBINE
LOT NUMBER : POLYS
DOSE : 25 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2-11 MOS.
RACE : BLACK

CLINICAL COMPLAINTS	NUMBER OF VACCINEES (16 VACCINEES) - INJECTION OVERALL DAYS POST VACCINATION 0	1	2	3			NUMBER WITH COMPLAINTS **********
SYSTEMIC	1 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)			1 (25.0%)
BODY AS A WHOLE/SITE UNSPEC.	1 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)			1 (25.0%)
FATIGUE	1 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)			1 (25.0%)
NERVOUS SYSTEM & PSYCHIATRIC	1 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)			1 (25.0%)
IRRITABILITY	1 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)			1 (25.0%)
VACCINEES WITH COMPLAINTS	1 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)			1 (25.0%)
VACCINEES WITH NO COMPLAINTS	3 (75.0%)	4 (100.0%)	4 (100.0%)	4 (100.0%)			3 (75.0%)
TOTAL VACCINEES REPORTING	4	4	4	4			4
VACCINEES WITH NO DATA	12	12	12	12			12

TABLE 12 (cont.)

CLINICAL COMPLAINTS

BOOSTER VACCINATION

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : COMBINE
LOT NUMBER : POLYS
DOSE : 25 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2-11 MOS.
RACE : UNKNOWN

CLINICAL COMPLAINTS	NUMBER OF VACCINEES (25 VACCINEES) - INJECTION OVERALL							NUMBER WITH COMPLAINTS
	DAYS POST VACCINATION							
	0	1	2	3				
LOCAL REACTIONS	2 (8.3%)	2 (8.3%)	0 (0.0%)	0 (0.0%)				3 (12.5%)
ERYTHEMA, INJECTION SITE (>1 INCH	0 (0.0%)	1 (4.2%)	0 (0.0%)	0 (0.0%)				1 (4.2%)
ERYTHEMA, INJECTION SITE (1 INCH, <)	2 (8.3%)	1 (4.2%)	0 (0.0%)	0 (0.0%)				2 (8.3%)
SYSTEMIC	1 (4.2%)	1 (4.2%)	0 (0.0%)	0 (0.0%)				1 (4.2%)
BODY AS A WHOLE/SITE UNSPEC.	1 (4.2%)	1 (4.2%)	0 (0.0%)	0 (0.0%)				1 (4.2%)
FATIGUE	1 (4.2%)	1 (4.2%)	0 (0.0%)	0 (0.0%)				1 (4.2%)
NERVOUS SYSTEM & PSYCHIATRIC	1 (4.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (4.2%)
IRRITABILITY	1 (4.2%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (4.2%)
VACCINEES WITH COMPLAINTS	3 (12.5%)	3 (12.5%)	0 (0.0%)	0 (0.0%)				4 (16.7%)
VACCINEES WITH NO COMPLAINTS	21 (87.5%)	21 (87.5%)	24 (100.0%)	24 (100.0%)				20 (83.3%)
TOTAL VACCINEES REPORTING	24	24	24	24				24

TABLE 12 (cont.)

CLINICAL COMPLAINTS
BOOSTER VACCINATION

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : COMBINE
LOT NUMBER : POLYS
DOSE : 25 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2-11 MOS.
RACE : UNKNOWN

CLINICAL COMPLAINTS	NUMBER OF VACCINEES (25 VACCINEES) - INJECTION OVERALL						
	DAYS POST VACCINATION						NUMBER WITH COMPLAINTS
	0	1	2	3			
VACCINEES WITH NO DATA	1	1	1	1			1

TABLE 12 (cont.)

CLINICAL COMPLAINTS
BOOSTER VACCINATION

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : COMBINE
LOT NUMBER : POLYS
DOSE : 25 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.
RACE : BLACK

CLINICAL COMPLAINTS	NUMBER OF VACCINEES (16 VACCINEES) - INJECTION OVERALL DAYS POST VACCINATION 0	1	2	3			NUMBER WITH COMPLAINTS
SYSTEMIC	0 (0.0%)	1 (14.3%)	1 (14.3%)	1 (14.3%)			1 (14.3%)
BODY AS A WHOLE/SITE UNSPEC.	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (14.3%)			1 (14.3%)
FATIGUE	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (14.3%)			1 (14.3%)
NERVOUS SYSTEM & PSYCHIATRIC	0 (0.0%)	1 (14.3%)	1 (14.3%)	0 (0.0%)			1 (14.3%)
CRYING, EXCESSIVE	0 (0.0%)	1 (14.3%)	1 (14.3%)	0 (0.0%)			1 (14.3%)
HYPERKINESIA	0 (0.0%)	0 (0.0%)	1 (14.3%)	0 (0.0%)			1 (14.3%)
IRRITABILITY	0 (0.0%)	1 (14.3%)	1 (14.3%)	0 (0.0%)			1 (14.3%)
NERVOUSNESS	0 (0.0%)	1 (14.3%)	0 (0.0%)	0 (0.0%)			1 (14.3%)
VACCINEES WITH COMPLAINTS	0 (0.0%)	1 (14.3%)	1 (14.3%)	1 (14.3%)			1 (14.3%)
VACCINEES WITH NO COMPLAINTS	7 (100.0%)	6 (85.7%)	6 (85.7%)	6 (85.7%)			6 (85.7%)
TOTAL VACCINEES REPORTING	7	7	7	7			7

TABLE 12 (cont.)

CLINICAL COMPLAINTS

BOOSTER VACCINATION

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : COMBINE
LOT NUMBER : POLYS
DOSE : 25 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.
RACE : BLACK

CLINICAL COMPLAINTS	NUMBER OF VACCINEES (16 VACCINEES) - INJECTION OVERALL						
	DAYS POST VACCINATION						NUMBER WITH COMPLAINTS
	0	1	2	3			
VACCINEES WITH NO DATA	9	9	9	9			9

TABLE 12 (cont.)

CLINICAL COMPLAINTS
BOOSTER VACCINATION

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : COMBINE
LOT NUMBER : POLYS
DOSE : 25 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.
RACE : UNKNOWN

CLINICAL COMPLAINTS	NUMBER OF VACCINEES (5 VACCINEES) - INJECTION OVERALL						NUMBER WITH COMPLAINTS
	DAYS POST VACCINATION						
	0	1	2	3			**********
VACCINEES WITH COMPLAINTS	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)			0 (0.0%)
VACCINEES WITH NO COMPLAINTS	4 (100.0%)	4 (100.0%)	4 (100.0%)	4 (100.0%)			4 (100.0%)
TOTAL VACCINEES REPORTING	4	4	4	4			4
VACCINEES WITH NO DATA	1	1	1	1			1

TABLE 13

MAXIMUM TEMPERATURES

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CL680
DOSE : 7 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2-11 MOS.
RACE : UNKNO

MAX TEMPERATURE (DEG F, ORAL)	NUMBER OF VACCINEES (10 VACCINEES) - INJECTION 1 — DAYS POST VACCINATION 0	1	2	3				NUMBER WITH MAX TEMP
< 99	5 (50.0%)	3 (30.0%)	4 (40.0%)	3 (30.0%)				2 (20.0%)
99 - 99.9	3 (30.0%)	6 (60.0%)	6 (60.0%)	7 (70.0%)				6 (60.0%)
100 - 100.9	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (10.0%)
101 - 101.9	0 (0.0%)	1 (10.0%)	0 (0.0%)	0 (0.0%)				0 (0.0%)
103 - 103.9	1 (10.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (10.0%)
TEMPERATURE TAKEN	10 (100.0%)	10 (100.0%)	10 (100.0%)	10 (100.0%)				10 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				0 (0.0%)

TABLE 13 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CL680
DOSE : 7 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2-11 MOS.
RACE : UNKNO

MAX TEMPERATURE (DEG F, ORAL)	NUMBER OF VACCINEES (8 VACCINEES) - INJECTION 2							NUMBER WITH MAX TEMP
	DAYS POST VACCINATION							
	0	1	2	3				
< 99	3 (37.5%)	3 (37.5%)	3 (37.5%)	3 (37.5%)				1 (12.5%)
99 - 99.9	3 (37.5%)	2 (25.0%)	2 (25.0%)	3 (37.5%)				3 (37.5%)
100 - 100.9	1 (12.5%)	1 (12.5%)	1 (12.5%)	1 (12.5%)				1 (12.5%)
101 - 101.9	0 (0.0%)	1 (12.5%)	1 (12.5%)	1 (12.5%)				0 (0.0%)
102 - 102.9	0 (0.0%)	0 (0.0%)	1 (12.5%)	0 (0.0%)				1 (12.5%)
103 - 103.9	1 (12.5%)	1 (12.5%)	0 (0.0%)	0 (0.0%)				2 (25.0%)
TEMPERATURE TAKEN	8 (100.0%)	8 (100.0%)	8 (100.0%)	8 (100.0%)				8 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				0 (0.0%)

TABLE 13 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CL680
DOSE : 7 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.
RACE : UNKNO

MAX TEMPERATURE (DEG F, ORAL)	NUMBER OF VACCINEES (3 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
	0	1	2	3				
< 99	2 (66.7%)	2 (66.7%)	3 (100.0%)	1 (33.3%)				1 (33.3%)
99 - 99.9	1 (33.3%)	1 (33.3%)	0 (0.0%)	2 (66.7%)				2 (66.7%)
TEMPERATURE TAKEN	3 (100.0%)	3 (100.0%)	3 (100.0%)	3 (100.0%)				3 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				0 (0.0%)

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TABLE 13 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE - SALINE
LOT NUMBER : CL680
DOSE : 7 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.
RACE : UNKNO

MAX TEMPERATURE (DEG F, ORAL)	NUMBER OF VACCINEES (3 VACCINEES) - INJECTION 2							NUMBER WITH MAX TEMP
	DAYS POST VACCINATION							
	0	1	2	3				
< 99	2 (66.7%)	0 (0.0%)	1 (33.3%)	2 (66.7%)				0 (0.0%)
99 - 99.9	0 (0.0%)	1 (33.3%)	2 (66.7%)	1 (33.3%)				1 (33.3%)
100 - 100.9	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)				1 (33.3%)
102 - 102.9	0 (0.0%)	1 (33.3%)	0 (0.0%)	0 (0.0%)				0 (0.0%)
105 - 105.9	1 (33.3%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (33.3%)
TEMPERATURE TAKEN	3 (100.0%)	3 (100.0%)	3 (100.0%)	3 (100.0%)				3 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				0 (0.0%)

TABLE 13 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE
LOT NUMBER : CL680
DOSE : 7 MCG
PATIENT CLASS: HEALTHY ADULTS
AGE RANGE : 20-45 YRS.
RACE : UNKNO

	NUMBER OF VACCINEES (6 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3				WITH MAX TEMP
NORMAL	3 (60.0%)	3 (60.0%)	3 (60.0%)	3 (60.0%)				3 (60.0%)
< 99	2 (40.0%)	2 (40.0%)	2 (40.0%)	2 (40.0%)				2 (40.0%)
TEMPERATURE TAKEN	5 (83.3%)	5 (83.3%)	5 (83.3%)	5 (83.3%)				5 (83.3%)
TEMPERATURE NOT TAKEN	1 (16.7%)	1 (16.7%)	1 (16.7%)	1 (16.7%)				1 (16.7%)

TABLE 13 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE
LOT NUMBER : CL680
DOSE : 7 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2-11 MOS.
RACE : UNKNO

MAX TEMPERATURE (DEG F, ORAL)	NUMBER OF VACCINEES (29 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
	0	1	2	3				
< 99	7 (24.1%)	12 (42.9%)	10 (35.7%)	9 (33.3%)				4 (13.8%)
99 - 99.9	15 (51.7%)	14 (50.0%)	14 (50.0%)	18 (66.7%)				14 (48.3%)
100 - 100.9	7 (24.1%)	2 (7.1%)	4 (14.3%)	0 (0.0%)				11 (37.9%)
TEMPERATURE TAKEN	29 (100.0%)	28 (96.6%)	28 (96.6%)	27 (93.1%)				29 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	1 (3.4%)	1 (3.4%)	2 (6.9%)				0 (0.0%)

TABLE 13 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE
LOT NUMBER : CL680
DOSE : 7 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2-11 MOS.
RACE : UNKNO

	NUMBER OF VACCINEES (24 VACCINEES) - INJECTION 2							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3				
< 99	7 (30.4%)	11 (52.4%)	12 (57.1%)	11 (52.4%)				4 (17.4%)
99 - 99.9	12 (52.2%)	9 (42.9%)	9 (42.9%)	10 (47.6%)				14 (60.9%)
100 - 100.9	4 (17.4%)	1 (4.8%)	0 (0.0%)	0 (0.0%)				5 (21.7%)
TEMPERATURE TAKEN	23 (95.8%)	21 (87.5%)	21 (87.5%)	21 (87.5%)				23 (95.8%)
TEMPERATURE NOT TAKEN	1 (4.2%)	3 (12.5%)	3 (12.5%)	3 (12.5%)				1 (4.2%)

TABLE 13 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE
LOT NUMBER : CL680
DOSE : 7 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.
RACE : UNKNO

MAX TEMPERATURE (DEG F, ORAL)	NUMBER OF VACCINEES (10 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
	0	1	2	3				
NORMAL	0 (0.0%)	0 (0.0%)	1 (10.0%)	1 (11.1%)				0 (0.0%)
< 99	3 (30.0%)	5 (50.0%)	4 (40.0%)	3 (33.3%)				2 (20.0%)
99 - 99.9	7 (70.0%)	4 (40.0%)	4 (40.0%)	4 (44.4%)				7 (70.0%)
100 - 100.9	0 (0.0%)	1 (10.0%)	1 (10.0%)	1 (11.1%)				1 (10.0%)
TEMPERATURE TAKEN	10 (100.0%)	10 (100.0%)	10 (100.0%)	9 (90.0%)				10 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (10.0%)				0 (0.0%)

TABLE 13 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE
LOT NUMBER : CL680
DOSE : 7 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.
RACE : UNKNO

	NUMBER OF VACCINEES (2 VACCINEES) - INJECTION 2							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
MAX TEMPERATURE (DEG F, ORAL)	0	1	2	3				
< 99	1 (50.0%)	2 (100.0%)	0 (0.0%)	0 (0.0%)				1 (50.0%)
99 - 99.9	1 (50.0%)	0 (0.0%)	1 (100.0%)	0 (0.0%)				0 (0.0%)
100 - 100.9	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (100.0%)				1 (50.0%)
TEMPERATURE TAKEN	2 (100.0%)	2 (100.0%)	1 (50.0%)	1 (50.0%)				2 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	0 (0.0%)	1 (50.0%)	1 (50.0%)				0 (0.0%)

TABLE 13 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE
LOT NUMBER : CM679
DOSE : 13 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2-11 MOS.
RACE : UNKNO

MAX TEMPERATURE (DEG F, ORAL)	NUMBER OF VACCINEES (53 VACCINEES) - INJECTION 1							NUMBER WITH MAX TEMP
	DAYS POST VACCINATION							
	0	1	2	3				
< 99	22 (41.5%)	14 (26.4%)	20 (43.5%)	21 (46.7%)				8 (15.1%)
99 - 99.9	26 (49.1%)	27 (50.9%)	21 (45.7%)	20 (44.4%)				31 (58.5%)
100 - 100.9	3 (5.7%)	9 (17.0%)	3 (6.5%)	2 (4.4%)				9 (17.0%)
101 - 101.9	1 (1.9%)	3 (5.7%)	2 (4.3%)	2 (4.4%)				4 (7.5%)
102 - 102.9	1 (1.9%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (1.9%)
TEMPERATURE TAKEN	53 (100.0%)	53 (100.0%)	46 (86.8%)	45 (84.9%)				53 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	0 (0.0%)	7 (13.2%)	8 (15.1%)				0 (0.0%)

TABLE 13 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE
LOT NUMBER : CM679
DOSE : 13 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2-11 MOS.
RACE : UNKNO

MAX TEMPERATURE (DEG F, ORAL)	NUMBER OF VACCINEES (50 VACCINEES) - INJECTION 2							NUMBER WITH MAX TEMP
	DAYS POST VACCINATION							
	0	1	2	3				
NORMAL	1 (2.1%)	1 (2.1%)	1 (2.2%)	1 (2.4%)				1 (2.1%)
< 99	24 (51.1%)	15 (31.3%)	14 (31.1%)	17 (40.5%)				6 (12.5%)
99 - 99.9	16 (34.0%)	27 (56.3%)	27 (60.0%)	24 (57.1%)				28 (58.3%)
100 - 100.9	5 (10.6%)	4 (8.3%)	2 (4.4%)	0 (0.0%)				10 (20.8%)
101 - 101.9	1 (2.1%)	1 (2.1%)	1 (2.2%)	0 (0.0%)				3 (6.3%)
TEMPERATURE TAKEN	47 (94.0%)	48 (96.0%)	45 (90.0%)	42 (84.0%)				48 (96.0%)
TEMPERATURE NOT TAKEN	3 (6.0%)	2 (4.0%)	5 (10.0%)	8 (16.0%)				2 (4.0%)

TABLE 13 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE
LOT NUMBER : CM679
DOSE : 6 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2-11 MOS.
RACE : BLACK

MAX TEMPERATURE (DEG F, ORAL)	NUMBER OF VACCINEES (25 VACCINEES) - INJECTION 1							
	DAYS POST VACCINATION							NUMBER WITH MAX TEMP
	0	1	2	3				
NORMAL	2 (8.3%)	4 (17.4%)	4 (23.5%)	5 (31.3%)				2 (8.3%)
< 99	19 (79.2%)	17 (73.9%)	11 (64.7%)	9 (56.3%)				15 (62.5%)
99 - 99.9	2 (8.3%)	1 (4.3%)	1 (5.9%)	2 (12.5%)				4 (16.7%)
100 - 100.9	1 (4.2%)	1 (4.3%)	0 (0.0%)	0 (0.0%)				2 (8.3%)
101 - 101.9	0 (0.0%)	0 (0.0%)	1 (5.9%)	0 (0.0%)				1 (4.2%)
TEMPERATURE TAKEN	24 (96.0%)	23 (92.0%)	17 (68.0%)	16 (64.0%)				24 (96.0%)
TEMPERATURE NOT TAKEN	1 (4.0%)	2 (8.0%)	8 (32.0%)	9 (36.0%)				1 (4.0%)

TABLE 13 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE
LOT NUMBER : CM679
DOSE : 6 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.
RACE : BLACK

MAX TEMPERATURE (DEG F, ORAL)	NUMBER OF VACCINEES (28 VACCINEES) - INJECTION 1							NUMBER WITH MAX TEMP
	DAYS POST VACCINATION							
	0	1	2	3				
NORMAL	4 (14.3%)	3 (11.1%)	3 (13.6%)	3 (15.8%)				2 (7.1%)
< 99	20 (71.4%)	21 (77.8%)	17 (77.3%)	13 (68.4%)				22 (78.6%)
99 - 99.9	4 (14.3%)	3 (11.1%)	2 (9.1%)	3 (15.8%)				4 (14.3%)
TEMPERATURE TAKEN	28 (100.0%)	27 (96.4%)	22 (78.6%)	19 (67.9%)				28 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	1 (3.6%)	6 (21.4%)	9 (32.1%)				0 (0.0%)

TABLE 13 (cont.)

MAXIMUM TEMPERATURES

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : HIB CONJUGATE
LOT NUMBER : CM679
DOSE : 18 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2-11 MOS.
RACE : BLACK

MAX TEMPERATURE (DEG F, ORAL)	NUMBER OF VACCINEES (3 VACCINEES) - INJECTION 1							NUMBER WITH MAX TEMP
	DAYS POST VACCINATION							
	0	1	2	3				
< 99	0 (0.0%)	1 (50.0%)	0 (0.0%)	0 (0.0%)				1 (50.0%)
99 - 99.9	1 (100.0%)	1 (50.0%)	0 (0.0%)	0 (0.0%)				0 (0.0%)
100 - 100.9	0 (0.0%)	0 (0.0%)	1 (100.0%)	0 (0.0%)				0 (0.0%)
102 - 102.9	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (100.0%)				1 (50.0%)
TEMPERATURE TAKEN	1 (33.3%)	2 (66.7%)	1 (33.3%)	1 (33.3%)				2 (66.7%)
TEMPERATURE NOT TAKEN	2 (66.7%)	1 (33.3%)	2 (66.7%)	2 (66.7%)				1 (33.3%)

TABLE 13

MAXIMUM TEMPERATURES

BOOSTER VACCINATION

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : COMBINE
LOT NUMBER : CM679
DOSE : 6 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2-11 MOS.
RACE : UNKNOWN

MAX TEMPERATURE (DEG F, ORAL)	NUMBER OF VACCINEES (9 VACCINEES) - INJECTION OVERALL							NUMBER WITH MAX TEMP
	DAYS POST VACCINATION							
	0	1	2	3				
< 99	2 (25.0%)	1 (12.5%)	1 (14.3%)	2 (33.3%)				1 (12.5%)
99 - 99.9	3 (37.5%)	5 (62.5%)	5 (71.4%)	3 (50.0%)				3 (37.5%)
100 - 100.9	2 (25.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				1 (12.5%)
101 - 101.9	1 (12.5%)	1 (12.5%)	0 (0.0%)	1 (16.7%)				2 (25.0%)
102 - 102.9	0 (0.0%)	0 (0.0%)	1 (14.3%)	0 (0.0%)				0 (0.0%)
103 - 103.9	0 (0.0%)	1 (12.5%)	0 (0.0%)	0 (0.0%)				1 (12.5%)
TEMPERATURE TAKEN	8 (88.9%)	8 (88.9%)	7 (77.8%)	6 (66.7%)				8 (88.9%)
TEMPERATURE NOT TAKEN	1 (11.1%)	1 (11.1%)	2 (22.2%)	3 (33.3%)				1 (11.1%)

TABLE 13 (cont.)

MAXIMUM TEMPERATURES
BOOSTER VACCINATION

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : COMBINE
LOT NUMBER : CM679
DOSE : 6 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.
RACE : UNKNOWN

MAX TEMPERATURE (DEG F, ORAL)	NUMBER OF VACCINEES (1 VACCINEES) - INJECTION OVERALL							NUMBER WITH MAX TEMP
	DAYS POST VACCINATION							
	0	1	2	3				
< 99	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)				1 (100.0%)
TEMPERATURE TAKEN	1 (100.0%)	1 (100.0%)	1 (100.0%)	1 (100.0%)				1 (100.0%)
TEMPERATURE NOT TAKEN	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)				0 (0.0%)

TABLE 13 (cont.)

MAXIMUM TEMPERATURES
BOOSTER VACCINATION

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : COMBINE
LOT NUMBER : POLYS
DOSE : 25 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2-11 MOS.
RACE : BLACK

MAX TEMPERATURE (DEG F, ORAL)	NUMBER OF VACCINEES (16 VACCINEES) - INJECTION OVERALL DAYS POST VACCINATION 0	1	2	3				NUMBER WITH MAX TEMP
< 99	5 (100.0%)	5 (100.0%)	5 (100.0%)	4 (100.0%)				5 (100.0%)
TEMPERATURE TAKEN	5 (31.3%)	5 (31.3%)	5 (31.3%)	4 (25.0%)				5 (31.3%)
TEMPERATURE NOT TAKEN	11 (68.8%)	11 (68.8%)	11 (68.8%)	12 (75.0%)				11 (68.8%)

01647

TABLE 13 (cont.)

MAXIMUM TEMPERATURES

BOOSTER VACCINATION

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : COMBINE
LOT NUMBER : POLYS
DOSE : 25 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 2-11 MOS.
RACE : UNKNOWN

MAX TEMPERATURE (DEG F, ORAL)	NUMBER OF VACCINEES (25 VACCINEES) - INJECTION OVERALL							NUMBER WITH MAX TEMP
	DAYS POST VACCINATION							
	0	1	2	3				
NORMAL	2 (9.1%)	2 (9.5%)	2 (10.5%)	2 (10.5%)				2 (9.1%)
< 99	9 (40.9%)	11 (52.4%)	8 (42.1%)	6 (31.6%)				6 (27.3%)
99 - 99.9	9 (40.9%)	7 (33.3%)	7 (36.8%)	9 (47.4%)				10 (45.5%)
100 - 100.9	2 (9.1%)	1 (4.8%)	2 (10.5%)	2 (10.5%)				4 (18.2%)
TEMPERATURE TAKEN	22 (88.0%)	21 (84.0%)	19 (76.0%)	19 (76.0%)				22 (88.0%)
TEMPERATURE NOT TAKEN	3 (12.0%)	4 (16.0%)	6 (24.0%)	6 (24.0%)				3 (12.0%)

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TABLE 13 (cont.)

MAXIMUM TEMPERATURES
BOOSTER VACCINATION

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : COMBINE
LOT NUMBER : POLYS
DOSE : 25 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.
RACE : BLACK

MAX TEMPERATURE (DEG F, ORAL)	NUMBER OF VACCINEES (16 VACCINEES) - INJECTION OVERALL DAYS POST VACCINATION 0	1	2	3				NUMBER WITH MAX TEMP
NORMAL	1 (16.7%)	1 (16.7%)	1 (16.7%)	1 (16.7%)				1 (16.7%)
< 99	2 (33.3%)	3 (50.0%)	3 (50.0%)	3 (50.0%)				2 (33.3%)
99 - 99.9	3 (50.0%)	1 (16.7%)	2 (33.3%)	2 (33.3%)				2 (33.3%)
100 - 100.9	0 (0.0%)	1 (16.7%)	0 (0.0%)	0 (0.0%)				1 (16.7%)
TEMPERATURE TAKEN	6 (37.5%)	6 (37.5%)	6 (37.5%)	6 (37.5%)				6 (37.5%)
TEMPERATURE NOT TAKEN	10 (62.5%)	10 (62.5%)	10 (62.5%)	10 (62.5%)				10 (62.5%)

TABLE 13 (cont.)

MAXIMUM TEMPERATURES
BOOSTER VACCINATION

INVESTIGATOR : GRANOFF, DAN
STUDY : 087301
VACCINE : COMBINE
LOT NUMBER : POLYS
DOSE : 25 MCG
PATIENT CLASS: HEALTHY CHILDREN
AGE RANGE : 12-71 MOS.
RACE : UNKNOWN

MAX TEMPERATURE (DEG F, ORAL)	NUMBER OF VACCINEES (5 VACCINEES) - INJECTION OVERALL							NUMBER WITH MAX TEMP
	DAYS POST VACCINATION							
	0	1	2	3				
NORMAL	1 (25.0%)	1 (25.0%)	1 (33.3%)	1 (50.0%)				1 (25.0%)
< 99	2 (50.0%)	2 (50.0%)	2 (66.7%)	1 (50.0%)				2 (50.0%)
99 - 99.9	1 (25.0%)	1 (25.0%)	0 (0.0%)	0 (0.0%)				1 (25.0%)
TEMPERATURE TAKEN	4 (80.0%)	4 (80.0%)	3 (60.0%)	2 (40.0%)				4 (80.0%)
TEMPERATURE NOT TAKEN	1 (20.0%)	1 (20.0%)	2 (40.0%)	3 (60.0%)				1 (20.0%)

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BLACK INFANTS WHO LACK KM(1) IG ALLOTYPE SHOW HIGH ANTICAPSULAR ANTIBODY RESPONSES TO H. INFLUENZAE B - N. MENINGITIDIS OUTER MEMBRANE PROTEIN CONJUGATE VACCINE (Hib PS-OMP).

MS Clanton, DM Granoff, B Pilot, JP Pandey, TV Murphy*. U. Tx Southwestern Med. Ctr., Dallas, TX, Med. Univ. of S.C., Charleston, SC, Wash. U., St. Louis, Mo.

Blacks lacking Km(1) have a higher relative risk of meningitis and lower conc. of antibody following vaccination with plain Hib-PS vaccine than blacks with the Km(1). However, 7-17 mo. old blacks lacking Km(1) had a good antibody response to a single injection of Hib PS-OMP conjugate vaccine (Study #1, J Infect Dis, in press). The purpose of study #2 was to compare the responses of 2-5 mo old black infants given 2 doses of Hib PS-OMP, given 2 mo. apart. In study #2, black infants lacking Km(1) had higher total antibody responses. IgG responses were not significantly different (5.8 vs 3.0 ug/ml, p=0.24).

				Total anti-PS antibody (Geo. mean, ug/ml)				
Study	Km(1)	No.	Mean Age(mo)	Pre	Post-dose #1		Post-dose#2	
1	Pos.	22	11.5	ND	5.0	p>.5	ND	
	Neg.	27	11.9	ND	4.1		ND	
2	Pos.	10	2.9	0.10	2.0	p=.09	5.1	p=.03
	Neg.	13	2.4	0.12	4.8		14.8	

Lack of the Km(1) allotype does not correlate with lower total or IgG responses to conjugate vaccine. Infants lacking Km(1), a phenotype associated with increased risk of meningitis, have comparable or higher antibody responses to 2 doses of conjugate than infants with Km(1).

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IMMUNOGENICITY IN INFANTS OF HAEMOPHILUS INFLUENZAE TYPE B POLYSACCHARIDE IN A CONJUGATE VACCINE WITH NEISSERIA MENINGITIDIS OUTER-MEMBRANE PROTEIN

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Summary 63 children, aged 2–17 months, were given a new conjugate vaccine composed of the capsular polysaccharide of *Haemophilus influenzae* type b linked to a *Neisseria meningitidis* outer-membrane protein. Subjects under 7 months received two injections separated by 1 month, and older subjects received either one or two injections. There were no systemic reactions to this vaccine when it was given with aluminium hydroxide. A single injection of vaccine was highly immunogenic; the geometric mean serum anticapsular antibody concentrations before immunisation and 1 month later were 0·35 μg/ml and 0·98 μg/ml for babies of 2–3 months, 0·12 μg/ml and 1·85 μg/ml for those of 4–6 months, and 0·15 μg/ml and 4·1 μg/ml for those of 8–17 months ($p \leq 0.003$ for each age group). After a second injection of vaccine, 80% and 76% of infants of 2–3 and 4–6 months, respectively, had antibody concentrations >1·0 μg/ml. Most subjects showed evidence of IgG responses as measured by enzyme-linked immunosorbent assay. 6–12 months after immunisation, serum antibody levels had fallen ($p < 0.05$) but they remained higher than those of unimmunised controls ($p < 0.001$).

Introduction

SERUM antibodies against the capsular polysaccharide of *Haemophilus influenzae* type b confer protection against invasive *H influenzae* type b disease.[1,2] In a field study in Finland, a capsular polysaccharide vaccine was protective in children older than 18–23 months,[2,3] but not in younger children. To date, the most successful approach to enhance the immunogenicity of the *H influenzae* type b polysaccharide is based on the hapten-carrier concept.[4] In animals[5] and in human beings[6] the immune response to the polysaccharide can be enhanced by covalently coupling it to a protein. In contrast to the plain polysaccharide vaccine, *H influenzae* type b conjugate vaccines elicit booster responses of antibody against capsular polysaccharide.[5,7] Several prototype conjugate vaccines have been reported to be immunogenic in infants as young as 6–7 months. However, the responses of infants younger than 6 months to one or two injections of vaccine have been meagre.[8,9] Infants in this age group account for approximately 20% of cases of *H influenzae* type b meningitis in the continental United States[10] and for approximately 35–50% of cases in Eskimos in Alaska.[11,12]

A conjugate vaccine composed of the *H influenzae* type b polysaccharide and an outer-membrane protein of *Neisseria meningitidis* group B was prepared at Merck Sharp and Dohme Research Laboratories, West Point, Pennsylvania. Both the coupling method and the protein carrier were different from those used to construct other experimental conjugate vaccines. The purpose of our study was to determine the safety and immunogenicity of this vaccine in children aged 2–17 months. Preliminary data from animal studies suggested that the vaccine was more immunogenic when administered with aluminium hydroxide than with saline alone. Therefore, we also compared the clinical and serological responses to the vaccine reconstituted with and without aluminium hydroxide.

Patients and Methods

Vaccine

The conjugate vaccine consists of the *H influenzae* type b capsular polysaccharide (molecular weight approximately 500 Kd by gel filtration on 'CL-4B Sepharose') covalently coupled to a meningococcal outer-membrane protein. Preparation and characterisation of the conjugate have been described elsewhere.[13] In brief, the solvent dimethylformamide and a column of tetra-n-butyl-ammonium-'Dowex-50' were used to form a soluble polysaccharide-$(butyl)_4$ ammonium salt; the polysaccharide was then sequentially activated by carbonyl di-imidazole and 1,4-butane diamine; the resulting pendant aminoalkyl groups were then bromoacetylated. A 40 Kd outer-membrane protein[14] was purified from group B *N meningitidis* (strain B-11, from Dr M. Artenstein,

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Walter Reed Army Institute of Research, Washington, DC[15]). The protein was independently activated with the introduction of pendant thiol groups by acylation with N-acetyl-homocysteine thiolactone. The activated polysaccharide and outer-membrane protein then reacted together to give a covalent conjugate containing a thioether linkage. This linkage is resistant to acid hydrolysis, so a novel aminoacid (S-carboxymethyl homocysteine) is produced by acid hydrolysis. Therefore, formation of the predicted thioether linkage was monitored by the S-carboxymethyl homocysteine content of the acid hydrolysis digest of the vaccine.

Two lots of vaccine were tested. A 0·5 ml dose of vaccine from lot 1 (1003/C-L680) contained 7 μg polysaccharide and 43 μg outer-membrane protein; the same volume of vaccine from lot 2 (1002/C-L466) contained 10 μg polysaccharide and 62 μg outer-membrane protein. The vaccine passed all safety and toxicity tests in animals. The endotoxin content of both vaccines was 1–6 μg/ml by Limulus lysate assay. Lot 1 was also assayed for glucosamine;[16] it was estimated to contain 0·25 μg/ml lipopolysaccharide. Both lots of vaccine were provided lyophilised and were stored at or below −40°C. After rehydration the vaccine was used within 1–4 h. The diluents used contained either sodium chloride or aluminium hydroxide; the same diluent was used for all injections in a particular subject.

Design

The study subjects were: 6 healthy adult volunteers from the staff of Washington University; 52 healthy children, 2–17 months old, recruited from private practices of paediatricians in St Louis or Batavia; and 11 healthy children, 2–6 months old, from private practices in Huntington, West Virginia. Of the 63 children, 32 were male and 31 female, 60 white and 3 black. No subject had a history of *H influenzae* type b disease. Informed consent was obtained from the adults and from one or both parents of the children. The protocol was approved by the IND Branch of the National Center for Drugs and Biologics (under BB-IND-1966) and local ethical committees.

Subjects were not enrolled if there was any indication of previous substantial adverse reactions to vaccines or an underlying immunodeficiency. Other reasons for exclusion were diphtheria-typhoid-pertussis vaccination in the preceding 10 days and a febrile illness (> 37·9°C) in the preceding 1–3 days.

To verify the safety of lot 1, 6 adults were given 0·5 ml vaccine with aluminium hydroxide by deep intramuscular injection into the deltoid muscle; no substantial reactions occurred. The first phase of the study in children was designed to compare the safety and immunogenicity of the same lot of vaccine given with either aluminium hydroxide or saline. 26 children (2–17 months) were randomly assigned to receive vaccine with either aluminium hydroxide or saline. Two injections of 0·5 ml were given 4 weeks apart by deep intramuscular injection into the quadriceps femoris. The second injection was not given if a substantial adverse reaction occurred after the first. After completion of this phase, it was apparent that side-effects were more common after saline injections than after aluminium hydroxide injections ($p < 0·001$). Therefore, only vaccine with aluminium hydroxide was used to immunise 26 other children. Also, because one injection of the vaccine was found to be highly immunogenic in most older children, only one injection was given routinely to children older than 8 months.

11 infants (2–6 months from West Virginia) were immunised with lot 2 by the same protocol, except that the dose was 10 μg capsular polysaccharide instead of 7 μg, and all children received vaccine suspended in saline.

Clinical Observations

At enrolment, a brief medical and immunisation history was taken. Before each injection the temperature, heart rate, respiratory rate, and weight were recorded. The child was observed for evidence of an immediate reaction for 15 min after the injection. A reporting card was given to the parents, who were instructed to record the child's axillary temperature and any local or systemic reactions, 4 h, 24 h, 48 h, and 72 h after the injection. In addition, all parents were contacted 24 h after the injection to ensure that any adverse reactions during that period were reported. Systemic reaction was defined as fever (temperature > 38°C during the 72 h after immunisation) or persistent crying for more than 1 h. Local reactions were swelling or redness at the injection site ≥ 1·5 cm or pain in the leg associated with reduced use of the leg.

Serology

Serum samples were obtained before vaccination and 1 month after the first and second injections (when applicable). In West Virginia, serum samples were obtained before immunisation and 1 month after the second injection. All samples were assayed at Washington University and at Merck Sharp and Dohme Research Laboratories. The results from the two laboratories were highly correlated ($r = 0·9$) and only the data from Washington University are reported. Total serum antibody against capsular polysaccharide was measured by the radioantigen binding assay of Kuo et al,[17] except that iodine-125 rather than tritium[6,18] was used to label the antigen. IgG antibody against capsular polysaccharide was measured by enzyme-linked immunosorbent assay (ELISA) with the type b polysaccharide coupled to poly-L-lysine as the antigen on the plate.[18] IgG antibody concentrations were determined by comparing the titration curve of the test serum samples with that obtained with the US Bureau of Biologics *H influenzae* type b immune reference pool. Undiluted, this reference pool was found to have an IgG antibody concentration of 62 μg/ml. All serum samples were tested at dilutions of 1/100 or greater, and all samples from each subject were assayed together. The sensitivity of the assay was approximately 0·4 μg/ml.

Statistics

Student's *t* test was used to compare the geometric mean concentrations of serum antibody between groups given vaccine in aluminium hydroxide and vaccine in saline. A *t* test (one-tailed) was used to compare the geometric mean antibody concentrations before and after immunisation within a group. Analysis of response was done on logarithmically transformed data. A chi-square test was used to compare the rates of adverse reactions in the different groups.

Results

All 6 adults given vaccine with aluminium hydroxide experienced only mild pain and tenderness at the injection site. These reactions were greatest 4 h after vaccination and resolved gradually within 48 h. 111 doses of vaccine (46 saline, 65 aluminium hydroxide) were given to 63 children (24 saline, 39 aluminium hydroxide). The frequency of systemic or local reactions was not related to the age of the subjects, the number of injections, the vaccine lot, or the dose. Therefore, the rates of reaction in all children were combined. 10 (22%) injections of vaccine in saline but none of vaccine with aluminium hydroxide were associated with possible adverse systemic reactions ($p < 0·001$)—fever (38·2°–40°C) in 8 children and persistent crying for 1–4 h in 2 children. The children were also irritable and 3 had varying degrees of local reaction. In 6 of the 10 children, the systemic reactions were noted within 4 h of vaccine administration and resolved by approximately 24 h. In the other 4 fever began 48 h after injection, without local reactions. 2 of these children had evidence of otitis media at the time of the fever.

Local reactions occurred after 9 injections (8%); 7 (15%) were associated with vaccine in saline and 2 (3%) with vaccine in aluminium hydroxide ($p = 0·02$). The 2 reactions to vaccine in aluminium hydroxide were very slight (1·5–3·0 cm of erythema or swelling associated with pain or tenderness), whereas 2 of the 7 reactions to vaccine in saline were more severe (erythema, pain, and swelling in a wide area of the thigh above and below the injection site).

The antibody responses did not differ significantly with

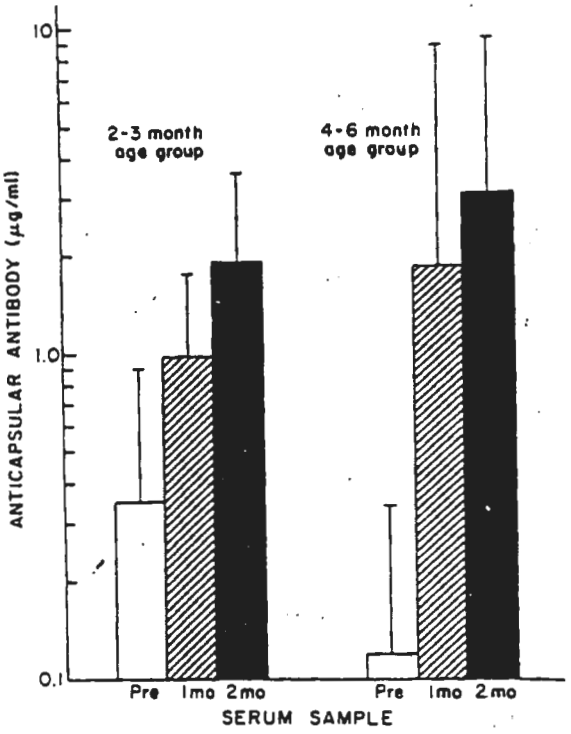

Fig 1—Geometric mean (SD) serum anticapsular-polysaccharide antibody levels in 17 infants aged 2–3 months and 21 infants aged 4–6 months at initial injection.

vaccine lot or dose or the diluent used so the results were combined. Subjects aged 8–17 months had high antibody responses to one injection of the vaccine. The geometric mean serum antibody concentrations before immunisation and 1 month later were 0·15 μg/ml and 4·1 μg/ml ($p < 0·001$). 84% of the 25 subjects had postimmunisation levels of antibody against capsular polysaccharide > 1·0 μg/ml. In a previous study with the plain polysaccharide vaccine[19,20] this postimmunisation level correlated with protection.

Fig 1 summarises the antibody responses of the 38 infants, aged 2–6 months, who were immunised routinely with two injections of conjugate vaccine, separated by a month. In this age group, a single injection was also immunogenic. In infants aged 2–3 months at first injection there were significant rises in antibody levels after both first (from 0·35 μg/ml to 0·98 μg/ml; $p = 0·003$) and second (to 1·9 μg/ml; $p = 0·005$) injections. In infants aged 4–6 months the rise in antibody level after the first injection was significant (from 0·12 μg/ml to 1·85 μg/ml; $p < 0·001$) but the rise after the second injection (to 3·1 μg/ml) was not significant. There were no significant differences between the age groups in the antibody levels achieved. After two injections, 80% of subjects immunised at 2–3 months and 76% of those immunised at 4–6 months had serum antibody concentrations > 1·0 μg/ml.

The radioantigen binding assay measures all antibody (IgM, IgG, and IgA) against the capsular polysaccharide. We were interested to see whether the immunised subjects showed specific IgG responses, since in vitro in the presence of complement, IgG antibody against capsular polysaccharide is more opsonic than IgM.[21,22] IgG antibody also persists longer in serum than IgM and, therefore, is likely to confer longer-lasting protection. Infants 2–3 and 4–6 months of age showed significant ($p < 0·01$) increases in

IgG ANTICAPSULAR ANTIBODY RESPONSES OF IMMUNISED CHILDREN BY ELISA

Age	No tested	Geometric mean (μg/ml)		% with ≥ two-fold rise
		Before immunisation	1 mo after second injection	
2–3 mo	15	<0·4	0·88	54
4–6 mo	21	<0·4	2·08	76

IgG antibody 1 month after the second injection (table). The geometric mean postimmunisation antibody level was significantly higher in the 4–6-month-olds than in the younger babies ($p = 0·02$). 54% of the younger babies and 76% of the older ones showed greater than two-fold increases in antibody. However, this is a minimum estimate of response, particularly in the younger age group. For example, 3 infants had high antibody levels before immunisation (reflecting maternal antibody). The antibody levels in these infants increased after immunisation but did not show a two-fold rise. (In the absence of immunisation, the levels would probably have declined.)

To date, serum samples have been obtained 6–12 months (mean ± SD = 7·3 ± 1·8) after the last injection of vaccine from 31 children. The antibody concentrations in these samples are shown in fig 2. The geometric means of the serum antibody levels declined significantly during the follow-up period ($p < 0·05$), from 1·8 μg/ml to 0·8 μg/ml in infants immunised at 2–6 months and from 4·9 μg/ml to 1·0 μg/ml in those immunised at 8–17 months. Nevertheless,

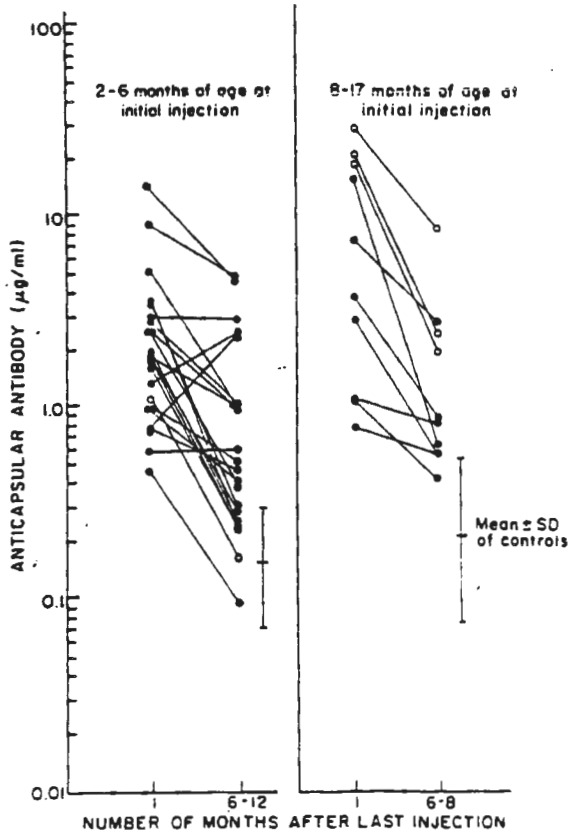

Fig 2—Serum anticapsular-polysaccharide antibody concentrations 6–12 months after immunisation.

○ = one injection only; ● = two injections 4 weeks apart.

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the levels at follow-up were significantly higher than those of 67 unimmunised children[23] of comparable age ($p \leq 0.001$).

Discussion

This conjugate vaccine, when administered with aluminium hydroxide, was well tolerated in both adults and infants. No systemic reactions were observed and slight local reactions occurred with only 3% of injections. In contrast, when the vaccine was given in saline alone reactions, both systemic and local, were frequent. The lower reaction rate with aluminium hydroxide may result from slower systemic release of vaccine adsorbed to aluminium hydroxide.

The vaccine was highly immunogenic, even in infants of 2–6 months. After one injection, the geometric mean increase in antibody concentration in infants of 2–6 months was 7·2 fold ($p < 0.001$), and two-thirds of subjects showed serum antibody levels > 1 μg/ml. In contrast, in previous trials with other *H influenzae* type b conjugate vaccines, infants of this age showed either a fall or no significant rise in total serum antibody levels after one or two injections of vaccine.[8,9] It is unlikely that the different results reflect differences in the assays between laboratories. Our results are based on two different assays and comparable results were obtained independently with the same samples at Merck Sharp and Dohme Laboratories. The greater antibody responses of the infants in our study may relate to the vaccine's carrier protein, a group-B meningococcal outer-membrane protein containing a small amount of endotoxin, or to the novel method used for coupling the polysaccharide to the protein.

The presence of high levels of maternal antibody in very young infants did not prevent a strong response to the vaccine. However, in babies aged 2–3 months there was a trend towards an inverse correlation between antibody levels before and after immunisation ($r = -0.47$, $p = 0.08$). There were no significant differences in the responses of infants immunised with two different lots of vaccine at slightly different doses (postimmunisation geometric means of 2·4 μg/ml and 2·8 μg/ml in infants immunised at 2–6 months of age in St Louis and West Virginia, respectively). We have also tested a third lot of vaccine in approximately 80 subjects (2–17 months) and have observed comparable immunogenicity and low reactivity (unpublished).

Much evidence indicates that serum antibody against the capsular polysaccharide protects against invasive *H influenzae* type b disease.[2,3] However, the precise level of antibody required to confer protection is not known. Previous estimates of 0·15 μg/ml of antibody after immunisation are probably too low and a concentration as high as 1·0 μg/ml may be required.[19,20] Furthermore, the contributions of other immunological mechanisms to protection of infants are not well understood. These questions are particularly relevant for the children who show a fall in serum antibody levels in the 6–12 months after immunisation (fig 2). A study with another *H influenzae* type b conjugate vaccine showed that children primed with conjugate vaccine had higher responses to a subsequent injection of conventional *H influenzae* polysaccharide vaccine than children who had not received conjugate vaccine.[9] We have made similar observations in children primed with the polysaccharide/outer-membrane-protein vaccine (unpublished). Thus, some immunised children may remain protected against disease, even in the face of declining serum antibodies, as a result of immunological priming.

Preliminary data indicate that the antibody produced by immunisation of our subjects with the polysaccharide/outer-membrane-protein conjugate vaccine activates complement-mediated bactericidal activity in vitro and confers protection against bacteraemia in infant rats (unpublished, Merck Sharp and Dohme Research Laboratories). These data suggest that the antibody elicited by the vaccine is biologically active and that the antigenic activity of the polysaccharide was preserved during coupling to the protein.

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REFERENCES

1. Anderson P, Johnston RB Jr, Smith DH. Human serum activities against *Haemophilus influenzae* type b. *J Clin Invest* 1972; 51: 31–38.
2. Peltola H, Käyhty H, Sivonen A, Mäkelä PH. *Haemophilus influenzae* type b capsular polysaccharide vaccine in children: a double-blind field study of 100,000 vaccinees 3 months to 5 years of age in Finland. *Pediatrics* 1977; 60: 730–37.
3. Peltola H, Käyhty H, Virtanen, M, Mäkelä PH. Prevention of *Haemophilus influenzae* type b bacteremic infections with the capsular polysaccharide vaccine. *N Engl J Med* 1984; 310: 1561–66.
4. Goebel WF, Avery OT. Chemo-immunological studies on conjugated carbohydrate-proteins. I. The synthesis of p-aminophenol β-glucoside, p-aminophenol β-galactoside, and their coupling with serum globulin. *J Exp Med* 1929; 50: 521–31.
5. Schneerson R, Barrera O, Sutton A, Robbins JB. Preparation, characterization, and immunogenicity of *Haemophilus influenzae* type b polysaccharide-protein conjugates. *J Exp Med* 1980; 152: 361–76.
6. Granoff DM, Boies EG, Munson RS Jr. Immunogenicity of *Haemophilus influenzae* type b polysaccharide-diphtheria toxoid conjugate vaccine in adults. *J Pediatr* 1984; 105: 22–27.
7. Lepow ML, Samuelson JS, Gordon LK. Safety and immunogenicity of *Haemophilus influenzae* type b-polysaccharide diphtheria toxoid conjugate vaccine in infants 9 to 15 months of age. *J Pediatr* 1985; 106: 185–89.
8. Eskola J, Käyhty H, Peltola H, et al. Antibody levels achieved in infants by course of *Haemophilus influenzae* type b polysaccharide diphtheria toxoid conjugate vaccine. *Lancet* 1985; i: 1184–86.
9. Anderson P, Pichichero ME, Insel RA. Immunization of two-month-old infants with protein-coupled oligosaccharides derived from the capsule of *Haemophilus influenzae* type b. *J Pediatr* 1985; 107: 346–51.
10. Schlech WF III, Ward JI, Band JD, Hightower A, Fraser DW, Broome CV. Bacterial meningitis in the United States, 1978 through 1981. The national bacterial meningitis surveillance study. *JAMA* 1985; 253: 1749–54.
11. Gilsdorf JR. Bacterial meningitis in southwestern Alaska. *Am J Epidemiol* 1977; 106: 388–91.
12. Ward JI, Lum MKW, Hall DB, Silimperi DR, Bender TR. Invasive *Haemophilus influenzae* type b disease in Alaska: background epidemiology for a vaccine efficacy trial. *J Infect Dis* 1986; 153: 17–26.
13. Marburg S, Jorn D, Tolman RL, et al. Bimolecular chemistry of macromolecules: synthesis of bacterial polysaccharide conjugates with *N. meningitidis* membrane protein. *J Am Chem Soc* (in press).
14. Helting TB, Guthöhrlein G, Blackkolb F, Ronnenberger H. Serotype determinant protein of *Neisseria meningitidis*. *Acta Path Microbiol Scand* 1981; 89: 69–78.
15. Goldschneider I, Gotschlich EC, Artenstein MS. Human immunity to the meningococcus. I. The role of humoral antibodies. *J Exp Med* 1969; 129: 1307–26.
16. Dixit VM, Grant GA, Santoro SA, Frazier WA. Isolation and characterization of a heparin-binding domain from the amino terminus of a platelet thrombospondin. *J Biol Chem* 1984; 259: 10100–05.
17. Kuo JS-C, Monji N, Schwalbe RS, McCoy DW. A radioactive antigen-binding assay for the measurement of antibody to *Haemophilus influenzae* type b capsular polysaccharide. *J Immunol Method* 1981; 43: 35–47.
18. Granoff DM, Shackelford PG, Pandey JP, Boies EG. Antibody responses to *Haemophilus influenzae* type b polysaccharide vaccine in relation to Km(1; and G,m(23) immunoglobulin allotypes. *J Infect Dis* (in press).
19. Käyhty H, Peltola H, Karanko V, Mäkelä PH. The protective level of serum antibodies to the capsular polysaccharide of *Haemophilus influenzae* type b. *J Infect Dis* 1983; 147: 1100.
20. Anderson P. The protective level of serum antibodies to the capsular polysaccharide of *Haemophilus influenzae* type b. *J Infect Dis* 1984; 149: 1034.
21. Cates KL. Serum opsonic activity for *Haemophilus influenzae* type b in infants immunized with polysaccharide-protein conjugate vaccines. *J Infect Dis* 1985; 152: 1076–77.
22. Schreiber JR, Barrus V, Cates KL, Siber GR. Functional characterization of human IgG, IgM, and IgA antibody directed to the capsule of *Haemophilus influenzae* type b. *J Infect Dis* 1986; 153: 8–16.
23. Granoff DM, Munson RS Jr. Prospects for prevention of *Haemophilus influenzae* type b disease by immunization. *J Infect Dis* 1986; 153: 448–61.

ABSTRACT Submitted to The American Pediatric Society 1988

ANTIBODY RESPONSES OF VACCINE FAILURE (VF) PATIENTS REIMMUNIZED WITH HAEMOPHILUS INFLUENZAE TYPE b POLYSACCHARIDE (HIB PS) OR HIB-PS MENINGOCOCCAL OUTER MEMBRANE PROTEIN (OMP) CONJUGATE VACCINE.

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Children who develop invasive Hib disease despite previous vaccination with Hib PS vaccine (i.e. VF) have impaired serum anticapsular antibody responses following recovery from disease (NEJM 315:1584, 1986). 30 VF patients with <2.0 ug/ml of anti-Hib PS antibody in convalescent sera were enrolled in a trial comparing the immunogenicity of Hib PS vaccine to that of Hib PS-OMP conjugate vaccine. Subjects were reimmunized 2 to 26 months after onset of disease (Mean=11.5 mos). Results are available from 26 subjects.

Hib Vaccine	No. Tested	Mean Age (mos)	Geo. mean antibody, ug/ml Pre Total	Post Total	Post IgG	Post IgG1	Post IgG2
PS	16	44	0.3	0.7	<1.0	<0.5	<0.3
PS-OMP	10	45	0.3	13.2	6.0	3.3	0.5

VF subjects given conjugate showed significantly higher geometric mean total, IgG and IgG1 responses, than those given PS ($p<.002$). The predominant IgG isotype evoked by the conjugate was IgG1. Only 5 of 16 (31%) subjects given Hib PS developed total serum antibody >1 ug/ml compared to 10 of 10 given conjugate ($p<0.002$). To date, 5 subjects with <1 ug/ml antibody after reimmunization with PS were given conjugate and all developed antibody >4.6 ug/ml. Thus, VF children with low serum levels of anti-Hib PS antibody have impaired antibody responses to reimmunization with Hib PS vaccine but develop high antibody responses to this Hib conjugate vaccine. Therefore, this conjugate is not only immunogenic in infants, but also in older children who may fail to respond to Hib PS vaccine because of genetic or other causes.

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Immunogenicity of *Haemophilus influenzae* Type b Polysaccharide-*Neisseria meningitidis* Outer Membrane Protein Conjugate Vaccine in 2- to 6-Month-Old Infants

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ABSTRACT. Fifty infants, 2 to 6 months of age, were vaccinated with *Haemophilus influenzae* type b capsular polysaccharide covalently linked to an outer membrane protein from *Neisseria meningitidis* group B. Subjects were given two injections and were randomly assigned to receive the injections separated by 1 or 2 months. Each dose contained 15 μg of polysaccharide and 51 μg of protein, or approximately twice the amount of polysaccharide as used in our previous trial (*Lancet* 1986;2:299). Fevers of 38.0° to 38.8°C developed in three infants (6%) within 24 hours after vaccination, but there were no other notable reactions. Following one injection, the geometric mean antibody concentration increased from 0.13 μg/mL in preimmune serum to 1.50 μg/mL in serum obtained 1 to 2 months later ($P < .001$). After a second injection, there was a further increase in serum antibody (geometric mean = 3.11 μg/mL, $P < .007$). The geometric mean antibody concentration of the group reimmunized 2 months after the first injection was higher than that in the group reimmunized after 1 month (3.95 *v* 2.32 μg/mL, $P = .05$, by analysis of covariance with age as the covariant). These data confirm our previous preliminary observations on the safety and immunogenicity of this new conjugate vaccine in infants 2 to 6 months of age. The data suggest that a 2-month interval between the first and second injections results in higher levels of serum antibody than a 1-month interval. *Pediatrics* 1987;80:283–287; *Haemophilus influenzae type b, conjugate vaccine, Neisseria meningitidis, infant.*

Haemophilus influenzae type b is the leading cause of bacterial meningitis in the United States.[1] The organism is also an important cause of other serious infections such as bacteremia, epiglottitis, cellulitis, and septic arthritis. In 1985, a *Haemophilus* vaccine consisting of the purified type b capsular polysaccharide was licensed for use in the United States. Based on an efficacy study done in Finland, this vaccine was not effective in children younger than 18 to 24 months.[2,3] In the United States, approximately 80% of cases of invasive *Haemophilus* disease occur in children younger than 24 months of age.[4] Therefore, a more immunogenic vaccine is needed for children in this younger age group.

Although poorly understood, failure of the type b polysaccharide to be immunogenic in young children has been attributed to delayed maturation of immune responses to certain thymic-independent antigens.[5,6] In contrast, infants show high serum antibody responses to vaccination with many protein antigens that are classified as thymic-dependent antigens.[7,8] Studies have shown that conjugation of a polysaccharide with a protein carrier increases the immunogenicity of the polysaccharide, possibly by conferring thymic-dependent properties to the polysaccharide.[9] These observations led to the development of several *Haemophilus* type b polysaccharide-protein conjugate vaccines which are currently under clinical investigation in infants.[10–13]

We have reported preliminary data on the safety and immunogenicity of a vaccine composed of the type b capsular polysaccharide covalently coupled to a *Neisseria meningitidis* group B outer membrane protein by a novel thioether linkage.[13,14] A single injection of this vaccine was immunogenic in the majority of 2- to 6-month-old infants. However, the antibody responses to a second injection were var-

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iable, with less than half of the subjects showing a significant increase in antibody.[13] In our previous study, the infants received two injections of vaccine separated by 1 month. Recent data from a preliminary study of children vaccinated with another conjugate vaccine suggest that increasing the interval between injections may enhance the antibody response to the booster injection.[12] In the present study, in an effort to increase immunogenicity of the booster injection, we compared the antibody responses of children revaccinated at 1- ν 2-month intervals following their primary vaccination. The longer interval also had the added advantage of better conforming to currently recommended immunization schedules. We also evaluated the use of a new lot of vaccine at a higher dose, ie, 15 μg of polysaccharide combined with 51 μg of protein instead of 7 μg of polysaccharide combined with 43 μg of protein as used previously.

PATIENTS AND METHODS

Study Population

Healthy children were recruited from pediatric practices and clinics in Missouri and Illinois. Informed parental consent was obtained, and 54 children, 2 to 6 months of age, were enrolled. A brief history and physical examination were performed prior to each immunization. Children were excluded if there was a history of a serious reaction to any previous vaccination or if there was a suspicion of underlying immunodeficiency. Vaccination was deferred if there was a history of fever within the previous 72 hours or if the child had received any other vaccine within the previous week.

Parents were given thermometers and report cards and were asked to record axillary temperatures four hours after vaccination and once daily for the next three days. They also were asked to note any reactions, local or systemic, that they believed might be attributable to the vaccine. The parents were instructed to notify one of the study physicians for any axillary temperature ≥38°C or for any other possible reaction of concern.

Vaccination

The vaccine was stored frozen at −70°C. After reconstitution with saline containing alum (lot 1015), each 0.5-mL dose of vaccine contained 15 μg of type b capsular polysaccharide and 51 μg meningococcal group B outer membrane protein. The vaccine was kept at 4°C and used within four hours after reconstitution.

The children were given two IM injections of *H influenzae* type b conjugate vaccine (lot 1018, Merck Sharp and Dohme). On entry into the study, the subjects were assigned consecutive numbers. Those in group 1 (odd numbers) received their second injection 1 month after the first injection. Subjects assigned to group 2 (even numbers) were given the two injections separated by 2 months.

Assays

Total antibody to *H influenzae* type b capsular polysaccharide was measured by radioantigen binding assay on serum samples obtained prior to both injections and 1 month after the second injection. The assay was performed as previously described by Kuo et al,[15] with the exception that ^{125}I-extrinsically labeled antigen was used instead of ^{3}H-labeled antigen.[16] Pre- and postimmunization sera from each child were measured in the same assay, and each assay contained samples from children assigned to both treatment groups. In addition, 36 samples were assayed on more than one occasion. The mean ± SD percentage variation from the average value for each sample was 10.7 ± 10.2.

Statistical Analyses

Statistical analysis was performed using SAS and RS1 software on a VAX 11/785 computer (Digital Equipment Co, Marlboro, MA). Within a group, a paired *t* test was used to compare the geometric mean antibody concentrations in sera before and after immunizations, with each child serving as his or her own control. Although subjects were randomly assigned to the two interval groups, analysis indicated a chance difference in mean age between them. Even if their mean ages had been identical at the time of the initial immunization, age at reimmunization and length of interval are necessarily comfounded because infants reimmunized after an interval of 2 months will be slightly older than infants reimmunized after an interval of only 1 month. Thus, for the comparison of the geometric mean antibody concentrations, age was used as a covariate in the one-way analysis of variance. In this analysis, age, however important,[13] can be thought of as a "nuisance" variable. Accordingly, its linear effect on the mean log antibody concentrations was removed prior to the comparison. Also, because of the previous data suggesting that a longer interval between injections was associated with higher antibody responses,[12] a one-tailed test was used for comparison of the geometric mean responses of the two groups to the second injection.

RESULTS

Characteristics of the Study Groups

Fifty-four subjects were enrolled in the study. The mean age at the time of the first injection was

TABLE 1. Characteristics of Study Groups*

Characteristic	All Children (n = 54)	1-Mo Interval Between Injections (n = 24)	2-Mo Interval Between Injections (n = 26)
Age (mean mo ± SD)			
Dose 1	3.6 ± 1.5	3.2 ± 1.3	4.1 ± 1.6
Dose 2	5.1 ± 1.8	4.2 ± 1.3	6.1 ± 1.6
No. (%) boys	33 (63)	17 (71)	16 (62)
No. (%) white race	43 (80)	19 (79)	22 (85)

* Four children, three in the 1-month interval group (group 1) and one in the 2-month interval group (group 2), were excluded for purposes of comparison of the responses of the two treatment groups. The mean age of group 2 was older than that of group 1 ($P \leq .04$ for first injection; $P < .001$ for second injection). There were no significant differences in the percentages for sex or race in the two groups ($P > .10$ by Fisher exact test).

3.6 months (Table 1). Initially, 27 children were assigned to group 1 to be revaccinated after 1 month and 27 were assigned to group 2 to be revaccinated after 2 months. However, for comparison of the antibody responses of the two groups, data from four children were excluded. Two were subjects assigned to group 1 who did not return for the second injection. A third child assigned to group 1 was revaccinated but not within the appointed time period. One child assigned to group 2 did not receive a second dose because a fever developed (38.8°C) 12 hours after the first injection of vaccine. By chance, the infants remaining in group 1 were younger at entry into the study than those in group 2, with mean ages of 3.2 *v* 4.1 months (Table 1). The two different dosing intervals also resulted in an increase in this age difference at the time of the second injection (4.2 *v* 6.1 months). In addition to age, there were no other significant differences in the characteristics of the two treatment groups. As summarized in Table 1, there were more boys than girls and more white than black children enrolled in both groups.

Reactions to Vaccination

A total of 105 injections were given to the 54 children. Local reactions, defined as erythema or induration ≥2 cm at the injection site, were reported after four of 54 initial doses (7.4%) and two of 51 second doses (3.9%). The largest local reaction was 5 cm of induration. Five possible systemic reactions were reported. A temperature elevation to 38.8°C occurred in one child 12 hours after vaccination. This child was reexamined, evidence of acute otitis media found, and the fever resolved promptly with antibiotic therapy. Two other children had isolated temperature elevations to 38.0°C, one at 4 hours and the other at 24 hours after the second injections. Two other children had possible systemic reactions without fever. In one, mild nasal congestion occurred on the day of initial immunization and then resolved within 72 hours. In the second child, mild diarrhea occurred 48 hours after the second injection but resolved after 1 week.

Antibody Responses

Serum samples were obtained from 47 children prior to the initial immunization, from 49 children 1 to 2 months after the first dose and from 51 children 1 month after the second dose. The geometric mean antibody concentration in preimmunization sera was 0.13 μg/mL, increasing to 1.50 μg/mL in sera obtained after the first dose ($P < .001$) and 3.11 μg/mL after the second dose ($P < .007$). After the first injection, 64% of the samples measured contained antibody concentrations >1 μg/mL. In the Finnish trial, in which conventional polysaccharide vaccine was tested, antibody concentrations >1.0 μg/mL in postimmunization sera correlated with protection from disease.[17] In the present study, after a second dose of vaccine, 88% of the children had levels greater than this concentration.

The present data confirm our previous observations that infants vaccinated as young as 2 to 3 months of age can make high serum antibody responses to *Haemophilus* type b polysaccharide. For example, in the present study, there were 29 subjects vaccinated initially at 2 to 3 months of age. After one injection, ten of 26 (38%) tested achieved antibody levels >1 μg/mL. The serum antibody concentrations of the infants who failed to achieve this level ranged from 0.16 to 0.98 μg/mL (geometric mean = 0.58 μg/mL). After a second injection, 21 of 28 (75%) children enrolled at 2 to 3 months of age and revaccinated 1 or 2 months later achieved levels >1 μg/mL. This group included ten of 15 tested (67%) who had not achieved this concentration after the first injection.

The geometric mean serum antibody concentrations before and after immunization of the children reimmunized after 1- or 2-month intervals after the first injection are summarized in Table 2. Shown are the least square values, that is, the geometric means of each group have been age adjusted by analysis of covariance to correct for the older ages of the subjects in group 2 at the time of the first and second injections.

Prior to the first injection, there were no significant differences in the geometric mean antibody concentrations in the two groups (0.14 and 0.11 μg/mL, $P = .49$). After the first vaccination, both groups showed approximately tenfold increases in geometric mean antibody, and there was no signif-

TABLE 2. Serum Anticapsular Antibody Responses in Children 2 to 6 Months of Age Immunized With *Haemophilus influenzae* Type b Polysaccharide-Outer Membrane Protein Conjugate Vaccine*

Group	Interval (mo) Between Injections	Preimmunization†		After First Injection‡		After Second Injection§	
		Geometric Mean (μg/mL)	Mean Log_{10} ± SEM	Geometric Mean (μg/mL)	Mean Log_{10} ± SEM	Geometric Mean (μg/mL)	Mean Log_{10} ± SEM
1	1	0.14	−0.77 ± 0.12	1.71	0.23 ± 0.10	2.32	0.37 ± 0.10
2	2	0.11	−1.00 ± 0.10	1.28	0.11 ± 0.10	3.95	0.60 ± 0.09

* Shown are least square values, ie, the geometric mean antibody levels have been adjusted by analysis of covariance to correct for the different ages of the groups at the time of each injection.
† $P = .49$, two-tailed t test.
‡ $P = .37$, two-tailed t test.
§ $P = .05$, one-tailed t test.

icant difference between the geometric mean concentrations ($P = .37$). Following the second injection, there were further significant increases in antibody in both groups ($P \leq .007$). However, the geometric mean antibody concentration was higher in the group revaccinated 2 months after the first injection than in the group revaccinated after a 1-month interval (3.95 *v* 2.32 μg/mL; $P = .05$). If one compares the geometric means of the raw data (ie, not adjusted for age difference), the higher responses of the group vaccinated after 2 months are even more apparent (4.48 *v* 2.02 μg/mL, $P = .01$).

DISCUSSION

In the present study, the *H influenzae* type b polysaccharide-outer membrane protein conjugate vaccine was well tolerated. Only six minor local reactions occurred following 105 injections, and fever was noted following only three injections. These observations are similar to those reported by us previously in children vaccinated with a lower dose of vaccine (7 *v* 15 μg of polysaccharide and 43 *v* 51 μg of protein).[13] Thus, although different lots of vaccine were used in the two studies, increasing the dose in the present study was not associated with an increased rate of adverse reactions.

Anderson et al[12] observed higher antibody responses in subjects vaccinated with a *Haemophilus* type b oligosaccharide-protein conjugate vaccine at 9 to 15 months of age when the second injection was given 6 to 14 weeks after the primary immunization, compared with an interval of 2 to 4 weeks. Therefore, we used a one-tailed t test to evaluate the hypothesis that a longer interval between injections (2 *v* 1 month) would result in higher antibody responses in our subjects. Indeed, infants given a second injection after a 2-month interval made nearly twice as much antibody as those reinjected after 1 month, and the difference was significant after statistical correction for the older ages of the group reinjected at 2 months ($P = .05$, Table 2).

In summary, the combined results from our previous and present studies indicate that this new *H influenzae* type b polysaccharide-outer membrane protein conjugate vaccine is safe and immunogenic in infants as young as 2 months of age. A dose containing between 7 and 15 μg of polysaccharide is in a highly immunogenic range. In infants vaccinated at 2 to 6 months of age, 2 months between injections results in higher antibody responses than a 1-month interval. Recent data from our laboratory also suggest that vaccination of infants at 2 to 6 months of age with this conjugate vaccine results in immunologic priming such that high serum *Haemophilus* polysaccharide antibody responses are observed when the children are revaccinated 10 to 15 months later with either the polysaccharide outer membrane protein conjugate vaccine or conventional type b polysaccharide vaccine.[18] These results are encouraging and suggest that complete protection against *H influenzae* type b disease may be conferred by as few as two injections of conjugate vaccine given at 2 to 6 months of age with a booster injection of conjugate or conventional vaccine given in the second year of life. However, questions that remain to be answered include the immunogenicity and safety of this conjugate vaccine when given concurrently with diphtheria-tetanus-pertussis and oral polio vaccines at 2 to 6 months of age and the optimal interval between the first series of two injections and subsequent booster immunization with conjugate or conventional polysaccharide vaccine. Finally, a large scale clinical trial will be needed to address the question of vaccine efficacy (prevention of disease) and safety.

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REFERENCES

1. Schlech WF, Ward JI, Band JD, et al: Bacterial meningitis in the U.S., 1978 through 1981. *JAMA* 1985;253:1749–1754
2. Peltola H, Käyhty H, Sivonen A, et al.: *Haemophilus influenzae* type b capsular polysaccharide vaccines in children: A double-blind field study of 100,000 vaccinees 3 months to 5 years of age in Finland. *Pediatrics* 1977;60:730–737
3. Peltola H, Käyhty H, Virtanen M, et al: Prevention of *Haemophilus influenzae* type b bacteremic infection with the capsular polysaccharide vaccine. *N Engl J Med* 1984;310:1561–1566
4. Murphy TV, Osterholm MT, Pierson LM, et al: Prospective surveillance of *Haemophilus influenzae* type b disease in Dallas, County, Texas, and in Minnesota. *Pediatrics* 1987;79:173–180
5. Robbins JB, Parke JC Jr, Schneerson R, et al: Quantitative measurement of "natural" and immunization-induced *Haemophilus influenzae* type b capsular polysaccharide antibodies. *Pediatr Res* 1973;7:103–110
6. Mosier DE, Subbarao B: Thymus-independent antigens: Complexity of B-lymphocyte activation revealed. *Immun Today* 1982;3:217–222
7. Stevens RH, Saxon A: Immunoregulation in humans: Control of antitetanus antibody production after booster immunization. *J Clin Invest* 1978;62:1154–1160
8. Pabst HF, Kretch HW: Ontogeny of the immune response as a basis of childhood disease. *J Pediatr* 1980;97:519–534
9. Schneerson R, Barrera O, Sutton A, et al: Preparation, characterization and immunogenicity of *Haemophilus influenzae* type b polysaccharide-protein conjugate. *J Exp Med* 1980;152:361–376
10. Eskola J, Peltola H, Mäkelä PH, et al: Antibody levels achieved in infants by course of *Haemophilus influenzae* type b polysaccharide/diphtheria toxoid conjugate vaccine. *Lancet* 1985;1:1184–1186
11. Lepow ML, Samuelson JS, Gordon LK: Safety and immunogenicity of *Haemophilus influenzae* type b-polysaccharide diphtheria toxoid conjugate vaccine in infants 9 to 15 months of age. *J Pediatr* 1985;106:185–189
12. Anderson PW, Pichichero ME, Insel RE, et al: Vaccines consisting of periodate-cleaved oligosaccharides from the capsule of *Haemophilus influenzae* type b coupled to a protein carrier: Structural and temporal requirements for priming in the human infant. *J Immunol* 1986;137:1181–1186
13. Einhorn MS, Weinberg GA, Anderson EL, et al: Immunogenicity in infants of *Haemophilus influenzae* type b polysaccharide conjugate vaccine with *Neisseria meningitidis* outer-membrane protein. *Lancet* 1986;2:299–302
14. Marburg S, Jorn D, Tolman RL, et al: Bimolecular chemistry of macromolecules—Synthesis of bacterial polysaccharide conjugates with *Neiserria meningitidis* membrane protein. *J Am Chem Soc* 1986;108:5282–5287
15. Kuo JS-C, Monji N, Schwalbe RS, et al: A radioactive antigen-binding assay for the measurement of antibody to *Haemophilus influenzae* type b capsular polysaccharide. *J Immunol Method* 1981;43:35–47
16. Granoff DM, Shackelford PG, Pandey JP, et al: Antibody responses to *Haemophilus influenzae* type b polysaccharide vaccine in relation to Km(1) and G2m(23) immunoglobulin allotypes. *J Infect Dis* 1986;154:257–264
17. Käyhty H, Peltola H, Karanko V, et al: The protective level of serum antibodies to the capsular polysaccharide of *Haemophilus influenzae* type b. *J Infect Dis* 1983;147:1100
18. Weinberg GA, Einhorn MS, Lenoir AA, et al: Immunologic priming to capsular polysaccharide in infants immunized with *Haemophilus influenzae* type b polysaccharide-*Neisseria meningitidis* outer membrane protein conjugate vaccine. *J Pediatr*, in press, 1987

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trol of intractable urinary-tract infection. Lancet 1979;2: 1205–9
9. Stamm WE, Counts GW, Wagner KF, Martin D, Gregory D, McKevitt M, Turck M, Holmes KK. Antimicrobial prophylaxis of recurrent urinary tract infections. A double-blind, placebo-controlled trial. Ann Intern Med 1980; 92:770–5
10. Brumfitt W, Cooper J, Hamilton-Miller JMT. Prevention of recurrent urinary infections in women: a comparative trial between nitrofurantoin and methenamine hippurate. J Urol 1981;126:71–4
11. Harding GKM, Ronald AR, Nicolle LE, Thomson MJ, Gray GJ. Long-term antimicrobial prophylaxis for recurrent urinary tract infection in women. Rev Infect Dis 1982;4:438–43
12. Brumfitt W, Hamilton-Miller JMT, Gargan RA, Cooper J, Smith GW. Long-term prophylaxis of urinary infections in women: comparative trial of trimethoprim, methenamine hippurate, and topical povidone-iodine. J Urol 1983;130:1110–4
13. Martinez FC, Kindrachuk RW, Thomas E, Stamey TA. Effect of prophylactic, low dose cephalexin on fecal and vaginal bacteria. J Urol 1985;133:994–6
14. Brumfitt W, Smith GW, Hamilton-Miller JMT, Gargan RA. A clinical comparison between macrodantin and trimethoprim for prophylaxis in women with recurrent urinary tract infections. J Antimicrob Chemother 1985;16:111–20

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Antibody Responses of Black Children to *Haemophilus influenzae* Type b Polysaccharide–*Neisseria meningitidis* Outer-Membrane Protein Conjugate Vaccine in Relation to the Km(1) Allotype

Evidence is accumulating that genetic factors may play a role in regulating immune responses to certain bacterial polysaccharides and may affect susceptibility to bacterial infections [1–3]. For example, we found that black children positive for the Km(1) immunoglobulin allotype have a lower relative risk of developing haemophilus meningitis [1] and have higher responses of IgG antibody to *Haemophilus influenzae* type b (Hib) polysaccharide (Hib PS) vaccine than do those who are negative for this allotype [1, 2].

Several new Hib PS-protein conjugate vaccines have been tested and have been shown to be more immunogenic in experimental animals and human infants than conventional Hib PS vaccine. Furthermore, repeated injections of conjugate vaccines elicit booster antibody responses and prime human infants for an anamnestic IgG response to a subsequent injection of conventional Hib PS vaccine [4, 5]. Studies in experimental animals suggest that alteration of the presentation of an antigen can affect immune responses such that genetic nonresponders can be made to respond to a given antigen [6]. The purpose of the present study was to determine whether the previously observed allotype-associated differences in the antibody responses of black children immunized with Hib PS vaccine are also present in subjects immunized with Hib PS covalently coupled to a protein carrier. In addition, we analyzed the antibody responses with respect to Km(1) allotype in children receiving a booster injection of conventional Hib PS vaccine six to 15 months after priming with conjugate vaccine.

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Informed consent was obtained from the parents of the children in this study.

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Subjects and Methods

The conjugate vaccine, prepared by Merck Sharp & Dohme Research Laboratories (West Point, Pa), consisted of Hib PS covalently coupled to a partially purified outer-membrane protein from group B *Neisseria meningitidis*. In recent studies, this conjugate has been shown to be immunogenic in infants as young as two to three months of age [7] and to prime infants for an anamnestic IgG antibody response to a booster injection with either conventional Hib PS vaccine or conjugate vaccine [5].

In the present study, 49 healthy black children seven to 17 months of age (mean ± SD, 11.7 mo ± 3.1 mo) were recruited from pediatric clinics and private practices in Missouri. The children received one im injection of 0.3 mL

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Table 1. Serum antibody response to capsular antigen of black children, in relation to Km(1) allotype.

Vaccination, Km(1) allotype, mean age (*n*)	Geometric mean titer of antibody (μg/mL)			
	Total, before vaccination	1 Mo after vaccination		
		Total	IgG	IgG2
Primary immunization*				
Positive, 11.5 mo (22)	ND	5.0	2.1	0.19
Negative, 11.9 mo (27)	ND	4.1	2.1	0.18
Booster immunization†				
Positive, 18.7 mo (10)	1.72	70.1	54.4	3.0
Negative, 19.7 mo (17)	1.66	76.9	52.8	8.0

NOTE. ND, not done.

* Children received conjugate vaccine.

† Children received Hib PS vaccine.

of vaccine lot 1018 containing 7 μg of Hib PS and 23.5 μg of *N. meningitidis* group B outer-membrane protein. The vaccine was stored frozen at −70 C. After reconstitution, the vials were kept at 4 C and were used within 4 h.

Twenty-seven of the 49 subjects were given booster injections of conventional Hib PS vaccine six to 11 months after priming with conjugate. Selection of these subjects was based on their willingness to participate. The conventional Hib PS vaccine used for the booster injection was prepared by Praxis Biologics (Rochester, NY) and was purchased from Mead Johnson (Evansville, Ind). Each 0.5-mL dose contained 25 μg of PS.

Total levels of antibody to Hib PS were measured by a radioantigen binding assay [2] in serum obtained one month after vaccination. IgG antibody to Hib PS was measured by an ELISA done as previously described [2, 8]. In previous studies, we found that black children with the Km(1) allotype have similar serum concentrations of IgG1 but higher total IgG2 concentrations than do children who are negative for this allotype [2, 9]. Therefore, in the present study, we also compared the IgG2-specific capsular antibody responses of the vaccinees. Levels of IgG2 antibody to the type b polysaccharide were measured by ELISA as previously described [8], except that in the present study we used a murine monoclonal antibody (HP6014; ICN Immunobiologics, Lisle, Ill) rather than a polyclonal monkey antiserum. Because the monoclonal antibody was available as ascites, we used a biotin-conjugated goat antibody to mouse IgG (Tago, Burlingame, Calif) to detect binding of the monoclonal antibody. This goat antiserum had been adsorbed with human IgG to remove reactivity. Quantitation of antibody by ELISA was accomplished by comparing the titration curves of test sera with those obtained for the Hib adult immune reference serum (U.S. Office of Biologics, Bethesda, Md) [8].

Km(1) allotype status was determined by HAI on coded samples as previously described [2]. Allotype determinations were done on serum samples obtained from subjects seven months of age or older to avoid interference by maternal antibody.

Statistical analysis was performed by using SAS and RS1 software on a VAX 11/785 computer (Digital Equipment, Marlboro, Mass). Because age can affect antibody response to immunization, we used analysis of covariance, with age as the covariate, to compare the geometric mean antibody concentrations for the different groups stratified by allotype status. To analyze the booster responses with respect to allotype status, we used age, antibody concentration prior to boosting, and the interval between priming and boosting as covariates in a multivariate analysis, because all three variables were found to have a significant effect ($P < .10$) on the booster response in a univariate analysis.

Results

Table 1 summarizes the antibody responses of the children to Hib PS with respect to their Km(1) allotype status. After primary immunization with the conjugate vaccine, there were no significant differences between the geometric means of the concentrations of total, IgG, or IgG2 capsular antibody in postimmunization sera from children positive for Km(1) and those from children who were negative for this allotype ($P > .5$ for each comparison). Twenty-one (95%) of the 22 Km(1)-positive children, compared with 23 (85%) of 27 Km(1)-negative children, had total antibody levels >1.0 μg/mL ($P = .36$, by Fisher's exact test); 18 (82%) of 22 Km(1)-positive children, compared with 17 (63%) of 27 Km(1)-negative children, achieved levels of >2.0 μg/mL ($P = .21$).

In both groups, there was relatively little IgG2 antibody in the postimmunization sera of the children who received conjugate vaccine, despite the presence of relatively high concentrations of IgG antibody. This finding is consistent with our previous observations that IgG1 is the predominant isotype evoked in infants immunized with this conjugate vaccine [10].

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Twenty-seven subjects were given a booster injection of conventional Hib PS vaccine six to 11 months after priming with conjugate (table 1). The mean interval between priming and boosting was the same in the 10 Km(1)-positive and the 17 Km(1)-negative subjects (7.9 mo). Before the booster injection, there was no significant difference in geometric mean antibody concentrations in Km(1)-positive and Km(1)-negative children (1.72 vs. 1.66 μg/mL; $P = .95$). After the booster immunization, there were no significant differences in the respective geometric means of the concentrations of total, IgG, or IgG2 antibody ($P \geq .20$ for all comparisons).

Discussion

In previous studies, we found that Km(1)-positive black children vaccinated with either Hib PS vaccine or Hib PS vaccine mixed with pertussis vaccine had higher capsular antibody responses than did Km(1)-negative black children [1, 2]. The higher responses in the Km(1)-positive children were limited to the levels of IgG [1, 2]; there was no significant difference in the IgM responses with respect to this allotype. Black children positive for the Km(1) allotype were also found to have higher total serum IgG2 concentrations than were black children who were negative for Km(1) [2, 9].

In contrast, Ambrosino et al. [11] have reported that white adults positive for Km(1) have lower antibody responses to certain polysaccharide antigens, including Hib PS, than do adults negative for this allotype. The fact that this result in white adults is opposite to that previously found by us in black infants may reflect differences in the ages or races of the subjects studied [12].

In the present study, we found no significant differences with respect to Km(1) allotype status in the respective total, IgG, or IgG2 antibody responses of black children immunized with a Hib PS-protein conjugate vaccine. Nor did we find a difference with respect to Km(1) allotype status in the antibody responses to Hib PS booster vaccination in black children previously primed with conjugate vaccine (table 1).

The conventional Hib PS is thought to be a thymic-independent (TI) type of immunogen. Coupling the polysaccharide with a protein carrier confers thymic-dependent (TD) features on the polysaccharide [4–7]. Thus the lack of a significant relation between Km(1) allotype and antibody response to Hib PS in the present study may reflect a difference in genetic regulation of antibody responses to certain TD immunogens, as compared with TI immunogens. The conjugate vaccine used in this study, however, contains a small amount of lipopolysaccharide associated with the outer-membrane protein. The contribution of the presence of this mitogen to the immunogenicity of the vaccine is unknown.

The mechanism involved in the genetic regulation of antibody response by genes associated with immunoglobulin allotypes remains unknown. Recent data in mice support the presence of a regulatory gene linked to immunoglobulin allotype loci that affects some isotype responses but not others [14]. Possible cellular mechanisms by which such a gene could be expressed include regulation of class switching at the B cell level and T cell–B cell interactions. Whatever the mechanism, immunization of children with the TD form of the Hib PS antigen appears to circumvent the allotype-associated differences in antibody response found in subjects immunized with conventional Hib PS vaccine.

In summary, the ability of a conjugate vaccine to circumvent previously reported genetic differences in antibody response to conventional Hib PS vaccine has potential clinical importance. The high immunogenicity of this conjugate vaccine in children with phenotypes previously associated with low antibody responses to conventional Hib PS vaccine suggests that conjugation of the polysaccharide to a protein may result in a vaccine that is not only effective in preventing Hib disease in infants, but is also effective in populations that may be at increased risk of disease because of genetic factors. A similar result has been reported for children with selective IgG2 deficiency; these children have increased susceptibility to Hib disease and impaired antibody responses to conventional polysaccharide vaccine [13].

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References

1. Granoff DM, Pandey JP, Boies E, Squires J, Munson RS Jr, Suarez B. Response to immunization with *Haemophilus influenzae* type b polysaccharide-pertussis vaccine and risk of *Haemophilus* meningitis in children with the Km(1) immunoglobulin allotype. J Clin Invest 1984;74:1708–14
2. Granoff DM, Shackelford PG, Pandey JP, Boies EG. Antibody responses to *Haemophilus influenzae* type b polysaccharide vaccine in relation to Km(1) and G2m(23) immunoglobulin allotypes. J Infect Dis 1986;154:257–64
3. Ambrosino DM, Schiffman G, Gotschlich EC, Schur PH, Rosenberg GA, DeLange GG, van Logheme E, Siber GR. Correlation between G2m(n) immunoglobulin allotype and human antibody response and susceptibility to polysaccharide encapsulated bacteria. J Clin Invest 1985;75:1935–42
4. Insel RA, Anderson PW. Oligosaccharide-protein conjugate vaccines induce and prime for oligoclonal IgG antibody responses to the *Haemophilus influenzae* b capsular polysaccharide in human infants. J Exp Med 1986;163:262–9
5. Weinberg GA, Einhorn MS, Lenoir AA, Granoff PD, Granoff DM. Immunologic priming to capsular polysaccharide in

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infants immunized with *Haemophilus influenzae* type b polysaccharide-*Neisseria meningitidis* outer membrane protein conjugate vaccine. J Pediatr 1987;111:22–7

6. Green I, Paul WE, Benacerraf B. The behavior of hapten-poly-L-lysine conjugates as complete antigens in genetic responder and as haptens in nonresponder guinea pigs. J Exp Med 1966;123:859–79
7. Lenoir AA, Granoff PD, Granoff DM. Immunogenicity of *Haemophilus influenzae* type b polysaccharide-*Neisseria meningitidis* outer membrane protein conjugate vaccine in 2 to 6 month old infants. Pediatrics 1987;80:283–7
8. Shackelford PG, Granoff DM, Nelson SJ, Scott MG, Smith DS, Nahm MH. Subclass distribution of human antibodies to *Haemophilus influenzae* type b capsular polysaccharide. J Immunol 1987;138:587–92
9. Shackelford PG, Granoff DM, Nahm MH, Scott MG, Suarez B, Pandey JP, Nelson SJ. Relation of age, race, and allotype to immunoglobulin subclass concentrations. Pediatr Res 1985;19:846–9
10. Weinberg GA, Einhorn MS, Lenoir AA, Granoff PD, Granoff DM. Immunization of infants with *Haemophilus influenzae* type b (Hib) polysaccharide-outer membrane protein (PS-OMP) conjugate vaccine primes for IgG1 booster responses to conventional Hib PS vaccine [abstract 879]. Pediatr Res 1987;21:320A
11. Ambrosino DM, Barrus VA, DeLange G, Siber GR. Correlation of the Km(1) immunoglobulin allotype with anti-polysaccharide antibodies in Caucasian adults. J Clin Invest 1986;78:361–5
12. Whittingham S, Propert DN. Gm and Km allotypes, immune response and disease susceptibility. Monogr Allergy 1986; 19:52–70
13. Insel RA, Anderson PW. Response to oligosaccharide-protein conjugate vaccine against *Haemophilus influenzae* b in two patients with IgG2 deficiency unresponsive to capsular polysaccharide vaccine. N Engl J Med 1986;315:499–502
14. Slack JH. Strain-dependent IgG subclass response patterns. J Immunol 1987;139:3734–8

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Immunologic priming to capsular polysaccharide in infants immunized with *Haemophilus influenzae* type b polysaccharide–*Neisseria meningitidis* outer membrane protein conjugate vaccine

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Thirty children vaccinated at 2 to 17 months of age with *Haemophilus influenzae* type b polysaccharide linked to a partially purified 40,000 dalton outer membrane protein of *Neisseria meningitidis* were revaccinated 10 to 14 months later with conventional *H. influenzae* type b polysaccharide vaccine. The geometric mean anti-type b antibody concentration before reimmunization was 0.68 μg/mL and rose to 31 μg/mL in sera obtained 1 month later. The mean level after immunization was not significantly different than that in sera from 12 adults immunized with type b polysaccharide vaccine (51 μg/mL, P = 0.3), and was 10-fold higher than that of 13 control children immunized with type b polysaccharide for the first time (2.7 μg/mL, P <0.001). The IgG responses of the children first given conjugate vaccine and then conventional type b polysaccharide vaccine were of a similar magnitude as those in the immunized adults. Further, the children maintained high levels of serum antibody 6 to 8 months later. Ten other children vaccinated in infancy with conjugate vaccine, and again with conjugate vaccine 10 to 15 months later, showed similar antibody responses to those of the group given conjugate vaccine in infancy, and booster with conventional polysaccharide vaccine. Thus vaccination with *H. influenzae* type b polysaccharide–outer membrane protein conjugate vaccine primes the immune system to an IgG memory antibody response to either type b polysaccharide or conjugate vaccine. Post-booster sera from all children tested showed high titers of functional activity in a complement-mediated bactericidal assay. These data suggest that protection of most infants from type b *Haemophilus* disease may be achieved by a combination of immunization at 2 to 4 months of age with this conjugate vaccine, and reimmunization 1 year later with conjugate or conventional type b polysaccharide vaccine.
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Hib	*Haemophilus influenzae* type b
OMP	Outer membrane protein
ELISA	Enzyme-linked immunosorbent assay

Conventional *Haemophilus influenzae* type b polysaccharide vaccine is thought to be a thymus-independent immunogen.[1-3] Booster responses are not observed after reinjection.[3-5] In an effort to enhance the immunogenicity of the polysaccharide, several covalently coupled Hib polysaccharide–protein conjugate vaccines have been developed and tested in experimental animals and humans.[5-12] These conjugate vaccines are thought to confer thymus-dependent properties to the polysaccharide.[7] The conjugate vaccines are more immunogenic than the conventional polysaccharide vaccine in infants, and result in booster antibody responses after reinjection of the conjugate.[6,8,12,14] Preliminary data[9] also suggest that children first given an Hib oligosaccharide–protein conjugate vaccine and reinjected with conventional polysaccharide vaccine develop an IgG memory response to the polysaccharide.

We recently evaluated the safety and immunogenicity of an Hib polysaccharide–*Neisseria meningitidis* outer membrane protein conjugate vaccine (Hib polysaccharide–OMP vaccine) prepared by Merck Sharp & Dohme.[6] A single injection was immunogenic in children vaccinated as young as 2 to 3 months of age, and the majority of the infants showed evidence of IgG anti-Hib polysaccharide antibody responses. Six to 12 months after immunization, the serum antibody concentrations in these children had declined, but the levels remained higher than those in unimmunized children.[6]

The purposes of the present study were to obtain additional information on the persistence of serum antibody in these children and to measure their antibody responses to a booster injection of either conventional Hib polysaccharide vaccine or Hib polysaccharide–OMP conjugate vaccine given approximately 1 year after the last injection of conjugate vaccine.

METHODS

Vaccines. The conjugate vaccine contained Hib polysaccharide covalently coupled to a partially purified OMP from *N. meningitidis* group B.[6,15] Two lots of conjugate vaccine were used. The lot used for primary immunization of the infants (Lot 1003/C-L680, Merck Sharp & Dohme Research Laboratories, West Point, Pa.) has been described[6]; each 0.5 mL dose contained 7 μg polysaccharide and 43 μg OMP. Each 0.3 mL dose of the lot used for reimmunization (Lot 1018/C-M679, Merck Sharp & Dohme Research Laboratories) contained 7 μg polysaccharide and 23 μg OMP. The conventional Hib polysaccharide vaccine was prepared by Praxis Biologics, Inc. (Rochester, N.Y.), and was purchased from Mead Johnson (Evansville, Ind.); each 0.5 mL dose contained 25 μg Hib polysaccharide.

Clinical design. The subjects were 43 healthy children, 14 to 31 months of age, who had been vaccinated previously with Hib polysaccharide–OMP conjugate vaccine.[6] Informed consent was obtained from the parents at the time of the initial immunization and again at the time of the reimmunization. Both immunization protocols were approved by the Human Studies Committee of Washington University School of Medicine. Thirty children were 2 to 6 months of age at the time of the initial immunization. Twenty-eight received two injections of conjugate vaccine separated by 1 month, and the remaining two children received only one injection. In the latter two, second injections were deferred because of febrile episodes associated with the first injection. Thirteen children were 8 to 17 months of age at the time of the initial immunization. Six received one injection of vaccine, and the remaining seven received two monthly injections of vaccine. In this group of children, second injections were given to those seven who showed relatively low antibody responses to the first injection (<2 μg/mL).[6]

In the first phase of the reimmunization protocol, 30 of the 43 children, aged 14 to 30 months, received conventional Hib polysaccharide vaccine subcutaneously in the thigh 10 to 14 months after the completion of the last immunization with conjugate vaccine. In the second phase, 10 other children, aged 14 to 31 months, received conjugate vaccine intramuscularly in the thigh 10 to 15 months after completion of the primary conjugate immunization. Selection of patients for immunization with the different vaccines was based on availability of the children and willingness of the parents to participate during different times during the follow-up period. Three of the original 43 patients provided follow-up serum 11 to 12 months after completion of the primary conjugate immunization but were not reimmunized.

Twelve healthy adults were immunized with 25 μg conventional Hib polysaccharide vaccine subcutaneously, and served as controls. They represent an independent sample, not previously reported. A second group of controls consisted of eight children with a history of culture-proved invasive Hib disease at 3 to 17 months of age (meningitis, five; buccal cellulitis, two; periorbital cellulitis, one). These children were vaccinated with 25 μg conventional Hib polysaccharide vaccine subcutaneously 7 to 21 months after recovery from disease (at 24 to 27 months of age).

Serology. Serum samples were obtained before immunization and 1 to 2 months after. Total serum anti-Hib polysaccharide antibody was measured by radioantigen

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Table I. Persistence of serum anticapsular antibody in 43 children immunized with Hib polysaccharide-OMP vaccine and observed for 10 to 15 months

Age at first injection (mo)	No. tested	Geometric mean antibody (μg/mL)		
		1 mo post	10-15 mo post	Control*
2-3	11	1.59	0.43	0.16
4-6	19	2.60	1.05	0.18
8-17	13	4.06	0.63	0.23

*Age-matched, unimmunized historical controls[12] (n = 20 to 29 children in each age group). Geometric mean antibody concentration of vaccinated children in each group was greater than that of the respective control group ($P < 0.01$ for each comparison, t test). There were no significant differences in antibody concentrations at 10 to 15 months between vaccinated children in each age group ($P > 0.10$).

binding assay.[3, 16] IgG anti-Hib polysaccharide antibody was measured by ELISA, using the type b polysaccharide coupled to poly-L-lysine as the antigen on the plate.[16, 17] Serum antibody measurements were determined on paired pre- and post-immunization sera to minimize interassay variation. The sensitivity and precision of these assays have been described.[16]

The functional activity of serum antibody was measured by a complement-mediated bactericidal assay as described.[18, 19] The test organism was Hib strain Eagan,[20] and the complement source was serum from an adult with agammaglobulinemia and normal complement levels.[19] The percentage of survival of Hib after incubation in the assay mixture was calculated by comparing colony counts at 0 and 60 minutes. The bactericidal activity was determined graphically by plotting the log of the serum dilution versus the percentage of survival of Hib cells[18]; the dilution giving 50% survival was defined as the bactericidal titer.

Statistics. The Student t test (two tailed) was used to compare the geometric mean concentrations of serum antibody between the groups of children and adults. A paired t test (one tailed) was used to compare the geometric mean antibody concentrations before and after immunization within a group. Analysis of antibody response was performed on logarithmically transformed data.

RESULTS

Forty-three children immunized with conjugate vaccine at 2 to 17 months of age had a significant decline in geometric mean serum antibody levels at 10 to 15 months follow-up, compared with the peak levels obtained 1 month after the last injection of vaccine ($P < 0.01$ for each age group tested, paired t test; Table I). However, the concentrations of antibody present at follow-up in the immunized children remained higher ($P < 0.01$) than those in unimmunized control children of comparable age. For this analysis, historical controls[12] were matched by age with the vaccinated patients, and the geometric mean antibody levels of the respective groups were compared. During the follow-up period, three of the 43 vaccinated infants respectively showed two-, six-, and 20-fold increases in antibody, although none of the three had a clinically apparent Hib illness. These children may have experienced natural exposure to either Hib or other bacteria with cross-reacting antigens.[21]

Forty of the 43 children were reinjected with either Hib polysaccharide vaccine or polysaccharide-OMP vaccine. In the first phase, 30 children were immunized with conventional Hib polysaccharide vaccine. No notable systemic reactions occurred, although two children had 1 to 3 cm erythema and tenderness at the injection site. In the second phase, 10 children were revaccinated with Hib polysaccharide–OMP vaccine. Of these, fever (temperature 39° to 40° C) developed in three, 4 to 36 hours after injection. The frequency of fever was significantly greater in the group reinjected with conjugate vaccine than in the group reinjected with conventional polysaccharide vaccine (30% vs 0%, $P = 0.02$, Fisher exact test). All three of the children with fever were apparently healthy at the time of immunization, but had evidence of otitis media or upper respiratory tract infections when reexamined 8 to 48 hours after onset of fever.

Table II summarizes the antibody responses of the 30 children who received conjugate vaccine in infancy and were vaccinated approximately 1 year later with conventional Hib polysaccharide vaccine at a mean (±SD) age of 20.0 ± 4.4 months. There were no significant differences in the antibody responses to the booster injection in children who received either one or two injections of conjugate vaccine; therefore the data were combined. The children first immunized with conjugate vaccine and reinjected with conventional polysaccharide vaccine showed substantial increases in both total and IgG anti-Hib polysaccharide antibody ($P < 0.01$). The geometric mean total or IgG antibody concentrations in sera obtained 1 month after immunization were not significantly different than those in post-immunization sera from 12 adults immunized for the first time with conventional Hib polysaccharide vaccine ($P > 0.3$, Table II). The serum levels present after immunization in the children who had previously received conjugate vaccine in infancy were approximately 10-fold higher than those in healthy children who had not received conjugate vaccine. The latter group was immunized with Hib polysaccharide vaccine for the first time at an age similar to that of the former group at the time of their booster immunization. In addition, children who had recovered from invasive Hib disease at 3 to 17 months of age and who were immunized with conventional

Table II. Serum antibody response to conventional Hib polysaccharide vaccine in relation to previous immunologic priming with polysaccharide-OMP conjugate vaccine

	Age at polysaccharide vaccine (mo)	n	Geometric mean antibody (μg/mL)		
			Total		IgG
			Pre	Post	Post
Children primed with conjugate vaccine*	14-20	19	0.73	31.8	16.7
	22-30	11	0.60	30.0	13.4
Children recovered from disease†	24-27	8	0.67	2.0	1.1
Healthy children‡	24-30	13	0.26	2.7	0.6
Healthy adults	—	12	2.83	51.0	10.4

*There were no significant differences ($P > 0.3$) in respective total or IgG post-immunization antibody concentrations in children first immunized with conjugate vaccine and revaccinated with conventional Hib polysaccharide vaccine, and those of healthy adults vaccinated first with conventional Hib polysaccharide vaccine. However, total and IgG post-immunization antibody concentrations of primed children were significantly greater ($P < 0.001$) than those of vaccinated children recovered from Hib disease and those of vaccinated healthy children.

†Hib disease at 3 to 17 months of age. There were no significant differences ($P > 0.4$) between post-immunization levels of vaccinated children recovered from disease and those of vaccinated healthy children.

‡Historical controls immunized with 5 μg Hib polysaccharide vaccine (dose within maximally immunogenic range).[12,24]

Hib polysaccharide vaccine at 24 to 27 months of age did not show an enhanced anti-Hib polysaccharide antibody response (Table II).

One month after vaccination, all 30 children whose primary immunization was with conjugate vaccine and who were given a booster injection of Hib polysaccharide vaccine had >3.5 μg/mL anti-Hib polysaccharide antibody in post-immunization serum; 23 (77%) had concentrations >10 μg/mL, and 15 (50%) children had concentrations ≥30 μg/mL. The group with concentrations ≥30 μg/mL included five children who were given conjugate vaccine at 2 to 4 months of age and were reimmunized with conventional polysaccharide vaccine at 14 to 17 months of age.

Ten additional children who had been vaccinated between 2 and 16 months of age with conjugate vaccine were reimmunized 10 to 15 months later with conjugate vaccine; the mean age at the time of reimmunization was 18.8 ± 5.3 months (range 14 to 31 months). The geometric mean antibody levels before and 1 month after booster vaccination were 1.0 and 41.7 μg/mL, respectively. The geometric mean IgG antibody concentration after booster vaccination was 16.9 μg/mL. These values are not significantly different from those of the children first given conjugate vaccine, then reinjected with conventional Hib polysaccharide vaccine ($P > 0.5$, t test). All 10 children reimmunized with conjugate vaccine developed >10 μg/mL serum anti-Hib polysaccharide antibody in post-immunization sera, and seven of the 10 had concentrations ≥30 μg/mL. The percentages were not significantly different from those of the children whose primary immunization was with conjugate vaccine, then given conventional Hib polysaccharide booster vaccine ($P > 0.2$, Fisher exact test).

To date, 12 children have been observed for 6 to 8 months after booster immunization. Ten received conventional Hib polysaccharide vaccine, and two conjugate vaccine. There was a significant decline in serum antibody during the period after the booster injection, but the antibody concentrations were maintained at high levels in all children (geometric mean antibody concentration in this group was 22.3 μg/mL 1 month after booster, and 11.9 μg/mL 6 to 8 months later, $P = 0.02$, paired t test). During this period, one of the 12 children showed a fivefold further increase in anti-Hib polysaccharide antibody in the absence of clinical illness.

Sera obtained before booster immunization and 1 month later from 14 representative children were tested for functional activity using a complement-mediated bactericidal assay.[18,19] Seven of these children were given the conventional Hib polysaccharide vaccine, and seven the polysaccharide-OMP vaccine. The geometric mean bactericidal titer increased from 1:3 to 1:120 in the children given conventional Hib polysaccharide vaccine, and from 1:1.5 to 1:208 in the children reimmunized with polysaccharide-OMP conjugate vaccine. There was no significant difference in the respective geometric mean titers of the two groups ($P > 0.3$). In the post-immunization sera, there was a linear relationship between the log of the anti-Hib polysaccharide antibody concentration and the log of the reciprocal bactericidal titer ($r = 0.86$, $P = 0.001$; Figure).

DISCUSSION

Previous data indicate that children or adults immunized with conventional Hib polysaccharide vaccine do not have booster antibody responses to reinjection with conventional vaccine.[2,3] (They may have increased serum anti-

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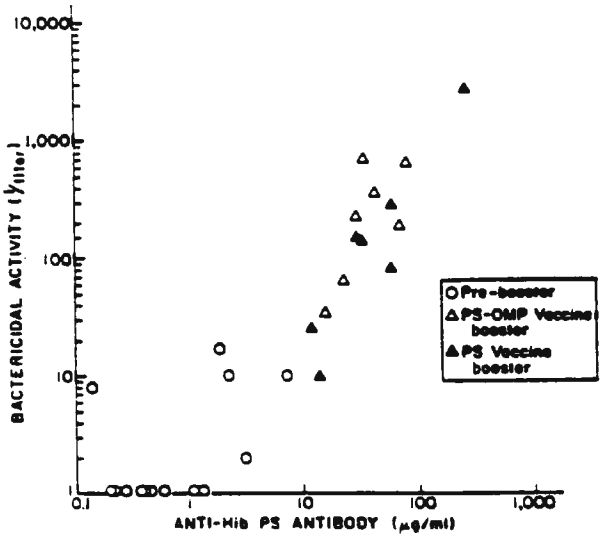

Figure. Relation between bactericidal titer and anti-Hib polysaccharide antibody concentration in sera from 14 children given two injections of Hib polysaccharide–outer membrane protein (PS-OMP) conjugate vaccine in infancy and reimmunized 10 to 15 months later with conventional Hib polysaccharide vaccine (n = 7) or conjugate vaccine (n = 7). Antibody concentrations were determined on serum samples obtained at the time of booster immunization and 1 month later.

body after reimmunization, but the levels achieved are not different from those of children of similar age immunized for the first time.[4]) In contrast, our data demonstrate that children vaccinated with Hib polysaccharide–OMP conjugate vaccine between 2 and 17 months of age have high IgG antibody responses on reinjection 10 to 15 months later with Hib polysaccharide vaccine or with Hib polysaccharide–OMP conjugate vaccine. The magnitude of the antibody responses to the "booster" injection is comparable to that of adults immunized for the first time with Hib polysaccharide vaccine. Further, in the vaccinated children, high levels of serum antibody persist after the booster injection. These observations are consistent with immunologic priming by vaccination in infants with conjugate vaccine and induction of a secondary or memory antibody response to the booster injection.

Anderson et al.[9] immunized six infants at 2, 4, and 6 months of age with an Hib capsular oligosaccharide–diphtheria toxoid conjugate vaccine and also observed enhanced antibody responses to conventional Hib polysaccharide vaccine administered 3 to 5 months later; however, in their study, the antibody responses to conventional Hib polysaccharide were inconsistent, and were about 10-fold lower than those we observed. The lower responses in their study may have resulted, in part, from the younger ages of the children at the time of reinjection (9 to 11 months, compared with 14 to 31 months in our study).

Our results and those of Anderson et al.[9] suggest that the initial vaccination with conjugate vaccine induces memory B cells. Further, these cells may be triggered to produce antibody by immunization with conventional Hib polysaccharide, even when a child is vaccinated at an age considered too young for successful immunization with this vaccine.[22] The ability to respond with an IgG "memory" antibody response on reexposure to Hib polysaccharide, as a result of immunologic priming, may be important for protection against Hib disease, especially in infants with declining levels of serum antibody.

In contrast to the group vaccinated in infancy with conjugate vaccine, the group who had had Hib disease in infancy did not show evidence of immunologic priming. Evidence for priming also was not observed by Norden et al.[23] in a previous study of patients who had recovered from Hib disease and who were then vaccinated with Hib polysaccharide vaccine. The reasons for the lack of priming are unclear. During Hib disease, the immune system encounters many antigens simultaneously (e.g., capsular polysaccharide, outer membrane proteins, lipopolysaccharide). However, the doses may be inappropriate for priming, or covalent coupling of polysaccharide and protein (as in the conjugate vaccine) may be required for priming to the polysaccharide.

We found no significant differences in the antibody responses of children with immunologic priming when reinjected with either conjugate vaccine or with conventional type b polysaccharide vaccine. However, the sample size of patients reinjected with conjugate was small, limiting the power of our study to detect a significant difference. Lepow et al.[13] also reported high antibody responses in children who received Hib polysaccharide–diphtheria toxoid conjugate vaccine at 9 to 15 months of age and were reinjected with conjugate vaccine at 24 months of age. However, their study did not include a comparison group of children reinjected with conventional Hib polysaccharide vaccine.

In our study, the anti-Hib polysaccharide antibody induced by revaccination had functional activity as measured by a complement-mediated bactericidal assay. The serum bactericidal titer appeared to be directly related to the level of anti-Hib polysaccharide antibody evoked by immunization. There did not appear to be any differences between the functional activity of the antibody elicited by conventional or conjugate vaccine.

These data indicate that vaccination of infants in the first 6 months with Hib polysaccharide–OMP conjugate vaccine induces immunologic priming such that the children show IgG memory antibody responses 10 to 14 months later when vaccinated with conventional Hib polysaccharide vaccine. Boosting with Hib polysaccharide–OMP conjugate vaccine is also highly immunogenic.

but may be associated with a higher frequency of febrile reactions. Further data are needed on the safety and efficacy of this conjugate vaccine, and on the optimal immunization schedule. However, a combination of immunologic priming in infancy with this conjugate vaccine, followed by boosting approximately 1 year later with conventional Hib polysaccharide vaccine (or conjugate vaccine), may be highly efficacious, potentially preventing most serious Hib disease in childhood.[12]

We thank Kathleen Lottenbach, Venita Boelloeni, Judy Adams, R.N., and Katherine Sheetz, R.N., for technical assistance.

REFERENCES

1. Paul WE, Kung J, Ahmed A, Stein K. B lymphocyte subpopulations and responses to polysaccharide antigens. In: Sell SH, Wright PF, eds. *Haemophilus influenzae:* epidemiology, immunology, and prevention of disease. New York: Elsevier Science Publishing Co., 1982:121-8.
2. Mosier DE, Subbarao B. Thymus-independent antigens: complexity of B-lymphocyte activation revealed. Immunol Today 1982;3:217-22.
3. Peltola H, Käyhty H, Sivonen A, Mäkelä PH. *Haemophilus influenzae* type b capsular polysaccharide vaccine in children: a double-blind field study of 100,000 vaccinees 3 months to 5 years of age in Finland. Pediatrics 1977;60:730-7.
4. Käyhty H, Karanko V, Peltola H, Mäkelä PH. Serum antibodies after vaccination with *Haemophilus influenzae* type b capsular polysaccharide and responses to reimmunization: no evidence of immunologic tolerance or memory. Pediatrics 1984;74:857-65.
5. Granoff DM, Boies EG, Munson RS Jr. Immunogenicity of *Haemophilus influenzae* type b polysaccharide–diphtheria toxoid conjugate vaccine in adults. J PEDIATR 1984;105:22-7.
6. Einhorn MS, Weinberg GA, Anderson EL, Granoff PD, Granoff DM. Immunogenicity in infants of *Haemophilus influenzae* type b polysaccharide in a conjugate vaccine with *Neisseria meningitidis* outer-membrane protein. Lancet 1986;2:299-302.
7. Schneerson R, Barrera O, Sutton A, Robbins JB. Preparation, characterization and immunogenicity of *Haemophilus influenzae* type b polysaccharide–protein conjugates. J Exp Med 1980;152:361-76.
8. Lepow ML, Samuelson JS, Gordon LK. Safety and immunogenicity of *Haemophilus influenzae* type b–polysaccharide diphtheria toxoid conjugate vaccine in infants 9 to 15 months of age. J PEDIATR 1985;106:185-9.
9. Anderson P, Pichichero ME, Insel RA. Immunization of 2-month-old infants with protein-coupled oligosaccharides derived from the capsule of *Haemophilus influenzae* type b. J PEDIATR 1985;107:346-51.
10. Schneerson R, Robbins JB, Parke JC Jr, et al. Quantitative and qualitative analysis of serum antibodies elicited in adults by *Haemophilus influenzae* type b and pneumococcus type 6A capsular polysaccharide–tetanus toxoid conjugates. Infect Immun 1986;52:519-28.
11. Anderson PW, Pichichero ME, Insel RA, Betts R, Eby R, Smith DH. Vaccines consisting of periodate-cleaved oligosaccharides from the capsule of *Haemophilus influenzae* type b coupled to a protein carrier: structural and temporal requirements for priming in the human infant. J Immunol 1986; 137:1181-6.
12. Granoff DM, Munson RS Jr. Prospects for prevention of *Haemophilus influenzae* type b disease by immunization. J Infect Dis 1986;153:448-61.
13. Lepow M, Randolph M, Cimma R, et al. Persistence of antibody and response to booster dose of *Haemophilus influenzae* type b polysaccharide–diphtheria toxoid conjugate vaccine in infants immunized at 9 to 15 months of age. J PEDIATR 1986;108:882-6.
14. Eskola J, Käyhty H, Peltola H, et al. Antibody levels achieved in infants by course of *Haemophilus influenzae* type b polysaccharide/diphtheria toxoid conjugate vaccine. Lancet 1985;1:1184-6.
15. Marburg S, Jorn D, Tolman RL, et al. Bimolecular chemistry of macromolecules: synthesis of bacterial polysaccharide conjugates with *Neisseria meningitidis* membrane protein. J Am Chem Soc 1986;108:5282-7.
16. Granoff DM, Shackelford PG, Pandey JP, Boies EG. Antibody responses to *Haemophilus influenzae* type b polysaccharide vaccine in relation to Km(1) and G2(m)23 immunoglobulin allotypes. J Infect Dis 1986;154:257-64.
17. Shackelford PG, Granoff DM, Nelson SJ, Scott MG, Smith DS, Nahm MH. Subclass distribution of human antibodies to *Haemophilus influenzae* type b capsular polysaccharide. J Immunol 1987;138:587-92.
18. Weinberg GA, Granoff DM, Nahm MH, Shackelford PG. Functional activity of different IgG subclass antibodies against type b capsular polysaccharide of *Haemophilus influenzae*. J Immunol 1986;136:4232-6.
19. Steele NP, Munson RS Jr, Granoff DM, Cummins JE, Levine RP. Antibody-dependent alternative pathway killing of *Haemophilus influenzae* type b. Infect Immun 1984; 44:452-8.
20. Anderson P, Johnston RB Jr, Smith DH. Human serum activities against *Haemophilus influenzae* type b. J Clin Invest 1972;51:31-8.
21. Schneerson R, Robbins JB. Induction of serum *Haemophilus influenzae* type b capsular antibodies in adult volunteers fed cross-reacting *Escherichia coli* 075:K100:H5. N Engl J Med 1975;292:1093-6.
22. Insel RA, Anderson PW. Oligosaccharide-protein conjugate vaccines induce and prime for oligoclonal IgG antibody responses to the *Haemophilus influenzae* b capsular polysaccharide in human infants. J Exp Med 1986;163:262-9.
23. Norden CW, Michaels RH, Melish M. Effect of previous infection on antibody response of children to vaccination with capsular polysaccharide of *Haemophilus influenzae* type b. J Infect Dis 1975;132:69-74.
24. Granoff DM, Cates KL. *Haemophilus influenzae* type b polysaccharide vaccines. J PEDIATR 1985;107:330-6.

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Infectious Diseases

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IMMUNIZATION OF INFANTS WITH Haemophilus influenzae TYPE b (Hib) POLYSACCHARIDE-OUTER MEMBRANE PROTEIN (PS-OMP) CONJUGATE VACCINE PRIMES FOR IgG1 BOOSTER RESPONSES TO CONVENTIONAL Hib PS VACCINE. Geoffrey A. Weinberg, Menachem S. Einhorn, Allen A. Lenoir, Paul D. Granoff, and Dan M. Granoff, Washington Univ. Sch. of Med., Dept. of Peds., St. Louis, MO.

A conjugate vaccine of Hib PS linked to an OMP of N. meningitidis is immunogenic in infants as young as 2-3 mo. (Lancet 1986;2:299). 43 children immunized at ages 2-17 mo. have been followed for 10-15 mo. The geo. mean serum Hib PS antibody (Ab) concentration declined but remained higher than that of unimmunized controls ($p<0.01$). 30 children were reinjected with conventional PS vaccine at ages 14-30 mo., and showed 20-50 fold average increases in total and IgG Ab. Serum Ab has persisted at high levels for >6 mo. The geo. mean Ab response of the reimmunized children was 10-fold higher than that of control children immunized with rS for the first time, and was not significantly different than that of adults immunized with PS vaccine. However, the IgG Ab responses of the adults were composed of both IgG1 and IgG2 (geo. mean G1/G2=1.7), while those of the infants were restricted to IgG1 (G1/G2=9.7, $p=0.01$). Thus, exposure to PS-OMP primes infants to an IgG1 memory Ab response to PS vaccine. In contrast, infants with Hib disease at ages 3-17 mo., and immunized with PS vaccine 7-21 mo. later did not show a memory Ab response.

PRIMED IN INFANCY	AGE AT PS VACCINE (mo.)	NO.	GEO. MEAN ANTI-Hib PS (µg/ml) PRE	POST	IgG POST
YES (PS-OMP)	14-20	19	0.73	31.8	16.7
YES (PS-OMP)	22-30	11	0.60	30.0	13.4
NO (HEALTHY)	24-30	13	0.26	2.7	0.6
NO (DISEASE)	24-27	8	0.67	2.0	ND
NO (HEALTHY)	ADULTS	12	2.83	51.0	10.4

Haemophilus b Conjugate Vaccine
(Neisseria meningitidis Outer Membrane Protein Complex)

VIII. STATISTICAL METHODS

Throughout this report vaccines, vaccine lots, vaccine treatment groups, or other groups were compared.

All tests of significance were two-sided with the exception of the interaction studies where the H_a increased clinical reaction rates or decreased immunologic response with concurrent administration. A result was considered significant if the p-value was ≤ 0.05.

The demographic characteristics, sex and race, were compared using Chi-square or Fisher's Exact test. The Mantel-Haenszel test was used when the comparison was stratified on age group (<12 months or $\geq$12 months).

Ages were compared by an analysis of variance or two-sample Student's t-test.

The analyses of anti-PRP titers and fold rises from baseline were performed on log-transformed data as these variables appear normally distributed in the log scale. For anti-PRP values reported as <0.125, 0.125 was used to calculate the fold rise and 0.0625 was used to calculate the geometric mean titer. For other antibody measures reported as <x, x was used to calculate the fold rise and x/2 the geometric mean titer. Geometric mean fold rises and titers were obtained by exponentiating the mean of the log values.

Anti-PRP levels were compared among groups using an analysis of covariance on all children regardless of baseline, with the log-transformed baseline titer as the covariate. When the comparison was in the subset of children whose baseline values were $\leq$0.15 mcg/ml, an analysis of variance was used. Group, age category 2 to 6 months, 7 to 11 months, 12 to 17 months, 18 to 23 months, $\geq$24 months), and sometimes race were the main effects. First a model fitting the interaction terms was used. Since the interaction terms were not significant, they were removed from the model. Fold rises were similarly compared in all children, regardless of baseline value.

A two-sample Student t-test was used to compare antibody levels when there were only two groups and the age range was narrow. If the assumptions of normality or equal variances were violated, Wilcoxon's two-sample test was used, as in the comparison of vaccines for immunoglobulin class and subclass levels.

A regression model with log titer as the dependent variable and age (in months) as the independent variable was used to test the effect of age on level of response within each vaccination regimen in the children whose baseline values were ≤0.15 mcg/ml.

Tests for log fold rises greater than zero were done using a paired t-test or signed rank test.

The Mantel-Haenszel test was used to compare groups for the proportion of children achieving levels >1.0 mcg/ml stratified on age categories (2 to 6 months, 7 to 11 months, 12 to 17 months, 18 to 23 months, ≥24 months) and baseline antibody categories (≤0.15 mcg/ml or >0.15 to 1.0 mcg/ml). Age group, race, and sex were compared stratified on baseline antibody category.

Chi-square or Fisher's Exact test was used to compare groups for the proportion of children with functional antibody measures (opsonins and SBA), the proportion seroconverting for antibody to the measles, mumps, or rubella antigen, the proportion developing 2-fold rises in anti-PRP titers, or the proportion developing 4-fold rises in antibody to diptheria or pertussis.

Chi-square or Fisher's Exact test was used to compare groups for clinical reaction rates. The Mantel-Haenszel test was used when these comparisons were stratified on age groups (<12 months, ≥12 months).

IX. REFERENCES

1. Ahonkhai, V. I., Brown, K., Lukacs, L., Matthews, H., Finney, L., Vella, P., Staub, J.: Response of 2 and 3 Month Old Infants to Haemophilus b Conjugate - Neisseria meningitidis Outer Membrane Protein Vaccine. Paper presented at the 27th Interscience Conference on Antimicrobial Agents and Chemotherapy, New York, New York, Oct. 4-7, 1987, Program Abstract No. 323.

2. Ahonkhai, V. I., Lukacs, L., Brown, K. R., Weibel, R., Vella, P. P., Marburg, S., Tai, J.: Conjugation of Haemophilus influenzae Type b (Hib) Capsular Polysaccharide (PS) to a Carrier Protein by a Measurable Covalent Bond Enhances Immunogenic Response in Infants. Paper presented at the 26th Interscience Conference on Antimicrobial Agents and Chemotherapy, New Orleans, LA, Sept. 29 - Oct. 1, 1986, Program Abstract No. 215.

3. Ahonkhai, V.I., Lukacs, L.J., Matthews, H., Vella, P., Gerety, R.J.: Continuing Evaluation of Safety and Immunogenicity of Haemophilus b Conjugate - N. meningitidis Outer Membrane Protein Vaccine (Hb-NOMP). Paper to be presented at the 28th Interscience Conference on Antimicrobial Agents and Chemotherapy, Los Angeles, CA, Oct. 23-26, 1988, Program Abstract No. 1027.

4. Clanton, M.S., Granoff, D.M., Pilot, B., Pandey, J.P., Murphy, T.V.: Black Infants Who Lack Km(1) Allotype Show Higher Anticapsular Antibody Responses to H. influenzae b - N. meningitidis Outer Membrane Protein Conjugate Vaccine (Hib PS-OMP). Paper to be presented at the 28th Interscience Conference on Antimicrobial Agents and Chemotherapy, Los Angeles, CA, Oct. 23-26, 1988, Program Abstract No. 1131.

5 Einhorn, M. S., Weinberg, G. A., Anderson, E. L., Granoff, P. D. and Granoff, D. M.: Immunogenicity in Infants of Haemophilus influenzae Type b Polysaccharide in a Conjugate Vaccine with Neisseria meningitidis Outer Membrane Protein. Lancet 2(8502): 299-302, Aug. 9, 1986.

6. Granoff, D. M., Chacko, A., Lottenbach, K., Sheetz, K.: Antibody Responses of Vaccine Failure (VF) Patients Reimmunized with Haemophilus influenzae Type b Polysaccharide (HIB PS) or HIB-PS Meningococcal Outer Membrane Protein (OMP) Conjugate Vaccine. Submitted to the American Pediatric Society, 1988.

7. Kim, K. S., Schoettler, J. S., Hong, J. K., Heiner, D. C.: Protective Activity Against Haemophilus influenzae Type b (Hib) of Human Sera from Recipients of Different Hib Vaccines. Paper presented at the 27th Interscience Conference of Antimicrobial Agents and Chemotherapy, New York, N. Y., Oct. 4-7, 1987, Program Abstract No. 890.

8. Lenoir, A. A., Granoff, P. D. and Granoff, D. M.: Immunogenicity of Haemophilus influenzae Type b Polysaccharide - Neisseria meningitidis Outer Membrane Protein Conjugate Vaccine in 2 to 6 Month Old Infants. Pediatrics 80(2): 283-287, Aug. 1987.

9. Lenoir, A. A., Pandey, J. P., Granoff, D. M.: Antibody Responses of Black Children to Haemophilus influenzae Type b Polysaccharide - Neisseria meningitidis Outer Membrane Protein Conjugate Vaccine in Relation to the Km(1) Allotype. J. Infectious Diseases 157(6): 1242-1245, June, 1988.

10. Marburg, S., Jorn, D., Tolman, R. L., Arison, B., McCauley, J., Kniskern, P. J., Hagopian, A., Vella, P. P.: Bimolecular Chemistry of Macromolecules: Synthesis of Bacterial Polysaccharide Conjugates with Neisseria meningitidis Membrane Protein. J. Am. Chem. Soc. 108(17): 5282-5287, 1986.

11. Shapiro, E.D., Capobianco, L.A., Zitt, M.Q.: Immunogenicity of H. influenzae Type b (Hib) Polysaccharide - N. menigitidis Outer Membrane Protein (PS-OMP) Conjugate Vaccine in Infants and Young Children. Paper to be presented at the 28th Interscience Conference on Antimicrobial Agents and Chemotherapy, Los Angeles, CA, Oct. 23-26, 1988, Program Abstract No. 1031.

12. Shapiro, E. D, Pramburg, J. C. and Daum, R. S.: Immunologic Priming of Infants with a Single Dose of H. influenzae Type (Hib) Polysaccharide - Neisseria meningitidis Outer Membrane Protein (PS-OMP) Conjugate Vaccine. Pediatr. Res. 21(4, Part 2): 334A, Apr. 1987 (in Soc. Proc.).

13. Ward, J.I., Berkowitz, C., Burkhart, K., Brenneman, G., Pescetti, J., Marcy, M.: Comparative Immunogenicity of H. influenzae Type b (Hib) Conjugate Vaccines (PRP-D/PRP-OMP) in Infants <6 Months of Age. Paper to be presented at the 28th Interscience Conference on Antimicrobial Agents and Chemotherapy, Los Angeles, CA, Oct. 23-26, 1988, Program Abstract No. 1128.

14. Weinberg, G. A., Einhorn, M. S., Lenoir, A. A., Granoff, P. D. and Granoff, D. M.: Immunologic Priming to Capsular Polysaccharide in Infants Immunized with Haemophilus influenzae Type b Polysaccharide-Neisseria meningitidis Outer Membrane Protein Conjugate Vaccine. J. Pediatr. 111(1): 22-27, July 1987.

15. Weinberg, G. A., Einhorn, M. S., Lenoir, A. A., Granoff, P. D. and Granoff, D. M.: Immunization of Infants with Haemophilus influenzae Type b (Hib) Polysaccharide - Outer Membrane Protein (PS-OMP) Conjugate Vaccine Primes for IgG_1 Booster Responses to Conventional Hib PS Vaccine. Pediatr. Res. 21(4, Part 2): 320A, Apr. 1987.

16. Wong, V.K., Adle, R., Steinberg, E.A., Kim, K.S.: A Comparative Study of the Safety, Tolerance and Immunogenicity of 3 Licensed Haemophilus influenzae Type b Capsular Polysaccharide (Hib-PRP) Vaccines in Children. Paper to be presented at the 28th Interscience Conference on Antimicrobial Agents and Chemotherapy, Los Angeles, CA, Oct. 23-26, 1988, Program Abstract No. 1028.

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323 **Response of 2 And 3 Month Old Infants to Haemophilus b Conjugate - Neisseria meningitidis Outer Membrane Protein (Hb-NOMP) Vaccine.**

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Hb-NOMP has been shown to induce a high antibody (Ab) response to Hb capsular polysaccharide in adults and children. We now report the response of young infants 2 to 3 months of age, in whom a successful immunization strategy could offer optimum control of Hb disease. Subjects were given two intramuscular injections of the vaccine separated by one month, and Ab response was measured by radioimmunoassay on sera obtained preimmunization (T_0) and one month after each injection (T_1, T_2). Reactions following 87 injections were mild, and included minor local erythema/induration (37.9%), transient fretfulness (40.2%) and fever $\geq$ 38.3°C (2.3%). Increase in Ab geometric mean titer (GMT) from T_0 to T_1 was higher ($p < 0.01$) than from T_1 to T_2 ($p = 0.20$). GMT at T_2 reached a level currently associated with protection (1.0 µg/ml). These results suggest that Hb-NOMP appears tolerable in young infants and induces levels of Ab that correlate with protection after two doses.

		Ab-GMT	Ab (µg/ml) above:		GMT Fold rise
	N	µg/ml	0.15	1.0	
T_0	42	0.16	9/41(46%)	1/42(2%)	-
T_1	26	0.72	25/26(96%)	10/26(38%)	3.5
T_2	30	1.05	30/30(100%)	18/30(60%)	4.7

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215 **Conjugation of Haemophilus influenzae type b (Hib) capsular polysaccharide (PS) to a carrier protein by a measurable covalent bond enhances immunogenic response in infants.**

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In the search for an immunogenic vaccine for infants, Hib PS was conjugated with N. meningitidis group B outer membrane protein (OMP) by two methods. Vaccine A was prepared by coupling OMP to PS with aminocaproic acid, and B by a multi-step procedure involving chemical modification of PS and OMP yielding a covalent linkage. The components of each conjugate and the covalency ratio of Vaccine B are characterizable by chemical analysis and nuclear magnetic resonance. Each vaccine was evaluated at 8 µg PS per dose in infants ≤ 18 months. Anti PS antibody (Ab) was measured by radioimmunoassay and geometric mean titer (GMT) of Ab was determined prior to (pre), and after the first ($post_1$) (N=31), or second ($post_2$) injection (N=15). Results are displayed in the table. Infants 7-18 months old responded to both vaccines as judged by Ab GMT and individual Ab ≥1.0 µg/ml. Infants 2-6 months old showed a high degree of response to 2 doses of vaccine B, but not to vaccine A. These results suggest that vaccine B is more immunogenic in infants. We believe that assured covalency in the conjugation of vaccine B is a major contributory factor in its enhanced immunogenicity. Additional studies with vaccine B are in progress.

Age	Vaccine	Ab GMT(µg/ml)			#Subjects with Ab≥ 1.0 µg/ml	
(Mo)		pre	$post_1$	$post_2$	post 1	post 2
7-18	A	0.14	0.34	0.73	3/9	2/3
	B	0.13	1.12	12.46	5/10	4/4
2-6	A	0.14	0.11	0.14	0/6	0/4
	B	0.10	0.22	3.06	0/6	4/4

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Continuing Evaluation of Safety and Immunogenicity of Haemophilus b Conjugate - N. meningitidis Outer Membrane Protein Vaccine (Hb-NOMP)

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Hb-NOMP clinical trials are continuing with 2 injections given 2 months apart to infants below 12 months of age and a single injection to older subjects. Reactions have been mild in over 2200 doses given to about 1700 subjects and include fever >38.3°C in 2% (14/844 injections) and local inflammation >2.5 cm in 3% (32/964 injections). Capsular polysaccharide antibody measured by radioimmunoassay at specified periods are shown below.

Age (Mo.)	Time	N	Antibody GMT (mcg/ml)	% Vaccinees With Antibody >2 Fold Rise	>0.15 (mcg/ml)	>1.0 (mcg/ml)
2-6	Pre	149	0.12	—	40	3
	Post 1	143	3.1	94	100	83
	Post 2	123	5.7	98	99	94
7-11	Pre	78	0.09	—	23	3
	Post 1	72	3.6	92	99	85
	Post 2	66	8.1	98	100	92
12-23	Pre	187	0.13	—	37	4
	Post	186	6.0	98	100	90
24-71	Pre	108	0.29	—	60	19
	Post	108	15.8	97	100	96

Postvaccination antibody GMTs exceeded 1.0 mcg/ml (protective correlate) in all age groups including in most (83%) infants vaccinated at 2 months of age. We conclude that Hb-NOMP can induce protective levels of antibody in the majority of vaccinated infants by the age of 4 months.

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BLACK INFANTS WHO LACK KM(1) IG ALLOTYPE SHOW HIGH ANTICAPSULAR ANTIBODY RESPONSES TO H. INFLUENZAE B - N. MENINGITIDIS OUTER MEMBRANE PROTEIN CONJUGATE VACCINE (Hib PS-OMP).

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Blacks lacking Km(1) have a higher relative risk of meningitis and lower conc. of antibody following vaccination with plain Hib-PS vaccine than blacks with the Km(1). However, 7-17 mo. old blacks lacking Km(1) had a good antibody response to a single injection of Hib PS-OMP conjugate vaccine (Study #1, J Infect Dis, in press). The purpose of study #2 was to compare the responses of 2-5 mo old black infants given 2 doses of Hib PS-OMP, given 2 mo. apart. In study #2, black infants lacking Km(1) had higher total antibody responses. IgG responses were not significantly different (5.8 vs 3.0 ug/ml, p=0.24).

				Total anti-PS antibody (Geo. mean, ug/ml)				
Study	Km(1)	No.	Mean Age(mo)	Pre	Post-dose #1		Post-dose#2	
1	Pos.	22	11.5	ND	5.0	p>.5	ND	
	Neg.	27	11.9	ND	4.1		ND	
2	Pos.	10	2.9	0.10	2.0	p=.09	5.1	p=.03
	Neg.	13	2.4	0.12	4.8		14.8	

Lack of the Km(1) allotype does not correlate with lower total or IgG responses to conjugate vaccine. Infants lacking Km(1), a phenotype associated with increased risk of meningitis, have comparable or higher antibody responses to 2 doses of conjugate than infants with Km(1).

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IMMUNOGENICITY IN INFANTS OF HAEMOPHILUS INFLUENZAE TYPE B POLYSACCHARIDE IN A CONJUGATE VACCINE WITH NEISSERIA MENINGITIDIS OUTER-MEMBRANE PROTEIN

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Summary 63 children, aged 2–17 months, were given a new conjugate vaccine composed of the capsular polysaccharide of *Haemophilus influenzae* type b linked to a *Neisseria meningitidis* outer-membrane protein. Subjects under 7 months received two injections separated by 1 month, and older subjects received either one or two injections. There were no systemic reactions to this vaccine when it was given with aluminium hydroxide. A single injection of vaccine was highly immunogenic; the geometric mean serum anticapsular antibody concentrations before immunisation and 1 month later were 0·35 μg/ml and 0·98 μg/ml for babies of 2–3 months, 0·12 μg/ml and 1·85 μg/ml for those of 4–6 months, and 0·15 μg/ml and 4·1 μg/ml for those of 8–17 months ($p \leq 0.003$ for each age group). After a second injection of vaccine, 80% and 76% of infants of 2–3 and 4–6 months, respectively, had antibody concentrations >1·0 μg/ml. Most subjects showed evidence of IgG responses as measured by enzyme-linked immunosorbent assay. 6–12 months after immunisation, serum antibody levels had fallen ($p < 0.05$) but they remained higher than those of unimmunised controls ($p < 0.001$).

Introduction

SERUM antibodies against the capsular polysaccharide of *Haemophilus influenzae* type b confer protection against invasive *H influenzae* type b disease.[1,2] In a field study in Finland, a capsular polysaccharide vaccine was protective in children older than 18–23 months,[2,3] but not in younger children. To date, the most successful approach to enhance the immunogenicity of the *H influenzae* type b polysaccharide is based on the hapten-carrier concept.[4] In animals[5] and in human beings[6] the immune response to the polysaccharide can be enhanced by covalently coupling it to a protein. In contrast to the plain polysaccharide vaccine, *H influenzae* type b conjugate vaccines elicit booster responses of antibody against capsular polysaccharide.[5,7] Several prototype conjugate vaccines have been reported to be immunogenic in infants as young as 6–7 months. However, the responses of infants younger than 6 months to one or two injections of vaccine have been meagre.[8,9] Infants in this age group account for approximately 20% of cases of *H influenzae* type b meningitis in the continental United States[10] and for approximately 35–50% of cases in Eskimos in Alaska.[11,12]

A conjugate vaccine composed of the *H influenzae* type b polysaccharide and an outer-membrane protein of *Neisseria meningitidis* group B was prepared at Merck Sharp and Dohme Research Laboratories, West Point, Pennsylvania. Both the coupling method and the protein carrier were different from those used to construct other experimental conjugate vaccines. The purpose of our study was to determine the safety and immunogenicity of this vaccine in children aged 2–17 months. Preliminary data from animal studies suggested that the vaccine was more immunogenic when administered with aluminium hydroxide than with saline alone. Therefore, we also compared the clinical and serological responses to the vaccine reconstituted with and without aluminium hydroxide.

Patients and Methods

Vaccine

The conjugate vaccine consists of the *H influenzae* type b capsular polysaccharide (molecular weight approximately 500 Kd by gel filtration on 'CL-4B Sepharose') covalently coupled to a meningococcal outer-membrane protein. Preparation and characterisation of the conjugate have been described elsewhere.[13] In brief, the solvent dimethylformamide and a column of tetra-n-butyl-ammonium-'Dowex-50' were used to form a soluble polysaccharide-$(butyl)_4$ ammonium salt; the polysaccharide was then sequentially activated by carbonyl di-imidazole and 1,4-butane diamine; the resulting pendant aminoalkyl groups were then bromoacetylated. A 40 Kd outer-membrane protein[14] was purified from group B *N meningitidis* (strain B-11, from Dr M. Artenstein,

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Walter Reed Army Institute of Research, Washington, DC[15]). The protein was independently activated with the introduction of pendant thiol groups by acylation with N-acetyl-homocysteine thiolactone. The activated polysaccharide and outer-membrane protein then reacted together to give a covalent conjugate containing a thioether linkage. This linkage is resistant to acid hydrolysis, so a novel aminoacid (S-carboxymethyl homocysteine) is produced by acid hydrolysis. Therefore, formation of the predicted thioether linkage was monitored by the S-carboxymethyl homocysteine content of the acid hydrolysis digest of the vaccine.

Two lots of vaccine were tested. A 0·5 ml dose of vaccine from lot 1 (1003/C-L680) contained 7 μg polysaccharide and 43 μg outer-membrane protein; the same volume of vaccine from lot 2 (1002/C-L466) contained 10 μg polysaccharide and 62 μg outer-membrane protein. The vaccine passed all safety and toxicity tests in animals. The endotoxin content of both vaccines was 1–6 μg/ml by Limulus lysate assay. Lot 1 was also assayed for glucosamine;[16] it was estimated to contain 0·25 μg/ml lipopolysaccharide. Both lots of vaccine were provided lyophilised and were stored at or below −40°C. After rehydration the vaccine was used within 1–4 h. The diluents used contained either sodium chloride or aluminium hydroxide; the same diluent was used for all injections in a particular subject.

Design

The study subjects were: 6 healthy adult volunteers from the staff of Washington University; 52 healthy children, 2–17 months old, recruited from private practices of paediatricians in St Louis or Batavia; and 11 healthy children, 2½–6 months old, from private practices in Huntington, West Virginia. Of the 63 children, 32 were male and 31 female, 60 white and 3 black. No subject had a history of *H influenzae* type b disease. Informed consent was obtained from the adults and from one or both parents of the children. The protocol was approved by the IND Branch of the National Center for Drugs and Biologics (under BB-IND-1966) and local ethical committees.

Subjects were not enrolled if there was any indication of previous substantial adverse reactions to vaccines or an underlying immunodeficiency. Other reasons for exclusion were diphtheria-typhoid-pertussis vaccination in the preceding 10 days and a febrile illness (>37·9°C) in the preceding 1–3 days.

To verify the safety of lot 1, 6 adults were given 0·5 ml vaccine with aluminium hydroxide by deep intramuscular injection into the deltoid muscle; no substantial reactions occurred. The first phase of the study in children was designed to compare the safety and immunogenicity of the same lot of vaccine given with either aluminium hydroxide or saline. 26 children (2–17 months) were randomly assigned to receive vaccine with either aluminium hydroxide or saline. Two injections of 0·5 ml were given 4 weeks apart by deep intramuscular injection into the quadriceps femoris. The second injection was not given if a substantial adverse reaction occurred after the first. After completion of this phase, it was apparent that side-effects were more common after saline injections than after aluminium hydroxide injections ($p < 0·001$). Therefore, only vaccine with aluminium hydroxide was used to immunise 26 other children. Also, because one injection of the vaccine was found to be highly immunogenic in most older children, only one injection was given routinely to children older than 8 months.

11 infants (2–6 months from West Virginia) were immunised with lot 2 by the same protocol, except that the dose was 10 μg capsular polysaccharide instead of 7 μg, and all children received vaccine suspended in saline.

Clinical Observations

At enrolment, a brief medical and immunisation history was taken. Before each injection the temperature, heart rate, respiratory rate, and weight were recorded. The child was observed for evidence of an immediate reaction for 15 min after the injection. A reporting card was given to the parents, who were instructed to record the child's axillary temperature and any local or systemic reactions, 4 h, 24 h, 48 h, and 72 h after the injection. In addition, all parents were contacted 24 h after the injection to ensure that any adverse reactions during that period were reported. Systemic reaction was defined as fever (temperature >38°C during the 72 h after immunisation) or persistent crying for more than 1 h. Local reactions were swelling or redness at the injection site ≥1·5 cm or pain in the leg associated with reduced use of the leg.

Serology

Serum samples were obtained before vaccination and 1 month after the first and second injections (when applicable). In West Virginia, serum samples were obtained before immunisation and 1 month after the second injection. All samples were assayed at Washington University and at Merck Sharp and Dohme Research Laboratories. The results from the two laboratories were highly correlated ($r = 0·9$) and only the data from Washington University are reported. Total serum antibody against capsular polysaccharide was measured by the radioantigen binding assay of Kuo et al,[17] except that iodine-125 rather than tritium[6,18] was used to label the antigen. IgG antibody against capsular polysaccharide was measured by enzyme-linked immunosorbent assay (ELISA) with the type b polysaccharide coupled to poly-L-lysine as the antigen on the plate.[18] IgG antibody concentrations were determined by comparing the titration curve of the test serum samples with that obtained with the US Bureau of Biologics *H influenzae* type b immune reference pool. Undiluted, this reference pool was found to have an IgG antibody concentration of 62 μg/ml. All serum samples were tested at dilutions of 1/100 or greater, and all samples from each subject were assayed together. The sensitivity of the assay was approximately 0·4 μg/ml.

Statistics

Student's *t* test was used to compare the geometric mean concentrations of serum antibody between groups given vaccine in aluminium hydroxide and vaccine in saline. A *t* test (one-tailed) was used to compare the geometric mean antibody concentrations before and after immunisation within a group. Analysis of response was done on logarithmically transformed data. A chi-square test was used to compare the rates of adverse reactions in the different groups.

Results

All 6 adults given vaccine with aluminium hydroxide experienced only mild pain and tenderness at the injection site. These reactions were greatest 4 h after vaccination and resolved gradually within 48 h. 111 doses of vaccine (46 saline, 65 aluminium hydroxide) were given to 63 children (24 saline, 39 aluminium hydroxide). The frequency of systemic or local reactions was not related to the age of the subjects, the number of injections, the vaccine lot, or the dose. Therefore, the rates of reaction in all children were combined. 10 (22%) injections of vaccine in saline but none of vaccine with aluminium hydroxide were associated with possible adverse systemic reactions ($p < 0·001$)—fever (38·2°–40°C) in 8 children and persistent crying for 1–4 h in 2 children. The children were also irritable and 3 had varying degrees of local reaction. In 6 of the 10 children, the systemic reactions were noted within 4 h of vaccine administration and resolved by approximately 24 h. In the other 4 fever began 48 h after injection, without local reactions. 2 of these children had evidence of otitis media at the time of the fever.

Local reactions occurred after 9 injections (8%); 7 (15%) were associated with vaccine in saline and 2 (3%) with vaccine in aluminium hydroxide ($p = 0·02$). The 2 reactions to vaccine in aluminium hydroxide were very slight (1·5–3·0 cm of erythema or swelling associated with pain or tenderness), whereas 2 of the 7 reactions to vaccine in saline were more severe (erythema, pain, and swelling in a wide area of the thigh above and below the injection site).

The antibody responses did not differ significantly with

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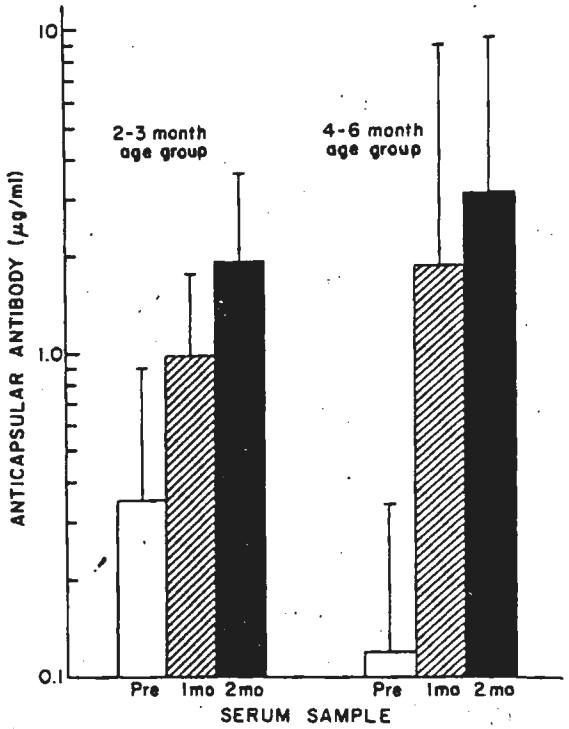

Fig 1—Geometric mean (SD) serum anticapsular-polysaccharide antibody levels in 17 infants aged 2–3 months and 21 infants aged 4–6 months at initial injection.

vaccine lot or dose or the diluent used so the results were combined. Subjects aged 8–17 months had high antibody responses to one injection of the vaccine. The geometric mean serum antibody concentrations before immunisation and 1 month later were 0·15 μg/ml and 4·1 μg/ml ($p < 0·001$). 84% of the 25 subjects had postimmunisation levels of antibody against capsular polysaccharide > 1·0 μg/ml. In a previous study with the plain polysaccharide vaccine[19,20] this postimmunisation level correlated with protection.

Fig 1 summarises the antibody responses of the 38 infants, aged 2–6 months, who were immunised routinely with two injections of conjugate vaccine, separated by a month. In this age group, a single injection was also immunogenic. In infants aged 2–3 months at first injection there were significant rises in antibody levels after both first (from 0·35 μg/ml to 0·98 μg/ml; $p = 0·003$) and second (to 1·9 μg/ml; $p = 0·005$) injections. In infants aged 4–6 months the rise in antibody level after the first injection was significant (from 0·12 μg/ml to 1·85 μg/ml; $p < 0·001$) but the rise after the second injection (to 3·1 μg/ml) was not significant. There were no significant differences between the age groups in the antibody levels achieved. After two injections, 80% of subjects immunised at 2–3 months and 76% of those immunised at 4–6 months had serum antibody concentrations > 1·0 μg/ml.

The radioantigen binding assay measures all antibody (IgM, IgG, and IgA) against the capsular polysaccharide. We were interested to see whether the immunised subjects showed specific IgG responses, since in vitro in the presence of complement, IgG antibody against capsular polysaccharide is more opsonic than IgM.[21,22] IgG antibody also persists longer in serum than IgM and, therefore, is likely to confer longer-lasting protection. Infants 2–3 and 4–6 months of age showed significant ($p < 0·01$) increases in IgG antibody 1 month after the second injection (table). The geometric mean postimmunisation antibody level was significantly higher in the 4–6-month-olds than in the younger babies ($p = 0·02$). 54% of the younger babies and 76% of the older ones showed greater than two-fold increases in antibody. However, this is a minimum estimate of response, particularly in the younger age group. For example, 3 infants had high antibody levels before immunisation (reflecting maternal antibody). The antibody levels in these infants increased after immunisation but did not show a two-fold rise. (In the absence of immunisation, the levels would probably have declined.)

IgG ANTICAPSULAR ANTIBODY RESPONSES OF IMMUNISED CHILDREN BY ELISA

Age	No tested	Geometric mean (μg/ml)		% with ≥ two-fold rise
		Before immunisation	1 mo after second injection	
2–3 mo	15	<0·4	0·88	54
4–6 mo	21	<0·4	2·08	76

To date, serum samples have been obtained 6–12 months (mean ± SD = 7·3 ± 1·8) after the last injection of vaccine from 31 children. The antibody concentrations in these samples are shown in fig 2. The geometric means of the serum antibody levels declined significantly during the follow-up period ($p < 0·05$), from 1·8 μg/ml to 0·8 μg/ml in infants immunised at 2–6 months and from 4·9 μg/ml to 1·0 μg/ml in those immunised at 8–17 months. Nevertheless,

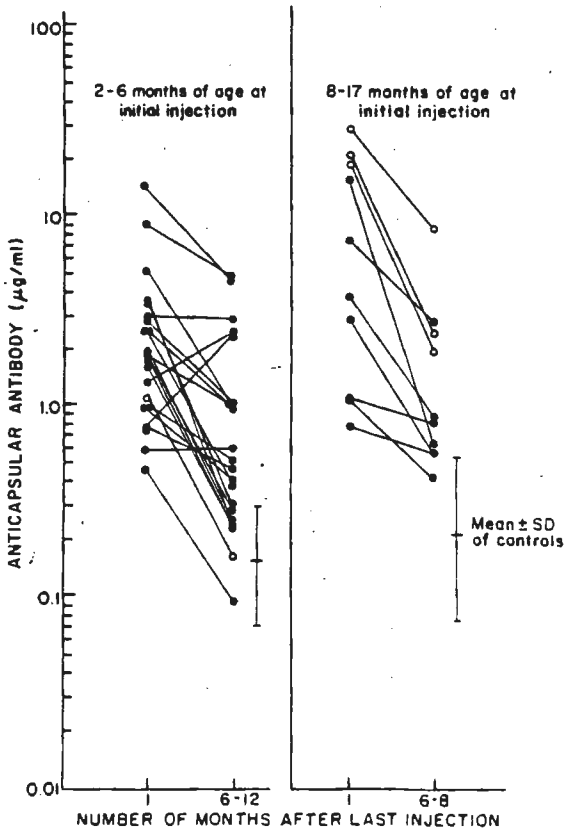

Fig 2—Serum anticapsular-polysaccharide antibody concentrations 6–12 months after immunisation.

○ = one injection only; ● = two injections 4 weeks apart.

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the levels at follow-up were significantly higher than those of 67 unimmunised children[23] of comparable age ($p \leq 0.001$).

Discussion

This conjugate vaccine, when administered with aluminium hydroxide, was well tolerated in both adults and infants. No systemic reactions were observed and slight local reactions occurred with only 3% of injections. In contrast, when the vaccine was given in saline alone reactions, both systemic and local, were frequent. The lower reaction rate with aluminium hydroxide may result from slower systemic release of vaccine adsorbed to aluminium hydroxide.

The vaccine was highly immunogenic, even in infants of 2–6 months. After one injection, the geometric mean increase in antibody concentration in infants of 2–6 months was 7·2 fold ($p < 0.001$), and two-thirds of subjects showed serum antibody levels >1 μg/ml. In contrast, in previous trials with other *H influenzae* type b conjugate vaccines, infants of this age showed either a fall or no significant rise in total serum antibody levels after one or two injections of vaccine.[8,9] It is unlikely that the different results reflect differences in the assays between laboratories. Our results are based on two different assays and comparable results were obtained independently with the same samples at Merck Sharp and Dohme Laboratories. The greater antibody responses of the infants in our study may relate to the vaccine's carrier protein, a group-B meningococcal outer-membrane protein containing a small amount of endotoxin, or to the novel method used for coupling the polysaccharide to the protein.

The presence of high levels of maternal antibody in very young infants did not prevent a strong response to the vaccine. However, in babies aged 2–3 months there was a trend towards an inverse correlation between antibody levels before and after immunisation ($r = -0.47$, $p = 0.08$). There were no significant differences in the responses of infants immunised with two different lots of vaccine at slightly different doses (postimmunisation geometric means of 2·4 μg/ml and 2·8 μg/ml in infants immunised at 2–6 months of age in St Louis and West Virginia, respectively). We have also tested a third lot of vaccine in approximately 80 subjects (2–17 months) and have observed comparable immunogenicity and low reactivity (unpublished).

Much evidence indicates that serum antibody against the capsular polysaccharide protects against invasive *H influenzae* type b disease.[2,3] However, the precise level of antibody required to confer protection is not known. Previous estimates of 0·15 μg/ml of antibody after immunisation are probably too low and a concentration as high as 1·0 μg/ml may be required.[19,20] Furthermore, the contributions of other immunological mechanisms to protection of infants are not well understood. These questions are particularly relevant for the children who show a fall in serum antibody levels in the 6–12 months after immunisation (fig 2). A study with another *H influenzae* type b conjugate vaccine showed that children primed with conjugate vaccine had higher responses to a subsequent injection of conventional *H influenzae* polysaccharide vaccine than children who had not received conjugate vaccine.[9] We have made similar observations in children primed with the polysaccharide/outer-membrane-protein vaccine (unpublished). Thus, some immunised children may remain protected against disease, even in the face of declining serum antibodies, as a result of immunological priming.

Preliminary data indicate that the antibody produced by immunisation of our subjects with the polysaccharide/outer-membrane-protein conjugate vaccine activates complement-mediated bactericidal activity in vitro and confers protection against bacteraemia in infant rats (unpublished, Merck Sharp and Dohme Research Laboratories). These data suggest that the antibody elicited by the vaccine is biologically active and that the antigenic activity of the polysaccharide was preserved during coupling to the protein.

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REFERENCES

1. Anderson P, Johnston RB Jr, Smith DH. Human serum activities against *Haemophilus influenzae* type b. *J Clin Invest* 1972; 51: 31–38.
2. Peltola H, Käyhty H, Sivonen A, Mäkelä PH. *Haemophilus influenzae* type b capsular polysaccharide vaccine in children: a double-blind field study of 100,000 vaccinees 3 months to 5 years of age in Finland. *Pediatrics* 1977; 60: 730–37.
3. Peltola H, Käyhty H, Virtanen, M, Mäkelä PH. Prevention of *Haemophilus influenzae* type b bacteremic infections with the capsular polysaccharide vaccine. *N Engl J Med* 1984; 310: 1561–66.
4. Goebel WF, Avery OT. Chemo-immunological studies on conjugated carbohydrate-proteins. I. The synthesis of p-aminophenol β-glucoside, p-aminophenol β-galactoside, and their coupling with serum globulin. *J Exp Med* 1929; 50: 521–31.
5. Schneerson R, Barrera O, Sutton A, Robbins JB. Preparation, characterization, and immunogenicity of *Haemophilus influenzae* type b polysaccharide-protein conjugates. *J Exp Med* 1980; 152: 361–76.
6. Granoff DM, Boies EG, Munson RS Jr. Immunogenicity of *Haemophilus influenzae* type b polysaccharide-diphtheria toxoid conjugate vaccine in adults. *J Pediatr* 1984; 105: 22–27.
7. Lepow ML, Samuelson JS, Gordon LK. Safety and immunogenicity of *Haemophilus influenzae* type b-polysaccharide diphtheria toxoid conjugate vaccine in infants 9 to 15 months of age. *J Pediatr* 1985; 106: 185–89.
8. Eskola J, Käyhty H, Peltola H, et al. Antibody levels achieved in infants by course of *Haemophilus influenzae* type b polysaccharide/diphtheria toxoid conjugate vaccine. *Lancet* 1985; i: 1184–86.
9. Anderson P, Pichichero ME, Insel RA. Immunization of two-month-old infants with protein-coupled oligosaccharides derived from the capsule of *Haemophilus influenzae* type b. *J Pediatr* 1985; 107: 346–51.
10. Schlech WF III, Ward JI, Band JD, Hightower A, Fraser DW, Broome CV. Bacterial meningitis in the United States, 1978 through 1981. The national bacterial meningitis surveillance study. *JAMA* 1985; 253: 1749–54.
11. Giladorf JR. Bacterial meningitis in southwestern Alaska. *Am J Epidemiol* 1977; 106: 388–91.
12. Ward JI, Lum MKW, Hall DB, Silimperi DR, Bender TR. Invasive *Haemophilus influenzae* type b disease in Alaska: background epidemiology for a vaccine efficacy trial. *J Infect Dis* 1986; 153: 17–26.
13. Marburg S, Jorn D, Tolman RL, et al. Bimolecular chemistry of macromolecules: synthesis of bacterial polysaccharide conjugates with *N. meningitidis* membrane protein. *J Am Chem Soc* (in press).
14. Helting TB, Guthöhrlein G, Blackkolb F, Ronnenberger H. Serotype determinant protein of *Neisseria meningitidis*. *Acta Path Microbiol Scand* 1981; 89: 69–78.
15. Goldschneider I, Gotschlich EC, Artenstein MS. Human immunity to the meningococcus. I. The role of humoral antibodies. *J Exp Med* 1969; 129: 1307–26.
16. Dixit VM, Grant GA, Santoro SA, Frazier WA. Isolation and characterization of a heparin-binding domain from the amino terminus of a platelet thrombospondin. *J Biol Chem* 1984; 259: 10100–05.
17. Kuo JS-C, Monji N, Schwalbe RS, McCoy DW. A radioactive antigen- binding assay for the measurement of antibody to *Haemophilus influenzae* type b capsular polysaccharide. *J Immunol Method* 1981; 43: 35–47.
18. Granoff DM, Shackelford PG, Pandey JP, Boies EG. Antibody responses to *Haemophilus influenzae* type b polysaccharide vaccine in relation to the Km(1) and $G_2m(23)$ immunoglobulin allotypes. *J Infect Dis* (in press).
19. Käyhty H, Peltola H, Karanko V, Mäkelä PH. The protective level of serum antibodies to the capsular polysaccharide of *Haemophilus influenzae* type b. *J Infect Dis* 1983; 147: 1100.
20. Anderson P. The protective level of serum antibodies to the capsular polysaccharide of *Haemophilus influenzae* type b. *J Infect Dis* 1984; 149: 1034.
21. Cates KL. Serum opsonic activity for *Haemophilus influenzae* type b in infants immunized with polysaccharide-protein conjugate vaccines. *J Infect Dis* 1985; 152: 1076–77.
22. Schreiber JR, Barrus V, Cates KL, Siber GR. Functional characterization of human IgG, IgM, and IgA antibody directed to the capsule of *Haemophilus influenzae* type b. *J Infect Dis* 1986; 153: 8–16.
23. Granoff DM, Munson RS Jr. Prospects for prevention of *Haemophilus influenzae* type b disease by immunization. *J Infect Dis* 1986; 153: 448–61.

ABSTRACT Submitted to The American Pediatric Society 1988

ANTIBODY RESPONSES OF VACCINE FAILURE (VF) PATIENTS REIMMUNIZED WITH HAEMOPHILUS INFLUENZAE TYPE b POLYSACCHARIDE (HIB PS) OR HIB-PS MENINGOCOCCAL OUTER MEMBRANE PROTEIN (OMP) CONJUGATE VACCINE.

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Children who develop invasive Hib disease despite previous vaccination with Hib PS vaccine (i.e. VF) have impaired serum anticapsular antibody responses following recovery from disease (NEJM 315:1584, 1986). 30 VF patients with <2.0 µg/ml of anti-Hib PS antibody in convalescent sera were enrolled in a trial comparing the immunogenicity of Hib PS vaccine to that of Hib PS-OMP conjugate vaccine. Subjects were reimmunized 2 to 26 months after onset of disease (Mean=11.5 mos). Results are available from 26 subjects.

Hib Vaccine	No. Tested	Mean Age (mos)	Geo. mean antibody, µg/ml Pre Total	Post Total	Post IgG	Post IgG1	Post IgG2
PS	16	44	0.3	0.7	<1.0	<0.5	<0.3
PS-OMP	10	45	0.3	13.2	6.0	3.3	0.5

VF subjects given conjugate showed significantly higher geometric mean total, IgG and IgG1 responses, than those given PS ($p<.002$). The predominant IgG isotype evoked by the conjugate was IgG1. Only 5 of 16 (31%) subjects given Hib PS developed total serum antibody >1 µg/ml compared to 10 of 10 given conjugate ($p<0.002$). To date, 5 subjects with <1 µg/ml antibody after reimmunization with PS were given conjugate and all developed antibody >4.6 µg/ml. Thus, VF children with low serum levels of anti-Hib PS antibody have impaired antibody responses to reimmunization with Hib PS vaccine but develop high antibody responses to this Hib conjugate vaccine. Therefore, this conjugate is not only immunogenic in infants, but also in older children who may fail to respond to Hib PS vaccine because of genetic or other causes.

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890 Protective Activity against Haemophilus influenzae Type b (Hib) of Human Sera from Recipients of Different Hib Vaccines. K. S. KIM,* J. S. SCHOETTLER, J. K. HONG and D. C. HEINER, Childrens Hospital of Los Angeles, CA, and Harbor-UCLA Medical Center, Torrance, CA.

We evaluated and compared the protective activity against Hib of sera from 13 children, 3 of whom were immunized with polyribosylribitol phosphate(PRP), 4 with PRP conjugated to diptheria toxoid(PRP-D), and 6 with PRP conjugated to outer membrane protein of N. meningitidis(PRP-OMP). Each serum was administered intraperitoneally to 5-day-old rats, followed by subcutaneous inoculation of Hib strain Eagan. The dose of PRP antibody required to prevent Hib bacteremia and/or meningitis in 50% of rats varied widely and did not correlate with total PRP antibody: 140-347 ng/10 gm of wt for sera of PRP recipients, 13-916 ng/10 gm of wt for sera of PRP-D recipients and 32- > 121 ng/10 gm of wt for sera of PRP-OMP recipients. Analysis of PRP antibodies of IgM, IgG and IgG subclasses suggested that high IgM and high IgG antibodies were associated with greater activity. No single IgG subclass response was consistently protective, but a drop in protection was associated with low antibodies of two or more IgG subclasses. High IgM antibody alone did not compensate for low levels of two or more IgG subclass antibodies. Thus, full protective activity cannot be expected when there are low levels of PRP antibody of 2 or more of the heavy chain genotypes tested (IgM, IgG 1-4).

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Immunogenicity of *Haemophilus influenzae* Type b Polysaccharide-*Neisseria meningitidis* Outer Membrane Protein Conjugate Vaccine in 2- to 6-Month-Old Infants

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ABSTRACT. Fifty infants, 2 to 6 months of age, were vaccinated with *Haemophilus influenzae* type b capsular polysaccharide covalently linked to an outer membrane protein from *Neisseria meningitidis* group B. Subjects were given two injections and were randomly assigned to receive the injections separated by 1 or 2 months. Each dose contained 15 μg of polysaccharide and 51 μg of protein, or approximately twice the amount of polysaccharide as used in our previous trial (*Lancet* 1986;2:299). Fevers of 38.0° to 38.8°C developed in three infants (6%) within 24 hours after vaccination, but there were no other notable reactions. Following one injection, the geometric mean antibody concentration increased from 0.13 μg/mL in preimmune serum to 1.50 μg/mL in serum obtained 1 to 2 months later ($P < .001$). After a second injection, there was a further increase in serum antibody (geometric mean = 3.11 μg/mL, $P < .007$). The geometric mean antibody concentration of the group reimmunized 2 months after the first injection was higher than that in the group reimmunized after 1 month (3.95 *v* 2.32 μg/mL, $P = .05$, by analysis of covariance with age as the covariant). These data confirm our previous preliminary observations on the safety and immunogenicity of this new conjugate vaccine in infants 2 to 6 months of age. The data suggest that a 2-month interval between the first and second injections results in higher levels of serum antibody than a 1-month interval. *Pediatrics* 1987;80:283–287; *Haemophilus influenzae type b, conjugate vaccine, Neisseria meningitidis, infant.*

Haemophilus influenzae type b is the leading cause of bacterial meningitis in the United States.[1] The organism is also an important cause of other serious infections such as bacteremia, epiglottitis, cellulitis, and septic arthritis. In 1985, a *Haemophilus* vaccine consisting of the purified type b capsular polysaccharide was licensed for use in the United States. Based on an efficacy study done in Finland, this vaccine was not effective in children younger than 18 to 24 months.[2,3] In the United States, approximately 80% of cases of invasive *Haemophilus* disease occur in children younger than 24 months of age.[4] Therefore, a more immunogenic vaccine is needed for children in this younger age group.

Although poorly understood, failure of the type b polysaccharide to be immunogenic in young children has been attributed to delayed maturation of immune responses to certain thymic-independent antigens.[5,6] In contrast, infants show high serum antibody responses to vaccination with many protein antigens that are classified as thymic-dependent antigens.[7,8] Studies have shown that conjugation of a polysaccharide with a protein carrier increases the immunogenicity of the polysaccharide, possibly by conferring thymic-dependent properties to the polysaccharide.[9] These observations led to the development of several *Haemophilus* type b polysaccharide-protein conjugate vaccines which are currently under clinical investigation in infants.[10–13]

We have reported preliminary data on the safety and immunogenicity of a vaccine composed of the type b capsular polysaccharide covalently coupled to a *Neisseria meningitidis* group B outer membrane protein by a novel thioether linkage.[13,14] A single injection of this vaccine was immunogenic in the majority of 2- to 6-month-old infants. However, the antibody responses to a second injection were var-

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iable, with less than half of the subjects showing a significant increase in antibody.[13] In our previous study, the infants received two injections of vaccine separated by 1 month. Recent data from a preliminary study of children vaccinated with another conjugate vaccine suggest that increasing the interval between injections may enhance the antibody response to the booster injection.[12] In the present study, in an effort to increase immunogenicity of the booster injection, we compared the antibody responses of children revaccinated at 1- *v* 2-month intervals following their primary vaccination. The longer interval also had the added advantage of better conforming to currently recommended immunization schedules. We also evaluated the use of a new lot of vaccine at a higher dose, ie, 15 μg of polysaccharide combined with 51 μg of protein instead of 7 μg of polysaccharide combined with 43 μg of protein as used previously.

PATIENTS AND METHODS

Study Population

Healthy children were recruited from pediatric practices and clinics in Missouri and Illinois. Informed parental consent was obtained, and 54 children, 2 to 6 months of age, were enrolled. A brief history and physical examination were performed prior to each immunization. Children were excluded if there was a history of a serious reaction to any previous vaccination or if there was a suspicion of underlying immunodeficiency. Vaccination was deferred if there was a history of fever within the previous 72 hours or if the child had received any other vaccine within the previous week.

Parents were given thermometers and report cards and were asked to record axillary temperatures four hours after vaccination and once daily for the next three days. They also were asked to note any reactions, local or systemic, that they believed might be attributable to the vaccine. The parents were instructed to notify one of the study physicians for any axillary temperature ≥38°C or for any other possible reaction of concern.

Vaccination

The vaccine was stored frozen at −70°C. After reconstitution with saline containing alum (lot 1015), each 0.5-mL dose of vaccine contained 15 μg of type b capsular polysaccharide and 51 μg meningococcal group B outer membrane protein. The vaccine was kept at 4°C and used within four hours after reconstitution.

The children were given two IM injections of *H influenzae* type b conjugate vaccine (lot 1018, Merck Sharp and Dohme). On entry into the study, the subjects were assigned consecutive numbers. Those in group 1 (odd numbers) received their second injection 1 month after the first injection. Subjects assigned to group 2 (even numbers) were given the two injections separated by 2 months.

Assays

Total antibody to *H influenzae* type b capsular polysaccharide was measured by radioantigen binding assay on serum samples obtained prior to both injections and 1 month after the second injection. The assay was performed as previously described by Kuo et al,[15] with the exception that ^{125}I-extrinsically labeled antigen was used instead of ^{3}H-labeled antigen.[16] Pre- and postimmunization sera from each child were measured in the same assay, and each assay contained samples from children assigned to both treatment groups. In addition, 36 samples were assayed on more than one occasion. The mean ± SD percentage variation from the average value for each sample was 10.7 ± 10.2.

Statistical Analyses

Statistical analysis was performed using SAS and RS1 software on a VAX 11/785 computer (Digital Equipment Co, Marlboro, MA). Within a group, a paired *t* test was used to compare the geometric mean antibody concentrations in sera before and after immunizations, with each child serving as his or her own control. Although subjects were randomly assigned to the two interval groups, analysis indicated a chance difference in mean age between them. Even if their mean ages had been identical at the time of the initial immunization, age at reimmunization and length of interval are necessarily comfounded because infants reimmunized after an interval of 2 months will be slightly older than infants reimmunized after an interval of only 1 month. Thus, for the comparison of the geometric mean antibody concentrations, age was used as a covariate in the one-way analysis of variance. In this analysis, age, however important,[13] can be thought of as a "nuisance" variable. Accordingly, its linear effect on the mean log antibody concentrations was removed prior to the comparison. Also, because of the previous data suggesting that a longer interval between injections was associated with higher antibody responses,[12] a one-tailed test was used for comparison of the geometric mean responses of the two groups to the second injection.

RESULTS

Characteristics of the Study Groups

Fifty-four subjects were enrolled in the study. The mean age at the time of the first injection was

TABLE 1. Characteristics of Study Groups*

Characteristic	All Children (n = 54)	1-Mo Interval Between Injections (n = 24)	2-Mo Interval Between Injections (n = 26)
Age (mean mo ± SD)			
Dose 1	3.6 ± 1.5	3.2 ± 1.3	4.1 ± 1.6
Dose 2	5.1 ± 1.8	4.2 ± 1.3	6.1 ± 1.6
No. (%) boys	33 (63)	17 (71)	16 (62)
No. (%) white race	43 (80)	19 (79)	22 (85)

* Four children, three in the 1-month interval group (group 1) and one in the 2-month interval group (group 2), were excluded for purposes of comparison of the responses of the two treatment groups. The mean age of group 2 was older than that of group 1 ($P \leq .04$ for first injection; $P < .001$ for second injection). There were no significant differences in the percentages for sex or race in the two groups ($P > .10$ by Fisher exact test).

3.6 months (Table 1). Initially, 27 children were assigned to group 1 to be revaccinated after 1 month and 27 were assigned to group 2 to be revaccinated after 2 months. However, for comparison of the antibody responses of the two groups, data from four children were excluded. Two were subjects assigned to group 1 who did not return for the second injection. A third child assigned to group 1 was revaccinated but not within the appointed time period. One child assigned to group 2 did not receive a second dose because a fever developed (38.8°C) 12 hours after the first injection of vaccine. By chance, the infants remaining in group 1 were younger at entry into the study than those in group 2, with mean ages of 3.2 *v* 4.1 months (Table 1). The two different dosing intervals also resulted in an increase in this age difference at the time of the second injection (4.2 *v* 6.1 months). In addition to age, there were no other significant differences in the characteristics of the two treatment groups. As summarized in Table 1, there were more boys than girls and more white than black children enrolled in both groups.

Reactions to Vaccination

A total of 105 injections were given to the 54 children. Local reactions, defined as erythema or induration ≥2 cm at the injection site, were reported after four of 54 initial doses (7.4%) and two of 51 second doses (3.9%). The largest local reaction was 5 cm of induration. Five possible systemic reactions were reported. A temperature elevation to 38.8°C occurred in one child 12 hours after vaccination. This child was reexamined, evidence of acute otitis media found, and the fever resolved promptly with antibiotic therapy. Two other children had isolated temperature elevations to 38.0°C, one at 4 hours and the other at 24 hours after the second injections. Two other children had possible systemic reactions without fever. In one, mild nasal congestion occurred on the day of initial immunization and then resolved within 72 hours. In the second child, mild diarrhea occurred 48 hours after the second injection but resolved after 1 week.

Antibody Responses

Serum samples were obtained from 47 children prior to the initial immunization, from 49 children 1 to 2 months after the first dose and from 51 children 1 month after the second dose. The geometric mean antibody concentration in preimmunization sera was 0.13 μg/mL, increasing to 1.50 μg/mL in sera obtained after the first dose ($P < .001$) and 3.11 μg/mL after the second dose ($P < .007$). After the first injection, 64% of the samples measured contained antibody concentrations >1 μg/mL. In the Finnish trial, in which conventional polysaccharide vaccine was tested, antibody concentrations >1.0 μg/mL in postimmunization sera correlated with protection from disease.[17] In the present study, after a second dose of vaccine, 88% of the children had levels greater than this concentration.

The present data confirm our previous observations that infants vaccinated as young as 2 to 3 months of age can make high serum antibody responses to *Haemophilus* type b polysaccharide. For example, in the present study, there were 29 subjects vaccinated initially at 2 to 3 months of age. After one injection, ten of 26 (38%) tested achieved antibody levels >1 μg/mL. The serum antibody concentrations of the infants who failed to achieve this level ranged from 0.16 to 0.98 μg/mL (geometric mean = 0.58 μg/mL). After a second injection, 21 of 28 (75%) children enrolled at 2 to 3 months of age and revaccinated 1 or 2 months later achieved levels >1 μg/mL. This group included ten of 15 tested (67%) who had not achieved this concentration after the first injection.

The geometric mean serum antibody concentrations before and after immunization of the children reimmunized after 1- or 2-month intervals after the first injection are summarized in Table 2. Shown are the least square values, that is, the geometric means of each group have been age adjusted by analysis of covariance to correct for the older ages of the subjects in group 2 at the time of the first and second injections.

Prior to the first injection, there were no significant differences in the geometric mean antibody concentrations in the two groups (0.14 and 0.11 μg/mL, $P = .49$). After the first vaccination, both groups showed approximately tenfold increases in geometric mean antibody, and there was no signif-

TABLE 2. Serum Anticapsular Antibody Responses in Children 2 to 6 Months of Age Immunized With *Haemophilus influenzae* Type b Polysaccharide-Outer Membrane Protein Conjugate Vaccine*

Group	Interval (mo) Between Injections	Preimmunization†		After First Injection‡		After Second Injection§	
		Geometric Mean (μg/mL)	Mean Log_{10} ± SEM	Geometric Mean (μg/mL)	Mean Log_{10} ± SEM	Geometric Mean (μg/mL)	Mean Log_{10} ± SEM
1	1	0.14	−0.77 ± 0.12	1.71	0.23 ± 0.10	2.32	0.37 ± 0.10
2	2	0.11	−1.00 ± 0.10	1.28	0.11 ± 0.10	3.95	0.60 ± 0.09

* Shown are least square values, ie, the geometric mean antibody levels have been adjusted by analysis of covariance to correct for the different ages of the groups at the time of each injection.
† $P = .49$, two-tailed t test.
‡ $P = .37$, two-tailed t test.
§ $P = .05$, one-tailed t test.

icant difference between the geometric mean concentrations ($P = .37$). Following the second injection, there were further significant increases in antibody in both groups ($P \leq .007$). However, the geometric mean antibody concentration was higher in the group revaccinated 2 months after the first injection than in the group revaccinated after a 1-month interval (3.95 *v* 2.32 μg/mL; $P = .05$). If one compares the geometric means of the raw data (ie, not adjusted for age difference), the higher responses of the group vaccinated after 2 months are even more apparent (4.48 *v* 2.02 μg/mL, $P = .01$).

DISCUSSION

In the present study, the *H influenzae* type b polysaccharide-outer membrane protein conjugate vaccine was well tolerated. Only six minor local reactions occurred following 105 injections, and fever was noted following only three injections. These observations are similar to those reported by us previously in children vaccinated with a lower dose of vaccine (7 *v* 15 μg of polysaccharide and 43 *v* 51 μg of protein).[13] Thus, although different lots of vaccine were used in the two studies, increasing the dose in the present study was not associated with an increased rate of adverse reactions.

Anderson et al[12] observed higher antibody responses in subjects vaccinated with a *Haemophilus* type b oligosaccharide-protein conjugate vaccine at 9 to 15 months of age when the second injection was given 6 to 14 weeks after the primary immunization, compared with an interval of 2 to 4 weeks. Therefore, we used a one-tailed t test to evaluate the hypothesis that a longer interval between injections (2 *v* 1 month) would result in higher antibody responses in our subjects. Indeed, infants given a second injection after a 2-month interval made nearly twice as much antibody as those reinjected after 1 month, and the difference was significant after statistical correction for the older ages of the group reinjected at 2 months ($P = .05$, Table 2).

In summary, the combined results from our previous and present studies indicate that this new *H influenzae* type b polysaccharide-outer membrane protein conjugate vaccine is safe and immunogenic in infants as young as 2 months of age. A dose containing between 7 and 15 μg of polysaccharide is in a highly immunogenic range. In infants vaccinated at 2 to 6 months of age, 2 months between injections results in higher antibody responses than a 1-month interval. Recent data from our laboratory also suggest that vaccination of infants at 2 to 6 months of age with this conjugate vaccine results in immunologic priming such that high serum *Haemophilus* polysaccharide antibody responses are observed when the children are revaccinated 10 to 15 months later with either the polysaccharide outer membrane protein conjugate vaccine or conventional type b polysaccharide vaccine.[18] These results are encouraging and suggest that complete protection against *H influenzae* type b disease may be conferred by as few as two injections of conjugate vaccine given at 2 to 6 months of age with a booster injection of conjugate or conventional vaccine given in the second year of life. However, questions that remain to be answered include the immunogenicity and safety of this conjugate vaccine when given concurrently with diphtheria-tetanus-pertussis and oral polio vaccines at 2 to 6 months of age and the optimal interval between the first series of two injections and subsequent booster immunization with conjugate or conventional polysaccharide vaccine. Finally, a large scale clinical trial will be needed to address the question of vaccine efficacy (prevention of disease) and safety.

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REFERENCES

1. Schlech WF, Ward JI, Band JD, et al: Bacterial meningitis in the U.S., 1978 through 1981. *JAMA* 1985;253:1749–1754
2. Peltola H, Käyhty H, Sivonen A, et al.: *Haemophilus influenzae* type b capsular polysaccharide vaccines in children: A double-blind field study of 100,000 vaccinees 3 months to 5 years of age in Finland. *Pediatrics* 1977;60:730–737
3. Peltola H, Käyhty H, Virtanen M, et al: Prevention of *Haemophilus influenzae* type b bacteremic infection with the capsular polysaccharide vaccine. *N Engl J Med* 1984;310:1561–1566
4. Murphy TV, Osterholm MT, Pierson LM, et al: Prospective surveillance of *Haemophilus influenzae* type b disease in Dallas, County, Texas, and in Minnesota. *Pediatrics* 1987;79:173–180
5. Robbins JB, Parke JC Jr, Schneerson R, et al: Quantitative measurement of "natural" and immunization-induced *Haemophilus influenzae* type b capsular polysaccharide antibodies. *Pediatr Res* 1973;7:103–110
6. Mosier DE, Subbarao B: Thymus-independent antigens: Complexity of B-lymphocyte activation revealed. *Immun Today* 1982;3:217–222
7. Stevens RH, Saxon A: Immunoregulation in humans: Control of antitetanus antibody production after booster immunization. *J Clin Invest* 1978;62:1154–1160
8. Pabst HF, Kreth HW: Ontogeny of the immune response as a basis of childhood disease. *J Pediatr* 1980;97:519–534
9. Schneerson R, Barrera O, Sutton A, et al: Preparation, characterization and immunogenicity of *Haemophilus influenzae* type b polysaccharide-protein conjugate. *J Exp Med* 1980;152:361–376
10. Eskola J, Peltola H, Mäkelä PH, et al: Antibody levels achieved in infants by course of *Haemophilus influenzae* type b polysaccharide/diphtheria toxoid conjugate vaccine. *Lancet* 1985;1:1184–1186
11. Lepow ML, Samuelson JS, Gordon LK: Safety and immunogenicity of *Haemophilus influenzae* type b-polysaccharide diphtheria toxoid conjugate vaccine in infants 9 to 15 months of age. *J Pediatr* 1985;106:185–189
12. Anderson PW, Pichichero ME, Insel RE, et al: Vaccines consisting of periodate-cleaved oligosaccharides from the capsule of *Haemophilus influenzae* type b coupled to a protein carrier: Structural and temporal requirements for priming in the human infant. *J Immunol* 1986;137:1181–1186
13. Einhorn MS, Weinberg GA, Anderson EL, et al: Immunogenicity in infants of *Haemophilus influenzae* type b polysaccharide conjugate vaccine with *Neisseria meningitidis* outer-membrane protein. *Lancet* 1986;2:299–302
14. Marburg S, Jorn D, Tolman RL, et al: Bimolecular chemistry of macromolecules—Synthesis of bacterial polysaccharide conjugates with *Neisseria meningitidis* membrane protein. *J Am Chem Soc* 1986;108:5282–5287
15. Kuo JS-C, Monji N, Schwalbe RS, et al: A radioactive antigen-binding assay for the measurement of antibody to *Haemophilus influenzae* type b capsular polysaccharide. *J Immunol Method* 1981;43:35–47
16. Granoff DM, Shackelford PG, Pandey JP, et al: Antibody responses to *Haemophilus influenzae* type b polysaccharide vaccine in relation to Km(1) and G2m(23) immunoglobulin allotypes. *J Infect Dis* 1986;154:257–264
17. Käyhty H, Peltola H, Karanko V, et al: The protective level of serum antibodies to the capsular polysaccharide of *Haemophilus influenzae* type b. *J Infect Dis* 1983;147:1100
18. Weinberg GA, Einhorn MS, Lenoir AA, et al: Immunologic priming to capsular polysaccharide in infants immunized with *Haemophilus influenzae* type b polysaccharide-*Neisseria meningitidis* outer membrane protein conjugate vaccine. *J Pediatr*, in press, 1987

trol of intractable urinary-tract infection. Lancet 1979;2: 1205–9

9. Stamm WE, Counts GW, Wagner KF, Martin D, Gregory D, McKevitt M, Turck M, Holmes KK. Antimicrobial prophylaxis of recurrent urinary tract infections. A double-blind, placebo-controlled trial. Ann Intern Med 1980; 92:770–5
10. Brumfitt W, Cooper J, Hamilton-Miller JMT. Prevention of recurrent urinary infections in women: a comparative trial between nitrofurantoin and methenamine hippurate. J Urol 1981;126:71–4
11. Harding GKM, Ronald AR, Nicolle LE, Thomson MJ, Gray GJ. Long-term antimicrobial prophylaxis for recurrent urinary tract infection in women. Rev Infect Dis 1982;4:438–43
12. Brumfitt W, Hamilton-Miller JMT, Gargan RA, Cooper J, Smith GW. Long-term prophylaxis of urinary infections in women: comparative trial of trimethoprim, methenamine hippurate, and topical povidone-iodine. J Urol 1983;130:1110–4
13. Martinez FC, Kindrachuk RW, Thomas E, Stamey TA. Effect of prophylactic, low dose cephalexin on fecal and vaginal bacteria. J Urol 1985;133:994–6
14. Brumfitt W, Smith GW, Hamilton-Miller JMT, Gargan RA. A clinical comparison between macrodantin and trimethoprim for prophylaxis in women with recurrent urinary tract infections. J Antimicrob Chemother 1985;16:111–20

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Antibody Responses of Black Children to *Haemophilus influenzae* Type b Polysaccharide–*Neisseria meningitidis* Outer-Membrane Protein Conjugate Vaccine in Relation to the Km(1) Allotype

Evidence is accumulating that genetic factors may play a role in regulating immune responses to certain bacterial polysaccharides and may affect susceptibility to bacterial infections [1–3]. For example, we found that black children positive for the Km(1) immunoglobulin allotype have a lower relative risk of developing haemophilus meningitis [1] and have higher responses of IgG antibody to *Haemophilus influenzae* type b (Hib) polysaccharide (Hib PS) vaccine than do those who are negative for this allotype [1, 2].

Several new Hib PS–protein conjugate vaccines have been tested and have been shown to be more immunogenic in experimental animals and human infants than conventional Hib PS vaccine. Furthermore, repeated injections of conjugate vaccines elicit booster antibody responses and prime human infants for an anamnestic IgG response to a subsequent injection of conventional Hib PS vaccine [4, 5]. Studies in experimental animals suggest that alteration of the presentation of an antigen can affect immune responses such that genetic nonresponders can be made to respond to a given antigen [6]. The purpose of the present study was to determine whether the previously observed allotype-associated differences in the antibody responses of black children immunized with Hib PS vaccine are also present in subjects immunized with Hib PS covalently coupled to a protein carrier. In addition, we analyzed the antibody responses with respect to Km(1) allotype in children receiving a booster injection of conventional Hib PS vaccine six to 15 months after priming with conjugate vaccine.

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Informed consent was obtained from the parents of the children in this study.

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Subjects and Methods

The conjugate vaccine, prepared by Merck Sharp & Dohme Research Laboratories (West Point, Pa), consisted of Hib PS covalently coupled to a partially purified outer-membrane protein from group B *Neisseria meningitidis*. In recent studies, this conjugate has been shown to be immunogenic in infants as young as two to three months of age [7] and to prime infants for an anamnestic IgG antibody response to a booster injection with either conventional Hib PS vaccine or conjugate vaccine [5].

In the present study, 49 healthy black children seven to 17 months of age (mean ± SD, 11.7 mo ± 3.1 mo) were recruited from pediatric clinics and private practices in Missouri. The children received one im injection of 0.3 mL

Table 1. Serum antibody response to capsular antigen of black children, in relation to Km(1) allotype.

Vaccination, Km(1) allotype, mean age (*n*)	Geometric mean titer of antibody (μg/mL)			
	Total, before vaccination	1 Mo after vaccination		
		Total	IgG	IgG2
Primary immunization*				
Positive, 11.5 mo (22)	ND	5.0	2.1	0.19
Negative, 11.9 mo (27)	ND	4.1	2.1	0.18
Booster immunization†				
Positive, 18.7 mo (10)	1.72	70.1	54.4	3.0
Negative, 19.7 mo (17)	1.66	76.9	52.8	8.0

NOTE. ND, not done.
* Children received conjugate vaccine.
† Children received Hib PS vaccine.

of vaccine lot 1018 containing 7 μg of Hib PS and 23.5 μg of *N. meningitidis* group B outer-membrane protein. The vaccine was stored frozen at −70 C. After reconstitution, the vials were kept at 4 C and were used within 4 h.

Twenty-seven of the 49 subjects were given booster injections of conventional Hib PS vaccine six to 11 months after priming with conjugate. Selection of these subjects was based on their willingness to participate. The conventional Hib PS vaccine used for the booster injection was prepared by Praxis Biologics (Rochester, NY) and was purchased from Mead Johnson (Evansville, Ind). Each 0.5-mL dose contained 25 μg of PS.

Total levels of antibody to Hib PS were measured by a radioantigen binding assay [2] in serum obtained one month after vaccination. IgG antibody to Hib PS was measured by an ELISA done as previously described [2, 8]. In previous studies, we found that black children with the Km(1) allotype have similar serum concentrations of IgG1 but higher total IgG2 concentrations than do children who are negative for this allotype [2, 9]. Therefore, in the present study, we also compared the IgG2-specific capsular antibody responses of the vaccinees. Levels of IgG2 antibody to the type b polysaccharide were measured by ELISA as previously described [8], except that in the present study we used a murine monoclonal antibody (HP6014; ICN Immunobiologics, Lisle, Ill) rather than a polyclonal monkey antiserum. Because the monoclonal antibody was available as ascites, we used a biotin-conjugated goat antibody to mouse IgG (Tago, Burlingame, Calif) to detect binding of the monoclonal antibody. This goat antiserum had been adsorbed with human IgG to remove reactivity. Quantitation of antibody by ELISA was accomplished by comparing the titration curves of test sera with those obtained for the Hib adult immune reference serum (U.S. Office of Biologics, Bethesda, Md) [8].

Km(1) allotype status was determined by HAI on coded samples as previously described [2]. Allotype determinations were done on serum samples obtained from subjects seven months of age or older to avoid interference by maternal antibody.

Statistical analysis was performed by using SAS and RS1 software on a VAX 11/785 computer (Digital Equipment, Marlboro, Mass). Because age can affect antibody response to immunization, we used analysis of covariance, with age as the covariate, to compare the geometric mean antibody concentrations for the different groups stratified by allotype status. To analyze the booster responses with respect to allotype status, we used age, antibody concentration prior to boosting, and the interval between priming and boosting as covariates in a multivariate analysis, because all three variables were found to have a significant effect ($P < .10$) on the booster response in a univariate analysis.

Results

Table 1 summarizes the antibody responses of the children to Hib PS with respect to their Km(1) allotype status. After primary immunization with the conjugate vaccine, there were no significant differences between the geometric means of the concentrations of total, IgG, or IgG2 capsular antibody in postimmunization sera from children positive for Km(1) and those from children who were negative for this allotype ($P > .5$ for each comparison). Twenty-one (95%) of the 22 Km(1)-positive children, compared with 23 (85%) of 27 Km(1)-negative children, had total antibody levels >1.0 μg/mL ($P = .36$, by Fisher's exact test); 18 (82%) of 22 Km(1)-positive children, compared with 17 (63%) of 27 Km(1)-negative children, achieved levels of >2.0 μg/mL ($P = .21$).

In both groups, there was relatively little IgG2 antibody in the postimmunization sera of the children who received conjugate vaccine, despite the presence of relatively high concentrations of IgG antibody. This finding is consistent with our previous observations that IgG1 is the predominant isotype evoked in infants immunized with this conjugate vaccine [10].

Twenty-seven subjects were given a booster injection of conventional Hib PS vaccine six to 11 months after priming with conjugate (table 1). The mean interval between priming and boosting was the same in the 10 Km(1)-positive and the 17 Km(1)-negative subjects (7.9 mo). Before the booster injection, there was no significant difference in geometric mean antibody concentrations in Km(1)-positive and Km(1)-negative children (1.72 vs. 1.66 μg/mL; $P = .95$). After the booster immunization, there were no significant differences in the respective geometric means of the concentrations of total, IgG, or IgG2 antibody ($P \geq .20$ for all comparisons).

Discussion

In previous studies, we found that Km(1)-positive black children vaccinated with either Hib PS vaccine or Hib PS vaccine mixed with pertussis vaccine had higher capsular antibody responses than did Km(1)-negative black children [1, 2]. The higher responses in the Km(1)-positive children were limited to the levels of IgG [1, 2]; there was no significant difference in the IgM responses with respect to this allotype. Black children positive for the Km(1) allotype were also found to have higher total serum IgG2 concentrations than were black children who were negative for Km(1) [2, 9].

In contrast, Ambrosino et al. [11] have reported that white adults positive for Km(1) have lower antibody responses to certain polysaccharide antigens, including Hib PS, than do adults negative for this allotype. The fact that this result in white adults is opposite to that previously found by us in black infants may reflect differences in the ages or races of the subjects studied [12].

In the present study, we found no significant differences with respect to Km(1) allotype status in the respective total, IgG, or IgG2 antibody responses of black children immunized with a Hib PS-protein conjugate vaccine. Nor did we find a difference with respect to Km(1) allotype status in the antibody responses to Hib PS booster vaccination in black children previously primed with conjugate vaccine (table 1).

The conventional Hib PS is thought to be a thymic-independent (TI) type of immunogen. Coupling the polysaccharide with a protein carrier confers thymic-dependent (TD) features on the polysaccharide [4–7]. Thus the lack of a significant relation between Km(1) allotype and antibody response to Hib PS in the present study may reflect a difference in genetic regulation of antibody responses to certain TD immunogens, as compared with TI immunogens. The conjugate vaccine used in this study, however, contains a small amount of lipopolysaccharide associated with the outer-membrane protein. The contribution of the presence of this mitogen to the immunogenicity of the vaccine is unknown.

The mechanism involved in the genetic regulation of antibody response by genes associated with immunoglobulin allotypes remains unknown. Recent data in mice support the presence of a regulatory gene linked to immunoglobulin allotype loci that affects some isotype responses but not others [14]. Possible cellular mechanisms by which such a gene could be expressed include regulation of class switching at the B cell level and T cell–B cell interactions. Whatever the mechanism, immunization of children with the TD form of the Hib PS antigen appears to circumvent the allotype-associated differences in antibody response found in subjects immunized with conventional Hib PS vaccine.

In summary, the ability of a conjugate vaccine to circumvent previously reported genetic differences in antibody response to conventional Hib PS vaccine has potential clinical importance. The high immunogenicity of this conjugate vaccine in children with phenotypes previously associated with low antibody responses to conventional Hib PS vaccine suggests that conjugation of the polysaccharide to a protein may result in a vaccine that is not only effective in preventing Hib disease in infants, but is also effective in populations that may be at increased risk of disease because of genetic factors. A similar result has been reported for children with selective IgG2 deficiency; these children have increased susceptibility to Hib disease and impaired antibody responses to conventional polysaccharide vaccine [13].

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References

1. Granoff DM, Pandey JP, Boies E, Squires J, Munson RS Jr, Suarez B. Response to immunization with *Haemophilus influenzae* type b polysaccharide–pertussis vaccine and risk of *Haemophilus* meningitis in children with the Km(1) immunoglobulin allotype. J Clin Invest 1984;74:1708–14
2. Granoff DM, Shackelford PG, Pandey JP, Boies EG. Antibody responses to *Haemophilus influenzae* type b polysaccharide vaccine in relation to Km(1) and G2m(23) immunoglobulin allotypes. J Infect Dis 1986;154:257–64
3. Ambrosino DM, Schiffman G, Gotschlich EC, Schur PH, Rosenberg GA, DeLange GG, van Logheme E, Siber GR. Correlation between G2m(n) immunoglobulin allotype and human antibody response and susceptibility to polysaccharide encapsulated bacteria. J Clin Invest 1985;75:1935–42
4. Insel RA, Anderson PW. Oligosaccharide-protein conjugate vaccines induce and prime for oligoclonal IgG antibody responses to the *Haemophilus influenzae* b capsular polysaccharide in human infants. J Exp Med 1986;163:262–9
5. Weinberg GA, Einhorn MS, Lenoir AA, Granoff PD, Granoff DM. Immunologic priming to capsular polysaccharide in

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infants immunized with *Haemophilus influenzae* type b polysaccharide–*Neisseria meningitidis* outer membrane protein conjugate vaccine. J Pediatr 1987;111:22–7

6. Green I, Paul WE, Benacerraf B. The behavior of hapten-poly-L-lysine conjugates as complete antigens in genetic responder and as haptens in nonresponder guinea pigs. J Exp Med 1966;123:859–79
7. Lenoir AA, Granoff PD, Granoff DM. Immunogenicity of *Haemophilus influenzae* type b polysaccharide–*Neisseria meningitidis* outer membrane protein conjugate vaccine in 2 to 6 month old infants. Pediatrics 1987;80:283–7
8. Shackelford PG, Granoff DM, Nelson SJ, Scott MG, Smith DS, Nahm MH. Subclass distribution of human antibodies to *Haemophilus influenzae* type b capsular polysaccharide. J Immunol 1987;138:587–92
9. Shackelford PG, Granoff DM, Nahm MH, Scott MG, Suarez B, Pandey JP, Nelson SJ. Relation of age, race, and allotype to immunoglobulin subclass concentrations. Pediatr Res 1985;19:846–9
10. Weinberg GA, Einhorn MS, Lenoir AA, Granoff PD, Granoff DM. Immunization of infants with *Haemophilus influenzae* type b (Hib) polysaccharide-outer membrane protein (PS-OMP) conjugate vaccine primes for IgG1 booster responses to conventional Hib PS vaccine [abstract 879]. Pediatr Res 1987;21:320A
11. Ambrosino DM, Barrus VA, DeLange G, Siber GR. Correlation of the Km(1) immunoglobulin allotype with anti-polysaccharide antibodies in Caucasian adults. J Clin Invest 1986;78:361–5
12. Whittingham S, Propert DN. Gm and Km allotypes, immune response and disease susceptibility. Monogr Allergy 1986; 19:52–70
13. Insel RA, Anderson PW. Response to oligosaccharide-protein conjugate vaccine against *Haemophilus influenzae* b in two patients with IgG2 deficiency unresponsive to capsular polysaccharide vaccine. N Engl J Med 1986;315:499–502
14. Slack JH. Strain-dependent IgG subclass response patterns. J Immunol 1987;139:3734–8

Bimolecular Chemistry of Macromolecules: Synthesis of Bacterial Polysaccharide Conjugates with *Neisseria meningitidis* Membrane Protein

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Abstract: Covalently linked macromolecules of biological importance (bacterial–polysaccharide conjugates) are prepared by a general, multistep synthetic method employing a bigeneric spacer that is an oligopeptide spacer molecule whose parts are derived from each of the two modified macromolecules to be covalently linked. The strengths of this synthetic approach are (a) the covalency of the resulting conjugate is readily and absolutely determined and (b) analysis for the bigeneric spacer defines the purification of the conjugate and facilitates the identification of separation procedures that remove contaminating, unconjugated macromolecules. The multistep bigeneric spacer method includes the following steps: (1) covalent modification of one macromolecule to attach basic amine groups that are then bromoacetylated; (2) covalent modification of the second macromolecule with *N*-acetylhomocysteine thiolactone to attach pendant thiol groups; (3) coupling of these macromolecules under mildly basic conditions; (4) determination of the covalency ratio by amino acid analysis of *S*-(carboxymethyl)homocysteine, formed by reaction of bromoacetyl and homocysteinyl moieties, relative to a standard endogenous amino acid; (5) purification of the mixture to maximize the covalency ratio. By this method several conjugates of polydisperse bacterial polysaccharides with an immunogenic *Neisseria meningitidis* membrane protein were prepared and characterized by NMR and chemical analysis.

It has become clear that biological macromolecules have different domains that are independently responsible for such diverse functions as receptor recognition, cell entry, effector control, and effector activity. Moreover, these domains are often physically separable, and appreciation of this fact has generated an increasing body of research devoted to preparing hybrid macromolecules that combine particular properties in a desired way. Thus, the so-called immunotoxins or "magic bullets" seek to destroy cancer cells with high specificity by combining the recognition power of antibodies with highly toxic effector molecules (toxins).[1] A synthetic blood substitute has been prepared by binding an altered hemoglobin molecule to the polysaccharide inulin.[2] Modified hormonal responses have been obtained by coupling insulin to macromolecules

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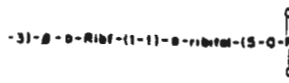
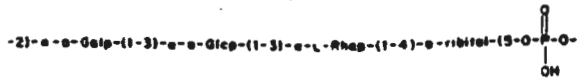
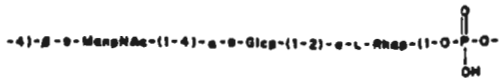
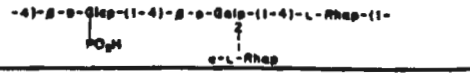
(1) Uhr, J. S.; Vitetta, E. S. *Monoclonal Antibodies and Cancer*; Boss, B. D., Langman, R., Trobridge, I., Dulbecco, R., Eds.; Academic: Orlando, FL, 1983; pp 85–98.
(2) Iwasaki, K.; Ajisaka, K.; Iwashita, Y. *Biochem. Biophys. Res. Commun.* **1983**, *113*, 513–518.

0002-7863/86/1508-5282$01.50/0 © 1986 American Chemical Society

Table I. Polysaccharide Structures:[a] Monomeric Units

	*H. influenzae* type b
	*S. pneumoniae* type 6B
	*S. pneumoniae* type 14
	*S. pneumoniae* type 19F
	*S. pneumoniae* 23F

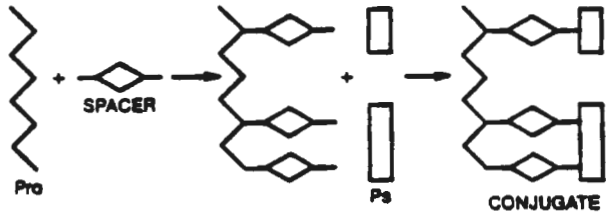
[a] Reference 20.

with particular binding properties.[3] In the area of immunology, an attempt has been made to change the isotype response to tetanus toxoid by coupling it to the polysaccharide pullulan.[4] Another application involves the enhancement of immunogenicity of various antigens, notably bacterial polysaccharides[5] and synthetic polypeptides. The word "conjugate" is most commonly used to describe these linked macromolecules, and it will be used in this paper.

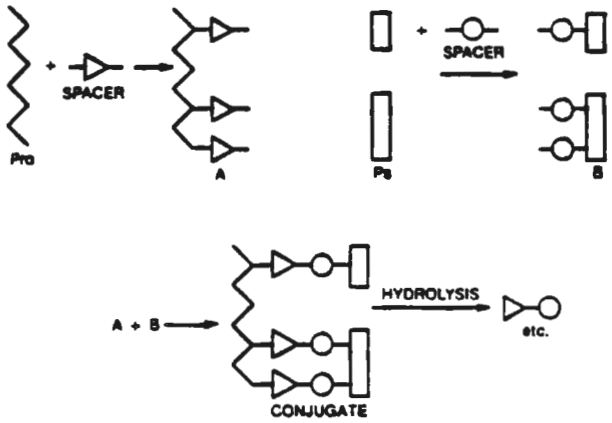
In the course of an effort to prepare conjugates of polysaccharides (Ps) and an immunogenic protein (Pro), we have addressed a number of interrelated problems. They involve the conjugation strategy, the chemistry used to effect that strategy, and the analytical approach to the structural and constitutional definition of the product. There are obvious complexities that arise when a polyfunctional Ps of polydisperse molecular weight (ca. M_r 5×10^5–1.5×10^6) is conjugated to a polyfunctional Pro (M_r 3×10^7). For instance, it is clear that *one* covalent bond between the two reaction partners will be very difficult to detect by conventional means, yet such a situation will produce an aggregate product similar to one where multiple covalent bonds are involved. Ambiguities also arise when several low molecular weight Ps molecules are conjugated to a given Pro vis-à-vis fewer high molecular weight Ps molecules bonded to the same Pro. It was therefore felt that the degree of conjugation is an important parameter to define especially if one wants to correlate biological results with chemical constitution. Another problem is that the constitutions of the substrates under consideration make them soluble only in water, which severely limits the available conjugation chemistry. It thus became clear that solubilization of one of these, the Ps, in a nonhydroxylic solvent was important for the chemical solution to the problem. A third problem involves the separation of unconjugated material from the conjugate, a situation again complicated by the polyfunctionality and polydispersity of the system. Such separations can sometimes be effected by size-exclusion chromatography when the products and the reactants differ significantly in their molecular weights and hydrodynamic properties. However, small percentage increases in molecular weight that obtain when a few Ps molecules (M_r 10^5) are added to a Pro (M_r 10^7) do not allow this approach. Our solution to these problems is the subject of this paper.

Our system evolved from the need to conjugate the capsular Ps of *Haemophilus influenzae* type b (PRP; Table I) with a protein carrier so that the polysaccharide would become immunogenic (i.e., elicit an immune response to its antigenic surface)

Scheme I. Monogeneric Spacer Conjugate



Scheme II. Bigeneric Spacer Conjugate



in children under 1 year of age. Since such infants do not respond to the unconjugated polysaccharide, an effective conjugate might provide a vaccine that would protect against *H. influenzae* type b caused meningitis.[6] The highly immunogenic serotype 2 outer membrane protein of *N. meningitidis*[7] was chosen as the protein partner for the conjugation. Ultimately, this protein, with our new methodologies, was conjugated to the streptococcal polysaccharides (vide infra) with the view that an infant otitis media vaccine might result. Useful immune responses have been afforded by all conjugates, the details of which will be published elsewhere.

Results and Discussion

A. Covalency and Degree of Conjugation. There are currently two published protein conjugates of PRP. One[8] is prepared by reducing, with $NaBH_3CN$, the Schiff base formed between the amino groups of the protein (a nontoxic variant of diphtheria toxin) and the reducing end of PRP. The product was not separated in a controlled way from unconjugated Ps and Pro, and one cannot

(3) (a) Roth, R. A.; Iwamoto, Y.; Maddux, B.; Goldfine, I. D. *Endocrinology* **1983**, *112*, 2193–2199. (b) Roth, R. A.; Maddux, B. *J. Cell. Physiol.* **1983**, *115*, 151–158.

(4) Mitani, S.; Yamamoto, A.; Ikegami, H.; Usui, M.; Matuhasi, T. *Infect. Immun.* **1982**, *36*, 971–976.

(5) (a) Robbins, J. B., Hill, J. C., Sadoff, J. C., Eds. *Bacterial Vaccines*; Georg Thieme Verlag Thieme Stratton Inc.: New York, 1982; Vol. IV, Chapter 34, 37, 43, and 45. (b) Goebel, W. F.; Avery, O. T. *J. Exp. Med.* **1931**, *54*, 437–447.

(6) (a) Schneerson, R.; Barrera, O.; Sutton, A.; Robbins, J. *J. Exp. Med.* **1980**, *152*, 361–376. (b) Robbins, J. S.; Schneerson, R.; Pittman, M. *Bacterial Vaccines*; Germanier, R., Ed.; Academic: Orlando, FL, 1984; pp 290–316.

(7) Frasch, C. E.; Robbins, J. D. *J. Exp. Med.* **1978**, *147*, 629–644.

(8) Anderson, P. *Infect. Immun.* **1983**, *39*, 233–238.

Table II. Characteristics of Polysaccharides and Their Derivatives

Ps	deriv	K_D[a]	rate nephelometry[a]	% N calcd	% N found
PRP		0.05 – 0.43[d]			
	Bu_4N			2.39	2.29
	BuA_2	0.68 ± 0.05	123 ± 25[b]		
	BuA_2–BrAc	0.67 ± 0.10	105 ± 30[b]		
6B		0.33			
	Bu_4N			8.02	8.19
	BuA_2	0.43	136		
	BuA_2–BrAc	0.35	64		
14		0.07			
	BuA_2	0.57	153		
	BuA_2–BrAc	0.79	120		
19F		0.17 – 0.58[d]			
	Bu_4Na			3.36	3.09
	BuA_2	0.49	142		
	BuA_2–BrAc				
23F[c]		0.26			
	Bu_4N			1.49	1.53
	BuA_2	0.23	97		

[a] Percent of native Ps. [b] Average of three separate preparations. [c] The bromoacetyl derivative was not isolated because of its insolubility. [d] Bimodal elution. [e] PRP was determined on Sepharose Cl 4B; all other, on Sepharose C1 2B.

rigorously conclude that the product was covalent. Assuming the putative chemistry was effected, the conjugate could be considered to be branches of Ps chains attached at their ends to a central axis of protein. A second approach[6] involves coupling the protein (diphtheria toxin, tetanus toxoid) to one end of the bifunctional molecule adipic acid dihydrazide. This is accomplished with carbodiimide and presumably forms a diacylated hydrazine with the pendant glutamic or aspartic carboxyl groups. This product is then reacted with a cyanogen bromide activated Ps, presumably forming an *O*-alkyl-4-acylated isosemicarbazide. Characterization and purification proceeded via size-exclusion chromatography, and covalency was inferred from an aggregate molecular weight. However, control experiments that exclude electrostatically bonded complexes were not reported. We suggest the term "monogeneric spacer" conjugate to describe this product and represent this scenario in Scheme I.

Our approach, which results in a "bigeneric spacer" product (Scheme II) involves functionalizing each reaction partner with a bifunctional "spacer" molecule. Each is chosen so that the remaining valency can react with that of its opposite partner to form a stable covalent bond. Furthermore, the system is designed so that the bond formed in the conjugation step is stable to conditions that degrade (e.g., hydrolyze) the final conjugation product and can form in that process a readily assayable molecule. This molecule then unambiguously represents a covalent bond between the two macromolecules, providing that the bonds formed in the initial steps (i.e., functionalizing the Ps and Pro with their respective bifunctional spacer) and can be established as covalent. In our system we can assert this from NMR evidence (Ps) and separation experiments (Pro). The system is schematically represented in Scheme II.

B. Chemistry. Our first concern was to develop chemistry that would allow us to functionalize our polysaccharides (Table I) in water. Hitherto, the most effective way of functionalizing a polyhydroxy compound in water was to activate it with cyanogen bromide, a reagent that presumably acquires some rate advantage when reacting with *vic*-diols. This chemistry is not uniformly effective (unpublished results), and the functionalization yields are low, typically 75–100 nmol/mg. It was felt that the best way to circumvent competition with H_2O was to work in a nonaqueous system. In the case of acidic polysaccharides such as the capsular coats of *H. influenzae* type b (PRP) and *Streptococcus pneumoniae* types 6B, 19F, and 23F (Table I), which contain as part of their monomeric unit a phosphodiester function, this is accomplished by replacing the remaining acidic hydrogen by a hydrophobic cation such as tetra- or tributylammonium. The resulting products (1) can be characterized by their elemental analyses, molecular weight distribution (K_d),[9] and topologies (rate nephelometry units)[10] (Table II). For a nonacidic Ps such as *S. pneumoniae*, solubilization was effected by molecular weight reduction via a short aqueous hydrazine or pH 10 treatment. All of these products were adequately soluble in either dimethylformamide (DMF) or dimethyl sulfoxide (Me_2SO). Although this concept has been applied before embodying an extensive hydrolysis of PRP for preparing NMR solutions,[11] in our hands those procedures afforded products of greatly reduced antigenicities and were not appropriate to our purposes.

Once in nonaqueous solutions, the polysaccharides may be reacted with a bis electrophile such as carbonyldiimidazole[12] ($COIm_2$) to form, putatively, an imidazolylurethane (2). 2 is then susceptible to nucleophile substitution, in aqueous systems if necessary, with bis nucleophiles such as diamines. Under appropriate circumstances (e.g., diamine excess), a stable covalent urethane with pendant amine is produced. Using 1,4-butanediamine and using a fluorescamine assay[13] to quantify the amine titer, we prepared 3 and used it for a variety of aqueous-based chemistries.

$$\mathrm{PsOH} + \text{Dowex 50 } (Bu_4N^+ \text{ form}) \longrightarrow \mathrm{PsOH{-}}Bu_4N^+ \text{ salt} \quad \text{(a)}$$

1 (a, Ps = PRP)

$$1 + COIm_2 \xrightarrow{DMF} \mathrm{PsOCIm} \quad \text{(b)}$$

2

$$2 + H_2N(CH_2)_4NH_2 \xrightarrow{aq} \mathrm{PsOCNH(CH_2)_4NH_2} \quad \text{(c)}$$

3 (a, Ps = PRP)

The amine levels can be readily controlled by the level of $COIm_2$ and have reached a titer of 700 nmol/mg (3a), which may be compared to the cyanogen bromide chemistry (vide supra). It should be noted that this level of substitution yields a product with significantly different antigenicity from the reactant, and for our purposes lower degrees of substitution were appropriate. The evidence for a carbamate functionality in 3 can be inferred from the ^{13}C and ^1H NMR spectra (vide infra).

As shown in Scheme II, one of the conjugation partners is a protein that can be analyzed, after acidic hydrolysis, for its constituent amino acids. Therefore, generation of a new, unique amino acid in the process of forming the bimacromolecular bond would afford a readily assayable small molecule, assuming it appeared in "window" in the amino acid spectrum. Moreover, since this new amino acid could be related in the same assay to one of the constituent amino acids of the protein, an internal standard is available, and the titer of the new amino acid need not be based on other assays of the conjugate. This obviates the problems of purification, drying, standards, etc. A thioether bond seemed appropriate for this strategy since it is readily formed in aqueous systems by alkylation of thiols with halides[14] and is stable to the conditions of the amino acid analysis. After a survey of several amino acids containing a thioether linkage, it was found that *S*-(carboxymethyl)homocysteine (8, SCMHC) is detected in a window in the analytical amino acid "spectrum" of the constituent acids of proteins. It was also found to be stable to the conditions of the hydrolysis and chromatography even in the presence of the polysaccharide. It was therefore decided to use conjugation reactions that would result in the generation of 8 at

(9) McCauley, J. A.; Mancinelli, R. J.; Downing, G. V.; Robbins, J. B. *J. Biol. Standard.* **1981**, *9*, 461–468.
(10) Steinberg, J. C. *Clin. Chem.* (*Winston-Salem, N.C.*) **1977**, *23*, 1456–1464.
(11) Egan, W.; Schneerson, R.; Werner, K. E.; Zon, G. *J. Am. Chem. Soc.* **1982**, *104*, 2898–2910.
(12) Bethell, G. S.; Ayres, J. S.; Hancock, W. S.; Hearn, M. T. W. *J. Biol. Chem.* **1979**, *254*, 2572–2574.
(13) Udenfriend, S.; Stein, S.; Bohlen, P.; Dairman, W.; Leimgruber, W.; Weigele, M. *Science* (*Washington, D.C.*) **1972**, *178*, 871–872.
(14) Rowley, G. L.; Leung, D.; Singh, P. U.S. Patent 4 328 311, 1982.

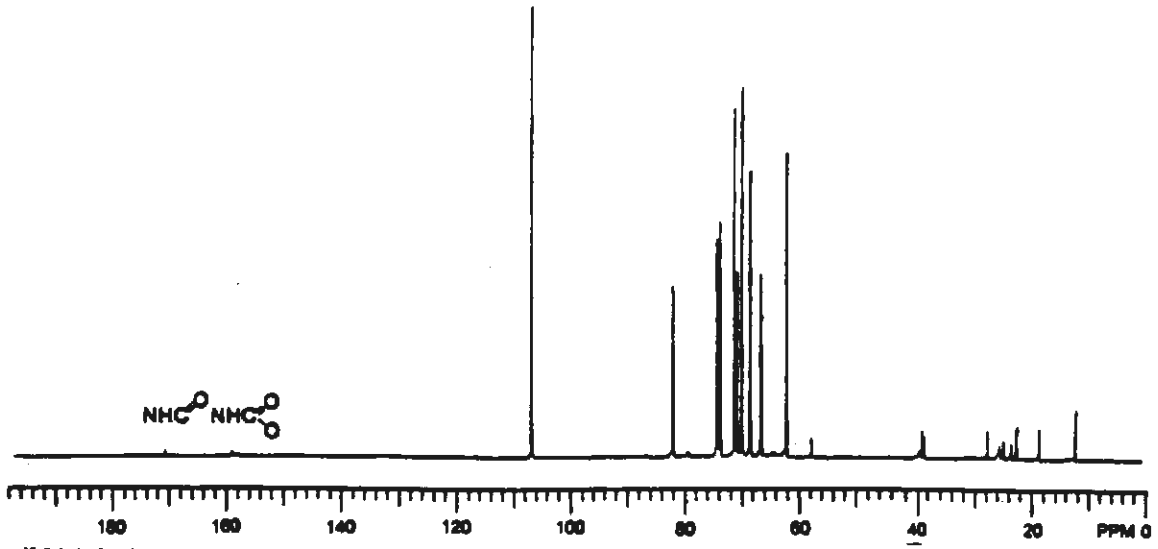


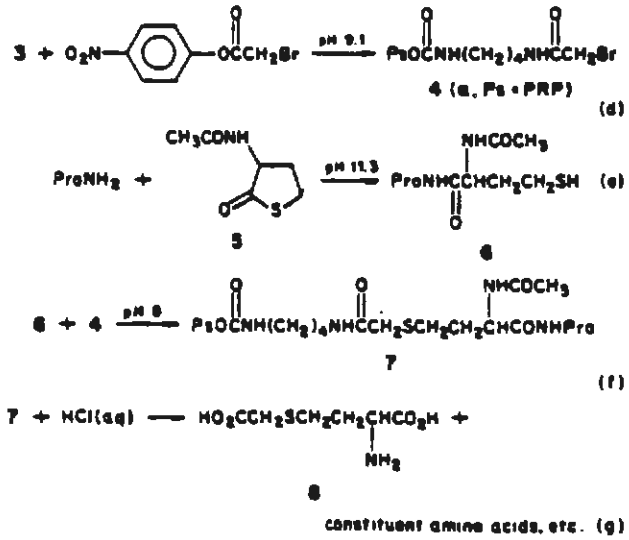
Figure 1. ^{13}C NMR of PRP–BuA_1–BrAc.

Table III. Ps Conjugates of NMP[a]

Ps	Δ[b]	Ps/Pro[c]	SCMHC/Lys	recovery,[d] wt %: Ps based	recovery,[d] wt %: Pro based
6B	138	0.66	0.084	12	15.8
14	146	0.37	0.128	8.2	19.7
19F	125	0.39	0.027	23.8	43
	130	0.20	0.032	6.6	35
23F	136	0.31	0.057	5.9	19
PRP					
column	340	0.09	0.019	3.6	33
uncapped	300	0.33	0.060	12.8	39.8
capped[e]	300	0.26	0.035	12.5	48

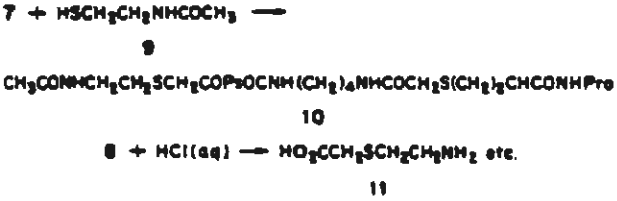
[a] Prepared by centrifugation method. [b] Δ, fluorescamine titer of 3 minus titer of 4. [c] Determined as in the Experimental Section. [d] Based on assay of final product solutions/weight of starting material × 100. [e] *S*-(Carboxymethyl)cysteamine/Lys = 0.197.

the site of junction. The following reactions were used to effect this strategy:



The bromoacetylation product 4 is assayed for residual amine by fluorescamine, and the difference between its titer and that of 3 defines a value Δ, which is indicative of the bromoacetyl (BrAc) level in 4. It should be noted that alkylation of nitrogen in 3 is very unlikely considering that the reaction of *p*-nitrophenyl bromoacetate with 6-aminohexanol results only in acylation and no detectable bromide ion.

From the Spinco amino acid analysis of 7 (after hydrolysis) on can obtain a ratio of moles of 8/mole of lysine (any protein constituent amino acid would be appropriate if it is stable to the hydrolysis conditions). This value (SCMHC/Lys) reflects the degree of covalency between the two macromolecules and may be likened to the number of rungs between the rails of a ladder. From the data it was generally clear that not all bromoacetamide moieties in 7 were reacted, and it was desired for reasons of vaccine safety that their alkylating potential be eliminated. Therefore, a "capping" procedure was developed that utilizes *N*-acetylcysteamine (9) and affords a capped conjugate 10. On hydrolysis 10 affords another unique, determinable amino acid, *S*-(carboxymethyl)cysteamine (11, SCMCA). The sum of 8 and 11 is found as expected to be equal to the number of bromoacetyl groups established by the value of Δ.



The outer membrane protein of *N. meningitidis* described by Helting[7] was chosen as the protein partner since it is a very effective inducer of the immune response and was expected to elicit antibodies to the polysaccharides (Table I) when conjugated to the latter. This protein is a multimer of a 40 000-Da unit with molecular weights in the (3–5) × 10^7 range. It is isolated as a milky colloidal suspension and will not resuspend if it is lyophilized to a dry state. However, ultracentrifugation pellets the protein in a form that can be resuspended by homogenization with a Dounce tissue homogenizer. Derivatives of the protein (i.e., 4) and the polysaccharide conjugates share this property, and this allows a convenient way of separating unconjugated polysaccharides and their derivatives (i.e., 2 and 3) from the conjugates. All nonconjugated materials in these systems were shown *not* to pellet under the same centrifugation conditions. These separations are important since the vaccine dosage is based on the polysaccharide titer of the conjugate, but available assays can only determine total polysaccharides. The protein is readily acylated by *N*-acetylhomocysteine thiolactone (5), liberating a thiol group whose titer can be determined by Ellman assay.[15] The level

(15) Ellman, G. L. *Arch. Biochem. Biophys.* 1959, *82*, 70–77.

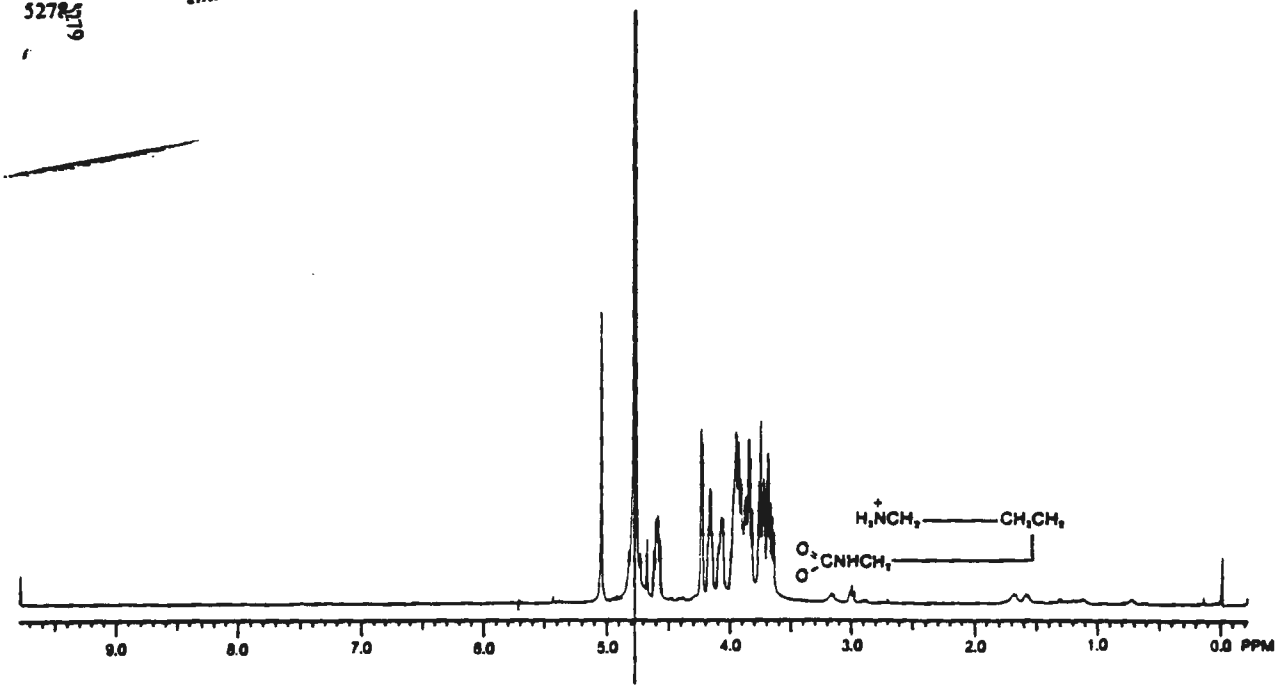


Figure 2. 400-MHz ^{1}H NMR spectrum of PRP–BuP_2 (3a).

corresponds to about 25% of the number of lysines in the protein that are presumed to be the sites of acylation. All efforts to increase this percentage have been unsuccessful. The bigeneric spacer analysis, to be meaningful, requires scrupulous removal of any free homocysteine or thiolactone, a consideration that also applies to subsequent chemistry and analysis. This can be accomplished by Sephadex G-25 chromatography, but this is accompanied by unacceptably large losses of protein that stick to the column. More efficiently, the separation can be effected by ultracentrifugation. No more than 4% of thiols found in the pellet are small molecules as shown by the control experiment where rethiolation is done with an iodoacetamide-capped protein. This 4% may also be due to an incremental thiolation of the protein. Considering the separation and thiol titer of the product, one can infer that reaction with thiolactone had produced a covalent product.

The final conjugate **10** is then characterized by its SCMHC/Lys ratio, its SCMCA/Lys ratio, and its polysaccharide/protein ratio as determined by conventional assays (Table III). Additionally, the values of K_d (Table II) of the intermediate derivatives afford another parameter that can be varied and correlated with the biological and other properties of the conjugate.

C. NMR. In order to argue that **7** is a covalent conjugate, it is important to establish that derivatives **3** and **4** are covalent. A nondialyzable amine titer does not necessarily imply covalency since the acidic Ps could bind amine electrostatically in the same way as a cation-exchange resin. Utilizing NMR spectroscopy, we established our structural formulation of **3a** and **4a** in accord with the following arguments. ^{13}C NMR signals (Figures 1) at 159.1 and 170.7 ppm are consistent with carbamate and amide carbonyl carbons, respectively. The latter signal was not present in PRP or **3a**, and the former was absent in PRP. The ^{1}H NMR spectrum is also supportive of our contention.

In Figure 2, the signals between 3.6 and 5.1 ppm represent the Ps protons, while those at higher field are attributable to the 1,4-butanediamine methylene protons and some resonances due to residual tetrabutylammonium ion. The peaks at 3.0 and 3.2 ppm are typical chemical shifts for methylene protons bonded to nonbasic or protonated nitrogen, and these two types may be distinguished by comparing D_2O spectra with those obtained at higher pH. Removal of a positive charge normally results in a 0.3–0.5 ppm upfield shift of the adjacent methylene protons, whereas the α-methylene protons in a nonbasic (i.e., carbamate) nitrogen compound were unaffected. It can be inferred from the spectrum after spiking with 1,4-butanediamine dihydrochloride that the 3.0 ppm signal, which is overlayed by added compounds, is attributable to $CH_2NH_3^+$ and the 3.2 ppm signal to the CH_2NHCO_2. This view was confirmed when the spectrum obtained after addition of deuterated NH_3 revealed that the 3.0 ppm peak but not the 3.2 ppm peak was displaced upfield. The spectrum of **3a** in which the remaining traces of tetrabutylammonium ion had been removed by additional dialysis shows four separate signals for the 1,4-butanediamine methylenes. This indicates that the two nitrogens are nonequivalent, which supports our contention that one is acylated and one is a basic amine. Their comparable areas indicate that little, if any, cross-linking of Ps has occurred.

Experimental Section

Preparation of the Tetra-*n*-butylammonium Salt of *H. influenzae* Type b Polysaccharide (1a). A 250-mL round-bottom flask fitted with a magnetic stirrer was charged with 3.29 g of PRP and 84 mL of water. The mixture was stirred for 20 min, and then an additional 15 mL of water was added. Stirring was continued for an additional 0.5 h until all PRP was in solution. The PRP solution was then applied to 150 mL of Dowex 50X8 (200–400 mesh; tetrabutylammonium form) in a 45–270-mm column. Ten milliliters of water was used as a rinse. The column was topped with water, and pressure was applied with a hand pump. Fractions of 50 mL were collected, and each tube was assayed for organic material by spotting on a silica gel plate, spraying with 1% $Ce^{IV}SO_4/H_2SO_4$, and heating on a hot plate. A total of 190 mL of organic-containing eluent was lyophilized, affording 3.56 g of **1a**. The product was stored in vacuo over P_2O_5 at −20 °C.

Preparation of 3a. 1,4-Butanediamine dihydrochloride (1.46 g) was dissolved in 58 mL of H_2O and the pH adjusted to 10.35 with 5 mL of 2.5 N NaOH. To a flask containing 0.64 g of **1a** was added 17.5 mL of DMF, and the mixture was stirred at room temperature for 25 min at which point almost all the material appeared to be in solution. Eighty milligrams of $COIm_2$ was then added in one portion to the DMF solution. The flask was capped, and the solution was stirred at room temperature for 35 min. The solution was then added to 32 mL of the ice-cooled 1,4-butanediamine solution, and the resultant solution was stirred in an ice bath for 15 min and at room temperature for an additional 17 min. The solution was then transferred to 17-in Spectropor 2 dialysis tubing (cylinder volume 0.21 mL/mm), was dialyzed in a 4 °C room vs. 8 L of 0.01 M pH 7.0 phosphate buffer for 5 h, and then was dialyzed twice vs. a fresh 8 L of phosphate buffer first for 5 h and then for 11 h. Finally, the solution was dialyzed vs. 18 L of water for 6 h. The solution was then

lyophilized, and there was obtained 0.48 g of 3a. The fluorescamine assay indicated 468 nmol of NH_2/mg.

Preparation of 4a. To 380 mg of 3a dissolved in 37 mL of a pH 9.15 buffer was added 346 mg of *p*-nitrophenyl bromoacetate in 9 mL of acetonitrile, and the mixture was stirred at 4 °C for 24 h and then transferred to 18 in. of dialysis tubing (Spectropor 2). This solution was then dialyzed vs. 18 L of H_2O for 5.25 h and then vs. a fresh 18 L of H_2O for 17.25 h at 4 °C. After lyophilization, 0.25 g of 4a was obtained, which had a titer of 128 nmol of NH_2/mg, resulting in a Δ of 340 nmol of BrAc groups/mg.

Conjugation of 4a to Functionalized *N. meningitidis* Membrane Protein (NMP). Column Method. Forty-two milligrams of ethylenediaminetetraacetic acid disodium salt and 8 mg of dithiothreitol were added to 5 mL of a pH 11.3 borate buffer. Then, 3.8 mL of this solution and 11.5 mL of an NMP solution (5.5 mg/mL) were mixed, and the pH was adjusted to 11.39 with 0.05 mL of 2.5 N NaOH. After the solution was degassed and the air replaced by N_2, 53 mg of *N*-acetylhomocysteine thiolactone was added in an N_2 box and the resultant solution aged at room temperature for 16.7 h. It was then applied to a 120-mL Sephadex G-25 (fine) column (in the N_2 box). The column had been equilibrated and was eluted with 0.1 M pH 8 phosphate buffer. Fractions of 5 mL were collected, and base-line separation of high from low molecular weight thiols, as assayed by Ellman reagent, was effected. The high molecular weight fractions were combined and added to 0.06 g of 4a and aged for 6 h at room temperature in N_2. The solution was then twice dialyzed vs. 18 L of H_2O for 15 and 25 h. The dialysate (32 mL) was centrifuged in polycarbonate tubes at 37 000 rpm for 2 h in a Ti 60 rotor. After resuspension of the pellets in H_2O and recentrifugation with the same conditions, the second pellets were resuspended with a Dounce homogenizer in 15 mL of H_2O. Found: Pro, 1800 μg/mL; PRP, 166 μg/mL; SCMHC/Lys, 0.027.

Conjugation–Centrifugation Method. All centrifugations were performed in polycarbonate tubes and unless otherwise noted at 43 000 rpm for 2 h at 4 °C in a Beckman Ti 75 rotor. All manipulations of thiolated material were done in an N_2 box. The unfunctionalized NMP (20 mL, 5.5 mg/mL) was centrifuged, and the pellets were resuspended with a Dounce homogenizer in 8 mL of a thiolation solution (126 mg of ethylenediaminetetraacetic acid disodium salt, 24 mg of dithiothreitol in 15 mL of pH 11 borate buffer). After the solution was degassed and the air replaced with N_2, 110 mg of *N*-acetylhomocysteine thiolactone was added in an N_2 box. The solution was aged for 18.7 h at room temperature and then diluted with 5 mL of 1 M KH_2PO_4 and 5.2 mL of 0.1 M pH 8 phosphate buffer (the resultant pH is 7.15). This solution was centrifuged, and the pellets were resuspended in 20 mL of the pH 8 buffer and recentrifuged. The pellets from this second centrifugation were resuspended with a Dounce homogenizer in 9 mL of pH 8 buffer. An Ellman assay indicated a total of 9 μmol of SH. To this resuspended thiolated NMP solution was added 112 mg of 4a (Δ = 300) and the solution was degassed and aged for 17.8 h. Then, 11 mL of H_2O was added and the solution centrifuged. The pellets were resuspended in 20 mL of a "capping" solution (212 mg of *N*-acetylcysteamine/30 mL of pH 8 buffer) and aged under N_2 for 18 h. The solution was then centrifuged, the pellets were resuspended in 20 mL of H_2O, and the solution was recentrifuged. The final pellets were resuspended (Dounce) in 50 mL of H_2O, affording the "capped" PRP–NMP conjugate. Found: Pro, 905 μg/mL; PRP, 233 μg/mL; SCMHC/Lys, 0.035; SCMCA/Lys, 0.197.

Control Experiment Concerning Thiol Content of Centrifugation Pellet. Ten milliliters of a solution containing 59 mg of NMP was centrifuged and then "thiolated" with 54 mg of *N*-acetylhomocysteine thiolactone exactly as in the above example except that a Ti 80 rotor was used in all centrifugations. The pH of the reaction solution was adjusted to 8.5, the solution centrifuged, the pellet resuspended at pH 8.0, and the solution centrifuged a second time. The resultant pellet, resuspended in 10 mL of pH 8 buffer, was assayed and found to contain a total of 6.0 μmol of thiol. Fifty milligrams of iodoacetamide was added to this solution, which was then aged for 18 h. The resultant reaction mixture was centrifuged, the pellet resuspended in 10 mL of H_2O, and the solution was recentrifuged. The resulting capped pellet was thiolated exactly as above (using 54 mg of *N*-acetylhomocysteine thiolactone/19 h). The reaction solution was centrifuged, the pellet resuspended (pH 8 buffer), and the solution recentrifuged. The second pellet was resuspended in 6.5 mL of pH 8 buffer, assayed, and found to have a total of 0.26 μmol of thiol corresponding to 4% of the first thiolation.

General Procedures. Ribose assays were done by the method of Dische and Schwarz,[16] methylpentose assays by the method of Dische and Shettles,[17] and hexose assays by the method of Scott and Melvin.[18] Protein assays were done by the method of Lowry,[19] and amino acid analyses were performed on Beckman 121 M13 and Beckman System 6300 amino acid analyzers.

A general concept, the bigeneric spacer concept, has been conceived, which allows the unambiguous assignment of the level of covalency of protein–polysaccharide conjugates. A general method has been devised, transforming acidic polysaccharides from water-soluble to organic-soluble entities by converting them to their tetrabutylammonium salts. This allows a variety of chemistries not assessible in aqueous systems. Both of these have allowed the preparation of unique Pn–Pro conjugates, which are useful as vaccines.

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Registry No. $COIm_2$, 530-62-1; $NH_2(CH_2)_4NH_2$, 110-60-1.

(16) Dische, Z.; Schwarz, K. *Mikrochim. Acta* **1937**, *2*, 13–19.
(17) Dische, Z.; Shettles, L. B. *J. Biol. Chem.* **1948**, *175*, 595–603.
(18) Scott, T. A.; Melvin, E. H. *Anal. Chem.* **1953**, *25*, 1656–1661.
(19) Lowry, O. H.; Rosebrough, N. J.; Farr, A. L.; Randall, R. J. *J. Biol. Chem.* **1951**, *193*, 265–275.
(20) Kenne, L.; Lindberg, B. *The Polysaccharides*; Aspinall, G. O., Ed.; Academic: New York, 1983; Vol. 2, pp 287–363.

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Immunogenicity of H. Influenzae Type b (Hib) Polysaccharide-N. Meningitidis Outer Membrane Protein (PS-OMP) Conjugate Vaccine in Infants and Young Children. E.D. SHAPIRO*, L.A. CAPOBIANCO, M.Q. ZITT. Yale School of Medicine, New Haven, CT.

In an on-going study Hib PS-OMP conjugate vaccine (Merck, Sharp & Dohme) was administered in 1 dose to children ≥12 mos. of age and in 2 doses (separated by 2 mos.) to children 2-11 mos. of age. Concentrations of antibody against Hib capsular PS (PRP) in serum before each dose of the vaccine and at follow-up 1 month after immunization were determined at Merck Laboratories by radioimmunoassay with ^{125}I extrinsic labelled antigen. The results, expressed as the geometric mean (GM) concentration of anti-PRP antibody/ml. and the proportion of subjects with concentrations ≥1.0 ug/ml, for Groups I (ages 2-11 mos;median=6 mos; N=43), II (ages 12-23 mos;median=14 mos;N=52), and III (ages ≥24 mos;median=26 mos;N=31) are shown below:

	Anti-PRP Antibody (ug/ml)					
Grp	Before 1st Dose		Before 2nd Dose			
	GM	≥1.0	GM	≥1.0	GM	≥1.0
I	0.17	0/43(0%)	2.34	32/43(74%)	5.30	38/43(80%)
II	0.19	3/52(6%)	-	-	5.89	46/52(89%)
III	0.32	6/31(19%)	-	-	16.07	28/31(90%)

There were no substantial differences in the responses by race or to different lots of the vaccine and no serious and few minor adverse reactions occurred. This Hib PS-OMP vaccine is highly immunogenic in infants and young children.

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Infectious Diseases
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† 963 **IMMUNOLOGIC PRIMING OF INFANTS WITH A SINGLE DOSE OF H. INFLUENZAE TYPE B (Hib) POLYSACCHARIDE-N. MENINGITIDIS OUTER MEMBRANE PROTEIN (PS-OMP) CONJUGATE VACCINE.** Eugene D. Shapiro, James C. Pramberg, Robert S. Daum, Yale and Tulane U. Schools of Medicine, Depts. of Pediatrics, New Haven and New Orleans.

In a trial of its immunogenicity, 13 children from 2-6 months of age received a single dose of PS-OMP conjugate vaccine. Titers of antibody against Hib capsular PS(PRP) one month after immunization were determined at Merck Laboratories by radioimmunoassay with the use of ^{125}I extrinsic labelled antigen. All 13 children had <0.4ug of antibody/ml before receiving PS-OMP vaccine and 6/13 (46%) had ≥1.0ug/ml after a single dose (geometric mean: 5.2ug/ml).

Because additional PS-OMP vaccine was not available and previous work suggested that the conjugate vaccine may prime infants to respond to plain PRP we administered PRP vaccine to all 7 children with <0.1ug of antibody/ml after PS-OMP vaccine and to 4 children with >1.0ug of antibody/ml after PS-OMP vaccine. Of the 7 children with <1.0ug of antibody/ml (geometric mean: 0.4ug/ml), 4 (57%) developed ≥1.0ug of antibody/ml (geometric mean: 5.2ug/ml) one month after "boosting" with PRP vaccine. Of the four children with >1.0ug of antibody/ml after PS-OMP vaccine, the titers of antibody one month after "boosting" with PRP vaccine increased in one child (from 19.6 to 31.2ug/ml), changed little in one child (from 1.0 to 1.1ug/ml) and decreased in two children (from 1.3 to 0.4ug/ml and from 1.5 to 0.4ug/ml, respectively). We conclude that the antibody responses of young infants to a single dose of PS-OMP conjugate vaccine vary: titers of antibody ≥1.0ug/ml develop in some infants, others are primed to achieve ≥1.0ug/ml after subsequent "boosting" with PRP vaccine, while others fail to have a substantial response.

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Comparative Immunogenicity of *H.influenzae* type b (Hib) Conjugate Vaccines (PRP-D/PRP-OMP) in Infants < 6 Months of Age.

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We conducted 3 studies of the immunogenicity and safety of two Hib conjugate vaccines in 2 populations of infants. Three doses of PRP-D (Connaught) were given at 2, 4 and 6 months of age and bloods were obtained at 2, 4, 6 and 7-9 months. Two doses of PRP-OMP (Merck) were given at 2 and 4 months and sera obtained at 2, 4, and 6 months. All sera were assayed simultaneously by FDA standard RIA. GM levels (ug/ml) were:

Age (dose)	PRP-OMP(CA) (N=27)	PRP-D(CA) (N=20)	PRP-D(AK) (N=13)
2 months (pre)	0.1	0.04	0.2
4 months (post-1)	1.77	0.04	0.05
6 months (post-2)	3.9	0.1	0.08
7 months (post-3)	NA	0.3	NA
9 months (post-3)	NA	NA	0.3

Even after 1 dose given at 2 months, PRP-OMP was clearly more immunogenic than PRP-D after 3 doses given at 2, 4 and 6 months.

Immunologic priming to capsular polysaccharide in infants immunized with *Haemophilus influenzae* type b polysaccharide–*Neisseria meningitidis* outer membrane protein conjugate vaccine

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Thirty children vaccinated at 2 to 17 months of age with *Haemophilus influenzae* type b polysaccharide linked to a partially purified 40,000 dalton outer membrane protein of *Neisseria meningitidis* were revaccinated 10 to 14 months later with conventional *H. influenzae* type b polysaccharide vaccine. The geometric mean anti-type b antibody concentration before reimmunization was 0.68 μg/mL, and rose to 31 μg/mL in sera obtained 1 month later. The mean level after immunization was not significantly different than that in sera from 12 adults immunized with type b polysaccharide vaccine (51 μg/mL, P = 0.3), and was 10-fold higher than that of 13 control children immunized with type b polysaccharide for the first time (2.7 μg/mL, P <0.001). The IgG responses of the children first given conjugate vaccine and then conventional type b polysaccharide vaccine were of a similar magnitude as those in the immunized adults. Further, the children maintained high levels of serum antibody 6 to 8 months later. Ten other children vaccinated in infancy with conjugate vaccine, and again with conjugate vaccine 10 to 15 months later, showed similar antibody responses to those of the group given conjugate vaccine in infancy, and booster with conventional polysaccharide vaccine. Thus vaccination with *H. influenzae* type b polysaccharide–outer membrane protein conjugate vaccine primes the immune system to an IgG memory antibody response to either type b polysaccharide or conjugate vaccine. Post-booster sera from all children tested showed high titers of functional activity in a complement-mediated bactericidal assay. These data suggest that protection of most infants from type b *Haemophilus* disease may be achieved by a combination of immunization at 2 to 4 months of age with this conjugate vaccine, and reimmunization 1 year later with conjugate or conventional type b polysaccharide vaccine. (J Pediatr 1987;111:22-7)

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Hib	*Haemophilus influenzae* type b
OMP	Outer membrane protein
ELISA	Enzyme-linked immunosorbent assay

Conventional *Haemophilus influenzae* type b polysaccharide vaccine is thought to be a thymus-independent immunogen.[1,2] Booster responses are not observed after reinjection.[2,3] In an effort to enhance the immunogenicity of the polysaccharide, several covalently coupled Hib polysaccharide–protein conjugate vaccines have been developed and tested in experimental animals and humans.[5-12] These conjugate vaccines are thought to confer thymus-dependent properties to the polysaccharide.[7] The conjugate vaccines are more immunogenic than the conventional polysaccharide vaccine in infants, and result in booster antibody responses after reinjection of the conjugate.[6,8,13,14] Preliminary data[9] also suggest that children first given an Hib oligosaccharide–protein conjugate vaccine and reinjected with conventional polysaccharide vaccine develop an IgG memory response to the polysaccharide.

We recently evaluated the safety and immunogenicity of an Hib polysaccharide–*Neisseria meningitidis* outer membrane protein conjugate vaccine (Hib polysaccharide–OMP vaccine) prepared by Merck Sharp & Dohme.[6] A single injection was immunogenic in children vaccinated as young as 2 to 3 months of age, and the majority of the infants showed evidence of IgG anti-Hib polysaccharide antibody responses. Six to 12 months after immunization, the serum antibody concentrations in these children had declined, but the levels remained higher than those in unimmunized children.[6]

The purposes of the present study were to obtain additional information on the persistence of serum antibody in these children and to measure their antibody responses to a booster injection of either conventional Hib polysaccharide vaccine or Hib polysaccharide–OMP conjugate vaccine given approximately 1 year after the last injection of conjugate vaccine.

METHODS

Vaccines. The conjugate vaccine contained Hib polysaccharide covalently coupled to a partially purified OMP from *N. meningitidis* group B.[6,15] Two lots of conjugate vaccine were used. The lot used for primary immunization of the infants (Lot 1003/C-L680, Merck Sharp & Dohme Research Laboratories, West Point, Pa.) has been described[6]; each 0.5 mL dose contained 7 μg polysaccharide and 43 μg OMP. Each 0.3 mL dose of the lot used for reimmunization (Lot 1018/C-M679, Merck Sharp & Dohme Research Laboratories) contained 7 μg polysaccharide and 23 μg OMP. The conventional Hib polysaccharide vaccine was prepared by Praxis Biologics, Inc. (Rochester, N.Y.), and was purchased from Mead Johnson (Evansville, Ind.); each 0.5 mL dose contained 25 μg Hib polysaccharide.

Clinical design. The subjects were 43 healthy children, 14 to 31 months of age, who had been vaccinated previously with Hib polysaccharide–OMP conjugate vaccine.[6] Informed consent was obtained from the parents at the time of the initial immunization and again at the time of the reimmunization. Both immunization protocols were approved by the Human Studies Committee of Washington University School of Medicine. Thirty children were 2 to 6 months of age at the time of the initial immunization. Twenty-eight received two injections of conjugate vaccine separated by 1 month, and the remaining two children received only one injection. In the latter two, second injections were deferred because of febrile episodes associated with the first injection. Thirteen children were 8 to 17 months of age at the time of the initial immunization. Six received one injection of vaccine, and the remaining seven received two monthly injections of vaccine. In this group of children, second injections were given to those seven who showed relatively low antibody responses to the first injection (<2 μg/mL).[6]

In the first phase of the reimmunization protocol, 30 of the 43 children, aged 14 to 30 months, received conventional Hib polysaccharide vaccine subcutaneously in the thigh 10 to 14 months after the completion of the last immunization with conjugate vaccine. In the second phase, 10 other children, aged 14 to 31 months, received conjugate vaccine intramuscularly in the thigh 10 to 15 months after completion of the primary conjugate immunization. Selection of patients for immunization with the different vaccines was based on availability of the children and willingness of the parents to participate during different times during the follow-up period. Three of the original 43 patients provided follow-up serum 11 to 12 months after completion of the primary conjugate immunization but were not reimmunized.

Twelve healthy adults were immunized with 25 μg conventional Hib polysaccharide vaccine subcutaneously, and served as controls. They represent an independent sample, not previously reported. A second group of controls consisted of eight children with a history of culture-proved invasive Hib disease at 3 to 17 months of age (meningitis, five; buccal cellulitis, two; periorbital cellulitis, one). These children were vaccinated with 25 μg conventional Hib polysaccharide vaccine subcutaneously 7 to 21 months after recovery from disease (at 24 to 27 months of age).

Serology. Serum samples were obtained before immunization and 1 to 2 months after. Total serum anti-Hib polysaccharide antibody was measured by radioantigen

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Table I. Persistence of serum anticapsular antibody in 43 children immunized with Hib polysaccharide-OMP vaccine and observed for 10 to 15 months

Age at first injection (mo)	No. tested	Geometric mean antibody (μg/mL)		
		1 mo post	10-15 mo post	Control*
2-3	11	1.59	0.43	0.16
4-6	19	2.60	1.05	0.18
8-17	13	4.06	0.63	0.23

*Age-matched, unimmunized historical controls[12] (n = 20 to 29 children in each age group). Geometric mean antibody concentration of vaccinated children in each group was greater than that of the respective control group ($P < 0.01$ for each comparison, t test). There were no significant differences in antibody concentrations at 10 to 15 months between vaccinated children in each age group ($P > 0.10$).

binding assay.[5, 16] IgG anti-Hib polysaccharide antibody was measured by ELISA, using the type b polysaccharide coupled to poly-L-lysine as the antigen on the plate.[16, 17] Serum antibody measurements were determined on paired pre- and post-immunization sera to minimize interassay variation. The sensitivity and precision of these assays have been described.[16]

The functional activity of serum antibody was measured by a complement-mediated bactericidal assay as described.[18, 19] The test organism was Hib strain Eagan,[20] and the complement source was serum from an adult with agammaglobulinemia and normal complement levels.[19] The percentage of survival of Hib after incubation in the assay mixture was calculated by comparing colony counts at 0 and 60 minutes. The bactericidal activity was determined graphically by plotting the log of the serum dilution versus the percentage of survival of Hib cells[18]; the dilution giving 50% survival was defined as the bactericidal titer.

Statistics. The Student t test (two tailed) was used to compare the geometric mean concentrations of serum antibody between the groups of children and adults. A paired t test (one tailed) was used to compare the geometric mean antibody concentrations before and after immunization within a group. Analysis of antibody response was performed on logarithmically transformed data.

RESULTS

Forty-three children immunized with conjugate vaccine at 2 to 17 months of age had a significant decline in geometric mean serum antibody levels at 10 to 15 months follow-up, compared with the peak levels obtained 1 month after the last injection of vaccine ($P < 0.01$ for each age group tested, paired t test; Table I). However, the concentrations of antibody present at follow-up in the immunized children remained higher ($P < 0.01$) than those in unimmunized control children of comparable age. For this analysis, historical controls[12] were matched by age with the vaccinated patients, and the geometric mean antibody levels of the respective groups were compared. During the follow-up period, three of the 43 vaccinated infants respectively showed two-, six-, and 20-fold increases in antibody, although none of the three had a clinically apparent Hib illness. These children may have experienced natural exposure to either Hib or other bacteria with cross-reacting antigens.[21]

Forty of the 43 children were reinjected with either Hib polysaccharide vaccine or polysaccharide-OMP vaccine. In the first phase, 30 children were immunized with conventional Hib polysaccharide vaccine. No notable systemic reactions occurred, although two children had 1 to 3 cm erythema and tenderness at the injection site. In the second phase, 10 children were revaccinated with Hib polysaccharide–OMP vaccine. Of these, fever (temperature 39° to 40° C) developed in three, 4 to 36 hours after injection. The frequency of fever was significantly greater in the group reinjected with conjugate vaccine than in the group reinjected with conventional polysaccharide vaccine (30% vs 0%, $P = 0.02$, Fisher exact test). All three of the children with fever were apparently healthy at the time of immunization, but had evidence of otitis media or upper respiratory tract infections when reexamined 8 to 48 hours after onset of fever.

Table II summarizes the antibody responses of the 30 children who received conjugate vaccine in infancy and were vaccinated approximately 1 year later with conventional Hib polysaccharide vaccine at a mean (±SD) age of 20.0 ± 4.4 months. There were no significant differences in the antibody responses to the booster injection in children who received either one or two injections of conjugate vaccine; therefore the data were combined. The children first immunized with conjugate vaccine and reinjected with conventional polysaccharide vaccine showed substantial increases in both total and IgG anti-Hib polysaccharide antibody ($P < 0.01$). The geometric mean total or IgG antibody concentrations in sera obtained 1 month after immunization were not significantly different than those in post-immunization sera from 12 adults immunized for the first time with conventional Hib polysaccharide vaccine ($P > 0.3$, Table II). The serum levels present after immunization in the children who had previously received conjugate vaccine in infancy were approximately 10-fold higher than those in healthy children who had not received conjugate vaccine. The latter group was immunized with Hib polysaccharide vaccine for the first time at an age similar to that of the former group at the time of their booster immunization. In addition, children who had recovered from invasive Hib disease at 3 to 17 months of age and who were immunized with conventional

Table II. Serum antibody response to conventional Hib polysaccharide vaccine in relation to previous immunologic priming with polysaccharide-OMP conjugate vaccine

	Age at polysaccharide vaccine (mo)	n	Geometric mean antibody (μg/mL)		
			Total		IgG
			Pre	Post	Post
Children primed with conjugate vaccine*	14-20	19	0.73	31.8	16.7
	22-30	11	0.60	30.0	13.4
Children recovered from disease†	24-27	8	0.67	2.0	1.1
Healthy children‡	24-30	13	0.26	2.7	0.6
Healthy adults	—	12	2.83	51.0	10.4

*There were no significant differences ($P > 0.3$) in respective total or IgG post-immunization antibody concentrations in children first immunized with conjugate vaccine and revaccinated with conventional Hib polysaccharide vaccine, and those of healthy adults vaccinated first with conventional Hib polysaccharide vaccine. However, total and IgG post-immunization antibody concentrations of primed children were significantly greater ($P < 0.001$) than those of vaccinated children recovered from Hib disease and those of vaccinated healthy children.

†Hib disease at 3 to 17 months of age. There were no significant differences ($P > 0.4$) between post-immunization levels of vaccinated children recovered from disease and those of vaccinated healthy children.

‡Historical controls immunized with 5 μg Hib polysaccharide vaccine (dose within maximally immunogenic range).[12, 20]

Hib polysaccharide vaccine at 24 to 27 months of age did not show an enhanced anti-Hib polysaccharide antibody response (Table II).

One month after vaccination, all 30 children whose primary immunization was with conjugate vaccine and who were given a booster injection of Hib polysaccharide vaccine had >3.5 μg/mL anti-Hib polysaccharide antibody in post-immunization serum; 23 (77%) had concentrations >10 μg/mL, and 15 (50%) children had concentrations ≥30 μg/mL. The group with concentrations ≥30 μg/mL included five children who were given conjugate vaccine at 2 to 4 months of age and were reimmunized with conventional polysaccharide vaccine at 14 to 17 months of age.

Ten additional children who had been vaccinated between 2 and 16 months of age with conjugate vaccine were reimmunized 10 to 15 months later with conjugate vaccine; the mean age at the time of reimmunization was 18.8 ± 5.3 months (range 14 to 31 months). The geometric mean antibody levels before and 1 month after booster vaccination were 1.0 and 41.7 μg/mL, respectively. The geometric mean IgG antibody concentration after booster vaccination was 16.9 μg/mL. These values are not significantly different from those of the children first given conjugate vaccine, then reinjected with conventional Hib polysaccharide vaccine ($P > 0.5$, t test). All 10 children reimmunized with conjugate vaccine developed >10 μg/mL serum anti-Hib polysaccharide antibody in post-immunization sera, and seven of the 10 had concentrations ≥30 μg/mL. The percentages were not significantly different from those of the children whose primary immunization was with conjugate vaccine, then given conventional Hib polysaccharide booster vaccine ($P > 0.2$, Fisher exact test).

To date, 12 children have been observed for 6 to 8 months after booster immunization. Ten received conventional Hib polysaccharide vaccine, and two conjugate vaccine. There was a significant decline in serum antibody during the period after the booster injection, but the antibody concentrations were maintained at high levels in all children (geometric mean antibody concentration in this group was 22.3 μg/mL 1 month after booster, and 11.9 μg/mL 6 to 8 months later, $P = 0.02$, paired t test). During this period, one of the 12 children showed a fivefold further increase in anti-Hib polysaccharide antibody in the absence of clinical illness.

Sera obtained before booster immunization and 1 month later from 14 representative children were tested for functional activity using a complement-mediated bactericidal assay.[18, 19] Seven of these children were given the conventional Hib polysaccharide vaccine, and seven the polysaccharide-OMP vaccine. The geometric mean bactericidal titer increased from 1:3 to 1:120 in the children given conventional Hib polysaccharide vaccine, and from 1:1.5 to 1:208 in the children reimmunized with polysaccharide-OMP conjugate vaccine. There was no significant difference in the respective geometric mean titers of the two groups ($P > 0.3$). In the post-immunization sera, there was a linear relationship between the log of the anti-Hib polysaccharide antibody concentration and the log of the reciprocal bactericidal titer ($r = 0.86$, $P = 0.001$; Figure).

DISCUSSION

Previous data indicate that children or adults immunized with conventional Hib polysaccharide vaccine do not have booster antibody responses to reinjection with conventional vaccine.[1-3] (They may have increased serum anti-

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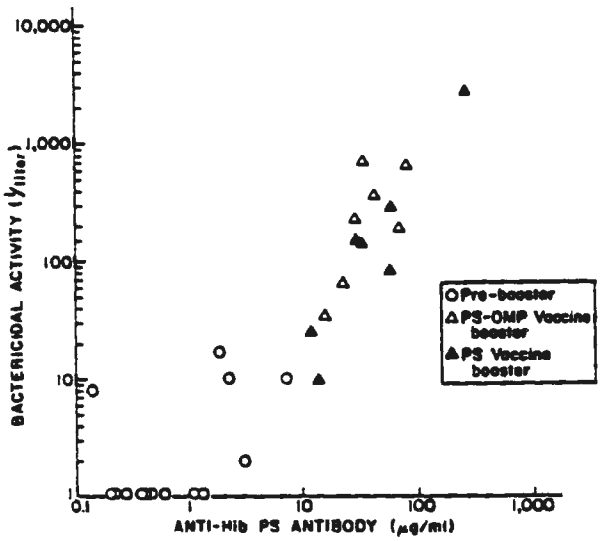

Figure. Relation between bactericidal titer and anti-Hib polysaccharide antibody concentration in sera from 14 children given two injections of Hib polysaccharide–outer membrane protein (PS-OMP) conjugate vaccine in infancy and reimmunized 10 to 15 months later with conventional Hib polysaccharide vaccine (n = 7) or conjugate vaccine (n = 7). Antibody concentrations were determined on serum samples obtained at the time of booster immunization and 1 month later.

body after reimmunization, but the levels achieved are not different from those of children of similar age immunized for the first time.[4]) In contrast, our data demonstrate that children vaccinated with Hib polysaccharide–OMP conjugate vaccine between 2 and 17 months of age have high IgG antibody responses on reinjection 10 to 15 months later with Hib polysaccharide vaccine or with Hib polysaccharide–OMP conjugate vaccine. The magnitude of the antibody responses to the "booster" injection is comparable to that of adults immunized for the first time with Hib polysaccharide vaccine. Further, in the vaccinated children, high levels of serum antibody persist after the booster injection. These observations are consistent with immunologic priming by vaccination in infants with conjugate vaccine and induction of a secondary or memory antibody response to the booster injection.

Anderson et al.[9] immunized six infants at 2, 4, and 6 months of age with an Hib capsular oligosaccharide–diphtheria toxoid conjugate vaccine and also observed enhanced antibody responses to conventional Hib polysaccharide vaccine administered 3 to 5 months later; however, in their study, the antibody responses to conventional Hib polysaccharide were inconsistent, and were about 10-fold lower than those we observed. The lower responses in their study may have resulted, in part, from the younger ages of the children at the time of reinjection (9 to 11 months, compared with 14 to 31 months in our study).

Our results and those of Anderson et al.[9] suggest that the initial vaccination with conjugate vaccine induces memory B cells. Further, these cells may be triggered to produce antibody by immunization with conventional Hib polysaccharide, even when a child is vaccinated at an age considered too young for successful immunization with this vaccine.[22] The ability to respond with an IgG "memory" antibody response on reexposure to Hib polysaccharide, as a result of immunologic priming, may be important for protection against Hib disease, especially in infants with declining levels of serum antibody.

In contrast to the group vaccinated in infancy with conjugate vaccine, the group who had had Hib disease in infancy did not show evidence of immunologic priming. Evidence for priming also was not observed by Norden et al.[23] in a previous study of patients who had recovered from Hib disease and who were then vaccinated with Hib polysaccharide vaccine. The reasons for the lack of priming are unclear. During Hib disease, the immune system encounters many antigens simultaneously (e.g., capsular polysaccharide, outer membrane proteins, lipopolysaccharide). However, the doses may be inappropriate for priming, or covalent coupling of polysaccharide and protein (as in the conjugate vaccine) may be required for priming to the polysaccharide.

We found no significant differences in the antibody responses of children with immunologic priming when reinjected with either conjugate vaccine or with conventional type b polysaccharide vaccine. However, the sample size of patients reinjected with conjugate was small, limiting the power of our study to detect a significant difference. Lepow et al.[13] also reported high antibody responses in children who received Hib polysaccharide–diphtheria toxoid conjugate vaccine at 9 to 15 months of age and were reinjected with conjugate vaccine at 24 months of age. However, their study did not include a comparison group of children reinjected with conventional Hib polysaccharide vaccine.

In our study, the anti-Hib polysaccharide antibody induced by revaccination had functional activity as measured by a complement-mediated bactericidal assay. The serum bactericidal titer appeared to be directly related to the level of anti-Hib polysaccharide antibody evoked by immunization. There did not appear to be any differences between the functional activity of the antibody elicited by conventional or conjugate vaccine.

These data indicate that vaccination of infants in the first 6 months with Hib polysaccharide–OMP conjugate vaccine induces immunologic priming such that the children show IgG memory antibody responses 10 to 14 months later when vaccinated with conventional Hib polysaccharide vaccine. Boosting with Hib polysaccharide–OMP conjugate vaccine is also highly immunogenic,

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but may be associated with a higher frequency of febrile reactions. Further data are needed on the safety and efficacy of this conjugate vaccine, and on the optimal immunization schedule. However, a combination of immunologic priming in infancy with this conjugate vaccine, followed by boosting approximately 1 year later with conventional Hib polysaccharide vaccine (or conjugate vaccine), may be highly efficacious, potentially preventing most serious Hib disease in childhood.[12]

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REFERENCES

1. Paul WE, Kung J, Ahmed A, Stein K. B lymphocyte subpopulations and responses to polysaccharide antigens. In: Sell SH, Wright PF, eds. *Haemophilus influenzae*: epidemiology, immunology, and prevention of disease. New York: Elsevier Science Publishing Co., 1982:121-8.
2. Mosier DE, Subbarao B. Thymus-independent antigens: complexity of B-lymphocyte activation revealed. Immunol Today 1982;3:217-22.
3. Peltola H, Käyhty H, Sivonen A, Mäkelä PH. *Haemophilus influenzae* type b capsular polysaccharide vaccine in children: a double-blind field study of 100,000 vaccinees 3 months to 5 years of age in Finland. Pediatrics 1977;60:730-7.
4. Käyhty H, Karanko V, Peltola H, Mäkelä PH. Serum antibodies after vaccination with *Haemophilus influenzae* type b capsular polysaccharide and responses to reimmunization: no evidence of immunologic tolerance or memory. Pediatrics 1984;74:857-65.
5. Granoff DM, Boies EG, Munson RS Jr. Immunogenicity of *Haemophilus influenzae* type b polysaccharide–diphtheria toxoid conjugate vaccine in adults. J PEDIATR 1984;105:22-7.
6. Einhorn MS, Weinberg GA, Anderson EL, Granoff PD, Granoff DM. Immunogenicity in infants of *Haemophilus influenzae* type b polysaccharide in a conjugate vaccine with *Neisseria meningitidis* outer-membrane protein. Lancet 1986;2:299-302.
7. Schneerson R, Barrera O, Sutton A, Robbins JB. Preparation, characterization and immunogenicity of *Haemophilus influenzae* type b polysaccharide–protein conjugates. J Exp Med 1980;152:361-76.
8. Lepow ML, Samuelson JS, Gordon LK. Safety and immunogenicity of *Haemophilus influenzae* type b–polysaccharide diphtheria toxoid conjugate vaccine in infants 9 to 15 months of age. J PEDIATR 1985;106:185-9.
9. Anderson P, Pichichero ME, Insel RA. Immunization of 2-month-old infants with protein-coupled oligosaccharides derived from the capsule of *Haemophilus influenzae* type b. J PEDIATR 1985;107:346-51.
10. Schneerson R, Robbins JB, Parke JC Jr, et al. Quantitative and qualitative analysis of serum antibodies elicited in adults by *Haemophilus influenzae* type b and pneumococcus type 6A capsular polysaccharide–tetanus toxoid conjugates. Infect Immun 1986;52:519-28.
11. Anderson PW, Pichichero ME, Insel RA, Betts R, Eby R, Smith DH. Vaccines consisting of periodate-cleaved oligosaccharides from the capsule of *Haemophilus influenzae* type b coupled to a protein carrier: structural and temporal requirements for priming in the human infant. J Immunol 1986;137:1181-6.
12. Granoff DM, Munson RS Jr. Prospects for prevention of *Haemophilus influenzae* type b disease by immunization. J Infect Dis 1986;153:448-61.
13. Lepow M, Randolph M, Cimma R, et al. Persistence of antibody and response to booster dose of *Haemophilus influenzae* type b polysaccharide–diphtheria toxoid conjugate vaccine in infants immunized at 9 to 15 months of age. J PEDIATR 1986;108:882-6.
14. Eskola J, Käyhty H, Peltola H, et al. Antibody levels achieved in infants by course of *Haemophilus influenzae* type b polysaccharide/diphtheria toxoid conjugate vaccine. Lancet 1985;1:1184-6.
15. Marburg S, Jorn D, Tolman RL, et al. Bimolecular chemistry of macromolecules: synthesis of bacterial polysaccharide conjugates with *Neisseria meningitidis* membrane protein. J Am Chem Soc 1986;108:5282-7.
16. Granoff DM, Shackelford PG, Pandey JP, Boies EG. Antibody responses to *Haemophilus influenzae* type b polysaccharide vaccine in relation to Km(1) and G2(m)23 immunoglobulin allotypes. J Infect Dis 1986;154:257-64.
17. Shackelford PG, Granoff DM, Nelson SJ, Scott MG, Smith DS, Nahm MH. Subclass distribution of human antibodies to *Haemophilus influenzae* type b capsular polysaccharide. J Immunol 1987;138:587-92.
18. Weinberg GA, Granoff DM, Nahm MH, Shackelford PG. Functional activity of different IgG subclass antibodies against type b capsular polysaccharide of *Haemophilus influenzae*. J Immunol 1986;136:4232-6.
19. Steele NP, Munson RS Jr, Granoff DM, Cummins JE, Levine RP. Antibody-dependent alternative pathway killing of *Haemophilus influenzae* type b. Infect Immun 1984;44:452-8.
20. Anderson P, Johnston RB Jr, Smith DH. Human serum activities against *Haemophilus influenzae* type b. J Clin Invest 1972;51:31-8.
21. Schneerson R, Robbins JB. Induction of serum *Haemophilus influenzae* type b capsular antibodies in adult volunteers fed cross-reacting *Escherichia coli* 075:K100:H5. N Engl J Med 1975;292:1093-6.
22. Insel RA, Anderson PW. Oligosaccharide-protein conjugate vaccines induce and prime for oligoclonal IgG antibody responses to the *Haemophilus influenzae* b capsular polysaccharide in human infants. J Exp Med 1986;163:262-9.
23. Norden CW, Michaels RH, Melish M. Effect of previous infection on antibody response of children to vaccination with capsular polysaccharide of *Haemophilus influenzae* type b. J Infect Dis 1975;132:69-74.
24. Granoff DM, Cates KL. *Haemophilus influenzae* type b polysaccharide vaccines. J PEDIATR 1985;107:330-6.

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Infectious Diseases

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IMMUNIZATION OF INFANTS WITH *Haemophilus influenzae* TYPE b (Hib) POLYSACCHARIDE-OUTER MEMBRANE PROTEIN (PS-OMP) CONJUGATE VACCINE PRIMES FOR IgG1 BOOSTER RESPONSES TO CONVENTIONAL Hib PS VACCINE. Geoffrey A. Weinberg, Menachem S. Zinhorn, Allen A. Lenoir, Paul D. Granoff, and Dan M. Granoff, Washington Univ. Sch. of Med., Dept. of Peds., St. Louis, MO.

A conjugate vaccine of Hib PS linked to an OMP of *N. meningitidis* is immunogenic in infants as young as 2-3 mo. (Lancet 1986;2:299). 43 children immunized at ages 2-17 mo. have been followed for 10-15 mo. The geo. mean serum Hib PS antibody (Ab) concentration declined but remained higher than that of unimmunized controls ($p<0.01$). 30 children were reinjected with conventional PS vaccine at ages 14-30 mo., and showed 20-50 fold average increases in total and IgG Ab. Serum Ab has persisted at high levels for >6 mo. The geo. mean Ab response of the reimmunized children was 10-fold higher than that of control children immunized with PS for the first time, and was not significantly different than that of adults immunized with PS vaccine. However, the IgG Ab responses of the adults were composed of both IgG1 and IgG2 (geo. mean G1/G2=1.7), while those of the infants were restricted to IgG1 (G1/G2=9.7, $p=0.01$). Thus, exposure to PS-OMP primes infants to an IgG1 memory Ab response to PS vaccine. In contrast, infants with Hib disease at ages 3-17 mo., and immunized with PS vaccine 7-21 mo. later did not show a memory Ab response.

PRIMED IN INFANCY	AGE AT PS VACCINE (mo.)	NO.	GEO. MEAN ANTI-Hib PS (ug/ml) PRE	POST	IgG POST
YES (PS-OMP)	14-20	19	0.73	31.8	16.7
YES (PS-OMP)	22-30	11	0.60	30.0	13.4
NO (HEALTHY)	24-30	13	0.26	2.7	0.6
NO (DISEASE)	24-27	8	0.67	2.0	ND
NO (HEALTHY)	ADULTS	12	2.83	51.0	10.4

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A Comparative Study of the Safety,Tolerance and Immunogenicity of 3 Licensed *Haemophilus influenzae* Type B Capsular Polysaccharide (Hib-PRP) Vaccines in Children.

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The efficacy of Hib-PRP vaccines in the United States has been shown to be unpredictable. We undertook a prospective randomized study to evaluate the safety, tolerance and immunogenicity of the Lederle(n=46), Connaught (n=46)and Praxis(n=55) Hib-PRP vaccines in children 18-24 mos(n=14) and 24-58 mos(n=133) of age. Total serum anti-PRP antibody (Ab) levels were measured by RIA before and 1 month following vaccination(vac). Mild systemic or local reactions were observed in 24% of the vac recipients with all 3 vaccines being tolerated equally well. Pre- and post-vac anti-PRP Ab ranged from <0.125-66.4 µg/ml and <0.125-265 µg/ml, respectively. Overall, 58% of the children had post-vac anti-PRP Ab≥1.0 µg/ml. There was no significant difference in Ab response by age or vaccine group. However, patients with pre-vac Ab ≥0.15 µg/ml were more likely to have post-vac Ab ≥1.0 µg/ml (75% vs 33% for those with pre-vac Ab <0.15 µg/ml, p<0.0001). Hib-PRP vac in children in the Los Angeles area was well tolerated but only half of the patients had anti-PRP Ab >1.0 µg/ml after vac. The low rate of Ab response especially in children with pre-vac anti-PRP Ab <0.15 µg/ml was apparent in all 3 of the vaccines studied. Alternative methods to prevent invasive Hib disease in children is warranted.

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