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October 9, 1987

Elaine C. Esber, M.D., Director
Office of Biologics Research & Review
ATT: Division of Product Certification,
HFN-825
Room 9B-05, Parklawn Building
5600 Fishers Lane
Rockville, MD 20857

REFERENCE NO. 83-087

Dear Dr. Esber:

Enclosed is a progress report on the study of P. Ogra and H. Faden,
SUNY, Buffalo.

This report covers data currently available on the results of two
primary doses of Merieux IPV. Data from Johns Hopkins are not as
advanced and are not included in this report.

Sincerely yours,

Pinya Cohen, Ph.D.
Vice President
Quality Control and
Regulatory Affairs

PC (b) (6)
87507

Attachments

CLINICAL STUDIES OF
MERIEUX IPV AT SUNY/CHILDRENS HOSPITAL, BUFFALO
PROGRESS REPORT

SUMMARY

Two doses of Merieux IPV at 2 and 4 months of age gave excellent neutralizing antibody responses at 5 months to three types of poliovirus. IPV and OPV alone produced similar levels of neutralizing antibody and IgA in the nasopharyngeal secretions. A combined schedule of IPV and OPV resulted in a strong priming effect by IPV on mucosal immune response of OPV for neutralizing antibody and IgA in the nasopharyngeal secretions and for IgA in the stool. Merieux IPV induced comparable responses in premature and full term infants. Single and two dose boosters in adults showed high anamnestic responses in all recipients and that a second dose of IPV did not increase the GMT compared to only one dose.

Introduction

The Merieux Inactivated Polio Vaccine (M-IPV) produced from continuous cell lines of Vero cells using micro-carrier culture has been extensively tested in Finland, Israel, India, Brazil, Indonesia, Mali, France, and the United States. This highly purified more potent vaccine has been shown to be safe, highly immunogenic and efficacious when used in a two-dose schedule for primary immunization followed by a booster dose.

A clinical trial at Johns Hopkins comparing M-IPV to the oral polio vaccine

currently used in the United States showed that approximately 99% of children had neutralizing antibodies to all three types of polio virus after receiving M-IPV at 2 and 4 months of age and that a significant boost in titers occurred after the third dose at 18 months of age. The titers to M-IPV for Types I and III poliovirus were superior to OPV, but equivalent for Type II when given in the same 3 dose schedule. This vaccine was made exactly as the Vero cell vaccine intended for license except the cell substrate for the Johns Hopkins trial was primary monkey kidney cells.

The Office of Biologics requested, December 1985, that 75-100 children and 25-30 adults be immunized according to the United States schedule. In response to this request clinical studies on children and adults were carried out at Childrens Hospital/State University of New York, Buffalo by Drs. H. Faden and P. Ogra. Supplemental studies on groups of children using only IPV or a combined schedule were also initiated at Johns Hopkins by Drs. McBean and Modlin at a later date.

To meet the FDA request for M-IPV licensure, data are now presented on sufficient children and adults only from Buffalo. The studies are still in progress at Buffalo and Baltimore and will be completed in late 1988.

METHODS

Details of the methods used are outlined in the protocols already submitted under IND. Merieux IPV Lots Z1102, Z1103 and A0304 were used. The general approach was to compare immunogenicity of two primary doses of M-IPV, OPV or a combined schedule in children 2 months old. Originally, a minimum of 15-20 children were to be recruited in Groups A, C, and D and 50-60 were to be recruited in Group B.

At this time, 114 children are available for analysis. The groups and vaccines are shown below:

IMMUNIZATION PLAN FOR CHILDREN

<u>GROUP</u>	<u>2 MONTHS</u>	<u>4 MONTHS</u>	<u>12 MONTHS</u>
A	OPV	OPV	OPV
B	IPV	IPV	IPV
C	IPV	OPV	OPV
D	IPV	IPV	OPV

Blood samples for antibody determinations were collected at 2 and 4 months of age just prior to administration of vaccine and one month after the second and third doses of vaccine. There are insufficient data on the booster dose given at 12 months for presentation at this time. A detectable antibody titer was considered $\geq 1:10$. GMT's were computed and also expressed in international units based on the FDA reference serum results.

Groups B and D are identical for the first two doses of vaccine, therefore, their data have been combined for this report.

The numbers of subjects in the OPV control (Group A) was small at the time of this report.

For the adult studies, 30 individuals were immunized and available for the analysis. Half received one dose (Group F1) and half received a second dose 4 weeks later (Group F2). Serum antibody titers were done prior to immunization

and 4 weeks after each dose of vaccine.

RESULTS IN CHILDREN

M-IPV induced detectable neutralizing antibodies after two doses of vaccine in 97.6% (Type I), 100% (Type II) and 97.6% (Type III) of the children (Table 1). Two doses of OPV gave 100% response for all types of poliovirus and a mixed schedule of IPV + OPV induced nearly 95% response for Types I and III and 100% response for Type II.

The GMT (Table I) was the same in all groups for Type I. For Type II two doses of IPV gave lower GMT's than OPV or a mixed schedule. The GMT obtained for Type III with a mixed schedule was significantly lower than in the other two groups.

Table 2 shows that two doses of M-IPV produced neutralizing antibodies in the nasopharyngeal secretions (NPS) to Type I poliovirus in 34%, to Type II in 53% and to Type III in 42% of the children. OPV produced neutralizing antibodies to Type I in 50%, to Type II in 70%, and to Type III in 50% of the children. The mixed schedule resulted in NPS neutralizing antibody in 47, 90 and 42% of the children, respectively. The GMT for Type II antibody in the mixed schedule was significantly higher than schedules of only IPV or only OPV indicating a priming effect by IPV on Type II OPV induced antibody.

The percentage of children with IgA antibodies in the NPS (Table 3) were generally at similar levels for M-IPV and OPV for all types of poliovirus, but were highest in children receiving the mixed schedule. The GMT of IgA was

highest in the mixed schedule suggesting IPV exerts a priming effect on a subsequent dose of OPV. The GMT for all OPV or all IPV recipients was similar for types I and II but OPV was higher for type III.

The percentage of children with detectable neutralizing antibody in the stool (Table 4) was generally 5 to 33% regardless of schedule except for Type II poliovirus with OPV (56%) and the mixed schedule (42%). The percentage of children with detectable stool neutralizing antibody for Types I & II poliovirus was low in those receiving OPV, however the number of children analyzed was small. The GMT's for OPV, IPV and mixed schedules were similar.

The percent detectable IgA levels in the stool ranged from 5 to 20% for IPV, 11 to 33% for OPV and 15 to 36% for the mixed schedule (Table 5). The mixed schedule resulted in the highest GMT's for Types II and III antibodies. IPV induced a moderate priming effect for OPV for Type II antibody.

Tables 6 and 7 summarize results of serum neutralizing antibodies in children 6 to 13 weeks of age at the time of entry into the study compared to those over 13 weeks. The percentage with detectable neutralizing antibody was the same for the two groups, however, those over 13 weeks of age had higher GMT values.

The NPS neutralizing antibody data for the two age groups (Tables 8 and 9) showed that OPV, IPV or a mixed schedule induced detectable antibody to any type of poliovirus in approximately 60% to 93% of recipients. In 6-13 week old children, combined use of IPV and OPV produced detectable Type I and II antibody in nearly

twice the number of vaccinees compared to IPV only and in nearly 50% more recipients of OPV only. The GMT for Type II was 6 times higher in children immunized with a mixed schedule than in children receiving only IPV and twice the level of children receiving only OPV. Similar NPS data was obtained for children over 13 weeks who received a combined schedule. The data from both age groups suggest a strong priming effect exerted by IPV on a subsequent dose of OPV.

Tables 10 and 11 show that neutralizing antibody in the stool specimens was highest with OPV only, intermediate with a mixed schedule and lowest with IPV only.

Detectable IgA in the NPS ranging from 50 to 100% was observed in children 6-13 weeks old and those over 13 weeks regardless of the vaccines used and virus types (Tables 12 & 13). The combined schedule of IPV and OPV gave GMT's for IgA two to nearly 10 times greater than schedules of OPV or IPV alone.

Overall 50% or less of recipients for either age group or for any vaccine schedule had detectable stool IgA antibody. The combined schedule gave percentages of detectable stool IgA twice those observed for IPV alone and GMT's approximately 50% higher (Tables 14 & 15).

Premature and full term infants developed detectable serum neutralizing antibody levels with equal frequency to two doses of M-IPV and had comparable GMT's (Table 16).

Children who had potential contact with an OPV recipient had significantly higher

GMT's for serum neutralizing antibody (Tables 17 & 18), NPS neutralizing antibody (Tables 19 & 20) and NPS IgA (Tables 21 & 22). This difference was not seen in stool neutralizing antibody levels of children who had contact with OPV compared to those whom were not exposed to OPV (Tables 23 & 24) or in stool IgA levels of the same children (Tables 25 & 26), however, this analysis is based on small numbers of children with OPV contacts.

RESULTS IN ADULTS

Nearly all adults had detectable neutralizing antibodies at the time of entry into the study so that a single dose of M-IPV ensured a 100% response (Table 27).

A single dose of M-IPV induced increases in GMT of nearly 30 fold for Type I, 50 fold for Type II and 125 fold for Type III. A second dose of IPV did not significantly increase the GMT compared to only a single dose (Table 27).

The results of neutralizing antibodies in the NPS (Table 28) show that the percent of subjects with detectable antibody was the same with one or two doses and suggests that a greater increase over base titer and higher GMT is obtained in individuals who had a lower antibody titer upon entry.

In contrast, both the percent of individuals with stool neutralizing antibody and the GMT were higher in adults receiving two doses of M-IPV compared to only one dose (Table 29).

The IgA antibody levels in the NPS and stool were similar for one or two doses although there was a higher percentage of detectable antibody in NPS of recipients of two doses compared to one dose of M-IPV (Tables 30 & 31).

There were no major differences in antibody responses whether this was exposure or nonexposure to OPV (Tables 32 & 33).

DISCUSSION

The interim results of this study have demonstrated that two doses of M-IPV given at 2 and 4 months of age produce excellent neutralizing antibody responses to all three types of poliovirus one month after the second dose. The percentage of children at 5 months of age with detectable antibody to the Vero cell vaccine is similar to and the GMT's higher than results obtained with children 6 months old in the earlier Johns Hopkins/CDC/FDA study with M-IPV produced in primary monkey kidney cells.

Two children (b) (6) immunized at the same private clinic with two doses of M-IPV formed good neutralizing antibody titers to Type II but not the Types I and III poliovirus. The Type II preimmunization titer and titer one month post 12 month booster was 320 for both children. The Types I and III titers at baseline and post booster were for (b) (6) 10 and 10 and 40 and 20, respectively, and for (b) (6) 10 and 10 and 10 and 20 respectively. Both children had normal IgG at 5 months of age and measurable tetanus antibody levels at 13 months of age. The children are apparently immunocompetent but the reasons for poor Types I and III response are unclear.

This study has shown that children given two doses of only OPV or only IPV produce similar levels of neutralizing antibodies and IgA in the NPS, however, of particular interest was the finding that a dose of IPV followed by a dose of OPV produced significantly higher levels of neutralizing antibody and IgA in the NPS than two doses of OPV or two doses of IPV. This clearly shows that the M-IPV has a strong priming effect on the mucosal antibody induced by OPV and that it is greater than the priming effect of OPV alone. This finding confirms the observation of Ogra et al with less potent, killed poliovirus vaccine. However, in the earlier studies of Ogra, priming was seen using three doses of IPV followed by an OPV booster whereas in his current study priming was seen with only a single dose of the new M-IPV. These data clearly show that IPV stimulates local immunity when used alone or in combination with OPV.

Based on stool antibody data "gut immunity" appears to be a concept applicable to both M-IPV and OPV. Both vaccines used alone or in combination gave detectable neutralizing antibody in the stool with similar GMT's. Furthermore both IPV and OPV, alone or in combination, induced stool IgA. The GMT Type II IgA was the same for IPV or OPV alone and lower for Types I and III when IPV was used alone. Of particular interest is that the highest GMT for Types II and III IgA antibodies was obtained with a combined schedule, again demonstrating that a single dose of IPV can prime a subsequent dose of OPV producing a GMT of IgA higher than either vaccine alone.

The relatively low percentage of children (approximately 50%) with detectable

stool neutralizing antibodies and detectable IgA antibodies (30%) is surprising in view of the "gut immunity" usually attributed to OPV. In fact, the GMT's for IPV and OPV were similar for Types I & III neutralizing antibody and for Type II IgA antibody.

Because nearly 30% of the infants receiving two doses of IPV were premature births it was possible to compare responses to full term infants. Although full term infants had higher maternal antibody levels, as expected, both premature and full term infants had similar percentages of responders and comparable GMT's after two doses of IPV.

The studies in adults showed that a single dose of M-IPV produced booster responses of very high titers of neutralizing antibodies and that a second dose is unnecessary. However, stool neutralizing antibody levels were higher in adults receiving a second dose of IPV.

TABLE 1

Polio Protocol 01

SERUM NEUTRALIZING ANTIBODIES

PERCENT WITH DETECTABLE ANTIBODY TITER

TYPE	2 Months		4 Months		5 Months	
I	PLAN A	9/10 (90.0)	7/10 (70.0)	10/10 (100.0)		
	PLAN BD	66/85 (77.6)	53/84 (63.1)	81/83 (97.6)		
	PLAN C	15/19 (78.9)	16/19 (84.2)	18/19 (94.7)		
II	PLAN A	10/10 (100.0)	10/10 (100.0)	10/10 (100.0)		
	PLAN BD	72/85 (84.7)	80/84 (95.2)	83/83 (100.0)		
	PLAN C	18/19 (94.7)	19/19 (100.0)	19/19 (100.0)		
III	PLAN A	9/10 (90.0)	10/10 (100.0)	10/10 (100.0)		
	PLAN BD	62/85 (72.9)	68/84 (81.0)	81/83 (97.6)		
	PLAN C	14/19 (73.7)	15/19 (78.9)	18/19 (94.7)		
ANY	PLAN A	10/10 (100.0)	10/10 (100.0)	10/10 (100.0)		
	PLAN BD	83/85 (97.6)	84/85 (98.8)	83/85 (97.6)		
	PLAN C	18/19 (94.7)	19/19 (100.0)	19/19 (100.0)		

GEOMETRIC MEAN TITERS

TYPE	2 Months		4 Months		5 Months		
	N	GMT	N	GMT	N	GMT	
I	PLAN A	10	25.81	10	28.35	10	259.92
	PLAN BD	85	17.11	84	7.94	83	251.92
	PLAN C	19	19.08	19	12.46	19	263.53
II	PLAN A	10	60.63	10	519.84	10	3151.73
	PLAN BD	85	33.11	84	33.01	83	857.28
	PLAN C	19	79.07	19	38.57	19	2212.41
III	PLAN A	10	27.66	10	52.78	10	735.17
	PLAN BD	85	13.37	84	17.65	83	889.04
	PLAN C	19	10.14	19	17.74	19	131.77

GEOMETRIC MEAN TITERS IN INTERNATIONAL UNITS

TYPE	2 Months		4 Months		5 Months		
	N	GMT	N	GMT	N	GMT	
I	PLAN A	10	0.30	10	0.33	10	3.03
	PLAN BD	85	0.20	84	0.09	83	2.94
	PLAN C	19	0.22	19	0.15	19	3.08
II	PLAN A	10	0.34	10	2.94	10	17.81
	PLAN BD	85	0.19	84	0.19	83	4.84
	PLAN C	19	0.45	19	0.22	19	12.50
III	PLAN A	10	0.28	10	0.53	10	7.35
	PLAN BD	85	0.13	84	0.18	83	8.89
	PLAN C	19	0.10	19	0.18	19	1.32

NASOPHARYNGEAL SECRETIONS NEUTRALIZING ANTIBODIES

PERCENT WITH DETECTABLE ANTIBODY TITER

TYPE	2 Months		4 Months		5 Months	
I	PLAN A	0/ . (0.0)	3/ 9 (33.3)	5/10 (50.0)		
	PLAN BD	0/ . (0.0)	1/82 (1.2)	27/79 (34.2)		
	PLAN C	0/ . (0.0)	0/18 (0.0)	9/19 (47.4)		
II	PLAN A	0/ . (0.0)	7/ 9 (77.8)	7/10 (70.0)		
	PLAN BD	0/ . (0.0)	1/82 (1.2)	42/79 (53.2)		
	PLAN C	0/ . (0.0)	2/18 (11.1)	17/19 (89.5)		
III	PLAN A	0/ . (0.0)	2/ 9 (22.2)	5/10 (50.0)		
	PLAN BD	0/ . (0.0)	2/82 (2.4)	33/79 (41.8)		
	PLAN C	0/ . (0.0)	1/18 (5.6)	8/19 (42.1)		
ANY	PLAN A	0/ . (0.0)	7/10 (70.0)	7/10 (70.0)		
	PLAN BD	0/ . (0.0)	3/85 (3.5)	49/85 (57.6)		
	PLAN C	0/ . (0.0)	3/19 (15.8)	17/19 (89.5)		

GEOMETRIC MEAN TITERS

TYPE	2 Months		4 Months		5 Months		
	N	GMT	N	GMT	N	GMT	
I	PLAN A	0	.	9	1.71	10	3.03
	PLAN BD	6	1.00	82	1.02	79	1.90
	PLAN C	0	.	18	0.00	19	3.10
II	PLAN A	0	.	9	8.00	10	9.19
	PLAN BD	6	1.00	82	1.03	79	3.30
	PLAN C	0	.	18	1.17	19	19.20
III	PLAN A	0	.	9	2.00	10	5.28
	PLAN BD	6	1.00	82	1.03	79	2.82
	PLAN C	0	.	18	1.08	19	2.40

GEOMETRIC MEAN TITERS IN INTERNATIONAL UNITS

TYPE	2 Months		4 Months		5 Months		
	N	GMT	N	GMT	N	GMT	
I	PLAN A	0	.	9	0.02	10	0.04
	PLAN BD	6	0.01	82	0.01	79	0.02
	PLAN C	0	.	18	0.00	19	0.04
II	PLAN A	0	.	9	0.05	10	0.05
	PLAN BD	6	0.01	82	0.01	79	0.02
	PLAN C	0	.	18	0.01	19	0.11
III	PLAN A	0	.	9	0.02	10	0.05
	PLAN BD	6	0.01	82	0.01	79	0.03
	PLAN C	0	.	18	0.01	19	0.02

NASOPHARYNGEAL SECRETIONS (b) (4) IgA ANTIBODIES

PERCENT WITH DETECTABLE ANTIBODY TITER

TYPE	2 Months		4 Months		5 Months	
I	PLAN A	0/ . (0.0)	7/ 9 (77.8)	6/10 (60.0)		
	PLAN BD	0/ . (0.0)	33/82 (40.2)	45/80 (56.3)		
	PLAN C	0/ . (0.0)	9/18 (50.0)	15/19 (78.9)		
II	PLAN A	0/ . (0.0)	7/ 9 (77.8)	6/10 (60.0)		
	PLAN BD	0/ . (0.0)	33/82 (40.2)	49/80 (61.3)		
	PLAN C	0/ . (0.0)	9/18 (50.0)	16/19 (84.2)		
III	PLAN A	0/ . (0.0)	7/ 9 (77.8)	8/10 (80.0)		
	PLAN BD	0/ . (0.0)	34/82 (41.5)	49/80 (61.3)		
	PLAN C	0/ . (0.0)	10/18 (55.6)	17/19 (89.5)		
ANY	PLAN A	0/ . (0.0)	7/10 (70.0)	8/10 (80.0)		
	PLAN BD	0/ . (0.0)	39/85 (45.9)	53/85 (62.4)		
	PLAN C	0/ . (0.0)	10/19 (52.6)	17/19 (89.5)		

GEOMETRIC MEAN TITERS

TYPE	2 Months		4 Months		5 Months	
	N	GMT	N	GMT	N	GMT
I	PLAN A	0	9	8.63	10	7.46
	PLAN BD	6	82	3.13	80	5.81
	PLAN C	0	18	4.50	19	14.87
II	PLAN A	0	9	8.00	10	7.46
	PLAN BD	6	82	3.29	80	6.01
	PLAN C	0	18	4.16	19	16.59
III	PLAN A	0	9	9.33	10	13.93
	PLAN BD	6	82	3.32	80	6.39
	PLAN C	0	18	5.66	19	21.42

STOOL SPECIMENS NEUTRALIZING ANTIBODIES

PERCENT WITH DETECTABLE ANTIBODY TITER

TYPE	2 Months		4 Months		5 Months	
I	PLAN A	0/ . (0.0)	1/10 (10.0)	1/ 9 (11.1)		
	PLAN BD	0/ . (0.0)	0/75 (0.0)	4/78 (5.1)		
	PLAN C	0/ . (0.0)	0/18 (0.0)	3/19 (15.8)		
II	PLAN A	0/ . (0.0)	4/10 (40.0)	5/ 9 (55.6)		
	PLAN BD	0/ . (0.0)	3/75 (4.0)	9/78 (11.5)		
	PLAN C	0/ . (0.0)	0/18 (0.0)	8/19 (42.1)		
III	PLAN A	0/ . (0.0)	1/10 (10.0)	3/ 9 (33.3)		
	PLAN BD	0/ . (0.0)	2/75 (2.7)	6/78 (7.7)		
	PLAN C	0/ . (0.0)	0/18 (0.0)	2/19 (10.5)		
ANY	PLAN A	0/ . (0.0)	4/10 (40.0)	5/10 (50.0)		
	PLAN BD	0/ . (0.0)	4/85 (4.7)	16/85 (18.8)		
	PLAN C	0/ . (0.0)	0/18 (0.0)	8/19 (42.1)		

GEOMETRIC MEAN TITERS

TYPE	2 Months		4 Months		5 Months		
	N	GMT	N	GMT	N	GMT	
I	PLAN A	0	.	10	1.15	9	1.17
	PLAN BD	5	0.00	75	0.00	78	1.10
	PLAN C	0	.	18	0.00	19	1.44
II	PLAN A	0	.	10	3.73	9	5.04
	PLAN BD	5	0.00	75	1.08	78	1.22
	PLAN C	0	.	18	0.00	19	2.49
III	PLAN A	0	.	10	1.15	9	1.59
	PLAN BD	5	0.00	75	1.06	78	1.16
	PLAN C	0	.	18	0.00	19	1.29

GEOMETRIC MEAN TITERS IN INTERNATIONAL UNITS

TYPE	2 Months		4 Months		5 Months		
	N	GMT	N	GMT	N	GMT	
I	PLAN A	0	.	10	0.01	9	0.01
	PLAN BD	5	0.00	75	0.00	78	0.01
	PLAN C	0	.	18	0.00	19	0.02
II	PLAN A	0	.	10	0.02	9	0.03
	PLAN BD	5	0.00	75	0.01	78	0.01
	PLAN C	0	.	18	0.00	19	0.01
III	PLAN A	0	.	10	0.01	9	0.02
	PLAN BD	5	0.00	75	0.01	78	0.01
	PLAN C	0	.	18	0.00	19	0.01

STOOL SPECIMENS (b) (4) IgA ANTIBODIES

PERCENT WITH DETECTABLE ANTIBODY TITER

TYPE	2 Months		4 Months		5 Months	
I	PLAN A	0/ . (0.0)	2/10 (20.0)	3/ 9 (33.3)		
	PLAN BD	0/ . (0.0)	5/74 (6.8)	4/77 (5.2)		
	PLAN C	0/ . (0.0)	1/18 (5.6)	3/19 (15.8)		
II	PLAN A	0/ . (0.0)	1/10 (10.0)	1/ 9 (11.1)		
	PLAN BD	0/ . (0.0)	9/74 (12.2)	8/77 (10.4)		
	PLAN C	0/ . (0.0)	3/18 (16.7)	7/19 (36.8)		
III	PLAN A	0/ . (0.0)	3/10 (30.0)	3/ 9 (33.3)		
	PLAN BD	0/ . (0.0)	8/74 (10.8)	15/77 (19.5)		
	PLAN C	0/ . (0.0)	3/18 (16.7)	7/19 (36.8)		
ANY	PLAN A	0/ . (0.0)	3/10 (30.0)	3/10 (30.0)		
	PLAN BD	0/ . (0.0)	13/85 (15.3)	16/85 (18.8)		
	PLAN C	0/ . (0.0)	4/19 (21.1)	7/19 (36.8)		

GEOMETRIC MEAN TITERS

TYPE	2 Months		4 Months		5 Months	
	N	GMT	N	GMT	N	GMT
I	PLAN A	0	10	1.52	9	2.00
	PLAN BD	6	74	1.17	77	1.12
	PLAN C	0	18	1.13	19	1.39
II	PLAN A	0	10	1.23	9	1.36
	PLAN BD	6	74	1.35	77	1.29
	PLAN C	0	18	1.47	19	2.23
III	PLAN A	0	10	1.87	9	2.33
	PLAN BD	6	74	1.30	77	1.55
	PLAN C	0	18	1.53	19	2.49

TABLE 6

Polio Protocol 01

SERUM NEUTRALIZING ANTIBODIES
AGE 6 - 13 WEEKS

PERCENT WITH DETECTABLE ANTIBODY TITER

TYPE	2 Months		4 Months		5 Months	
I	Plan A	9/10 (90.0)	7/10 (70.0)	10/10 (100.0)	10/10 (100.0)	10/10 (100.0)
	Plan BD	58/70 (82.9)	43/69 (62.3)	66/68 (97.1)	66/68 (97.1)	66/68 (97.1)
	Plan C	13/15 (86.7)	12/15 (80.0)	14/15 (93.3)	14/15 (93.3)	14/15 (93.3)
II	Plan A	10/10 (100.0)	10/10 (100.0)	10/10 (100.0)	10/10 (100.0)	10/10 (100.0)
	Plan BD	64/70 (91.4)	56/69 (95.7)	68/68 (100.0)	68/68 (100.0)	68/68 (100.0)
	Plan C	14/15 (93.3)	15/15 (100.0)	15/15 (100.0)	15/15 (100.0)	15/15 (100.0)
III	Plan A	9/10 (90.0)	10/10 (100.0)	10/10 (100.0)	10/10 (100.0)	10/10 (100.0)
	Plan BD	53/70 (75.7)	55/69 (79.7)	66/68 (97.1)	66/68 (97.1)	66/68 (97.1)
	Plan C	11/15 (73.3)	12/15 (80.0)	14/15 (93.3)	14/15 (93.3)	14/15 (93.3)
ANY	Plan A	10/10 (100.0)	10/10 (100.0)	10/10 (100.0)	10/10 (100.0)	10/10 (100.0)
	Plan BD	70/70 (100.0)	69/70 (98.6)	68/70 (97.1)	68/70 (97.1)	68/70 (97.1)
	Plan C	14/15 (93.3)	15/15 (100.0)	15/15 (100.0)	15/15 (100.0)	15/15 (100.0)

GEOMETRIC MEAN TITERS

TYPE	2 Months		4 Months		5 Months		
	N	GMT	N	GMT	N	GMT	
I	Plan A	10	25.81	10	28.35	10	259.92
	Plan BD	70	22.55	69	7.75	68	213.62
	Plan C	15	22.30	15	9.56	15	228.14
II	Plan A	10	60.63	10	519.84	10	3151.73
	Plan BD	70	48.79	69	31.44	68	666.63
	Plan C	15	94.82	15	40.00	15	2228.61
III	Plan A	10	27.66	10	52.78	10	735.17
	Plan BD	70	14.94	69	16.77	68	748.45
	Plan C	15	9.87	15	15.90	15	78.82

GEOMETRIC MEAN TITERS IN INTERNATIONAL UNITS

TYPE	2 Months		4 Months		5 Months		
	N	GMT	N	GMT	N	GMT	
I	Plan A	10	0.30	10	0.33	10	3.03
	Plan BD	70	0.26	69	0.09	68	2.49
	Plan C	15	0.26	15	0.11	15	2.66
II	Plan A	10	0.34	10	2.94	10	17.81
	Plan BD	70	0.28	69	0.18	68	3.77
	Plan C	15	0.54	15	0.23	15	12.59
III	Plan A	10	0.28	10	0.53	10	7.35
	Plan BD	70	0.15	69	0.17	68	7.48
	Plan C	15	0.10	15	0.16	15	0.79

TABLE 7

Polio Protocol 01

SERUM NEUTRALIZING ANTIBODIES
AGE > 13 WEEKS

PERCENT WITH DETECTABLE ANTIBODY TITER

TYPE	2 Months		4 Months		5 Months	
I	Plan BD	8/15 (53.3)	10/15 (66.7)	15/15 (100.0)	15/15 (100.0)	15/15 (100.0)
	Plan C	2/ 4 (50.0)	4/ 4 (100.0)	4/ 4 (100.0)	4/ 4 (100.0)	4/ 4 (100.0)
II	Plan BD	8/15 (53.3)	14/15 (93.3)	15/15 (100.0)	15/15 (100.0)	15/15 (100.0)
	Plan C	4/ 4 (100.0)	4/ 4 (100.0)	4/ 4 (100.0)	4/ 4 (100.0)	4/ 4 (100.0)
III	Plan BD	9/15 (60.0)	13/15 (86.7)	15/15 (100.0)	15/15 (100.0)	15/15 (100.0)
	Plan C	3/ 4 (75.0)	3/ 4 (75.0)	3/ 4 (75.0)	4/ 4 (100.0)	4/ 4 (100.0)
ANY	Plan BD	13/15 (86.7)	15/15 (100.0)	15/15 (100.0)	15/15 (100.0)	15/15 (100.0)
	Plan C	4/ 4 (100.0)	4/ 4 (100.0)	4/ 4 (100.0)	4/ 4 (100.0)	4/ 4 (100.0)

GEOMETRIC MEAN TITERS

TYPE	2 Months		4 Months		5 Months		
	N	GMT	N	GMT	N	GMT	
I	Plan BD	15	4.72	15	8.86	15	531.99
	Plan C	4	10.64	4	33.64	4	452.55
II	Plan BD	15	5.42	15	41.27	15	2681.07
	Plan C	4	40.00	4	33.64	4	2152.69
III	Plan BD	15	7.96	15	22.30	15	1940.12
	Plan C	4	11.25	4	26.75	4	905.10

GEOMETRIC MEAN TITERS IN INTERNATIONAL UNITS

TYPE	2 Months		4 Months		5 Months		
	N	GMT	N	GMT	N	GMT	
I	Plan BD	15	0.06	15	0.10	15	6.21
	Plan C	4	0.12	4	0.39	4	5.28
II	Plan BD	15	0.03	15	0.23	15	15.15
	Plan C	4	0.23	4	0.19	4	12.16
III	Plan BD	15	0.08	15	0.22	15	19.40
	Plan C	4	0.11	4	0.27	4	9.05

TABLE 8

Polio Protocol 01

NASOPHARYNGEAL SECRETIONS NEUTRALIZING ANTIBODIES
AGE 6 - 13 WEEKS

PERCENT WITH DETECTABLE ANTIBODY TITER

TYPE	2 Months		4 Months		5 Months	
I	Plan A	0/ . (0.0)	3/ 9 (33.3)	5/10 (50.0)		
	Plan BD	0/ . (0.0)	1/67 (1.5)	23/65 (35.4)		
	Plan C	0/ . (0.0)	0/67 (0.0)	8/15 (53.3)		
II	Plan A	0/ . (0.0)	7/ 9 (77.8)	7/10 (70.0)		
	Plan BD	0/ . (0.0)	1/67 (1.5)	34/65 (52.3)		
	Plan C	0/ . (0.0)	2/14 (14.3)	14/15 (93.3)		
III	Plan A	0/ . (0.0)	2/ 9 (22.2)	5/10 (50.0)		
	Plan BD	0/ . (0.0)	2/67 (3.0)	29/65 (44.6)		
	Plan C	0/ . (0.0)	1/14 (7.1)	6/15 (40.0)		
ANY	Plan A	0/ . (0.0)	7/10 (70.0)	7/10 (70.0)		
	Plan BD	0/ . (0.0)	3/70 (4.3)	41/70 (58.6)		
	Plan C	0/ . (0.0)	3/15 (20.0)	14/15 (93.3)		

GEOMETRIC MEAN TITERS

TYPE	2 Months		4 Months		5 Months		
	N	GMT	N	GMT	N	GMT	
	Plan A	0	.	9	1.71	10	3.03
I	Plan BD	1	1.00	67	1.02	65	1.96
	Plan C	0	1.00	14	1.00	15	3.82
	Plan A	0	.	9	8.00	10	9.19
II	Plan BD	1	1.00	67	1.03	65	3.23
	Plan C	0	1.00	14	1.22	15	18.38
	Plan A	0	.	9	2.00	10	5.28
III	Plan BD	1	1.00	67	1.04	65	3.13
	Plan C	0	1.00	14	1.10	15	2.19

GEOMETRIC MEAN TITERS IN INTERNATIONAL UNITS

TYPE	2 Months		4 Months		5 Months		
	N	GMT	N	GMT	N	GMT	
Plan A	0	.	9	0.02	10	0.04	
I	Plan BD	1	0.01	67	0.01	65	0.02
	Plan C	0	0.01	14	0.01	15	0.04
	Plan A	0	.	9	0.05	10	0.05
II	Plan BD	1	0.01	67	0.01	65	0.02
	Plan C	0	0.01	14	0.01	15	0.10
	Plan A	0	.	9	0.02	10	0.05
III	Plan BD	1	0.01	67	0.01	65	0.03
	Plan C	0	0.01	14	0.01	15	0.02

NASOPHARYNGEAL SECRETIONS NEUTRALIZING ANTIBODIES
AGE > 13 WEEKS

PERCENT WITH DETECTABLE ANTIBODY TITER

TYPE		2 Months		4 Months		5 Months	
I	Plan BD	0/	(0.0)	0/	(0.0)	4/14	(28.6)
	Plan C	0/	(0.0)	0/	(0.0)	1/ 4	(25.0)
II	Plan BD	0/	(0.0)	0/	(0.0)	8/14	(57.1)
	Plan C	0/	(0.0)	0/	(0.0)	3/ 4	(75.0)
III	Plan BD	0/	(0.0)	0/	(0.0)	4/14	(28.6)
	Plan C	0/	(0.0)	0/	(0.0)	2/ 4	(50.0)
ANY	Plan BD	0/	(0.0)	0/	(0.0)	8/15	(53.3)
	Plan C	0/	(0.0)	0/	(0.0)	3/ 4	(75.0)

GEOMETRIC MEAN TITERS

TYPE		2 Months		4 Months		5 Months	
		N	GMT	N	GMT	N	GMT
I	Plan BD	5	1.00	15	1.00	14	1.64
	Plan C	0	1.00	4	1.00	4	1.41
II	Plan BD	5	1.00	15	1.00	14	3.62
	Plan C	0	1.00	4	1.00	4	22.63
III	Plan BD	5	1.00	15	1.00	14	1.72
	Plan C	0	1.00	4	1.00	4	3.36

GEOMETRIC MEAN TITERS IN INTERNATIONAL UNITS

TYPE		2 Months		4 Months		5 Months	
		N	GMT	N	GMT	N	GMT
I	Plan BD	5	0.01	15	0.01	14	0.02
	Plan C	0	0.01	4	0.01	4	0.02
II	Plan BD	5	0.01	15	0.01	14	0.02
	Plan C	0	0.01	4	0.01	4	0.13
III	Plan BD	5	0.01	15	0.01	14	0.02
	Plan C	0	0.01	4	0.01	4	0.03

TABLE 10

Polio Protocol 01

STOOL SPECIMENS NEUTRALIZING ANTIBODIES
AGE 6 - 13 WEEKS

PERCENT WITH DETECTABLE ANTIPODY TITER

TYPE	2 Months		4 Months		5 Months	
	N	GMT	N	GMT	N	GMT
I	Plan A	0/ . (0.0)	1/10 (10.0)		1/ 9 (11.1)	
	Plan BD	0/ . (0.0)	0/10 (0.0)		4/63 (6.3)	
	Plan C	0/ . (0.0)	0/ . (0.0)		2/15 (13.3)	
II	Plan A	0/ . (0.0)	4/10 (40.0)		5/ 9 (55.6)	
	Plan BD	0/ . (0.0)	3/61 (4.9)		8/63 (12.7)	
	Plan C	0/ . (0.0)	0/61 (0.0)		5/15 (33.3)	
III	Plan A	0/ . (0.0)	1/10 (10.0)		3/ 9 (33.3)	
	Plan BD	0/ . (0.0)	2/61 (3.3)		5/63 (7.9)	
	Plan C	0/ . (0.0)	0/61 (0.0)		1/15 (6.7)	
ANY	Plan A	0/ . (0.0)	4/10 (40.0)		5/10 (50.0)	
	Plan BD	0/ . (0.0)	4/70 (5.7)		14/70 (20.0)	
	Plan C	0/ . (0.0)	0/70 (0.0)		5/15 (33.3)	

GEOMETRIC MEAN TITERS

TYPE	2 Months		4 Months		5 Months	
	N	GMT	N	GMT	N	GMT
I	Plan A	0	10	1.15	9	1.17
	Plan BD	1	61	1.00	63	1.13
	Plan C	0	14	1.00	15	1.45
II	Plan A	0	10	3.73	9	5.04
	Plan BD	1	61	1.10	63	1.25
	Plan C	0	14	1.00	15	2.41
III	Plan A	0	10	1.15	9	1.59
	Plan BD	1	61	1.07	63	1.17
	Plan C	0	14	1.00	15	1.26

GEOMETRIC MEAN TITERS IN INTERNATIONAL UNITS

TYPE	2 Months		4 Months		5 Months	
	N	GMT	N	GMT	N	GMT
I	Plan A	0	10	0.01	9	0.01
	Plan BD	1	61	0.01	63	0.01
	Plan C	0	14	0.01	15	0.02
II	Plan A	0	10	0.02	9	0.03
	Plan BD	1	61	0.01	63	0.01
	Plan C	0	14	0.01	15	0.01
III	Plan A	0	10	0.01	9	0.02
	Plan BD	1	61	0.01	63	0.01
	Plan C	0	14	0.01	15	0.01

TABLE 11

Polio Protocol 01

STOOL SPECIMENS NEUTRALIZING ANTIBODIES
AGE > 13 WEEKS

PERCENT WITH DETECTABLE ANTIBODY TITER

TYPE	2 Months		4 Months		5 Months	
I	Plan BD	0/ . (0.0)	0/ . (0.0)	0/ . (0.0)	0/ . (0.0)	
	Plan C	0/ . (0.0)	0/ . (0.0)	0/ . (0.0)	1/ 4 (25.0)	
II	Plan BD	0/ . (0.0)	0/ . (0.0)	0/ . (0.0)	1/15 (6.7)	
	Plan C	0/ . (0.0)	0/ . (0.0)	0/ . (0.0)	3/ 4 (75.0)	
III	Plan BD	0/ . (0.0)	0/ . (0.0)	0/ . (0.0)	1/15 (6.7)	
	Plan C	0/ . (0.0)	0/ . (0.0)	0/ . (0.0)	1/ 4 (25.0)	
ANY	Plan BD	0/ . (0.0)	0/ . (0.0)	0/ . (0.0)	2/15 (13.3)	
	Plan C	0/ . (0.0)	0/ . (0.0)	0/ . (0.0)	3/ 4 (75.0)	

GEOMETRIC MEAN TITERS

TYPE	2 Months		4 Months		5 Months		
	N	GMT	N	GMT	N	GMT	
I	Plan BD	4	1.00	14	1.00	15	1.00
	Plan C	0	1.00	4	1.00	4	1.41
II	Plan BD	4	1.00	14	1.00	15	1.10
	Plan C	0	1.00	4	1.00	4	2.83
III	Plan BD	4	1.00	14	1.00	15	1.15
	Plan C	0	1.00	4	1.00	4	1.41

GEOMETRIC MEAN TITERS IN INTERNATIONAL UNITS

TYPE	2 Months		4 Months		5 Months		
	N	GMT	N	GMT	N	GMT	
I	Plan BD	4	0.01	14	0.01	15	0.01
	Plan C	0	0.01	4	0.01	4	0.02
II	Plan BD	4	0.01	14	0.01	15	0.01
	Plan C	0	0.01	4	0.01	4	0.02
III	Plan BD	4	0.01	14	0.01	15	0.01
	Plan C	0	0.01	4	0.01	4	0.01

TABLE 12

Polio Protocol v1

NASOPHARYNGEAL SECRETIONS (b) (4) IgA ANTIBODIES
AGE 6 - 13 WEEKS

PERCENT WITH DETECTABLE ANTIBODY TITER

TYPE	2 Months		4 Months		5 Months	
	N	GMT	N	GMT	N	GMT
I	Plan A	0/ . (0.0)	7/ 9 (77.8)	6/10 (60.0)		
	Plan BD	0/ . (0.0)	30/67 (44.8)	38/66 (57.6)		
	Plan C	0/ . (0.0)	8/14 (57.1)	12/15 (80.0)		
II	Plan A	0/ . (0.0)	7/ 9 (77.8)	6/10 (60.0)		
	Plan BD	0/ . (0.0)	31/67 (46.3)	41/66 (62.1)		
	Plan C	0/ . (0.0)	8/14 (57.1)	12/15 (80.0)		
III	Plan A	0/ . (0.0)	7/ 9 (77.8)	8/10 (80.0)		
	Plan BD	0/ . (0.0)	31/67 (46.3)	40/66 (60.6)		
	Plan C	0/ . (0.0)	9/14 (64.3)	13/15 (86.7)		
ANY	Plan A	0/ . (0.0)	7/10 (70.0)	8/10 (80.0)		
	Plan BD	0/ . (0.0)	36/70 (51.4)	44/70 (62.9)		
	Plan C	0/ . (0.0)	9/15 (60.0)	13/15 (86.7)		

GEOMETRIC MEAN TITERS

TYPE	2 Months		4 Months		5 Months	
	N	GMT	N	GMT	N	GMT
I	Plan A	0	9	0.00	10	7.46
	Plan BD	1	67	3.46	66	6.09
	Plan C	0	14	0.00	15	14.59
II	Plan A	0	9	8.00	10	7.46
	Plan BD	1	67	3.96	66	6.48
	Plan C	0	14	5.38	15	13.30
III	Plan A	0	9	9.33	10	13.93
	Plan BD	1	67	3.88	66	6.69
	Plan C	0	14	7.61	15	19.25

TABLE 13

Polio Protocol 01

NASOPHARYNGEAL SECRETIONS (b) (4) IgA ANTIBODIES
AGE > 13 WEEKS

PERCENT WITH DETECTABLE ANTIBODY TITER

TYPE	2 Months		4 Months		5 Months	
I	Plan BD	0/ . (0.0)	3/15 (20.0)	7/14 (50.0)		
	Plan C	0/ . (0.0)	1/ 4 (25.0)	3/ 4 (75.0)		
II	Plan BD	0/ . (0.0)	2/15 (13.3)	8/14 (57.1)		
	Plan C	0/ . (0.0)	1/ 4 (25.0)	4/ 4 (100.0)		
III	Plan BD	0/ . (0.0)	3/15 (20.0)	9/14 (64.3)		
	Plan C	0/ . (0.0)	1/ 4 (25.0)	4/ 4 (100.0)		
ANY	Plan BD	0/ . (0.0)	3/15 (20.0)	9/15 (60.0)		
	Plan C	0/ . (0.0)	1/ 4 (25.0)	4/ 4 (100.0)		

GEOMETRIC MEAN TITERS

TYPE	2 Months		4 Months		5 Months		
	N	GMT	N	GMT	N	GMT	
I	Plan BD	5	1.00	15	2.00	14	4.64
	Plan C	0	1.00	4	0.00	4	16.00
II	Plan BD	5	1.00	15	1.45	14	4.20
	Plan C	0	1.00	4	1.68	4	38.05
III	Plan BD	5	1.00	15	1.66	14	5.12
	Plan C	0	1.00	4	2.00	4	32.00

TABLE 14

Polio Protocol 01

STOOL SPECIMENS (b) (4) IgA ANTIBODIES
AGE 6 - 13 WEEKS

PERCENT WITH DETECTABLE ANTIBODY TITER

TYPE		2 Months		4 Months		5 Months	
I	Plan A	0/ .	(0.0)	2/10	(20.0)	3/ 9	(33.3)
	Plan BD	0/ .	(0.0)	4/60	(6.7)	4/63	(6.3)
	Plan C	0/ .	(0.0)	1/14	(7.1)	2/15	(13.3)
II	Plan A	0/ .	(0.0)	1/10	(10.0)	1/ 9	(11.1)
	Plan BD	0/ .	(0.0)	6/60	(10.0)	7/63	(11.1)
	Plan C	0/ .	(0.0)	3/14	(21.4)	5/15	(33.3)
III	Plan A	0/ .	(0.0)	3/10	(30.0)	3/ 9	(33.3)
	Plan BD	0/ .	(0.0)	5/60	(8.3)	11/63	(17.5)
	Plan C	0/ .	(0.0)	3/14	(21.4)	5/15	(33.3)
ANY	Plan A	0/ .	(0.0)	3/10	(30.0)	3/10	(30.0)
	Plan BD	0/ .	(0.0)	9/70	(12.9)	12/70	(17.1)
	Plan C	0/ .	(0.0)	4/15	(26.7)	5/15	(33.3)

GEOMETRIC MEAN TITERS

TYPE		2 Months		4 Months		5 Months	
		N	GMT	N	GMT	N	GMT
I	Plan A	0	.	10	0.00	9	2.00
	Plan BD	2	1.00	60	1.18	63	1.15
	Plan C	0	1.00	14	0.00	15	1.32
II	Plan A	0	.	10	1.23	9	1.36
	Plan BD	2	1.00	60	1.27	63	1.30
	Plan C	0	1.00	14	1.64	15	2.09
III	Plan A	0	.	10	1.87	9	2.33
	Plan BD	2	1.00	60	1.22	63	1.50
	Plan C	0	1.00	14	1.72	15	2.30

TABLE 15

Polio Protocol 01

STOOL SPECIMENS (b) (4) IgA ANTIBODIES
AGE > 13 WEEKS

PERCENT WITH DETECTABLE ANTIBODY TITER

TYPE	2 Months		4 Months		5 Months	
I	Plan BD	0/ . (0.0)	1/14 (7.1)	0/ . (0.0)	0/ . (0.0)	1/ 4 (25.0)
	Plan C	0/ . (0.0)	0/14 (0.0)			
II	Plan BD	0/ . (0.0)	3/14 (21.4)	1/14 (7.1)		
	Plan C	0/ . (0.0)	0/14 (0.0)	2/ 4 (50.0)		
III	Plan BD	0/ . (0.0)	3/14 (21.4)	4/14 (28.6)		
	Plan C	0/ . (0.0)	0/14 (0.0)	2/ 4 (50.0)		
ANY	Plan BD	0/ . (0.0)	4/15 (26.7)	4/15 (26.7)		
	Plan C	0/ . (0.0)	0/15 (0.0)	2/ 4 (50.0)		

GEOMETRIC MEAN TITERS

TYPE	2 Months		4 Months		5 Months		
	N	GMT	N	GMT	N	GMT	
I	Plan BD	4	1.00	14	1.16	14	1.00
	Plan C	0	1.00	4	0.00	4	1.68
II	Plan BD	4	1.00	14	1.72	14	1.22
	Plan C	0	1.00	4	1.00	4	2.83
III	Plan BD	4	1.00	14	1.72	14	1.81
	Plan C	0	1.00	4	1.00	4	3.36

TABLE 16

Polio Protocol 01

SERUM NEUTRALIZING ANTIBODIES
PLAN BD

PERCENT WITH DETECTABLE ANTIBODY TITER

TYPE	2 Months		4 Months		5 Months	
I	PREME	12/19 (63.2)	8/19 (42.1)	19/19 (100.0)		
	TERM	54/66 (81.8)	45/65 (69.2)	62/64 (96.9)		
II	PREME	16/19 (84.2)	16/19 (84.2)	19/19 (100.0)		
	TERM	56/66 (84.8)	64/65 (98.5)	64/64 (100.0)		
III	PREME	15/19 (78.9)	14/19 (73.7)	19/19 (100.0)		
	TERM	47/66 (71.2)	54/65 (83.1)	62/64 (96.9)		
ANY	PREME	18/19 (94.7)	19/19 (100.0)	19/19 (100.0)		
	TERM	65/66 (98.5)	65/66 (98.5)	64/66 (97.0)		

GEOMETRIC MEAN TITERS

TYPE	2 Months		4 Months		5 Months		
	N	GMT	N	GMT	N	GMT	
I	PREME	19	6.88	19	4.39	19	308.54
	TERM	66	22.25	65	9.44	64	237.21
II	PREME	19	20.02	19	24.92	19	1147.31
	TERM	66	38.27	65	35.83	64	786.23
III	PREME	19	14.78	19	15.15	19	888.74
	TERM	66	12.99	65	18.45	64	889.13

GEOMETRIC MEAN TITERS IN INTERNATIONAL UNITS

TYPE	2 Months		4 Months		5 Months		
	N	GMT	N	GMT	N	GMT	
I	PREME	19	0.08	19	0.05	19	3.60
	TERM	66	0.26	65	0.11	64	2.77
II	PREME	19	0.11	19	0.14	19	6.48
	TERM	66	0.22	65	0.20	64	4.44
III	PREME	19	0.15	19	0.15	19	8.89
	TERM	66	0.13	65	0.18	64	8.89

SERUM NEUTRALIZING ANTIBODIES
PATIENTS HAD CONTACT WITH OPV

PERCENT WITH DETECTABLE ANTIBODY TITER

TYPE	2 Months			4 Months			5 Months		
I	Plan A	2/ 2	(100.0)	2/ 2	(100.0)	2/ 2	(100.0)	2/ 2	(100.0)
	Plan BD	14/19	(73.7)	10/18	(55.6)	18/18	(100.0)	18/18	(100.0)
	Plan C	2/ 3	(66.7)	3/ 3	(100.0)	3/ 3	(100.0)	3/ 3	(100.0)
II	Plan A	2/ 2	(100.0)	2/ 2	(100.0)	2/ 2	(100.0)	2/ 2	(100.0)
	Plan BD	16/19	(84.2)	17/18	(94.4)	18/18	(100.0)	18/18	(100.0)
	Plan C	3/ 3	(100.0)	3/ 3	(100.0)	3/ 3	(100.0)	3/ 3	(100.0)
III	Plan A	1/ 2	(50.0)	2/ 2	(100.0)	2/ 2	(100.0)	2/ 2	(100.0)
	Plan BD	12/19	(63.2)	13/18	(72.2)	18/18	(100.0)	18/18	(100.0)
	Plan C	2/ 3	(66.7)	2/ 3	(66.7)	3/ 3	(100.0)	3/ 3	(100.0)
ANY	Plan A	2/ 2	(100.0)	2/ 2	(100.0)	2/ 2	(100.0)	2/ 2	(100.0)
	Plan BD	19/19	(100.0)	18/19	(94.7)	18/19	(94.7)	18/19	(94.7)
	Plan C	3/ 3	(100.0)	3/ 3	(100.0)	3/ 3	(100.0)	3/ 3	(100.0)

GEOMETRIC MEAN TITERS

TYPE	2 Months		4 Months		5 Months		
	N	GMT	N	GMT	N	GMT	
I	Plan A	2	28.28	2	80.00	2	640.00
	Plan BD	19	13.09	18	4.89	18	570.18
	Plan C	3	11.70	3	20.00	3	806.35
II	Plan A	2	40.00	2	452.55	2	14481.55
	Plan BD	19	22.34	18	32.59	18	1810.19
	Plan C	3	50.40	3	25.20	3	1612.70
III	Plan A	2	6.32	2	160.00	2	2560.00
	Plan BD	19	8.56	18	13.29	18	1185.12
	Plan C	3	5.85	3	7.37	3	507.97

GEOMETRIC MEAN TITERS IN INTERNATIONAL UNITS

TYPE	2 Months		4 Months		5 Months		
	N	GMT	N	GMT	N	GMT	
I	Plan A	2	0.33	2	0.93	2	7.47
	Plan BD	19	0.15	18	0.06	18	6.65
	Plan C	3	0.14	3	0.23	3	9.41
II	Plan A	2	0.23	2	2.56	2	81.82
	Plan BD	19	0.13	18	0.18	18	10.23
	Plan C	3	0.28	3	0.14	3	9.11
III	Plan A	2	0.06	2	1.60	2	25.60
	Plan BD	19	0.09	18	0.13	18	11.85
	Plan C	3	0.06	3	0.07	3	5.08

SERUM NEUTRALIZING ANTIBODIES
PATIENTS DID NOT HAVE CONTACT WITH OPV

PERCENT WITH DETECTABLE ANTIBODY TITER

TYPE	2 Months		4 Months		5 Months	
I	Plan A	7/ 8 (87.5)	5/ 8 (62.5)	8/ 8 (100.0)	8/ 8 (100.0)	
	Plan BD	52/66 (78.8)	43/66 (65.2)	63/65 (96.9)	63/65 (96.9)	
	Plan C	13/16 (81.3)	13/16 (81.3)	15/16 (93.8)	15/16 (93.8)	
II	Plan A	8/ 8 (100.0)	8/ 8 (100.0)	8/ 8 (100.0)	8/ 8 (100.0)	
	Plan BD	56/66 (84.8)	63/66 (95.5)	65/65 (100.0)	65/65 (100.0)	
	Plan C	15/16 (93.8)	16/16 (100.0)	16/16 (100.0)	16/16 (100.0)	
III	Plan A	8/ 8 (100.0)	8/ 8 (100.0)	8/ 8 (100.0)	8/ 8 (100.0)	
	Plan BD	50/66 (75.8)	55/66 (83.3)	63/65 (96.9)	63/65 (96.9)	
	Plan C	12/16 (75.0)	13/16 (81.3)	15/16 (93.8)	15/16 (93.8)	
ANY	Plan A	8/ 8 (100.0)	8/ 8 (100.0)	8/ 8 (100.0)	8/ 8 (100.0)	
	Plan BD	64/66 (97.0)	66/66 (100.0)	65/66 (98.5)	65/66 (98.5)	
	Plan C	15/16 (93.8)	16/16 (100.0)	16/16 (100.0)	16/16 (100.0)	

GEOMETRIC MEAN TITERS

TYPE	2 Months		4 Months		5 Months		
	N	GMT	N	GMT	N	GMT	
I	Plan A	8	25.22	8	21.87	8	207.49
	Plan BD	66	18.48	66	9.06	65	200.92
	Plan C	16	20.92	16	11.40	16	213.68
II	Plan A	8	67.27	8	538.17	8	2152.69
	Plan BD	66	37.08	66	33.12	65	697.00
	Plan C	16	86.03	16	41.77	16	2347.53
III	Plan A	8	40.00	8	40.00	8	538.17
	Plan BD	66	15.20	66	19.07	65	821.01
	Plan C	16	11.25	16	20.92	16	102.31

GEOMETRIC MEAN TITERS IN INTERNATIONAL UNITS

TYPE	2 Months		4 Months		5 Months		
	N	GMT	N	GMT	N	GMT	
I	Plan A	8	0.29	8	0.26	8	2.42
	Plan BD	66	0.22	66	0.11	65	2.34
	Plan C	16	0.24	16	0.13	16	2.49
II	Plan A	8	0.38	8	3.04	8	12.16
	Plan BD	66	0.21	66	0.19	65	3.94
	Plan C	16	0.49	16	0.24	16	13.26
III	Plan A	8	0.40	8	0.40	8	5.38
	Plan BD	66	0.15	66	0.19	65	8.21
	Plan C	16	0.11	16	0.21	16	1.02

TABLE 19

Polio Protocol 01

NASOPHARYNGEAL SECRETIONS NEUTRALIZING ANTIBODIES
PATIENTS HAD CONTACT WITH OPV

PERCENT WITH DETECTABLE ANTIBODY TITER

TYPE	2 Months		4 Months		5 Months	
	N	GMT	N	GMT	N	GMT
I	Plan A	0/ . (0.0)	1/ 2 (50.0)	1/ 2 (50.0)	1/ 2 (50.0)	
	Plan BD	0/ . (0.0)	0/ 2 (0.0)	9/18 (50.0)		
	Plan C	0/ . (0.0)	0/ . (0.0)	2/ 3 (66.7)		
II	Plan A	0/ . (0.0)	2/ 2 (100.0)	1/ 2 (50.0)		
	Plan BD	0/ . (0.0)	0/ 2 (0.0)	14/18 (77.8)		
	Plan C	0/ . (0.0)	0/ . (0.0)	3/ 3 (100.0)		
III	Plan A	0/ . (0.0)	1/ 2 (50.0)	1/ 2 (50.0)		
	Plan BD	0/ . (0.0)	1/19 (5.3)	11/18 (61.1)		
	Plan C	0/ . (0.0)	0/19 (0.0)	2/ 3 (66.7)		
ANY	Plan A	0/ . (0.0)	2/ 2 (100.0)	1/ 2 (50.0)		
	Plan BD	0/ . (0.0)	1/19 (5.3)	16/19 (84.2)		
	Plan C	0/ . (0.0)	0/19 (0.0)	3/ 3 (100.0)		

GEOMETRIC MEAN TITERS

TYPE	2 Months		4 Months		5 Months	
	N	GMT	N	GMT	N	GMT
I	Plan A	0	2	2.00	2	8.00
	Plan BD	0	19	1.00	18	3.05
	Plan C	0	3	1.00	3	4.00
II	Plan A	0	2	11.31	2	11.31
	Plan BD	0	19	1.00	18	6.86
	Plan C	0	3	1.00	3	20.16
III	Plan A	0	2	11.31	2	11.31
	Plan BD	0	19	1.08	18	5.88
	Plan C	0	3	1.00	3	6.35

GEOMETRIC MEAN TITERS IN INTERNATIONAL UNITS

TYPE	2 Months		4 Months		5 Months	
	N	GMT	N	GMT	N	GMT
I	Plan A	0	2	0.02	2	0.09
	Plan BD	0	19	0.01	18	0.04
	Plan C	0	3	0.01	3	0.05
II	Plan A	0	2	0.06	2	0.06
	Plan BD	0	19	0.01	18	0.04
	Plan C	0	3	0.01	3	0.11
III	Plan A	0	2	0.11	2	0.11
	Plan BD	0	19	0.01	18	0.06
	Plan C	0	3	0.01	3	0.05

TABLE 20

Polio Protocol 01

NASOPHARYNGEAL SECRETIONS NEUTRALIZING ANTIBODIES
PATIENTS DID NOT HAVE CONTACT WITH OPV

PERCENT WITH DETECTABLE ANTIBODY TITER

TYPE	2 Months		4 Months		5 Months	
	N	GMT	N	GMT	N	GMT
I	Plan A	0/ . (0.0)	2/ 7 (28.6)	4/ 8 (50.0)		
	Plan BD	0/ . (0.0)	1/63 (1.6)	18/61 (29.5)		
	Plan C	0/ . (0.0)	0/63 (0.0)	7/16 (43.8)		
II	Plan A	0/ . (0.0)	5/ 7 (71.4)	6/ 8 (75.0)		
	Plan BD	0/ . (0.0)	1/63 (1.6)	28/61 (45.9)		
	Plan C	0/ . (0.0)	2/15 (13.3)	14/16 (87.5)		
III	Plan A	0/ . (0.0)	1/ 7 (14.3)	4/ 8 (50.0)		
	Plan BD	0/ . (0.0)	1/63 (1.6)	22/61 (36.1)		
	Plan C	0/ . (0.0)	1/15 (6.7)	6/16 (37.5)		
ANY	Plan A	0/ . (0.0)	5/ 8 (62.5)	6/ 8 (75.0)		
	Plan BD	0/ . (0.0)	2/66 (3.0)	33/66 (50.0)		
	Plan C	0/ . (0.0)	3/16 (18.8)	14/16 (87.5)		

GEOMETRIC MEAN TITERS

TYPE	2 Months		4 Months		5 Months	
	N	GMT	N	GMT	N	GMT
I	Plan A	0	7	1.64	8	2.38
	Plan BD	6	63	1.02	61	1.65
	Plan C	0	15	1.00	16	2.95
II	Plan A	0	7	7.25	8	8.72
	Plan BD	6	63	1.03	61	2.66
	Plan C	0	15	1.20	16	19.03
III	Plan A	0	7	1.22	8	4.36
	Plan BD	6	63	1.02	61	2.27
	Plan C	0	15	1.10	16	2.00

GEOMETRIC MEAN TITERS IN INTERNATIONAL UNITS

TYPE	2 Months		4 Months		5 Months	
	N	GMT	N	GMT	N	GMT
I	Plan A	0	7	0.02	8	0.03
	Plan BD	6	63	0.01	61	0.02
	Plan C	0	15	0.01	16	0.03
II	Plan A	0	7	0.04	8	0.05
	Plan BD	6	63	0.01	61	0.02
	Plan C	0	15	0.01	16	0.11
III	Plan A	0	7	0.01	8	0.04
	Plan BD	6	63	0.01	61	0.02
	Plan C	0	15	0.01	16	0.02

TABLE 21

Polio Protocol 01

9

NASOPHARYNGEAL SECRETIONS (b) (4) IgA ANTIBODIES
PATIENTS HAD CONTACT WITH OPV

PERCENT WITH DETECTABLE ANTIBODY TITER

TYPE	2 Months		4 Months		5 Months	
I	Plan A	0/ . (0.0)	1/ 2 (50.0)	1/ 2 (50.0)		
	Plan BD	0/ . (0.0)	9/19 (47.4)	14/18 (77.8)		
	Plan C	0/ . (0.0)	1/ 3 (33.3)	2/ 3 (66.7)		
II	Plan A	0/ . (0.0)	1/ 2 (50.0)	1/ 2 (50.0)		
	Plan BD	0/ . (0.0)	9/19 (47.4)	15/18 (83.3)		
	Plan C	0/ . (0.0)	1/ 3 (33.3)	3/ 3 (100.0)		
III	Plan A	0/ . (0.0)	1/ 2 (50.0)	2/ 2 (100.0)		
	Plan BD	0/ . (0.0)	9/19 (47.4)	15/18 (83.3)		
	Plan C	0/ . (0.0)	1/ 3 (33.3)	3/ 3 (100.0)		
ANY	Plan A	0/ . (0.0)	1/ 2 (50.0)	2/ 2 (100.0)		
	Plan BD	0/ . (0.0)	9/19 (47.4)	15/19 (78.9)		
	Plan C	0/ . (0.0)	1/ 3 (33.3)	3/ 3 (100.0)		

GEOMETRIC MEAN TITERS

TYPE	2 Months		4 Months		5 Months	
	N	GMT	N	GMT	N	GMT
I	Plan A	0	2	0.00	2	4.00
	Plan BD	0	19	0.00	18	13.72
	Plan C	0	3	0.00	3	20.16
II	Plan A	0	2	5.66	2	4.00
	Plan BD	0	19	4.80	18	14.81
	Plan C	0	3	2.52	3	25.40
III	Plan A	0	2	4.00	2	16.00
	Plan BD	0	19	4.63	18	16.00
	Plan C	0	3	2.52	3	40.32

NASOPHARYNGEAL SECRETIONS (b) (4) IgA ANTIODIES
 PATIENTS DID NOT HAVE CONTACT WITH OPV

PERCENT WITH DETECTABLE ANTIBODY TITER

TYPE	2 Months		4 Months		5 Months	
	N	GMT	N	GMT	N	GMT
I	Plan A	0/ . (0.0)	6/ 7 (85.7)	5/ 8 (62.5)		
	Plan BD	0/ . (0.0)	24/63 (38.1)	31/62 (50.0)		
	Plan C	0/ . (0.0)	8/15 (53.3)	13/16 (81.3)		
II	Plan A	0/ . (0.0)	6/ 7 (85.7)	5/ 8 (62.5)		
	Plan BD	0/ . (0.0)	24/63 (38.1)	34/62 (54.8)		
	Plan C	0/ . (0.0)	8/15 (53.3)	13/16 (81.3)		
III	Plan A	0/ . (0.0)	6/ 7 (85.7)	6/ 8 (75.0)		
	Plan BD	0/ . (0.0)	25/63 (39.7)	34/62 (54.8)		
	Plan C	0/ . (0.0)	9/15 (60.0)	14/16 (87.5)		
ANY	Plan A	0/ . (0.0)	6/ 8 (75.0)	6/ 8 (75.0)		
	Plan BD	0/ . (0.0)	30/66 (45.5)	38/66 (57.6)		
	Plan C	0/ . (0.0)	9/16 (56.3)	14/16 (87.5)		

GEOMETRIC MEAN TITERS

TYPE	2 Months		4 Months		5 Months	
	N	GMT	N	GMT	N	GMT
I	Plan A	0	7	0.00	8	8.72
	Plan BD	6	63	2.75	62	4.52
	Plan C	0	15	0.00	16	14.05
II	Plan A	0	7	8.83	8	8.72
	Plan BD	6	63	2.94	62	4.63
	Plan C	0	15	4.59	16	15.32
III	Plan A	0	7	11.89	8	13.45
	Plan BD	6	63	3.00	62	4.89
	Plan C	0	15	6.65	16	19.03

TABLE 23

Polio Protocol 01

STOOL SPECIMENS NEUTRALIZING ANTIBODIES
PATIENTS HAD CONTACT WITH OPV

PERCENT WITH DETECTABLE ANTIBODY TITER

TYPE	2 Months		4 Months		5 Months	
I	Plan A	0/ . (0.0)	1/ 2 (50.0)	0/ . (0.0)	0/ . (0.0)	
	Plan BD	0/ . (0.0)	0/ 2 (0.0)	2/17 (11.8)		
	Plan C	0/ . (0.0)	0/ . (0.0)	1/ 3 (33.3)		
II	Plan A	0/ . (0.0)	1/ 2 (50.0)	1/ 2 (50.0)		
	Plan BD	0/ . (0.0)	0/ 2 (0.0)	2/17 (11.8)		
	Plan C	0/ . (0.0)	0/ . (0.0)	2/ 3 (66.7)		
III	Plan A	0/ . (0.0)	1/ 2 (50.0)	0/ . (0.0)		
	Plan BD	0/ . (0.0)	1/18 (5.6)	2/17 (11.8)		
	Plan C	0/ . (0.0)	0/18 (0.0)	1/ 3 (33.3)		
ANY	Plan A	0/ . (0.0)	1/ 2 (50.0)	1/ 2 (50.0)		
	Plan BD	0/ . (0.0)	1/19 (5.3)	5/19 (26.3)		
	Plan C	0/ . (0.0)	0/19 (0.0)	2/ 3 (66.7)		

GEOMETRIC MEAN TITERS

TYPE	2 Months		4 Months		5 Months	
	N	GMT	N	GMT	N	GMT
I	Plan A	0	2	2.00	2	1.00
	Plan BD	0	18	1.00	17	1.33
	Plan C	0	3	1.00	3	1.59
II	Plan A	0	2	5.66	2	2.83
	Plan BD	0	18	1.00	17	1.18
	Plan C	0	3	1.00	3	2.52
III	Plan A	0	2	2.00	2	1.00
	Plan BD	0	18	1.08	17	1.18
	Plan C	0	3	1.00	3	1.59

GEOMETRIC MEAN TITERS IN INTERNATIONAL UNITS

TYPE	2 Months		4 Months		5 Months	
	N	GMT	N	GMT	N	GMT
I	Plan A	0	2	0.02	2	0.01
	Plan BD	0	18	0.01	17	0.02
	Plan C	0	3	0.01	3	0.02
II	Plan A	0	2	0.03	2	0.02
	Plan BD	0	18	0.01	17	0.01
	Plan C	0	3	0.01	3	0.01
III	Plan A	0	2	0.02	2	0.01
	Plan BD	0	18	0.01	17	0.01
	Plan C	0	3	0.01	3	0.02

STOOL SPECIMENS NEUTRALIZING ANTIBODIES
 PATIENTS DID NOT HAVE CONTACT WITH OPV

PERCENT WITH DETECTABLE ANTIPODY TITER

TYPE	2 Months		4 Months		5 Months	
I	Plan A	0/ . (0.0)	0/ . (0.0)	1/ 7 (14.3)		
	Plan BD	0/ . (0.0)	0/ . (0.0)	2/61 (3.3)		
	Plan C	0/ . (0.0)	0/ . (0.0)	2/16 (12.5)		
II	Plan A	0/ . (0.0)	3/ 8 (37.5)	4/ 7 (57.1)		
	Plan BD	0/ . (0.0)	3/57 (5.3)	7/61 (11.5)		
	Plan C	0/ . (0.0)	0/57 (0.0)	6/16 (37.5)		
III	Plan A	0/ . (0.0)	0/ . (0.0)	3/ 7 (42.9)		
	Plan BD	0/ . (0.0)	1/57 (1.8)	4/61 (6.6)		
	Plan C	0/ . (0.0)	0/57 (0.0)	1/16 (6.3)		
ANY	Plan A	0/ . (0.0)	3/ 8 (37.5)	4/ 8 (50.0)		
	Plan BD	0/ . (0.0)	3/66 (4.5)	11/66 (16.7)		
	Plan C	0/ . (0.0)	0/66 (0.0)	6/16 (37.5)		

GEOMETRIC MEAN TITERS

TYPE	2 Months		4 Months		5 Months	
	N	GMT	N	GMT	N	GMT
I	Plan A	0	8	1.00	7	1.22
	Plan BD	5	57	1.00	61	1.05
	Plan C	0	15	1.00	16	1.41
II	Plan A	0	8	3.36	7	5.94
	Plan BD	5	57	1.11	61	1.23
	Plan C	0	15	1.00	16	2.48
III	Plan A	0	8	1.00	7	1.81
	Plan BD	5	57	1.05	61	1.16
	Plan C	0	15	1.00	16	1.24

GEOMETRIC MEAN TITERS IN INTERNATIONAL UNITS

TYPE	2 Months		4 Months		5 Months	
	N	GMT	N	GMT	N	GMT
I	Plan A	0	8	0.01	7	0.01
	Plan BD	5	57	0.01	61	0.01
	Plan C	0	15	0.01	16	0.02
II	Plan A	0	8	0.02	7	0.03
	Plan BD	5	57	0.01	61	0.01
	Plan C	0	15	0.01	16	0.01
III	Plan A	0	8	0.01	7	0.02
	Plan BD	5	57	0.01	61	0.01
	Plan C	0	15	0.01	16	0.01

TABLE 25

Polio Protocol 01

STOOL SPECIMENS (b) (4) IgA ANTIBODIES
 PATIENTS HAD CONTACT WITH OPV

PERCENT WITH DETECTABLE ANTIBODY TITER

TYPE	2 Months		4 Months		5 Months	
I	Plan A	0/ . (0.0)	1/ 2 (50.0)	0/ . (0.0)	0/ . (0.0)	
	Plan BD	0/ . (0.0)	1/18 (5.6)	0/ . (0.0)	0/ . (0.0)	
	Plan C	0/ . (0.0)	0/18 (0.0)	1/ 3 (33.3)		
II	Plan A	0/ . (0.0)	0/ . (0.0)	0/ . (0.0)	0/ . (0.0)	
	Plan BD	0/ . (0.0)	2/18 (11.1)	1/17 (5.9)	1/17 (5.9)	
	Plan C	0/ . (0.0)	0/18 (0.0)	1/ 3 (33.3)		
III	Plan A	0/ . (0.0)	1/ 2 (50.0)	0/ . (0.0)	0/ . (0.0)	
	Plan BD	0/ . (0.0)	0/ 2 (0.0)	1/17 (5.9)	1/17 (5.9)	
	Plan C	0/ . (0.0)	0/ . (0.0)	1/ 3 (33.3)		
ANY	Plan A	0/ . (0.0)	1/ 2 (50.0)	0/ . (0.0)	0/ . (0.0)	
	Plan BD	0/ . (0.0)	3/19 (15.8)	1/19 (5.3)	1/19 (5.3)	
	Plan C	0/ . (0.0)	0/19 (0.0)	1/ 3 (33.3)		

GEOMETRIC MEAN TITERS

TYPE	2 Months		4 Months		5 Months	
	N	GMT	N	GMT	N	GMT
I	Plan A	0	2	0.00	2	1.00
	Plan BD	0	18	0.00	17	1.00
	Plan C	0	3	0.00	3	2.00
II	Plan A	0	2	1.00	2	1.00
	Plan BD	0	18	1.31	17	1.13
	Plan C	0	3	1.00	3	2.00
III	Plan A	0	2	2.83	2	1.00
	Plan BD	0	18	1.00	17	1.13
	Plan C	0	3	1.00	3	2.52

TABLE 26

Polio Protocol 01

STOOL SPECIMENS (b) (4) IgA ANTIBODIES
 PATIENTS DID NOT HAVE CONTACT WITH OPV

PERCENT WITH DETECTABLE ANTIBODY TITER

TYPE	2 Months		4 Months		5 Months	
	N	GMT	N	GMT	N	GMT
I	Plan A	0/ . (0.0)	1/ 8 (12.5)	3/ 7 (42.9)		
	Plan BD	0/ . (0.0)	4/56 (7.1)	4/60 (6.7)		
	Plan C	0/ . (0.0)	1/15 (6.7)	2/16 (12.5)		
II	Plan A	0/ . (0.0)	1/ 8 (12.5)	1/ 7 (14.3)		
	Plan BD	0/ . (0.0)	7/56 (12.5)	7/60 (11.7)		
	Plan C	0/ . (0.0)	3/15 (20.0)	6/16 (37.5)		
III	Plan A	0/ . (0.0)	2/ 8 (25.0)	3/ 7 (42.9)		
	Plan BD	0/ . (0.0)	8/56 (14.3)	14/60 (23.3)		
	Plan C	0/ . (0.0)	3/15 (20.0)	6/16 (37.5)		
ANY	Plan A	0/ . (0.0)	2/ 8 (25.0)	3/ 8 (37.5)		
	Plan BD	0/ . (0.0)	10/66 (15.2)	15/66 (22.7)		
	Plan C	0/ . (0.0)	4/16 (25.0)	6/16 (37.5)		

GEOMETRIC MEAN TITERS

TYPE	2 Months		4 Months		5 Months	
	N	GMT	N	GMT	N	GMT
I	Plan A	0	8	0.00	7	2.44
	Plan BD	6	56	1.19	60	1.16
	Plan C	0	15	0.00	16	1.30
II	Plan A	0	8	1.30	7	1.49
	Plan BD	6	56	1.36	60	1.33
	Plan C	0	15	1.59	16	2.28
III	Plan A	0	8	1.68	7	2.97
	Plan BD	6	56	1.41	60	1.70
	Plan C	0	15	1.66	16	2.48

SERUM NEUTRALIZING ANTIBODIES

PERCENT WITH DETECTABLE ANTIBODY TITER

TYPE	Visit 1		Visit 2		Visit 3	
I	PLAN F1	14/15 (93.3)	14/15 (93.3)	15/15 (100.0)	15/15 (100.0)	15/15 (100.0)
	PLAN F2	15/15 (100.0)	15/15 (100.0)	15/15 (100.0)	15/15 (100.0)	15/15 (100.0)
II	PLAN F1	14/15 (93.3)	15/15 (100.0)	15/15 (100.0)	15/15 (100.0)	15/15 (100.0)
	PLAN F2	15/15 (100.0)	15/15 (100.0)	15/15 (100.0)	15/15 (100.0)	15/15 (100.0)
III	PLAN F1	14/15 (93.3)	15/15 (100.0)	15/15 (100.0)	15/15 (100.0)	15/15 (100.0)
	PLAN F2	14/15 (93.3)	15/15 (100.0)	15/15 (100.0)	15/15 (100.0)	15/15 (100.0)
ANY	PLAN F1	14/15 (93.3)	15/15 (100.0)	15/15 (100.0)	15/15 (100.0)	15/15 (100.0)
	PLAN F2	15/15 (100.0)	15/15 (100.0)	15/15 (100.0)	15/15 (100.0)	15/15 (100.0)

GEOMETRIC MEAN TITERS

TYPE	Visit 1		Visit 2		Visit 3	
	N	GMT	N	GMT	N	GMT
I	PLAN F1	15 172.90	15 4816.60	15 4888.79	15 4888.79	
	PLAN F2	15 335.13	15 4003.74	15 5615.74	15 5615.74	
II	PLAN F1	15 250.23	15 7760.48	15 12319.00	15 12319.00	
	PLAN F2	15 531.99	15 17828.90	15 17828.88	15 17828.88	
III	PLAN F1	15 143.72	15 13511.81	15 17828.90	15 17828.90	
	PLAN F2	15 345.80	15 14150.80	15 19555.19	15 19555.19	

GEOMETRIC MEAN TITERS IN INTERNATIONAL UNITS

TYPE	Visit 1		Visit 2		Visit 3	
	N	GMT	N	GMT	N	GMT
I	PLAN F1	15 2.02	15 56.21	15 57.05	15 57.05	
	PLAN F2	15 3.91	15 46.72	15 65.54	15 65.54	
II	PLAN F1	15 1.41	15 43.85	15 69.60	15 69.60	
	PLAN F2	15 3.01	15 100.73	15 100.73	15 100.73	
III	PLAN F1	15 1.44	15 135.12	15 178.29	15 178.29	
	PLAN F2	15 3.46	15 141.51	15 195.55	15 195.55	

TABLE 28

Polio Protocol 01

NASOPHARYNGEAL SECRETIONS NEUTRALIZING ANTIBODIES

PERCENT WITH DETECTABLE ANTIBODY TITER

TYPE	Visit 1		Visit 2		Visit 3	
I	PLAN F1	0/15 (0.0)	11/15 (73.3)	8/15 (53.3)		
	PLAN F2	4/15 (26.7)	9/15 (60.0)	10/15 (66.7)		
II	PLAN F1	2/15 (13.3)	12/15 (80.0)	10/15 (66.7)		
	PLAN F2	1/15 (6.7)	12/15 (80.0)	10/15 (66.7)		
III	PLAN F1	4/15 (26.7)	13/15 (86.7)	14/15 (93.3)		
	PLAN F2	6/15 (40.0)	12/15 (80.0)	11/15 (73.3)		
ANY	PLAN F1	5/15 (33.3)	14/15 (93.3)	14/15 (93.3)		
	PLAN F2	8/15 (53.3)	14/15 (93.3)	14/15 (93.3)		

GEOMETRIC MEAN TITERS

TYPE	Visit 1		Visit 2		Visit 3		
	N	GMT	N	GMT	N	GMT	
I	PLAN F1	15	0.00	15	6.35	15	6.65
	PLAN F2	15	1.45	15	3.17	15	5.79
II	PLAN F1	15	1.45	15	7.29	15	9.62
	PLAN F2	15	1.15	15	9.19	15	7.64
III	PLAN F1	15	1.74	15	12.70	15	20.16
	PLAN F2	15	2.19	15	10.56	15	11.58

GEOMETRIC MEAN TITERS IN INTERNATIONAL UNITS

TYPE	Visit 1		Visit 2		Visit 3		
	N	GMT	N	GMT	N	GMT	
I	PLAN F1	15	0.00	15	0.07	15	0.08
	PLAN F2	15	0.02	15	0.04	15	0.07
II	PLAN F1	15	0.01	15	0.04	15	0.05
	PLAN F2	15	0.01	15	0.05	15	0.04
III	PLAN F1	15	0.02	15	0.13	15	0.20
	PLAN F2	15	0.02	15	0.11	15	0.12

STOOL SPECIMENS NEUTRALIZING ANTIBODIES

PERCENT WITH DETECTABLE ANTIBODY TITER

TYPE	Visit 1		Visit 2		Visit 3	
I	PLAN F1	0/15 (0.0)	3/15 (20.0)	1/15 (6.7)		
	PLAN F2	2/15 (13.3)	2/14 (14.3)	2/15 (13.3)		
II	PLAN F1	0/15 (0.0)	2/15 (13.3)	1/15 (6.7)		
	PLAN F2	2/15 (13.3)	2/14 (14.3)	7/15 (46.7)		
III	PLAN F1	0/15 (0.0)	3/15 (20.0)	5/15 (33.3)		
	PLAN F2	1/15 (6.7)	7/14 (50.0)	7/15 (46.7)		
ANY	PLAN F1	0/15 (0.0)	6/15 (40.0)	5/15 (33.3)		
	PLAN F2	3/15 (20.0)	8/15 (53.3)	8/15 (53.3)		

GEOMETRIC MEAN TITERS

TYPE	Visit 1		Visit 2		Visit 3		
	N	GMT	N	GMT	N	GMT	
I	PLAN F1	15	0.00	15	1.32	15	1.20
	PLAN F2	15	1.26	14	1.28	15	1.45
II	PLAN F1	15	0.00	15	1.32	15	1.32
	PLAN F2	15	1.32	14	1.49	15	3.48
III	PLAN F1	15	0.00	15	1.59	15	2.19
	PLAN F2	15	1.15	14	2.97	15	3.48

GEOMETRIC MEAN TITERS IN INTERNATIONAL UNITS

TYPE	Visit 1		Visit 2		Visit 3		
	N	GMT	N	GMT	N	GMT	
I	PLAN F1	15	0.00	15	0.02	15	0.01
	PLAN F2	15	0.01	14	0.01	15	0.02
II	PLAN F1	15	0.00	15	0.01	15	0.01
	PLAN F2	15	0.01	14	0.01	15	0.02
III	PLAN F1	15	0.00	15	0.02	15	0.02
	PLAN F2	15	0.01	14	0.03	15	0.03

TABLE 30

Polio Protocol 01

NASOPHARYNGEAL SECRETIONS (b) (4) IgA ANTIBODIES

PERCENT WITH DETECTABLE ANTIBODY TITER

TYPE	Visit 1		Visit 2		Visit 3	
I	PLAN F1	8/14 (57.1)	11/15 (73.3)	10/15 (66.7)	10/15 (66.7)	12/15 (80.0)
	PLAN F2	10/15 (66.7)	10/15 (66.7)	10/15 (66.7)	10/15 (66.7)	13/15 (86.7)
II	PLAN F1	10/14 (71.4)	10/15 (66.7)	10/15 (66.7)	10/15 (66.7)	11/15 (73.3)
	PLAN F2	10/15 (66.7)	10/15 (66.7)	10/15 (66.7)	10/15 (66.7)	14/15 (93.3)
III	PLAN F1	10/14 (71.4)	12/15 (80.0)	12/15 (80.0)	11/15 (73.3)	11/15 (73.3)
	PLAN F2	11/15 (73.3)	10/15 (66.7)	10/15 (66.7)	14/15 (93.3)	14/15 (93.3)
ANY	PLAN F1	10/15 (66.7)	12/15 (80.0)	12/15 (80.0)	11/15 (73.3)	11/15 (73.3)
	PLAN F2	11/15 (73.3)	10/15 (66.7)	10/15 (66.7)	14/15 (93.3)	14/15 (93.3)

GEOMETRIC MEAN TITERS

TYPE	Visit 1		Visit 2		Visit 3	
	N	GMT	N	GMT	N	GMT
I	PLAN F1	14 8.41	15 8.77	15 13.93	15 10.56	
	PLAN F2	15 12.13	15 6.96	15 10.56	15 10.56	
II	PLAN F1	14 9.28	15 8.77	15 12.70	15 14.59	
	PLAN F2	15 8.00	15 7.29	15 14.59	15 14.59	
III	PLAN F1	14 13.79	15 13.30	15 19.25	15 20.16	
	PLAN F2	15 10.56	15 10.08	15 20.16	15 20.16	

TABLE 31

Polio Protocol 01

STOOL SPECIMENS (b) (4) IgA ANTIBODIES

PERCENT WITH DETECTABLE ANTIBODY TITER

TYPE	Visit 1		Visit 2		Visit 3	
I PLAN F1	3/15	(20.0)	2/15	(13.3)	5/15	(33.3)
I PLAN F2	3/15	(20.0)	1/15	(6.7)	3/15	(20.0)
II PLAN F1	3/15	(20.0)	4/15	(26.7)	6/15	(40.0)
II PLAN F2	4/15	(26.7)	6/15	(40.0)	5/15	(33.3)
III PLAN F1	3/15	(20.0)	5/15	(33.3)	6/15	(40.0)
III PLAN F2	3/15	(20.0)	5/15	(33.3)	4/15	(26.7)
ANY PLAN F1	3/15	(20.0)	5/15	(33.3)	7/15	(46.7)
ANY PLAN F2	4/15	(26.7)	8/15	(53.3)	6/15	(40.0)

GEOMETRIC MEAN TITERS

TYPE	Visit 1		Visit 2		Visit 3	
	N	GMT	N	GMT	N	GMT
I PLAN F1	15	1.82	15	1.32	15	2.19
I PLAN F2	15	1.82	15	1.15	15	1.59
II PLAN F1	15	1.66	15	1.82	15	2.52
II PLAN F2	15	1.91	15	2.30	15	2.19
III PLAN F1	15	1.82	15	2.19	15	2.52
III PLAN F2	15	1.59	15	2.19	15	2.00

SERUM NEUTRALIZING ANTIBODIES
PATIENTS HAD CONTACT WITH OPV

PERCENT WITH DETECTABLE ANTIBODY TITER

TYPE	Visit 1		Visit 2		Visit 3	
I	Plan F1	7/ 7 (100.0)	7/ 7 (100.0)	7/ 7 (100.0)	7/ 7 (100.0)	7/ 7 (100.0)
	Plan F2	5/ 5 (100.0)	5/ 5 (100.0)	5/ 5 (100.0)	5/ 5 (100.0)	5/ 5 (100.0)
II	Plan F1	7/ 7 (100.0)	7/ 7 (100.0)	7/ 7 (100.0)	7/ 7 (100.0)	7/ 7 (100.0)
	Plan F2	5/ 5 (100.0)	5/ 5 (100.0)	5/ 5 (100.0)	5/ 5 (100.0)	5/ 5 (100.0)
III	Plan F1	7/ 7 (100.0)	7/ 7 (100.0)	7/ 7 (100.0)	7/ 7 (100.0)	7/ 7 (100.0)
	Plan F2	5/ 5 (100.0)	5/ 5 (100.0)	5/ 5 (100.0)	5/ 5 (100.0)	5/ 5 (100.0)
ANY	Plan F1	7/ 7 (100.0)	7/ 7 (100.0)	7/ 7 (100.0)	7/ 7 (100.0)	7/ 7 (100.0)
	Plan F2	5/ 5 (100.0)	5/ 5 (100.0)	5/ 5 (100.0)	5/ 5 (100.0)	5/ 5 (100.0)

GEOMETRIC MEAN TITERS

TYPE	Visit 1		Visit 2		Visit 3	
	N	GMT	N	GMT	N	GMT
I	Plan F1	7 215.34	7 8400.23	7 7608.30		
	Plan F2	5 422.24	5 2940.67	5 5881.34		
II	Plan F1	7 430.69	7 6891.02	7 12482.72		
	Plan F2	5 211.12	5 8914.46	5 8914.44		
III	Plan F1	7 118.88	7 10240.02	7 16800.50		
	Plan F2	5 557.15	5 17828.92	5 23525.40		

GEOMETRIC MEAN TITERS IN INTERNATIONAL UNITS

TYPE	Visit 1		Visit 2		Visit 3	
	N	GMT	N	GMT	N	GMT
I	Plan F1	7 2.51	7 98.03	7 88.79		
	Plan F2	5 4.93	5 34.32	5 68.64		
II	Plan F1	7 2.43	7 38.93	7 70.53		
	Plan F2	5 1.19	5 50.37	5 50.37		
III	Plan F1	7 1.19	7 102.40	7 168.00		
	Plan F2	5 5.57	5 178.29	5 235.25		

Polio Protocol 01

SERUM NEUTRALIZING ANTIBODIES
PATIENTS DID NOT HAVE CONTACT WITH OPV

PERCENT WITH DETECTABLE ANTIBODY TITER

TYPE	Visit 1		Visit 2		Visit 3	
I	Plan F1	7/ 8 (87.5)	7/ 8 (87.5)	8/ 8 (100.0)	8/ 8 (100.0)	8/ 8 (100.0)
	Plan F2	10/10 (100.0)	10/10 (100.0)	10/10 (100.0)	10/10 (100.0)	10/10 (100.0)
II	Plan F1	7/ 8 (87.5)	8/ 8 (100.0)	8/ 8 (100.0)	8/ 8 (100.0)	8/ 8 (100.0)
	Plan F2	10/10 (100.0)	10/10 (100.0)	10/10 (100.0)	10/10 (100.0)	10/10 (100.0)
III	Plan F1	7/ 8 (87.5)	8/ 8 (100.0)	8/ 8 (100.0)	8/ 8 (100.0)	8/ 8 (100.0)
	Plan F2	9/10 (90.0)	10/10 (100.0)	10/10 (100.0)	10/10 (100.0)	10/10 (100.0)
ANY	Plan F1	7/ 8 (87.5)	8/ 8 (100.0)	8/ 8 (100.0)	8/ 8 (100.0)	8/ 8 (100.0)
	Plan F2	10/10 (100.0)	10/10 (100.0)	10/10 (100.0)	10/10 (100.0)	10/10 (100.0)

GEOMETRIC MEAN TITERS

TYPE	Visit 1		Visit 2		Visit 3	
	N	GMT	N	GMT	N	GMT
I	Plan F1	8 142.68	8 2960.63	8 3319.91		
	Plan F2	10 298.57	10 4671.71	10 5487.48		
II	Plan F1	8 155.60	8 8610.79	8 12177.50		
	Plan F2	10 844.49	10 25213.87	10 25213.84		
III	Plan F1	8 169.68	8 17221.64	8 18780.27		
	Plan F2	10 272.43	10 12606.92	10 17828.90		

GEOMETRIC MEAN TITERS IN INTERNATIONAL UNITS

TYPE	Visit 1		Visit 2		Visit 3	
	N	GMT	N	GMT	N	GMT
I	Plan F1	8 1.67	8 34.55	8 38.74		
	Plan F2	10 3.48	10 54.52	10 64.04		
II	Plan F1	8 0.88	8 48.65	8 68.80		
	Plan F2	10 4.77	10 142.46	10 142.46		
III	Plan F1	8 1.70	8 172.22	8 187.80		
	Plan F2	10 2.72	10 126.07	10 178.29		