

Centers for Disease Control and Prevention (CDC) Atlanta GA 30333 July 27, 2020

SENT VIA EMAIL

Aaron Siri Siri and Glimstad, LLP 200 Park Avenue Seventeenth Floor New York, New York 10166 Email: aaron@sirillp.com

Dear Mr. Siri:

This letter is regarding to your Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) Freedom of Information Act (FOIA) request of April 8, 2020, assigned #20-01206-FOIA, for:

"The subject matter of this request is the publication by PL Moro found here: https://www.ncbi.nlm.nih.gov/pubmed/26021988. By this letter, please conduct an email enterprise search utilizing the following criteria: Date range for the search: Jan. 1, 2014 to Feb. 28, 2014

Individual(s) whose email account should be searched: Frank DeStefano-found in 20-00183 Pedro L. Moro-found in 20-00183 (emails) word Vaers Jorge Arana-Found (20-00183) Maria Cano- ok (found in 20-00183) Paige Lewis-found in abstract Tom T. Shimabukuro- found in abstract (draft)

Limit search to emails with any of the following terms in the subject line and/or body of the email: VAERS Vaccine Adverse Event Reporting System Moro Study Death SIDS

Since this is related to article please, I recommend that you include the following key term in the subject line: 1997-2013."

We located 224 pages of responsive records (23 released in full; 81 pages withheld in part; 118 pages withheld in full; 2 pages referred to the Food and Drug Administration). After a careful review of these pages, some information was withheld from release pursuant to 5 U.S.C. §552 Exemptions (b)(4), (b)(5), and (b)(6).

EXEMPTION 4

Page 2 - Aaron Siri

Exemption 4 protects trade secrets and commercial or financial information obtained from a person that is privileged or confidential. The information withheld is commercial or financial information, such as a personal (author's copy) of copyrighted article, and we have determined that the individual to whom this information pertains have a substantial commercial or financial interest in withholding it.

EXEMPTION 5

Exemption 5 protects inter-agency or intra-agency memorandums or letters which would not be available by law to a party other than an agency in litigation with the agency. Exemption 5 therefore incorporates the privileges that protect materials from discovery in litigation, including the deliberative process, attorney work-product, and attorney-client privileges. Information withheld under this exemption was protected under the <u>deliberative process privilege</u>. The deliberative process privilege protects the decision-making process of government agencies. The deliberative process privilege protects materials that are both predecisional and deliberative. The materials that have been withheld under the deliberative process privilege of Exemption 5 are both predecisional and deliberative, and do not contain or represent formal or informal agency policies or decisions. Examples of information withheld include recommendations, opinions, or comments, and draft documents.

EXEMPTION 6

Exemption 6 protects information in personnel and medical files and similar files when disclosure would constitute a clearly unwarranted invasion of personal privacy. The information that has been withheld under Exemption 6 consists of personal information, such as laboratory sample identification numbers and private email accounts. We have determined that the individuals to whom this information pertains has a substantial privacy interest in withholding it.

Additionally, the search of CDC files produced records (2 pages) that originated with the Food and Drug Administration (FDA). These documents were referred to FDA, for review and direct response to you. Contact information for FDA is provided below.

Sarah Kotler, Director Division of Freedom of Information, OES U.S. Food & Drug Administration 5630 Fishers Lane Room-1035 Rockville, Maryland 20857 Main: 301-796-3900 Fax: 301-827-9267

You may contact our FOIA Public Liaison at 770-488-6277 for any further assistance and to discuss any aspect of your request. Additionally, you may contact the Office of Government Information Services (OGIS) at the National Archives and Records Administration to inquire about the FOIA mediation services they offer. The contact information for OGIS is as follows: Office of Government Information Services, National Archives and Records Administration, 8601 Adelphi Road-OGIS, College Park, Maryland 20740-6001, e-mail at ogis@nara.gov; telephone at 202-741-5770; toll free at 1-877-684-6448; or facsimile at 202-741-5769.

Page 3 – Aaron Siri

If you are not satisfied with the response to this request, you may administratively appeal by writing to the Deputy Agency Chief FOIA Officer, Office of the Assistant Secretary for Public Affairs, U.S. Department of Health and Human Services, Hubert H. Humphrey Building, 200 Independence Avenue, Suite 729H, Washington, D.C. 20201. You may also transmit your appeal via email to FOIARequest@psc.hhs.gov. Please mark both your appeal letter and envelope "FOIA Appeal." Your appeal must be postmarked or electronically transmitted by October 26, 2020.

Sincerely,

Roger Andoh CDC/ATSDR FOIA Officer Office of the Chief Operating Officer Phone: (770) 488-6399 Fax: (404) 235-1852

Enclosures

#20-01206-FOIA

From:Miller, Elaine R. (CDC/OID/NCEZID)Sent:Mon, 13 Jan 2014 15:58:19 -0500To:Shimabukuro, Tom (CDC/OID/NCEZID);Moro, Pedro (CDC/OID/NCEZID)Subject:RE: SIDS/vaccinations, Priority: Medium, Mode: Email [ref:_00DU0YCBU._500U0ALGVL:ref]

Thank you

From: Shimabukuro, Tom (CDC/OID/NCEZID)
Sent: Monday, January 13, 2014 3:49 PM
To: Miller, Elaine R. (CDC/OID/NCEZID); Moro, Pedro (CDC/OID/NCEZID)
Subject: RE: SIDS/vaccinations, Priority: Medium, Mode: Email [ref:_00DU0YCBU._500U0ALGVL:ref]

No, it looks good

From: Miller, Elaine R. (CDC/OID/NCEZID)
Sent: Monday, January 13, 2014 3:40 PM
To: Moro, Pedro (CDC/OID/NCEZID); Shimabukuro, Tom (CDC/OID/NCEZID)
Subject: RE: SIDS/vaccinations, Priority: Medium, Mode: Email [ref:_00DU0YCBU._500U0ALGVL:ref]

Thanks Pedro. Tom-please let me know if you have further comments. Elaine

From: Moro, Pedro (CDC/OID/NCEZID)
Sent: Monday, January 13, 2014 2:57 PM
To: Miller, Elaine R. (CDC/OID/NCEZID); Shimabukuro, Tom (CDC/OID/NCEZID)
Subject: RE: SIDS/vaccinations, Priority: Medium, Mode: Email [ref:_00DU0YCBU._500U0ALGVL:ref]

I think

(b)(5)

Pedro

From: Miller, Elaine R. (CDC/OID/NCEZID)
Sent: Monday, January 13, 2014 1:35 PM
To: Moro, Pedro (CDC/OID/NCEZID); Shimabukuro, Tom (CDC/OID/NCEZID)
Subject: RE: SIDS/vaccinations, Priority: Medium, Mode: Email [ref:_00DU0YCBU._500U0ALGVL:ref]

Thanks Pedro-Revised response is below.

Dear Mr. Green.

(b)(5)

Sincerely,

(b)(5)

From: Moro, Pedro (CDC/OID/NCEZID)
Sent: Monday, January 13, 2014 1:31 PM
To: Miller, Elaine R. (CDC/OID/NCEZID); Shimabukuro, Tom (CDC/OID/NCEZID)
Subject: RE: SIDS/vaccinations, Priority: Medium, Mode: Email [ref:_00DU0YCBU._500U0ALGVL:ref]

I think (b)(5)

Pedro

From: Miller, Elaine R. (CDC/OID/NCEZID)
Sent: Monday, January 13, 2014 1:30 PM
To: Moro, Pedro (CDC/OID/NCEZID); Shimabukuro, Tom (CDC/OID/NCEZID)
Subject: FW: SIDS/vaccinations, Priority: Medium, Mode: Email [ref:_00DU0YCBU._500U0ALGVL:ref]

Tom, Pedro:	
Please let me know if this needs edits. Do you think	(b)(5)
(b)(5)	
Thanks,	
Elaine	

Dear Mr. Green,

Thank you for question regarding SIDS and vaccines.	(b)(5)
(b)(5))
Sincerely,	

From: Miller, Elaine R. (CDC/OID/NCEZID)
Sent: Monday, January 13, 2014 9:55 AM
To: Shimabukuro, Tom (CDC/OID/NCEZID)
Subject: RE: SIDS/vaccinations, Priority: Medium, Mode: Email [ref:_00DU0YCBU._500U0ALGVL:ref]

Thanks Tom. I have not responded yet so this is very helpful. Elaine

From: Shimabukuro, Tom (CDC/OID/NCEZID)
Sent: Saturday, January 11, 2014 9:56 AM
To: Miller, Elaine R. (CDC/OID/NCEZID)
Subject: RE: SIDS/vaccinations, Priority: Medium, Mode: Email [ref:_00DU0YCBU._500U0ALGVL:ref]

Although this report doesn't directly address the methodology in this paper,	(b)(5)
(b)(5)	

From: Miller, Elaine R. (CDC/OID/NCEZID)
Sent: Friday, January 10, 2014 12:05 PM
To: Shimabukuro, Tom (CDC/OID/NCEZID); Moro, Pedro (CDC/OID/NCEZID)
Subject: RE: SIDS/vaccinations, Priority: Medium, Mode: Email [ref:_00DU0YCBU._500U0ALGVL:ref]

I can do that. I still think	(b)(5)

Thanks, Elaine

From: Shimabukuro, Tom (CDC/OID/NCEZID) Sent: Friday, January 10, 2014 12:00 PM To: Moro, Pedro (CDC/OID/NCEZID); Miller, Elaine R. (CDC/OID/NCEZID) Subject: RE: SIDS/vaccinations, Priority: Medium, Mode: Email [ref:_00DU0YCBU._500U0ALGVL:ref]

(b)(5)

From: Moro, Pedro (CDC/OID/NCEZID)
Sent: Friday, January 10, 2014 11:55 AM
To: Miller, Elaine R. (CDC/OID/NCEZID)
Cc: Shimabukuro, Tom (CDC/OID/NCEZID)
Subject: RE: SIDS/vaccinations, Priority: Medium, Mode: Email [ref:_00DU0YCBU._500U0ALGVL:ref]

Elaine, Tom,

I can try to read this but I would ask someone from VSD for help, could be Natalie (she published the VSD study on deaths), Shahed, or Eric

Pedro

From: Miller, Elaine R. (CDC/OID/NCEZID)
Sent: Friday, January 10, 2014 11:49 AM
To: Moro, Pedro (CDC/OID/NCEZID)
Cc: Shimabukuro, Tom (CDC/OID/NCEZID)
Subject: FW: SIDS/vaccinations, Priority: Medium, Mode: Email [ref:_00DU0YCBU._500U0ALGVL:ref]

Hi Pedro,

I think (b)(5) Let me know who will answer it and I can give them a copy of the article that he is referring to. Thanks, Elaine

From: Miller, Elaine R. (CDC/OID/NCEZID)
Sent: Thursday, January 09, 2014 2:19 PM
To: NIPINFO (CDC)
Cc: Moro, Pedro (CDC/OID/NCEZID)
Subject: RE: SIDS/vaccinations, Priority: Medium, Mode: Email [ref:_00DU0YCBU._500U0ALGVL:ref]

Thanks Skip. We will get back to you with a response. Elaine

From: Wolfe, Skip (CDC/OID/NCIRD) On Behalf Of NIPINFO (CDC) Sent: Thursday, January 09, 2014 1:56 PM To: Miller, Elaine R. (CDC/OID/NCEZID) Subject: SIDS/vaccinations, Priority: Medium, Mode: Email [ref:_00DU0YCBU._500U0ALGVL:ref]

Hi Elaine,

Do you know whether ISO is familiar with this paper, and if you have, or would be willing to create, a response for our correspondent? The lead author of the paper, Neil Z. Miller, as you probably know, is a long-time anti-vaccine advocate.

Thanks,

Skip

[ref:_00DU0YCBU._500U0ALGVL:ref] LH

Original Email
From : null
To :cdcinfo0cdc.gov
Date :2014-01-09 00:58:46
Subject :CDC-INFC: Inquiry
Subject: Sudden Infant Death Syndrome (SIDS) and Vaccines
Other: [othersubject]
From: Educator
Contact: Richard Green, Lecturer, XJTLU
Email Address: <u>richard.green@xjtlu.edu.cn</u>
Your Question: I read with interest your information about Sudden Infant Death Syndrome (SIDS) and Vaccines: <u>http://www.cdc.gov/vaccinesafety/Concerns/sids.html</u> I am trying to decide about how many vaccines my child should have and was disturbed to read a

about how many vaccines my child should have and was disturbed to read a report on SAGE: "Infant mortality rates regressed against number of vaccine doses routinely given":

http://het.sagepub.com/content/30/9/1420.full.pdf+html Do you have any advice as to the validity of the claims in this report as it appears to contradict your information about studies using the VEARS dataset? Any advice would be appreciated, Thank you, Richard Green

From:	Miller, Elaine R. (CDC/OID/NCEZID)
Sent:	Mon, 13 Jan 2014 16:07:50 -0500
То:	NIPINFO (CDC);Wolfe, Skip (CDC/OID/NCIRD)
Cc:	Moro, Pedro (CDC/OID/NCEZID);Shimabukuro, Tom (CDC/OID/NCEZID)
Subject:	FW: SIDS/vaccinations, Priority: Medium, Mode: Email [
ref:_00DU0YCBU500U	JOALGVL:ref]

Hi Skip,		
	ISO response for this inquiry. For our tracking purposes,	(b)(5)
(b)(5)	-	
Thanks,		

Elaine

Dear Mr. Green,

(b)(5)

Sincerely,

From: Miller, Elaine R. (CDC/OID/NCEZID)
Sent: Thursday, January 09, 2014 2:19 PM
To: NIPINFO (CDC)
Cc: Moro, Pedro (CDC/OID/NCEZID)
Subject: RE: SIDS/vaccinations, Priority: Medium, Mode: Email [ref:_00DU0YCBU._500U0ALGVL:ref]

Thanks Skip. We will get back to you with a response. Elaine

From: Wolfe, Skip (CDC/OID/NCIRD) On Behalf Of NIPINFO (CDC)
Sent: Thursday, January 09, 2014 1:56 PM
To: Miller, Elaine R. (CDC/OID/NCEZID)
Subject: SIDS/vaccinations, Priority: Medium, Mode: Email [ref:_00DU0YCBU._500U0ALGVL:ref]

Hi Elaine,

Do you know whether ISO is familiar with this paper, and if you have, or would be willing to create, a response for our correspondent? The lead author of the paper, Neil Z. Miller, as you probably know, is a long-time anti-vaccine advocate.

Thanks,

Skip

[ref:_00DU0YCBU._500U0ALGVL:ref] LH

----- Original Email -----

From : null

To :cdcinfo@cdc.gov

Date :2014-01-09 00:58:46

Subject :CDC-INFO: Inquiry

Subject: Sudden Infant Death Syndrome (SIDS) and Vaccines

Other: [othersubject]

From: Educator

Contact: Richard Green, Lecturer, XJTLU

Email Address: richard.green@xjtlu.edu.cn

Your Question: I read with interest your information about Sudden Infant Death Syndrome (SIDS) and Vaccines:

<u>http://www.cdc.gov/vaccinesafety/Concerns/sids.html</u> I am trying to decide about how many vaccines my child should have and was disturbed to read a report on SAGE: "Infant mortality rates regressed against number of vaccine doses routinely given":

<u>http://het.sagepub.com/content/30/9/1420.full.pdf+html</u> Do you have any advice as to the validity of the claims in this report as it appears to contradict your information about studies using the VEARS dataset? Any advice would be appreciated, Thank you, Richard Green From:Shimabukuro, Tom (CDC/OID/NCEZID)Sent:Mon, 13 Jan 2014 14:18:53 -0500To:Moro, Pedro (CDC/OID/NCEZID);Miller, Elaine R. (CDC/OID/NCEZID)Subject:RE: SIDS/vaccinations, Priority: Medium, Mode: Email [ref:_00DU0YCBU._500U0ALGVL:ref]

Agreed.

Tom Shimabukuro, MD, MPH, MBA

Captain, U.S. Public Health Service Acting Deputy Director Immunization Safety Office Centers for Disease Control and Prevention (CDC) 1600 Clifton Road, MS D-26, Atlanta, GA 30333

Phone: 404-639-4848, Fax: 404-639-8834 Email: <u>TShimabukuro@ede.gov</u>

From: Moro, Pedro (CDC/OID/NCEZID)
Sent: Monday, January 13, 2014 1:31 PM
To: Miller, Elaine R. (CDC/OID/NCEZID); Shimabukuro, Tom (CDC/OID/NCEZID)
Subject: RE: SIDS/vaccinations, Priority: Medium, Mode: Email [ref:_00DU0YCBU._500U0ALGVL:ref]

I think it should be included.

Pedro

From: Miller, Elaine R. (CDC/OID/NCEZID)
Sent: Monday, January 13, 2014 1:30 PM
To: Moro, Pedro (CDC/OID/NCEZID); Shimabukuro, Tom (CDC/OID/NCEZID)
Subject: FW: SIDS/vaccinations, Priority: Medium, Mode: Email [ref:_00DU0YCBU._500U0ALGVL:ref]

Tom, Pedro: <u>Please let me know</u> if this needs edits. Do you think (b)(5) Thanks, Elaine

Dear Mr. Green,

From: Miller, Elaine R. (CDC/OID/NCEZID)
Sent: Monday, January 13, 2014 9:55 AM
To: Shimabukuro, Tom (CDC/OID/NCEZID)
Subject: RE: SIDS/vaccinations, Priority: Medium, Mode: Email [ref:_00DU0YCBU._500U0ALGVL:ref]

Thanks Tom. I have not responded yet so this is very helpful. Elaine

From: Shimabukuro, Tom (CDC/OID/NCEZID)
Sent: Saturday, January 11, 2014 9:56 AM
To: Miller, Elaine R. (CDC/OID/NCEZID)
Subject: RE: SIDS/vaccinations, Priority: Medium, Mode: Email [ref:_00DU0YCBU._500U0ALGVL:ref]

Although this report doesn't directly address the methodology in this paper,	(b)(5)	
(b)(5)		

From: Miller, Elaine R. (CDC/OID/NCEZID)
Sent: Friday, January 10, 2014 12:05 PM
To: Shimabukuro, Tom (CDC/OID/NCEZID); Moro, Pedro (CDC/OID/NCEZID)
Subject: RE: SIDS/vaccinations, Priority: Medium, Mode: Email [ref:_00DU0YCBU._500U0ALGVL:ref]

I can do that. I still think (b)(5) Thanks,

Elaine

From: Shimabukuro, Tom (CDC/OID/NCEZID)
Sent: Friday, January 10, 2014 12:00 PM
To: Moro, Pedro (CDC/OID/NCEZID); Miller, Elaine R. (CDC/OID/NCEZID)
Subject: RE: SIDS/vaccinations, Priority: Medium, Mode: Email [ref:_00DU0YCBU._500U0ALGVL:ref]

From: Moro, Pedro (CDC/OID/NCEZID) Sent: Friday, January 10, 2014 11:55 AM To: Miller, Elaine R. (CDC/OID/NCEZID) Cc: Shimabukuro, Tom (CDC/OID/NCEZID) Subject: RE: SIDS/vaccinations, Priority: Medium, Mode: Email [ref:_00DU0YCBU._500U0ALGVL:ref]

Elaine, Tom,

I can try to read this but I would ask someone from VSD for help, could be Natalie (she published the VSD study on deaths), Shahed, or Eric

Pedro

From: Miller, Elaine R. (CDC/OID/NCEZID)
Sent: Friday, January 10, 2014 11:49 AM
To: Moro, Pedro (CDC/OID/NCEZID)
Cc: Shimabukuro, Tom (CDC/OID/NCEZID)
Subject: FW: SIDS/vaccinations, Priority: Medium, Mode: Email [ref:_00DU0YCBU._500U0ALGVL:ref]

Hi Pedro,

l think (b)(5) (b)(5)

Elaine

From: Miller, Elaine R. (CDC/OID/NCEZID)
Sent: Thursday, January 09, 2014 2:19 PM
To: NIPINFO (CDC)
Cc: Moro, Pedro (CDC/OID/NCEZID)
Subject: RE: SIDS/vaccinations, Priority: Medium, Mode: Email [ref:_00DU0YCBU._500U0ALGVL:ref]

Thanks Skip. We will get back to you with a response. Elaine

From: Wolfe, Skip (CDC/OID/NCIRD) On Behalf Of NIPINFO (CDC)
Sent: Thursday, January 09, 2014 1:56 PM
To: Miller, Elaine R. (CDC/OID/NCEZID)
Subject: SIDS/vaccinations, Priority: Medium, Mode: Email [ref:_00DU0YCBU._500U0ALGVL:ref]

Hi Elaine,

Do you know whether ISO is familiar with this paper, and if you have, or would be willing to create, a response for our correspondent? The lead author of the paper, Neil Z. Miller, as you probably know, is a long-time anti-vaccine advocate.

Thanks,

Skip

[ref:_00DU0YCBU._500U0ALGVL:ref] LH

----- Original Email ------ From : null

To :cdcinfo@cdc.gov

Date :2014-01-09 00:58:46

Subject :CDC-INFO: Inquiry

Subject: Sudden Infant Death Syndrome (SIDS) and Vaccines

Other: [othersubject]

From: Educator

Contact: Richard Green, Lecturer, XJTLU

Email Address: <a href="mailto:mailto:mailto:mailto:smailto:mailt

Your Question: I read with interest your information about Sudden Infant Death Syndrome (SIDS) and Vaccines:

<u>http://www.cdc.gov/vaccinesafety/Concerns/sids.html</u> I am trying to decide about how many vaccines my child should have and was disturbed to read a report on SAGE: "Infant mortality rates regressed against number of vaccine doses routinely given":

<u>http://het.sagepub.com/content/30/9/1420.full.pdf+html</u> Do you have any advice as to the validity of the claims in this report as it appears to contradict your information about studies using the VEARS dataset? Any advice would be appreciated, Thank you, Richard Green

From:	Miller, Elaine R. (CDC/OID/NCEZID)
Sent:	Tue, 7 Jan 2014 12:31:12 -0500
То:	Destefano, Frank (CDC/OID/NCEZID)
Cc:	Moro, Pedro (CDC/OID/NCEZID);Gee, Julianne (CDC/OID/NCEZID)
Subject:	FW: RESPONSE REQUIRED: Topic: HPV Vaccine Death, Priority: Medium, Mode:
Email [ref:_00DU0YCB	U500U0AKo8S:ref]

Thanks Frank. The revised response is below with the addition in red. Please let me know if this needs any further edits. Elaine

(b)(5); (b)(6)

Sincerely,

From: Destefano, Frank (CDC/OID/NCEZID)
Sent: Tuesday, January 07, 2014 12:15 PM
To: Miller, Elaine R. (CDC/OID/NCEZID); Gee, Julianne (CDC/OID/NCEZID)
Cc: Moro, Pedro (CDC/OID/NCEZID)
Subject: RE: RESPONSE REQUIRED: Topic: HPV Vaccine Death, Priority: Medium, Mode: Email [ref:_00DU0YCBU._500U0AKo8S:ref]

Yes, I would still like to review the responses on HPV vaccine. In addition, in the draft response below I would add (b)(5)

(b)(5)

Thanks, Frank

From: Miller, Elaine R. (CDC/OID/NCEZID)
Sent: Tuesday, January 07, 2014 12:02 PM
To: Destefano, Frank (CDC/OID/NCEZID)
Cc: Moro, Pedro (CDC/OID/NCEZID)
Subject: FW: RESPONSE REQUIRED: Topic: HPV Vaccine Death, Priority: Medium, Mode: Email [ref:_00DU0YCBU._500U0AKo8S:ref]

HI Frank,

(b)(5); (b)(6)

Sincerely,

From: Hamborsky, Jennifer (CDC/OID/NCIRD) On Behalf Of NIPINFO (CDC)
Sent: Monday, January 06, 2014 7:30 PM
To: Miller, Elaine R. (CDC/OID/NCEZID)
Subject: FW: RESPONSE REQUIRED: Topic: HPV Vaccine Death, Priority: Medium, Mode: Email [
ref:_00DU0YCBU._500U0AKo8S:ref]

Hi Elaine, Not sure what to do with this one... CISA consult? I guess it depends on autopsy findings.

From: CDC-INFO Response (CDC)
Sent: Monday, January 06, 2014 5:22 PM
To: NIPINFO (CDC)
Subject: RESPONSE REQUIRED: Topic: HPV Vaccine Death, Priority: Medium, Mode: Email [
ref:_00DU0YCBU._500U0AKo8S:ref]

Below, you will find an inquiry regarding a death that occurred after an HPV vaccination. We are not sure how to advise on this one; therefore, we are escalating for assistance.

Please let us know as soon as possible if your group will provide the answer to the inquiry below or if the inquiry should be referred elsewhere, for example to a state or local health department, another CDC program, or other federal agency. Specific guidance on a referral and contact information would be appreciated.

Programs are asked to reply within 3 business days of receipt of this escalation. If there is a delay, please let us know when to expect the answer so we can share that information with the inquirer. A reminder will be sent in 8 days; the inquiry will be closed after 10 days.

Questions about this inquiry can be directed to the CDC-INFO Correspondence Team by replying to this e-mail. Please reference the inquiry number below and include the e-mail thread line in your response. The thread line is the e-mail chain including this e-mail and the original e-mail request. To include the thread line, reply to this message without deleting the historical e-mail chain.

Thank ycu,

ΗW

The privacy of the inquirer should be protected in any transmission or storage of this e-mail.

----- Original Email -----

From : null

To :cdcinfo@cdc.gov

Date :2014-01-05 01:41:47

Subject :CDC-INFO: Inquiry

Subject: HPV Vaccination

Other: [othersubject]

From: General Public

Email Address: (b)(6)

(b)(5); (b)(6)	

From:Miller, Elaine R. (CDC/OID/NCEZID)Sent:Tue, 7 Jan 2014 12:36:03 -0500To:Gee, Julianne (CDC/OID/NCEZID);Destefano, Frank (CDC/OID/NCEZID)Cc:Moro, Pedro (CDC/OID/NCEZID)Subject:RE: RESPONSE REQUIRED: Topic: HPV Vaccine Death, Priority: Medium, Mode:Email [ref: 00DU0YCBU. _500U0AKo8S:ref]

Thanks-this document will be very helpful with future responses!

From: Gee, Julianne (CDC/OID/NCEZID)
Sent: Tuesday, January 07, 2014 12:34 PM
To: Destefano, Frank (CDC/OID/NCEZID); Miller, Elaine R. (CDC/OID/NCEZID)
Cc: Moro, Pedro (CDC/OID/NCEZID)
Subject: RE: RESPONSE REQUIRED: Topic: HPV Vaccine Death, Priority: Medium, Mode: Email [ref:_00DU0YCBU._500U0AKo8S:ref]

Hi Elaine-

Attached is a document that Staci has put together to help with Frank and I with responses for HPV inquiries. They are what has been sent from you, Angela, Tom, and others over the past 6-8 mos and the responses have been cleared.

Perhaps you can revise to say something like this:

(b)(5)

From: Destefano, Frank (CDC/OID/NCEZID)
Sent: Tuesday, January 07, 2014 12:15 PM
To: Miller, Elaine R. (CDC/OID/NCEZID); Gee, Julianne (CDC/OID/NCEZID)
Cc: Moro, Pedro (CDC/OID/NCEZID)
Subject: RE: RESPONSE REQUIRED: Topic: HPV Vaccine Death, Priority: Medium, Mode: Email [ref:_00DU0YCBU._500U0AKo8S:ref]

Yes, I would still like to review the responses on HPV vaccine. In addition, in the draft response below I would add (b)(5)

(b)(5) Thanks,

Frank

From: Miller, Elaine R. (CDC/OID/NCEZID) Sent: Tuesday, January 07, 2014 12:02 PM To: Destefano, Frank (CDC/OID/NCEZID) Cc: Moro, Pedro (CDC/OID/NCEZID) Subject: FW: RESPONSE REQUIRED: Topic: HPV Vaccine Death, Priority: Medium, Mode: Email [ref:_00DU0YCBU._500U0AKo8S:ref]

HI Frank,

(b)(5)

Elaine

(b)(5); (b)(6)

Sincerely,

From: Hamborsky, Jennifer (CDC/OID/NCIRD) **On Behalf Of** NIPINFO (CDC) **Sent:** Monday, January 06, 2014 7:30 PM **To:** Miller, Elaine R. (CDC/OID/NCEZID) **Subject:** FW: RESPONSE REQUIRED: Topic: HPV Vaccine Death, Priority: Medium, Mode: Email [ref:_00DU0YCBU._500U0AKo8S:ref]

Hi Elaine, Not sure what to do with this one... CISA consult? I guess it depends on autopsy findings.

From: CDC-INFO Response (CDC)
Sent: Monday, January 06, 2014 5:22 PM
To: NIPINFO (CDC)
Subject: RESPONSE REQUIRED: Topic: HPV Vaccine Death, Priority: Medium, Mode: Email [
ref:_00DU0YCBU._500U0AKo8S:ref]

Below, you will find an inquiry regarding a death that occurred after an HPV vaccination. We are not sure how to advise on this one; therefore, we are escalating for assistance.

Please let us know as soon as possible if your group will provide the answer to the inquiry below or if the inquiry should be referred elsewhere, for example to a state or local health department, another CDC program, or other federal agency. Specific guidance on a referral and contact information would be appreciated.

Programs are asked to reply within 3 business days of receipt of this escalation. If there is a delay, please let us know when to expect the answer so we can share that information with the inquirer. A reminder will be sent in 8 days; the inquiry will be closed after 10 days.

Questions about this inquiry can be directed to the CDC-INFO Correspondence Team by replying to this e-mail. Please reference the inquiry number below and include the e-mail thread line in your response. The thread line is the e-mail chain including this e-mail and the original e-mail request. To include the thread line, reply to this message without deleting the historical e-mail chain.

Thank you,

ΗW

The privacy of the inquirer should be protected in any transmission or storage of this e-mail.

----- Original Email -----

From : null

To :cdcinf0@cdc.gov Date :2014-01-05 01:41:47 Subject :CDC-INFO: Inquiry Subject: HPV Vaccination

Other: [othersubject]

From: General Public

Email Address: (b)(6)

(b)(5); (b)(6)

From:Gee, Julianne (CDC/OID/NCEZID)Sent:Tue, 7 Jan 2014 12:33:40 -0500To:Destefano, Frank (CDC/OID/NCEZID);Miller, Elaine R. (CDC/OID/NCEZID)Cc:Moro, Pedro (CDC/OID/NCEZID)Subject:RE: RESPONSE REQUIRED: Topic: HPV Vaccine Death, Priority: Medium, Mode:Email [ref:_00DU0YCBU._500U0AKo8S:ref]HPV Vaccine Safety Responses.pdf

Hi Elaine-

Attached is a document that Staci has put together to help with Frank and I with responses for HPV inquiries. They are what has been sent from you, Angela, Tom, and others over the past 6-8 mos and the responses have been cleared.

Perhaps you can revise to say something like this:

(b)(5)

Hope this helps. Also, we have saved the attached on the share drive for easy access for future inquiries. It can be found at \\cdc\project\NCPDCID_DHQP_ISO\HPV Julianne

From: Destefano, Frank (CDC/OID/NCEZID)
Sent: Tuesday, January 07, 2014 12:15 PM
To: Miller, Elaine R. (CDC/OID/NCEZID); Gee, Julianne (CDC/OID/NCEZID)
Cc: Moro, Pedro (CDC/OID/NCEZID)
Subject: RE: RESPONSE REQUIRED: Topic: HPV Vaccine Death, Priority: Medium, Mode: Email [ref:_00DU0YCBU._500U0AKo8S:ref]

Yes, I would still like to review the responses on HPV vaccine. In addition, in the draft response below I

would add		(b)(5)	_
	(b)(5)		

Thanks, Frank

From: Miller, Elaine R. (CDC/OID/NCEZID)
Sent: Tuesday, January 07, 2014 12:02 PM
To: Destefano, Frank (CDC/OID/NCEZID)
Cc: Moro, Pedro (CDC/OID/NCEZID)
Subject: FW: RESPONSE REQUIRED: Topic: HPV Vaccine Death, Priority: Medium, Mode: Email [ref:_00DU0YCBU._500U0AKo8S:ref] HI Frank, Are you still reviewing all HPV inquiries that we receive? At the bottom of this chain is an inquiry on HPV and the response that we were planning to have NIPINFO to send out. Please let me know if you want any revisions. Thanks, Elaine

(b)(5); (b)(6)

Sincerely,

From: Hamborsky, Jennifer (CDC/OID/NCIRD) On Behalf Of NIPINFO (CDC)
Sent: Monday, January 06, 2014 7:30 PM
To: Miller, Elaine R. (CDC/OID/NCEZID)
Subject: FW: RESPONSE REQUIRED: Topic: HPV Vaccine Death, Priority: Medium, Mode: Email [ref:_00DU0YCBU._500U0AKo8S:ref]

Hi Elaine, Not sure what to do with this one... CISA consult? I guess it depends on autopsy findings.

From: CDC-INFO Response (CDC) Sent: Monday, January 06, 2014 5:22 PM To: NIPINFO (CDC) **Subject:** RESPONSE REQUIRED: Topic: HPV Vaccine Death, Priority: Medium, Mode: Email [ref:_00DU0YCBU._500U0AKo8S:ref]

Below, you will find an inquiry regarding a death that occurred after an HPV vaccination. We are not sure how to advise on this one; therefore, we are escalating for assistance.

Please let us know as soon as possible if your group will provide the answer to the inquiry below or if the inquiry should be referred elsewhere, for example to a state or local health department, another CDC program, or other federal agency. Specific guidance on a referral and contact information would be appreciated.

Programs are asked to reply within 3 business days of receipt of this escalation. If there is a delay, please let us know when to expect the answer so we can share that information with the inquirer. A reminder will be sent in 8 days; the inquiry will be closed after 10 days.

Questions about this inquiry can be directed to the CDC-1NFO Correspondence Team by replying to this e-mail. Please reference the inquiry number below and include the e-mail thread line in your response. The thread line is the e-mail chain including this e-mail and the original e-mail request. To include the thread line, reply to this message without deleting the historical e-mail chain.

Thank you,

ΗW

The privacy of the inquirer should be protected in any transmission or storage of this e-mail.

----- Original Email -----

From : null

To :cdcinfo@cdc.gov

Date :2014-01-05 01:41:47

Subject :CDC-INFC: Inquiry

Subject: HPV Vaccination

Other: [othersubject]

From: General Public

Email Address: (b)(6)

(b)(5); (b)(6)

From:Miller, Elaine R. (CDC/OID/NCEZID)Sent:Tue, 7 Jan 2014 11:54:48 -0500To:Moro, Pedro (CDC/OID/NCEZID)Subject:RE: RESPONSE REQUIRED: Topic: HPV Vaccine Death, Priority: Medium, Mode:Email [ref:_00DU0YCBU._500U0AKo8S:ref]

Thanks Pedro

From: Moro, Pedro (CDC/OID/NCEZID)
Sent: Tuesday, January 07, 2014 11:10 AM
To: Miller, Elaine R. (CDC/OID/NCEZID)
Subject: RE: RESPONSE REQUIRED: Topic: HPV Vaccine Death, Priority: Medium, Mode: Email [
ref:_00DU0YCBU._500U0AKo8S:ref]

Hi Elaine,

Sorry for not responding sooner but I got pulled with other things

I think it looks good. I don't have any comments

Pedro

From: Miller, Elaine R. (CDC/OID/NCEZID)
Sent: Tuesday, January 07, 2014 8:19 AM
To: Moro, Pedro (CDC/OID/NCEZID)
Subject: FW: RESPONSE REQUIRED: Topic: HPV Vaccine Death, Priority: Medium, Mode: Email [ref:_00DU0YCBU._500U0AKo8S:ref]

Hi Pedro: Please let me know if this revised response needs edits. After you view it, I will send to Frank since he views all HPV inquiries. Thanks, Elaine

(b)(5); (b)(6)

Sincerely,

From: Hamborsky, Jennifer (CDC/OID/NCIRD) On Behalf Of NIPINFO (CDC)
Sent: Monday, January 06, 2014 7:30 PM
To: Miller, Elaine R. (CDC/OID/NCEZID)
Subject: FW: RESPONSE REQUIRED: Topic: HPV Vaccine Death, Priority: Medium, Mode: Email [ref:_00DU0YCBU._500U0AKo8S:ref]

Hi Elaine, Not sure what to do with this one... CISA consult? I guess it depends on autopsy findings.

From: CDC-INFO Response (CDC)
Sent: Monday, January 06, 2014 5:22 PM
To: NIPINFO (CDC)
Subject: RESPONSE REQUIRED: Topic: HPV Vaccine Death, Priority: Medium, Mode: Email [
ref:_00DU0YCBU._500U0AKo8S:ref]

Below, you will find an inquiry regarding a death that occurred after an HPV vaccination. We are not sure how to advise on this one; therefore, we are escalating for assistance.

Please let us know as soon as possible if your group will provide the answer to the inquiry below or if the inquiry should be referred elsewhere, for example to a state or local health department, another CDC program, or other federal agency. Specific guidance on a referral and contact information would be appreciated.

Programs are asked to reply within 3 business days of receipt of this escalation. If there is a delay, please let us know when to expect the answer so we can share that information with the inquirer. A reminder will be sent in 8 days; the inquiry will be closed after 10 days.

Questions about this inquiry can be directed to the CDC-INFO Correspondence

Team by replying to this e-mail. Please reference the inquiry number below and include the e-mail thread line in your response. The thread line is the e-mail chain including this e-mail and the original e-mail request. To include the thread line, reply to this message without deleting the historical e-mail chain. _____ _____ Thank you, ΗW The privacy of the inquirer should be protected in any transmission or storage of this e-mail. ----- Original Email -----_____ From : null To :cdcinfo@cdc.gov Date :2014-01-05 01:41:47 Subject :CDC-INFO: Inquiry Subject: HPV Vaccination Other: [othersubject] From: General Public Email Address: (b)(6) (b)(5); (b)(6)

From:Miller, Elaine R. (CDC/OID/NCEZID)Sent:Tue, 7 Jan 2014 13:23:38 -0500To:Destefano, Frank (CDC/OID/NCEZID)Cc:Moro, Pedro (CDC/OID/NCEZID);Gee, Julianne (CDC/OID/NCEZID)Subject:RE: RESPONSE REQUIRED: Topic: HPV Vaccine Death, Priority: Medium, Mode:Email [ref:_00DU0YCBU._500U0AKo8S:ref]

Thanks Frank

From: Destefano, Frank (CDC/OID/NCEZID)
Sent: Tuesday, January 07, 2014 1:19 PM
To: Miller, Elaine R. (CDC/OID/NCEZID)
Cc: Moro, Pedro (CDC/OID/NCEZID); Gee, Julianne (CDC/OID/NCEZID)
Subject: RE: RESPONSE REQUIRED: Topic: HPV Vaccine Death, Priority: Medium, Mode: Email [ref:_00DU0YCBU._500U0AKo8S:ref]

Looks good, except I would suggest moving the sentence as indicated below. Thanks, Frank

From: Miller, Elaine R. (CDC/OID/NCEZID)
Sent: Tuesday, January 07, 2014 12:31 PM
To: Destefano, Frank (CDC/OID/NCEZID)
Cc: Moro, Pedro (CDC/OID/NCEZID); Gee, Julianne (CDC/OID/NCEZID)
Subject: FW: RESPONSE REQUIRED: Topic: HPV Vaccine Death, Priority: Medium, Mode: Email [ref:_00DU0YCBU._500U0AKo8S:ref]

Thanks Frank. The revised response is below with the addition in red. Please let me know if this needs any further edits. Elaine

(b)(5)

Sincerely,

From: Destefano, Frank (CDC/OID/NCEZID)
Sent: Tuesday, January 07, 2014 12:15 PM
To: Miller, Elaine R. (CDC/OID/NCEZID); Gee, Julianne (CDC/OID/NCEZID)
Cc: Moro, Pedro (CDC/OID/NCEZID)
Subject: RE: RESPONSE REQUIRED: Topic: HPV Vaccine Death, Priority: Medium, Mode: Email [ref:_00DU0YCBU._500U0AKo8S:ref]

Yes, I would still like to review the responses on HPV vaccine. In addition, in the draft response below I would add (b)(5)

(b)(5)	
Thanks,	
Frank	
 From: Miller, Elaine R. (CDC/OID/NCEZID) Sent: Tuesday, January 07, 2014 12:02 PM To: Destefano, Frank (CDC/OID/NCEZID) Cc: Moro, Pedro (CDC/OID/NCEZID) Subject: FW: RESPONSE REQUIRED: Topic: HPV Vaccine Death, P ref:_00DU0YCBU500U0AKo8S:ref] 	riority: Medium, Mode: Email [
HI Frank, Are you still reviewing all HPV inquiries that we receive? At the bottom of this chain is an inquiry on HPV and the response t NIPINFO to send out. Please let me know if you want any revisions. Thanks,	

Elaine

(b)(5); (b)(6)

Sincerely,

From: Hamborsky, Jennifer (CDC/OID/NCIRD) On Behalf Of NIPINFO (CDC)
Sent: Monday, January 06, 2014 7:30 PM
To: Miller, Elaine R. (CDC/OID/NCEZID)
Subject: FW: RESPONSE REQUIRED: Topic: HPV Vaccine Death, Priority: Medium, Mode: Email [
ref:_00DU0YCBU._500U0AKo8S:ref]

Hi Elaine, Not sure what to do with this one... CISA consult? I guess it depends on autopsy findings.

From: CDC-INFO Response (CDC)
Sent: Monday, January 06, 2014 5:22 PM
To: NIPINFO (CDC)
Subject: RESPONSE REQUIRED: Topic: HPV Vaccine Death, Priority: Medium, Mode: Email [
ref:_00DU0YCBU._500U0AKo8S:ref]

Below, you will find an inquiry regarding a death that occurred after an HPV vaccination. We are not sure how to advise on this one; therefore, we are escalating for assistance.

Please let us know as soon as possible if your group will provide the answer to the inquiry below or if the inquiry should be referred elsewhere, for example to a state or local health department, another CDC program, or other federal agency. Specific guidance on a referral and contact information would be appreciated.

Programs are asked to reply within 3 business days of receipt of this escalation. If there is a delay, please let us know when to expect the answer so we can share that information with the inquirer. A reminder will be sent in 8 days; the inquiry will be closed after 10 days.

Questions about this inquiry can be directed to the CDC-INFO Correspondence Team by replying to this e-mail. Please reference the inquiry number below and include the e-mail thread line in your response. The thread line is the e-mail chain including this e-mail and the original e-mail request. To include the thread line, reply to this message without deleting the historical e-mail chain.

```
------
```

Thank you,

ΗW

The privacy of the inquirer should be protected in any transmission or storage of this e-mail.

----- Original Email -----

From : null

To :cdcinfo@cdc.gov

Date :2014-01-05 01:41:47

Subject :CDC-INFO: Inquiry

Subject: HPV Vaccination

Other: [othersubject]

From: General Public

Email	Address:	(b)(6)

From:Miller, Elaine R. (CDC/OID/NCEZID)Sent:Tue, 7 Jan 2014 13:29:20 -0500To:NIPINFO (CDC)Cc:Moro, Pedro (CDC/OID/NCEZID);Destefano, Frank (CDC/OID/NCEZID);Gee,Julianne (CDC/OID/NCEZID)Subject:FW: RESPONSE REQUIRED: Topic: HPV Vaccine Death, Priority: Medium, Mode:Email [ref:_00DU0YCBU._500U0AKo8S:ref]

Hi Jennifer and NIPINFO, Below is the ISO response for this inquiry. Please blind copy me when you send this out for our tracking purposes. Thanks, Elaine

(b)(5); (b)(6)

Sincerely,

From: Hamborsky, Jennifer (CDC/OID/NCIRD) On Behalf Of NIPINFO (CDC)
Sent: Monday, January 06, 2014 7:30 PM
To: Miller, Elaine R. (CDC/OID/NCEZID)
Subject: FW: RESPONSE REQUIRED: Topic: HPV Vaccine Death, Priority: Medium, Mode: Email [
ref:_00DU0YCBU._500U0AKo8S:ref]

Hi Elaine,

Not sure what to do with this one... CISA consult? I guess it depends on autopsy findings.

From: CDC-INFO Response (CDC)
Sent: Monday, January 06, 2014 5:22 PM
To: NIPINFO (CDC)
Subject: RESPONSE REQUIRED: Topic: HPV Vaccine Death, Priority: Medium, Mode: Email [
ref:_00DU0YCBU._500U0AKo8S:ref]

Below, you will find an inquiry regarding a death that occurred after an HPV vaccination. We are not sure how to advise on this one; therefore, we are escalating for assistance.

Please let us know as soon as possible if your group will provide the answer to the inquiry below or if the inquiry should be referred elsewhere, for example to a state or local health department, another CDC program, or other federal agency. Specific guidance on a referral and contact information would be appreciated.

Programs are asked to reply within 3 business days of receipt of this escalation. If there is a delay, please let us know when to expect the answer so we can share that information with the inquirer. A reminder will be sent in 8 days; the inquiry will be closed after 10 days.

Questions about this inquiry can be directed to the CDC-INFO Correspondence Team by replying to this e-mail. Please reference the inquiry number below and include the e-mail thread line in your response. The thread line is the e-mail chain including this e-mail and the original e-mail request. To include the thread line, reply to this message without deleting the historical e-mail chain.

ΗW

The privacy of the inquirer should be protected in any transmission or storage of this e-mail.

----- Original Email -----

From : null

To :cdcinfo@cdc.gov

Date :2014-01-05 01:41:47

Subject :CDC-INFO: Inquiry

Subject: HPV Vaccination

Other: [othersubject]

From: General Public

Email Address: (b)(6)

From:Miller, Elaine R. (CDC/OID/NCEZID)Sent:Tue, 7 Jan 2014 08:10:21 -0500To:Moro, Pedro (CDC/OID/NCEZID)Subject:RE: RESPONSE REQUIRED: Topic: HPV Vaccine Death, Priority: Medium, Mode:Email [ref:_00DU0YCBU._500U0AKo8S:ref]

Pedro, I have an edit on this. Please wait and I will resend in a minute. Thanks, Elaine

From: Miller, Elaine R. (CDC/OID/NCEZID)
Sent: Tuesday, January 07, 2014 8:07 AM
To: Moro, Pedro (CDC/OID/NCEZID)
Subject: FW: RESPONSE REQUIRED: Topic: HPV Vaccine Death, Priority: Medium, Mode: Email [
ref:_00DU0YCBU._500U0AKo8S:ref]

Hi Pedro:

Please let me know if this response needs edits. After you view it, I will send to Frank since he views all HPV inquiries.

Thanks,

Elaine

(b)(5); (b)(6)

Sincerely,

From: Hamborsky, Jennifer (CDC/OID/NCIRD) On Behalf Of NIPINFO (CDC)
Sent: Monday, January 06, 2014 7:30 PM
To: Miller, Elaine R. (CDC/OID/NCEZID)
Subject: FW: RESPONSE REQUIRED: Topic: HPV Vaccine Death, Priority: Medium, Mode: Email [
ref:_00DU0YCBU._500U0AKo8S:ref]

Hi Elaine,

Not sure what to do with this one... CISA consult? I guess it depends on autopsy findings.

From: CDC-INFO Response (CDC)
Sent: Monday, January 06, 2014 5:22 PM
To: NIPINFO (CDC)
Subject: RESPONSE REQUIRED: Topic: HPV Vaccine Death, Priority: Medium, Mode: Email [
ref:_00DU0YCBU._500U0AKo8S:ref]

Below, you will find an inquiry regarding a death that occurred after an HPV vaccination. We are not sure how to advise on this one; therefore, we are escalating for assistance.

Please let us know as soon as possible if your group will provide the answer to the inquiry below or if the inquiry should be referred elsewhere, for example to a state or local health department, another CDC program, or other federal agency. Specific guidance on a referral and contact information would be appreciated.

Programs are asked to reply within 3 business days of receipt of this escalation. If there is a delay, please let us know when to expect the answer so we can share that information with the inquirer. A reminder will be sent in 8 days; the inquiry will be closed after 10 days.

Questions about this inquiry can be directed to the CDC-INFO Correspondence Team by replying to this e-mail. Please reference the inquiry number below and include the e-mail thread line in your response. The thread line is the e-mail chain including this e-mail and the original e-mail request. To include the thread line, reply to this message without deleting the historical e-mail chain.

 HW

The privacy of the inquirer should be protected in any transmission or storage of this e-mail.

----- Original Email -----

From : null

To :cdcinfo@cdc.gov

Date :2014-01-05 01:41:47

Subject :CDC-INFO: Inquiry

Subject: HPV Vaccination

Other: [othersubject]

From: General Public

Email Address: (b)(6)

From:Miller, Elaine R. (CDC/OID/NCEZID)Sent:Tue, 7 Jan 2014 07:43:56 -0500To:NIPINFO (CDC)Cc:Moro, Pedro (CDC/OID/NCEZID)Subject:RE: RESPONSE REQUIRED: Topic: HPV Vaccine Death, Priority: Medium, Mode:Email [ref: 00DU0YCBU. _500U0AKo8S:ref]

Thanks Jennifer. We will get back to you. Elaine

From: Hamborsky, Jennifer (CDC/OID/NCIRD) On Behalf Of NIPINFO (CDC)
Sent: Monday, January 06, 2014 7:30 PM
To: Miller, Elaine R. (CDC/OID/NCEZID)
Subject: FW: RESPONSE REQUIRED: Topic: HPV Vaccine Death, Priority: Medium, Mode: Email [
ref:_00DU0YCBU._500U0AKo8S:ref]

Hi Elaine,

Not sure what to do with this one... CISA consult? I guess it depends on autopsy findings.

From: CDC-INFO Response (CDC)
Sent: Monday, January 06, 2014 5:22 PM
To: NIPINFO (CDC)
Subject: RESPONSE REQUIRED: Topic: HPV Vaccine Death, Priority: Medium, Mode: Email [
ref:_00DU0YCBU._500U0AKo8S:ref]

Below, you will find an inquiry regarding a death that occurred after an HPV vaccination. We are not sure how to advise on this one; therefore, we are escalating for assistance.

Please let us know as soon as possible if your group will provide the answer to the inquiry below or if the inquiry should be referred elsewhere, for example to a state or local health department, another CDC program, or other federal agency. Specific guidance on a referral and contact information would be appreciated.

Programs are asked to reply within 3 business days of receipt of this escalation. If there is a delay, please let us know when to expect the answer so we can share that information with the inquirer. A reminder will be sent in 8 days; the inquiry will be closed after 10 days.

Questions about this inquiry can be directed to the CDC-1NFO Correspondence Team by replying to this e-mail. Please reference the inquiry number below and include the e-mail thread line in your response. The thread line is the e-mail chain including this e-mail and the original e-mail request. To include the thread line, reply to this message without deleting the historical e-mail chain.

Thank you,

ΗW

The privacy of the inquirer should be protected in any transmission or storage of this e-mail.

----- Original Email -----

From : null

To :cdcinf0@cdc.gov

Date :2014-01-05 01:41:47

Subject :CDC-INFO: Inquiry

Subject: HPV Vaccination

Other: [othersubject]

From: General Public

Email Address: (b)(6)

From: **Death Reports** Sent: Fri, 3 Jan 2014 08:56:20 -0500 Niu, Manette (FDA/CBER);Barash, Faith (FDA/CBER);Zinderman, Craig E To: (FDA/CBER);Martin, David (FDA/CBER);Nguyen, Michael D. (FDA/CBER);Menschik, David (FDA/CBER);Moro, Pedro (CDC/OID/NCEZID);Miller, Elaine R. (CDC/OID/NCEZID);Binkley, Joanne (FDA/CBER);Broder, Karen (CDC/OID/NCEZID);Rohan, Patricia (FDA/CBER);Bryant, Marthe (FDA/CBER);Stacey_Neloms@sra.com;Patricia_Ray@sra.com;Kenneth_Kraska@sra.com;ana_dayton@sr a.com;Mehra_Blott@sra.com;Elisa Lara;Luis Santos;Arana, Jorge E. (CDC/OID/NCEZID) (CTR);Harrington, Theresa (CDC/OID/NCEZID); Museru, Oidda I. (CDC/OID/NCEZID); Winiecki, Scott (FDA/CBER); Qiang, Yandong (FDA/CBER);Polakowski, Laura (FDA/CBER);Goud, Ravi (FDA/CBER);Hua, Wei (FDA/CBER);Mba-Jonas, Adamma (CBER) (FDA/CBER) Death Reports 12/27/2013 through 1/2/2014 Subject:

The following are death certificates and autopsy reports received between 12/27/2013 and 1/2/2014.

	VAERS ID	Severity	Record Type	Record Received	Vaccines
(b)(6)		Death	Death Certificate	01/02/2014	Havrix, PedvaxHIB, Prevnar13, Varivax, Virivac
	(b)(6)	Death	Autopsy Report	12/30/2013	ActHIB, Daptacel, Engerix-B, Ipol, Prevnar13, Rotateq

From:	Moro, Pedro (CDC/OID/NCEZID)
Sent:	Fri, 7 Feb 2014 17:04:48 -0500
То:	Iqbal, Shahed (CDC/OID/NCEZID)
Cc:	Moro, Pedro (CDC/OID/NCEZID)
Subject:	Death report

Shahed,

I looked at this case and there was no autopsy report or death certificate, just medical records which indicated the patient had a diagnosis of seizures / stauts epilepticus. So there is really no cause of death stated for this report

Pedro

(b)(6)

From:Destefano, Frank (CDC/OID/NCEZID)Sent:Tue, 7 Jan 2014 18:23:13 +0000To:Shimabukuro, Tom (CDC/OID/NCEZID);Broder, Karen (CDC/OID/NCEZID)Subject:RE: COPY_NCEZID_Case_Report_vv-assoc_death_NY0007_082312_CLEAN.docx_e420.docx

Iguess

(b)(5)

(b)(5)

Thanks, Frank

From: Shimabukuro, Tom (CDC/OID/NCEZID)
Sent: Tuesday, January 07, 2014 12:39 PM
To: Leroy, Zanie C. (CDC/ONDIEH/NCCDPHP); Destefano, Frank (CDC/OID/NCEZID); Broder, Karen
(CDC/OID/NCEZID)
Subject: RE: COPY_NCEZID_Case_Report_vv-assoc_death_NY0007_082312_CLEAN.docx_e420.docx

Okay, I remember this now. It came over to DHQP in cross clearance and came down from Cindy.

From: Leroy, Zanie C. (CDC/ONDIEH/NCCDPHP)
Sent: Tuesday, January 07, 2014 12:38 PM
To: Shimabukuro, Tom (CDC/OID/NCEZID); Destefano, Frank (CDC/OID/NCEZID); Broder, Karen
(CDC/OID/NCEZID)
Subject: FW: COPY_NCEZID_Case_Report_vv-assoc_death_NY0007_082312_CLEAN.docx_e420.docx

Hi,

Here is the email chain from Oct 2012 requesting our review.

Thanks, Zanie

From: Weinbaum, Cindy (CDC/OID/NCEZID)
Sent: Thursday, October 25, 2012 4:17 PM
To: Leroy, Zanie C. (CDC/OID/NCEZID)
Cc: Destefano, Frank (CDC/OID/NCEZID)
Subject: Re: COPY_NCEZID_Case_Report_vv-assoc_death_NY0007_082312_CLEAN.docx_e420.docx

Thanks Zanie.

From: Leroy, Zanie C. (CDC/OID/NCEZID) Sent: Thursday, October 25, 2012 03:51 PM To: Weinbaum, Cindy (CDC/OID/NCEZID) Cc: Destefano, Frank (CDC/OID/NCEZID) Subject: RE: COPY_NCEZID_Case_Report_vv-assoc_death_NY0007_082312_CLEAN.docx_e420.docx

Hi Cindy,

I have reviewed this document and my previous comments have been incorporated. I have no further edits or comments.

Thanks, Zanie

From: Destefano, Frank (CDC/OID/NCEZID)
Sent: Wednesday, October 24, 2012 3:31 PM
To: Leroy, Zanie C. (CDC/OID/NCEZID)
Cc: Weinbaum, Cindy (CDC/OID/NCEZID)
Subject: FW: COPY_NCEZID_Case_Report_vv-assoc_death_NY0007_082312_CLEAN.docx_e420.docx

Zanie, Could you review this report for cross-clearance? Thanks, Frank

From: Weinbaum, Cindy (CDC/OID/NCEZID)
Sent: Wednesday, October 24, 2012 12:47 PM
To: Destefano, Frank (CDC/OID/NCEZID)
Subject: COPY_NCEZID_Case_Report_vv-assoc_death_NY0007_082312_CLEAN.docx_e420.docx

Hi Frank:

We received this report of death associated with varicella vaccination in cross-clearance. Could you have an SME review it by Tuesday? Cindy.

From:	Gee, Julianne (CDC/OID/NCEZID)
Sent:	Fri, 7 Feb 2014 11:52:18 -0500
То:	Destefano, Frank (CDC/OID/NCEZID)
Subject:	FW: HPV Death Report

FYI

From: Arana, Jorge E. (CDC/OID/NCEZID) (CTR)
Sent: Friday, February 07, 2014 11:42 AM
To: Moro, Pedro (CDC/OID/NCEZID); Cano, Maria (CDC/OID/NCEZID); Shimabukuro, Tom (CDC/OID/NCEZID); Gee, Julianne (CDC/OID/NCEZID)
Subject: HPV Death Report

Hi all,

FYI today's death report received	(b)(5); (b)(6)
	(b)(5)

Thanks,

-Jorge

From: VAERS Priority Report [mailto:PriorityReports@vaers.org] **Sent:** Friday, February 07, 2014 9:44 AM **To:** Patricia Ray; Miller, Elaine R. (CDC/OID/NCEZID); Gee, Julianne (CDC/OID/NCEZID); Rashard Etheridge; Arana, Jorge E. (CDC/OID/NCEZID) (CTR); Museru, Oidda I. (CDC/OID/NCEZID); Vellozzi, Claudia (CDC/ONDIEH/NCBDDD); Stacey Neloms; Karen Elms; Elisa Lara; Ana Dayton; Luis Santos; Joy Pulley; <u>Brittany Clyatt@sra.com</u>; <u>Natasha Young@sra.com</u>; <u>Erika Sykes@sra.com</u>; Larry Gottenberg@sra.com; info@vaers.org; Cano, Maria (CDC/OID/NCEZID) **Subject:** HPV Priority Report

HPV (Gardasil) / Merck & Co. Inc.:

Death

(b)(6)

From:	Broder, Karen (CDC/OID/NCEZID)		
Sent:	Tue, 7 Jan 2014 12:40:21 -0500		
То:	Shimabukuro, Tom (CDC/OID/NCEZID);Leroy, Zanie C.		
(CDC/ONDIEH/NCCDPHP);Destefano, Frank (CDC/OID/NCEZID)			
Subject:	RE: COPY_NCEZID_Case_Report_vv-		
assoc_death_	(b)(6) CLEAN.docx_e420.docx		

Thanks,

From: Shimabukuro, Tom (CDC/OID/NCEZID)		
Sent: Tuesday, January 07, 2014 12:39 PM		
To: Leroy, Zanie C. (CDC/ONDIEH/NCCDPHP); Destefano,	Frank (CDC/OID/NO	EZID); Broder, Karen
(CDC/OID/NCEZID)	·	1
Subject: RE: COPY_NCEZID_Case_Report_vv-assoc_death	(b)(6)	CLEAN.docx_e420.docx

Okay, I remember this now. It came over to DHQP in cross clearance and came down from Cindy.

 From: Leroy, Zanie C. (CDC/ONDIEH/NCCDPHP)

 Sent: Tuesday, January 07, 2014 12:38 PM

 To: Shimabukuro, Tom (CDC/OID/NCEZID); Destefano, Frank (CDC/OID/NCEZID); Broder, Karen (CDC/OID/NCEZID)

 Subject: FW: COPY_NCEZID_Case_Report_vv-assoc_death

 (b)(6)
 CLEAN.docx_e420.docx

Hi,

Here is the email chain from Oct 2012 requesting our review.

Thanks, Zanie

 From: Weinbaum, Cindy (CDC/OID/NCEZID)

 Sent: Thursday, October 25, 2012 4:17 PM

 To: Leroy, Zanie C. (CDC/OID/NCEZID)

 Cc: Destefano, Frank (CDC/OID/NCEZID)

 Subject: Re: COPY_NCEZID_Case_Report_vv-assoc_death_____(b)(6)
 CLEAN.docx_e420.docx

Thanks Zanie.

From: Leroy, Zanie C. (CDC/OID/NCEZID)
Sent: Thursday, October 25, 2012 03:51 PM
To: Weinbaum, Cindy (CDC/OID/NCEZID)
Cc: Destefano, Frank (CDC/OID/NCEZID)
Subject: RE: COPY_NCEZID_Case_Report_vv-assoc_death (b)(6) __CLEAN.docx_e420.docx

Hi Cindy,

I have reviewed this document and my previous comments have been incorporated. I have no further edits or comments.

Thanks, Zanie

From: Destefano, Frank (CDC/OID/NCEZID) Sent: Wednesday, October 24, 2012 3:31 PM To: Leroy, Zanie C. (CDC/OID/NCEZID) Cc: Weinbaum, Cindy (CDC/OID/NCEZID) Subject: FW: COPY_NCEZID_Case_Report_vv-assoc_death	(b)(6)	LEAN.docx_e420.docx
Zanie,		
Could you review this report for cross-clearance?		
Thanks,		
Frank		
From: Weinbaum, Cindy (CDC/OID/NCEZID) Sent: Wednesday, October 24, 2012 12:47 PM To: Destefano, Frank (CDC/OID/NCEZID) Subject: COPY_NCEZID_Case_Report_vv-assoc_death	(b)(6)	LEAN.docx_e420.docx
·	(~)(~)	
Hi Frank:		
We received this report of death associated with varicella va	accination in o	cross-clearance. Could you

have an SME review it by Tuesday? Cindy.

From:	Lewis, Paige W. (CDC/OID/NCEZID)
Sent:	Fri, 10 Jan 2014 14:54:33 -0500
То:	Moro, Pedro (CDC/OID/NCEZID)
Subject:	RE: Death reports
Attachments:	DTAP Death Reports (1990-2013).xls

From: Moro, Pedro (CDC/OID/NCEZID) Sent: Friday, January 10, 2014 11:41 AM **To:** Lewis, Paige W. (CDC/OID/NCEZID) Subject: RE: Death reports

I guess		(b)(5)
	(b)(5)	

Pedro

From: Lewis, Paige W. (CDC/OID/NCEZID) Sent: Friday, January 10, 2014 11:38 AM To: Moro, Pedro (CDC/OID/NCEZID) Subject: RE: Death reports

Is that with or without vaccination date?

From: Moro, Pedro (CDC/OID/NCEZID) Sent: Friday, January 10, 2014 11:37 AM To: Lewis, Paige W. (CDC/OID/NCEZID) Subject: RE: Death reports

But the DTaP line list should have ALL deaths since 1990

Pedro

From: Lewis, Paige W. (CDC/OID/NCEZID) Sent: Friday, January 10, 2014 11:36 AM **To:** Moro, Pedro (CDC/OID/NCEZID) Subject: RE: Death reports

It should ... starting 07/01/1997 .. if they have a vaccination date

From: Moro, Pedro (CDC/OID/NCEZID) Sent: Friday, January 10, 2014 11:35 AM To: Lewis, Paige W. (CDC/OID/NCEZID) Subject: RE: Death reports

Does the main line list for all vaccines include the HIB deaths. I would think (b)(5)

(b)(5)

Pedro

From: Lewis, Paige W. (CDC/OID/NCEZID) Sent: Friday, January 10, 2014 11:14 AM To: Moro, Pedro (CDC/OID/NCEZID) Subject: RE: Death reports

The new deaths start at line 1887. I did not include the info you had already included for the DTAP. I will rerun the dtap now.

From: Moro, Pedro (CDC/OID/NCEZID) Sent: Thursday, January 09, 2014 3:48 PM To: Lewis, Paige W. (CDC/OID/NCEZID) Subject: RE: Death reports

Hi Paige,

(b)(5)

Pedro

From: Lewis, Paige W. (CDC/OID/NCEZID) Sent: Thursday, January 09, 2014 2:05 PM To: Moro, Pedro (CDC/OID/NCEZID) Subject: RE: Death reports

From: Moro, Pedro (CDC/OID/NCEZID) Sent: Tuesday, January 07, 2014 4:52 PM To: Lewis, Paige W. (CDC/OID/NCEZID) Subject: RE: Death reports

Yes, I'll keep those

Pedro

From: Lewis, Paige W. (CDC/OID/NCEZID) Sent: Tuesday, January 07, 2014 4:52 PM To: Moro, Pedro (CDC/OID/NCEZID) Subject: RE: Death reports

Do you want me to keep the three I mentioned before that you had in your list?

From: Moro, Pedro (CDC/OID/NCEZID) Sent: Tuesday, January 07, 2014 4:22 PM To: Lewis, Paige W. (CDC/OID/NCEZID) Subject: RE: Death reports

Let's exclude them

Pedro

From: Lewis, Paige W. (CDC/OID/NCEZID) Sent: Tuesday, January 07, 2014 4:21 PM To: Moro, Pedro (CDC/OID/NCEZID) Subject: RE: Death reports

(b)(5)

From: Moro, Pedro (CDC/OID/NCEZID) Sent: Thursday, January 02, 2014 8:27 PM To: Lewis, Paige W. (CDC/OID/NCEZID) Subject: RE: Death reports

Paige,

I think

(b)(5)

(b)(5)

Pedro

From: Lewis, Paige W. (CDC/OID/NCEZID) Sent: Thursday, January 02, 2014 5:00 PM To: Moro, Pedro (CDC/OID/NCEZID) Subject: RE: Death reports

Hey Pedro,

(b)(5); (b)(6)

From: Moro, Pedro (CDC/OID/NCEZID) Sent: Monday, December 30, 2013 1:36 PM To: Lewis, Paige W. (CDC/OID/NCEZID) Subject: Death reports

Paige,

(b)(5)

Let me know if you have any questions

Pedro

This page uses frames, but your browser doesn't support them.

From: **Death Reports** Sent: Fri, 10 Jan 2014 11:14:24 -0500 Niu, Manette (FDA/CBER);Barash, Faith (FDA/CBER);Zinderman, Craig E To: (FDA/CBER);Martin, David (FDA/CBER);Nguyen, Michael D. (FDA/CBER);Menschik, David (FDA/CBER);Moro, Pedro (CDC/OID/NCEZID);Miller, Elaine R. (CDC/OID/NCEZID);Binkley, Joanne (FDA/CBER);Broder, Karen (CDC/OID/NCEZID);Rohan, Patricia (FDA/CBER);Bryant, Marthe (FDA/CBER);Stacey_Neloms@sra.com;Patricia_Ray@sra.com;Kenneth_Kraska@sra.com;ana_dayton@sr a.com;Mehra_Blott@sra.com;Elisa Lara;Luis Santos;Arana, Jorge E. (CDC/OID/NCEZID) (CTR);Harrington, Theresa (CDC/OID/NCEZID); Museru, Oidda I. (CDC/OID/NCEZID); Winiecki, Scott (FDA/CBER); Qiang, Yandong (FDA/CBER);Polakowski, Laura (FDA/CBER);Goud, Ravi (FDA/CBER);Hua, Wei (FDA/CBER);Mba-Jonas, Adamma (CBER) (FDA/CBER) Subject: Death Reports 1/3/2014 through 1/9/2014

The following are death certificates and autopsy reports received between 1/3/2014 and 1/9/2014.

Source: Data query from VAERS (1/3/2014 - 1/9/2014)

VAERS ID	Severity	Record Type	Record Received	Vaccines
(b)(6)	Death	Death Certificate	01/06/2014	Fluzone High-Dose
(b)(6) Death		Death Certificate	01/06/2014	no brand name

From:	Lewis, Paige W. (CDC/OID/NCEZID)
Sent:	Fri, 10 Jan 2014 11:37:47 -0500
То:	Moro, Pedro (CDC/OID/NCEZID)
Subject:	RE: Death reports

Ohhh ... I did not do that... sorry about that

From: Moro, Pedro (CDC/OID/NCEZID) Sent: Friday, January 10, 2014 11:37 AM To: Lewis, Paige W. (CDC/OID/NCEZID) Subject: RE: Death reports

But the DTaP line list should have ALL deaths since 1990

Pedro

From: Lewis, Paige W. (CDC/OID/NCEZID) Sent: Friday, January 10, 2014 11:36 AM To: Moro, Pedro (CDC/OID/NCEZID) Subject: RE: Death reports

It should ... starting 07/01/1997 .. if they have a vaccination date

From: Moro, Pedro (CDC/OID/NCEZID) Sent: Friday, January 10, 2014 11:35 AM To: Lewis, Paige W. (CDC/OID/NCEZID) Subject: RE: Death reports

Does the main line list for all vaccines include the HIB deaths. I would think (b)(5)

(b)(5)

Pedro

From: Lewis, Paige W. (CDC/OID/NCEZID) Sent: Friday, January 10, 2014 11:14 AM To: Moro, Pedro (CDC/OID/NCEZID) Subject: RE: Death reports

The new deaths start at line 1887. I did not include the info you had already included for the DTAP. I will rerun the dtap now.

From: Moro, Pedro (CDC/OID/NCEZID) Sent: Thursday, January 09, 2014 3:48 PM To: Lewis, Paige W. (CDC/OID/NCEZID) Subject: RE: Death reports

Hi Paige,

(b)(5)

Pedro

From: Lewis, Paige W. (CDC/OID/NCEZID) Sent: Thursday, January 09, 2014 2:05 PM To: Moro, Pedro (CDC/OID/NCEZID) Subject: RE: Death reports

From: Moro, Pedro (CDC/OID/NCEZID) Sent: Tuesday, January 07, 2014 4:52 PM To: Lewis, Paige W. (CDC/OID/NCEZID) Subject: RE: Death reports

Yes, I'll keep those

Pedro

From: Lewis, Paige W. (CDC/OID/NCEZID) Sent: Tuesday, January 07, 2014 4:52 PM To: Moro, Pedro (CDC/OID/NCEZID) Subject: RE: Death reports

Do you want me to keep the three I mentioned before that you had in your list?

From: Moro, Pedro (CDC/OID/NCEZID) Sent: Tuesday, January 07, 2014 4:22 PM To: Lewis, Paige W. (CDC/OID/NCEZID) Subject: RE: Death reports

Let's exclude them

Pedro

From: Lewis, Paige W. (CDC/OID/NCEZID) Sent: Tuesday, January 07, 2014 4:21 PM To: Moro, Pedro (CDC/OID/NCEZID) Subject: RE: Death reports

(b)(5)	
--------	--

From: Moro, Pedro (CDC/OID/NCEZID) Sent: Thursday, January 02, 2014 8:27 PM To: Lewis, Paige W. (CDC/OID/NCEZID) Subject: RE: Death reports

Paige,

I think	(b)(5)

(b)(5)

Pedro

From: Lewis, Paige W. (CDC/OID/NCEZID) **Sent:** Thursday, January 02, 2014 5:00 PM **To:** Moro, Pedro (CDC/OID/NCEZID) **Subject:** RE: Death reports

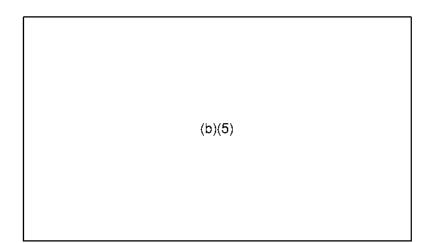
Hey Pedro,

(b)(5); (b)(6)

From: Moro, Pedro (CDC/OID/NCEZID) Sent: Monday, December 30, 2013 1:36 PM To: Lewis, Paige W. (CDC/OID/NCEZID) Subject: Death reports

Paige,

As I explained today,	(b)(5)
	(b)(5)



Let me know if you have any questions

Pedro

From: **Death Reports** Sent: Fri, 17 Jan 2014 10:20:54 -0500 Niu, Manette (FDA/CBER);Barash, Faith (FDA/CBER);Zinderman, Craig E To: (FDA/CBER);Martin, David (FDA/CBER);Nguyen, Michael D. (FDA/CBER);Menschik, David (FDA/CBER);Moro, Pedro (CDC/OID/NCEZID);Miller, Elaine R. (CDC/OID/NCEZID);Binkley, Joanne (FDA/CBER);Broder, Karen (CDC/OID/NCEZID);Rohan, Patricia (FDA/CBER);Bryant, Marthe (FDA/CBER);Stacey_Neloms@sra.com;Patricia_Ray@sra.com;Kenneth_Kraska@sra.com;ana_dayton@sr a.com;Mehra_Blott@sra.com;Elisa Lara;Luis Santos;Arana, Jorge E. (CDC/OID/NCEZID) (CTR);Harrington, Theresa (CDC/OID/NCEZID); Museru, Oidda I. (CDC/OID/NCEZID); Winiecki, Scott (FDA/CBER); Qiang, Yandong (FDA/CBER);Polakowski, Laura (FDA/CBER);Goud, Ravi (FDA/CBER);Hua, Wei (FDA/CBER);Mba-Jonas, Adamma (CBER) (FDA/CBER) Subject: Death Reports 1/10/2014 through 1/16/2014

The following are death certificates and autopsy reports received between 1/10/2014 and 1/16/2014.

VAERS ID	Severity	Record Type	Record Received	Vaccines
(b)(6)	Death	Autopsy Report	01/10/2014	AGRIFLU
	Death	Autopsy Report	01/10/2014	Fluzone, Infanrix, PedvaxHIB, Varivax

Source: Data query from VAERS (1/10/2014 - 1/16/2014)

From:Iqbal, Shahed (CDC/OID/NCEZID)Sent:Thu, 16 Jan 2014 15:01:39 -0500To:Moro, Pedro (CDC/OID/NCEZID);Lewis, Paige W.(CDC/OID/NCEZID);Shimabukuro, Tom (CDC/OID/NCEZID);Shi, Jing (CDC/OID/NCEZID) (CTR)Subject:RE: Death reports for polio vaccines

Pedro,

Once you send the database, I will touch base with Paige to see how we can extract the information from your database and add variables from VAERS in an efficient manner so that we don't have to do it over an over again.

Thanks very much, Pedro. You've saved us a lot of work.

Shahed

From: Moro, Pedro (CDC/OID/NCEZID) Sent: Thursday, January 16, 2014 2:58 PM To: Lewis, Paige W. (CDC/OID/NCEZID); Iqbal, Shahed (CDC/OID/NCEZID); Shimabukuro, Tom (CDC/OID/NCEZID); Shi, Jing (CDC/OID/NCEZID) (CTR) Subject: RE: Death reports for polio vaccines

Shahed,

Do you want Paige to identify the different brands where IPV is present? She could add a variable with the IPV brand names

Pedro

From: Lewis, Paige W. (CDC/OID/NCEZID)
Sent: Thursday, January 16, 2014 2:55 PM
To: Moro, Pedro (CDC/OID/NCEZID); Iqbal, Shahed (CDC/OID/NCEZID); Shimabukuro, Tom (CDC/OID/NCEZID); Shi, Jing (CDC/OID/NCEZID) (CTR)
Subject: RE: Death reports for polio vaccines

ok

From: Moro, Pedro (CDC/OID/NCEZID)
Sent: Thursday, January 16, 2014 2:55 PM
To: Iqbal, Shahed (CDC/OID/NCEZID); Lewis, Paige W. (CDC/OID/NCEZID); Shimabukuro, Tom (CDC/OID/NCEZID); Shi, Jing (CDC/OID/NCEZID) (CTR)
Subject: RE: Death reports for polio vaccines

Paige,

You could use

(b)(5)

(b)(5)

Pedro

From: Iqbal, Shahed (CDC/OID/NCEZID)
Sent: Thursday, January 16, 2014 2:51 PM
To: Lewis, Paige W. (CDC/OID/NCEZID); Moro, Pedro (CDC/OID/NCEZID); Shimabukuro, Tom (CDC/OID/NCEZID); Shi, Jing (CDC/OID/NCEZID) (CTR)
Subject: Death reports for polio vaccines

Paige,

It seems like	(b)(5)
	(b)(5)

Thanks,

Shahed

S. Iqbal PhD MBBS MPH

Epidemiologist Immunization Safety Office CDC/OID/NCEZID/DHQP 1600 Clifton Road NE, MS D26 Atlanta, GA 30333 Voice: 404.639.7705 cell: 404.997.9208 Fax: 404.639.8834

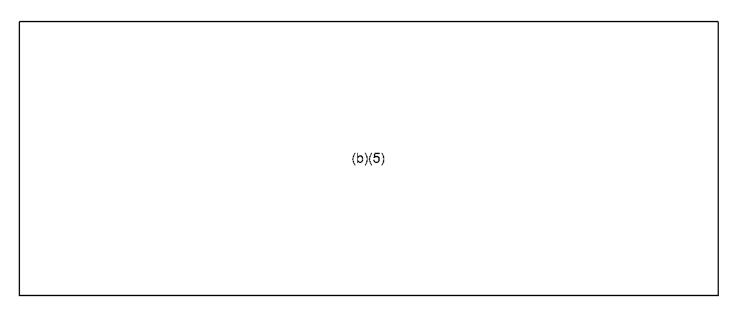
a kan bara kan bara da kan bara kan bara kan kan kan bara da bura bara kan bara da bara da bara da kan bara da Kanakara da bara da kan bara da kan bara da kan bara kan bara kan bara da kan bara da bara da kan bara da kan b Kanakara da bara da bara da kan bara da bara da bara da kan bara da kan bara da kan bara da bara da bara da ba From:Lewis, Paige W. (CDC/OID/NCEZID)Sent:Fri, 17 Jan 2014 12:15:15 -0500To:Iqbal, Shahed (CDC/OID/NCEZID)Cc:Moro, Pedro (CDC/OID/NCEZID);Shi, Jing (CDC/OID/NCEZID) (CTR);Shimabukuro,Tom (CDC/OID/NCEZID)RE: Death reports

Thanks Shahed, In regards to our earlier discussion,	(b)(5)	
	(b)(5)	

From: Iqbal, Shahed (CDC/OID/NCEZID)
Sent: Friday, January 17, 2014 11:21 AM
To: Lewis, Paige W. (CDC/OID/NCEZID)
Cc: Moro, Pedro (CDC/OID/NCEZID); Shi, Jing (CDC/OID/NCEZID) (CTR); Shimabukuro, Tom (CDC/OID/NCEZID)
Subject: RE: Death reports

Paige and all,

We'd like to have the following variables in addition to what we have in Pedro's excel sheet. See below. Please let us know if you think some other variables would be helpful.



Thanks,

Shahed

S. Iqbal, PhD, MBBS, MPH

Senior Epidemiologist Immunization Safety Office Centers for Disease Control and Prevention 1600 Clifton Road NE, MS D 26, Atlanta, GA 30333 *voice*: 404.639.7705, *cell*: 404.997.9208 *fax*: 404.639.8834

(a) A set of the set of the set of the data of the data of the set of the

From: Lewis, Paige W. (CDC/OID/NCEZID)
Sent: Thursday, January 16, 2014 5:53 PM
To: Iqbal, Shahed (CDC/OID/NCEZID)
Cc: Moro, Pedro (CDC/OID/NCEZID); Shi, Jing (CDC/OID/NCEZID) (CTR)
Subject: RE: Death reports

Shahed,

Please look over the spreadsheet and let us know if there are other variables you are interested in.

From: Moro, Pedro (CDC/OID/NCEZID)
Sent: Thursday, January 16, 2014 3:08 PM
To: Lewis, Paige W. (CDC/OID/NCEZID); Iqbal, Shahed (CDC/OID/NCEZID); Shimabukuro, Tom (CDC/OID/NCEZID); Shi, Jing (CDC/OID/NCEZID) (CTR)
Subject: FW: Death reports

Paige,

This is what you sent me

Pedro

From: Lewis, Paige W. (CDC/OID/NCEZID) Sent: Thursday, January 09, 2014 2:05 PM To: Moro, Pedro (CDC/OID/NCEZID) Subject: RE: Death reports

From: Moro, Pedro (CDC/OID/NCEZID) Sent: Tuesday, January 07, 2014 4:52 PM To: Lewis, Paige W. (CDC/OID/NCEZID) Subject: RE: Death reports Yes, I'll keep those

Pedro

From: Lewis, Paige W. (CDC/OID/NCEZID) Sent: Tuesday, January 07, 2014 4:52 PM To: Moro, Pedro (CDC/OID/NCEZID) Subject: RE: Death reports

Do you want me to keep the three I mentioned before that you had in your list?

From: Moro, Pedro (CDC/OID/NCEZID) Sent: Tuesday, January 07, 2014 4:22 PM To: Lewis, Paige W. (CDC/OID/NCEZID) Subject: RE: Death reports

Let's exclude them

Pedro

From: Lewis, Paige W. (CDC/OID/NCEZID) Sent: Tuesday, January 07, 2014 4:21 PM To: Moro, Pedro (CDC/OID/NCEZID) Subject: RE: Death reports

(b)(5)

From: Moro, Pedro (CDC/OID/NCEZID) Sent: Thursday, January 02, 2014 8:27 PM To: Lewis, Paige W. (CDC/OID/NCEZID) Subject: RE: Death reports

Paige,

I think

(b)(5)

(b)(5)

Pedro

From: Lewis, Paige W. (CDC/OID/NCEZID) Sent: Thursday, January 02, 2014 5:00 PM

To: Moro, Pedro (CDC/OID/NCEZID) Subject: RE: Death reports

Hey Pedro,

(b)(5); (b)(6)

From: Moro, Pedro (CDC/OID/NCEZID) Sent: Monday, December 30, 2013 1:36 PM To: Lewis, Paige W. (CDC/OID/NCEZID) Subject: Death reports

Paige,

As I explained today	(b)(5)

(b)(5)

Let me know if you have any questions

Pedro

From:	Kamiya, Hajime (CDC/OID/NCIRD) (CTR)
Sent:	Tue, 28 Jan 2014 12:19:23 -0500
То:	Moro, Pedro (CDC/OID/NCEZID)
Subject:	RE: VSD death study

Sure, thank you for your follow up

Hajime

From: Moro, Pedro (CDC/OID/NCEZID) Sent: Tuesday, January 28, 2014 12:15 PM To: Kamiya, Hajime (CDC/OID/NCIRD) (CTR) Subject: Re: VSD death study

Hajime, We'll have to cancel the meeting at 2 pm I'll reschedule

Pedro

From: Kamiya, Hajime (CDC/OID/NCIRD) (CTR)
Sent: Monday, January 27, 2014 04:15 PM Eastern Standard Time
To: Moro, Pedro (CDC/OID/NCEZID)
Subject: RE: VSD death study

Dear Pedro Thank you for the information. I have reviewed the medical chart for your section. Please refer to attached excel sheet

See you tomorrow

Hajime

From: Moro, Pedro (CDC/OID/NCEZID) Sent: Friday, January 24, 2014 5:44 PM To: Kamiya, Hajime (CDC/OID/NCIRD) (CTR) Subject: VSD death study

Hajime,

I include the VSD study I mentioned today

Have a nice weekend

Pedro

From:	Lewis, Paige W. (CDC/OID/NCEZID)
Sent:	Fri, 10 Jan 2014 15:46:33 -0500
То:	Moro, Pedro (CDC/OID/NCEZID)
Subject:	RE: Death reports
Attachments:	DTAP Death Reports 1990-2013 v2.xls

 $\top ry \ this$

From: Moro, Pedro (CDC/OID/NCEZID) Sent: Friday, January 10, 2014 3:14 PM To: Lewis, Paige W. (CDC/OID/NCEZID) Subject: RE: Death reports

Paige,

I could not open the file

Pedro

From: Lewis, Paige W. (CDC/OID/NCEZID) Sent: Friday, January 10, 2014 2:55 PM To: Moro, Pedro (CDC/OID/NCEZID) Subject: RE: Death reports

From: Moro, Pedro (CDC/OID/NCEZID) Sent: Friday, January 10, 2014 11:41 AM To: Lewis, Paige W. (CDC/OID/NCEZID) Subject: RE: Death reports

l guess	(b)(5)

(b)(5)

Pedro

From: Lewis, Paige W. (CDC/OID/NCEZID) Sent: Friday, January 10, 2014 11:38 AM To: Moro, Pedro (CDC/OID/NCEZID) Subject: RE: Death reports

Is that with or without vaccination date?

From: Moro, Pedro (CDC/OID/NCEZID) Sent: Friday, January 10, 2014 11:37 AM To: Lewis, Paige W. (CDC/OID/NCEZID) Subject: RE: Death reports

But the DTaP line list should have ALL deaths since 1990

Pedro

From: Lewis, Paige W. (CDC/OID/NCEZID) Sent: Friday, January 10, 2014 11:36 AM To: Moro, Pedro (CDC/OID/NCEZID) Subject: RE: Death reports

It should ... starting 07/01/1997 .. if they have a vaccination date

From: Moro, Pedro (CDC/OID/NCEZID) Sent: Friday, January 10, 2014 11:35 AM To: Lewis, Paige W. (CDC/OID/NCEZID) Subject: RE: Death reports

Does the main line list for all vaccines include the HIB deaths. I would think (b)(5)

(b)(5)

Pedro

From: Lewis, Paige W. (CDC/OID/NCEZID) Sent: Friday, January 10, 2014 11:14 AM To: Moro, Pedro (CDC/OID/NCEZID) Subject: RE: Death reports

The new deaths start at line 1887. I did not include the info you had already included for the DTAP. I will rerun the dtap now.

From: Moro, Pedro (CDC/OID/NCEZID) Sent: Thursday, January 09, 2014 3:48 PM To: Lewis, Paige W. (CDC/OID/NCEZID) Subject: RE: Death reports

Hi Paige,

(b)(5)

Pedro

From: Lewis, Paige W. (CDC/OID/NCEZID) Sent: Thursday, January 09, 2014 2:05 PM

To: Moro, Pedro (CDC/OID/NCEZID) **Subject:** RE: Death reports

From: Moro, Pedro (CDC/OID/NCEZID) Sent: Tuesday, January 07, 2014 4:52 PM To: Lewis, Paige W. (CDC/OID/NCEZID) Subject: RE: Death reports

Yes, I'll keep those

Pedro

From: Lewis, Paige W. (CDC/OID/NCEZID) Sent: Tuesday, January 07, 2014 4:52 PM To: Moro, Pedro (CDC/OID/NCEZID) Subject: RE: Death reports

Do you want me to keep the three I mentioned before that you had in your list?

From: Moro, Pedro (CDC/OID/NCEZID) Sent: Tuesday, January 07, 2014 4:22 PM To: Lewis, Paige W. (CDC/OID/NCEZID) Subject: RE: Death reports

Let's exclude them

Pedro

From: Lewis, Paige W. (CDC/OID/NCEZID) Sent: Tuesday, January 07, 2014 4:21 PM To: Moro, Pedro (CDC/OID/NCEZID) Subject: RE: Death reports

(b)(5)

From: Moro, Pedro (CDC/OID/NCEZID) Sent: Thursday, January 02, 2014 8:27 PM To: Lewis, Paige W. (CDC/OID/NCEZID) Subject: RE: Death reports Paige,

I think	(b)(5)
	(b)(5)

Pedro

From: Lewis, Paige W. (CDC/OID/NCEZID) Sent: Thursday, January 02, 2014 5:00 PM To: Moro, Pedro (CDC/OID/NCEZID) Subject: RE: Death reports

Hey Pedro,

(b)(5); (b)(6)

From: Moro, Pedro (CDC/OID/NCEZID) Sent: Monday, December 30, 2013 1:36 PM To: Lewis, Paige W. (CDC/OID/NCEZID) Subject: Death reports

Paige,

As I explained today,	(b)(5)
	(b)(5)

(b)(5)

Let me know if you have any questions

Pedro

From:	Kamiya, Hajime (CDC/OID/NCIRD) (CTR)
Sent:	Mon, 27 Jan 2014 16:15:32 -0500
То:	Moro, Pedro (CDC/OID/NCEZID)
Subject:	RE: VSD death study
Attachments:	DTAP Death Reports 1990-2013v3_hk_2.xls

Dear Pedro Thank you for the information. I have reviewed the medical chart for your section. Please refer to attached excel sheet

See you tomorrow

Hajime

From: Moro, Pedro (CDC/OID/NCEZID) Sent: Friday, January 24, 2014 5:44 PM To: Kamiya, Hajime (CDC/OID/NCIRD) (CTR) Subject: VSD death study

Hajime,

I include the VSD study I mentioned today

Have a nice weekend

Pedro

From:Lewis, Paige W. (CDC/OID/NCEZID)Sent:Thu, 9 Jan 2014 14:04:45 -0500To:Moro, Pedro (CDC/OID/NCEZID)Subject:RE: Death reportsAttachments:DTAP Death Reports (1997-2013).xls, Pedros Ids.docx, Death-VAERS-2013.xls

From: Moro, Pedro (CDC/OID/NCEZID) Sent: Tuesday, January 07, 2014 4:52 PM To: Lewis, Paige W. (CDC/OID/NCEZID) Subject: RE: Death reports

Yes, I'll keep those

Pedro

From: Lewis, Paige W. (CDC/OID/NCEZID) Sent: Tuesday, January 07, 2014 4:52 PM To: Moro, Pedro (CDC/OID/NCEZID) Subject: RE: Death reports

Do you want me to keep the three I mentioned before that you had in your list?

From: Moro, Pedro (CDC/OID/NCEZID) Sent: Tuesday, January 07, 2014 4:22 PM To: Lewis, Paige W. (CDC/OID/NCEZID) Subject: RE: Death reports

Let's exclude them

Pedro

From: Lewis, Paige W. (CDC/OID/NCEZID) Sent: Tuesday, January 07, 2014 4:21 PM To: Moro, Pedro (CDC/OID/NCEZID) Subject: RE: Death reports

From: Moro, Pedro (CDC/OID/NCEZID) Sent: Thursday, January 02, 2014 8:27 PM To: Lewis, Paige W. (CDC/OID/NCEZID) Subject: RE: Death reports

Paige,

I think

(b)(5)

(b)(5)

Pedro

From: Lewis, Paige W. (CDC/OID/NCEZID) Sent: Thursday, January 02, 2014 5:00 PM To: Moro, Pedro (CDC/OID/NCEZID) Subject: RE: Death reports

Hey Pedro,

(b)(5); (b)(6)

From: Moro, Pedro (CDC/OID/NCEZID) Sent: Monday, December 30, 2013 1:36 PM To: Lewis, Paige W. (CDC/OID/NCEZID) Subject: Death reports

Paige,

As I explained today	(b)(5)	1
	(b)(5)	

(b)(5)

Let me know if you have any questions

Pedro

(b)(5)

From:	Arana, Jorge E. (CDC/OID/NCEZID) (CTR)
Sent:	Fri, 7 Feb 2014 12:02:10 -0500
То:	Cano, Maria (CDC/OID/NCEZID)
Subject:	RE: HPV Death Report

Great ;)

From: Cano, Maria (CDC/OID/NCEZID) Sent: Friday, February 07, 2014 12:01 PM To: Arana, Jorge E. (CDC/OID/NCEZID) (CTR) Subject: Re: HPV Death Report

I saw that. I added the case to the HPV death list.

Sent from my BlackBerry Wireless Device

From: Arana, Jorge E. (CDC/OID/NCEZID) (CTR)
Sent: Friday, February 07, 2014 11:41 AM Eastern Standard Time
To: Moro, Pedro (CDC/OID/NCEZID); Cano, Maria (CDC/OID/NCEZID); Shimabukuro, Tom (CDC/OID/NCEZID); Gee, Julianne (CDC/OID/NCEZID)
Subject: HPV Death Report

Hi all,

FYI (b)(5) (b)(5)

Thanks,

-Jorge

From: VAERS Priority Report [mailto:PriorityReports@vaers.org]
Sent: Friday, February 07, 2014 9:44 AM
To: Patricia Ray; Miller, Elaine R. (CDC/OID/NCEZID); Gee, Julianne (CDC/OID/NCEZID); Rashard Etheridge; Arana, Jorge E. (CDC/OID/NCEZID) (CTR); Museru, Oidda I. (CDC/OID/NCEZID); Vellozzi, Claudia (CDC/ONDIEH/NCBDDD); Stacey Neloms; Karen Elms; Elisa Lara; Ana Dayton; Luis Santos; Joy Pulley; Brittany Clyatt@sra.com; Natasha Young@sra.com; Erika Sykes@sra.com; Larry Gottenberg@sra.com; info@vaers.org; Cano, Maria (CDC/OID/NCEZID)
Subject: HPV Priority Report

HPV (Gardasil) / Merck & Co. Inc.:

<u>Death</u> (b)(5); (b)(6)

From:Arana, Jorge E. (CDC/OID/NCEZID) (CTR)Sent:Mon, 24 Feb 2014 12:55:44 -0500To:Cano, Maria (CDC/OID/NCEZID)Subject:RE: HPV Priority Report_Death Report

Perfect. ;) -J

From: Cano, Maria (CDC/OID/NCEZID) Sent: Monday, February 24, 2014 12:55 PM To: Arana, Jorge E. (CDC/OID/NCEZID) (CTR) Subject: RE: HPV Priority Report_Death Report

Added the case into the line list for deaths.

From: Cano, Maria (CDC/OID/NCEZID) Sent: Monday, February 24, 2014 12:31 PM To: Arana, Jorge E. (CDC/OID/NCEZID) (CTR) Subject: FW: HPV Priority Report_Death Report

Thanks Jorge.

From: Moro, Pedro (CDC/OID/NCEZID)
Sent: Monday, February 24, 2014 10:39 AM
To: Arana, Jorge E. (CDC/OID/NCEZID) (CTR); Shimabukuro, Tom (CDC/OID/NCEZID); Cano, Maria (CDC/OID/NCEZID); Gee, Julianne (CDC/OID/NCEZID)
Subject: RE: HPV Priority Report_Death Report

Thanks for the update Jorge

Pedro

From: Arana, Jorge E. (CDC/OID/NCEZID) (CTR)
Sent: Monday, February 24, 2014 10:38 AM
To: Shimabukuro, Tom (CDC/OID/NCEZID); Moro, Pedro (CDC/OID/NCEZID); Cano, Maria (CDC/OID/NCEZID); Gee, Julianne (CDC/OID/NCEZID)
Subject: RE: HPV Priority Report_Death Report

FYI

Thanks,

-Jorge

From: VAERS Priority Report [mailto:PriorityReports@vaers.org]
Sent: Monday, February 24, 2014 9:47 AM
To: Patricia Ray; Miller, Elaine R. (CDC/OID/NCEZID); Gee, Julianne (CDC/OID/NCEZID); Rashard
Etheridge; Arana, Jorge E. (CDC/OID/NCEZID) (CTR); Museru, Oidda I. (CDC/OID/NCEZID); Vellozzi,
Claudia (CDC/ONDIEH/NCBDDD); Stacey Neloms; Karen Elms; Elisa Lara; Ana Dayton; Luis Santos; Joy
Pulley; <u>Brittany_Clyatt@sra.com</u>; <u>Natasha_Young@sra.com</u>; <u>Erika_Sykes@sra.com</u>; <u>info@vaers.org</u>;
Cano, Maria (CDC/OID/NCEZID)
Subject: HPV Priority Report

From:	Cano, Maria (CDC/OID/NCEZID)
Sent:	Wed, 8 Jan 2014 18:40:09 +0000
То:	Miller, Elaine R. (CDC/OID/NCEZID);Lewis, Paige W. (CDC/OID/NCEZID)
Subject:	RE: Death following Flu vaccine
Attachments:	Search_flu_deaths_thru2014-01-03.xlsx

Attached is the search that I did yesterday.

From: Miller, Elaine R. (CDC/OID/NCEZID)
Sent: Wednesday, January 08, 2014 1:36 PM
To: Cano, Maria (CDC/OID/NCEZID); Lewis, Paige W. (CDC/OID/NCEZID)
Subject: RE: Death following Flu vaccine

I am not sure why since this is entered as a death in the VPN. Elaine

From: Cano, Maria (CDC/OID/NCEZID) Sent: Wednesday, January 08, 2014 1:30 PM To: Lewis, Paige W. (CDC/OID/NCEZID) Cc: Miller, Elaine R. (CDC/OID/NCEZID) Subject: Death following Flu vaccine

(b)(5)

(b)(5)

From:	Cano, Maria (CDC/OID/NCEZID)
Sent:	Wed, 8 Jan 2014 20:00:18 +0000
То:	Miller, Elaine R. (CDC/OID/NCEZID)
Subject:	RE: Death following Flu vaccine

Thanks Elaine.

From: Miller, Elaine R. (CDC/OID/NCEZID)
Sent: Wednesday, January 08, 2014 2:54 PM
To: Cano, Maria (CDC/OID/NCEZID); Lewis, Paige W. (CDC/OID/NCEZID)
Subject: RE: Death following Flu vaccine

I'll tell SRA to add the date to the data.

From: Cano, Maria (CDC/OID/NCEZID)
Sent: Wednesday, January 08, 2014 2:53 PM
To: Lewis, Paige W. (CDC/OID/NCEZID); Miller, Elaine R. (CDC/OID/NCEZID)
Subject: RE: Death following Flu vaccine

Could the date of vaccination be added to the primary report so that the case is counted?

From: Lewis, Paige W. (CDC/OID/NCEZID)
Sent: Wednesday, January 08, 2014 2:51 PM
To: Cano, Maria (CDC/OID/NCEZID); Miller, Elaine R. (CDC/OID/NCEZID)
Subject: RE: Death following Flu vaccine

The primary report has a missing vaccination date. The tables require a vaccination date.

From: Cano, Maria (CDC/OID/NCEZID)
Sent: Wednesday, January 08, 2014 1:40 PM
To: Miller, Elaine R. (CDC/OID/NCEZID); Lewis, Paige W. (CDC/OID/NCEZID)
Subject: RE: Death following Flu vaccine

Attached is the search that I did yesterday.

From: Miller, Elaine R. (CDC/OID/NCEZID)
Sent: Wednesday, January 08, 2014 1:36 PM
To: Cano, Maria (CDC/OID/NCEZID); Lewis, Paige W. (CDC/OID/NCEZID)
Subject: RE: Death following Flu vaccine

I am not sure why since this is entered as a death in the VPN. Elaine

From: Cano, Maria (CDC/OID/NCEZID) Sent: Wednesday, January 08, 2014 1:30 PM To: Lewis, Paige W. (CDC/OID/NCEZID) Cc: Miller, Elaine R. (CDC/OID/NCEZID) Subject: Death following Flu vaccine

(b)(5)

From: **Death Reports** Sent: Fri, 21 Feb 2014 10:40:05 -0500 Niu, Manette (FDA/CBER);Barash, Faith (FDA/CBER);Zinderman, Craig E To: (FDA/CBER);Martin, David (FDA/CBER);Nguyen, Michael D. (FDA/CBER);Menschik, David (FDA/CBER);Moro, Pedro (CDC/OID/NCEZID);Miller, Elaine R. (CDC/OID/NCEZID);Binkley, Joanne (FDA/CBER);Broder, Karen (CDC/OID/NCEZID);Rohan, Patricia (FDA/CBER);Bryant, Marthe (FDA/CBER);Stacey_Neloms@sra.com;Patricia_Ray@sra.com;Kenneth_Kraska@sra.com;ana_dayton@sr a.com;Mehra_Blott@sra.com;Elisa Lara;Luis Santos;Arana, Jorge E. (CDC/OID/NCEZID) (CTR);Harrington, Theresa (CDC/OID/NCEZID); Museru, Oidda I. (CDC/OID/NCEZID); Winiecki, Scott (FDA/CBER); Qiang, Yandong (FDA/CBER);Polakowski, Laura (FDA/CBER);Goud, Ravi (FDA/CBER);Hua, Wei (FDA/CBER);Mba-Jonas, Adamma (CBER) (FDA/CBER);Cano, Maria (CDC/OID/NCEZID) Death Reports 2/14/2014 through 2/20/2014 Subject:

The following are death certificates and autopsy reports received between 2/14/2014 and 2/20/2014.

Source: Data query from VAERS (2/14/2014 - 2/20/2014)

VAERS ID	Severity	Record Type	Record Received	Vaccines
	Death	Death Certificate	02/20/2014	Fluzone, no brand name
(b)(6)	Death	Death Certificate	02/20/2014	Fluarix
	Death	Death Certificate	02/17/2014	no brand name

From: **Death Reports** Sent: Fri, 28 Feb 2014 08:25:05 -0500 Niu, Manette (FDA/CBER);Barash, Faith (FDA/CBER);Zinderman, Craig E To: (FDA/CBER);Martin, David (FDA/CBER);Nguyen, Michael D. (FDA/CBER);Menschik, David (FDA/CBER);Moro, Pedro (CDC/OID/NCEZID);Miller, Elaine R. (CDC/OID/NCEZID);Binkley, Joanne (FDA/CBER);Broder, Karen (CDC/OID/NCEZID);Rohan, Patricia (FDA/CBER);Bryant, Marthe (FDA/CBER);Stacey_Neloms@sra.com;Patricia_Ray@sra.com;Kenneth_Kraska@sra.com;ana_dayton@sr a.com;Mehra_Blott@sra.com;Elisa Lara;Luis Santos;Arana, Jorge E. (CDC/OID/NCEZID) (CTR);Harrington, Theresa (CDC/OID/NCEZID); Museru, Oidda I. (CDC/OID/NCEZID); Winiecki, Scott (FDA/CBER); Qiang, Yandong (FDA/CBER);Polakowski, Laura (FDA/CBER);Goud, Ravi (FDA/CBER);Hua, Wei (FDA/CBER);Mba-Jonas, Adamma (CBER) (FDA/CBER);Cano, Maria (CDC/OID/NCEZID) Death Reports 2/21/2014 through 2/27/2014 Subject:

The following are death certificates and autopsy reports received between 2/21/2014 and 2/27/2014.

Source: Data query from VAERS (2/21/2014 - 2/27/2014)

VAERS ID	Severity	Record Type	Record Received	Vaccines
(b)(6)	Death	Death Certificate	02/25/2014	Fluzone High-Dose, Zostavax
(b)(6)	Death	Death Certificate	02/25/2014	no brand name

From:	Miller, Elaine R. (CDC/OID/NCEZID)
Sent:	Fri, 31 Jan 2014 09:42:37 -0500
То:	'NURFU@vaers.org'
Cc:	Neloms, Stacey;Cano, Maria (CDC/OID/NCEZID)
Subject:	FW: Death Reports 1/24/2014 through 1/30/2014

Hi all,

Please add Maria Cano to this email distribution list. Her address is <u>mcano@cdc.gov</u> Thanks,

Elaine

From: Death Reports [mailto:PriorityReports@vaers.org]

Sent: Friday, January 31, 2014 8:38 AM

To: Niu, Manette (FDA/CBER); Barash, Faith (FDA/CBER); Zinderman, Craig E (FDA/CBER); Martin, David (FDA/CBER); Nguyen, Michael D. (FDA/CBER); Menschik, David (FDA/CBER); Moro, Pedro (CDC/OID/NCEZID); Miller, Elaine R. (CDC/OID/NCEZID); Binkley, Joanne (FDA/CBER); Broder, Karen (CDC/OID/NCEZID); Rohan, Patricia (FDA/CBER); Bryant, Marthe (FDA/CBER); <u>Stacey_Neloms@sra.com</u>; <u>Patricia_Ray@sra.com</u>; <u>Kenneth_Kraska@sra.com</u>; <u>ana_dayton@sra.com</u>; <u>Mehra_Blott@sra.com</u>; Elisa Lara; Luis Santos; Arana, Jorge E. (CDC/OID/NCEZID) (CTR); Harrington, Theresa (CDC/OID/NCEZID); Museru, Oidda I. (CDC/OID/NCEZID); Winiecki, Scott (FDA/CBER); Qiang, Yandong (FDA/CBER); Polakowski, Laura (FDA/CBER); Goud, Ravi (FDA/CBER); Hua, Wei (FDA/CBER); Mba-Jonas, Adamma (CBER) (FDA/CBER)

Subject: Death Reports 1/24/2014 through 1/30/2014

The following are death certificates and autopsy reports received between 1/24/2014 and 1/30/2014.

V	'AERS ID	Severity	Record Type	Record Received	Vaccines
	Death	Death Certificate	01/28/2014	FluLaval	
	Death	Death Certificate	01/28/2014	Fluzone	
	(b)(6)	Death	Autopsy Report	01/27/2014	Pentacel, Prevnar13, Recombivax HB, Rotateq
		Death	Autopsy Report	01/24/2014	Pediarix, Prevnar13, Rotateq
	Death	Autopsy Report	01/24/2014	Fluzone Quadrivalent	

Source: Data query from VAERS (1/24/2014 - 1/30/2014)

From: **Death Reports** Sent: Fri, 7 Feb 2014 09:30:32 -0500 Niu, Manette (FDA/CBER);Barash, Faith (FDA/CBER);Zinderman, Craig E To: (FDA/CBER); Martin, David (FDA/CBER); Nguyen, Michael D. (FDA/CBER); Menschik, David (FDA/CBER);Moro, Pedro (CDC/OID/NCEZID);Miller, Elaine R. (CDC/OID/NCEZID);Binkley, Joanne (FDA/CBER);Broder, Karen (CDC/OID/NCEZID);Rohan, Patricia (FDA/CBER);Bryant, Marthe (FDA/CBER);Stacey_Neloms@sra.com;Patricia_Ray@sra.com;Kenneth_Kraska@sra.com;ana_dayton@sr a.com;Mehra_Blott@sra.com;Elisa Lara;Luis Santos;Arana, Jorge E. (CDC/OID/NCEZID) (CTR);Harrington, Theresa (CDC/OID/NCEZID); Museru, Oidda I. (CDC/OID/NCEZID); Winiecki, Scott (FDA/CBER); Qiang, Yandong (FDA/CBER);Polakowski, Laura (FDA/CBER);Goud, Ravi (FDA/CBER);Hua, Wei (FDA/CBER);Mba-Jonas, Adamma (CBER) (FDA/CBER);Cano, Maria (CDC/OID/NCEZID) Death Reports 1/31/2014 through 2/6/2014 Subject:

The following are death certificates and autopsy reports received between 1/31/2014 and 2/6/2014.

	VAERS ID	Severity	Record Type	Record Received	Vaccines
ſ		Death	Autopsy Report	02/06/2014	Fluzone Quadrivalent
	(b)(6)	Death	Autopsy Report	02/04/2014	ActHIB, Daptacel, Ipol, Prevnar13, Rotateq

Source: Data query from VAERS (1/31/2014 - 2/6/2014)

From:	lqbal, Shahed (CDC/OID/NCEZID)
Sent:	Thu, 23 Jan 2014 17:06:51 -0500
To:	Shi, Jing (CDC/OID/NCEZID) (CTR);Lewis, Paige W. (CDC/OID/NCEZID)
Cc:	Moro, Pedro (CDC/OID/NCEZID);Shimabukuro, Tom (CDC/OID/NCEZID)
Subject:	RE: Updated IPV death line listing

Thanks, Jing. I'll have a look and let you know if I have any question.

S. Iqbal, PhD, MBBS, MPH Senior Epidemiologist Immunization Safety Office Centers for Disease Control and Prevention 1600 Clifton Road NE, MS D 26, Atlanta, GA 30333 *voice*: 404.639.7705, *cell*: 404.997.9208 *fax*: 404.639.8834

المراجع محمد المراجع من المراجع من المحمد المراجع من المراجع من المراجع من المراجع من المحمد المراجع المراجع ا المراجع محمد المراجع من المراجع من المراجع محمد المراجع من المراجع محمد المراجع

From: Shi, Jing (CDC/OID/NCEZID) (CTR)
Sent: Thursday, January 23, 2014 4:35 PM
To: Iqbal, Shahed (CDC/OID/NCEZID); Lewis, Paige W. (CDC/OID/NCEZID)
Cc: Moro, Pedro (CDC/OID/NCEZID); Shimabukuro, Tom (CDC/OID/NCEZID)
Subject: Updated IPV death line listing

Hi Shahed,

(b)(6); (b)(5)

Thanks,

Jing (Christine) Shi, MPH

Data Analyst ISO/OID/NCEZID 1600 Clifton Rd, MS D-26 Atlanta, GA 30033 PH: 404-718-1216 Email: <u>xag6@cdc.gov</u>

From:	Shi, Jing (CDC/OID/NCEZID) (CTR)
Sent:	Thu, 23 Jan 2014 16:35:01 -0500
To:	Iqbal, Shahed (CDC/OID/NCEZID);Lewis, Paige W. (CDC/OID/NCEZID)
Cc:	Moro, Pedro (CDC/OID/NCEZID);Shimabukuro, Tom (CDC/OID/NCEZID)
Subject:	Updated IPV death line listing
Attachments:	mismatched dose.docx, ipv_death_reports.xls

Hi Shahed,

(b)(6); (b)(5)

Thanks,

Jing (Christine) Shi, MPH Data Analyst ISO/OID/NCEZID 1600 Clifton Rd, MS D-26 Atlanta, GA 30033 PH: 404-718-1216 Email: xag6@cdc.gov

From:	Moro, Pedro (CDC/OID/NCEZID)
Sent:	Fri, 24 Jan 2014 22:43:58 +0000
То:	Kamiya, Hajime (CDC/OID/NCIRD) (CTR)
Subject:	VSD death study
Attachments:	McCarthy_Mortality_AJPM_2013.pdf

Hajime,

I include the VSD study I mentioned today

Have a nice weekend

Pedro

Provided for non-commercial research and education use. Not for reproduction, distribution or commercial use.



This article appeared in a journal published by Elsevier. The attached copy is furnished to the author for internal non-commercial research and education use, including for instruction at the authors institution and sharing with colleagues.

Other uses, including reproduction and distribution, or selling or licensing copies, or posting to personal, institutional or third party websites are prohibited.

In most cases authors are permitted to post their version of the article (e.g. in Word or Tex form) to their personal website or institutional repository. Authors requiring further information regarding Elsevier's archiving and manuscript policies are encouraged to visit:

http://www.elsevier.com/authorsrights

Mortality Rates and Cause-of-Death Patterns in a Vaccinated Population

Natalie L. McCarthy, MPH, Eric Weintraub, MPH, Claudia Vellozzi, MD, MPH, Jonathan Duffy, MD, MPH, Julianne Gee, MPH, James G. Donahue, DVM, PhD, Michael L. Jackson, PhD, MPH, Grace M. Lee, MD, MPH, Jason Glanz, PhD, Roger Baxter, MD, Marlene M. Lugg, DrPH, Allison Naleway, PhD, Saad B. Omer, MBBS, MPH, PhD, Cynthia Nakasato, MD, Gabriela Vazquez-Benitez, MS, PhD, Frank DeStefano, MD, MPH

Background: Determining the baseline mortality rate in a vaccinated population is necessary to be able to identify any unusual increases in deaths following vaccine administration. Background rates are particularly useful during mass immunization campaigns and in the evaluation of new vaccines.

Purpose: Provide background mortality rates and describe causes of death following vaccination in the Vaccine Safety Datalink (VSD).

Methods: Analyses were conducted in 2012. Mortality rates were calculated at 0–1 day, 0–7 days, 0–30 days, and 0–60 days following vaccination for deaths occurring between January 1, 2005, and December 31, 2008. Analyses were stratified by age and gender. Causes of death were examined, and findings were compared to National Center for Health Statistics (NCHS) data.

Results: Among 13,033,274 vaccinated people, 15,455 deaths occurred between 0 and 60 days following vaccination. The mortality rate within 60 days of a vaccination visit was 442.5 deaths per 100,000 person-years. Rates were highest in the group aged \geq 85 years, and increased from the 0–1-day to the 0–60-day interval following vaccination. Eleven of the 15 leading causes of death in the VSD and NCHS overlap in both systems, and the top four causes of death were the same in both systems.

Conclusions: VSD mortality rates demonstrate a healthy vaccinee effect, with rates lowest in the days immediately following vaccination, most apparent in the older age groups. The VSD mortality rate is lower than that in the general U.S. population, and the causes of death are similar. (Am J Prev Med 2013;45(1):91–97) Published by Elsevier Inc. on behalf of American Journal of Preventive Medicine

From:	Moro, Pedro (CDC/OID/NCEZID)
Sent:	Mon, 27 Jan 2014 21:19:57 +0000
То:	Kamiya, Hajime (CDC/OID/NCIRD) (CTR)
Subject:	RE: VSD death study

Thanks Hajime

See you tomorrow

Pedro

From: Kamiya, Hajime (CDC/OID/NCIRD) (CTR) Sent: Monday, January 27, 2014 4:16 PM To: Moro, Pedro (CDC/OID/NCEZID) Subject: RE: VSD death study

Dear Pedro Thank you for the information. I have reviewed the medical chart for your section. Please refer to attached excel sheet

See you tomorrow

Hajime

From: Moro, Pedro (CDC/OID/NCEZID) Sent: Friday, January 24, 2014 5:44 PM To: Kamiya, Hajime (CDC/OID/NCIRD) (CTR) Subject: VSD death study

Hajime,

I include the VSD study I mentioned today

Have a nice weekend

Pedro

Moro, Pedro (CDC/OID/NCEZID)
Thu, 2 Jan 2014 22:13:12 +0000
Lewis, Paige W. (CDC/OID/NCEZID)
Re: Death reports

Hi Paige, Happy new year!

Is there a way to tell if these reports were for a vaccine given during the period of interest? Because if we can (b)(5)

Can you tag or identify those reports

(b)(5)

Thanks

Pedro

From: Lewis, Paige W. (CDC/OID/NCEZID)
Sent: Thursday, January 02, 2014 05:00 PM Eastern Standard Time
To: Moro, Pedro (CDC/OID/NCEZID)
Subject: RE: Death reports

Hey Pedro,

(b)(5); (b)(6)

From: Moro, Pedro (CDC/OID/NCEZID) Sent: Monday, December 30, 2013 1:36 PM To: Lewis, Paige W. (CDC/OID/NCEZID) Subject: Death reports

Paige,

As I explained today,	(b)(5)
	(b)(5)

(b)(5)

Let me know if you have any questions

Pedro

From:	Moro, Pedro (CDC/OID/NCEZID)
Sent:	Thu, 16 Jan 2014 20:07:49 +0000
То:	Lewis, Paige W. (CDC/OID/NCEZID);Iqbal, Shahed
(CDC/OID/NCEZID);Shimabukuro, Tom (CDC/OID/NCEZID);Shi, Jing (CDC/OID/NCEZID) (CTR)	
Subject:	FW: Death reports
Attachments:	Death-VAERS-2013.xls

Paige,

This is what you sent me

Pedro

From: Lewis, Paige W. (CDC/OID/NCEZID) Sent: Thursday, January 09, 2014 2:05 PM To: Moro, Pedro (CDC/OID/NCEZID) Subject: RE: Death reports

From: Moro, Pedro (CDC/OID/NCEZID) Sent: Tuesday, January 07, 2014 4:52 PM To: Lewis, Paige W. (CDC/OID/NCEZID) Subject: RE: Death reports

Yes, I'll keep those

Pedro

From: Lewis, Paige W. (CDC/OID/NCEZID) Sent: Tuesday, January 07, 2014 4:52 PM To: Moro, Pedro (CDC/OID/NCEZID) Subject: RE: Death reports

Do you want me to keep the three I mentioned before that you had in your list?

From: Moro, Pedro (CDC/OID/NCEZID) Sent: Tuesday, January 07, 2014 4:22 PM To: Lewis, Paige W. (CDC/OID/NCEZID) Subject: RE: Death reports

Let's exclude them

Pedro

From: Lewis, Paige W. (CDC/OID/NCEZID) Sent: Tuesday, January 07, 2014 4:21 PM To: Moro, Pedro (CDC/OID/NCEZID) Subject: RE: Death reports

(b)(5)

From: Moro, Pedro (CDC/OID/NCEZID) Sent: Thursday, January 02, 2014 8:27 PM To: Lewis, Paige W. (CDC/OID/NCEZID) Subject: RE: Death reports

Paige,

I think

(b)(5)

(b)(5)

Pedro

From: Lewis, Paige W. (CDC/OID/NCEZID) Sent: Thursday, January 02, 2014 5:00 PM To: Moro, Pedro (CDC/OID/NCEZID) Subject: RE: Death reports

Hey Pedro,

(b)(5); (b)(6)

From: Moro, Pedro (CDC/OID/NCEZID) Sent: Monday, December 30, 2013 1:36 PM To: Lewis, Paige W. (CDC/OID/NCEZID) Subject: Death reports

Paige,

As I explained today.	(b)(5)
	(b)(5)
	(-)(-)

(b)(5)

Let me know if you have any questions

Pedro

(b)(5) ; (b)(6)

(b)(5) ; (b)(6)

From:	Moro, Pedro (CDC/OID/NCEZID)
Sent:	Fri, 10 Jan 2014 20:48:12 +0000
То:	Lewis, Paige W. (CDC/OID/NCEZID)
Subject:	RE: Death reports

Ok, it worked this time

Thanks!

Pedro

From: Lewis, Paige W. (CDC/OID/NCEZID) Sent: Friday, January 10, 2014 3:47 PM To: Moro, Pedro (CDC/OID/NCEZID) Subject: RE: Death reports

Try this

From: Moro, Pedro (CDC/OID/NCEZID) Sent: Friday, January 10, 2014 3:14 PM To: Lewis, Paige W. (CDC/OID/NCEZID) Subject: RE: Death reports

Paige,

I could not open the file

Pedro

From: Lewis, Paige W. (CDC/OID/NCEZID) Sent: Friday, January 10, 2014 2:55 PM To: Moro, Pedro (CDC/OID/NCEZID) Subject: RE: Death reports

From: Moro, Pedro (CDC/OID/NCEZID) Sent: Friday, January 10, 2014 11:41 AM To: Lewis, Paige W. (CDC/OID/NCEZID) Subject: RE: Death reports

l guess

(b)(5)

Pedro

From: Lewis, Paige W. (CDC/OID/NCEZID) Sent: Friday, January 10, 2014 11:38 AM To: Moro, Pedro (CDC/OID/NCEZID) Subject: RE: Death reports

Is that with or without vaccination date?

From: Moro, Pedro (CDC/OID/NCEZID) Sent: Friday, January 10, 2014 11:37 AM To: Lewis, Paige W. (CDC/OID/NCEZID) Subject: RE: Death reports

But the DTaP line list should have ALL deaths since 1990

Pedro

From: Lewis, Paige W. (CDC/OID/NCEZID) Sent: Friday, January 10, 2014 11:36 AM To: Moro, Pedro (CDC/OID/NCEZID) Subject: RE: Death reports

It should ... starting 07/01/1997 .. if they have a vaccination date

From: Moro, Pedro (CDC/OID/NCEZID) Sent: Friday, January 10, 2014 11:35 AM To: Lewis, Paige W. (CDC/OID/NCEZID) Subject: RE: Death reports

Does the main line list for all vaccines include the HIB deaths. I would think (b)(5); (b)(6) (b)(5); (b)(6)

Pedro

From: Lewis, Paige W. (CDC/OID/NCEZID) Sent: Friday, January 10, 2014 11:14 AM To: Moro, Pedro (CDC/OID/NCEZID) Subject: RE: Death reports

The new deaths start at line 1887. I did not include the info you had already included for the DTAP. I will rerun the dtap now.

From: Moro, Pedro (CDC/OID/NCEZID) Sent: Thursday, January 09, 2014 3:48 PM To: Lewis, Paige W. (CDC/OID/NCEZID) Subject: RE: Death reports Hi Paige,

(b)(5); (b)(6)

Pedro

From: Lewis, Paige W. (CDC/OID/NCEZID) Sent: Thursday, January 09, 2014 2:05 PM To: Moro, Pedro (CDC/OID/NCEZID) Subject: RE: Death reports

From: Moro, Pedro (CDC/OID/NCEZID) Sent: Tuesday, January 07, 2014 4:52 PM To: Lewis, Paige W. (CDC/OID/NCEZID) Subject: RE: Death reports

Yes, I'll keep those

Pedro

From: Lewis, Paige W. (CDC/OID/NCEZID) Sent: Tuesday, January 07, 2014 4:52 PM To: Moro, Pedro (CDC/OID/NCEZID) Subject: RE: Death reports

Do you want me to keep the three I mentioned before that you had in your list?

From: Moro, Pedro (CDC/OID/NCEZID) Sent: Tuesday, January 07, 2014 4:22 PM To: Lewis, Paige W. (CDC/OID/NCEZID) Subject: RE: Death reports

Let's exclude them

Pedro

From: Lewis, Paige W. (CDC/OID/NCEZID) Sent: Tuesday, January 07, 2014 4:21 PM To: Moro, Pedro (CDC/OID/NCEZID) Subject: RE: Death reports

From: Moro, Pedro (CDC/OID/NCEZID) Sent: Thursday, January 02, 2014 8:27 PM To: Lewis, Paige W. (CDC/OID/NCEZID) Subject: RE: Death reports

Paige,

l think	(b)(5)	
	(b)(5)	

Pedro

From: Lewis, Paige W. (CDC/OID/NCEZID) Sent: Thursday, January 02, 2014 5:00 PM To: Moro, Pedro (CDC/OID/NCEZID) Subject: RE: Death reports

Hey Pedro, I noticed that 3 of your ids were missing vaccination date. 215624 missing vaccination date 272954 missing vaccination date 368647 missing vaccination date

Do you want me to only include reports with a vaccination date between July 1, 1997 to December 31, 2013? If so, I would not have caught these three.

From: Moro, Pedro (CDC/OID/NCEZID) Sent: Monday, December 30, 2013 1:36 PM To: Lewis, Paige W. (CDC/OID/NCEZID) Subject: Death reports

Paige,

As I explained today,	y, (b)(5)			
	(b)(5)			

(b)(5)

Let me know if you have any questions

Pedro

From: Death Reports Sent: Fri, 24 Jan 2014 08:31:53 -0500 Niu, Manette (FDA/CBER);Barash, Faith (FDA/CBER);Zinderman, Craig E To: (FDA/CBER);Martin, David (FDA/CBER);Nguyen, Michael D. (FDA/CBER);Menschik, David (FDA/CBER);Moro, Pedro (CDC/OID/NCEZID);Miller, Elaine R. (CDC/OID/NCEZID);Binkley, Joanne (FDA/CBER);Broder, Karen (CDC/OID/NCEZID);Rohan, Patricia (FDA/CBER);Bryant, Marthe (FDA/CBER);Stacey_Neloms@sra.com;Patricia_Ray@sra.com;Kenneth_Kraska@sra.com;ana_dayton@sr a.com;Mehra_Blott@sra.com;Elisa Lara;Luis Santos;Arana, Jorge E. (CDC/OID/NCEZID) (CTR);Harrington, Theresa (CDC/OID/NCEZID); Museru, Oidda I. (CDC/OID/NCEZID); Winiecki, Scott (FDA/CBER); Qiang, Yandong (FDA/CBER);Polakowski, Laura (FDA/CBER);Goud, Ravi (FDA/CBER);Hua, Wei (FDA/CBER);Mba-Jonas, Adamma (CBER) (FDA/CBER) Subject: Death Reports 1/17/2014 through 1/23/2014

The following are death certificates and autopsy reports received between 1/17/2014 and 1/23/2014.

Source: Data query from VAERS (1/17/2014 - 1/23/2014)

VAERS ID	Severity	Record Type	Record Received	Vaccines
(b)(6)	Death	Autopsy Report	01/17/2014	Pentacel, Prevnar13, Recombivax HB, Rotateq
	Death	Death Certificate	01/17/2014	no brand name, Zostavax

FDA production of emails regarding deaths reported to VAERS publication by PL Moro (https://www.ncbi.nlm. nih.gov/pubmed/26021 988)

From:Leroy, Zanie C. (CDC/ONDIEH/NCCDPHP)Sent:Tue, 7 Jan 2014 12:42:09 -0500To:Destefano, Frank (CDC/OID/NCEZID);Shimabukuro, Tom(CDC/OID/NCEZID);Broder, Karen (CDC/OID/NCEZID)Subject:FW: varicella death case

A little more correspondence.

Thanks, Zanie

From: Leung, Jessica (CDC/OID/NCIRD)
Sent: Monday, October 22, 2012 8:11 AM
To: Woo, Jane (FDA/CBER)
Cc: Bialek, Stephanie R. (CDC/OID/NCIRD); Leroy, Zanie C. (CDC/OID/NCEZID); Barash, Faith (FDA/CBER); Winiecki, Scott (FDA/CBER); Marin, Mona (CDC/OID/NCIRD)
Subject: RE: varicella death case

Hi Jane,

Sorry about the confusion		(b)(5)
	(b)(5)	

Jessica

Jessica Leung, MPH Epidemiologist Division Viral Diseases National Center for Immunization and Respiratory Diseases (NCIRD)/CDC 1600 Clifton Rd, Mail Stop- A-34 Atlanta, GA 30333 Phone: (404) 639-6067 Mobile: (404) 319-1968 Fax: (404) 315-2486 E-mail: JLeung@edc.gov

From: Woo, Jane (FDA/CBER)
Sent: Monday, October 22, 2012 8:06 AM
To: Leung, Jessica (CDC/OID/NCIRD)
Cc: Barash, Faith (FDA/CBER); Winiecki, Scott (FDA/CBER)
Subject: varicella death case

Hi. VAERS recently a report of 15-month-old who died after varicella vaccine. The report came from Merck, and you're listed as the reporter (probably because of an abstract or other scientific presentation). The case was already in VAERS under a different ID (366004). In the future, will you please let us know if you're planning to publish something about an old VAERS case? The notification will help us avoid duplicates in the database, which are particularly undesirable for deaths.

(6)

Thanks, Jane Woo, MD, MPH

From: Barash, Faith Sent: Friday, October 19, 2012 10:21 AM To: Woo, Jane Subject: 470376 varicella death case

Child died of varicella pneumonia after vaccination.

Faith Barash, MD MPH FACOG FDA Center for Biologics Evaluation and Research Therapeutics and Blood Safety Branch Division of Epidemiology, Office of Biostatistics and Epidemiology WOC1, Room 438S 1401 Rockville Pike Rockville, MD 20852 301-827-6081