ADVISORY COMMISSION ON CHILDHOOD VACCINES
TABLE OF CONTENTS
June 4, 2015

- **MMWR,** "Sustained Decrease in Laboratory Detection of Rotavirus after Implementation of Routine Vaccination – United States, 2000-2014" 8.2
- **Pediatrics,** "First Use of Serogroup B Meningococcal Vaccine in the US in Response to a University Outbreak" 8.3
- **Registerguard.com,** "UO to resume mass clinics for meningitis vaccination" 8.4

- **Public Comments** 9
  - Jean Public

1

ADVISORY COMMISSION ON CHILDHOOD VACCINES

Agenda

June 1, 2015

ADVISORY COMMISSION ON CHILDHOOD VACCINES (ACCV)

Teleconference and Adobe Connect

June 4, 2015
(10:00 am – 4:30 pm Eastern Daylight Time)
Dial in: 1-877-917-4913
Passcode: ACCV

https://hrsa.connectsolutions.com/accv/

Time	Agenda Item	Presenter
10:00 AM	Welcome and Chair Report	Dr. Kristen Feemster, Chair
10:10 AM	Public Comment on Agenda Items	Dr. Kristen Feemster, Chair
10:15 AM	Approval of March 2015 Minutes	Dr. Kristen Feemster, Chair
10:20 AM	Report from the Division of Injury Compensation Programs	Dr. A. Melissa Houston Director, DICP
10:40 AM	Discussion on Program Funding	Dr. Kristen Feemster, Chair
11:00 AM	Report from the Department of Justice	Mr. Vince Matanoski Deputy Director Torts Branch, DOJ
12:00 PM	**Lunch**	
1:00 PM	Welcome	Mr. James Macrae, Acting Administrator, HRSA
1:30 PM	Feasibility of SIRVA Prevention	Dr. Terry Dalle-Tezze, Pediatrics Team Lead, DICP
1:45 PM	Report from the Adult Immunization Workgroup	Dr. Sylvia Villarreal, ACCV Member
2:00 PM	Review of Vaccine Information Statements	Mr. Skip Wolfe, CDC

Time	Agenda Item	Presenter
3:00 PM	Update on the Immunization Safety Office (ISO), Centers for Disease Control and Prevention (CDC) Vaccine Activities	Dr. Tom Shimabukuro CDC
3:15 PM	Update on the National Institute of Allergy and Infectious diseases (NIAID), National Institutes of Health (NIH) Vaccine Activities	Ms. Claire Schuster NIAID, NIH
3:30 PM	Update on the Center for Biologics, Evaluation and Research (CBER), Food and Drug Administration (FDA) Vaccine Activities	LCDR Valerie Marshall CBER, FDA
3:45 PM	Update from the National Vaccine Program Office (NVPO)	Dr. Karin Bok NVPO
4:00 PM	Public Comment (follows the preceding topic and may commence earlier or later than 4:00 pm)	
4:15 PM	Future Agenda Items/New Business	Dr. Kristen Feemster, Chair
4:30 PM	Adjournment of the June ACCV Meeting	Dr. Kristen Feemster, Chair

Charter

CHARTER

ADVISORY COMMISSION ON CHILDHOOD VACCINES

Authority

42 U.S.C. 300aa-19, Section 2119 of the PHS Act. The Advisory Commission on Childhood Vaccines (hereinafter referred to as the "Commission") is governed by the provisions of Public Law 92-463 (5 U.S.C. App. 2), which sets forth standards for the formation of advisory committees.

Objectives and Scope of Activities

The Secretary of Health and Human Services is mandated under Section 2119 of the Public Health Service (PHS) Act to appoint an advisory commission to give advice regarding the National Vaccine Injury Compensation Program (the Program), which provides compensation for certain vaccine-related injuries or deaths.

Description of Duties

The Commission shall: (1) advise the Secretary on the implementation of the Program; (2) on its own initiative or as the result of the filing of a petition, recommend changes in the Vaccine Injury Table; (3) advise the Secretary in implementing the Secretary's responsibilities under Section 2127 of the PHS Act regarding the need for childhood vaccination products that result in fewer or no significant adverse reactions; (4) survey Federal, State, and local programs and activities relating to the gathering of information on injuries associated with the administration of childhood vaccines, including the adverse reaction reporting requirements of Section 2125(b), and advise the Secretary on means to obtain, compile, publish, and use credible data related to the frequency and severity of adverse reactions associated with childhood vaccines; (5) recommend to the Director of the National Vaccine Program research related to vaccine injuries which should be conducted to carry out the Program; and (6) consult regarding the development or revision of vaccine information materials as required by Section 2126 of the PHS Act.

Agency or Official to Whom the Commission Reports

The Commission shall advise and make recommendations to the Secretary on matters related to the Program responsibilities.

Support

Management and support services shall be provided by the Division of Vaccine Injury Compensation, Healthcare Systems Bureau, Health Resources and Services Administration.

Estimated Annual Operating Costs and Staff Years

Estimated annual cost for operating the Commission, including compensation and travel expenses for members, but excluding staff support, is approximately $39,795. The estimate of annual person-years of staff support required is 1.5 at an estimated annual cost of $256,377.

Designated Federal Official

HRSA will select a full-time or permanent part-time Federal employee to serve as the Designated Federal Official (DFO) to attend each Commission meeting and ensure that all procedures are within applicable, statutory, regulatory, and HHS General Administration Manual directives. The DFO will approve and prepare all meeting agendas, approve all of the Commission or subcommittee meetings, adjourn any meeting when the DFO determines adjournment to be in the public interest, and chair meetings when directed to do so by the official to whom the Commission reports. The DFO or his/her designee shall be present at all meetings of the full Commission and subcommittees.

Estimated Number and Frequency of Meetings

The Commission shall meet no less than four times per year and at the call of the Chair. Meetings shall be open to the public except as determined otherwise by the Secretary or designee in accordance with the Government in the Sunshine Act 5 U.S.C. 552b(c) and the Federal Advisory Committee Act. Notice of all meetings shall be given to the public. Meetings shall be conducted, and records of the proceedings kept, as required by applicable laws and departmental regulations.

Duration

Continuing.

Termination

Unless renewed by appropriate action prior to its expiration, this charter will expire two years from the date the charter is filed.

Membership and Designation

The Secretary shall select members of the Commission. The members of the Commission shall select a Chair and Vice Chair from among the members. Appointed members of the Commission shall be appointed for a term of office of 3 years.

The Commission shall be composed of the following:

(1) Nine members appointed by the Secretary as follows:

(A) three members who are health professionals, who are not employees of the United States, and who have expertise in the health care of children, the epidemiology, etiology, and prevention of childhood diseases, and the adverse reactions associated with vaccines, of whom at least two shall be pediatricians;

(B) three members from the general public, of whom at least two shall be legal representatives of children who have suffered a vaccine-related injury or death; and

(C) three members who are attorneys, of whom at least one shall be an attorney whose specialty includes representation of persons who have suffered a vaccine-related injury or death and of whom one shall be an attorney whose specialty includes representation of vaccine manufacturers.

(2) The Director of the National Institutes of Health, the Assistant Secretary for Health, the Director of the Centers for Disease Control and Prevention, and the Commissioner of the Food and Drug Administration (or the designees of such officials), each of whom shall be a non-voting ex officio member.

The nine members appointed by the Secretary shall serve as Special Government Employees. The ex officio members and the DFO shall be Regular Government Employees.

Subcommittees

Subcommittees may be established with the approval of the Secretary or designee. Subcommittee members may be members of the parent Commission. The subcommittee shall make recommendations to be deliberated by the parent Commission. The Department's Committee Management Officer will be notified upon the establishment of the each subcommittee and will be provided information on the subcommittee's name, membership, function, and estimated frequency of meetings.

Recordkeeping

The records of the Commission, formally established subcommittees, or other subgroups of the Commission, shall be handled in accordance with General Records Schedule 26, Item 2 or other approved agency records disposition schedule. These records shall be available for public inspection and copying, subject to the Freedom of Information Act, 5 U.S.C. 552.

4 – ACCV Charter

Filing Date

July 21, 2014

Approved:

JUL 1 2014

Date

Bahar Niakan
Acting Director, Office of Management

Roster

ADVISORY COMMISSION ON CHILDHOOD VACCINES (ACCV) ROSTER
DIVISION OF INJURY COMPENSATION PROGRAMS (DICP)
Parklawn Building, Room 11C-26
5600 Fishers Lane
Rockville, MD 20857

ACCV MEMBERS

Kristen A. Feemster, M.D., M.P.H., M.S.H.P.,
Chair ('15)
Assistant Professor- UPenn School of Medicine,
Division of Infectious Diseases
The Children's Hospital of Philadelphia
CHOP North- 3535 Market St, Rm 1511
Philadelphia, PA 19104
(267)426-0192 (Direct)
(215)590-2025 (Fax)
email: feemster@email.chop.edu

Jason Smith, J.D.,
Vice-Chair ('15)
Assistant General Counsel
Pfizer Inc.
500 Arcola Road
Dock E – Office D 4214
Collegeville, PA 19426
(484)865-6196 (Direct)
(484)865-6419 (Fax)
e-mail: jason.smith@pfizer.com

Ann Linguiti Pron, DNP CPNP, R.N. ('15)
University of Pennsylvania
School of Nursing, 418 Curie Blvd
Philadelphia, PA 19104-4217;
Abington VNA, Community Services, Children's
Health Center,
1421 Highland Avenue,
Abington, PA 19001
(215)635-3642 (Direct)
e-mail: aljjp@aol.com

Michelle Williams, J.D., ('15)
Alston & Bird LLP
1201 West Peachtree Street
Atlanta, GA 30309
(404)881-7594 (Direct)
(404)253-8274 (Fax)
e-mail:michelle.williams@alston.com

David King, ('15)
4 Briarcliff Lane
Holmdel, NJ 07733
(732)758-1111 (Direct)
e-mail: dking@salesmotion.com

Charlene Douglas, Ph.D., M.P.H., R.N.
('15)
Associate Professor, George Mason
University
4400 University Drive, Mail Stop 3C4
Fairfax, VA 22030-4444
(703)993-1937 (Direct)
e-mail: cdouglas@gmu.edu

Sylvia Fernandez Villarreal, M.D., ('15)
Taos Clinic for Children & Youth
1393 Weimer Road
Taos, NM 87571
(515)758-8651(Direct)
e-mail: opus@taospeds.org

Edward Kraus, J.D., ('15)
Associate Professor of Clinical Practice
Chicago-Kent College of Law
565 West Adams, Suite 600
Chicago, IL 60661
(312)906-5072 (Direct)
e-mail: ekraus@kentlaw.edu

Luisita dela Rosa, Ph.D. ('15)
22640 Lamplight Place
Santa Clarita, CA 91350
(515)708-0838 (Direct)
e-mail: louiedrosa@gmail.com

EX OFFICIO MEMBERS

Bruce Gellin, M.D.
Director, National Vaccine Program Office
200 Independence Ave, S.W. Room 736E
Washington, D.C. 20201-0004
(202)690-5566 (Direct)
(202)690-7560 (Fax)
e-mail: bgellin@osophs.dhhs.gov

Marion Gruber, Ph.D.
Acting Director
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research
Food and Drug Administration
1451 Rockville Pike, Rm 3312
Rockville, MD 20852
(301)796-2630
(301)402-1290 (Fax)
e-mail: marion.gruber@hda.hhs.gov

Carole A. Heilman, Ph.D.
Director, Division of Microbiology
and Infectious Diseases,
NIAID, NIH
6700B Rockledge Drive - Room 3142,
MSC 7630 Bethesda, MD 20892-7630
For Federal Express Mailing:
(FED EX only: Bethesda, MD 20817)
(301)496-1884 (Direct)
(301)480-4528 (Fax)
e-mail: ch25v@nih.gov

Tom Shimabukuro, M.D., M.P.H., M.B.A
Immunization Safety Office
Centers for Disease Control and Prevention
1600 Clifton Road
Clifton Building, Mail Stop D-26
Atlanta, GA 30333
(404)639-4848 (Direct)
(404)639-8834 (Fax)
e-mail: tshimabukuro@cdc.gov

DVIC STAFF

A. Melissa Houston, M.D., M.P.H., F.A.A.P.
Director, DICP
Executive Secretary, ACCV
(301)443-9350 (Direct)
(301)443-0704 (Fax)
e-mail: ahouston@hrsa.gov

Andrea Herzog
Principal Staff Liaison, ACCV
(301)443-6634 (Direct)
(301)443-8196 (Fax)
e-mail: aherzog@hrsa.gov

OFFICE OF THE GENERAL COUNSEL

Andrea Davey, J.D.
Attorney
(301)443-4500 (Direct)
(301)443-2639 (Fax)
e-mail: Andrea.Davey@hhs.gov

2015 Meeting Dates

ADVISORY COMMISSION ON CHILDHOOD VACCINES

2015 MEETING DATES

June 4, 2015
September 2 & 3, 2015
December 3 & 4, 2015

2

Advisory Commission on Childhood Vaccines

March 5, 2015

95th Meeting

Members Present

Kirsten Feemster, M.D. ('15)
Charlene Douglas, Ph.D. ('15)
Edward Kraus, J.D. ('15)
Ann Linguiti Pron, DNP, CRNP, RN ('15)
David King, ('15)
Luisita dela Rosa, Ph.D. ('15)
Jason Smith, J.D. ('15)
Sylvia Fernandez Villarreal, M.D. ('15)
Michelle Williams, J.D. ('15)

Division of Vaccine Injury Compensation

Melissa Houston, MD., Director, DVIC
Andrea Herzog, Staff Liaison

Welcome, Report of the Chair and Approval of Minutes, Dr. Kristen Feemster, ACCV Chair

Dr. Feemster called the 95th meeting of the Advisory Commission on Childhood Vaccines to order and, after roll call and after introductions requested approval of the December 2014 meeting minutes. On motion duly made and seconded the minutes were unanimously approved.

Dr. Feemster invited the report from the DICP.

Report from the Division of Injury Compensation Programs, Dr. A. Melissa Houston, Director, DICP

Dr. Houston welcomed those present on the teleconference and briefly reviewed the meeting agenda. The agenda includes an update from the Department of Justice (DOJ), reports from the chairs of the Process and Adult Immunization Workgroups, a review of Vaccine Information Statements, and finally updates from the ex officio members from the Food and Drug Administration (FDA), Centers for Disease Control (CDC), National Institutes of Health (NIH) and the National Vaccine Program Office (NVPO).

Looking at petitions and adjudications, Dr. Houston noted that the number of petitions filed thus far in FY 2015 is on track with the cases filed in 2014 for the same period, and the

projection of total cases that will be filed for the full fiscal year is 696. The 160 cases adjudicated as of February 2, 2015. In FY 2014 480 cases were adjudicated, of which 357 were compensated and 123 were dismissed. Breaking that number down, it is anticipated that 69 cases will be conceded by HHS, 15 will require a court decision, and 297 will be resolved through settlement (78%, which is in line with the last few years). Concerning awards ($83 million to date), it is expected that total awards for FY 2015 will be about $250 million, with about $21 million for attorneys' fees and costs. The balance in the Vaccine Injury Compensation Trust fund was $3.5 billion as of December 31, 2014.

Dr. Houston reported that the several regulations related to the Vaccine Injury Table (Table) continue to be reviewed by the Department of Health and Human Services (HHS) under the standard clearance process. The National Vaccine Advisory Committee met on February 10-11, and the Advisory Committee on Immunization Practices held an abbreviated meeting, because of inclement weather, on February 26. Finally, the VICP has responded to several inquiries regarding the measles outbreaks in various parts of the country, providing information about the program's activities. Dr. Houston provided contact information for anyone interested in reaching the program through e-mail or telephone.

Report from the Department of Justice, Mr. Vince Matanoski, Deputy Director, Torts Branch

Mr. Matanoski referenced the Department of Justice PowerPoint materials (DOJ PP), dated March 5, 2015, as part of his presentation. Mr. Matanoski reported that 154 petitions were filed since the last report to the Commission (DOJ PP at 2). Of the 154 petitions, 23 were minors and 131 were adults. That number is slightly less than the same reporting period a year ago – November 2014 to mid-April 2015. Mr. Matanoski predicted that 700 petitions will be filed for fiscal year 2015. There is a seasonal variance in petition filings that corresponds to the seasonal administration of the flu vaccine, with the number of petitions filed increasing in late summer/early fall. There were 142 adjudications, which is close to matching the number of new petitions filed. (DOJ PP at 3). Of those adjudicated, 117 were compensated, with 92 settlements. Of the 25 petitions not compensated, 20 were non-OAP and 5 were OAP dismissal decisions. Two petitions were voluntarily withdrawn. (DOJ PP at 4).

Turning to appellate activity, two appeals were affirmed by the Court of Appeals for the Federal Circuit (CAFC) (DOJ PP at 5). Both appeals were filed by petitioners and both involved the human papillomavirus (HPV) vaccine. In *Flores v. HHS,* the CAFC affirmed the special master's denial of petitioner's claim that HPV vaccine caused a blood clot resulting in a stroke, finding that respondent's experts more convincing. In *Koehn v. HHS*, CAFC affirmed the special master's denial of petitioner's claim that HPV vaccine caused juvenile diabetes. Of the six pending appeals, three new cases were filed, all by petitioners. (DOJ PP at 6). In *Hirmiz v. HHS*, one of the new appeals, the CFC affirmed the special master's decision crediting respondent's expert witnesses' testimony that petitioner's claim that the flu vaccine did not cause the child's degenerative motor condition. Turning to the U.S. Court of Federal Claims (CFC), Mr. Matanoski noted that five cases were recently decided. (DOJ PP at 7). *Hirmiz* was discussed in the CAFC slide. In *Moriarty v. HHS*, the CFC affirmed the special master's decision denying petitioner's claim that the MMR vaccine caused epileptic encephalopathy, seizures, and impaired cognitive function. In *Lerwick v. HHS*, the CFC affirmed the special master's damages decision regarding the level and amount of skilled nursing care required for the injured child. In *Mosley v. HHS*, the CFC vacated and remanded for rehearing

the special master's decision denying petitioner's claim that the tetanus toxoid vaccine caused transverse myelitis because the special master failed to discuss the testimony of four treating physicians. In *Castaldi v. HHS*, the CFC affirmed the special master's decision that the first symptoms of loss of speech and motor control occurred well before the three-year statutory limitations period for filing the petition.

There are currently 10 cases pending at the CFC, all filed by petitioners (DOJ PP at 8). Of those, six were new. In *Barclay v. HHS*, the special master denied petitioner's claim that the DTaP vaccine caused Dravet's syndrome, consistent with other special master decisions addressing the syndrome. *Santini v. HHS* also involved the SCNIA mutation and was similarly dismissed by the special master. In *Rowan v. HHS*, the special master denied petitioner's claim that an adjuvant in the HPV vaccine caused autoimmune syndrome induced by adjuvants (ASIA), noting that petitioner's theory was unreliable. In *Milik v. HHS*, the special master denied petitioner's claim that the MMR vaccine caused injuries, finding that petitioner's theory failed to meet any of the *Althen* causation criteria. In *Somosot v. HHS*, the special master denied petitioner's claim for attorneys' fees and costs, finding no reasonable basis to support the application where the underlying petition was dismissed as untimely. In *Contreras v. HHS*, on a second remand, the special master denied petitioner's claim that his neurological problems that began one day after vaccination were vaccine-related.
No oral arguments were pending. (DOJ PP at 9).

Turning to settlements, Mr. Matanoski discussed the compilation of adjudicated settlements (by stipulation) during the preceding quarter (DOJ PP at 10-19). There were 92 settlements finalized in the last period. Of those, 82 were adults and 10 were children. Cases resolved within a year of the petition being filed accounted for 28% of all cases, within the second year 45%, and within the third year 9%. Overall, 82% of the cases were resolved in three years or less of petition filing. The majority of conceded cases involved the flu vaccine of the injury SIRVA (shoulder related to vaccine administration). Observing that SIRVA cases are on the rise, Mr. Matanoski referenced that, of the 22 conceded cases during the period, 17 involved SIRVA. SIRVA is among the injuries being reviewed by HHS for inclusion in the amended Vaccine Injury Table, which, as Dr. Houston noted earlier, is in the clearance process. Mr. Matanoski reiterated that DOJ continues to streamline case processing consistent with the expected Table changes. Thus, officially adding SIRVA to the Table should not result in dramatic changes in case processing.

After the conclusion of Mr. Matanoski's presentation, the ACCV discussed SIRVA. During discussion it was noted that SIRVA is related to the mechanical process of injection and not an allergic or physiological reaction to the vaccine being administered. Therefore it might be appropriate for the Commission to address ways to prevent that injury through proper training of vaccinators. Similarly, syncope, also not related to an allergic or physiological reaction of a vaccine, might be reduced by increased vigilance at the time of vaccination. Dr. Shimabukuro commented that there is significant guidance available concerning safe administration of vaccines through CDC and professional societies. It was noted that CDC has a web site entitled "Call the Shots," that provides such information. The new VAERS report includes a box to capture the location of the vaccine was administered. Ms. Pron added that nursing training programs provide a significant level of training in administering injections. There was a suggestion that a background report on the issue of injection technique, risks and precautions, be included in a future ACCV agenda. Mr. Matanoski offered that the majority of SIRVA-type claims involved flu vaccine and appeared to be administered outside of a medical facility at alternative points of health care delivery, such as pharmacy chains and supermarkets. It was questioned whether there is data on the level of training for those administering vaccinations.

There was agreement that an agenda item should be added for the next meeting to include background information about vaccine administration from the CDC and the professional societies. Dr. Houston offered to provide assistance in developing a presentation.

Report from the Process Workgroup, Ms. Luisita dela Rosa, ACCV Member

Ms. dela Rosa reported that Dr. Houston provided an update to the workgroup during the March 4th meeting on how recommendations to the Secretary of HHS are handled. She noted that, since the Secretary has just come on board, the process may or may not change. She added that senior HHS administrators had met with the Secretary to provide some background on the various advisory groups within HHS but that there was no written protocol for the process by which the Secretary reviews recommendations provided.

The Workgroup reviewed the information-gathering activities of the ACCV. An example is the proposed survey of petitioners' attorneys. It was noted that the National Childhood Vaccine Injury Act provides for a waiver of the requirements of the Paperwork Reduction Act if the information gathering is related to implementation of the Act. If that exemption applies, a proposal to collect information can be developed.

With regard to resources for identifying candidates as Commission members, an announcement is made in the Federal Register, public media is relied on to publicize the vacancies, and the Commission members are invited to submit nominations. The program welcomes any suggestions to improve the recruitment process. Finally, Ms. dela Rosa noted that, with regard to in-person meetings of the Commission, two are authorized for the year (June and September meetings are available), to be determined by the Commission. She added that HRSA prefers reliance on the virtual meetings via teleconference or webcast.

Asked about the selection process for new Commission members, Dr. Houston stated that the nominations have been submitted for approval. HHS has indicated that the process takes 6-9 months, but there has been no clarification of that process. The Federal Register notice for replacement of members leaving in December will be published and the Commission will be informed of the date of publication.

There was a brief discussion about the lack of response to recommendations submitted to the Secretary. The result was an expression of concern by several commissioners about the lack of communication with the Secretary's office. Dr. Feemster stated that a specific request should be resubmitted to the Secretary for a definitive clarification of the role of the Commission with regard to recommendations made to the Secretary's office. Dr. Houston clarified the specific request of the Commission: that the Secretary provides a description of the vetting process for recommendations received from the ACCV; and an update on the status of recommendations already submitted to the Secretary. Dr. Houston stated that she would convey the request to HRSA leadership. She observed, however, that some recommendations require legislative action by Congress, which may take a longer time to process.

Asked for clarification of the Paperwork Reduction Act exemption, Ms. Overby noted that the question of the exemption came up when the Commission was considering a survey of petitioners' attorneys. She added that if the information gathering relates to fulfilling the

implementing the Act, then the exemption would apply. She further clarified that the funds for the administrative requirements of the VICP, including conducting such surveys and/or other collection of information are appropriated by Congress.

Report from the Adult Immunization Workgroup, Dr. Sylvia Villarreal, ACCV Member

Dr. Villarreal expressed appreciation for the Workgroup members who participated in the teleconference which focused on making a recommendation to the Secretary regarding inclusion of Pneumococcal (PPSV23) and the zoster (shingles) vaccines, which are recommended for adults as additional vaccines covered under the National Vaccine Injury Compensation Program (VICP) and therefore subject to the excise tax. Dr. Shimabukuro has agreed to look at the PPSV23 vaccine and obtain the perspective of the CDC working group concerned with universal recommendation of the vaccine. Several Workgroup members will be looking at the legislative history of the VICP to determine if adult immunizations and immunizations for pregnant women have ever been addressed. They will also look at CMS Medicare/Medicaid payment recommendations for the two vaccines. Ms. Herzog will invite vaccine manufacturers to present concerns and recommendations to the working group. Ms. Davey will look at the effect of the tax code.

Dr. Villarreal stated that the Workgroup will meet every second Thursday of each month for six months, when a recommendation should be prepared for the Commission. She added that the pneumococcal vaccine was also administered to a limited population of children with specific disorders (sickle cell, asplenia, profound pulmonary disorders) and Dr. Shimabukuro would be looking at that issue as it is discussed in a separate CDC working group. The Adult Immunization Workgroup would also be amenable to looking at other vaccines that may be recommended by the ACIP for select subgroups. Dr. Shimabukuro observed that including children for PPV23 vaccine in the Program would require a legislative change, and without that a change in recommendations by ACIP or CDC would probably not have an effect. There was a brief discussion about whether there was precedent to reinterpret legislation to accommodate some of the issues under discussion.

Dr. Feemster stated that she had to leave the meeting and requested that Mr. Smith act as chair. Mr. Smith announced that the next agenda item was review of Vaccine Information Statements related to human papillomavirus vaccine (HPV), pneumococcal conjugate vaccine (PCV13), and pneumococcal polysaccharide vaccine. He stated that he would recuse himself from the discussion related to the PCV 13 vaccine. Dr. Pron also recused herself from the discussions of the PCV13 and HPV vaccines. Mr. Smith noted that anyone recused from a discussion could remain in the meeting, but would not participate.

Review of Vaccine Information Statements (VIS), Mr. Skip Wolfe and Ms. Suzanne Johnson-DeLeon, CDC

HPV (Human Papillomavirus Vaccine)

Mr. Wolfe invited Ms. Suzanne Johnson-DeLeon to participate in the discussion and began review of the first paragraph, Why Get Vaccinated. Mr. Kraus expressed concern that the

wording may suggest a broader prevention of cancers than is actually the case. Acknowledging that Gardasil 9 is effective against 70% of HPV that causes cancer, he agreed with the suggestion that a less rigid description of the benefits of the vaccine would be appropriate, *Gardasil 9, prevents many cancers caused by human papillomavirus, including: cervical cancer in females; vaginal and vulvar cancers in females; and anal cancer in females and males.* There was an observation that Section 1 includes statistics for cervical cancer, but none for the other cancers listed. Mr. Wolfe commented that such statistics could be included.

Turning to Section 2, Ms. Johnson-DeLeon noted that ACIP had voted to extend the age range for HPV vaccine to 21. Mr. Kraus mentioned that the duration of the Gardasil might indicate a booster dose, and Mr. Wolfe agreed that a two-dose schedule might have to be considered in the future. In Section 3, following a comment about the termination of pregnancy being unnecessary if an individual was not aware of the pregnancy when vaccinated, Dr. Shimabukuro suggested stating there is no medical intervention needed. There were no recommendations for Section 4, except that Mr. Wolfe noted that previous recommendation to remove the reference to temporary pain (second bullet under "Problems that could happen after any vaccine,") was inadvertently not corrected. He said it would be changed. There were no recommendations pertaining to Section 5. In Section 6, Mr. King suggested emphasizing the sentence concerning the time limit to file a claim for compensation, perhaps with an italic or bold typeface. There was a comment that in many cases individuals actually fail to file a claim within the 36-month time limit. Mr. Kraus added that the ACCV had considered a recommendation to extend that time limit. He recommended including the alert and the added emphasis. There were no recommendations related to Section 7.

Pneumococcal Conjugate Vaccine (PCV13)

It was noted that Mr. Smith and Dr. Pron had recused themselves from the discussion of this VIS. It was also noted that PPSV23 was originally on the agenda but was removed since it is not a covered VICP vaccine. Mr. Smith commented that he would give the Commission an opportunity to comment on the vaccine, even though it was not on the agenda.

Dr. Villarreal commented that the original indications for use of PCV13 included otitis media, which is not included in the VIS. Dr. Shimabukuro suggested that it might have been deleted because it was not very effective against that disorder. It was noted that the condition was listed in the statistics section stating that, before the vaccine was available, there were 5 million such infections in children. The Commission agreed that the statements should be investigated.

There was an observation that when Inactivated Influenza Vaccine and PCV13 are taken together there is a risk of febrile seizure, which should be noted on the VIS. Finally, there was the same comment about emphasizing the time limit for filing a claim that was made for the previous VIS.

Pneumococcal Polysaccharide Vaccine (PPSV23)

Although comment was invited concerning the vaccine, several Commissioners suggested that, since it was an adult vaccine, not covered by the Program, that discussing it would be inappropriate. Mr. Wolfe commented that, even if the Commissioners did not discuss the vaccine specifically, comments made about other vaccine would be taken into consideration in developing a VIS for PPSV23.

Mr. Smith thanked Mr. Wolfe and Ms. Johnson-DeLeon for their help in reviewing the two Vaccine Information Statements. Referring to the next presentation by Dr. Shimabukuro, Mr. Smith stated that he would recuse himself from any discussion related to the meningococcal B vaccine.

Update on the Immunization Safety Office (ISO), Centers for Disease Control and Prevention (CDC) Vaccine Activities, Dr. Tom Shimabukuro, CDC

Dr. Shimabukuro reported that the Vaccine Adverse Event Reporting System (VAERS) form 2.0 was posted in the Federal Register for a 60-day public comment period, which ended on January 23. Nineteen comments were received and review of those comments is in progress, which may result in some revisions to the form. In regards to ongoing Clinical Immunization Safety Assessment (CISA) project, Dr. Shimabukuro stated that currently there are eight studies in progress. A complete list of activities can be found at https://clinicaltrials.gov/.

Noting that the February 2015 Advisory Committee on Immunization Practices (ACIP) was shortened because of weather, Dr. Shimabukuro reported that, for meningococcal B vaccine a recommendation was made for administration to children 10 years of age and older who are considered at increased risk. Those risk groups include persons with complement deficiency, asplenia, certain lab workers or persons exposed during an outbreak. It does not include college students in general.

There was an ACIP vote to reaffirm the existing recommendation for influenza vaccinations for everyone 6 months of age or older. The preference for live attenuated influenza vaccine (LAIV) over inactivated influenza vaccine (IIV) in persons aged 2-8 years was removed and either product is acceptable. This was based on several effectiveness studies that did not support the superior effectiveness of LAIV over IIV. The HPV session focused on the newly licensed HPV9 vaccine, and the recommendation was to administer HPV 9, 4 or 2 to females aged 9 to 26; HPV 9 or 4 for males 9 to 21. HPV 9 was approved for use in boys 9 to 15, so that use in older adolescents and young adults is an off label use.

The ACIP recommended that a single dose of yellow fever vaccine (YFV) provides long-lasting protection and is adequate for most travelers. Additional doses were recommended for: certain travelers (e.g., women pregnant when they received their initial dose, hematopoietic stem cell transplantation recipients [once they are immunocompetent] and HIV infected individuals), certain individuals in high risk settings (i.e., travelers who received last YFV dose at least 10 years prior and who will be in high risk settings [e.g., rural W. Africa]), and laboratory workers who routinely handle wild type YF virus. International Health Regulations requiring travelers to show a YFV dose within 10 years for entry is being discontinued effective June 2016.

Dr. Shimabukuro reviewed several recent published papers:

- Klein et al. Safety of Measles-Containing Vaccines in 1-Year-Old Children. Pediatrics. 2015 Jan 5. pii: peds.2014-1822. This study did not identify any new safety concerns comparing MMRV with MMR + V or after either the MMRV or the MMR + V vaccine; outcomes included anaphylaxis, ITP, ataxia, arthritis, meningitis/encephalitis, acute disseminated encephalomyelitis, Kawasaki disease, seizure, and fever. Risks for the 7 main outcomes were not significantly different. Several outcomes had few or zero postvaccination events. This study provides reassurance that these outcomes are unlikely after either vaccine.
- Abrams et al. Childhood vaccines and Kawasaki disease, Vaccine Safety Datalink, 1996-2006. Vaccine. 2015 Jan 3;33(2):382-7. Childhood vaccinations studied did not increase the risk of Kawasaki disease; conversely, vaccination was associated with a transient decrease in Kawasaki disease incidence. Verifying and understanding this potential protective effect could yield clues to the underlying etiology of Kawasaki disease.
- Sukumaran et al. Adverse events following measles, mumps, and rubella vaccine in adults reported to the Vaccine Adverse Event Reporting System (VAERS), 2003-2013. Clin Infect Dis. 2015 Jan 30. pii: civ061. [Epub ahead of print]. In this review of VAERS data, there were no new or unexpected safety concerns detected for MMR vaccination in adults. There were reports identified of pregnant women exposed to MMR which is a group in whom the vaccine is contraindicated, suggesting the need for continued provider education on vaccine recommendations and screening.
- Moro et al. Adverse Events following Haemophilus influenzae Type b Vaccines in the Vaccine Adverse Event Reporting System, 1990-2013. J Pediatr. 2015 Jan 15. pii: S0022-3476(14)01163-9. This review of VAERS reports did not identify any new or unexpected safety concerns for Hib vaccines.
- Moro et al. Safety of quadrivalent human papillomavirus vaccine (Gardasil®) in pregnancy: Adverse events among non-manufacturer reports in the Vaccine Adverse Event Reporting System, 2006-2013. Vaccine. 2015 Jan 15;33(4):519-22. This review of VAERS non-manufacturer reports following vaccination with HPV4 in pregnancy did not find any unexpected patterns in maternal or fetal outcomes.

During discussion, Dr. Pron asked if there were any current reports on the measles outbreak. Dr. Shimabukuro noted that that area was covered by the National Center for Immunization and Respiratory Diseases, and he stated that he would request that an update be provided to the Commission.

Update on the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH) Vaccine Activities, Ms. Claire Schuster, NIAID, NIH

Ms. Schuster reported that a large Ebola clinical trial, sponsored by NIAID, is now open to volunteers in Liberia. The trial will assess the safety and efficacy of two experimental vaccines to prevent Ebola virus infection The study, known as PREVAIL, the Partnership for

Research on Ebola Vaccines in Liberia, is a Phase 2/3 study and designed to enroll approximately 27,000 healthy men and women aged 18 years and older.

Ms. Schuster recalled that she had described a series of consultations on pregnant women in clinical trials related to antimicrobials and vaccines. Participants in those meetings prepared a series of papers, which appeared in a recent supplement to the journal, Clinical Infectious Diseases. The papers looked at global and national initiatives to facilitate studies of vaccines in pregnant women, recruitment and retention of women in clinical studies, maternal immunization, and the design of drug trials.

Referring to a new feature on the NIAID web site, Ms. Schuster described the NIAID Showcase that highlights notable scientific advances made by NIAID labs and NIAID-funded researchers during FY 2014. Finally, Ms. Schuster commented on the Precision Medicine Initiative, announced by President Obama. Precision medicine focuses on the individual patient, including a genetic component.

Update on the Center for Biologics, Evaluation and Research (CBER), Food and Drug Administration (FDA) Vaccine Activities, LCDR Valerie Marshall, CBER, FDA

LCDR Marshall reported that FDA approved Trumenba in October 2014, a vaccine to prevent invasive meningococcal disease caused by Neisseria meningitides serogroup B, for individuals 10 to 25. In January 2015, FDA approved Bexsero, the second vaccine to prevent invasive meningococcal disease caused by Neisseria meningitides serogroup B, for individuals 10 to 25. Both were granted Breakthrough Therapy status, which allowed approval to be expedited. In January 2015 FDA approved HPV-9 vaccine for prevention of cervical, vulvar, vaginal and anal cancers caused by seven HPV types, and for prevention of genital warts caused by two HPV types. The HPV-9 is for females age 9 through 25 and males 9 through 15. In January 2015, the Office of Vaccine Research and Review (OVRR) approved a supplement to the BLA for Pneumococcal 13-valent conjugate vaccine (Prevnar 13), to include package insert language regarding the effect of fever-reducing medications given with routine pediatric vaccinations in healthy infants. Non-medication (prophylactic) use may reduce the response to some vaccine serotypes following PCV13 immunization. Finally, in December, FDA approved a Biologic License Application supplement to Pneumovax 23 to add a 2D barcode on single dose units that contains product identification information (including lot number and expiration date).

In December 2014, FDA published new requirements for pregnancy and lactation labeling. The Pregnancy and Lactation Labeling Rule removes pregnancy letter labels, and requires that package labels be updated when new information becomes available. The new labeling will include information on pregnancy, labor and delivery, lactation including nursing mothers, and information for males and females of reproductive potential.

Finally, LCDR Marshall noted that the Vaccine and Related Biological Products Advisory Committee met on March 4 to discuss the selection of influenza strains to be included in the vaccines for the 2015-2016 flu season.

During discussion, Dr. Houston clarified an issue related to meningococcal vaccines, since there was apparently some confusion about its coverage under the Program. She stated that all meningococcal vaccines are covered.

Update from the National Vaccine Program Office (NVPO) on Vaccine Safety Activities, Dr. Karin Bok, NVPO

Dr. Bok reported that the National Vaccine Program Office launched in January a cooperative agreement to look at research, monitoring and outcomes definitions for vaccine safety. The objective is to conduct research in vaccine safety that: determines the safety profile of new vaccines during the early development stage; develops or modifies existing vaccines to improve their safety; directly impacts the current vaccine safety monitoring system; and produces consensus definitions of vaccine safety outcomes that could be utilized to collect consensus data in clinical research conducted globally. Of particular interest are projects related to researching, establishing or testing the vaccine safety profile of vaccines that are either currently recommended for, or are expected to be routinely administered to pregnant women or newborns. Topics of research may cover, establishing the safety of a vaccine in the pregnant woman, her newborn or both, at any stage of the vaccine development, test and pre-clinical or clinical research and monitoring of vaccine safety.

There is now a Vaccine Safety Scientific Agenda, drafted by the Immunization Safety Task Force, to support a broad collaboration of federal partners that have any involvement in vaccine safety activities. A list of the leading institutions, safety systems and objectives can be found at http://www.hhs.gov/nvpo/vacc_plan/vaccine-safety-scientific-agenda.html that includes current and future research projects.

The National Vaccine Advisory Committee (NVAC) met on February 10th & 11th. Dr. Bok stated that the National Adult Immunization Plan has been released and is out for public comment and that NVPO expects to launch the Plan at the June NVAC meeting.

During discussion, Mr. Kraus asked about any plans for a study of vaccinated/unvaccinated children. Dr. Shimabukuro stated that CDC had addressed that issue through the Vaccine Safety Datalink, which had been identified as a system to look at outcomes in child with different levels of vaccination. The Institute of Medicine study concluded that conducting a randomized controlled trial would not be feasible.

During discussion, Mr. Kraus asked about any plans for a study of vaccinated/unvaccinated children. Dr. Shimabukuro stated that CDC had addressed that issue through the Vaccine Safety Datalink, which had been identified as a system to look at outcomes in child with different levels of vaccination. The Institute of Medicine study concluded that conducting a randomized controlled trial would not be feasible.

Public Comment

Mr. Smith invited public comment. There were no requests for public comment.

Future Agenda Items/New Business

Mr. Smith invited recommendations for future agenda items. He noted that Dr. Villarreal had mentioned discussing available guidance with respect to vaccine administration as a potential future agenda item. The discussion would include background information about vaccine administration from CDC and the professional society. He added that the issue of clarifying the relationship between the Secretary's office and the ACCV, in terms of recommendation submitted to the Department, should also be discussed.

Mr. King noted that a topic mentioned at the last meeting was not included in the agenda for the meeting, a discussion of a recommendation to increase funding for the Program to enhance processing of the increased number of claims filed. He requested that the discussion be scheduled for the June meeting. He also noted that the public comment opportunity, previously scheduled at the beginning of the meeting and related specifically to the agenda, was not included on the agenda for this meeting. He recommended including it in the June meeting agenda.

Adjournment

There being no further business, Mr. Smith invited a motion to adjourn. On motion duly made and seconded, the Commission unanimously approved adjournment.

3

Vaccine Injury Compensation Trust Fund

Balance as of March 31, 2015

$3,517,700,271.48

Figures for October 1, 2014 – March 31, 2015

Excise Tax Revenue: $95,890,171
Interest on Investments: $30,827,675
Net Income: $126,717,847
Interest as a Percentage of Net Income: 24%

Source: U.S. Treasury, Bureau of Public Debt
May 11, 2015

4

U.S. Department of Health and Human Services
HRSA
Health Resources and Services Administration

Data & Statistics

The United States has the safest, most effective vaccine supply in history. In the majority of cases, vaccines cause no side effects, however they can occur, as with any medication—but most are mild. Very rarely, people experience more serious side effects, like allergic reactions.

In those instances, the National Vaccine Injury Compensation Program (VICP) allows individuals to file a claim for financial compensation.

What does it mean to be awarded compensation?
Being awarded compensation for your claim does not necessarily mean that the vaccine caused the alleged injury. In fact:

- Over 80 percent of all compensation awarded by the VICP comes as result of a negotiated settlement between the parties in which HHS has not concluded, based upon review of the evidence, that the alleged vaccine(s) caused the alleged injury.

What reasons might a claim result in a negotiated settlement?

- Prior to a decision by the U.S. Court of Federal Claims, both parties decide to minimize risk of loss through settlement
- A desire to minimize the time and expense of litigating a case
- The need to resolve a case quickly

How many claims have been awarded compensation?
From 2006 to 2013, over 2.2 billion doses of covered vaccines were distributed in the U.S. according to the CDC. 2,903 claims were adjudicated by the Court in this time period and of those 1,709 were compensated. This means for every 1 million doses of vaccine that were distributed, 1 individual was compensated.

Since 1988, over 15,916 claims have been filed with the VICP. Over that 27 year time period, 13,976 claims have been adjudicated, with 4,083 of these determined to be compensable, while 9,893 were dismissed. Total compensation paid over the life of the program is approximately $3.1 billion.

The Latest Statistics
Read the current statistics report – updated as of May 4, 2015.

VICP Adjudication Categories, by Alleged Vaccine, For Claims Filed Since the Inclusion of Influenza as an Eligible Vaccine for Filings 01/06/2006 Through 12/30/2013

Name of Vaccine Listed First in a Petition (other vaccines may be alleged or basis for compensation)	Number of Doses Distributed in the U.S., 01/01/2006 through 12/31/2013 (source: CDC)	Compensable			Compensable Total	Dismissed/Non-Compensable Total	Grand Total
		Concession	Court Decision	Settlement			
DT	652,327	1		4	5	4	9
DTaP	75,888,233	12	18	75	105	77	182
DTaP-Hep B-IPV	43,929,797	4	7	18	29	36	65
DTaP-HIB	1,135,474				0	1	1
DTaP-IPV-HIB	39,590,896			7	7	11	18
DTP	0		1	2	3	2	5
DTP-HIB	0				0	1	1
Hep A-Hep B	11,662,755			9	9	2	11
Hep B-HIB	4,796,583	1	1	1	3	1	4
Hepatitis A (Hep A)	124,212,280	4	3	21	28	21	49
Hepatitis B (Hep B)	129,820,136	2	10	40	52	36	88
HIB	83,517,849		1	4	5	4	9
HPV	67,250,524	10		67	76	88	164
Influenza	944,000,000	45	75	876	996	176	1,172
IPV	58,019,052			4	4	2	6

Measles	135,660			1	1		1
Name of Vaccine Listed First in a Petition (other vaccines may be alleged or basis for compensation)	**Number of Doses Distributed in the U.S., 01/01/2006 through 12/31/2013 (source: CDC)**	**Compensable**			**Compensable Total**	**Dismissed/Non-Compensable Total**	**Grand Total**
		Concession	**Court Decision**	**Settlement**			
Meningococcal	58,412,363	1	2	24	28	4	32
MMR	73,441,556	17	13	57	87	74	161
MMR-Varicella	11,028,270	8		8	16	8	24
Nonqualified	N/A			1	1	21	22
OPV	0	1			1	3	4
Pneumococcal Conjugate	132,932,107		1	5	6	14	20
Rotavirus	70,719,103	1	3	15	19	5	24
Rubella	422,548		1		1		1
Td	55,742,830	6	6	51	63	17	80
Tdap	155,106,848	12	6	88	106	14	120
Tetanus	3,836,052	3		19	22	10	32
Unspecified	N/A	1		2	3	552	555
Varicella	90,425,492	4	6	23	33	10	43
Grand Total	**2,236,678,735**	**133**	**154**	**1,422**	**1,709**	**1,194**	**2,903**

Notes on the Adjudication Categories Table

The date range of 01/01/2006 through 12/31/2013 was selected to reflect petitions filed since the inclusion of influenza vaccine in July 2005. Influenza vaccine now is named in the majority of all VICP petitions.

In addition to the first vaccine alleged by a petitioner, which is the vaccine listed in this table, a VICP petition may allege other vaccines, which may form the basis of compensation.

Vaccine doses are self-reported distribution data provided by US-licensed vaccine manufacturers. The data provide an estimate of the annual national distribution and do not represent vaccine administration. In order to maintain confidentiality of an individual manufacturer or brand, the data are presented in an aggregate format by vaccine type. Flu doses are derived from CDC's FluFinder tracking system, which includes data provided to CDC by US-licensed influenza vaccine manufacturers as well as their first line distributors.

"Unspecified" means insufficient information was submitted to make an initial determination. The concession was for multiple unidentified vaccines that caused abscess formation at the vaccination site(s) and the settlements were for multiple vaccines later identified in the Special Master's decisions.

Definitions

Compensable – The injured person who filed a claim was paid money by the VICP. Compensation can be achieved through a concession by the U.S. Department of Health and Human Services (HHS), a decision on the merits of the claim by a special master or a judge of the U.S. Court of Federal Claims (Court), or a settlement between the parties.

- **Concession**: HHS concludes that a petition should be compensated based on a thorough review and analysis of the evidence, including medical records and the scientific and medical literature. The HHS review concludes that the petitioner is entitled to compensation, including a determination either that it is more likely than not that the vaccine caused the injury or the evidence supports fulfillment of the criteria of the Vaccine Injury Table. The Court also determines that the petition should be compensated.
- **Court Decision**: A special master or the court, within the United States Court of Federal Claims, issues a legal decision after weighing the evidence presented by both sides. HHS abides by the ultimate Court decision even if it maintains its position that the petitioner was not entitled to compensation (e.g., that the injury was not caused by the vaccine).
  For injury claims, compensable court decisions are based in part on one of the following determinations by the court:
  1. The evidence is legally sufficient to show that the vaccine more likely than not caused (or significantly aggravated) the injury; or
  2. The injury is listed on, and meets all of the requirements of, the Vaccine Injury Table, and HHS has not proven that a factor unrelated to the vaccine more likely than not caused or significantly aggravated the injury. An injury listed on the Table and meeting all Table requirements is given the legal presumption of causation. It should be noted that conditions are placed on the Table for both scientific and policy reasons.
- **Settlement**: The petition is resolved via a negotiated settlement between the parties. This settlement is not an admission by the United States or the Secretary of Health and Human Services that the vaccine caused the petitioner's alleged injuries, and, in settled cases, the Court does not determine that the vaccine caused the injury. A settlement therefore cannot be characterized as a decision by HHS or by the Court that the vaccine caused an injury. Claims may be resolved by settlement for many reasons, including consideration of prior court decisions; a recognition by both parties that there is a risk of loss in proceeding to a decision by the Court making the certainty of settlement more desirable; a desire by both parties to minimize the time and expense associated with litigating a case to conclusion; and a desire by both parties to resolve a case quickly and efficiently.
- **Non-compensable/Dismissed**: The injured person who filed a claim was ultimately not paid money. Non-compensable Court decisions include the following:
  1. The Court determines that the person who filed the claim did not demonstrate that the injury was caused (or significantly aggravated) by a covered vaccine or meet the requirements of the Table (for injuries listed on the Table).
  2. The claim was dismissed for not meeting other statutory requirements (such as not meeting the filing deadline, not receiving a covered vaccine, and not meeting the statute's severity requirement).
  3. The injured person voluntarily withdrew his or her claim.

Petitions Filed, Compensated and Dismissed, by Alleged Vaccine, Since the Beginning of VICP, 10/01/1988 through 05/04/2015

Vaccines	Filed			Compensated	Dismissed
	Injury	Death	Grand Total		
DT	69	9	78	25	51
DTaP	378	79	457	183	203
DTaP-Hep B-IPV	62	25	87	30	34
DTaP-HIB	10	1	11	4	3
DTaP-IPV	3	0	3	0	0
DTaP-IPV-HIB	28	17	45	6	12
DTP	3,286	696	3,982	1,271	2,706
DTP-HIB	20	8	28	5	21
Hep A-Hep B	21	0	21	9	2
Hep B-HIB	8	0	8	4	3
Hepatitis A (Hep A)	71	5	76	27	22
Hepatitis B (Hep B)	625	54	679	244	364
HIB	31	3	34	12	14
HPV	269	13	282	76	88
Influenza	1,793	87	1,880	1,087	163
IPV	264	14	278	8	267
Measles	143	19	162	55	107
Meningococcal	41	2	43	28	4
MMR	893	57	950	370	505
MMR-Varicella	32	1	33	16	8
MR	15	0	15	6	9
Mumps	10	0	10	1	9
Nonqualified[1]	85	9	94	2	87
OPV	280	28	308	158	150
Pertussis	4	3	7	2	5
Pneumococcal Conjugate	41	6	47	10	27
Rotavirus	66	1	67	40	18
Rubella	190	4	194	70	123
Td	184	3	187	109	65
Tdap	242	1	243	123	13
Tetanus	99	2	101	45	37
Unspecified[2]	5,411	8	5,419	4	4,753
Varicella	80	7	87	52	20
Grand Total	**14,754**	**1,162**	**15,916**	**4,083**	**9,893**

[1] Nonqualified petitions are those filed for vaccines not covered under the VICP.
[2] Unspecified petitions are those submitted with insufficient information to make a determination.

Petitions Filed

Fiscal Year	Total
FY 1988	24
FY 1989	148
FY 1990	1,492
FY 1991	2,718
FY 1992	189
FY 1993	140
FY 1994	107
FY 1995	180
FY 1996	84
FY 1997	104
FY 1998	120
FY 1999	411
FY 2000	164
FY 2001	215
FY 2002	958
FY 2003	2,592
FY 2004	1,214
FY 2005	735
FY 2006	325
FY 2007	410
FY 2008	417
FY 2009	397
FY 2010	448
FY 2011	386
FY 2012	401
FY 2013	503
FY 2014	633
FY 2015	401
Total	**15,916**

Adjudications

Generally, petitions are not adjudicated in the same fiscal year as filed.
On average, it takes 2 to 3 years to adjudicate a petition after it is filed.

Fiscal Year	Compensable	Dismissed	Total
FY 1989	9	12	21
FY 1990	100	33	133
FY 1991	141	447	588
FY 1992	166	487	653
FY 1993	125	588	713
FY 1994	162	446	608
FY 1995	160	575	735
FY 1996	162	408	570
FY 1997	189	198	387
FY 1998	144	181	325
FY 1999	98	139	237
FY 2000	125	104	229
FY 2001	86	87	173
FY 2002	104	103	207
FY 2003	56	99	155
FY 2004	62	233	295
FY 2005	60	121	181
FY 2006	69	191	260
FY 2007	82	121	203
FY 2008	147	134	281
FY 2009	134	231	365
FY 2010	180	293	473
FY 2011	266	1,370	1,636
FY 2012	263	2,438	2,701
FY 2013	367	627	994
FY 2014	369	167	536
FY 2015	257	60	317
Total	**4,083**	**9,893**	**13,976**

Awards Paid

Fiscal Year	Number of Compensated Awards	Petitioners' Award Amount	Attorneys' Fees/Costs Payments	Number of Payments to Attorneys (Dismissed Cases)	Attorneys' Fees/Costs Payments (Dismissed Cases)	Number of Payments to Interim Attorneys'	Interim Attorneys' Fees/Costs Payments	Total Outlays
FY 1989	6	$1,317,654.78	$54,107.14	0	$0.00	0	$0.00	$1,371,761.92
FY 1990	88	$53,252,510.46	$1,379,005.79	4	$57,699.48	0	$0.00	$54,689,215.73
FY 1991	114	$95,980,493.16	$2,364,758.91	30	$496,809.21	0	$0.00	$98,842,061.28
FY 1992	130	$94,538,071.30	$3,001,927.97	118	$1,212,677.14	0	$0.00	$98,752,676.41
FY 1993	162	$119,693,267.87	$3,262,453.06	272	$2,447,273.05	0	$0.00	$125,402,993.98
FY 1994	158	$98,151,900.08	$3,571,179.67	335	$3,166,527.38	0	$0.00	$104,889,607.13
FY 1995	169	$104,085,265.72	$3,652,770.57	221	$2,276,136.32	0	$0.00	$110,014,172.61
FY 1996	163	$100,425,325.22	$3,096,231.96	216	$2,364,122.71	0	$0.00	$105,885,679.89
FY 1997	179	$113,620,171.68	$3,898,284.77	142	$1,879,418.14	0	$0.00	$119,397,874.59
FY 1998	165	$127,546,009.19	$4,002,278.55	121	$1,936,065.50	0	$0.00	$133,484,353.24
FY 1999	96	$95,917,680.51	$2,799,910.85	117	$2,306,957.40	0	$0.00	$101,024,548.76
FY 2000	136	$125,945,195.64	$4,112,369.02	80	$1,724,451.08	0	$0.00	$131,782,015.74
FY 2001	97	$105,878,632.57	$3,373,865.88	57	$2,066,224.67	0	$0.00	$111,318,723.12
FY 2002	80	$59,799,604.39	$2,653,598.89	50	$656,244.79	0	$0.00	$63,109,448.07
FY 2003	65	$82,816,240.07	$3,147,755.12	69	$1,545,654.87	0	$0.00	$87,509,650.06
FY 2004	57	$61,933,764.20	$3,079,328.55	69	$1,198,615.96	0	$0.00	$66,211,708.71
FY 2005	64	$55,065,797.01	$2,694,664.03	71	$1,790,587.29	0	$0.00	$59,551,048.33
FY 2006	68	$48,746,162.74	$2,441,199.02	54	$1,353,632.61	0	$0.00	$52,540,994.37
FY 2007	82	$91,449,433.89	$4,034,154.37	61	$1,692,020.25	0	$0.00	$97,175,608.51
FY 2008	141	$75,716,552.06	$5,191,770.83	73	$2,511,313.26	2	$117,265.31	$83,536,901.46
FY 2009	131	$74,142,490.58	$5,404,711.98	36	$1,557,139.53	28	$4,241,362.55	$85,345,704.64
FY 2010	173	$179,387,341.30	$5,961,744.40	56	$1,886,239.95	22	$1,978,803.88	$189,214,129.53
FY 2011	251	$216,319,428.47	$9,572,042.87	403	$5,589,417.19	28	$2,001,770.91	$233,482,659.44
FY 2012	249	$163,491,998.82	$9,104,488.60	1,017	$8,621,182.32	37	$5,420,257.99	$186,637,927.73
FY 2013	375	$254,666,326.70	$13,333,179.53	703	$6,970,278.84	50	$1,454,851.74	$276,424,636.81
FY 2014	365	$202,084,196.12	$11,973,575.82	505	$6,801,345.79	38	$2,493,460.73	$223,352,578.46
FY 2015	311	$146,534,198.61	$8,513,775.30	68	$1,875,992.31	29	$1,537,517.17	$158,461,968.86
Total	**4,075**	**$2,948,506,198.61**	**$125,675,133.45**	**4,948**	**$65,984,027.04**	**234**	**$18,911,760.08**	**$3,159,410,649.38**

"Compensated" are claims that have been paid as a result of a settlement between parties or a decision made by the U.S. Court of Federal Claims (Court). The # of awards is the number of petitioner awards paid, including the attorneys' fees/costs payments, if made during a fiscal year. However, petitioners' awards and attorneys' fees/costs are not necessarily paid in the same fiscal year as when the petitions/claims are determined compensable. "Dismissed" includes the # of payments to attorneys and the total amount of payments for attorneys' fees/costs per fiscal year. The VICP will pay attorneys' fees/costs related to the claim, whether or not the petition/claim is awarded compensation by the Court, if certain minimal requirements are met. "Total Outlays" are the total amount of funds expended for compensation and attorneys' fees/costs from the Vaccine Injury Compensation Trust Fund by fiscal year.

Due to the populations receiving vaccines added to the VICP in recent years, the proportion of adults to children seeking compensation has changed. Since influenza vaccines (vaccines administered to large numbers of adults each year) were added to the VICP in 2005, many adult claims related to that vaccine have been filed.

5

5.1

The National Vaccine Injury Compensation Program (VICP)

Division of Injury Compensation Programs Update

Advisory Commission on Childhood Vaccines
June 4, 2015
A. Melissa Houston, M.D., M.P.H., F.A.A.P

Department of Health and Human Services
Health Resources and Services Administration

ACCV Meeting Highlights

- Update from the Department of Justice Vaccine Litigation Office
- Feasibility of SIRVA Prevention
- Report from the ACCV Adult Immunization Workgroup
- Review of Vaccine Information Statements
- Updates from ACCV Ex Officio Members – FDA, CDC, NIH, NVPO

Number of Petitions Filed as of May 4, 2015

Average annual number of petitions filed during FY 2010-2014 = 474

Fiscal Year	Total
FY 2010	448
FY 2011	386
FY 2012	401
FY 2013	503
FY 2014	633
FY 2015	401

Number of Adjudications as of May 4, 2015

Fiscal Year	Compensable	Dismissed	Total
FY 2010	180	293	473
FY 2011	266	1,370	1,636
FY 2012	263	2,438	2,701
FY 2013	367	627	994
FY 2014	369	167	536
FY 2015	257	60	317

Adjudication Categories for Non-Autism Claims FY 2013 – FY 2015 as of May 11, 2015

Adjudication Category	FY 2013	FY 2014	FY 2015
Compensable	367 (100%)	369 (100%)	269 (100%)
❖Concession	21 (6%)	40 (11%)	50 (18%)
❖Court Decision (includes proffers)	19 (5%)	34 (9%)	12 (5%)
❖Settlement	327 (89%)	295 (80%)	207 (77%)
Not Compensable	88	123	48
Adjudication Total	455	492	317

5

Award Amounts Paid as of May 4, 2015

Fiscal Year	Petitioners' Award	Attorneys' Fees & Costs
FY 2010	$179,387,341	$9,826,788
FY 2011	$216,319,428	$17,163,229
FY 2012	$163,491,999	$23,145,927
FY 2013	$254,666,326	$21,758,310
FY 2014	$202,084,196	$21,268,383
FY 2015	$146,534,199	$11,927,285

6

Vaccine Injury Compensation Trust Fund

- Balance as of March 31, 2015
  - $3,517,700,271.48
- Activity from October 1, 2014 to March 31, 2015
  - Excise Tax Revenue: $95,890,171
  - Interest on Investments: $30,827,675
  - Net Income: $126,717,847
  - Interest as a Percentage of Net Income: 24%

Source: U.S. Treasury, Bureau of Public Debt (May 11, 2015)

Significant Activities

- Status of VICP Regulations
- Status of New Commission Members
- National Vaccine Advisory Committee
  - June 9 – 10, 2015
- Advisory Committee on Immunization Practices
  - June 24 – 25, 2015
- Information on ACCV meetings, presentations and minutes can be found at http://www.hrsa.gov/vaccinecompensation/commissionchildvaccines.html

Public Comment/Participation in Commission Meetings

Annie Herzog
Parklawn Building, Room 11C-26
5600 Fishers Lane
Rockville, Maryland 20857
Phone: 301-443-6634
Email: aherzog@hrsa.gov

5.2

Report from the Department of Justice

June 4, 2015

Vincent J. Matanoski
Deputy Director, Torts Branch

1

Statistics

Reporting Period: 2/16/15 – 5/15/15

I. **Total Petitions Filed in the United States Court of Federal Claims this reporting period: 178**
   A. Minors: 30
   B. Adults: 148

2

Statistics

Reporting Period: 2/16/15 – 5/15/15

II. Total Petitions Adjudicated this reporting period: 163

A. Compensated: 136

i. Cases conceded by HHS: 32

1. Decision awarding damages: 0
2. Decision adopting Proffer: 32
3. Decision adopting Settlement: 0

ii. Cases not conceded by HHS: 104

1. Decision awarding damages: 0
2. Decision adopting Proffer: 1
3. Decision adopting Settlement: 103

B. Not Compensated/Dismissed: 27

i. Decision dismissing Non-OAP: 23

ii. Decision dismissing OAP: 4

3

Statistics

Reporting Period: 2/16/15 – 5/15/15

III. Total Petitions Voluntarily Withdrawn this reporting period (no judgment will be issued): 8

4

Appeals: U.S. Court of Appeals for the Federal Circuit

Recently Decided Cases

Appeals by Petitioner:

- *Simanski v. HHS*: Affirmed
- *Griffin v. HHS*: Affirmed

Appeals by Respondent:

- *Paluck v. HHS*: Affirmed

All decisions are available on the CAFC's website: http://www.cafc.uscourts.gov

5

Appeals: U.S. Court of Appeals for the Federal Circuit

Pending Cases

Appeals by Petitioner:

- *Greenberg v. HHS** (Entitlement)
- *Moriarty v. HHS** (Entitlement)
- *Hirmiz v. HHS* (Entitlement)
- *Crutchfield v. HHS* (Entitlement)
- *Stillwell v. HHS* (Entitlement)

*Yellow cases are new this reporting period

6

Appeals: U.S. Court of Federal Claims

Recently Decided Cases

Appeals by Petitioner:

- *Guerrero v. HHS*: Vacated and remanded (Attorneys' Fees and Costs)
- *Somosot v. HHS*: Affirmed (Attorneys' Fees and Costs)
- *Contreras v. HHS*: Affirmed (Entitlement)
- *Milik v. HHS*: Affirmed (Entitlement)

All decisions are available on the CFC's website: http://www.uscfc.uscourts.gov

7

Appeals: U.S. Court of Federal Claims

Pending Cases

Appeals by Petitioner:

- *Nutall v. HHS** (Entitlement)
- *McLeod-Hunt v. HHS** (Entitlement)
- *Mora v. HHS** (Entitlement)
- *Hodge v. HHS* (Entitlement)
- *Padmanabhan v. HHS* (Entitlement)
- *Barclay v. HHS* (Entitlement)
- *Santini v. HHS* (Entitlement)
- *Rowan v. HHS* (Entitlement)
- *Spahn v. HHS* (Entitlement
- *Godfrey v. HHS* (Entitlement)
- *D'Angiolini v. HHS* (Entitlement)

*Yellow cases are new this reporting period

8

Scheduled Oral Arguments

U.S. Court of Appeals for the Federal Circuit:

- *Stillwell v. HHS*: June 4, 2015
- *Crutchfield v. HHS*: June 5, 2015

U.S. Court of Federal Claims:

- None scheduled at this time

9

Adjudicated Settlements*

Reporting Period: 2/16/15 – 5/15/15

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
Flu	Guillain-Barré Syndrome	2 Years, 10 Months
Flu, Tdap, Varicella, Meningococcal	Guillain-Barré Syndrome	1 Year, 8 Months
Flu	Thrombocytopenic Purpura	1 Year, 3 Months
Flu	Allergic Reaction and Arm Injuries	10 Months
Tdap	Guillain-Barré Syndrome	8 Months
Flu, Tetanus	Tendinopathy	2 Years, 3 Months
DTaP	Brachial Plexus Neuritis	9 Months
Hep B	Death	15 Years, 8 Months
Flu	Guillain-Barré Syndrome	1 Year, 6 Months
Flu, Tdap	Chronic Inflammatory Demyelinating Polyneuropathy	1 Year, 2 Months

*Terms of settlement are memorialized by Stipulation

(continued . . .)

10

Adjudicated Settlements*

Reporting Period: 2/16/15 – 5/15/15

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
Tdap	Optic Neuritis	1 Year
Tdap	Lymphangitis, Cellulitis	11 Months
Flu	Guillain-Barré Syndrome	8 Months
Flu	Serum Sickness and Reactive Arthritis	7 Months
Tdap	Guillain-Barré Syndrome	6 Months
MMR	Opsoclonus Myoclonus Syndrome	8 Years, 1 Month
Tdap	headaches, chest pain, fatigue and dizziness/disorientation	1 Year, 11 Months
Flu	Chronic Fatigue Syndrome	1 Year, 5 Months
Flu	Chronic Fatigue Syndrome, Fibromyalgia	1 Year, 5 Months
Flu	Inflammatory Polyarthritis	1 Year, 5 Months

*Terms of settlement are memorialized by Stipulation

(continued . . .) 11

Adjudicated Settlements*

Reporting Period: 2/16/15 – 5/15/15

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
Tdap	Neurological Injury	1 Year
Flu, Tdap	Guillain-Barré Syndrome	1 Year, 1 Month
Tdap, Meningococcal	Acute Disseminated Encephalomyelitis	3 Years, 4 Months
Flu	Dysautonomia, Central Sensitization Syndrome	1 Year, 5 Months
Flu	Guillain-Barré Syndrome	1 Year, 5 Months
Flu	Transverse Myelitis	7 Months
HPV	Myofascitiitis, autoimmune syndrome	5 Years, 4 Months
Flu	Vasculitis, Vasculitic Neuropathy	3 Years
Hep A, Hep B, MMR	Guillain-Barré Syndrome	2 Years
Flu	Significant Aggravation of Pre-Existing Transverse Myelitis	1 Year, 6 Months

*Terms of settlement are memorialized by Stipulation

(continued . . .) 12

Adjudicated Settlements*

Reporting Period: 2/16/15 – 5/15/15

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
Flu	Hearing Loss	12 Months
Flu	Chronic Inflammatory Demyelinating Polyneuropathy	10 Months
Flu, Hep B	Guillain-Barré Syndrome	1 Year, 2 Months
Flu	Peripheral Neuropathy	11 Months
Flu	Guillain-Barré Syndrome	6 Months
Tdap	Guillain-Barré Syndrome	1 Year, 6 Months
Flu	Guillain-Barré Syndrome, Death	1 Year, 6 Months
Flu	Guillain-Barré Syndrome	1 Year, 6 Months
MMR, Hep A	Acute Disseminated Encephalomyelitis	1 Year
Flu	Transverse Myelitis, Multiple Sclerosis	10 Months

*Terms of settlement are memorialized by Stipulation

(continued . . .) 13

Adjudicated Settlements*

Reporting Period: 2/16/15 – 5/15/15

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
Flu	Guillain-Barré Syndrome	9 Months
Flu	Guillain-Barré Syndrome	8 Months
Flu	Guillain-Barré Syndrome	4 Years, 6 Months
Flu	Guillain-Barré Syndrome, Chronic Inflammatory Demyelinating Polyneuropathy	2 Years, 6 Months
Flu	Vaccine-Related Neuritis and Neuropathy or Guillain-Barré Syndrome	1 Year, 7 Months
Flu	Guillain-Barré Syndrome, Chronic Inflammatory Demyelinating Polyneuropathy	1 Year, 5 Months
Flu	Guillain-Barré Syndrome	1 Year, 4 Months
Flu	Arm pain, vomiting, nausea, tinnitus, vertigo, dizziness, loss of equilibrium, bruising (from falling), and hearing loss	1 Year, 3 Months
Flu	Guillain-Barré Syndrome	1 Year, 4 Months
Flu	Guillain-Barré Syndrome	1 Year, 1 Month

*Terms of settlement are memorialized by Stipulation

(continued . . .) 14

Adjudicated Settlements*

Reporting Period: 2/16/15 – 5/15/15

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
Flu	Acute Disseminated Encephalomyelitis, Death	11 Months
Flu, Tdap	Gastrointestinal Problems, Rheumatologic Symptoms	10 Months
Flu, Hep A	Guillain-Barré Syndrome	9 Months
Flu	SIRVA	10 Months
Tdap	Left Should Injuries, Tendonitis and Adhesive Capsulitis	7 Months
Flu, Td	Shoulder Injury	7 Months
Flu	Guillain-Barré Syndrome	1 Year
Flu	Brachial Neuritis, Inflammatory Polyarthritis, Inflammatory Reactive Tissue, Inflammatory Tendinitis	1 Year, 9 Months
Flu	Brachial Neuritis	1 Year, 5 Months
Flu	Guillain-Barré Syndrome	1 Year

*Terms of settlement are memorialized by Stipulation

(continued . . .) 15

Adjudicated Settlements*

Reporting Period: 2/16/15 – 5/15/15

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
Flu	Guillain-Barré Syndrome	10 Months
Flu	Guillain-Barré Syndrome	1 Year, 5 Months
Hep A, Tdap	Adhesive Capsulitis, Right Shoulder Injury	4 Months
Flu	Chronic Inflammatory Demyelinating Polyneuropathy	6 Months
Tdap	Guillain-Barré Syndrome	1 Year, 2 Months
Flu	Cellulitis, Neurologic Injuries	2 Years, 7 Months
Flu	Peripheral Neuropathy	2 Years, 5 Months
Td	Guillain-Barré Syndrome	1 Year, 9 Months
Flu	Guillain-Barré Syndrome	1 Year, 7 Months
Flu	Guillain-Barré Syndrome	1 Year, 5 Months

*Terms of settlement are memorialized by Stipulation

(continued . . .) 16

Adjudicated Settlements*

Reporting Period: 2/16/15 – 5/15/15

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
Tdap, Hep A	Brachial Neuritis, Demyelinating Polyradiculoneuropathy	11 Months
Flu	Transverse Myelitis	11 Months
Flu	Bell's Palsy	11 Months
Tdap	Brachial Neuritis	11 Months
Flu	Acute Disseminated Encephalomyelitis, Death	9 Months
Flu	SIRVA	6 Months
Flu	Polymyositis	2 Years, 6 Months
Td	Inflammatory Arthritis	2 Years, 1 Month
Flu	Optic Neuritis	1 Year, 6 Months
Flu	Transverse Myelitis	3 Months

*Terms of settlement are memorialized by Stipulation

(continued . . .) 17

Adjudicated Settlements*

Reporting Period: 2/16/15 – 5/15/15

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
HPV	Guillain-Barré Syndrome, Chronic Inflammatory Demyelinating Polyneuropathy	4 Years, 9 Months
Flu	Left Arm Injury	1 Year, 4 Months
Flu	Guillain-Barré Syndrome	6 Months
Flu	Sensorineural Hearing Loss	1 Year, 3 Months
Flu	Adhesive Capsulitis	7 Months
Tdap	Guillain-Barré Syndrome	2 Years, 11 Months
Flu	Psoriasiform Dermatitis	1 Year, 11 Months
Varicella	Lipodystrophy	1 Year, 9 Months
Flu	Guillain-Barré Syndrome	1 Year, 7 Months
Flu	Guillain-Barré Syndrome	8 Months

*Terms of settlement are memorialized by Stipulation

(continued . . .) 18

Adjudicated Settlements*

Reporting Period: 2/16/15 – 5/15/15

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
Flu	Shoulder Injury	8 Months
Flu	Guillain-Barré Syndrome	1 Year, 9 Months
Flu	Guillain-Barré Syndrome, Death	1 Year, 4 Months
Tdap	Guillain-Barré Syndrome	7 Months
Hep B	Pachymeningitis	3 Years, 1 Month
Flu	Guillain-Barré Syndrome	1 Year, 11 Months
Hep B, DTaP, Hib, PCV, IPV	Infantile spasms, relayed sequelae	4 Years, 1 Month
Flu	Guillain-Barré Syndrome	2 Years, 6 Months
Flu	Chronic Inflammatory Demyelinating Polyneuropathy	2 Years, 5 Months
Flu	Guillain-Barré Syndrome	1 Year, 5 Months

*Terms of settlement are memorialized by Stipulation

(continued . . .)

19

Adjudicated Settlements*

Reporting Period: 2/16/15 – 5/15/15

Vaccine(s)	Alleged Injury(ies)	Petition Filing to Settlement Filing
Hep B	Hyperthyroidism	1 Year, 3 Months
Flu	Left Shoulder Injury	7 Months
Flu	Shoulder Injury	8 Months

Total Number of Judgments Adopting Settlement this reporting period: 103

*Terms of settlement are memorialized by Stipulation

20

Appendix

21

Glossary of Terms

- **Petitions Adjudicated:** Final judgment has entered on the petition in the United States Court of Federal Claims.
- **Final Judgment:** Clerk of Court, United States Court of Federal Claims, enters judgment awarding or denying compensation.
- **Compensable:** Petitioner received an award of compensation, which can be achieved through a concession by HHS, settlement, or decision on the merits by the special master, United States Court of Federal Claims.
- **Conceded by HHS:** HHS concluded that a petition should be compensated based on review and analysis of the medical records.

22

Glossary of Terms

- **Settlement:** Petition is resolved via a negotiated settlement between the parties, and results in the filing of a stipulation that memorializes the terms of the settlement.
- **Decision:** Special Master issues decision on the merits of the petition.
- **Non-compensable/Dismissed:** Petition dismissed.
- **Proffer:** After discussions between the parties regarding a reasonable amount of damages, respondent will file a suggested award of compensation, known within the Program as a "Proffer," which is also agreed to by petitioners and their counsel. The Proffer is reviewed by the presiding special master to determine that it represents a reasonable measure of the amount of the award and describes compensation pursuant to 42 U.S.C. § 300aa-15(a). The special master issues a final decision consistent with the terms of the Proffer.

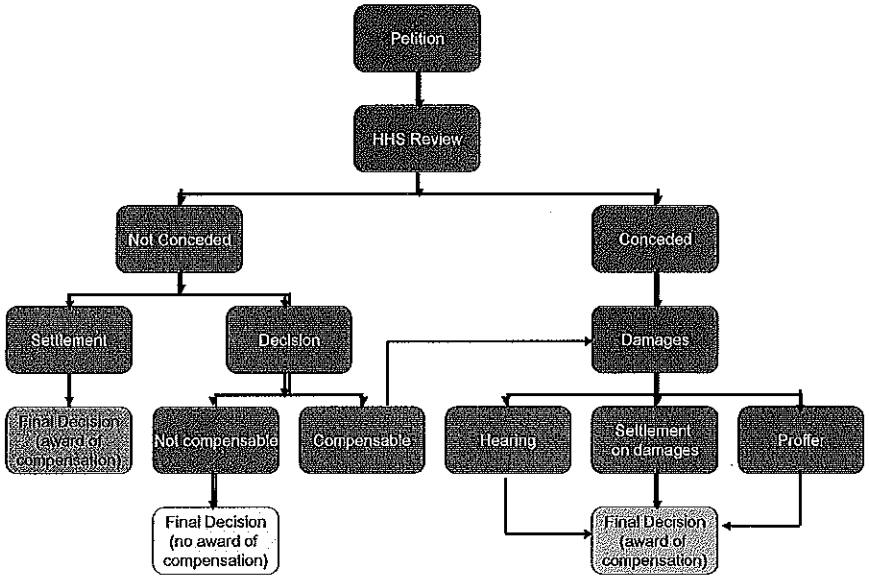
23

Glossary of Terms

- **Affirmed:** Case has been reviewed on appeal, and the court on appeal agreed with the decision of the lower court.
- **Reversed:** Case has been reviewed on appeal, and the court on appeal disagreed with the decision of the lower court. The court on appeal typically provides reasons for reversing, and that decision becomes the law of the case, absent further appeal.
- **Remanded:** Case has been reviewed on appeal, and the reviewing court has a problem with the decision, and sends it back to the lower court. Typically, a case is remanded with a specific question or issue for the lower court to address.
- **Vacated:** Case has been reviewed on appeal, and the reviewing court has voided the lower court's decision.

24

Petition Processing in the Office of Special Masters



25

Levels of Appeal in Vaccine Act Cases

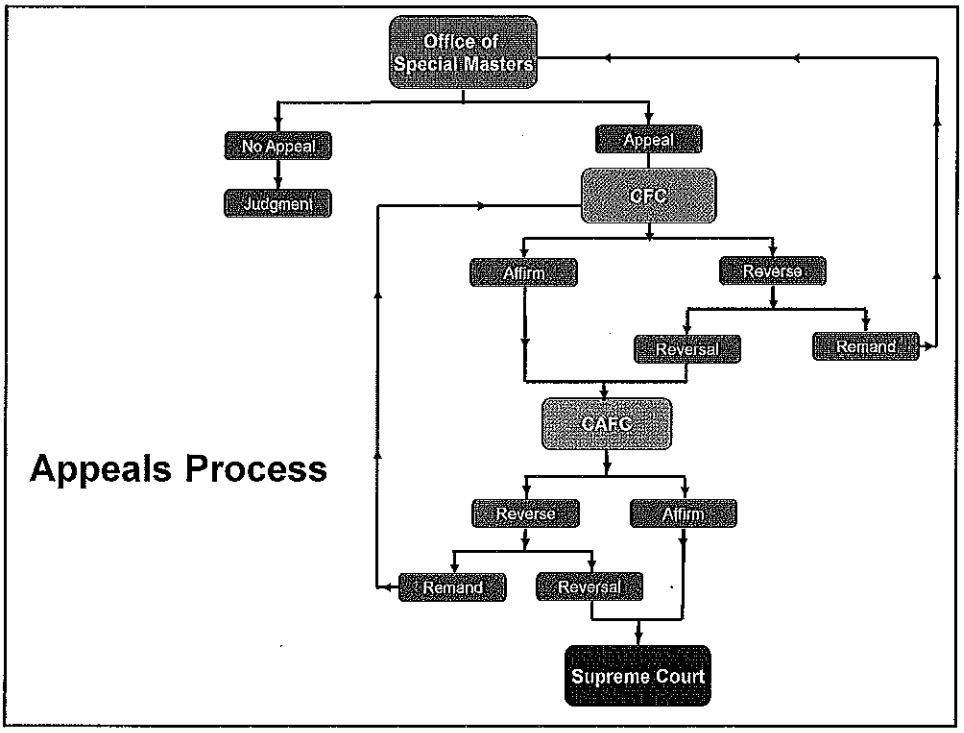
U.S. Supreme Court

U.S. Court of Appeals for the Federal Circuit

U.S. Court of Federal Claims

Office of Special Masters

Appeals Process



Updated for the June 2015 ACCV Meeting
Prepared by the U.S. Department of Justice (DOJ)
U.S. Court of Appeals for the Federal Circuit (CAFC) / U.S. Supreme Court

Entitlement

CASE NAME CITATION	HOLDING
STONE and HAMMITT 676 F.3d 1373 (Fed. Cir. 2012)	In a consolidated appeal, the CAFC reiterated prior precedent and held that the special master was not precluded from considering respondent's evidence of a genetic mutation as part of examining the record as a whole to determine whether or not petitioners met their burden of proof in establishing a prima facie case merely because that evidence was also relevant as to whether or not respondent had satisfied her burden of showing an alternate cause. Because the special master found that the genetic mutation was the sole cause of the children's condition, there was no need to analyze the question of superseding causes. The CAFC also found that the special master was not arbitrary or capricious in his fact finding and that petitioners failed to show that the DTaP vaccine was the more likely cause of the children's seizure disorder.
ROTOLI and PORTER 663 F.3d 1242 (Fed. Cir. 2011)	The CAFC found that the Claims Court judge incorrectly read Andreu to prohibit a special master from using credibility determinations to reject a petitioner's theory of causation. Rather, in Moberly, Broekelschen, and Doe 11, the CAFC had "unambiguously explained" that special masters are expected to consider credibility of expert witnesses in evaluating vaccine claims. Further, the Claims Court's blanket approach of setting aside the special master's findings of fact without ever determining whether the findings were arbitrary and capricious was legal error. Because the special master's decision contained a thorough and careful evaluation of all of the evidence, including records, tests, reports, medical literature, and expert's opinions and their credibility, the CAFC found that the special master's decision was not arbitrary, capricious, an abuse of discretion or otherwise not in accordance with law. The CAFC reversed the findings of the Claims Court and remanded with instructions that a decision be entered affirming the special master's denial of compensation.

CEDILLO 617 F.3d 1328 (Fed. Cir. 2010)	The CAFC affirmed the Court of Federal Claims' decision sustaining the special master's determination that thimerosal containing vaccines combined with the measles-mumps-rubella (MMR) vaccine do not cause autism. In this appeal, appellants argued that the special master improperly based his decision on evidence derived from litigation in the United Kingdom that should have been excluded, and disregarded other evidence that should have been considered. The CAFC disagreed and found that the special master committed no legal error, properly considered all relevant and reliable evidence, and appropriately exercised his discretion in weighing that evidence. Of particular note, the CAFC held that the special master's use of Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579 (1993), was an appropriate tool to assess the reliability of the parties' evidence, particularly the expert testimony.
HAZLEHURST 604 F.3d 1343 (Fed. Cir. 2010)	The CAFC found that the special master acted consistent with principles of fundamental fairness by admitting and considering respondent's expert's testimony and reports criticizing petitioners' evidence and offered petitioners ample time and opportunity to rebut respondent's evidence. Further, the special master did not commit legal error by according little weight to petitioners' evidence from a research facility, which the special master found to be unpublished, preliminary, and incomplete. The special master further committed no error in discounting testimony by petitioners' expert regarding causation because that opinion was based on studies that were unreliable.
DOE 11 601 F.3d 1349 (Fed. Cir. 2010)	The CAFC found that the special master correctly considered "the record as a whole" in determining whether compensation is warranted, and that the Government is not restricted by proving a "factor unrelated" as the burden never shifted from petitioner to establish a prima facie case. The Government may present evidence of an alternate cause and the special master is not limited or precluded from considering such evidence when deciding whether petitioner has established a prima facie case. Petitioners' failure to meet his burden of proof as to the cause of an injury or condition is different from a requirement that he affirmatively disprove an alternate cause.
MOBERLY 592 F.3d 1315 (Fed. Cir. 2010)	The CAFC found that the special master correctly interpreted and applied the traditional tort "preponderance" standard applicable in Vaccine Act cases, and that the petitioners' argument for a more relaxed standard was not consistent with the Act. The Court also held that a close temporal association and the lack of an identifiable alternative cause, standing alone, are insufficient to prove causation. The Court further held that when evaluating an expert's medical theory, a special master is expected to evaluate both the reliability and credibility of the expert's testimony.

ANDREU 569 F.3d 1367 (Fed. Cir. 2009)	The CAFC found that if a petitioner satisfies the first and third prongs of Althen, the second prong (whether there exists a logical sequence of cause and effect between the vaccination and the injury alleged) can be met through the testimony of a treating physician. The CAFC further found that the special master's determinations regarding the credibility of witnesses are distinct from determinations of the reliability of scientific evidence, and the special master must clearly differentiate between these determinations to allow appropriate review on appeal.
DE BAZAN 539 F.3d 1347 (Fed. Cir. 2008)	The CAFC found that as part of petitioner's evidence in establishing a prima facie case of actual causation, petitioner has the burden of proving a medically appropriate time frame between vaccination and the onset of injury. The Government, like any defendant, may offer evidence to demonstrate the inadequacy of the petitioner's evidence on a requisite element of the petitioner's case-in-chief, and a special master is obliged to consider all evidence when deciding whether or not petitioner has met his burden of proof.
WALTHER 485 F.3d 1146 (Fed. Cir. 2007)	The CAFC found that the Vaccine Act does not require petitioners to bear the burden of eliminating alternative causes where the other evidence on causation-in-fact is sufficient to establish a prima facie case.
PAFFORD 451 F.3d 1352 (Fed. Cir. 2006)	The CAFC found that petitioners must prove by a preponderance of the evidence that the vaccine, and not some other agent, was the actual cause of the injury, when petitioners' other evidence of causation-in-fact is insufficient to establish a prima facie case.
CAPIZZANO 440 F.3d 1317 (Fed. Cir. 2006)	The CAFC found that a claimant could satisfy prongs one and two of the three-prong Althen test but fail to satisfy prong two when medical records and medical opinions do not suggest that the vaccine caused the injury or where the evidence shows that the probability of coincidence or another cause prevents petitioner from establishing causation by a preponderance of the evidence. The CAFC found that statements in the medical records by treating physicians are relevant and should be afforded significant evidentiary weight.
ALTHEN 418 F.3d 1274 (Fed. Cir. 2005)	The CAFC found that in order to prove causation-in-fact, a petitioner must prove by a preponderance of the evidence: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury. Lack of peer reviewed literature does not, in and of itself, preclude a finding of causation-in-fact.

Statute of Limitations

CASE NAME CITATION	HOLDING
CLOER 654 F.3d 1322 (Fed. Cir. 2011)	On August 5, 2011, the CAFC, in an 8-4 en banc decision, held that the Vaccine Act does not contain a discovery rule, nor can a discovery rule be read by implication into the Act. Rather, the statute of limitations begins to run on a specific statutory date: the date of the occurrence of the first symptom or manifestation of onset of the injury for which a claimant seeks compensation. In addition, the Court overruled its prior precedent and further held that equitable tolling applies to the Vaccine Act, although it determined that the statute of limitations is not tolled due to unawareness of a causal link between an injury and administration of a vaccine.
WILKERSON 593 F.3d 1343 (Fed. Cir. 2010)	The CAFC found that, consistent with its holding in Markovich, the 36 month statute of limitations period under 42 U.S.C. § 300aa-16(a)(2) begins to run with ***either*** the occurrence of the first symptom of or the manifestation of onset of an alleged vaccine-related injury, whichever is first. The Court held that the Act's time for filing runs from "the date of the occurrence of the first symptom or manifestation of onset," not the date the medical profession recognizes that a symptom is related to an alleged vaccine-related injury, and the Court held that an expert's determination of the first symptom or manifestation of onset may be made in "hindsight," i.e., a medical professional need not have appreciated the significance of the symptom at the time it occurred.
MARKOVICH 477 F.3d 1353 (Fed. Cir. 2007)	The CAFC found that the determination of when the 36 month statute of limitations period under 42 U.S.C. § 16(a)(2) begins to run is made by an objective standard, that is, even if the petitioner reasonably would not have known at the time that the vaccine had caused injury.

Death Benefits/Survivorship

CASE NAME CITATION	HOLDING
ZATUCHNI (SNYDER) 516 F.3d 1312 (Fed. Cir. 2008)	The CAFC found that a petitioner who establishes vaccine-related injuries and a vaccine-caused death is entitled to recover the compensation for vaccine-related injuries and vaccine-related death benefits under 42 U.S.C. § 300aa-15(a)(1)(B), (a)(3), (a)(4), and the death benefit provided under Section 15(a)(2). This applies where petitioner filed a claim for vaccine-related injuries, received a favorable ruling that the injuries were vaccine-related, and then died before receiving compensation for those injuries.

Attorneys' Fees and Costs/Interim Fees Requests

CASE NAME CITATION	HOLDING
CLOER 133 S. Ct. 1886 (2013)	The U.S. Supreme Court affirmed the judgment of the CAFC, finding that a person whose petition under the National Vaccine Injury Compensation Program is dismissed as untimely may recover from the United States an award of attorneys' fees and costs.
RODRIGUEZ 632 F.3d 1381 (Fed. Cir. 2011)	The CAFC affirmed the special master's decision rejecting the Laffey matrix as prima facie evidence of a forum rate for petitioners' counsel. The issue was whether the reasonable hourly rate for attorneys handling Vaccine Act cases should be determined by applying the Laffey matrix, a schedule of rates maintained by DOJ to compensate attorneys prevailing in "complex federal litigation," or whether the rate should be determined by considering a variety of factors, which may or may not include the Laffey matrix. The CAFC held that Vaccine Act litigation, while potentially involving complicated medical issues and requiring highly skilled counsel, is not analogous to "complex federal litigation" as described in Laffey, so as to justify use of the matrix. Distinguishing between the type of litigation the Laffey matrix is designed to compensate, the CAFC stated that a party need not prevail under the Vaccine Act in order to receive an attorneys' fees award, that attorneys are practically assured of compensation in every case without regard to whether they win or lose and the skill with which they presented their clients' cases, and that the attorneys' fees provisions under the Act "were not designed as a form of economic relief to improve the financial lot of lawyers." Further, the CAFC noted that Vaccine Act proceedings are an alternative to the traditional civil forum, apply relaxed legal standards of causation, have eased procedural rules compared to other federal civil litigation, do not have formal discovery and thus avoid discovery disputes, do not apply the rules of evidence, and are tried in informal, streamlined proceedings before special masters well-versed in the issues commonly repeated in Vaccine Act cases.

RIGGINS 406 Fed. App'x. 479 (Fed. Cir. 2011)	The CAFC found that the special master appropriately reduced the amount of attorneys' fees and costs sought by petitioner's counsel for the general development of Hepatitis B vaccine cases from the requested sum of $204,619.18 to an award of $79,782.81. In doing so, the CAFC affirmed the special master's decision to reduce the $97,443.43 in fees and costs associated with the consulting work of two experts to $10,000.00. Among other things, the CAFC agreed with the special master's finding that a hypothetical client would not pay for costly travel by petitioner's counsel and his consultants to France for personal consultation with foreign experts and lawyers, or for time and expenses related to the consultants' attendance at a professional conference in Italy.
KAY 298 Fed. App'x. 985 (Fed. Cir. 2008) per curiam, affirmance, Nov. 10, 2008	The CAFC denied an award of attorneys' fees and costs where the petition was found to be time-barred under Markovich and dismissed for lack of jurisdiction, precluding an award of attorneys' fees in a case that was untimely filed.
AVERA 515 F.3d 1343 (Fed. Cir. 2008)	The CAFC affirmed that, in general, the forum rule should be used to calculate reasonable hourly rates for petitioners' attorneys in claims brought under the Vaccine Act, and found that Washington, DC is the forum for vaccine cases because it is where the CFC, which has exclusive jurisdiction over vaccine cases, is physically located. In applying the forum rule, the CAFC recognized and applied an exception derived from Davis v. U.S. E.P.A., 169 F.3d 755 (D.C. Cir. 1999). Applying Davis, the CAFC found that an exception to the forum rule applies where 1) the bulk of the work was done outside DC and 2) there is a very significant difference between the DC rates and the attorneys' hometown rates. The CAFC found that the appellants' vaccine attorneys hailing from Cheyenne, Wyoming were not entitled to forum rates in this case. The CAFC also held that interim attorneys' fees are permitted under the Vaccine Act. The CAFC considered an award of interim fees particularly appropriate when cases are protracted and costly experts must be retained. The CAFC found that there was no basis for an award of interim fees here because the petitioners only sought an award of interim fees pending an appeal; made no showing of undue hardship; the amount of fees was not substantial; no experts had been employed; and there was only a short delay in the award pending the appeal.

5.3

5.4

5.5

Vaccine Information Statement

Meningococcal ACWY Vaccines: What You Need to Know

Many Vaccine Information Statements are available in Spanish and other language3s. See www.immunize.org/vis.
Hojas de Información Sobre Vacunas están disponibles en español y en muchos otros idiomas. Visite http://www.immunize.org/vis

1. Why get vaccinated?

Meningococcal disease is a serious illness caused by a type of bacteria called *Neisseria meningitidis*. It can lead to meningitis (infection of the lining of the brain and spinal cord) and bacteremia or septicemia (infections of the blood). Meningococcal disease often strikes without warning – even people who are otherwise healthy.

There are at least 12 *Neisseria meningitidis* groups, or "serotypes." Serotypes A, B, C, W, and Y cause most meningococcal disease.

Meningococcal disease can spread from person to person through close contact (coughing or kissing) or lengthy contact, especially among people living in the same household.

Anyone can get meningococcal disease but certain people are at increased risk, including:

- Infants less than one year old
- Adolescents and young adults 16 through 23 years of age
- People with certain medical conditions
- People who routinely are exposed to the bacteria as part of their job duties
- People at risk because of an outbreak in their community

Even when it is treated, meningococcal disease kills 10 to 15 people out of 100. And of those who survive, about 10 to 20 out of every 100 will suffer disabilities such as hearing loss, brain damage, amputations, nervous system problems, or severe scars from skin grafts.

Meningococcal ACWY vaccines can prevent meningococcal disease caused by those four serogroups. A different meningococcal vaccine is recommended to help protect against serogroup B.

2. Meningococcal ACWY vaccine

There are two kinds of ACWY meningococcal vaccine licensed by the FDA:

- Meningococcal conjugate vaccine (**MCV4**) is the preferred vaccine for people 55 years of age and younger. Two doses of MCV4 are routinely recommended for adolescents 11 through 18 years of age: the first dose at 11 or 12 years of age, with a booster dose at age 16. Some adolescents, including those with HIV, should get three doses. Ask your healthcare provider for more information.

- Meningococcal polysaccharide vaccine (**MPSV4**) has been available since the 1970s. It is the only meningococcal vaccine licensed for people older than 55.

In addition to routine vaccination for adolescents, meningococcal ACWY vaccines are also recommended for certain groups of people:

- College freshmen living in dormitories
- Laboratory personnel who are routinely exposed to meningococcal bacteria
- U.S. military recruits
- Anyone traveling to, or living in, a part of the world where meningococcal disease is common, such as parts of Africa
- Anyone who has a damaged spleen, or whose spleen has been removed
- Anyone who has persistent complement component deficiency (an immune system disorder)
- People who might have been exposed to meningitis during an outbreak

Children between 9 and 23 months of age, and anyone else with certain medical conditions need 2 doses for adequate protection. Ask your doctor about the number and timing of doses, and the need for booster doses.

MCV4 is the preferred vaccine for people in these groups who are 9 months through 55 years of age. MPSV4 can be used for adults older than 55.

3. Some people should not get this vaccine

Tell the person who is giving you the vaccine:

- **If you have any severe, life-threatening allergies.**
  If you have ever had a life-threatening allergic reaction after a previous dose of meningococcal vaccine, or if you have a severe allergy to any part of this vaccine, you should not get this vaccine. Your provider can tell you about the vaccine's ingredients.

- **If you are pregnant or breastfeeding.**
  Meningococcal vaccines may be given to pregnant women. MCV4 is a relatively new vaccine and has not been studied in pregnant women as much as MPSV4 has. It should be used only if clearly needed. The manufacturers of MCV4 maintain pregnancy registries for women who are vaccinated while pregnant.

- **If you are not feeling well**
  It is usually okay to get a meningococcal vaccine when you have a mild illness, but you might be advised to come back when you feel better.

Except for children with sickle cell disease or without a working spleen, meningococcal vaccines may be given at the same time as other vaccines.

4. Risks of a vaccine reaction

With any medicine, including vaccines, there is a chance of side effects. These are usually mild and go away on their own within a few days, but serious reactions are also possible.

As many as than half of the people who get meningococcal ACWY vaccines have **mild problems** following vaccination, such as redness or pain where the shot was given. If these problems occur, they usually last for 1 or 2 days. They are more common after MCV4 than after MPSV4.

A small percentage of people who receive the vaccine develop a mild fever.

Problems that could happen after any vaccine:

- People sometimes faint after a medical procedure, including vaccination. Sitting or lying down for about 15 minutes can help prevent fainting, and injuries caused by a fall. Tell your doctor if you feel dizzy, or have vision changes or ringing in the ears.

- Some people get severe pain in the shoulder and have difficulty moving the arm where a shot was given. This happens very rarely.

- Any medication can cause a severe allergic reaction. Such reactions from a vaccine are very rare, estimated at about 1 in a million doses, and would happen within a few minutes to a few hours after the vaccination.

As with any medicine, there is a very remote chance of a vaccine causing a serious injury or death.

The safety of vaccines is always being monitored. For more information, visit:
www.cdc.gov/vaccinesafety/

6. What if there is a serious reaction?

What should I look for?

- Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or unusual behavior.

  Signs of a severe allergic reaction can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness – usually within a few minutes to a few hours after the vaccination.

What should I do?

- If you think it is a severe allergic reaction or other emergency that can't wait, call 9-1-1 and get to the nearest hospital. Otherwise, call your doctor.

- Afterward, the reaction should be reported to the "Vaccine Adverse Event Reporting System" (VAERS). Your doctor should file this report, or you can do it yourself through the VAERS web site at **www.vaers.hhs.gov**, or by calling **1-800-822-7967**.

VAERS does not give medical advice.

7. The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines.

Persons who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling **1-800-338-2382** or visiting the VICP website at **www.hrsa.gov/vaccinecompensation**. *There is a time limit to file a claim for compensation.*

8. How can I learn more?

- Ask your health care provider. He or she can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-800-232-4636 (1-800-CDC-INFO)** or
  - Visit CDC's website at **www.cdc.gov/vaccines**

Vaccine Information Statement
Meningococcal ACWY Vaccines
[Date]
42 U.S.C. § 300aa-26

Department of Health and Human Services
Centers for Disease Control and Prevention

Office Use Only
[Barcode]

Vaccine Information Statement

Serogroup B Meningococcal Vaccine: What you need to know

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis
Hojas de Información Sobre Vacunas están disponibles en Español y en muchos otros idiomas. Visite http://www.immunize.org/vis

1. Why get vaccinated?

Meningococcal disease is a serious illness caused by a type of bacteria called *Neisseria meningitidis*. It can lead to meningitis (infection of the lining of the brain and spinal cord) and bacteremia or septicemia (infections of the blood). Meningococcal disease often strikes without warning – even people who are otherwise healthy.

There are at least 12 *Neisseria meningitidis* groups, or "serotypes." Serotypes A, B, C, W, and Y cause most meningococcal disease.

Meningococcal disease can spread from person to person through close contact (coughing or kissing) or lengthy contact, especially among people living in the same household.

Anyone can get meningococcal disease but certain people are at increased risk, including:

- Infants less than one year old
- Adolescents and young adults 16 through 23 years of age
- People with certain medical conditions
- People who routinely are exposed to the bacteria as part of their job duties
- People at risk because of an outbreak in their community

Even when it is treated, meningococcal disease kills 10 to 15 people out of 100. And of those who survive, about 10 to 20 out of every 100 will suffer disabilities such as hearing loss, brain damage, amputations, nervous system problems, or severe scars from skin grafts.

Serogroup B meningococcal vaccine can prevent *serogroup B* meningococcal disease – a common form of meningococcal disease. Other meningococcal vaccines are recommended to help protect against different serogroups (A, C, W, and Y).

2. Serogroup B Meningococcal Vaccines

Two serogroup B meningococcal vaccines have been licensed by the Food and Drug Administration.

These vaccines are recommended for people 10 years old or older who are at increased risk for meningococcal B infections, including:

- Anyone whose spleen has been removed or does not work the way it should
- Anyone with a rare condition called persistent complement component deficiency
- Anyone taking a drug called Soliris
- Microbiologists who are routinely exposed to *Neisseria meningitidis*
- People at risk because of a serogroup B meningococcal disease outbreak

Depending on which vaccine you get, you will get either:

- **2 doses**, at least 1 month apart

  or

- **3 doses**, with the second dose at least 2 months after the first and the third dose at least 6 months after the first.

3. Some people should not get this vaccine

Tell the person who is giving you the vaccine:

- **If you have any severe life-threatening allergies.**
  If you have ever had a life-threatening allergic reaction after a previous dose of serogroup B meningococcal vaccine, or if you have a severe allergy to any part of this vaccine, you should not get this vaccine. Your healthcare provider can tell you about the vaccine's ingredients.

- **If you are pregnant or breastfeeding.**
  There is not very much information about the potential risks of this vaccine for a pregnant woman or breastfeeding mother. It should be used during pregnancy only if clearly needed.

- **If you are not feeling well.**
  It is usually okay to get this vaccine when you have a mild illness, but you might be advised to come back when you feel better.

4. Risks of a vaccine reaction

With any medicine, including vaccines, there is a chance of side effects. These are usually mild and go away on their own within a few days, but serious reactions are also possible.

More than half of the people who get serogroup B meningococcal vaccine have **mild problems** following vaccination. These reactions can last up to 2 or 3 days, and include:

- Soreness, redness, or swelling where the shot was given
- Tiredness or fatigue
- Headache
- Muscle or joint pain
- Fever or chills
- Nausea or diarrhea

Problems that could happen after any vaccine:

- People sometimes faint after a medical procedure, including vaccination. Sitting or lying down for about 15 minutes can help prevent fainting, and injuries caused by a fall. Tell your doctor if you feel dizzy, or have vision changes or ringing in the ears.

- Some people get severe pain in the shoulder and have difficulty moving the arm where a shot was given. This happens very rarely.

- Any medication can cause a severe allergic reaction. Such reactions from a vaccine are very rare, estimated at about 1 in a million doses, and would happen within a few minutes to a few hours after the vaccination.

As with any medicine, there is a very remote chance of a vaccine causing a serious injury or death.

The safety of vaccines is always being monitored. For more information, visit:
www.cdc.gov/vaccinesafety/

5. What if there is a serious reaction?

What should I look for?

- Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or unusual behavior.

  Signs of a severe allergic reaction can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness – usually within a few minutes to a few hours after the vaccination.

What should I do?

- If you think it is a severe allergic reaction or other emergency that can't wait, call 9-1-1 and get to the nearest hospital. Otherwise, call your doctor.

- Afterward, the reaction should be reported to the "Vaccine Adverse Event Reporting System" (VAERS). Your doctor should file this report, or you can do it yourself through the VAERS web site at **www.vaers.hhs.gov**, or by calling **1-800-822-7967**.

VAERS does not give medical advice.

6. The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines.

Persons who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling **1-800-338-2382** or visiting the VICP website at **www.hrsa.gov/vaccinecompensation**. *There is a time limit to file a claim for compensation.*

7. How can I learn more?

- Ask your health care provider. He or she can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-800-232-4636 (1-800-CDC-INFO)** or
  - Visit CDC's website at **www.cdc.gov/vaccines**

Vaccine Information Statement (Interim)
Serogroup B Meningococcal Vaccine
[Date]
42 U.S.C. § 300aa-26

Department of Health and Human Services
Centers for Disease Control and Prevention

Office Use Only
[Barcode]

Vaccine Information Statement

MMR Vaccine (Measles, Mumps and Rubella): What you need to know

Many Vaccine Information Statements are available in Spanish and other languages. See www.immunize.org/vis
Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1. Why get vaccinated?

Measles, mumps, and rubella are serious diseases. Before vaccines they were very common, especially among children.

Measles

- Measles virus causes fever, cough, runny nose, and eye irritation, followed by a rash.
- Measles can lead to ear infections, pneumonia, swelling of the brain causing seizures (jerking and staring), brain damage, and death.

Mumps

- Mumps virus causes fever, headache, muscle pain, loss of appetite, and swollen glands in the cheeks and neck.
- Mumps can lead to deafness, meningitis (infection of the brain and spinal cord covering), painful swelling of the testicles or ovaries, and rarely sterility.

Rubella (German Measles)

- Rubella virus causes rash, arthritis (mostly in teenage and adult women), and mild fever.
- If a woman gets rubella while she is pregnant, she could have a miscarriage or her baby could be born with serious birth defects.

These diseases spread from person to person through the air. You can easily catch them by being around someone who is already infected.

Measles, mumps, and rubella (MMR) vaccine can protect children (and adults) from all three of these diseases.

Vaccination programs have made these diseases much less common in the U.S. than they used to be. But if we stopped vaccinating they could return.

2. MMR vaccine

Children should get two doses of MMR vaccine:
1st Dose: 12–15 months of age
2nd Dose: 4–6 years of age (may be given earlier, if at least 28 days after the 1st dose)

Some infants younger than 12 months should get a dose of MMR if they are traveling out of the country. (This dose will not count toward their routine series.)

Some adults 18 years of age and older should also get MMR vaccine. Generally, anyone who has not received a dose of MMR vaccine who is 18 years or older should get at least one dose of MMR vaccine, unless they can show that they have either been vaccinated or had all three diseases. Most people born in or before 1956 have had these three diseases.

You can get MMR vaccine at the same time as other vaccines.

Children between 12 months and 12 years of age can get a combination vaccine called MMRV. MMRV contains both chickenpox and MMR vaccines. Ask your doctor for more information.

3. Some people should not get this vaccine

Tell your doctor:

- **If the patient has any severe (life-threatening) allergies.** If the patient has ever had a life-threatening allergic reaction after a dose of MMR vaccine, or has a severe allergy to neomycin or gelatin, or any other part of this vaccine, he or she should not get the vaccine.
- **If the patient is not feeling well.** Your doctor might suggest waiting until the patient feels better.
- **If the patient is pregnant.** Pregnant women should wait to get MMR vaccine until after they have given birth. Women should not get pregnant for 1 month after getting MMR vaccine.
- **If the patient's immune system is weakened because of a disease** (such as cancer or asymptomatic HIV/AIDS), or by medical treatments such as radiation, steroids or chemotherapy. *Your doctor will help you make a decision about getting this vaccine.*
- **If the patient has recently had a blood transfusion or received other blood products.** Your doctor might advise the patient to postpone MMR vaccination.
- **If the patient has ever had a low platelet count (a blood disorder).**
- **If the patient has gotten another vaccine within the past 4 weeks.** Some vaccines should be separated from one another by at least four weeks if they are not given together.

Ask your doctor for more information.

4. Risks of a vaccine reaction

With any medicine, including vaccines, there is a chance of side effects. These are usually mild and go away on their own, but serious reactions are also possible but are rare.

Getting MMR vaccine is much safer than getting measles, mumps, or rubella disease. Most people who get MMR vaccine do not have any problems with it.

Mild Problems following MMR vaccine:

- Fever (up to 1 person out of 6)
- Mild rash (about 1 person out of 20)
- Swelling of glands in the cheeks or neck (less than 1 person out of 100)

If these problems occur, it is usually within 6-14 days after the shot. They occur less often after the second dose.

Moderate problems following MMR vaccine:

- Seizure (jerking or staring) caused by fever (about 1 out of 3,000 doses)
- Temporary pain and stiffness in the joints, mostly in teenage or adult women (up to 1 out of 4)
- Temporary low platelet count, which can cause a bleeding disorder (about 1 out of 30,000 doses)

Severe problems following MMR vaccine:

- Several other severe problems have been reported after a child gets MMR vaccine, including:
    - Deafness
    - Long-term seizures, coma, or lowered consciousness
    - Permanent brain damage

These happen so rarely experts cannot tell whether they are caused by the vaccine or not. If they are, it is extremely rare.

Problems that could happen after any vaccine:

- People sometimes faint after a medical procedure, including vaccination. Sitting or lying down for about 15 minutes can help prevent fainting, and injuries caused by a fall. Tell your doctor if you feel dizzy, or have vision changes or ringing in the ears.

- Some people get severe pain in the shoulder and have difficulty moving the arm where a shot was given. This happens very rarely.

- Any medication can cause a severe allergic reaction. Such reactions from a vaccine are very rare, estimated at about 1 in a million doses, and usually happen within a few minutes to a few hours after the vaccination.

As with any medicine, there is a very remote chance of a vaccine causing a serious injury or death.

The safety of vaccines is always being monitored. For more information, visit:
www.cdc.gov/vaccinesafety/

5. What if there is a serious reaction?

What should I look for?

- Look for anything that concerns you, such as signs of a severe allergic reaction, very high fever, or unusual behavior.

  Signs of a severe allergic reaction can include hives, swelling of the face and throat, difficulty breathing, a fast heartbeat, dizziness, and weakness. These would usually start a few minutes to a few hours after the vaccination.

What should I do?

- If you think it is a severe allergic reaction or other emergency that can't wait, call 9-1-1 or get to the nearest hospital. Otherwise, call your doctor.
- Afterward, the reaction should be reported to the Vaccine Adverse Event Reporting System (VAERS). Your doctor might file this report, or you can do it yourself through the VAERS web site at www.vaers.hhs.gov, or by calling **1-800-822-7967**.

VAERS does not give medical advice.

6. The National Vaccine Injury Compensation Program

The National Vaccine Injury Compensation Program (VICP) is a federal program that was created to compensate people who may have been injured by certain vaccines.

Persons who believe they may have been injured by a vaccine can learn about the program and about filing a claim by calling **1-800-338-2382** or visiting the VICP website at www.hrsa.gov/vaccinecompensation. *There is a time limit to file a claim for compensation.*

7. How can I learn more?

- Ask your doctor. He or she can give you the vaccine package insert or suggest other sources of information.
- Call your local or state health department.
- Contact the Centers for Disease Control and Prevention (CDC):
  - Call **1-800-232-4636 (1-800-CDC-INFO)** or
  - Visit CDC's website at www.cdc.gov/vaccines

Vaccine Information Statement (Interim)
MMR Vaccine
(date of publication)

42 U.S.C. § 300aa-26

Department of Health and Human Services
Centers for Disease Control and Prevention

Office Use Only
[barcode here]

5.6

Immunization Safety Office Updates

Centers for Disease Control and Prevention

Tom Shimabukuro, MD, MPH, MBA
Immunization Safety Office
Division of Healthcare Quality Promotion
National Center for Emerging and Zoonotic Infectious Diseases
Centers for Disease Control and Prevention (CDC)

Advisory Commission on Childhood Vaccines (ACCV)
June 4, 2015

Topics

- Immunization Safety Office highlights
- Preview of selected sessions for the June 2015 Advisory Committee on Immunization Practices (ACIP) meeting
- Selected publications

Immunization Safety Office (ISO) highlights

- ISO continues to work with FDA partners to prepare for implementation of manufacturer reporting to the Vaccine Adverse Event Reporting System (VAERS) using the E2B(R3) message standard
  - Implementation date is June 10, 2015
- ISO will present a 2014-15 end-of-season analysis of influenza vaccine safety at the June 2015 ACIP meeting on June 24, 2015

3

June 2015 ACIP meeting preview

- Meningococcal vaccines
  - Policy options for routine use of meningococcal group B (MenB) vaccines in adolescents
  - GRADE presentation on evidence for use of MenB vaccine in adolescents and college students
  - Considerations for routine use of MenB vaccines in adolescents
  - Vote on proposed recommendations

http://www.cdc.gov/vaccines/acip/meetings/downloads/agenda-archive/agenda-2015-06.pdf

4

June 2015 ACIP meeting preview

- Influenza
  - Influenza surveillance update
  - Influenza vaccine safety update
  - High dose influenza vaccine update
  - Vote on proposed recommendations
- Influenza A (H5N1) vaccine
  - Influenza A (H5N1) epidemiology update
  - Vote on proposed recommendations

http://www.cdc.gov/vaccines/acip/meetings/downloads/agenda-archive/agenda-2015-06.pdf

5

June 2015 ACIP meeting preview

- Pertussis
  - Cocooning and Tdap vaccination
  - Acellular pertussis vaccine effectiveness among children in the setting of pertactin-deficient B. pertussis, Vermont, 2011-2013
- Pneumococcal vaccines
  - Intervals between 13-valent pneumococcal conjugate (PCV13) and 23-valent pneumococcal polysaccharide (PPSV23) vaccines, and supporting evidence and rationale for change
  - Vote on proposed recommendations

http://www.cdc.gov/vaccines/acip/meetings/downloads/agenda-archive/agenda-2015-06.pdf

6

June 2015 ACIP meeting preview

- Herpes zoster
  - Update on herpes zoster epidemiology and vaccine uptake
  - Results of GSK Phase 3 study of investigational adjuvant-based zoster vaccine

http://www.cdc.gov/vaccines/acip/meetings/downloads/agenda-archive/agenda-2015-06.pdf

7

Selected publications

- Petrosky et al; Centers for Disease Control and Prevention (CDC). Use of 9-valent human papillomavirus (HPV) vaccine: updated HPV vaccination recommendations of the advisory committee on immunization practices. MMWR Morb Mortal Wkly Rep. 2015 Mar 27;64(11):300-4.

- Iqbal et al. Relationship between Guillain-Barré syndrome, influenza-related hospitalizations, and influenza vaccine coverage. Vaccine. 2015 Apr 21;33(17):2045-9.
  - Pneumonia and influenza hospitalization rates were significantly correlated with hospitalization rates for Guillain-Barré syndrome
  - Vaccine coverage did not significantly affect the rates of Guillain-Barré syndrome hospitalization at the population level

8

Selected publications

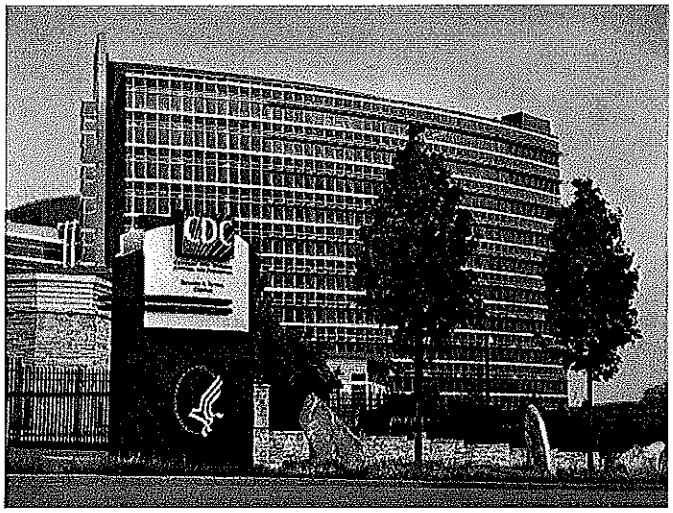
- McNamara et al. First Use of a Serogroup B Meningococcal Vaccine in the US in Response to a University Outbreak. Pediatrics. 2015 May;135(5):798-804.
  - No serogroup B meningococcal disease cases occurred in persons who received 1 or more doses of 4CMenB vaccine, suggesting 4CMenB may have protected vaccinated individuals from disease
  - However, a case occurred in an unvaccinated close contact of a vaccinated university student demonstrating that carriage of serogroup B Neisseria meningitidis among vaccinated persons was not eliminated

9

Selected publications

- Datwani et al. Chorioamnionitis following vaccination in the Vaccine Adverse Event Reporting System. Vaccine. 2015 May 11. [Epub ahead of print]
  - Chorioamnionitis was found to be uncommonly reported, representing 1% of pregnancy reports to VAERS; a majority of reports had at least one risk factor for chorioamnionitis.
- Hibbs et al. Vaccination errors reported to the vaccine adverse event reporting system, United States, 2000–2013. Vaccine (2015), http://dx.doi.org/10.1016/j.vaccine.2015.05.006
  - Vaccination error reports to VAERS have increased substantially from 2000-2013
  - Contributing factors might include changes in reporting practices, increasing complexity of the immunization schedule, availability of products with similar sounding names or acronyms, and increased attention to storage and temperature lapses

10



Centers for Disease Control and Prevention
Atlanta, GA

National Center for Emerging and Zoonotic Infectious Diseases
Division of Healthcare Quality Promotion -- Immunization Safety Office

Thank You

For more information please contact Centers for Disease Control and Prevention
1600 Clifton Road NE, Atlanta, GA 30333
Telephone, 1-800-CDC-INFO (232-4636)/TTY: 1-888-232-6348
E-mail: cdcinfo@cdc.gov Web: www.cdc.gov

National Center for Emerging and Zoonotic Infectious Diseases
Division of Healthcare Quality Promotion – Immunization Safety Office

5.7

Vaccine Activities Update

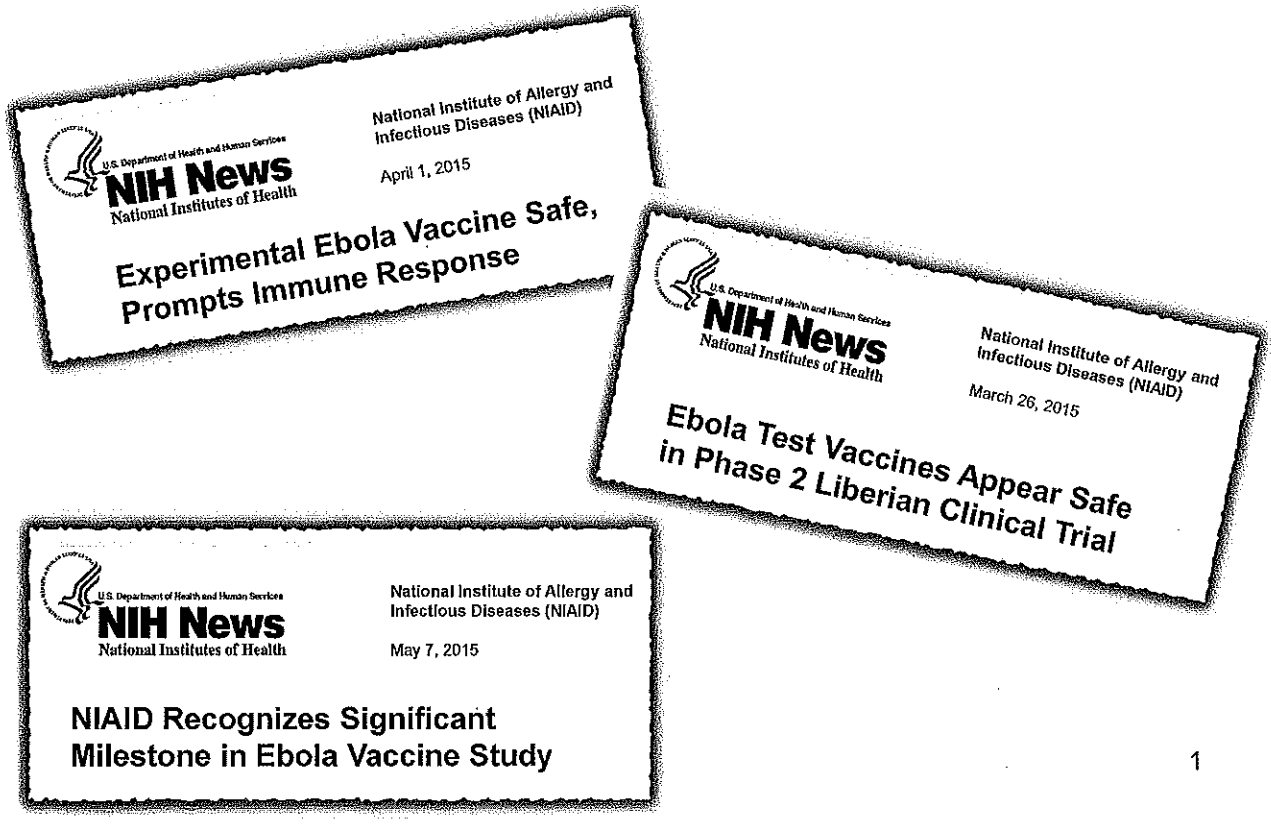
National Institute of Allergy and Infectious Diseases, National Institutes of Health

Claire Schuster, MPH
Division of Microbiology and Infectious Diseases
NIAID, NIH, DHHS

June 2015

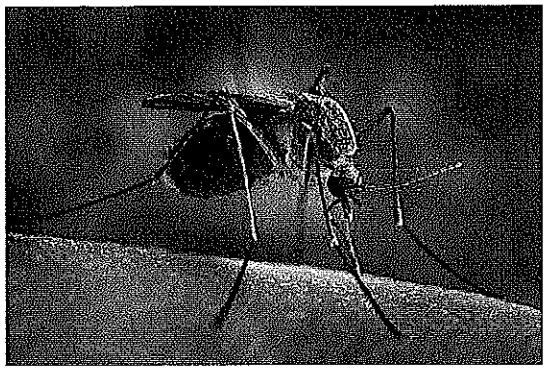
National Institute of Allergy and Infectious Diseases

NIAID Ebola Vaccine Research



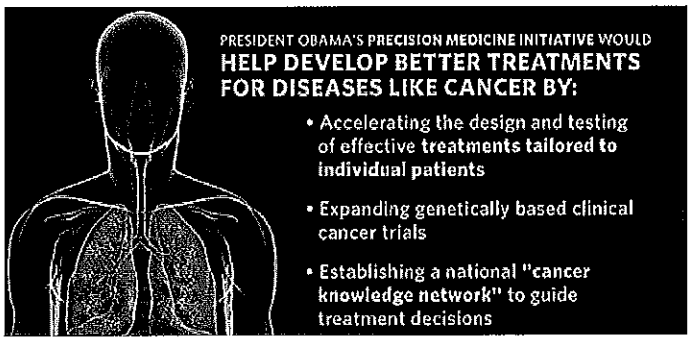
West Nile Virus Vaccine Phase 1 Trial Begins

- Currently, no human West Nile virus vaccine approved for commercial use
- Investigational vaccine developed by scientists at Oregon Health & Science University
- Phase 1 trial underway at NIAID-supported Vaccine and Treatment Evaluation Unit at Duke University



Credit: CDC/ James Gathany

Precision Medicine Initiative



U.S. Department of Health and Human Services
NIH News
National Institutes of Health

March 20, 2015

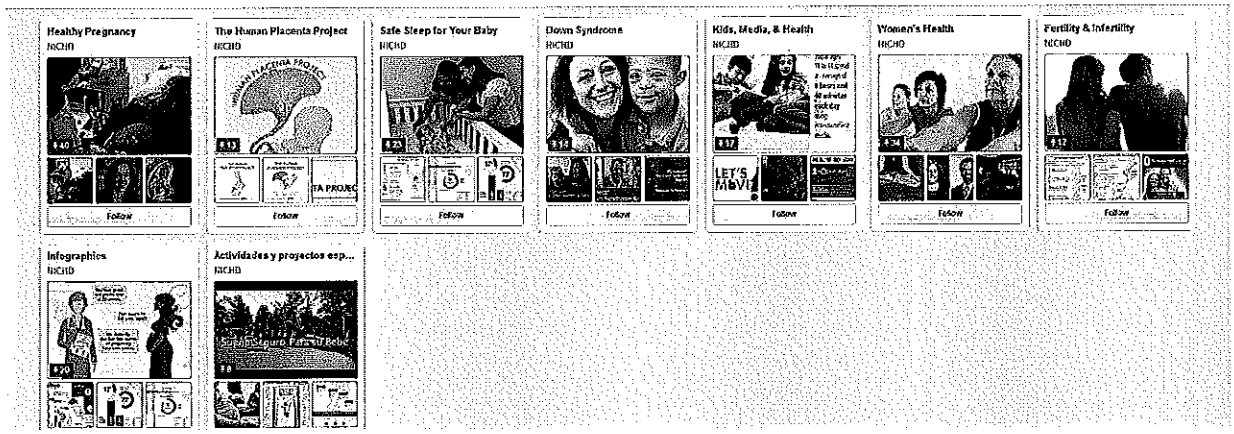
NIH forms team of experts to chart course for the President's Precision Medicine Initiative research network

Working Group to host public meetings, seek public input into the design of the Initiative

NIH National Institute of Allergy and Infectious Diseases

NICHD Launches Pinterest Site

Eunice Kennedy Shriver National Institute of Child Health and Human Development



https://www.pinterest.com/NICHD_NIH/

5.8

Advisory Commission on Childhood Vaccines (ACCV)

Food and Drug Administration Update

LCDR Valerie Marshall, MPH
Immediate Office of the Director
Office of Vaccines Research and Review (OVRR)
Center for Biologics Evaluation and Research (CBER)
Food and Drug Administration (FDA)

U.S. Food and Drug Administration
Protecting and Promoting Public Health
www.fda.gov

Outline

- Recent Approvals
- Past and Upcoming Meetings and Events
- Global Public Health

Vaccine Approvals

U.S. Food and Drug Administration
Protecting and Promoting Public Health
www.fda.gov

New Vaccine Approval - Quadracel

- **Approved: March 24, 2015**
- **Proper Name:** Diphtheria and Tetanus Toxoids and Acellular Pertussis Adsorbed and Inactivated Poliovirus Vaccine
- Indicated for active immunization against diphtheria, tetanus, pertussis and poliomyelitis.
- A single dose of Quadracel is approved for use in children 4 through 6 years of age as a fifth dose in the diphtheria, tetanus, pertussis vaccination (DTaP) series, and as a fourth or fifth dose in the inactivated poliovirus vaccination (IPV) series, in children who have received 4 doses of Pentacel and/or DAPTACEL vaccine.

Fluzone; Fluzone High Dose; Fluzone Intradermal; Fluzone Quadrivalent

- **Supplement Approved:** April 30, 2015
- To update the package insert to include efficacy data for children aged 6 – 24 months and adults aged 18-49 years

5

U.S. Food and Drug Administration
Protecting and Promoting Public Health
www.fda.gov

Human Papillomavirus Quadrivalent Vaccine, Recombinant (Gardasil)

- **BLA Supplement Approved:** April 24, 2015
- To add a new subsection titled, "Long-term follow-up studies" to the Clinical Studies Section of the Package Insert

6

Past and Upcoming Meetings

U.S. Food and Drug Administration
Protecting and Promoting Public Health
www.fda.gov

Advisory Committee Meeting

- On May 12, 2015, the Vaccines and Related Biological Products Advisory Committee (VRBPAC) met in an open session to discuss the development and licensure of Ebola Vaccines.

RSV Vaccines Workshop – June 1 and 2

- The purpose of the workshop was to identify obstacles to RSV vaccine development, discuss approaches to alleviating them, and identify gaps in research that could be addressed to enable vaccine development.
- The meeting will reviewed the basic science and clinical data that will inform the regulation of products under development including, for example, immune responses to RSV primary infection and reinfection, and the physiology and kinetics of placental antibody transfer as well as discuss progress towards standardization of immunologic agents and assays.
- Lessons learned from previous clinical trials of RSV vaccines, and polyclonal and monoclonal antibodies used for immune-prophylaxis was discussed to identify potential serological and clinical endpoints for upcoming pivotal trials.

9

U.S. Food and Drug Administration
Protecting and Promoting Public Health
www.fda.gov

Global Public Health Activities

10

Global Public Health

In response to the Ebola epidemic in West Africa, FDA is continuing to work with federal partners, the medical and scientific community, industry, and international organizations and regulators to assess investigational products and provide regulatory pathways that may expedite the development and availability of products.

11

5.9

National Vaccine Program Office Update

National Vaccine Program Office

ACCV, June 2015

Dr. Karin Bok

Cooperative agreement: Research, Monitoring and Outcomes Definitions for Vaccine Safety

NV-VSR-15-001

- Deadline for applications was April 15, 2015
- Received 8 applications
- Currently selecting reviewers, reviewing process
- Awards planned for late July, 2015

National Vaccine Program Office

COOPERATIVE AGREEMENT: RESEARCH, MONITORING AND OUTCOMES DEFINITIONS FOR VACCINE SAFETY

PILOT COOPERATIVE AGREEMENT

- TWO AWARDS OF $250,00 EACH
- ONE YEAR DURATION

http://www.grants.gov/web/grants/view-opportunity.html?oppId=271393

National Vaccine Program Office

SMART VACCINES TRANSITIONING TO NVPO

- Provision of capabilities to transform the existing SMART Vaccines tool to a web-based platform (html open-source model) that can be supported and sustained for public access;
- Iterative adaptation and refinement of the tool
- Expansion and updating of the data warehouse (model supporting data) and standardized formats for data sharing;
- Dissemination and use of the tool supported by direct engagement and training of the public sector, academic, and private sector stakeholders and decision-makers associated with vaccine development, purchasing, and deployment/implementation programs; safety profile
- Hosting of the tool that is sustainable and provides global access to the tool by embedding it an infrastructure that utilizes existing resources for maintenance of standards and capabilities

National Vaccine Program Office

THANK YOU

National Vaccine Program Office

6

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 62

[EPA–R06–OAR–2013–0763; FRL–9927–01–Region 6]

Approval and Promulgation of State Plans for Designated Facilities and Pollutants; Texas, Oklahoma, Arkansas, New Mexico, and the City of Albuquerque, New Mexico; Control of Emissions From Existing Sewage Sludge Incinerator Units

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve Clean Air Act (CAA) section 111(d)/129 negative declarations for the States of Texas, Oklahoma, Arkansas, New Mexico, and the City of Albuquerque, New Mexico, for existing sewage sludge incinerator (SSI) units. These negative declarations certify that existing SSI units subject to the requirements of sections 111(d) and 129 of the CAA do not exist within the jurisdictions of Texas, Oklahoma, Arkansas, and New Mexico (including the City of Albuquerque).

DATES: Written comments must be received on or before June 1, 2015.

ADDRESSES: Comments may be mailed to Mr. Guy Donaldson, Chief, Air Planning Section (6PD–L), Environmental Protection Agency, 1445 Ross Avenue, Suite 1200, Dallas, Texas 75202–2733. Comments may also be submitted electronically or through hand delivery/courier by following the detailed instructions in the **ADDRESSES** section of the direct final rule located in the rules section of this **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Mr. Kenneth Boyce, (214) 665–7259, *boyce.kenneth@epa.gov.*

SUPPLEMENTARY INFORMATION: In the final rules section of this **Federal Register**, EPA is approving the negative declarations submitted by the Texas Commission on Environmental Quality (TCEQ), the Oklahoma Department of Environmental Quality (ODEQ), the Arkansas Department of Environmental Quality (ADEQ), New Mexico Environment Department (NMED) and the City of Albuquerque, New Mexico, certifying that there are no existing sewage sludge incinerator (SSI) units within their respective jurisdictions. These negative declarations meet the requirements of 40 CFR 62.06. EPA is approving the negative declaration as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no relevant adverse comments are received in response to this action, no further activity is contemplated. If EPA receives relevant adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. The EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time. Please note that if EPA receives relevant adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment.

For additional information, see the direct final rule, which is located in the rules section of this **Federal Register**.

Dated: April 16, 2015.

Ron Curry,

Regional Administrator, Region 6.

[FR Doc. 2015–10041 Filed 4–29–15; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 100

National Vaccine Injury Compensation Program: Statement of Reasons for Not Conducting Rulemaking Proceedings

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Denial of petition for rulemaking.

SUMMARY: In accordance with section 2114(c)(2)(B) of the Public Health Service Act, 42 U.S.C. 300aa–14(c)(2)(B), notice is hereby given concerning the reasons for not conducting rulemaking proceedings to add diabetes mellitus as an injury associated with the measles-mumps-rubella vaccine to the Vaccine Injury Table.

DATES: Written comments are not being solicited.

FOR FURTHER INFORMATION CONTACT: Avril M. Houston, MD, MPH, Director, Division of Injury Compensation Programs, Healthcare Systems Bureau, HRSA, Parklawn Building, Room 11C–06, 5600 Fishers Lane, Rockville, Maryland 20857, or by telephone at (301) 443–6593.

SUPPLEMENTARY INFORMATION: The National Childhood Vaccine Injury Act of 1986, Title III of Public Law 99–660 (42 U.S.C. 300 aa–10 *et seq.*) established the National Vaccine Injury Compensation Program (VICP) for persons found to be injured by vaccines. Under this federal program, petitions for compensation are filed with the United States Court of Federal Claims (Court). The Court, acting through special masters, makes findings as to eligibility for, and amount of, compensation. In order to gain entitlement to compensation under the VICP for a covered vaccine, a petitioner must establish a vaccine-related injury or death, either by proving that the first symptom of an injury/condition, as defined by the Qualifications and Aids to Interpretation, occurred within the time period listed on the Vaccine Injury Table (Table), and, therefore, is presumed to be caused by a vaccine (unless another cause is found), or by proof of vaccine causation, if the injury/condition is not on the Table or did not occur within the time period specified on the Table.

The statute authorizing the VICP provides for the inclusion of additional vaccines in the VICP when they are recommended by the Centers for Disease Control and Prevention (CDC) for routine administration to children. *See* section 2114(e)(2) of the PHS Act, 42 U.S.C. 300aa–14(e)(2). Consistent with section 13632(a)(3) of Public Law 103–66, the regulations governing the VICP provide that such vaccines will be included in the Table as of the effective date of an excise tax to provide funds for the payment of compensation with respect to such vaccines. 42 CFR 100.3(c)(8). The statute authorizing the VICP also authorizes the Secretary to create and modify a list of injuries, disabilities, illnesses, conditions, and deaths (and their associated time frames) associated with each category of vaccines included on the Table. *See* sections 2114(c) and 2114(e)(2) of the PHS Act, 42 U.S.C. 300aa–14(c) and 300aa–14(e)(2). Finally, section 2114(c)(2) of the PHS Act, 42 U.S.C. 300aa–14(c)(2), provides that:

"[a]ny person (including the Advisory Commission on Childhood Vaccines) [the Commission] may petition the Secretary to propose regulations to amend the Vaccine Injury Table. Unless clearly frivolous, or initiated by the Commission, any such petition shall be referred to the Commission for its recommendations. Following—

(A) receipt of any recommendation of the Commission, or

(B) 180 days after the date of the referral to the Commission,

[w]hichever occurs first, the Secretary shall conduct a rulemaking proceeding on the matters proposed in the petition or publish in the **Federal Register** a statement of reasons for not conducting such proceeding."

On April 9, 2014, a private citizen submitted an email inquiry to the Secretary of Health and Human Services (HHS) regarding the VICP. This email asked why the condition of diabetes mellitus (DM) is not a listed injury on the Vaccine Injury Table (Table) in association with the measles, mumps, and rubella (MMR) vaccination, explaining that it is identified by the manufacturer as a possible adverse result of the MMR vaccine. The email also asked whether the Secretary would consider amending the Table to add DM as an injury for MMR vaccines. As such, the email was considered to be a petition to the Secretary to propose regulations to amend the Table to add the injury of DM for the category of MMR vaccines. Accordingly, pursuant to the VICP statute, the petition was referred to the Commission on June 5, 2014. The Commission voted unanimously to recommend that the Secretary not proceed with rulemaking to amend the Table as requested in the petition.

DM is a chronic disease in which there is a high level of sugar in the blood. There are two types: Type 1 and Type 2. Type 1 Diabetes is one of the most common chronic diseases in childhood. It is caused by insulin deficiency following destruction of the insulin producing pancreatic beta cells, resulting in absolute insulin deficiency. Type 2 Diabetes is characterized by hyperglycemia and insulin resistance and relative impairment in insulin secretion. Through the years, there have been many studies evaluating the risk of Type 1 Diabetes after MMR vaccination. However, HRSA's search of published literature did not reveal any studies discussing a causal relationship between Type 2 Diabetes and the MMR vaccine. The Secretary notes that vaccine package inserts list adverse events reported to vaccine manufacturers during clinical trials even though they may not have been shown to have been caused by the vaccines.

In 2008, the Secretary contracted with the Institute of Medicine (IOM) to review the epidemiological, clinical, and biological evidence regarding adverse health events associated with specific vaccines covered by the VICP.[1] The IOM committee reviewed the relevant studies through 2011 and concluded that "[t]he evidence favors rejection of a causal relationship between MMR vaccine and Type 1 Diabetes." Specifically, the epidemiologic studies consistently reported a null association, or no association between the MMR vaccine and Type 1 Diabetes. The IOM committee concluded that the mechanistic evidence regarding an association between MMR vaccine and Type 1 Diabetes was lacking.

In 2012, the Cochrane Collaboration reviewed and assessed studies in the Cochrane Central Register of Controlled Trials.[2] The specific conclusion was that MMR vaccine was unlikely associated with Type 1 Diabetes. A recent study by Duderstadt et al. (2012)[3] was not reviewed by the IOM Committee and the Cochrane Collaboration. This was a retrospective cohort study among U.S. military personnel, which evaluated whether vaccination increased the risk of Type 1 Diabetes. The result was that there was no increased risk of diagnosed Type 1 Diabetes after administration of any studied vaccines, including the MMR vaccine. Current scientific literature consistently shows that there is no causal association between MMR vaccination and Type 1 Diabetes. As noted above, the VICP's search of published literature did not reveal any studies discussing a causal relationship between Type 2 Diabetes and the MMR vaccine.

In light of the literature discussed above, I have determined that there is no reliable scientific evidence of a causal association between MMR vaccine and DM. Therefore, I will not amend the Table to add DM as an injury associated with the MMR vaccine.

Dated: April 23, 2015.

Sylvia M. Burwell,

Secretary.

[FR Doc. 2015–10110 Filed 4–29–15; 8:45 am]

BILLING CODE 4165–15–P

[1] IOM, Adverse Effects of Vaccines: Evidence and Causality (Washington, DC: The National Academies Press, 2012):204–211.

[2] Demicheli, V., A. Rivetti, et al. "Vaccines for Measles, Mumps and Rubella in Children." Cochrane Database System Rev 2: CD004407 (2012): 19.

[3] Duderstadt, S., C. Rose Jr., T. Real, J. Sabatier, B. Stewart, G. Ma, U. Yerubandi, A. Eick, J. Tokars, M. McNeil. "Vaccination and Risk of Type 1 Diabetes Mellitus in Active Component U.S. Military, 2002–2008. Vaccine 30:813–819, (2012).

7

Centers for Disease Control and Prevention
CDC 24/7: Saving Lives. Protecting People.™

Vaccines Home
Vaccines & Immunizations

Vaccine Administration

Recommendations and Guidelines

Guidelines

- Vaccine Administration Guidelines [1 MB, 17 pages] (../../pubs/pinkbook/downloads/appendices/D/vacc_admin.pdf)
  from Pink Book Appendix (includes pictures of sites)
- Vaccines with Diluents: How to Use Them [1 page] (http://www.immunize.org/catg.d/p3040.pdf) (http://www.cdc.gov/Other/disclaimer.html)
  Contains a chart that lists the vaccines that require reconstitution with a diluent before they can be administered including maximum time allowed between reconstituting each vaccine and having to discard it. Plus the general steps to follow when reconstituting vaccines.
- It's Federal Law - use of VISs (/vaccines/hcp/vis/about/facts-vis.html#law) and more in Pink Book appendix E [1 MB, 10 pages] (/vaccines/pubs/pinkbook/downloads/appendices/appdx-full-e.pdf)
  Appendix includes instructions for use of Vaccine Information Statements, how to get VISs, questions and answers, etc.
- Dosage, Route, Site:
  - All ages: Dose, Route, Site, and Needle Size [1 page] (http://www.immunize.org/catg.d/p3085.pdf) (http://www.cdc.gov/Other/disclaimer.html)
  - Adults: Dose, Route, Site, Needle Size, and Preparation [1 page] (http://www.immunize.org/catg.d/p3084.pdf) (http://www.cdc.gov/Other/disclaimer.html)
  - Adults: How to administer IM and SC Injections to Adults [1 page] (http://www.immunize.org/catg.d/p2020A.pdf) (http://www.cdc.gov/Other/disclaimer.html)
- Immunization Site Maps
  - Children [2 pages] (http://eziz.org/assets/docs/IMM-718.pdf) (http://www.cdc.gov/Other/disclaimer.html)
    California Department of Public Health
  - Adults [1 page] (http://www.eziz.org/assets/docs/IMM-718A.pdf) (http://www.cdc.gov/Other/disclaimer.html)
    California Department of Public Health
- Indications (http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM093833) (http://www.cdc.gov/Other/disclaimer.html)
- Managing vaccine reactions
  - in children and teens [3 pages] (http://www.immunize.org/catg.d/p3082a.pdf) (http://www.cdc.gov/Other/disclaimer.html) Jul 2011
  - in adults [2 pages] (http://www.immunize.org/catg.d/p3082.pdf) (http://www.cdc.gov/Other/disclaimer.html) Nov 2013
- Sample vaccine record form for CHILDREN and TEENS [6 pages] (http://www.immunize.org/catg.d/p2022.pdf) (http://www.cdc.gov/Other/disclaimer.html)
  Sample records include all recently licensed vaccines: MCV, HPV, Rota, Tdap, zoster
- Sample vaccine record form for ADULTS [4 pages]

(http://www.immunize.org/catg.d/p2023.pdf) (http://www.cdc.gov/Other/disclaimer.html)
- Report a suspected side effect (VAERS) (http://vaers.hhs.gov/) (http://www.cdc.gov/Other/disclaimer.html)
  See also reportable events (#ref) under Reference Tables below.
- Provider's Role: Importance of Vaccine Administration and Storage (providers-role-vacc-admin-storage.htm)
- Suggestions to improve your immunization services [3 pages] (http://www.immunize.org/catg.d/p2045.pdf) (http://www.cdc.gov/Other/disclaimer.html)
- Standing Orders
  HTML (http://www.immunize.org/standing-orders/) (http://www.cdc.gov/Other/disclaimer.html) | PDF [1 page] (http://www.immunize.org/catg.d/p3072.pdf) (http://www.cdc.gov/Other/disclaimer.html)
- Vaccine Recommendations for Emergency Situations (/vaccines/hcp/acip-recs/recs-emergency.html)
- Standards for Immunization Practices
  - for children and adolescents (http://pediatrics.aappublications.org/content/112/4/958.full) (http://www.cdc.gov/Other/disclaimer.html)
  - for adults (/vaccines/hcp/patient-ed/adults/for-practice/standards/index.html) Feb 2014

Screening and Checklists

- Skills Checklist for Pediatric Immunization [2 pages] (http://www.immunize.org/catg.d/2020skill.pdf) (http://www.cdc.gov/Other/disclaimer.html)
  Also in Pink Book appendix-D, pages 16-17
- Adult checklists:
  - Do I Need Any Vaccinations Today? [3 pages] (http://www.immunize.org/catg.d/4036need.pdf) (http://www.cdc.gov/Other/disclaimer.html)
  - You're Never Too Old to Get Shots [1 page] (http://www.immunize.org/catg.d/p4030.pdf) (http://www.cdc.gov/Other/disclaimer.html)
- Screening Questionnaires:
  - for Child and Teen Immunization [2 pages] (http://www.immunize.org/catg.d/p4060scr.pdf) (http://www.cdc.gov/Other/disclaimer.html)
  - for Adult Immunization [2 pages] (http://www.immunize.org/catg.d/p4065.pdf) (http://www.cdc.gov/Other/disclaimer.html)
- IAC's print materials for health professionals providing vaccines (http://www.immunize.org/handouts/administering-vaccines.asp) (http://www.cdc.gov/Other/disclaimer.html)
  Administering vaccines, documenting vaccination, handling and storage, supplies checklist, vaccine questions and answers, etc.
- Suggested Supplies Checklist for Adult Clinics [1 page] (http://www.immunize.org/catg.d/p3047.pdf) (http://www.cdc.gov/Other/disclaimer.html)

Reference Tables

- Contraindications
  - For **childhood** vaccines: Contraindications and Precautions to Commonly Used Vaccines (/vaccines/recs/vac-admin/contraindications-vacc.htm)
  - For **adult** vaccines: Contraindications and Precautions for Adults Only (/vaccines/recs/vac-admin/contraindications-adults.htm)
  - Conditions Commonly **Misperceived as Contraindications** to Vaccination

(/vaccines/recs/vac-admin/contraindications-misconceptions.htm)

- Table of Reportable Events after Vaccination [5 pages] (http://vaers.hhs.gov/resources/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf) (http://www.cdc.gov/Other/disclaimer.html). Also available as vaccine injury/compensation table (http://www.hrsa.gov/vaccinecompensation/vaccinetable.html) (http://www.cdc.gov/Other/disclaimer.html) on HRSA site.
- The VICP Vaccine Injury Table (http://www.hrsa.gov/vaccinecompensation/vaccinetable.html) (http://www.cdc.gov/Other/disclaimer.html)
- Anti-body Live Vaccine Interval Table [1 page] (/vaccines/pubs/pinkbook/downloads/appendices/A/mmr_ig.pdf)
- Immunization of Immunocompromised Patients Tables [2 pages] (/vaccines/pubs/pinkbook/downloads/appendices/A/immuno-table.pdf) Summary of ACIP Recommendations on Immunization of Immunocompromised Infants and Children (Vaccination of Persons with Primary and Secondary Immune Deficiences)
- Vaccine Excipient and Media Summary (also called formulations or ingredients) listed by vaccine [4 pages] (/vaccines/pubs/pinkbook/downloads/appendices/B/excipient-table-2.pdf)
- Minimum ages and intervals [2 pages] (/vaccines/pubs/pinkbook/downloads/appendices/A/age-interval-table.pdf)

Comforting Techniques

- DVD: Immunization Techniques "Safe, Effective, Caring" (http://www.immunize.org/dvd/) (http://www.cdc.gov/Other/disclaimer.html)
- Comforting children during vaccinations:
  - Be There for Your Child During Shots [1 MB, 2 pages] (http://www.eziz.org/PDF/IMM-686ES.pdf) (http://www.cdc.gov/Other/disclaimer.html) (full-color flyer) First page in Spanish and second page in English (Available for order (http://cdlhn.com/default_e.cfm?id=88&CFID=127855&CFTOKEN=19096589) (http://www.cdc.gov/Other/disclaimer.html))
  - Comforting Restraint for Immunizations [2 pages] (http://www.eziz.org/PDF/IMM-720ES.pdf) (http://www.cdc.gov/Other/disclaimer.html) (full-color flyer) First page in English and second page in Spanish (Available for order (http://cdlhn.com/default_e.cfm?id=88&CFID=127855&CFTOKEN=19096589) (http://www.cdc.gov/Other/disclaimer.html))
  - Comforting Measures [2 pages] (http://eziz.org/assets/docs/IMM-686ES.pdf) (http://www.cdc.gov/Other/disclaimer.html) (poster)

Related Pages

- Immunization Schedules (/vaccines/schedules/index.html)
- Contraindications (/vaccines/recs/vac-admin/contraindications.htm)
- Vaccine Information Statements (/vaccines/hcp/vis/index.html)
- Vaccine Price Lists (/vaccines/programs/vfc/awardees/vaccine-management/price-list/index.html)
- VFC Vaccine Prices (/vaccines/programs/vfc/awardees/vaccine-management/price-list/index.html)

Page last reviewed: July 15, 2014
Page last updated: October 19, 2013
Content source: National Center for Immunization and Respiratory Diseases

Centers for Disease Control and Prevention 1600 Clifton Road Atlanta, GA 30329-4027, USA
800-CDC-INFO (800-232-4636) TTY: (888) 232-6348 - Contact CDC--INFO

8

8.1

Childhood Vaccination Coverage Rates Among Military Dependents in the United States

Angela C. Dunn, MD, MPH[a,b], Carla L. Black, PhD, MPH[c], John Arnold, MD[d], Stephanie Brodine, MD[b], Jill Waalen, MD, MPH[a,b], Nancy Binkin, MD, MPH[b]

abstract

BACKGROUND AND OBJECTIVES: The Military Health System provides universal coverage of all recommended childhood vaccinations. Few studies have examined the effect that being insured by the Military Health System has on childhood vaccination coverage. The purpose of this study was to compare the coverage of the universally recommended vaccines among military dependents versus other insured and uninsured children using a nationwide sample of children.

METHODS: The National Immunization Survey is a multistage, random-digit dialing survey designed to measure vaccination coverage estimates of US children aged 19 to 35 months old. Data from 2007 through 2012 were combined to permit comparison of vaccination coverage among military dependent and all other children.

RESULTS: Among military dependents, 28.0% of children aged 19 to 35 months were not up to date on the 4:3:1:3:3:1 vaccination series excluding *Haemophilus influenzae* type b vaccine compared with 21.1% of all other children (odds ratio: 1.4; 95% confidence interval: 1.2–1.6). After controlling for sociodemographic characteristics, compared with all other US children, military dependent children were more likely to be incompletely vaccinated (odds ratio: 1.3; 95% confidence interval: 1.1–1.5).

CONCLUSIONS: Lower vaccination coverage rates among US military dependent children might be due to this population being highly mobile. However, the lack of a military-wide childhood immunization registry and incomplete documentation of vaccinations could contribute to the lower vaccination coverage rates seen in this study. These results suggest the need for further investigation to evaluate vaccination coverage of children with complete ascertainment of vaccination history, and if lower immunization rates are verified, assessment of reasons for lower vaccination coverage rates among military dependent children.

[a]*Department of Family and Preventive Medicine, University of California San Diego, La Jolla, California;* [b]*Graduate School of Public Health, San Diego State University, San Diego, California;* [c]*Centers for Disease Control and Prevention, National Center for Immunization and Respiratory Diseases, Atlanta, Georgia; and* [d]*Department of Pediatrics, Naval Medical Center San Diego, San Diego, California*

Dr Dunn conceptualized and designed the study, carried out the initial analyses, drafted the initial manuscript, and revised the manuscript; Dr Black contributed substantially to acquisition of data and analyses and critically reviewed and revised the manuscript; Drs Arnold, Brodine, Waalen, and Binkin contributed substantially to the design of the study, interpreted data, and critically reviewed the manuscript; and all authors approved the final manuscript as submitted.

The views expressed in this article are those of the authors and do not reflect the official policy or position of the Department of the Navy, Department of Defense, or the US Government. The findings and conclusions in this article are those of the authors and do not necessarily represent the views of the Centers for Disease Control and Prevention.

www.pediatrics.org/cgi/doi/10.1542/peds.2014-2101

DOI: 10.1542/peds.2014-2101

WHAT'S KNOWN ON THIS SUBJECT: Current childhood vaccination coverage rates among military dependents in the United States are not known. Past studies on childhood vaccination coverage in military dependents have shown mixed results, with the majority showing lower than ideal coverage rates.

WHAT THIS STUDY ADDS: This study analyzes a national database with 6 years of data and provider-confirmed vaccination status to describe the current documented vaccination coverage rates among military dependents in the United States.

Vaccines are considered 1 of the 10 greatest public health achievements of the 20th century. Each year, vaccinations save thousands of lives and result in substantial cost savings.[1,2] Although vaccination is an important cornerstone of routine pediatric care, a substantial proportion of US children remain susceptible to serious, vaccine-preventable diseases.

The US Department of Health and Human Services has established national objectives for select individual vaccinations and vaccination series in the Healthy People 2020 agenda. Most universally recommended vaccines (eg, diphtheria-tetanus-acellular pertussis [DTaP]; polio; measles, mumps, and rubella; *Haemophilus influenzae* type b [Hib]; hepatitis B; and varicella) have a target of 90% coverage by 2020 among young children. According to the 2011 National Immunization Survey (NIS) of children aged 19 to 35 months, >1 in 5 (22.4%) US children lack at least 1 recommended dose of DTaP, polio, measles antigen–containing vaccine, hepatitis B, or varicella.[3] Further efforts are needed to identify those at greatest risk of incomplete vaccination and to resolve health system factors impeding the attainment of the 2020 objectives.

A number of sociodemographic and health system factors have been identified as risk factors for incomplete vaccination. Sociodemographic characteristics associated with incomplete vaccination include nonwhite race/ethnicity, living in poverty, young maternal age, low maternal education, and large household size.[4–11] With respect to health system factors, barriers to primary care access, such as long waiting room times and difficulty making appointments, are also related to incomplete vaccination.[12,13] In addition, lack of an electronic health record system and errors in documentation have been associated with lower vaccination rates.[14–17] Type of health insurance can also play a role in vaccination coverage rates. Children with public insurance or uninsured children have a higher frequency of incomplete vaccination than those with private health insurance.[18,19]

Children of active-duty military members comprise 2.6% of the under-5 population in the United States[20] and represent a population of special interest because these children receive all well-child care and recommended immunizations free of charge with no copay, eliminating many financial barriers to attaining high coverage.[21] Despite the lack of such barriers, the 6 studies conducted to date on childhood vaccination coverage in military dependents have shown mixed results, with the majority showing lower than ideal vaccination coverage rates.[13,22–26] Several of these studies, however, have been limited by the potential biases introduced by the acute care clinic settings in which they were conducted.[23–25] Furthermore, most were performed in limited geographic settings and in single branches of the military,[13,22,24,25] and all were performed in the mid-1990s, which also limits their generalizability to the current situation.

As the United States seeks to achieve its vaccination objectives, it is important to understand the extent to which current financing and health care delivery systems, such as the universal care system for military dependents, are on track to reach the Healthy People 2020 targets and identify those systems that are particularly effective or which could benefit from further improvements. We therefore undertook a study to compare the coverage of the universally recommended vaccines among military dependents versus all other insured and uninsured children using a nationwide sample of children.

METHODS

We used data from the 2007–2012 NIS, an annual random-digit-dial telephone survey designed to provide vaccination coverage estimates of children aged 19 to 35 months in the United States.[27] Until 2011, all NIS interviews were conducted via landline telephone. Beginning in 2012, interviews were conducted on landline and cellular telephones.[28] The survey has 2 components, a questionnaire administered to a parent or caregiver and a form mailed to the parent-identified vaccination providers. After ascertaining that there is an eligible child in the household and obtaining informed consent, sociodemographic information is collected and the name of the child's vaccination provider(s) is obtained. Informed consent is obtained from the person in the household most knowledgeable about the eligible child's immunization history. Informed consent to contact the child's vaccination provider(s) is obtained at the end of the interview. A form is then mailed to providers to obtain specific information on the vaccinations received and the dates of vaccination. The data collected in each year's NIS are weighted to represent the general US population of children aged 19 to 35 months.

In 2006, a module was added to the NIS questionnaire to gather information on health insurance coverage of the child, and starting in 2007 this information was added to the NIS public use files. If the parent or caregiver responded "yes" to the question, "Is child covered by Military Health Care, TRICARE, CHAMPUS, or CHAMP-VA?" the child was considered to be a military dependent for the purpose of this analysis. If the answer was "no," the child was considered to have other insurance coverage or to be uninsured. To obtain sufficient numbers of military dependent children, we combined data from the years 2007 through the

2012 NIS. We limited our study to those children for whom adequate provider data were available. Adequate provider data are defined and determined by the NIS to mean sufficient vaccination history information was obtained from the provider(s) to determine whether a child is up to date with respect to the recommended vaccination schedule. Inadequate provider data are defined as having at least 1 identified provider not respond and that completeness of provider immunization history cannot be determined. All other provider data are deemed adequate. Adequate and inadequate provider data definitions take into account responses from identified provider(s), shot card documentation, and the child's immunization history per the respondent.

Up-to-date vaccination is defined as a complete 4:3:1:3:3:1 vaccination series at the time of interview. This series includes at least 4 doses of DTaP; 3 doses of poliovirus vaccine; 1 dose of measles, mumps, and rubella vaccine (or any measles-containing vaccine); 3 doses of Hib vaccine; 3 doses of hepatitis B vaccine; and at least 1 varicella vaccine dose at or after 12 months. Because of the Hib vaccine shortage from December 2007 through September 2009, we used the modified 4:3:1:_:3:1 vaccination series, which excludes the Hib vaccine from the series.[29]

The NIS included data on child, maternal, and household covariates. Child data included the child's gender, age group at the time of survey (19–23, 24–29, or 30–35 months), and race/ethnicity (Hispanic, non-Hispanic white, non-Hispanic black, or non-Hispanic other or mixed race). Available data on the mothers included education (≤12 years, >12 years non–college graduate, or college graduate), age (≤19 years, 20–29 years, or ≥30 years), and marital status (married or never married, widowed, divorced, or separated). Household information was also available for each child on poverty status as determined by federal poverty guidelines (below poverty or at or above poverty), the number of children <18 years in the household (1, 2–3, or ≥4), the number of vaccination providers identified by respondent (0, 1, or ≥2), and geographic mobility status (child moved states since birth or child has not moved states since birth). Because military families are concentrated in certain states and coverage levels vary widely between states, a state tertile variable was created on the basis of the combined 2007 through 2012 weighted vaccination coverage levels. Washington, DC, was considered its own state for the purposes of creating the state tertile variable. Children's state of residence was based on current location at the time of the survey.

In our analysis, we examined the sociodemographic characteristics and the coverage for individual vaccines as well as full 4:3:1:_:3:1 coverage for military dependents and for all others. We calculated odds ratios (ORs) and 95% confidence intervals (CIs) for not being up to date with the full series by each of the child characteristics, including military dependent status, maternal characteristics, and household characteristics. *P* values were calculated by using the χ^2 test. A logistic regression model was developed that included those variables that were thought a priori to be associated with incomplete vaccination and could potentially confound the relationship between military dependent status and incomplete coverage. The NIS weighting assigned for children with adequate provider data was used in all analyses to provide nationally representative estimates.[30] All statistical analyses were performed by using SAS 9.2 (SAS Institute, Cary, NC) taking into account the complex survey design. Because of the large number of children in the study, findings were considered to be statistically significant only if the *P* value was ≤.01.

RESULTS

The 2007–2012 NIS included data on 155 023 children, for whom 105 129 (67.8%) had adequate provider data. All children with adequate provider data were included in the description of risk factors for being not up to date. Children were excluded from analyses involving the military insurance variable if they had missing information for that variable (n = 1322; 1.3% of children with adequate provider data). Thus, the total population included in the final analyses was 103 807. There is no discernable trend in either increasing or decreasing undervaccination rates between 2007 and 2012.

Of the total study population, 3421 (weighted percentage: 2.8%) were military dependents. The characteristics of military dependents and all other children are depicted in Table 1. Except for child age group and gender, statistically significant differences were seen for all characteristics. The military dependent group was less likely to be Hispanic and more likely to be non-Hispanic white and to have mothers aged between 20 and 29 years, who had >12 years of education, and who were currently married. In addition, the households of military dependents were more likely to be at or above the poverty line and to have fewer children per household. Finally, a greater proportion of military dependents moved state residences since their birth or had ≥2 vaccination providers compared with those who were not military dependents.

Coverage estimates of individual vaccines and common vaccine series are shown in Table 2. Military dependents had lower levels of coverage for each of the individual vaccines, but differences were

TABLE 1 Characteristics of Military Dependents and All Other Children Aged 19 to 35 Months: NIS, 2007–2012

Characteristic	Military Dependents (n = 342; 2.8%), n (weighted %)	All Others (n = 100 386; 97.2%), n (weighted %)	Difference Between Military Dependents and All Others, P
Child age group			.69
19–23 months	1032 (30.6)	29 245 (29.9)	
24–29 months	1143 (34.8)	33 880 (34.1)	
30–35 months	1246 (34.6)	37 261 (36.0)	
Race/ethnicity			<.01*
White, non-Hispanic	2194 (57.4)	61 903 (49.6)	
Black, non-Hispanic	304 (12.3)	9690 (12.9)	
Hispanic	541 (19.6)	18 460 (27.7)	
Other, non-Hispanic	382 (10.8)	10 333 (9.8)	
Gender			.18
Male	1760 (53.3)	51 388 (51.1)	
Female	1661 (46.7)	48 998 (48.9)	
Maternal education			<.01*
≤12 years	633 (34.9)	29 441 (49.3)	
>12 years, non–college graduate	1376 (35.2)	26 036 (20.0)	
College graduate	1412 (29.9)	44 909 (30.8)	
Maternal age group			<.01*
≤19 years	32 (1.2)	1795 (2.9)	
20–29 years	1425 (50.1)	32 793 (39.4)	
≥30 years	1964 (48.7)	65 798 (57.8)	
Marital status			<.01*
Never/widowed/divorced/separated	379 (15.3)	25 179 (33.8)	
Currently married	3042 (84.7)	75 207 (66.2)	
Poverty level			<.01*
Below poverty	325 (13.7)	22 181 (33.9)	
At or above poverty	2980 (86.3)	74 697 (62.1)	
Vaccine coverage tertile in state of residence			<.01*
Highest	1011 (28.8)	28 870 (26.0)	
Middle	1519 (54.0)	41 019 (50.3)	
Lowest	891 (17.2)	30 497 (23.7)	
Number of children in household			<.01*
1	832 (27.0)	23 818 (24.2)	
2–3	2137 (61.5)	62 012 (60.0)	
≥4	452 (11.5)	14 556 (15.9)	
Currently living in a state other than birth state			<.01*
Yes	1262 (39.1)	7038 (6.9)	
No	2159 (61.0)	93 348 (93.1)	
Number of vaccination providers identified by respondent			<.01*
0	4 (0.15)	267 (0.18)	
1	1663 (45.1)	67 754 (65.6)	
≥2	1754 (54.7)	32 362 (34.3)	

N = 103 807. *Significant difference between military dependents and all others at $P \leq .01$.

statistically significant only for the DTaP and inactivated polio vaccine vaccines (77.9% vs 84.3%, $P < .01$, and 88.5% vs 93.3%, $P < .01$, respectively). In keeping with the findings for individual vaccines, military dependents also had lower coverage levels of the 4:3:1:_:3:1 series (72.0% vs 77.9%; $P < .01$).

The risk factors for being not up to date on the 4:3:1:_:3:1 vaccine series are presented in Table 3. Children who were military dependents, were non-Hispanic black, or who were younger than 30 months were at significantly higher risk of not being up to date, as were children whose mothers had less than a college education, were aged 20 to 29 years, or who were not currently married. Children who came from households below the poverty line, where there was >1 child in the household, who resided in a state in the lowest or middle tertile of vaccine coverage, who had moved states since birth, or who had ≥2 vaccine providers were also at significantly increased risk. Children who were non-Hispanic other race/ethnicity had a lower odds of incomplete vaccination compared with white children.

The results of the multivariable analysis are presented in Table 4. The odds of not being up to date on vaccination were 1.3-fold higher in military dependents compared with all others (95% CI: 1.1–1.5; $P < .01$). Having a mother with less than a college degree, maternal age 20 to 29 years, being younger than 30 months, having >1 child in the

TABLE 2 Vaccine Coverage Levels Among Military Dependent and All Other Children Aged 19–35 Months, by Selected Vaccines: NIS, 2007–2012

Vaccination	Military Dependents (n = 3421; 2.8%), n (weighted %; 95% CI)	All Others (n = 100 386; 97.2%), n (weighted %; 95% CI)
≥ 4 doses DTaP[a]	2679 (77.9; 75.3–80.4)	85 813 (84.3; 83.9–84.7)
≥ 3doses IPV	3088 (88.5; 86.5–90.1)	93 867 (93.3; 93.0–93.6)
≥ 1 dose MCV	3066 (90.2; 88.3–92.0)	92 798 (92.4; 92.1–92.7)
≥ 1 dose MMR	3035 (89.1; 87.2–91.1)	91 853 (91.4; 91.1–91.8)
≥ 3doses hepatitis B vaccine	3057 (89.0; 87.1–90.9)	95 372 (91.9; 91.6–92.2)
≥ 1 dose varicella vaccine	2988 (87.8; 85.8–89.7)	90 180 (90.3; 90.0–90.7)
Combined series 4:3:1:_:3:1[b]	2476 (72.0; 69.3–74.8)	78 550 (77.9; 77.4–78.3)

N = 103 807. IPV, inactivated poliovirus vaccine; MCV, measles-containing vaccine; measles, mumps, and rubella vaccine.
[a] Also includes children who might have been vaccinated with diphtheria-tetanus toxoids-pertussis vaccine, and diphtheria and tetanus toxoids vaccine.
[b] Four or more doses of DTaP, ≥3 doses of poliovirus vaccine, ≥1 doses of MCV, ≥3 doses of hepatitis B vaccine, and ≥1 doses of varicella vaccine.

household, residing in a state in the lowest or middle tertile of vaccine coverage,.having ≥2 vaccination providers, and moving states since birth remained statistically significant. In the multivariate analysis, being Hispanic or non-Hispanic other race/ethnicity was associated with a lower odds of incomplete vaccination compared with white children.

The majority of these children (81.3%) received their vaccinations from solely civilian providers or a mix of military and civilian providers, whereas 18.7% of these children received their vaccinations from solely military providers. Although not statistically significant at the 0.01 level, children who saw solely military providers had significantly higher rates of incomplete vaccination compared with children who did not see military providers only (35.4% vs 26.3%; P = 0.02). This finding remained true in a logistic regression model controlling for mobility; the odds of not being up to date on vaccination were 1.5-fold higher in military dependents who received vaccinations from solely military providers compared with those who did not see military providers only (95% CI: 1.1–2.1).

DISCUSSION

Our study found that being a military dependent or seeing solely military providers were risk factors for being not up to date on the 4:3:1:_:3:1 vaccine series. This finding held true even after controlling for potential confounding variables. In multivariate analysis, being a military dependent was associated with a greater risk than low maternal education, younger maternal age, living below the poverty level, and having ≥2 vaccination providers.

Our study is the first in recent years to examine the vaccination coverage levels of a large national sample of military dependent children. Furthermore, it was based on provider-reported vaccination data over a 6-year period. Although the large sample size of this study provides high power, the difference in vaccination coverage between military dependents and others is clinically significant when some vaccine-preventable diseases require a very high coverage to achieve herd immunity (eg, measles). A difference in vaccination coverage of just a few percentage points can mean the difference in halting or not halting the spread of disease in a population.

Nonetheless, our study has limitations. First, vaccination coverage may have been underreported for some military dependents. Caregivers may not have reported all providers, especially if they had moved frequently or if multiple providers saw their child. Failure of caregivers to recall all vaccination providers would result in an underrepresentation of immunization status. Second, the NIS determined health insurance status at the time of the survey and it is possible that some children who were covered by the Military Health System when the survey was done may not have had such coverage previously and vice versa. Last, the NIS is a telephone survey and although data are weighted for nonresponse and nontelephone households and the percentage of military dependents in the NIS was similar to the percentage in the general population, some bias may remain.

Despite these limitations, our findings are in keeping with 2 previous population-based household studies that did not focus on the military but identified children covered by the Military Health System.[13,26] The smaller of the 2, which had a total study population of 749 children including 295 military dependents, was a door-to-door household survey conducted in the state of Virginia and which used provider records to verify vaccine status. After controlling for sociodemographic variables, military dependents had higher odds of not being up to date on recommended vaccinations at 12 months (OR: 5.2; 95% CI: 2.9–9.5).[13] Zhao et al[26] used National Health Information Survey data for the years from 1993 to 1996 and had a total study population of 7535. This survey, which relied on parental or caregiver report of vaccination history, revealed that being a military dependent was a risk factor for incomplete vaccination after controlling for parental or caregiver educational level and urbanicity; children with military health insurance had an OR of 0.41 (95% CI: 0.28–0.61) of being up to date on the 4:3:1:3 vaccine series. Both studies, however, were conducted in the 1990s and the applicability of findings to the current situation is not clear.

TABLE 3 Risk Factors for Not Being Up to Date on the 4:3:1:_:3:1 Vaccination Series Among Children Aged 19 to 35 Months: NIS, 2007–2012

Characteristic	*n*	Not Up to Date on 4:3:1:_:3:1 Series, *n* (weighted %; 95% CI)
Military dependent		
Yes	3421	945 (28.0; 25.2–30.7)
No	100 386	21 836 (22.1; 21.7–22.6)
Child age group		
19–23 months	30 683	8800 (29.5; 28.6–30.4)
24–29 months	35 475	7215 (20.6; 19.9–21.4)
30–35 months	38 971	7083 (17.9; 17.2–18.6)
Race/ethnicity		
White, non-Hispanic	64 579	14 135 (22.5; 21.9–23.1)
Black, non-Hispanic	10 188	2445 (24.8; 23.5–26.1)
Hispanic	19 444	4205 (21.7; 20.6–22.8)
Other, non-Hispanic	8955	2313 (19.8; 18.5–21.2)
Gender		
Male	53 841	12 018 (22.4; 21.8–23.0)
Female	51 288	11 080 (22.2; 21.5–22.9)
Maternal education		
≤12 years	30 773	7624 (24.2; 23.4–24.9)
>12 years, non–college graduate	27 688	6404 (22.8; 21.9–23.7)
College graduate	46 668	9070 (18.9; 18.3–19.6)
Maternal age group		
≤19 years	1880	459 (24.5; 21.2–27.8)
20–29 years	34 745	8436 (25.7; 23.9–25.4)
≥30 years	68 504	14 203 (20.6; 20.0–21.1)
Marital status		
Never/widowed/divorced/separated	26 072	6343 (24.2; 23.3–25.1)
Currently married	79 057	16 755 (21.3; 20.8–21.9)
Poverty level		
Below poverty level	23 026	5789 (24.9; 24.0–25.9)
At or above poverty level	78 329	16 474 (21.0; 20.5–21.6)
Vaccine coverage tertile in state of residence		
Highest	30 306	5587 (19.1; 18.3–19.8)
Middle	43 083	9267 (22.2; 21.5–23.0)
Lowest	31 740	8244 (26.1; 25.3–26.9)
Number of children in household		
1	24 924	4746 (19.1; 18.2–19.9)
2–3	64 916	13 706 (21.7; 21.1–22.3)
≥4	15 289	4646 (29.4; 28.1–30.7)
Currently living in a state other than birth state		
Yes	8402	2374 (29.4; 27.5–31.3)
No	96 727	20 724 (21.7; 21.2–22.2)
Number of vaccination providers identified by respondent		
0	289	289 (100)
1	70 319	14 689 (21.4; 20.9–22.0)
≥2	34 518	8119 (23.5; 22.7–24.4)

N = 103 807. The 4:3:1:_:3:1 vaccination series = ≥4 doses of DTaP, ≥3 doses of poliovirus vaccine, ≥1 doses of measles-containing vaccine, ≥3 doses of hepatitis B vaccine, and ≥1 doses of varicella vaccine.

By contrast, 4 studies showed coverage levels among military dependents to be greater than those obtained in the general population at the time the surveys were performed in the mid-1990s.[31] However, 3 of the studies were performed in acute care settings, resulting in limited generalizability to the overall US military dependent population.[23–25] The fourth study used the Defense Enrollment Eligibility Reporting System to identify the study population, but the data were collected from a single site with a small study population of 457 children.[22]

Reducing financial barriers to vaccinations has been shown to result in improvements in coverage. Initiated in 1994, the Vaccines for Children (VFC) Program was designed to reduce the financial barrier for children who were eligible for Medicaid, uninsured or underinsured, or American Indian/Alaska Native.[32] Vaccination coverage rates for the 4:3:1 vaccine series (at least 4 doses of diphtheria-tetanus-pertussis vaccine or diphtheria-tetanus toxoid, 3 doses of poliovirus vaccine, 1 dose of any measles-containing vaccine) increased from 75% of children aged 19 to 35 months in 1994 to 81% of children aged 19 to 35 months in 1998, 1 year after nearly all states had implemented the VFC program.[31,33] The VFC program may be in part responsible for the lack of association between coverage and type of health insurance (public, private, or uninsured) in the 2000 to 2003 NIS surveys, a finding that persisted after controlling for sociodemographic variables.[18,34]

It is not clear why military dependents have reported lower rates of vaccination coverage in this study given their universal access to all recommended vaccinations and well-child care visits, without copays or cost sharing.[21] Furthermore, military dependents exhibited some protective factors against incomplete vaccination. Compared with all other children in the study population, military dependents were more likely to live at or above the poverty level and to have mothers who had >12 years of education, were older than 19 years, or were currently married. However, military dependents were more likely to have moved cities since birth or have ≥2 health care providers, both risk factors for being not up to date on childhood vaccinations. Still, even after controlling for these risk factors, being a military dependent resulted in higher odds of being not up to date.

The military is a highly mobile population and such mobility is essentially a nonmodifiable risk factor in this population. Mobility can

TABLE 4 Final Logistic Regression Model of Risk Factors for Not Being Up to Date on 4:3:1:_3:1 Vaccination Coverage of Military Dependent Children Aged 19 to 35 Months: NIS, 2007–2012

Characteristic	OR (95% CI)
Military dependent	
Yes	1.3 (1.1–1.5)
No	referent
Child age group	
19–23 months	2.0 (1.9–2.1)
24–29 months	1.2 (1.1–1.3)
30–35 months	Referent
Race/ethnicity	
White, non-Hispanic	Referent
Black, non-Hispanic	1.0 (0.9–1.1)
Hispanic	0.8 (0.8–0.9)
Other, non-Hispanic	0.8 (0.8–0.9)
Gender	
Male	Referent
Female	1.0 (0.9–1.0)
Maternal education	
≤ 2 years	1.2 (1.1–1.3)
>12 years, non–college graduate	1.1 (1.1–1.2)
College graduate	Referent
Maternal age group	
≤19 years	1.2 (0.9–1.5)
20–29 years	1.2 (1.1–1.3)
≥30 years	Referent
Marital status	
Never/widowed/divorced/separated	1.1 (1.0–1.2)
Currently married	Referent
Poverty level	
Below poverty level	1.0 (0.9–1.1)
At or above poverty level	Referent
Vaccine coverage tertile in state of residence	
Highest	Referent
Middle	1.3 (1.2–1.3)
Lowest	1.5 (1.4–1.7)
Number of children in household	
1	Referent
2–3	1.3 (1.2–1.4)
≥4	1.9 (1.7–2.1)
Currently living in a state other than birth state	
Yes	1.5 (1.3–1.7)
No	Referent
Number of vaccination providers identified by respondent	
0	N/A
1	Referent
≥2	1.1 (1.0–1.2)

N = 103 807. The 4:3:1:_3:1 vaccination series = ≥4 doses of DTaP, ≥3 doses of poliovirus vaccine, ≥1 doses of measles-containing vaccine, ≥3 doses of hepatitis B vaccine, and ≥1 doses of varicella vaccine. N/A, not applicable.

be associated with children having multiple health care providers, which may relate to incomplete reporting of providers by caregivers, leading to an incomplete provider record check and record scattering. Record scattering can compromise the ability to accurately depict a population's vaccination coverage.[35,36] Barriers to establishing new primary care providers with each move may impact vaccination rates. In addition, providers may be relying on caregiver recall due to lack of documentation to determine a child's immunization status. The Military Health System does have electronic medical records, which, in theory, should lessen the risk associated with moving or having multiple providers. However, it does not have a comprehensive childhood immunization registry. Studies have shown that immunization registries allow for more accurate surveillance of vaccination coverage rates, rather than relying on medical record review.[37,38] Within the military system, routine entry of vaccination data into records is problematic because in military treatment facilities failure to capture such data does not have the economic consequences seen in other settings. In addition, children may receive vaccinations at nonmilitary facilities where information is not readily shared with the military treatment facilities. As mentioned in the study limitations, the extent to which the lack of accurate and complete records rather than lack of actual vaccinations may have affected the results of this study is not known.

In addition to issues around record-keeping in a highly mobile population, other barriers associated with low childhood vaccination rates among military dependents have been missed opportunities, long clinic waiting times, and difficulty making appointments.[13,39] Furthermore, in some military treatment facilities, vaccinations are performed in separate clinic areas, which may also present an additional barrier, especially if clinic waiting times to see the primary care provider are already prolonged. Many of these barriers have been addressed by the implementation of a primary care medical home model within the Military Health System. This new model of military health was designed to streamline the delivery of primary care in the military and continues to evolve. Still, currently existing system barriers need to be researched further and more fully described to begin understanding the reason for lower vaccination coverage rates among military dependent children and to find a solution to increase the coverage in this population.

As the United States seeks to reform its health care system, it is essential

that we understand how policies will affect health indicators. The Affordable Care Act mandates that all new health insurance plans offer all childhood vaccinations recommended by the Advisory Committee on Immunization Practices at no cost to the patient, including eliminating all copays and cost-sharing arrangements.[40] All risk factors associated with incomplete vaccination, including financial barriers, should be clearly identified and addressed to ensure adequate vaccination coverage and to minimize the morbidity and mortality due to vaccine-preventable diseases.

CONCLUSIONS

Drawing from a database of provider-reported vaccination status, we show that compared with a national sample, children who are military dependents are less likely to be fully vaccinated. The reasons for this association are not clear and likely range from children being truly undervaccinated to lack of accurate and complete vaccination documentation. If the actual reason is the former, then a systematic process to identify individuals who are not up to date on vaccinations may be needed. If the latter is the cause, a more robust method of documenting vaccinations may be needed. The NIS relies on caregivers to recall all vaccination providers, and thus limits the use of the NIS to draw firm conclusions in the highly mobile military dependent population. Immunization registries can help document vaccinations and identify which vaccinations are necessary to ensure a child is up to date, which is especially important in populations with multiple providers.[41] Additional studies should be conducted to verify our findings and to further elucidate system factors associated with the reported incomplete vaccination within the Military Health System.

Accepted for publication Feb 26, 2015

Address correspondence to Angela C. Dunn, MD, MPH, Department of Family and Preventive Medicine, University of California San Diego, 9500 Gilman Dr, No. 0811, La Jolla, CA 92093-0811. E-mail: acdunn@cdc.gov

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

FINANCIAL DISCLOSURE: The authors have indicated they have no financial relationships relevant to this article to disclose.

FUNDING: No external funding.

POTENTIAL CONFLICT OF INTEREST: The authors have indicated they have no potential conflicts of interest to disclose.

REFERENCES

1. Centers for Disease Control and Prevention. Ten great public health achievements—United States, 2001-2010. *MMWR Morb Mortal Wkly Rep.* 2011; 60(19):619–623
2. Zhou F, Shefer A, Wenger J, et al. Economic evaluation of the routine childhood immunization program in the United States, 2009. *Pediatrics.* 2014; 133(4):577–585
3. Centers for Disease Control and Prevention. National, state, and local area vaccination coverage among children aged 19-35 months—United States, 2011. *MMWR Morb Mortal Wkly Rep.* 2012;61(35):689–696
4. Chu SY, Barker LE, Smith PJ. Racial/ethnic disparities in preschool immunizations: United States, 1996-2001. *Am J Public Health.* 2004;94(6): 973–977
5. Wood D, Donald-Sherbourne C, Halfon N, et al. Factors related to immunization status among inner-city Latino and African-American preschoolers. *Pediatrics.* 1995;96(2 pt 1):295–301
6. Klevens RM, Luman ETUS. U.S. children living in and near poverty: risk of vaccine-preventable diseases. *Am J Prev Med.* 2001;20(4 suppl):41–46
7. Gust DA, Strine TW, Maurice E, et al. Underimmunization among children: effects of vaccine safety concerns on immunization status. *Pediatrics.* 2004; 114(1). Available at: www.pediatrics.org/cgi/content/full/114/1/e16
8. Luman ET, McCauley MM, Shefer A, Chu SY. Maternal characteristics associated with vaccination of young children. *Pediatrics.* 2003;111(5 pt 2):1215–1218
9. Schuller KA, Probst JC. Factors associated with influenza vaccination among US children in 2008. *J Infect Public Health.* 2013;6(2):80–88
10. Kim SS, Frimpong JA, Rivers PA, Kronenfeld JJ. Effects of maternal and provider characteristics on up-to-date immunization status of children aged 19 to 35 months. *Am J Public Health.* 2007; 97(2):259–266
11. Lieu TA, Black SB, Ray P, Chellino M, Shinefield HR, Adler NE. Risk factors for delayed immunization among children in an HMO. *Am J Public Health.* 1994;84(10): 1621–1625
12. Connors J, Arushanyan E, Bellanca G, et al. A description of barriers and facilitators to childhood vaccinations in the military health system. *J Am Acad Nurse Pract.* 2012;24(12):716–725
13. Morrow AL, Rosenthal J, Lakkis HD, et al. A population-based study of access to immunization among urban Virginia children served by public, private, and military health care systems. *Pediatrics.* 1998;101(2). Available at: www.pediatrics.org/cgi/content/full/101/2/E5
14. Fiks AG, Grundmeier RW, Biggs LM, Localio AR, Alessandrini EA. Impact of clinical alerts within an electronic health record on routine childhood immunization in an urban pediatric

population. *Pediatrics.* 2007;120(4):707–714

15. Dini EF, Linkins RW, Sigafoos J. The impact of computer-generated messages on childhood immunization coverage. *Am J Prev Med.* 2000;19(1):68–70
16. Irigoyen MM, Findley S, Wang D, et al. Challenges and successes of immunization registry reminders at inner-city practices. *Ambul Pediatr.* 2006;6(2):100–104
17. Johnson KB, Davison CL. Information technology: its importance to child safety. *Ambul Pediatr.* 2004;4(1):64–72
18. Santoli JM, Huet NJ, Smith PJ, et al. Insurance status and vaccination coverage among US preschool children. *Pediatrics.* 2004;113(6 suppl):1959–1964
19. Smith PJ, Stevenson J, Chu SY. Associations between childhood vaccination coverage, insurance type, and breaks in health insurance coverage. *Pediatrics.* 2006;117(6):1972–1978
20. US Department of Defense, Office of the Deputy Under Secretary of Defense (Military Community and Family Policy). Demographics 2010: Profile of the military community. Available at: http://www.militaryonesource.mil/12038/MOS/Reports/2010_Demographics_Report.pdf. Accessed April 6, 2013
21. US Department of Defense. See what's covered—immunizations. TRICARE-covered immunizations. Available at: www.tricare.mil/CoveredServices/IsItCovered/Immunizations.aspx. Accessed February 20, 2013
22. Weese CB, Krauss MRA. A 'barrier-free' health care system does not ensure adequate vaccination of 2-year-old children. *Arch Pediatr Adolesc Med.* 1995;149(10):1130–1135
23. Lopreiato JO, Ottolini MC. Assessment of immunization compliance among children in the Department of Defense health care system. *Pediatrics.* 1996;97(3):308–311
24. Lopreiato JO, Moriarty R. Immunization status of a military dependent population. *Mil Med.* 1993;158(6):371–373
25. Jones WS, Hall BH, Smalley JR, Schelonka RL, Butzin CA, Ascher DP. Immunization status of preschool children in a military clinic. *Arch Pediatr Adolesc Med.* 1994;148(9):986–989
26. Zhao Z, Mokdad AH, Barker L. Impact of health insurance status on vaccination coverage in children 19-35 months old, United States, 1993-1996. *Public Health Rep.* 2004;119(2):156–162
27. Centers for Disease Control and Prevention. NIS—datasets and related documentation for the National Immunization Survey, 2005 to present. Available at: www.cdc.gov/nchs/nis/data_files.htm. Accessed March 22, 2013
28. Centers for Disease Control and Prevention. National, state, and local area vaccination coverage among children aged 19-35 months—United States, 2012. *MMWR Morb Mortal Wkly Rep.* 2013;62(36):733–740
29. Santibanez TA, Shefer A, Briere EC, Cohn AC, Groom AV. Effects of a nationwide Hib vaccine shortage on vaccination coverage in the United States. *Vaccine.* 2012;30(5):941–947
30. Smith PJ, Battaglia MP, Huggins VJ, et al. Overview of the sampling design and statistical methods used in the National Immunization Survey. *Am J Prev Med.* 2001;20(4 suppl):17–24
31. Centers for Disease Control and Prevention. State and national vaccination coverage levels among children aged 19-35 months—United States, April-December 1994. *MMWR.* 1995;44(33):619–623
32. Hinman AR, Orenstein WA, Schuchat A; Centers for Disease Control and Prevention. Vaccine-preventable diseases, immunizations, and MMWR—1961-2011. *MMWR Surveill Summ.* 2011;60(suppl 4):49–57
33. Herrera GA, Smith P, Daniels D, et al; Centers for Disease Control and Prevention. National, state, and urban area vaccination coverage levels among children aged 19-35 months—United States, 1998. *MMWR CDC Surveill Summ.* 2000;49(9 SS09):1–26
34. Allred NJ, Wooten KG, Kong Y. The association of health insurance and continuous primary care in the medical home on vaccination coverage for 19- to 35-month-old children. *Pediatrics.* 2007;119(suppl 1):S4–S11
35. Smith PJ, Stevenson J. Racial/ethnic disparities in vaccination coverage by 19 months of age: an evaluation of the impact of missing data resulting from record scattering. *Stat Med.* 2008;27(20):4107–4118
36. Stokley S, Rodewald LE, Maes EF. The impact of record scattering on the measurement of immunization coverage. *Pediatrics.* 2001;107(1):91–96
37. Stille CJ, Christison-Lagay J. Determining immunization rates for inner-city infants: statewide registry data vs medical record review. *Am J Public Health.* 2000;90(10):1613–1615
38. Kempe A, Beaty BL, Steiner JF, et al. The regional immunization registry as a public health tool for improving clinical practice and guiding immunization delivery policy. *Am J Public Health.* 2004;94(6):967–972
39. Mancuso JD. A limited measles outbreak in U.S.-born children living in a military community in Germany after vaccine refusal and other vaccination delays. *Mil Med.* 2008;173(8):776–779
40. US Department of Health and Human Services. The Affordable Care Act and Immunization. Available at: http://www.hhs.gov/healthcare/facts/factsheets/2010/09/The-Affordable-Care-Act-and-Immunization.html#Immunization.html. Accessed April 6, 2013
41. USA.gov. Increasing appropriate vaccination: immunization information systems. The Guide to Community Preventive Services. Available at: www.thecommunityguide.org/vaccines/universally/imminfosystems.html. Accessed November 1, 2013

8.2

Centers for Disease Control and Prevention
MMWR
Morbidity and Mortality Weekly Report
Weekly / Vol. 64 / No. 13
April 10, 2015

Sustained Decrease in Laboratory Detection of Rotavirus after Implementation of Routine Vaccination — United States, 2000–2014

Negar Aliabadi, MD[1,2], Jacqueline E. Tate, PhD[2], Amber K. Haynes, MPH[2], and Umesh D. Parashar, MD[2] (Author affiliations at end of text)

Rotavirus infection is the leading cause of severe gastroenteritis among infants and young children worldwide (*1,2*). Before the introduction of rotavirus vaccine in the United States in 2006, rotavirus infection caused significant morbidity among U.S. children, with an estimated 55,000–70,000 hospitalizations and 410,000 clinic visits annually (*3*). The disease showed a characteristic winter-spring seasonality and geographic pattern, with annual seasonal activity beginning in the West during December-January, extending across the country, and ending in the Northeast during April-May (*4*). To characterize changes in rotavirus disease trends and seasonality following introduction of rotavirus vaccines in the United States, CDC compared data from CDC's National Respiratory and Enteric Virus Surveillance System (NREVSS), a passive laboratory reporting system, for prevaccine (2000–2006) and postvaccine (2007–2014) years. National declines in rotavirus detection were noted, ranging from 57.8%–89.9% in each of the 7 postvaccine years compared with all 7 prevaccine years combined. A biennial pattern of rotavirus activity emerged in the postvaccine era, with years of low activity and highly erratic seasonality alternating with years of moderately increased activity and seasonality similar to that seen in the prevaccine era. These results demonstrate the substantial and sustained effect of rotavirus vaccine in reducing the circulation and changing the epidemiology of rotavirus among U.S. children.

NREVSS is a national laboratory-based passive reporting system for respiratory and enteric viruses, including rotavirus. Participating laboratories report weekly data to CDC, including the total number of stool samples tested for rotavirus by enzyme immunoassay and the number of specimens that tested positive. Annually, 75 to 90 laboratories report rotavirus testing data to NREVSS. A reporting year is defined as the period from July (epidemiologic week 27) to June (epidemiologic week 26) of the following year, beginning in July 2000. Rotavirus season onset is defined as the first of 2 consecutive weeks where 10% or more of specimens test positive for rotavirus. Similarly, season offset is defined as the last of 2 consecutive weeks where 10% or more of samples test positive. Peak season intensity is defined as the week with the highest proportion of tests positive for rotavirus. For analysis of season duration and peak intensity, data from all participating laboratories were included. The proportion of samples that tested positive for rotavirus and the mean decrease from the prevaccine years are reported for these data. Analyses of trends in disease were restricted to the 23 laboratories that consistently reported at least 26 weeks of data for each reporting year from July 2000 through June 2014. For this analysis, data are aggregated by week and reported as a 3-week moving average of total number of tests and rotavirus positive tests performed

INSIDE

Continuing Education examination available at http://www.cdc.gov/mmwr/cme/conted_info.html#weekly.

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

for the prevaccine period (2000–2006) and for each prevaccine season. Data are presented for the United States overall and for each U.S. census region.

Data from all participating NREVSS laboratories showed that with prevaccine seasons (2000–2006), median season onset was in epidemiologic week 50 (in December), peak activity was in week 9 (February/March, 43.1% positive samples) and season duration was 26 weeks. In comparison, these data showed that each of the 7 postvaccine seasons from 2007–2014 started later (if at all), had lower peak positivity for rotavirus (10.9%–27.3%), and were shorter in duration (0–18 weeks) (Table 1 and Figure 1). In the rotavirus reporting years spanning 2009–2010, 2011–2012 and 2013–2014, no seasonal onset occurred nationally, and the proportion of tests positive for rotavirus during the peak week was lower than the immediately preceding and following seasons. Examination of data for each region individually showed slight differences in seasonal onset, duration, and offset. Notably, in the South, season onset and duration varied, with some postvaccine years' season onset and duration comparable with median values from prevaccine years. This region also had only one reporting year where no season onset threshold was reached, whereas all other regions had at least two such reporting years. Regardless of these variations, most seasons within each region showed decreased length and activity compared with prevaccine years.

Data from 23 consistently reporting laboratories demonstrated a marked decline in rotavirus testing and positivity in the postvaccine years (Table 2 and Figure 2). Overall, after vaccine introduction, the number of total tests performed as well as the number of positive rotavirus tests declined each reporting year compared with those of the prevaccine years. Furthermore, the proportion of tests that were positive for rotavirus declined from 57.8%–89.9% in each of the seven postvaccine reporting years compared with prevaccine years combined, with alternating years of lower and greater positivity rates. Similar patterns were observed when the data were examined for each region.

Discussion

A marked and sustained decline in rotavirus activity was seen nationally in all seven rotavirus reporting years from 2007 to 2014 following the implementation of routine rotavirus vaccination of U.S. children. The decline was accompanied by changes in the predictable prevaccine seasonal pattern of rotavirus activity. The later onset and shorter duration of rotavirus seasons in the postvaccine era, including some years without a defined rotavirus season, could be a result of fewer unvaccinated, susceptible infants, resulting in reduced intensity and duration of rotavirus transmission (5). This reduced transmission of rotavirus likely also explains the declines in rates of rotavirus disease that have been seen in unvaccinated

The *MMWR* series of publications is published by the Center for Surveillance, Epidemiology, and Laboratory Services, Centers for Disease Control and Prevention (CDC), U.S. Department of Health and Human Services, Atlanta, GA 30329-4027.

Suggested citation: [Author names; first three, then et al., if more than six.] [Report title]. MMWR Morb Mortal Wkly Rep 2015;64:[inclusive page numbers].

TABLE 1. Rotavirus season onset, peak activity, offset, and duration, by region — National Respiratory and Enteric Virus Surveillance System, United States 2000–2014

Overall	Onset (week no.)	Peak (Week no.)	Peak (% tests positive)	Offset (week no.)	Season duration (no. weeks)
2000–2006	50	9	43.1	24	26
2007–2008	9	17	17.3	21	12
2008–2009	4	11	25.3	21	17
2009–2010	NA*	18	10.9	NA	NA
2010–2011	3	11	23.4	21	18
2011–2012	NA	22	12.2	NA	NA
2012–2013	1	13	27.3	18	17
2013–2014	NA	21	11.3	NA	NA
Northeast					
2000–2006	2	11	45.2	23	21
2007–2008	18	18	13.9	19	1
2008–2009	7	11	20.1	17	10
2009–2010	NA	20	13.5	NA	NA
2010–2011	6	14	23.6	18	12
2011–2012	NA	47	10.5	NA	NA
2012–2013	10	16	28.9	21	11
2013–2014	NA	23	11.0	NA	NA
Midwest					
2000–2006	1	9	49.0	21	20
2007–2008	6	18	27.5	25	19
2008–2009	3	10	34.0	19	16
2009–2010	NA	19	11.6	NA	NA
2010–2011	2	14	34.3	16	14
2011–2012	18	19	13.6	19	1
2012–2013	1	11	34.3	18	17
2013–2014	NA	21	6.8	NA	NA
South					
2000–2006	51	10	44.0	23	28
2007–2008	12	15	16.5	21	9
2008–2009	50	9	37.2	19	31
2009–2010	15	18	17.5	18	3
2010–2011	50	11	24.7	22	28
2011–2012	NA	13	12.7	NA	NA
2012–2013	49	13	28.9	18	31
2013–2014	17	21	22.1	21	4
West					
2000–2006	47	5	38.1	24	23
2007–2008	11	17	28.0	22	11
2008–2009	10	15	20.9	21	11
2009–2010	NA	18	11.5	NA	NA
2010–2011	7	12	19.5	21	14
2011–2012	22	22	24.1	23	1
2012–2013	1	13	25.9	23	22
2013–2014	NA	24	17.4	NA	NA

* NA indicates years in which seasonal onset and offset threshold were not reached.

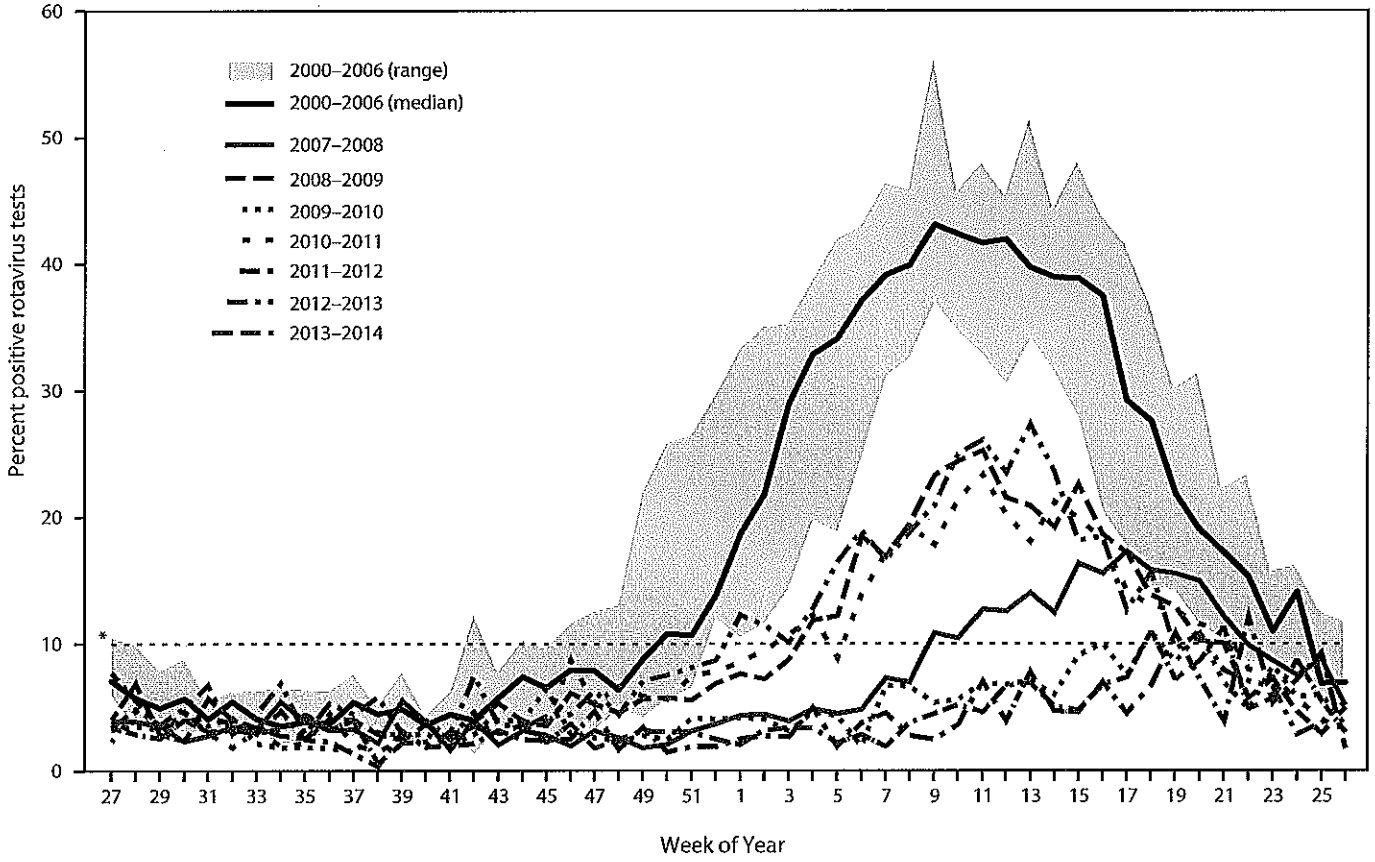
older children and even in some adult age groups in postvaccine years compared with the prevaccine era, resulting from the phenomenon known as herd immunity (*6*).

Biennial peaks in rotavirus activity also emerged in the postvaccine era in contrast to the annual peaks before vaccine implementation, although even the postvaccine reporting years with heavier rotavirus burden still demonstrated rotavirus activity levels that were substantially lower than those of the prevaccine years. This biennial pattern might be explained by an accumulation of a sufficient number of unvaccinated susceptible children over two successive reporting years to result in stronger rotavirus seasons every other year. Though rotavirus vaccine coverage among children aged 19–35 months has increased nationally since the vaccine was introduced, from 43.9% in 2009 to 72.6% 2013 (*7*), some children remain unvaccinated. In a low rotavirus reporting year, these unvaccinated children might not be exposed to wild-type rotavirus and thus remain susceptible in their second year of life. These susceptible children aged 12–23 months, together with unvaccinated infants from the next birth cohort, might form a critical mass of susceptible children sufficient to sustain more intense rotavirus transmission in alternate years.

The findings in this report are subject to at least four limitations. First, NREVSS only receives aggregate reports of the number of stool samples tested for rotavirus and the number of these that test positive, without any information on demographics or clinical features of individual patients, precluding detailed examination of these characteristics. Second, participating laboratory locations do not uniformly cover all areas of the United States, and as such regional biases might exist. Third, because testing for rotavirus does not alter clinical management of patients, testing practices might differ and affect comparability of data from site to site and year to year. Finally, any changes in rotavirus testing practices coinciding with implementation of the rotavirus vaccination program could affect interpretation of the disease trends, although the consistency of the declines in rotavirus activity across all regions and years argues against changes in testing being the main cause of the decline.

The declines in rotavirus activity seen in NREVSS data after vaccine introduction are supported by other U.S. studies showing declines in laboratory-confirmed rotavirus hospitalization (*4*) as well as reductions in outpatient visits, emergency room visits, acute gastroenteritis, and rotavirus-coded hospitalizations (*8*). During 2007–2011 more than 176,000 hospitalizations, 242,000 emergency department visits, and 1.1 million outpatients visits due to diarrhea were averted, resulting in costs savings of $924 million over this 4-year period (*9*). Given the sustained decline in rotavirus activity observed in the NREVSS data through 2014, we would expect additional medical visits due to diarrhea will have been prevented and additional cost savings accrued in the United States. The findings in this report are consistent with the high field effectiveness of vaccination observed in post-licensure epidemiologic studies (*10*). Taken together, these findings reaffirm the large public health impact of routine rotavirus vaccination in reducing the circulation of rotavirus among U.S. children.

FIGURE 1. Rotavirus season duration and peak activity by reporting years (prevaccine 2000–2006 and postvaccine 2007–2011), NREVSS data — United States, 2000–2014



* Dashed line indicates the 10% threshold of numbers of positive test results, which is used to determine onset and offset of a rotavirus season.

[1]Epidemic Intelligence Service, CDC; [2]Division of Viral Diseases, National Center for Immunization and Respiratory Diseases, CDC (Corresponding author: Negar Aliabadi, ydh6@cdc.gov, 404.639.6367)

References

1. Tate JE, Burton AH, Boschi-Pinto, Steele AD, Duque J, Parashar UD. 2008 estimate of worldwide rotavirus-associated mortality in children younger than 5 years before the introduction of universal rotavirus vaccination programmes: a systematic review and meta-analysis. Lancet Inf Dis 2012;12:136–41.
2. Parashar UD, Hummelman EG, Bresee JS, Miller MA, Glass RI. Global illness and deaths caused by rotavirus disease in children. Emerg Infect Dis 2003;9:565–72.
3. Cortese MM, Parashar UD. Prevention of rotavirus gastroenteritis among infants and children: recommendations of the advisory committee on immunization practices (ACIP). MMWR Recomm Rep 2009;58(No. RR-02):1–25.
4. Tate JE, Mutuc JD, Panozzo CA, et al. Sustained decline in rotavirus detections in the United States following the introduction of rotavirus vaccine in 2006. 2011 Peds Inf Dis Supp; 30(1).
5. Pitzer VE, Viboud C, Simonsen L, et al. Demographic variability, vaccination, and the spatiotemporal dynamics of rotavirus epidemics. Science 2009;325:290–4.
6. Gastanaduy PA, Curns AT, Parashar UD, Lopman BA. Gastroenteritis hospitalization in older children and adults in the United States before and after implementation of infant rotavirus vaccination. JAMA 2013;210:851–3.
7. Elam-Evans LD, Yankey D, Singleton JA, Kolasa M. National, state, and selected local area vaccination coverage among children aged 19–35 months — United States, 2013. 2014 MMWR Morbid Mortal Wkly Rep 2014;63;741–8.
8. Cortes JE, Curns AT, Tate JE, et al. Rotavirus vaccine and health care utilization for diarrhea in US children. N Engl J Med 2011; 365:1108–17.
9. Leshem E, Moritz RM, Curns AT et al. Rotavirus vaccines and health care utilization for diarrhea in the United States (2007-2011). Pediatrics 2014;134(1).
10. Payne DC, Boom JA, Staat MA, et al. Effectiveness of pentavalent and monovalent rotavirus vaccines in concurrent use among US children <5 years of age, 2009–2011. Clin Inf Dis 2013;57:14–20.

TABLE 2. Rotavirus tests and percent rotavirus positive results from 23 continuously reporting NREVSS laboratories , by season and region — National Respiratory and Enteric Virus Surveillance System, United States 2000–2014

Season	No. tests performed	Positive test results		Decline in no. of positive tests (%)*
		No.	%	
All regions (23 laboratories)				
2000–2006†	12,184	3,109	25.5	NA§
2007–2008	12,544	1,130	9	63.7
2008–2009	12,322	1,312	10.6	57.8
2009–2010	9,684	447	4.6	85.6
2010–2011	9,168	817	8.9	73.7
2011–2012	8,335	315	3.8	89.9
2012–2013	8,162	893	10.9	71.3
2013–2014	7,080	342	4.8	89
West (eight laboratories)				
2000–2006†	4,862	1,104	22.7	NA
2007–2008	5,813	556	9.6	49.6
2008–2009	5,127	360	7	67.4
2009–2010	4,504	196	4.4	82.2
2010–2011	3,909	257	6.6	76.7
2011–2012	3,385	144	4.3	87
2012–2013	3,043	286	9.4	74.1
2013–2014	2,939	158	5.4	85.7
South (eight laboratories)				
2000–2006†	3,893	1,024	26.3	NA
2007–2008	3,272	281	8.6	72.5
2008–2009	3,365	490	14.6	52.1
2009–2010	2,499	181	7.2	82.3
2010–2011	2,415	241	10	76.5
2011–2012	2,251	84	3.7	91.8
2012–2013	2,228	267	12	73.9
2013–2014	1,835	144	7.8	85.9
Midwest (six laboratories)				
2000–2006†	3,173	885	27.9	NA
2007–2008	3,276	281	8.6	68.2
2008–2009	3,603	450	12.5	49.1
2009–2010	2,506	63	2.5	92.9
2010–2011	2,689	298	11.1	66.3
2011–2012	2,538	84	3.3	90.5
2012–2013	2,776	330	11.9	62.7
2013–2014	2,180	36	1.7	95.9
Northeast (one laboratory)				
2000–2006†	194	39	19.9	NA
2007–2008	183	12	6.6	68.8
2008–2009	227	12	5.3	68.8
2009–2010	175	7	4	81.8
2010–2011	150	21	14	45.5
2011–2012	161	3	1.9	92.2
2012–2013	115	10	8.7	74
2013–2014	126	4	3.2	89.6

* This represents the decline in number of positive tests as compared to the prevaccine years (2000–2006) median; that is: (median number of positive tests 2000–2006)-(subsequent year number of positive tests)/ (median number of positive tests 2000–2006)

† Median data are reported for the prevaccine seasons spanning 2000–2006.

§ NA indicates the reference period, so no values are reported.

What is already known on this topic?

Following the introduction of rotavirus vaccine in the United States in 2006, large declines have been observed in diarrhea and rotavirus hospitalizations among children aged <5 years, and onset of the rotavirus season has occurred later.

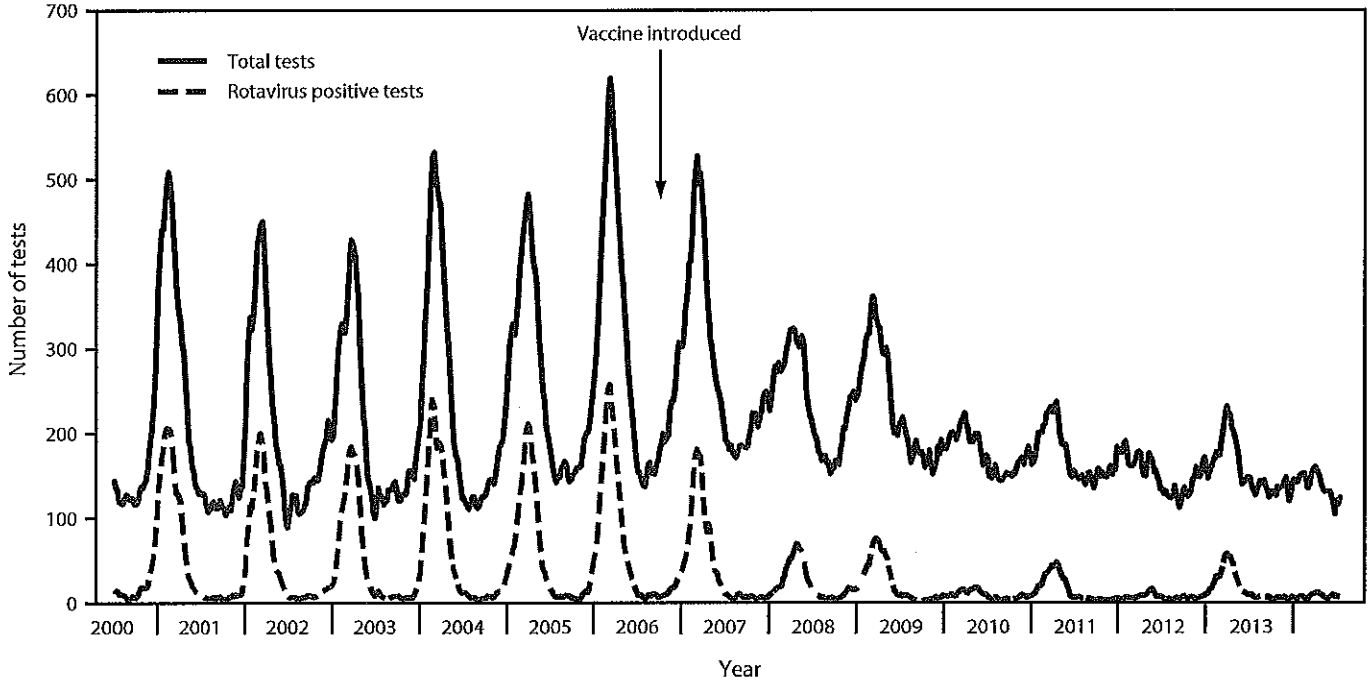
What is added by this report?

Analysis of data from the National Respiratory and Enteric Virus Surveillance System showed a marked and sustained decline in rotavirus activity nationally and regionally for the seven rotavirus reporting years from 2007 to 2014 following the implementation of routine rotavirus vaccination of U.S. children. In addition to rotavirus seasons with later onset and shorter duration, a biennial pattern of rotavirus activity emerged in the postvaccine era, with years of low activity and highly erratic seasonality alternating with years of greater activity and seasonality similar to those in the prevaccine era.

What are the implications for public health practice?

These findings reaffirm the large public health impact of routine rotavirus vaccination in reducing the circulation of rotavirus in U.S. children.

FIGURE 2. Total and positive rotavirus tests, NREVSS data — United States, 2000–2014



Work-Related Asthma — 22 States, 2012

Jacek M. Mazurek, MD[1], Gretchen E. White, MPH[1,2] (Author affiliations at end of text)

Work-related asthma* (WRA) is a preventable occupational disease associated with serious adverse health outcomes (*1–3*). Using the 2006–2009 Behavioral Risk Factor Surveillance System (BRFSS) Adult Asthma Call-back Survey (ACBS) data from 38 states and the District of Columbia, CDC estimated that among ever-employed adults with current asthma, the proportion of current asthma that is work-related was 9.0% (*4*). In 2011, the BRFSS cellular telephone samples were added to the traditional landline telephone samples and the weighting methodology was changed.† In 2012, a revised ACBS question on WRA diagnosis§ was asked. To provide updated estimates of current asthma prevalence and the proportion of asthma that is work-related, by state, CDC analyzed data from BRFSS and ACBS collected from 22 states using both landline and cellular telephone samples during 2012. This report summarizes the results of that analysis, which indicate that 9.0% of adults had current asthma and that among ever-employed adults with current asthma, the overall proportion of current asthma that is work-related was 15.7%. State-specific proportions of asthma that is work-related ranged from 9.0% to 23.1%. Distribution of the proportion of WRA significantly differed by age and was highest among persons aged 45–64 years (20.7%). These findings provide a new baseline after the implementation of changes in survey methodology (*5*) and the adoption of a revised WRA question. These results can assist states, other government agencies, health professionals, employers, workers, and worker representatives to better target intervention and prevention efforts to reduce the burden of WRA.

BRFSS is a state-based, random-digit–dialed telephone survey of the non-institutionalized U.S. civilian population aged ≥18 years that collects information on health risk factors, preventive health practices, and disease status.¶ The 2012 BRFSS included a standard set of core questions, 27 optional modules, and state-added questions. One of the optional modules, the CDC-funded ACBS, is designed to collect detailed information on asthma, including WRA. BRFSS respondents who answer "yes" to the question, "Have you ever been told by a doctor, nurse, or other health professional that you had asthma?" are invited to participate in ACBS.** Those who agree to participate are interviewed within 2 weeks of the BRFSS completion date. In 2012, ACBS was administered among adults in 22 states.

In 2011, in order to address the effect of an increasing number of cellular telephone–only households on BRFSS coverage, cellular telephone samples were added to landline telephone samples (*5*). To address this change and to reduce the potential for bias associated with declining response rates, BRFSS also adopted a new statistical weighting methodology (*5*). Also, in 2012, the content of the ACBS WRA section was revised. Adult data from 2012 BRFSS and ACBS collected from 22 states using both landline and cellular telephone samples are included in this analysis. The median response rate among the 22 states was 44.9% (range: 27.7%–56.8%) for BRFSS†† and 47.2% (range: 38.5%–60.6%) for ACBS.§§

For this analysis, BRFSS participants who responded "yes" to the questions, "Have you ever been told by a doctor or other health professional that you have asthma?" and "Do you still have asthma?" were identified as having current asthma. Ever-employed ACBS participants were those who indicated that they were currently employed full- or part-time or that they had ever been employed. Ever-employed adults with current asthma who responded "yes" to the question, "Have you ever been told by a doctor or other health professional that your asthma was caused by, or your symptoms made worse by, any job you ever had?" were classified as having WRA.

Data for 2012 from all 22 states collecting adult data using landline and cellular telephone samples were weighted¶¶ to account for noncoverage, unequal probability of sample

* WRA includes occupational asthma (i.e., new-onset asthma caused by factors related to work) and work-exacerbated asthma (i.e., preexisting or concurrent asthma worsened by factors related to work).

† Additional information is available at http://www.cdc.gov/brfss/annual_data/2012/pdf/Overview_2012.pdf and at http://www.cdc.gov/brfss/acbs/2012/pdf/ACBS_2012.pdf.

§ "Have you ever been told by a doctor or other health professional that your asthma was caused by, or your symptoms made worse by, any job you ever had?" Before 2012, the question was, "Were you ever told by a doctor or other health professional that your asthma was related to any job you ever had?"

¶ Additional information and survey data and documentation available at http://www.cdc.gov/brfss/about/index.htm and at http://www.cdc.gov/brfss/annual_data/annual_data.htm#2013.

** Additional information and survey data and documentation available at http://www.cdc.gov/brfss/acbs/index.htm.

†† Source: CDC. Behavioral Risk Factor Surveillance System, 2012 Summary Data Quality Report, July 3, 2013. Available at http://www.cdc.gov/brfss/annual_data/2012/pdf/summarydataqualityreport2012_20130712.pdf.

§§ Source: 2012 Behavioral Risk Factor Surveillance System, asthma call-back survey summary data quality. Available at http://www.cdc.gov/brfss/acbs/2012/pdf/SDQReportACBS_12.pdf.

¶¶ CDC. The BRFSS Data User Guide, August 15, 2013. Available at http://www.cdc.gov/brfss/data_documentation/PDF/UserguideJune2013.pdf.

selection, and nonresponse differences in the sample. Statistically significant differences in distribution were determined by using the Rao-Scott chi-square test of independence at $p \leq 0.05$.

In the 22 states, a sample of 205,755 adults participated in BRFSS (representing an estimated 137 million persons) and 9,893 adults participated in the ACBS (representing an estimated 18 million persons). In 2012, an estimated 9.0% of adults had current asthma in these 22 states (Table). The prevalence of current asthma significantly differed by age, sex, race/ethnicity, and education. Prevalence was highest among persons aged 45–64 years (9.4%), women (11.4%), blacks (12.5%), and those with less than a high school education (9.5%). By state, estimates of the current asthma prevalence ranged from 6.8% to 10.9%.

A total of 7,275 adults who participated in ACBS were ever-employed and had current asthma, representing an estimated 12 million adults in these 22 states. Of these, the estimated proportion who had WRA was 15.7% (an estimated 1.9 million persons) (Table). The proportion of WRA among ever-employed persons with current asthma differed significantly by age and was highest among persons aged 45–64 years (20.7%). By state, the estimated proportions of ever-employed adults with current asthma who had WRA ranged from 9.0% to 23.1%.

Discussion

Among ever-employed adults with current asthma, 15.7% had WRA, indicating that an estimated 1.9 million WRA cases (new-onset and work-exacerbated asthma) could potentially have been prevented in these 22 states. These findings provide a new baseline to be compared with future estimates. Several factors need to be considered when interpreting these results. First, the 2012 data are not comparable methodologically with those collected during preceding years and should be used as a baseline to compare with subsequent survey results. The addition of cellular telephone–only households to the survey sample improved the representativeness of data collected by BRFSS and likely increased the coverage of respondents who are younger and who have a lower income, less education, an unmet need for medical care, and a higher number of risk factors for chronic diseases (*5–8*). In 2012, the estimated median proportion of cellular telephone-only households in the 22 states included in this study was 36.7% (range: 23.5%–49.4%).*** Moreover, weights used in this analysis were computed by using an iterative proportional fitting (i.e., "raking") method, which offers several advantages over the method used previously (i.e., "poststratification"). Raking allows for the introduction of more demographic variables and the incorporation of telephone ownership into statistical weighting, thus reducing the potential for bias and improving the representativeness of estimates (*5,8*). Finally, in 2012 a revised question that identifies respondents with WRA was asked as part of ACBS.

Administration of ACBS should continue to allow state asthma programs to monitor the proportion of asthma that is work-related. In addition, the National Institute for Occupational Safety and Health (NIOSH) supported an optional module in 2013 and 2014††† to collect information on the current industry and occupation of participants. These data will inform the development of public health intervention strategies (i.e., occupations suspected to place workers at high risk for development of WRA should be evaluated, and effective exposure control measures should be implemented to prevent WRA) (*4*). Because a WRA diagnosis offers unique opportunities for prevention for the patient and among workers with similar occupational exposures, health-care providers should ask workers with asthma about occupational exposures and be alert to potential associations between workplace exposures and asthma symptoms (*2*).

The findings in this report are subject to at least six limitations. First, measures of current asthma and WRA were based on self-report and not validated by medical records review or follow-up with health-care providers. Previous studies have found self-report of adult asthma to be reliable compared with reviews of medical records (*9*). Moreover, because of the potential impact of a work-related asthma diagnosis on a patient's work (*3*), it is likely that respondents would report their work-related asthma history accurately whereas a diagnosis that did not lead to changes at work might be forgotten. Second, a study showed that clinicians documented occupational exposures in only 7% of adult-onset asthma cases (*10*) indicating that WRA is underdiagnosed in the United States; thus results are likely underestimates of the true proportion of WRA. Third, no data were available in BRFSS to assess the prevalence of current asthma among ever-employed adults. Therefore findings on the prevalence of current asthma and the proportion of current asthma that is work-related were calculated using different populations and should be interpreted with caution. Fourth, the data used in this analysis are limited to adults living in 22 states participating in ACBS; therefore, the estimates are not nationally representative or representative of nonparticipating states. Fifth, because the BRFSS and ACBS median response rates were <50%, nonresponse bias might have affected the results. Finally, small sample sizes for some subpopulations

*** Source: Blumberg SJ, Ganesh N, Luke JV, Gonzales G. Wireless substitution: state-level estimates from the National Health Interview Survey, 2012. Natl Health Stat Report 2013;1–16. Available at http://www.cdc.gov/nchs/data/nhsr/nhsr070.pdf.

††† NIOSH will also support the Industry and Occupation optional module in 2015 and 2016.

TABLE. Prevalence of current asthma* in adults and proportion of ever-employed† adults with current asthma who have been told by a health professional that their asthma was work-related,§ by state and selected characteristics — Behavioral Risk Factor Surveillance System (BRFSS) and Adult Asthma Call-Back Survey (ACBS), 22 states, 2012

	Adults				Ever-employed adults with current asthma			
			Prevalence of current asthma				Proportion with work-related asthma	
Characteristic	No. in sample¶	Weighted no. (in thousands)**	%**	(95% CI)	No. in sample¶	Weighted no. (in thousands)**	%**	(95% CI)
Total	**205,755**	**137,831**	**9.0**	**(8.7–9.2)**	**7,275**	**12,270**	**15.7**	**(13.7–17.7)**
Age group (yrs)††,§§								
18–44	57,172	65,456	8.8	(8.4–9.2)	1,514	5,562	13.0	(10.0–16.1)
45–64	79,883	46,997	9.4	(9.0–9.8)	3,363	4,550	20.7	(17.2–24.1)
≥65	66,978	24,566	8.7	(8.2–9.1)	2,373	2,133	12.1	(9.3–15.0)
Sex††								
Male	84,488	67,117	6.4	(6.1–6.7)	2,122	4,275	17.6	(13.5–21.6)
Female	121,267	70,714	11.4	(11.0–11.8)	5,153	7,995	14.8	(12.6–16.9)
Race/Ethnicity††,¶¶								
White	158,929	86,226	9.2	(8.9–9.4)	5,729	8,430	14.9	(13.1–16.7)
Black	12,899	12,829	12.5	(11.4–13.5)	554	1,299	12.3	(7.2–17.4)
Hispanic	15,907	24,813	6.8	(6.1–7.4)	332	1,452	18.2	(10.0–26.4)
Other race	15,498	12,407	8.7	(7.7–9.7)	583	993	23.5	(10.7–36.2)
Education††								
<High school	79,948	60,017	9.5	(9.1–9.9)	2,686	4,574	16.1	(13.1–19.0)
≥High school	125,115	77,297	8.6	(8.3–8.9)	4,584	7,694	15.5	(12.9–18.2)
State								
California	14,574	28,845	8.8	(8.2–9.5)	355	2,744	14.2	(8.5–19.9)
Hawaii	7,582	1,080	8.9	(7.9–9.9)	228	92	9.0	(3.8–14.2)
Illinois	5,579	9,810	8.5	(7.4–9.6)	215	729	16.0	(8.3–23.7)
Indiana	8,645	4,946	9.1	(8.3–9.8)	330	447	16.2	(10.9–21.4)
Iowa	7,166	2,345	8.1	(7.2–8.9)	233	181	18.0	(12.1–23.8)
Michigan	10,499	7,583	10.5	(9.6–11.3)	546	836	14.7	(10.3–19.1)
Mississippi	7,788	2,236	8.1	(7.3–9.0)	310	191	20.6	(13.7–27.5)
Missouri	6,754	4,609	10.4	(9.3–11.5)	278	449	23.1	(15.0–31.3)
Montana	8,679	781	9.5	(8.6–10.3)	292	75	14.5	(9.0–20.0)
Nebraska	19,173	1,391	7.4	(6.9–7.9)	633	101	15.7	(11.8–19.6)
Nevada	4,846	2,078	7.4	(6.3–8.4)	159	161	13.7	(6.6–20.8)
New Hampshire	7,530	1,041	10.2	(9.2–11.3)	294	109	14.4	(7.8–20.9)
New Mexico	8,776	1,582	9.2	(8.5–10.0)	375	155	13.5	(8.6–18.4)
New York	6,060	15,274	9.3	(8.3–10.3)	190	1,332	13.6	(6.0–21.2)
Ohio	13,026	8,856	10.5	(9.7–11.2)	424	948	20.3	(12.3–28.3)
Oklahoma	8,015	2,886	10.2	(9.3–11.0)	249	286	13.9	(7.2–20.6)
Oregon	5,302	3,039	10.6	(9.5–11.8)	218	315	—***	—
Pennsylvania	19,958	10,025	10.1	(9.4–10.8)	696	898	14.6	(10.9–18.5)
Texas	9,129	19,185	6.8	(6.1–7.6)	245	1,257	17.6	(10.2–25.0)
Vermont	6,056	501	10.9	(9.8–12.0)	271	57	14.3	(7.6–21.1)
Washington	15,319	5,336	9.7	(9.1–10.3)	515	515	14.2	(9.9–18.5)
Wisconsin	5,299	4,402	8.6	(7.4–9.7)	219	394	21.1	(13.4–28.9)

Abbreviation: CI = confidence interval.

* Based on a "yes" response to both questions, "Has a doctor, nurse, or other health professional ever told you that you had asthma?" (BRFSS) and "Do you still have asthma?"

† Current employment status described as "employed full-time" or "employed part-time" or a "yes" response to the question, "Have you ever been employed?"

§ Based on a "yes" response to the question, "Have you ever been told by a doctor or other health professional that your asthma was caused by, or your symptoms made worse by, any job you ever had?"

¶ Landline and cellular telephone combined unweighted sample size.

** Weighted to the state population using the survey sample weights for each BRFSS and ACBS participant.

†† For current asthma: Rao-Scott chi-square test; p-value <0.01.

§§ For work-related asthma: Rao-Scott chi-square test; p-value <0.01.

¶¶ Persons identified as Hispanic might be of any race. Persons identified as white, black, or other race are all non-Hispanic.

*** Relative standard error >0.30; estimate suppressed.

resulted in estimates with wide confidence intervals. Additional years of data are needed to calculate more precise estimates.

For many states, ACBS provides the only state-based estimates of WRA. These new, improved results can assist states, other government agencies, health professionals, employers, workers, and worker representatives to prioritize disease intervention and prevention efforts to reduce the burden of WRA.

Acknowledgments

BRFSS state coordinators; Jennifer Flattery, MPH, Occupational Health Branch, California Department of Public Health; Lee Petsonk, MD, National Institute for Occupational Safety and Health, CDC.

[1]Division of Respiratory Disease Studies, National Institute for Occupational Safety and Health, CDC; [2]Currently: Department of Epidemiology, Graduate School of Public Health, University of Pittsburgh (Corresponding author: Jacek Mazurek, jmazurek1@cdc.gov, 304-285-5983)

References

1. Chester DA, Hanna EA, Pickelman BG, Rosenman KD. Asthma death after spraying polyurethane truck bedliner. Am J Ind Med 2005;48:78–84.
2. Friedman-Jiménez G, Beckett WS, Szeinuk J, Petsonk EL. Clinical evaluation, management, and prevention of work-related asthma. Am J Ind Med 2000;37:121–41.
3. Tarlo SM, Balmes J, Balkissoon R, et al. Diagnosis and management of work-related asthma: American College Of Chest Physicians consensus statement. Chest 2008;134(Suppl):S1–41.
4. CDC. Work-related asthma—38 states and District of Columbia, 2006–2009. MMWR Morb Mortal Wkly Rep 2012;61:375–8.
5. CDC. Methodologic changes in the Behavioral Risk Factor Surveillance System in 2011 and potential effects on prevalence estimates. MMWR Morb Mortal Wkly Rep 2012;61:410–3.
6. Blumberg SJ, Luke JV. Reevaluating the need for concern regarding noncoverage bias in landline surveys. Am J Public Health 2009; 99:1806–10.
7. Hu SS, Balluz L, Battaglia MP, Frankel MR. The impact of cell phones on public health surveillance. Bull World Health Organ 2010;88:799.
8. Hu SS, Balluz L, Battaglia MP, Frankel MR. Improving public health surveillance using a dual-frame survey of landline and cell phone numbers. Am J Epidemiol 2011;173:703–11.
9. Jenkins MA, Clarke JR, Carlin JB, et al. Validation of questionnaire and bronchial hyperresponsiveness against respiratory physician assessment in the diagnosis of asthma. Int J Epidemiol 1996;25:609–16.
10. Sama SR, Hunt PR, Cirillo CI, et al. A longitudinal study of adult-onset asthma incidence among HMO members. Environ Health 2003;2:10.

What is already known on this topic?

Work-related asthma (WRA) is a preventable, often underdiagnosed, occupational lung disease. On the basis of the 2006–2009 Behavioral Risk Factor Surveillance System Adult Asthma Call-back Survey (ACBS) data from 38 states and the District of Columbia among ever-employed adults with current asthma, the overall proportion of current asthma that is work-related was estimated to be 9.0%.

What is added by this report?

An estimated 1.9 million cases of asthma among adults were work-related (new-onset and work-exacerbated), accounting for 15.7% of current asthma cases among ever-employed adults, and thus could potentially have been prevented in the 22 states conducting ACBS in 2012. This estimate provides a new baseline for comparison with future estimates and reflects Behavioral Risk Factor Surveillance System methodology changes including new, improved statistical weighting, improved data collection by addition of cellular telephone samples to landline telephone samples, and revision of the ACBS question on WRA diagnosis to specifically ask about asthma caused by or made worse by work.

What are the implications for public health practice?

For many states, ACBS provides the only state-based estimates of WRA. These new results can assist states, other government agencies, health professionals, employers, workers, and worker representatives in prioritizing disease intervention and prevention efforts to reduce the burden of WRA.

Ebola Active Monitoring System for Travelers Returning from West Africa — Georgia, 2014–2015

Mary Parham[1], Laura Edison[2,3], Karl Soetebier[2], Amanda Feldpausch[2], Audrey Kunkes[2], Wendy Smith[2], Taylor Guffey[2], Romana Fetherolf[4], Kathryn Sanlis[3], Julie Gabel[2], Alex Cowell[2], Cherie Drenzek[2] (Author affiliations at end of text)

The Ebola virus disease (Ebola) epidemic in West Africa has so far produced approximately 25,000 cases, more than 40 times the number in any previously documented Ebola outbreak (*1*). Because of the risk for imported disease from infected travelers, in October 2014 CDC recommended that all travelers to the United States from Ebola-affected countries receive enhanced entry screening and postarrival active monitoring for Ebola signs or symptoms until 21 days after their departure from an Ebola-affected country (*2*). The state of Georgia began its active monitoring program on October 25, 2014. The Georgia Department of Public Health (DPH) modified its existing, web-based electronic notifiable disease reporting system to create an Ebola Active Monitoring System (EAMS). DPH staff members developed EAMS from conceptualization to implementation in 6 days. In accordance with CDC recommendations, "low (but not zero) risk" travelers are required to report their daily health status to DPH, and the EAMS dashboard enables DPH epidemiologists to track symptoms and compliance with active monitoring. Through March 31, 2015, DPH monitored 1,070 travelers, and 699 (65%) used their EAMS traveler login instead of telephone or e-mail to report their health status. Medical evaluations were performed on 30 travelers, of whom three were tested for Ebola. EAMS has enabled two epidemiologists to monitor approximately 100 travelers daily,* and to rapidly respond to travelers reporting signs and symptoms of potential Ebola virus infection. Similar electronic tracking systems might be useful for other jurisdictions.

Active monitoring of travelers facilitates early detection of symptoms consistent with Ebola infection, rapid isolation of potential Ebola patients to prevent spread, and appropriate medical evaluation for prompt diagnosis. Active monitoring requires that travelers who are considered low (but not zero) risk (i.e., had been in Ebola-affected countries but had no reported contact with a person who was ill with Ebola) (*3*) report their health status to DPH once daily. The health status report includes their temperatures taken each morning and evening, whether they are experiencing any of a specified list of symptoms commonly associated with Ebola, and any other symptoms of illness. In Georgia, travelers categorized as having "some risk" for exposure (i.e., had contact with Ebola patients while wearing appropriate personal protective equipment) must be observed taking their temperatures each day by an epidemiologist via video direct active monitoring. "High-risk" travelers (i.e., had contact with an Ebola patient without adequate personal protective equipment) are quarantined upon arrival in their homes, or other location designated by DPH, if nonresidents, and also are observed via video connection for daily temperature checks. Active monitoring for Ebola can be labor intensive and costly (*4*). To reduce the burden of monitoring large numbers (>30 each week) of travelers arriving from Ebola-affected countries, DPH developed an automated system to assist with monitoring and data management.

Development and Implementation of EAMS

DPH used the infrastructures of its State Electronic Notifiable Disease Surveillance System (SendSS) and its Public Health Information Portal to rapidly develop and deploy the web-based EAMS. Through close collaboration between DPH information technology development staff and epidemiologists responsible for initiating the active monitoring program, the core functions of EAMS were developed and deployed in 6 days. EAMS's flexibility enables rapid updates for new data collection as surveillance needs are better understood.

EAMS consists of four components: 1) an online query capability designed to enable emergency departments to search EAMS by name and date of birth to quickly determine whether a patient is enrolled in active monitoring, 2) a traveler component that facilitates the online recording of daily symptom data, 3) a public health component that allows DPH epidemiologists to manage travelers throughout their active monitoring period, and 4) a reporting component that provides summary statistics, the capability to produce a line list of travelers, and a summary report to assist with weekly reporting to CDC. Epidemiologists in Georgia's 18 health districts can log into the system to view and follow up with travelers in their own district; however, 14 districts have designated DPH to conduct monitoring.

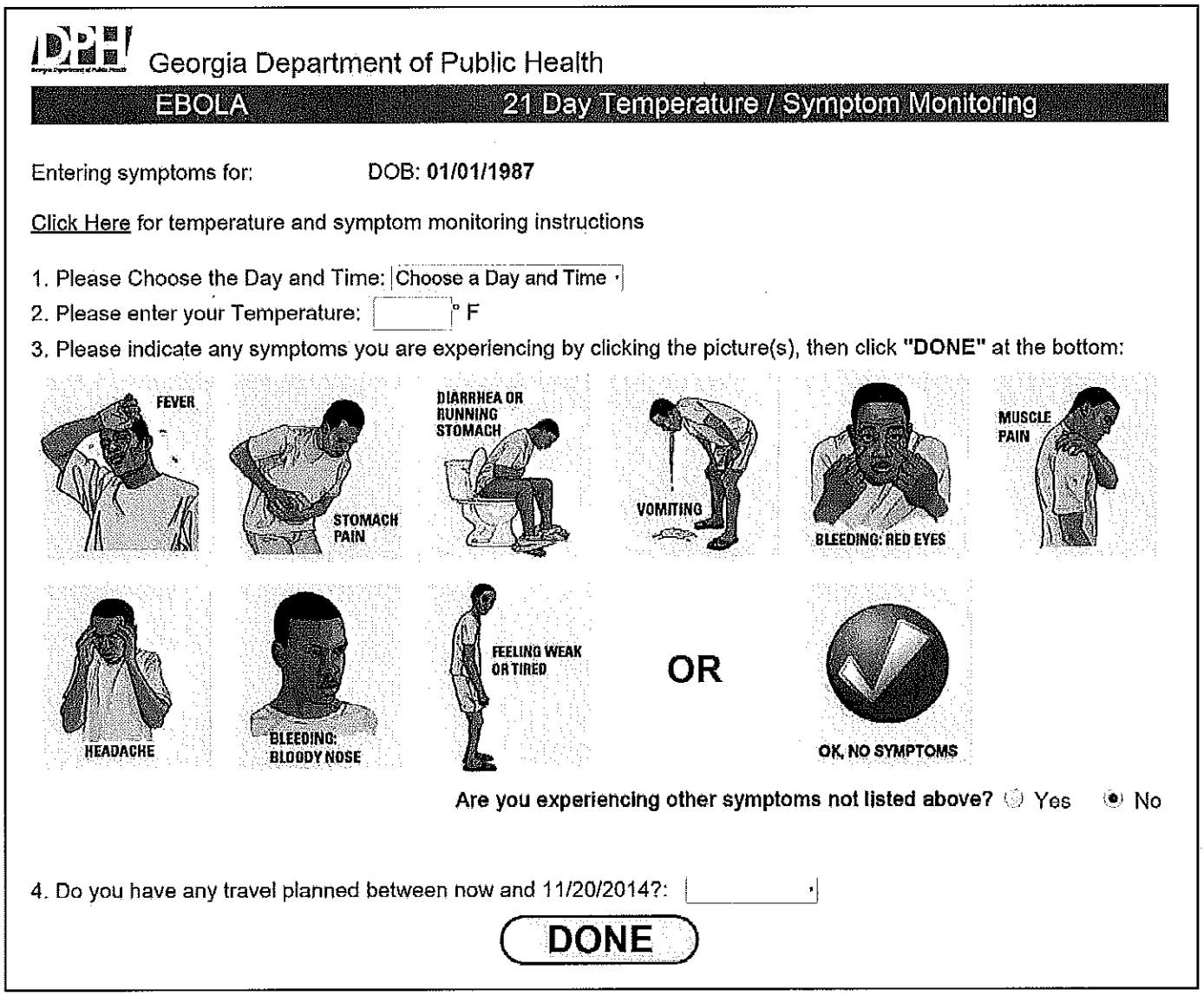
The EAMS process begins when DPH epidemiologists create a record for each traveler from information obtained during entry screening and provided by CDC. The record for each traveler includes demographics, contact information,

*Maintaining a precise count is difficult because persons move in and out of EAMS monitoring every day. Since December, however, the daily average has been 114, with a range of 81–153 per day.

travel-related information, and the traveler's risk categorization. Each record also contains a time-stamped progress notes section that facilitates communication among epidemiologists regarding individual records, including notes about noncompliance or symptomatic travelers. Once the record is created, an epidemiologist conducts a scripted telephone enrollment interview with the traveler to verify and complete information, and explain the system and monitoring requirements. The epidemiologist also provides the traveler with a legally binding Active Monitoring Agreement that explains the traveler's responsibilities, instructions for reporting, and consequences of not reporting. After the enrollment process is completed, an EAMS system–generated e-mail is sent to the traveler that includes an individual username and password for accessing their EAMS account. Using their account, travelers can input their temperature and symptom checks each day into the secure system. Travelers can also report by telephone or e-mail if they prefer.

When reporting through EAMS, travelers log in, select the day and time, then enter their measured body temperatures. The system then prompts the traveler to indicate specific Ebola symptoms using pictorial selection boxes taken from the CDC-developed Ebola care kit (5), and offers a free-text box to enter other symptoms (Figure 1). Travelers also can enter details of any planned upcoming interstate or international

FIGURE 1. Ebola active monitoring system traveler symptom input screen for a fictitious traveler returning from West Africa — Georgia, 2014–2015



travel during their monitoring period so that DPH can notify CDC and the receiving state.

Once travelers are enrolled, EAMS helps epidemiologists monitor travelers' health and compliance with active monitoring through automated e-mail alerts and dashboards. Automated e-mail alerts notify epidemiologists when a traveler reports symptoms or a temperature >99.4° F (>37.2° C). Automated status updates enable the EAMS dashboard to clearly identify travelers who have not reported their temperature and symptom checks by a designated time so that epidemiologists can follow up and assure compliance (Figure 2). The visual dashboard displays the traveler's name, the date of arrival in Georgia, the time remaining in the 21-day monitoring period, whether there are plans to travel to another state or country during the monitoring period, and whether this travel has been reported to CDC. Travelers who report fever or other signs or symptoms are labeled "symptomatic" and an email is sent to designated epidemiologists for follow-up. Travelers who do not report by 2 p.m., Eastern Time, are sent an automated email reminder. At 3 p.m., the status of travelers who have not reported becomes "noncompliant," prompting epidemiologists to attempt contact. A status of "complete" is assigned at the end of travelers' monitoring periods, and an automated e-mail informs them that they no longer need to report.

When symptoms are reported, the traveler is contacted by DPH. Low (but not zero) risk travelers who report mild symptoms (e.g., upper respiratory or gastrointestinal symptoms that don't typically require seeing a clinician) are asked to self-isolate until symptoms subside. If more severe symptoms are reported, including any fever ≥100.4° F (≥38° C) with no other likely diagnosis, DPH epidemiologists coordinate with hospital preparedness personnel in DPH's Emergency Preparedness Section to arrange medical evaluation at a designated hospital near the traveler's current location that has the necessary isolation capabilities and willingness to screen potential Ebola cases. If a traveler needs urgent care or does not have private transportation, DPH will arrange transportation.

Results of Active Monitoring

Active monitoring is conducted by two DPH epidemiologists each day. During October 25, 2014–March 31, 2015, DPH monitored 1,070 travelers (Table). The majority of travelers (65%) used the EAMS login system for one or more of their daily reports, and an estimated 85% reported on time each day to remain compliant. Thirty (2.8%) travelers received medical evaluations. Ebola testing was performed by real-time polymerase chain reaction on specimens from three travelers; all test results were negative. Among the 1,070 actively monitored travelers, 564 (53%) were CDC employees.

Discussion

In October 2014, Ebola was diagnosed in a traveler from West Africa staying in Dallas (*6*). Thereafter, active monitoring was developed and implemented (*2*), enabling the timely detection of illness in travelers, which can facilitate early isolation of potential Ebola patients to prevent the spread of disease, appropriate medical evaluation, and early detection and management of Ebola. EAMS makes it possible for two epidemiologists to monitor approximately 100 travelers each day. It achieves this 1) by allowing travelers to report their own monitoring information via computer or web-enabled mobile telephone, 2) by providing a summary dashboard to

FIGURE 2. Ebola active monitoring system sample visual dashboard — Georgia, 2014–2015

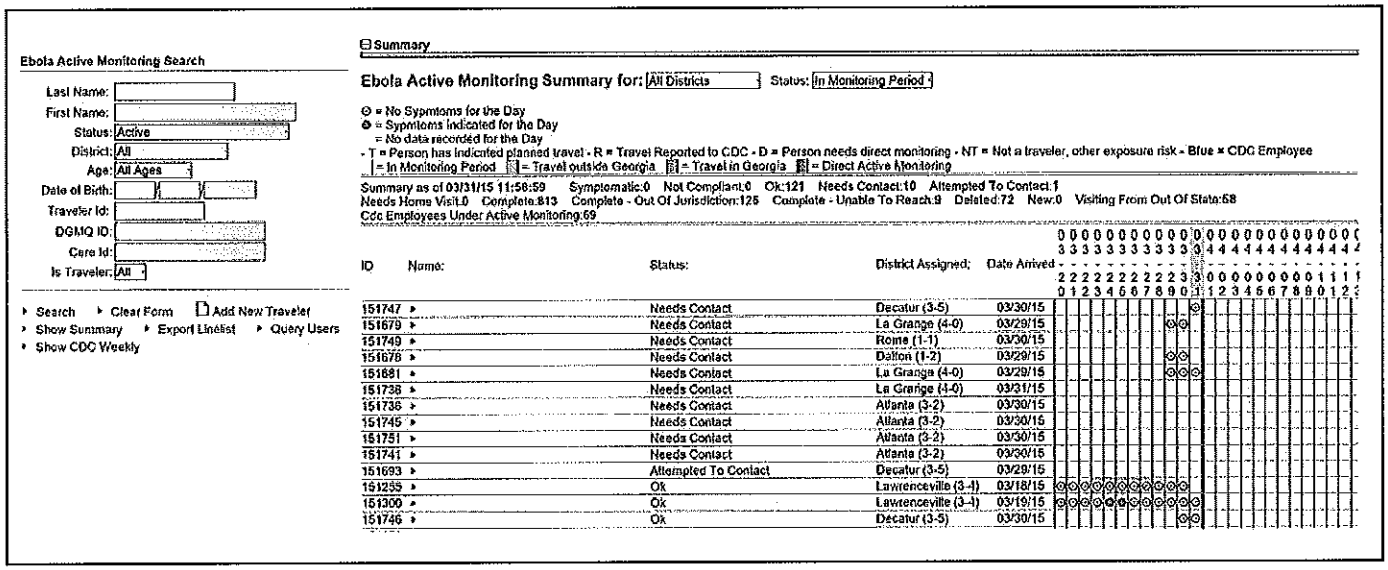


TABLE. Number of travelers from Ebola-affected countries (N = 1,070) actively monitored for signs and symptoms of Ebola, by selected characteristics — Georgia, October 25, 2014-March 31, 2015

Characteristic	No.	(%)
Total monitored	1,070	(100)
Average no. monitored per day*	114	—
Completed monitoring	957†	(89)
Reported using EAMS log-in§	699	(65)
CDC employees monitored	564	(53)
Medical evaluation performed	30	(2.8)
Tested for Ebola¶	3	(0.2)

Abbreviations: EAMS = Ebola Active Monitoring System.
* During December 2014–March 2015.
† As of March 31, 2015; a total of 113 other travelers were still being actively monitored.
§ Travelers logged temperature and symptom reports directly into EAMS for at least one daily report.
¶ Tested by real-time polymerase chain reaction at an Ebola reference laboratory.

allow epidemiologists to quickly assess the status of travelers, and 3) by sending automated e-mail alerts to epidemiologists when symptoms are reported.

Because monitoring must occur every day, including on weekends and holidays, having a web-based system that is accessible from any computer helped foster acceptability among monitoring personnel. The simplicity of EAMS enables travelers to enter their own information if they choose and allows for many travelers to be managed by few epidemiologists. Ease of use for the travelers has resulted in a high level of acceptability, with 65% of travelers choosing to use EAMS direct login over sending e-mails or telephone messages. Most importantly, the instant e-mail alert of reported symptoms to DPH epidemiologists provides timely notification of illness among travelers.

Monitoring for Ebola is necessary to detect and isolate cases early, facilitate medical evaluation, and prevent its spread. Georgia, with its large number of travelers and limited number of DPH epidemiologists, needed an efficient system to ensure the success of its monitoring program. Including DPH's information technology staff as members of Georgia's Ebola response team was crucial to Georgia's ability to develop this flexible online module in 6 days. Similar systems might be useful for other jurisdictions and might potentially reduce the cost of monitoring (*4*). EAMS also might serve as a model for meeting the surveillance needs of other public health programs in a timely manner.

What is already known on this topic?

Because Ebola can only be transmitted through close contact with a person who has developed symptoms, close monitoring of persons with potential exposure facilitates early identification of suspected cases, appropriate medical evaluation, and rapid isolation to prevent further spread.

What is added by this report?

Modifying and leveraging the existing infrastructure of the current Georgia State Electronic Notifiable Disease Surveillance System has provided the flexibility for two staff members to efficiently and effectively monitor approximately 100 travelers from Ebola-affected countries on a daily basis.

What are the implications for public health practice?

Simple electronic tools can be adapted or developed for active monitoring and make data easily accessible to epidemiologists. Such systems also can enable travelers being monitored to take an active role in their own reporting. The system has been instrumental in the successful monitoring of Georgia's travelers from Ebola-affected countries, and similar systems might be useful for other jurisdictions.

[1]Center for Surveillance, Epidemiology and Laboratory Services, CDC; [2]Georgia Department of Public Health; [3]Division of State and Local Readiness, CDC; [4]Office for State, Tribal, Local, and Territorial Support, CDC (Corresponding author: Mary Parham, maparham@cdc.gov, 404-657-6438)

References

1. CDC. Ebola (Ebola virus disease). Outbreaks chronology. Atlanta, GA: US Department of Health and Human Services, CDC; 2014. Available at http://www.cdc.gov/vhf/ebola/outbreaks/history/chronology.html.
2. CDC. Ebola (Ebola virus disease). Risk of exposure. Interim U.S. guidance for monitoring and movement of persons with potential Ebola virus exposure. Atlanta, GA: US Department of Health and Human Services, CDC; 2014. Available at http://www.cdc.gov/vhf/ebola/exposure/monitoring-and-movement-of-persons-with-exposure.html.
3. CDC. Ebola (Ebola virus disease). Risk of exposure. Epidemiologic risk factors to consider when evaluating a person for exposure to Ebola virus. Atlanta, GA: US Department of Health and Human Services, CDC; 2014. Available at http://www.cdc.gov/vhf/ebola/exposure/risk-factors-when-evaluating-person-for-exposure.html.
4. Yacisin K, Balter S, Fine A, et al. Ebola virus disease in a humanitarian aid worker—New York City, October 2014. MMWR Morb Mortal Wkly Rep 2015;64:321–3.
5. CDC. Ebola (Ebola virus disease). Travelers. Ebola care kit. Atlanta, GA: US Department of Health and Human Services, CDC; 2014. Available at http://www.cdc.gov/vhf/ebola/travelers/care-kit.html.
6. Chevalier MS, Chung W, Smith J, et al. Ebola virus disease cluster in the United States—Dallas County, Texas, 2014. MMWR Morb Mortal Wkly Rep 2014;63:1097–8.

Progress in Identifying Infants with Hearing Loss — United States, 2006–2012

Tonya R. Williams, PhD[1], Suhana Alam, MPH[1], Marcus Gaffney, MPH[1] (Author affiliations at end of text)

Congenital hearing loss affects one to three of every 1,000 live born infants (*1*) and negatively impacts children through delayed speech, language, social, and emotional development when undetected (*2,3*). To address this public health issue, jurisdiction-based Early Hearing Detection and Intervention (EHDI) programs are working to ensure all newborns are screened for hearing loss, receive follow-up diagnostic testing (DX) if they do not pass the screening, and are enrolled in early intervention (EI) services if diagnosed with a permanent hearing loss. Although substantial progress has been made in the provision and documentation of services, challenges remain because, unlike screening results, diagnostic test results and enrollment in EI are not consistently reported to the EHDI programs. Therefore, it is difficult for states and territories to know if infants received recommended follow-up services (diagnostic testing and/or EI services), often resulting in infants being classified at either stage as lost to follow-up (LFU)/lost to documentation (LTD). To assess progress toward identifying children with hearing loss and reducing LFU/LTD for DX (LFU/LTD-DX) and EI enrollment (LFU/LTD-EI*), CDC analyzed EHDI surveillance data for 2006–2012. Results indicated that the number of jurisdictions reporting data increased from 49 to 57, rates of screening increased from 95.2% to 96.6%, rates of referral from screening decreased from 2.3% to 1.6%, rates of diagnosis among infants not passing their final screening increased from 4.8% to 10.3%, and enrollment in EI among children diagnosed with hearing loss increased from 55.4% to 61.7%, whereas rates for both LFU/LTD-DX and LFU/LTD-EI declined. These findings show sustained progress toward screening, identification, and enrollment in EI as well as highlighting the need for continued improvements in the provision and documentation of EHDI services.

Data were gathered by using the EHDI Hearing Screening and Follow-up Survey (HSFS), which was fully implemented starting in 2006. This survey is sent annually to the EHDI program coordinator in each U.S. state, the District of Columbia, and each participating territory and freely associated state. The HSFS requests nonestimated, aggregate information about the receipt of hearing screening, diagnostic testing, and EI for every occurrent birth within the jurisdiction. The numbers of occurrent births are compared for accuracy with data from the jurisdiction's Vital Records program and the National Vital Statistics System. Infants were classified as LFU/LTD-DX or LFU/LTD-EI if they did not receive recommended follow-up services or if they received services without the results being reported to the jurisdictional EHDI program. LTD can occur because the results of diagnostic testing and enrollment in EI are not universally required to be reported. Although strategies used to target LFU and LTD differ, these two categories are grouped together in the HSFS because it is problematic for most programs to differentiate between these different types of cases. The denominators for LFU/LTD-DX and LFU/LTD-EI used by CDC are total infants not passing the final hearing screening and total infants identified with a permanent hearing loss, respectively. More details about the HSFS and data definitions have been published (*4,5*). The reasons for being LFU/LTD listed in the HSFS include the following: the parents/family were contacted but unresponsive, unable to contact, and unknown. Cases in which the infant died, the parents refused services, or the parents moved were not classified as LFU/LTD.[†]

Data for this report are based on the HSFS conducted for the years 2006–2012, using aggregate jurisdiction-reported totals. Some jurisdictions did not respond to the HSFS in ≥1 years because completion of the survey is voluntary, the requested data were not available at the time of reporting, or another reason. Data for individual years and data at the jurisdictional level are available online.[§] Eighty-three percent of jurisdictions responded to the survey in 2006, and 97% responded in 2012. Information was excluded if, after consultation with

* **Lost to follow-up (LFU)** describes an event in which an infant needs a specific follow-up action but does not receive it. LFU for diagnosis (LFU-DX) occurs when an infant does not pass the hearing screening, is referred for diagnostic testing by a qualified provider (e.g., an audiologist) but never receives the testing needed to confirm whether a hearing loss is present. LFU for early intervention (LFU-EI) occurs when an infant diagnosed with a permanent hearing loss is not enrolled in any early intervention services. **Lost to documentation (LTD)** describes an event in which an infant receives a specific follow-up action, but neither confirmation that the follow-up was provided nor the results are reported to the jurisdictional EHDI program. LTD for diagnosis (LTD-DX) occurs when an infant not passing the hearing screening does receive follow-up testing that either confirms a hearing loss or does not identify any loss but this information is not reported to the jurisdictional EHDI program. LTD for early intervention (LTD-EI) occurs when an infant diagnosed with a permanent hearing loss is enrolled in early intervention services but this information is not reported to the jurisdictional EHDI program.

† In 2006, of those infants needing diagnostic follow-up testing, 998 (2.2%) did not receive it because of parent refusals or infant deaths and 510 (1.1%) because of being nonresidents or moving out of state. In 2012, of those infants needing diagnostic follow-up testing, 2,141 (4.0%) did not receive it because of parent refusals or infant deaths and 1,505 (2.8%) because of being nonresidents or moving out of state.

§ Available at http://www.cdc.gov/ncbddd/hearingloss/ehdi-data.html.

TABLE 1. Number and percentages of infants screened, diagnosed, and enrolled in early intervention programs for hearing loss, by jurisdiction and birth year — United States, 2006*

	2006										
	Screening		Diagnosis					Early intervention			
	Screened	Not pass screening	Permanent hearing loss			LFU/LTD-DX		Enrolled		LFU/LTD-EI	
Jurisdiction†	(%)	No.	No.	%	Prevalence per 1,000 screened	No.	(%)	No.	(%)	No.	(%)
Alabama	(97.6)	2,699	43	(1.6)	0.7	572	(21.2)	32	(74.4)	11	(25.6)
Alaska	(90.4)	301	21	(7.0)	2.1	224	(74.4)	0	—	21	(100.0)
American Samoa	—	—	—	—	—	—	—	—	—	—	—
Arizona	(96.3)	1,982	107	(5.4)	1.1	1,722	(86.9)	98	(91.6)	2	(1.9)
Arkansas	(97.1)	948	45	(4.7)	1.2	590	(62.2)	12	(26.7)	32	(71.1)
California	—	—	—	—	—	—	—	—	—	—	—
Colorado	(98.0)	192	115	(59.9)	1.7	17	(8.9)	115	(100.0)	0	—
CNMI	98.9)	38	2	(5.3)	1.4	27	(71.1)	2	(100.0)	0	—
Connecticut	(99.0	383	62	(16.2)	1.5	41	(10.7)	40	(64.5)	14	(22.6)
Delaware	—	—	—	—	—	—	—	—	—	—	—
DC	(99.3)	241	8	(3.3)	0.5	0	—	8	(100.0)	0	—
Florida	(87.9)	2,655	185	(7.0)	0.8	2,470	(93.0)	121	(65.4)	55	(29.7)
Georgia	(97.5)	5,326	52	(1.0)	0.4	5,271	(99.0)	31	(59.6)	19	(36.5)
Guam	(83.8)	119	8	(6.7)	2.8	104	(87.4)	3	(37.5)	2	(25.0)
Hawaii	(98.6)	255	62	(24.3)	3.3	75	(29.4)	49	(79.0)	2	(3.2)
Idaho	(99.1)	1,039	30	(2.9)	1.3	63	(6.1)	28	(93.3)	0	—
Illinois	—	—	—	—	—	—	—	—	—	—	—
Indiana	(97.8)	1,665	112	(6.7)	1.3	248	(14.9)	—	—	—	—
Iowa	(97.7)	1,944	73	(3.8)	1.9	0	—	—	—	—	—
Kansas	(96.6)	1,196	68	(5.7)	1.7	0	—	12	(17.6)	54	(79.4)
Kentucky	(99.3)	2,193	33	(1.5)	0.6	1,348	(61.5)	23	(69.7)	10	(30.3)
Louisiana	(95.9)	1,617	34	(2.1)	0.6	1,484	(91.8)	18	(52.9)	15	(44.1)
Maine	(96.6)	305	13	(4.3)	1.0	194	(63.6)	0	—	13	(100.0)
Marshall Islands	—	—	—	—	—	—	—	—	—	—	—
Maryland	(94.8)	3,620	108	(3.0)	1.5	3,369	(93.1)	0	—	108	(100.0)
Massachusetts	(98.9)	1,299	226	(17.4)	2.9	93	(7.2)	152	(67.3)	54	(23.9)
Michigan	(98.0)	1,882	101	(5.4)	0.8	1,324	(70.4)	33	(32.7)	68	(67.3)
Micronesia	—	—	—	—	—	—	—	—	—	—	—
Minnesota	(82.6)	2,695	65	(2.4)	1.1	2,601	(96.5)	29	(44.6)	36	(55.4)
Mississippi	(98.6)	541	70	(12.9)	1.6	41	(7.6)	40	(57.1)	16	(22.9)
Missouri	(98.4)	1,387	35	(2.5)	0.4	509	(36.7)	25	(71.4)	9	(25.7)

See table footnotes on next page.

a jurisdictional EHDI program, the reported data were found to be incomplete or derived from estimated information. Because some jurisdictions did not respond to the survey in ≥1 years, there are differences in the number of jurisdictions reporting each year.

In 2012, an average of 96.6% of newborns were screened for hearing loss compared with 95.2% in 2006 (Tables 1 and 2). Overall, the number and average percentage of those infants that did not pass the hearing screening and were subsequently diagnosed with a permanent hearing loss increased from 4.8% (3,261) to 10.3% (5,475). The proportion of infants identified with hearing loss increased from 1.1 to 1.6 per 1,000 infants screened (Figure). For those infants with a confirmed, permanent hearing loss, an average of 61.7% were documented as receiving EI in 2012 compared with 55.4% in 2006 (Tables 1 and 2). The average percentage of LFU/LTD-DX decreased from 47.7% to 35.9%, and the average percentage of LFU/LTD-EI decreased from 40.3% to 24.6% (Figure).

Based on available data from the HSFS, a number of jurisdictions have made progress in documenting the diagnosis of infants with permanent hearing loss and their enrollment in EI. For example, 10 jurisdictions had an improvement of at least 10% for diagnosed hearing loss among infants who did not pass the hearing screening (Tables 1 and 2). Seventeen jurisdictions had at least a 10% improvement in infants enrolled in EI. In addition, 12 jurisdictions had a 30% decrease in LFU/LTD-DX, and 12 jurisdictions had at least a 30% decrease in their LFU/LTD-EI rates.

Discussion

Improvements in the provision and documentation of EHDI services between 2006 and 2012 have resulted in decreases in the rate of infants referred from screening and increases in

TABLE 1. (*Continued*) Number and percentages of infants screened, diagnosed, and enrolled in early intervention programs for hearing loss, by jurisdiction and birth year — United States, 2006*

	2006										
	Screening		Diagnosis					Early intervention			
	Screened	Not pass screening	Permanent hearing loss			LFU/LTD-DX		Enrolled		LFU/LTD-EI	
Jurisdiction†	(%)	No.	No.	%	Prevalence per 1,000 screened	No.	(%)	No.	(%)	No.	(%)
Montana	(93.0)	392	17	(4.3)	1.5	374	(95.4)	0	—	17	(100.0)
Nebraska	(98.9)	181	28	(15.5)	1.1	104	(57.5)	16	(57.1)	12	(42.9)
Nevada	—	—	—	—	—	—	—	—	—	—	—
New Hampshire	(98.7)	318	58	(18.2)	4.2	188	(59.1)	33	(56.9)	25	(43.1)
New Jersey	(98.9)	1,876	102	(5.4)	0.9	1,454	(77.5)	69	(67.6)	30	(29.4)
New Mexico	(71.5)	1,342	38	(2.8)	1.9	0	—	37	(97.4)	0	—
New York	(98.9)	—	—	—	—	—	—	—	—	—	—
North Carolina	(98.2)	1,505	234	(15.5)	1.8	808	(53.7)	146	(62.4)	88	(37.6)
North Dakota	(96.6)	424	6	(1.4)	0.8	397	(93.6)	0	—	6	(100.0)
Ohio	—	—	—	—	—	—	—	—	—	—	—
Oklahoma	(95.0)	1,875	81	(4.3)	1.6	468	(25.0)	70	(86.4)	7	(8.6)
Oregon	(38.6)	930	78	(8.4)	4.2	359	(38.6)	53	(67.9)	17	(21.8)
Palau	(74.1)	—	—	—	—	—	—	—	—	—	—
Pennsylvania	(95.5)	1,400	143	(10.2)	1.0	290	(20.7)	143	(100.0)	0	—
Rhode Island	(98.9)	141	15	(10.6)	1.2	17	(12.1)	12	(80.0)	2	(13.3)
South Carolina	(98.3)	1,911	77	(4.0)	1.3	509	(26.6)	56	(72.7)	21	(27.30
South Dakota	(97.8)	427	4	(0.9)	0.3	381	(89.2)	0	—	4	(100.0)
Tennessee	(89.9)	3,499	50	(1.4)	0.6	1,297	(37.1)	28	(56.0)	15	(30.0)
Texas	(98.7)	7,656	259	(3.4)	0.7	487	(6.4)	0	—	259	(100.0)
Utah	(98.4)	731	56	(7.7)	1.1	414	(56.6)	33	(58.9)	20	(35.7)
Vermont	(96.3)	59	9	(15.3)	1.5	29	(49.2)	5	(55.6)	4	(44.4)
Virginia	(97.6)	2,318	132	(5.7)	1.3	486	(21.0)	93	(70.5)	21	(15.9)
Washington	(93.9)	2,302	119	(5.2)	1.5	1,731	(75.2)	0	—	119	(100.0)
West Virginia	(96.0)	67	11	(16.4)	0.5	3	(4.5)	6	(54.5)	3	(27.3)
Wisconsin	(93.9)	1,586	52	(3.3)	0.8	0	—	24	(46.2)	28	(53.8)
Wyoming	(98.6)	28	14	(50.0)	2.0	6	(21.4)	8	(57.1)	0	—
Totals	**(95.2)**	**67,490**	**3,261**	**(4.8)**	**1.1**	**32,189**	**(47.7)**	**1,703**	**(55.4)**	**1,239**	**(40.3)**

Abbreviations: CNMI = Commonwealth of Northern Mariana Islands; DC = District of Columbia; LFU/LTD-DX = lost to follow-up/lost to documentation for diagnostic testing; LFU/LTD-EI = lost to follow-up/lost to documentation for early intervention.
Source: The Early Hearing Detection and Intervention program's Hearing Screening and Follow-up Survey.
* Some jurisdictions did not provide complete data.
† More comparisons can be made using interactive maps at http://ehdidash.cdc.gov/IAS_WebApp/.

infants receiving the testing needed to confirm a hearing loss. This progress has helped drive increases in the number of children reported with permanent hearing loss from 3,261 (2006) to 5,475 (2012) and an increase in prevalence from 1.1 to per 1.6 per 1,000 screened. The increase in documented cases was accompanied by a decrease in LFU/LTD-DX of 11.8% between 2006 and 2012. Similarly, the documented receipt of EI services increased by 6.3% while LFU/LTD-EI decreased by 15.7%. Other factors that contributed at least in part to this progress include 1) improvements in the functionality of state and territorial EHDI information systems, 2) increased awareness among health care providers about the importance of documenting the receipt of follow-up services, 3) continued progress by state and territorial EHDI programs in tracking infants needing follow-up services, and 4) active support by national agencies and organizations.

To build on the progress already made in diagnosing and enrolling infants with hearing loss in EI services, continued work is needed to further reduce the number of infants classified as LFU/LTD each year. Unless infants with hearing loss receive recommended diagnostic and EI services, they are still at risk for avoidable delays in their speech and language development (*2,3*). In addition, without appropriate documentation, it is difficult to ensure infants are receiving recommended services. Additional coordination among audiologists, physicians, jurisdictional EHDI, and EI programs can further improve documentation and provision of services.

This report updates an earlier summary of EHDI data during 1999–2007 that provided information on infants with hearing loss (*4*). Since that time, there have been several important policy and practice changes that could have had a direct impact on rates of LFU/LTD. For example, some hospitals

TABLE 2. Number and percentages of infants screened, diagnosed, and enrolled in early intervention programs for hearing loss, by jurisdiction and birth year — United States, 2012*

	2012										
	Screening		Diagnosis					Early intervention			
	Screened	Not pass screening	Permanent hearing loss			LFU/LTD-DX		Enrolled		LFU/LTD-EI	
Jurisdiction†	(%)	No.	No.	(%)	Prevalence per 1,000 screened	No.	(%)	No.	(%)	No.	(%)
Alabama	(98.5)	222	60	(27.0)	1.1	86	(38.7)	35	(58.3)	10	(16.7)
Alaska	(95.8)	159	22	(13.8)	2.1	72	(45.3)	11	(50.0)	6	(27.3)
American Samoa	(99.2)	10	1	(10.0)	0.9	4	(40.0)	0	—	0	—
Arizona	(98.8)	833	157	(18.8)	1.8	410	(49.2)	61	(38.9)	8	(5.1)
Arkansas	(95.4)	743	40	(5.4)	1.1	248	(33.4)	13	(32.5)	10	(25.0)
California	(95.9)	2,770	945	(34.1)	2.0	436	(15.7)	718	(76.0)	54	(5.7)
Colorado	(97.9)	716	116	(16.2)	1.8	538	(75.1)	55	(47.4)	35	(30.2)
CNMI	(97.8)	27	3	(11.1)	2.7	15	(55.6)	3	(100.0)	0	—
Connecticut	(98.9)	579	50	(8.6)	1.4	202	(34.9)	35	(70.0)	13	(26.0)
Delaware	(99.0)	209	20	(9.6)	1.8	101	(48.3)	0	—	20	(100.0)
DC	(86.3)	374	25	(6.7)	2.1	52	(13.9)	21	(84.0)	4	(16.0)
Florida	(97.3)	1,625	225	(13.8)	1.1	736	(45.3)	167	(74.2)	34	(15.1)
Georgia	(97.3)	1,115	229	(20.5)	1.8	491	(44.0)	143	(62.4)	28	(12.2)
Guam	(99.1)	25	9	(36.0)	2.9	3	(12.0)	8	(88.9)	0	—
Hawaii	(98.3)	221	54	(24.4)	2.9	33	(14.9)	36	(66.7)	9	(16.7)
Idaho	(99.3)	720	64	(8.9)	3.0	226	(31.4)	62	(96.9)	1	(1.6)
Illinois	(99.4)	—	—	—	—	—	—	198	(81.5)	44	(18.1)
Indiana	(96.6)	2,364	145	(6.1)	1.8	257	(10.9)	83	(57.2)	48	(33.1)
Iowa	(98.7)	461	48	(10.4)	1.3	127	(27.5)	36	(75.0)	9	(18.8)
Kansas	(98.7)	354	93	(26.3)	2.3	42	(11.9)	67	(72.0)	17	(18.3)
Kentucky	(99.6)	2,344	58	(2.5)	1.1	240	(10.2)	38	(65.5)	20	(34.5)
Louisiana	(98.9)	3,404	66	(1.9)	1.1	1,073	(31.5)	43	(65.2)	15	(22.7)
Maine	(97.9)	208	23	(11.1)	1.9	33	(15.9)	13	(56.5)	8	(34.8)
Marshall Islands	(52.1)	47	2	(4.3)	4.3	39	(83.0)	0	—	2	(100.0)
Maryland	(99.4)	820	78	(9.5)	1.1	257	(31.3)	49	(62.8)	24	(30.8)
Massachusetts	(99.1)	1,153	200	(17.3)	2.8	29	(2.5)	143	(71.5)	18	(9.0)
Michigan	(99.0)	1,173	162	(13.8)	1.5	569	(48.5)	32	(19.8)	125	(77.2)
Micronesia	(91.6)	—	—	—	—	—	—	—	—	—	—
Minnesota	(98.1)	601	162	(27.0)	2.4	150	(25.0)	83	(51.2)	48	(29.6)
Mississippi	(98.9)	492	76	(15.4)	2.0	26	(5.3)	58	(76.3)	9	(11.8)
Missouri	(97.9)	1,431	100	(7.0)	1.3	461	(32.2)	66	(66.0)	7	(7.0)

See table footnotes on next page.

and EHDI programs now assist parents in making appointments for follow-up testing and calling families to remind them about upcoming appointments. These and other changes were developed during a collaborative improvement project funded by the Health Resources and Services Administration. All jurisdictions participated in this project and worked to develop strategies specific to their jurisdiction to increase the rates of documented follow-up testing and enrollment in EI services.¶

The findings in this report are subject to at least five limitations. First, some states and territories either did not respond to the HSFS or were only able to provide limited data in ≥1 reporting years. As a result there are differences in the number of jurisdictions reporting data each year. Second, the data reported only reflect those services that infants were documented to have received. Because reporting of newborn hearing screening and follow-up data are not required in each state and territory, it is possible for a jurisdiction to have a higher percentage of infants receiving diagnostic and EI services (and therefore lower rates of LFU/LTD) than what was reported by the HSFS. Third, there are multiple ways to calculate LFU/LTD, and the CDC definition might not fully reflect the progress jurisdictions have made in ensuring that infants receive recommended follow-up services. Fourth, there is variation between jurisdictions in the percentage diagnosed with permanent hearing loss and the reasons for this, including the impact of different screening protocols, cannot be assessed with currently available HSFS data. Fifth, all HSFS data are reported voluntarily and might include inaccuracies because some jurisdictions did not correctly report LFU/LTD and other data in accordance with the HSFS data definitions.

¶ Additional information available at http://newbornhearing.nichq.org/solutions/ihsis.

TABLE 2. (*Continued*) Number and percentages of infants screened, diagnosed, and enrolled in early intervention programs for hearing loss, by jurisdiction and birth year — United States, 2012*

	2012										
	Screening		Diagnosis					Early intervention			
	Screened	Not pass screening	Permanent hearing loss			LFU/LTD-DX		Enrolled		LFU/LTD-EI	
Jurisdiction†	(%)	No.	No.	(%)	Prevalence per 1,000 screened	No.	(%)	No.	(%)	No.	(%)
Montana	(96.3)	193	14	(7.3)	1.2	94	(48.7)	7	(50.0)	5	(35.7)
Nebraska	(99.4)	120	36	(30.0)	1.4	34	(28.3)	30	(83.3)	2	(5.6)
Nevada	(95.8)	340	41	(12.1)	1.2	174	(51.2)	34	(82.9)	3	(7.3)
New Hampshire	(97.8)	356	13	(3.7)	1.1	129	(36.2)	12	(92.3)	0	—
New Jersey	(99.4)	883	129	(14.6)	1.3	378	(42.8)	92	(71.3)	24	(18.6)
New Mexico	(66.6)	911	46	(5.0)	2.6	693	(76.1)	37	(80.4)	9	(19.6)
New York	(83.2)	—	—	—	—	—	—	—	—	—	—
North Carolina	(99.1)	854	190	(22.2)	1.6	323	(37.8)	161	(84.7)	13	(6.8)
North Dakota	(98.8)	369	24	(6.5)	2.1	182	(49.3)	24	(100.0)	0	—
Ohio	(98.6)	3,945	213	(5.4)	1.5	1,254	(31.8)	129	(60.6)	68	(31.9)
Oklahoma	(99.0)	2,386	74	(3.1)	1.5	592	(24.8)	57	(77.0)	17	(23.0)
Oregon	(96.3)	1,287	82	(6.4)	1.9	624	(48.5)	56	(68.3)	18	(22.0)
Palau	(99.3)	4	0	—	0.0	2	(50.0)	—	—	—	—
Pennsylvania	(95.6)	2,270	206	(9.1)	1.5	176	(7.8)	162	(78.6)	16	(7.8)
Rhode Island	(99.4)	116	12	(10.3)	1.0	24	(20.7)	11	(91.7)	0	—
South Carolina	(96.9)	775	85	(11.0)	1.6	388	(50.1)	40	(47.1)	45	(52.9)
South Dakota	(98.1)	280	27	(9.6)	2.2	234	(83.6)	0	—	27	(100.0)
Tennessee	(97.9)	3,585	84	(2.3)	1.0	1,239	(34.6)	73	(86.9)	9	(10.7)
Texas	(98.8)	4,927	412	(8.4)	1.1	3,776	(76.6)	70	(17.0)	241	(58.5)
Utah	(98.9)	696	100	(14.4)	1.9	381	(54.7)	70	(70.0)	19	(19.0)
Vermont	(99.9)	155	3	(1.9)	0.5	46	(29.7)	2	(66.7)	0	—
Virginia	(98.4)	1,100	161	(14.6)	1.6	407	(37.0)	110	(68.3)	48	(29.8)
Washington	(95.0)	988	154	(15.6)	1.9	495	(50.1)	0	—	154	(100.0)
West Virginia	(85.7)	597	8	(1.3)	0.4	310	(51.9)	4	(50.0)	4	(50.0)
Wisconsin	(99.1)	577	110	(19.1)	1.7	85	(14.7)	54	(49.1)	56	(50.9)
Wyoming	(96.3)	47	18	(38.3)	2.7	10	(21.3)	15	(83.3)	0	—
Totals	**(96.6)**	**52,961**	**5,475**	**(10.3)**	**1.6**	**19,006**	**(35.9)**	**3,527**	**(61.7)**	**1,404**	**(24.6)**

Abbreviations: CNMI = Commonwealth of Northern Mariana Islands; DC = District of Columbia; LFU/LTD-DX = lost to follow-up/lost to documentation for diagnostic testing; LFU/LTD-EI = lost to follow-up/lost to documentation for early intervention.
Source: The Early Hearing Detection and Intervention program's Hearing Screening and Follow-up Survey.
* Some jurisdictions did not provide complete data.
† More comparisons can be made using interactive maps at http://ehdidash.cdc.gov/IAS_WebApp/.

To build on the recent improvements summarized here and ensure continued progress toward identifying and providing EI for all infants with permanent hearing loss, current practices should evolve and take advantage of new collaborations and opportunities, such as emerging technologies. Improvements in existing clinical and public health infrastructures and adoption of technologies, such as electronic health records and clinical decision support tools, can assist providers and EHDI programs in improving coordination, delivery, and documentation of recommended EHDI services (*6–9*).

Acknowledgments

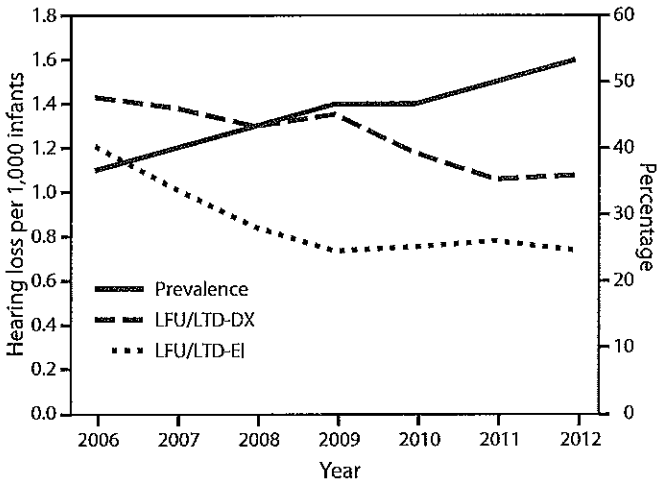
EHDI programs in U.S. states, American Samoa, the Commonwealth of the Northern Mariana Islands, the District of Columbia, Guam, the Marshall Islands and Palau.

[1]Division of Human Development and Disability, National Center on Birth Defects and Developmental Disabilities, CDC (Corresponding author: Tonya R. Williams, twilliams10@cdc.gov, 404-498-3026)

References

1. Vohr B. Overview: Infants and children with hearing loss—part I. Ment Retard Dev Disabil Res Rev 2003;9:62–4.
2. Kusché CA, Greenberg MT. Evaluative understanding and role-taking ability: a comparison of deaf and hearing children. Child Dev 1983;54:141–7.
3. Culbertson JL, Gilbert LE. Children with unilateral sensorineural hearing loss: cognitive, academic, and social development. Ear Hear 1986;7:38–42.
4. CDC. Identifying infants with hearing loss—United States, 1999–2007. MMWR Morb Mortal Wkly Rep 2010;59:220–3.
5. Mason CA, Gaffney M, Green DR, Grosse SD. Measures of follow-up in early hearing detection and intervention programs: a need for standardization. Am J Audiol 2008;17:60–7.

FIGURE. Prevalence of infants identified with hearing loss and percentage of those infants who were lost to follow-up/lost to documentation (LFU/LTD) for diagnostic testing (DX) or for early intervention (EI) — United States, 2006–2012



6. Ross DS, Visser SN. Pediatric primary care physicians' practices regarding newborn hearing screening. J Prim Care Community Health 2012; 3:256–63.
7. Frieden TR, Mostashari F. Health care as if health mattered. JAMA 2008;299:950–2.
8. Congressional Budget Office. Evidence on the costs and benefits of health information technology. Pub. No. 2976. Washington, DC: Congressional Budget Office; 2008. Available at https://www.cbo.gov/sites/default/files/05-20-healthit.pdf.
9. Chaudhry B, Wang J, Wu S, et al. Systematic review: impact of health information technology on quality, efficiency, and costs of medical care. Ann Intern Med 2006;144:742–52.

What is already known on this topic?

Progress has been made in screening and diagnosing infants with hearing loss, reducing the number of infants lost to follow-up/lost to documentation, and increasing enrollment in early intervention. Ensuring infants receive recommended services is crucial to help prevent delays in speech, language, social, and emotional development that can occur when permanent hearing loss is not identified early.

What is added by this report?

Analysis of Early Hearing Detection and Intervention program survey data showed that, during 2006–2012, the number of jurisdictions reporting data increased from 49 to 57, rates of screening increased from 95.2% to 96.6%, rates of diagnosis among infants not passing the final screening increased from 4.8% to 10.3%, and enrollment in early intervention of infants diagnosed with permanent hearing loss increased from 55.4% to 61.7%, while the rates of lost to follow-up/lost to documentation declined.

What are the implications for public health practice?

EHDI programs should continue to work with health care providers who provide diagnostic and early intervention services to accurately document the receipt of necessary follow-up services, thereby increasing the opportunities for infants to receive proper care to minimize the negative impact that hearing loss can have on their speech, language, and emotional development.

Progress Toward Measles Elimination — Philippines, 1998–2014

Yoshihiro Takashima, MD[1], W. William Schluter, MD[1], Kayla Mae L. Mariano[1], Sergey Diorditsa, MD[1], Maricel de Quiroz Castro[2], Alan C. Ou, MD[2], Maria Joyce U. Ducusin, MD[3], Luzviminda C. Garcia,[3] Dulce C. Elfa,[3] Alya Dabbagh, PhD[4], Paul Rota, PhD[5], James L. Goodson, MPH[6]
(Author affiliations at end of text)

In 2005, the Regional Committee for the World Health Organization (WHO) Western Pacific Region (WPR) established a goal to eliminate measles* by 2012 (*1*).The recommended elimination strategies in WPR include 1) ≥95% 2-dose coverage with measles-containing vaccine (MCV) through routine immunization services and supplementary immunization activities (SIAs)†; 2) high-quality case-based measles surveillance; 3) laboratory surveillance with timely and accurate testing of specimens to confirm or discard suspected cases and detect measles virus genotypes; and 4) measles outbreak preparedness, rapid response, and appropriate case management (*2*). In the WPR, the Philippines set a national goal in 1998 to eliminate measles by 2008 (*3*). This report describes progress toward measles elimination in the Philippines during 1998–2014 and challenges remaining to achieve the goal. WHO–United Nations Children's Fund (UNICEF)–estimated coverage with the routine first dose of MCV (MCV1) increased from 80% in 1998 to 90% in 2013, and coverage with the routine second dose of MCV (MCV2) increased from 10% after nationwide introduction in 2010 to 53% in 2013. After nationwide SIAs in 1998 and 2004, historic lows in the numbers and incidence of reported measles cases occurred in 2006. Despite nationwide SIAs in 2007 and 2011, the number of reported cases and incidence generally increased during 2007–2012, and large measles outbreaks occurred during 2013–2014 that affected infants, young children, older children, and young adults and that were prolonged by delayed and geographically limited outbreak response immunization activities during 2013–2014. For the goal of measles elimination in WPR to be achieved, sustained investments are required in the Philippines to strengthen health systems, implement the recommended elimination strategies, and develop additional strategies to identify and reduce measles susceptibility in specific geographic areas and older age groups.

Immunization Activities

MCV1 and MCV2 coverage data are reported each year from the 17 regions§ in the Philippines to the National Immunization Programme; national coverage data are reported annually to WHO and UNICEF. WHO and UNICEF use reported data from administrative records and surveys to estimate coverage with MCV1 and MCV2 through routine immunization services. In the Philippines, MCV1 administered at age 9 months was introduced nationwide in 1983, and MCV2 administered at age 12–15 months was introduced nationwide in 2010.¶ WHO-UNICEF–estimated MCV1 coverage increased nationally from 80% in 1998 to 92% during 2004–2008, decreased to 79% in 2011, and increased to 90% in 2013. The number of regions with >95% MCV1 coverage decreased from seven in 2007 to none in 2013. Estimated MCV2 coverage increased nationally from 10% in 2010 to 53% in 2013. During 1998–2014, approximately 76.4 million children received MCV during SIAs. Nationwide SIA coverage was 94%–95% in 1998, 2004, and 2007, but only 84% in 2011 and 91% in 2014. There was significant regional variation in vaccination coverage with MCV1 and with SIAs (Table 1).

Surveillance Activities

Sentinel site-based surveillance with reporting of line lists of suspected measles cases started in 1989; nationwide measles case-based surveillance with laboratory testing started in 1992, and virus genotyping started in 2010. Key surveillance performance indicators include 1) rate of discarded (i.e., nonmeasles) suspected cases reported per 100,000 population (target: ≥2); 2) percentage of suspected cases with adequate investigation (target: ≥80%); 3) percentage of suspected cases with adequate blood specimens collected for laboratory testing (target: ≥80%); and 4) percentage of suspected cases with

*Measles elimination is defined as the absence of endemic measles virus transmission in a defined geographical area (e.g. region or country) for ≥12 months in the presence of a well-performing surveillance system..

†Measles SIAs generally are carried out using two target age ranges. An initial, nationwide catch-up SIA targets all children aged 9 months–14 years, with the goal of eliminating susceptibility to measles in the general population. Periodic follow-up SIAs then target all children born since the most recent SIA. Follow-up SIAs generally are conducted nationwide every 2–4 years and target children aged 9–59 months; their goal is to eliminate any measles susceptibility that has developed in recent birth cohorts and to protect children who did not respond to the first measles vaccination.

§The 17 administrative regions in the Philippines include the Cordillera Autonomous Region (CAR), the National Capital Region (NCR), Region 1 (Ilocos), Region 2 (Cagayan Valley), Region 3 (Central Luzon), Region 4A (Calabarzon), Region 4B (Mimaropa) and Region 5 (Bicol) in Luzon; Region 6 (Western Visayas), Region 7 (Central Visayas), and Region 8 (Eastern Visayas) in Visayas; and Region 9 (Zamboanga Peninsula), Region 10 (Northern Mindanao), Region 11 (Davao), Region 12 (SOCCSKSARGEN), Caraga, and ARMM (Autonomous Region in Muslim Mindanao) in Mindanao.

¶MCV2 was introduced in Regions 4A, 5, 6, 7, and 12 in 2009 and introduced nationwide in 2010.

TABLE 1. Coverage with measles-containing vaccine by vaccination delivery strategy and measles surveillance performance — Philippines, 1998–2014

Immunization activities				No. (%) of regions,* by coverage					National	
Delivery strategy	Vaccine	Target age group	Year	<80%	80%–89%	90%–94%	≥95%	Range by region (%)	Reported	WUENIC
SIA	M	9 mos–14 yrs	1998	0 (0)	1 (6)	5 (31)	10 (62)	89–105	94	
		9 mos–7 yrs	2004	0 (0)	6 (35)	3 (17)	8 (47)	85–100	95	
		9–48 mos	2007	0 (0)	2 (11)	6 (35)	9 (52)	85–99	95	
	MR	9–95 mos	2011	4 (23)	9 (52)	4 (23)	0 (0)	75–91	84	
	M	6–59 mos	2014†	2 (66)	0 (0)	1 (33)	0 (0)	76–92		
	MR	9–59 mos	2014	0 (0)	2 (11)	9 (52)	6 (35)	82–103	91	
MCV1§	M	9 mos	1998					NA	87	80
			1999					NA	ND	80
			2000					NA	80	78
			2001	12 (80)	3 (20)	0 (0)	0 (0)	49–89	75	81
			2002	11 (68)	5 (31)	0 (0)	0 (0)	59–88	82	82
			2003	8 (50)	6 (37)	2 (12)	0 (0)	66–90	87	87
			2004	6 (37)	9 (56)	1 (6)	0 (0)	75–93	81	92
			2005	1 (5)	5 (29)	7 (41)	4 (23)	78–102	82	92
			2006	0 (0)	7 (41)	7 (41)	3 (17)	82–106	92	92
			2007	1 (5)	4 (23)	5 (29)	7 (41)	72–100	92	92
			2008	0 (0)	8 (47)	5 (29)	4 (23)	81–98	86	92
			2009	1 (5)	11 (64)	5 (29)	0 (0)	63–93	88	88
			2010	5 (29)	8 (47)	2 (11)	2 (11)	73–95	80	80
			2011	5 (29)	8 (47)	4 (23)	0 (0)	70–94	79	79
			2012	2 (11)	10 (58)	5 (29)	0 (0)	62–92	85	85
			2013	10 (58)	5 (29)	2 (11)	0 (0)	39–91	90	90
MCV2¶	MMR	12 mos	2010	7 (100)	0 (0)	0 (0)	0 (0)	2–35	10	10
		12–15 mos	2011	16 (100)	0 (0)	0 (0)	0 (0)	5–55	28	28
			2012	17 (100)	0 (0)	0 (0)	0 (0)	11–62	38	38
			2013	17 (100)	0 (0)	0 (0)	0 (0)	5–63	53	53

See table footnotes on next page.

results reported within 7 days of the laboratory receiving the specimen (target: ≥80%). During 2009–2011, surveillance performance improved: the discarded non-measles case rate increased from 1.6 to 3.1; the adequate case investigation rate increased from 29.5% to 88.6%; the adequate specimen collection rate increased from 74.1% to 98.0%; and the timeliness of laboratory reporting increased from 53.8% to 72.6%. However, performance declined or varied in 2012 and during the 2013–2014 measles resurgence (Table 1).

Measles Incidence and Measles Viral Genotypes

During 1998–2014, the number of annual reported measles cases varied in relation to SIAs, declining after SIAs were conducted and then increasing in subsequent years (Figure 1). Overall, annual reported measles cases and incidence per 1 million population decreased from 1,984 and 27.1 in 1998 to nine and 0.1 in 2006 and then increased to 21,403 and 233.2 in 2014. On the basis of SIAs conducted, 2007–2014 can be divided into two periods (Figure 1). During the 2007–2011 inter-SIA period,** 14,142 measles cases were reported. During the 2011–2014 inter-SIA period††, 58,700 measles cases were reported. At the national level, the proportion of measles cases in children aged 9 months–4 years decreased from 38% in the first inter-SIA period to 28% in the second inter-SIA period, and the proportion of measles cases in adolescents and adults aged ≥15 years increased from 18% in the first period to 29% in the second period (Table 2). The nationwide measles resurgence started with outbreaks in Calabarzon (Region 4A), Central Luzon (Region 3), the Cordillera Autonomous Region (CAR), and Western Visayas (Region 6) during the first half of 2013 and spread to many parts of Luzon and Visayas geographical divisions during October–December 2013. Outbreak response immunization activities targeting children aged 6–59 months were implemented in Calabarzon, Central Luzon, and the National Capital Region during January–February 2014; however, by that time the whole country was affected by measles outbreaks (Figure 2). After implementation of the nationwide SIA in September 2014 targeting children aged 9–59 months, 642 (37%) of the 1,719 measles cases during October–December 2014 were in persons aged ≥15 years (Table 2). The predominant measles virus genotype was D3 before 2007, then D9 and G3 during 2007–2009 (*4*) and

** From the end of the nationwide SIA targeting children aged 9–48 months in October 2007 until the completion of the nationwide SIA targeting children aged 9–95 months in April–May 2011.

†† From the end of the nationwide SIA in April–May 2011 until the completion of the nationwide SIA targeting children aged 9–59 months in September 2014.

TABLE 1. (*Continued*) Coverage with measles-containing vaccine by vaccination delivery strategy and measles surveillance performance — Philippines, 1998–2014

Surveillance performance			No. (%) of regions, by performance				Range by region	National
Performance indicator	Target	Year	0–0.5	0.6–0.9	1–1.9	≥2		
Discarded nonmeasles rate per 100,000 population	≥2	2009	2 (11)	1 (5)	10 (58)	4 (23)	0.1–4.2	1.6
		2010	1 (5)	0 (0)	3 (17)	13 (76)	0.3–21.4	4.3
		2011	1 (5)	1 (5)	5 (29)	10 (58)	0.2–19.1	3.1
		2012	4 (23)	1 (5)	5 (29)	7 (41)	0.1–7.5	2.1
		2013	1 (5)	1 (5)	5 (29)	10 (58)	0.3–7.6	3.3
		2014	0 (0)	2 (11)	5 (29)	10 (58)	0.8–5.1	3.3
			<60%	60%–69%	70%–79%	≥80%		
% suspected cases with adequate investigation**	≥80%	2009	17 (100)	0 (0)	0 (0)	0 (0)	6.3–47.0	29.5
		2010	17 (100)	0 (0)	0 (0)	0 (0)	8.1–59.3	40.6
		2011	8 (47)	4 (23)	3 (17)	2 (11)	23.2–81.6	88.6
		2012	10 (58)	2 (11)	2 (11)	3 (17)	15.7–88.3	57.1
		2013	9 (52)	3 (17)	3 (17)	2 (11)	4.2–81.3	46.1
		2014	12 (70)	1 (5)	3 (17)	1 (5)	5.1–90.4	52.5
% suspected cases with adequate blood specimens††	≥80%	2009	6 (35)	5 (29)	2 (11)	4 (23)	25.3–89.6	74.1
		2010	6 (35)	2 (11)	5 (29)	4 (23)	24.1–95.4	87.1
		2011	4 (23)	1 (5)	6 (35)	6 (35)	27.7–93.9	98.0
		2012	3 (17)	3 (17)	3 (17)	8 (47)	33.9–98.1	80.4
		2013	1 (5)	1 (5)	7 (41)	8 (47)	35.0–95.3	63.2
		2014	5 (29)	3 (17)	4 (23)	5 (29)	18.0–94.7	82.0
% serology laboratory results ≤ 7 days of receipt	≥80%	2009	8 (47)	6 (35)	1 (5)	2 (11)	22.1–100.0	53.8
		2010	15 (88)	1 (5)	1 (5)	0 (0)	27.5–71.9	43.9
		2011	6 (35)	3 (17)	6 (35)	2 (11)	44.7–81.0	72.6
		2012	0 (0)	1 (5)	0 (0)	16 (94)	66.7–100.0	95.3
		2013	0 (0)	1 (5)	4 (23)	12 (70)	68.4–100.0	80.2
		2014	17 (100)	0 (0)	0 (0)	0 (0)	0–23.5	1.3

Abbreviations: M = measles vaccine; MCV = measles-containing vaccine; MMR = measles, mumps, and rubella vaccine; MR = measles and rubella vaccine; NA = not available; ND = no data; SIAs = supplementary immunization activities; WUENIC = World Health Organization–UNICEF estimate of national immunization coverage.

* The total number of regions in the Philippines is 17 after 2004.

† SIAs with measles vaccine targeting children aged 6–59 months were carried out only in Regions 3 and 4A and in the National Capital Region.

§ Routine first dose of measles-containing vaccine. MCV1 coverage by region is not available before 2001.

¶ Routine second dose of measles-containing vaccine. Introduction of MCV2 started in 2009 in Regions 4A, 5, 6, 7, and 12. In 2010, MCV2 was introduced into the routine immunization nationwide; however, reporting was incomplete until the recording/reporting tool was updated in 2012 to accommodate the addition of MCV2.

** Adequate investigation is defined as investigation initiated within 48 hours of notification, with collection of all 10 core variables (case identification, date of birth/age, sex, place of residence, vaccination status or date of last vaccination, date of rash onset, date of notification, date of investigation, date of blood specimen collection, and place of infection or travel history).

†† Adequate specimens are minimum of 5 ml of blood sample for older children and adults and 1 ml for infants and younger children or dried blood sample with at least three fully filled circles on filter paper collected within 28 days of rash onset.

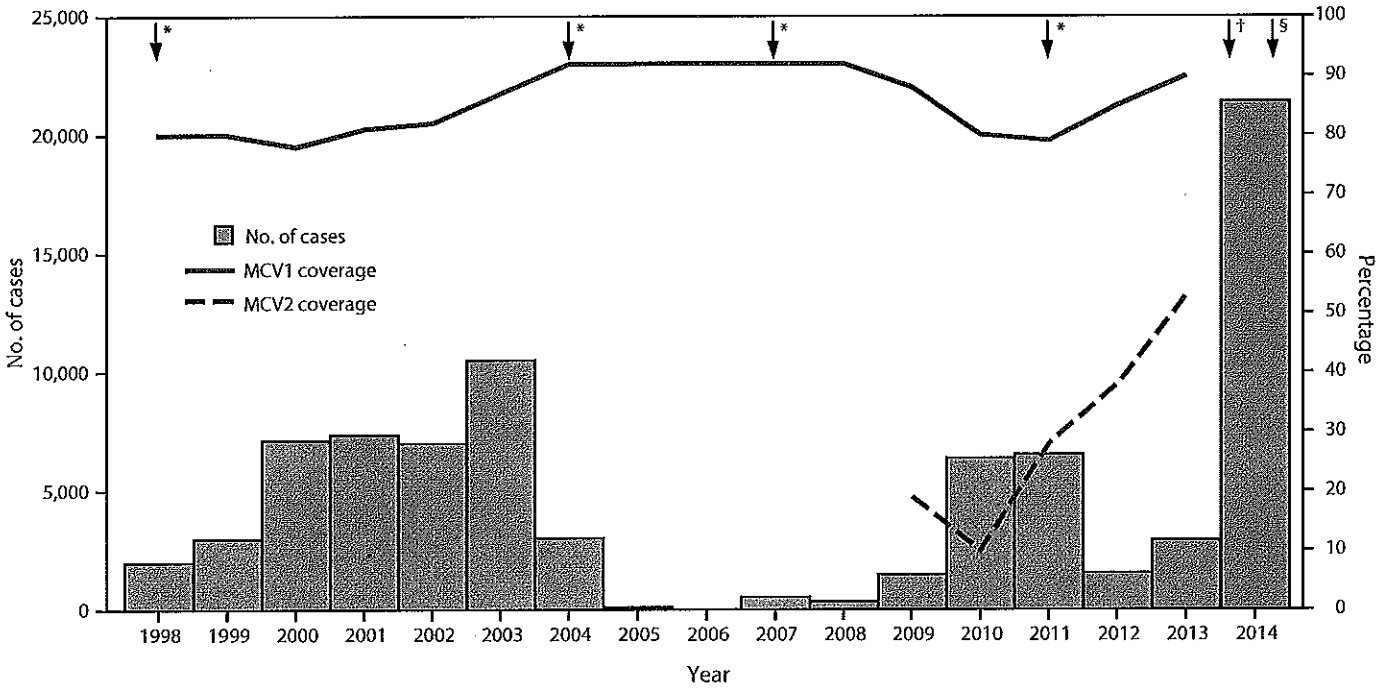
D9 during 2010–2012. During 2013–2014, of 69 cases with genotyping, 68 were B3 and one was D9. Genotypes D3 and G3 have not been reported since 2005 and 2010, respectively.

Discussion

The nationwide measles resurgence in the Philippines during 2013–2014 reflected the insufficient implementation of measles elimination strategies. Persistent low vaccination coverage since 1998 combined with the relatively low level of circulation of measles virus after SIAs resulted in the accumulation of measles-susceptible cohorts of older age children and young adults and a change in the epidemiology of measles in the Philippines. The resurgence highlighted key program challenges: 1) persistent suboptimal MCV1 coverage, 2) low MCV2 coverage since introduction during 2009–2010; 3) suboptimal SIA coverage with large variations in coverage by region; 4) recent SIA target age groups too narrow to interrupt measles virus transmission among older children, evidenced by the proportion of cases occurring outside the SIA target age group; and 5) inadequate outbreak response activities before widespread measles virus transmission started. The failure to achieve high population immunity among the targeted age groups before 2013 contributed to the observed increase in the proportion of measles cases among older children and young adults that indicated a shift in the age of the measles-susceptible population from young children to a wider age group during the nationwide measles resurgence in 2013–2014. This shift will require special strategies for vaccination activities.

In June 2014, the WPR Immunization and Vaccine-Preventable Diseases Technical Advisory Group recommended that countries achieve and maintain ≥95% 2-dose MCV

FIGURE 1. Number of reported measles cases and estimated percentage of MCV1 and MCV2 coverage, by year — Philippines, 1998–2014



Abbreviation: MCV = measles-containing vaccine.

Source: World Health Organization (WHO)–UNICEF estimates of national immunization coverage are available at http://www.who.int/immunization_monitoring/routine/immunization_coverage/en/index4.htm. Estimated coverage with the routine first dose of measles-containing vaccine (MCV1) was among children aged 1 year; estimated coverage with the routine second dose of measles-containing vaccine (MCV2) was among children at the recommended age of administration of MCV2, as per the national immunization schedule. Introduction of MCV2 started in 2009 in Regions 4A, 5, 6, 7, and 12. In 2010, MCV2 was introduced into the routine immunization nationwide; however, reporting was incomplete until the recording/reporting tool was updated in 2012 to accommodate the addition of MCV2. The number of reported measles cases during 1998–2013 is as reported to the World Health Organization (WHO) and UNICEF through the Joint Reporting Form and during 2014 as reported in monthly reports to the WHO Western Pacific Regional Office by December 20, 2014.

* Supplementary immunization activities using measles-containing vaccine were implemented in 1998 (nationwide) for children aged 9 months–14 years, 2004 (nationwide) for children aged 9 months–7 years, 2007 (nationwide) for children aged 9–48 months, and using measles-rubella vaccine in 2011 (nationwide) for children aged 9–95 months.

† Outbreak response immunization activities using measles vaccine during January–February 2014 targeting children aged 6–59 months in Calabarzon, Central Luzon, and the National Capital Region.

§ Nationwide supplementary immunization activity using measles-rubella vaccine implemented during September 2014 for children aged 9–59 months.

coverage through routine services and periodic SIAs, and, in addition, that endemic countries and countries experiencing nation-wide resurgence 1) update national plans and develop subnational plans with focus on high-risk and measles-susceptible groups; 2) enhance surveillance activities, including rapid case detection and outbreak investigation; 3) annually review and identify districts and age groups with suboptimal population immunity; and 4) increase population immunity by taking corrective actions such as periodic selective immunization activities and more frequent subnational or national SIAs (*5*). The Technical Advisory Group also recommended maintaining a national outbreak response plan for implementation of timely and prompt response activities.

Based on these recommendations, the Philippines Department of Health proposed new activities for measles elimination in the draft National Immunization Programme Strategic Plan for 2015–2019 (*6*), with plans to conduct 1) selective immunization activities[§§] for children aged 12–35 months in all regions in 2015 and 2) nonselective SIAs for a wide target age group during 2015–2017 in regions with sustained measles virus transmission or identified measles susceptibility among older children and adults. In October 2014, the Department of Health issued an administrative order to strengthen local government capacity to identify measles outbreaks, plan outbreak response activities, and provide health workers with guidance on how to respond appropriately to new outbreaks and

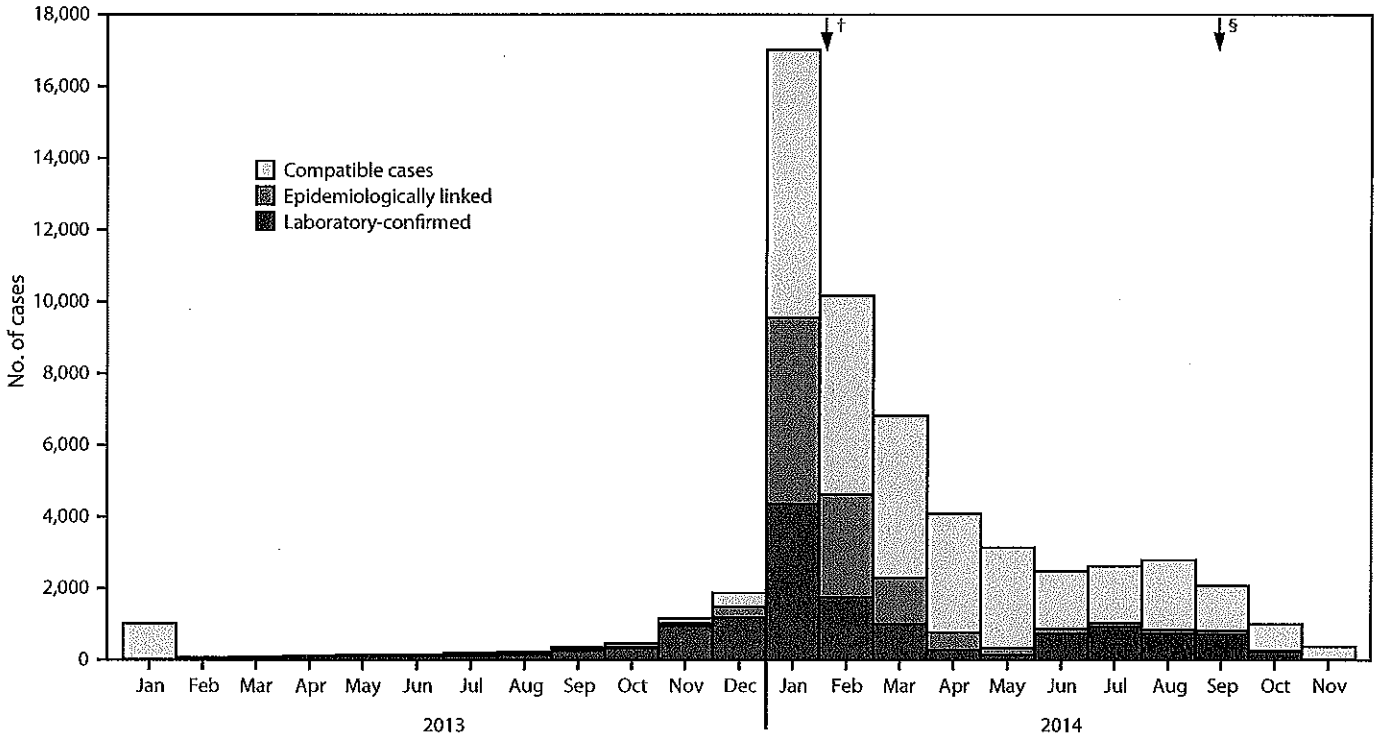
[§§] Selective immunization activities will be carried out for children aged 12–35 months who have not yet been fully vaccinated with 2 doses of measles-containing vaccines while nonselective SIAs will be done for any person in the target age group regardless of past vaccination history.

TABLE 2. Reported measles cases* before and after supplementary immunization activities (SIAs)† in 2011 and 2014, by age group — Philippines, November 1, 2007–December 31, 2014

	Time Period					
	Nov 2007–May 2011		June 2011–Sept 2014		Oct 2014–Dec 2014	
Age group	No.	(%)	No.	(%)	No.	(%)
0–8 mos	1,831	(13)	18,033	(31)	462	(27)
9 mos–4 yrs	5,412	(38)	16,671	(28)	357	(21)
5–9 yrs	2,664	(19)	2,846	(5)	115	(7)
10–14 yrs	1,222	(9)	4,188	(7)	141	(8)
15–29 yrs	2,073	(15)	12,552	(21)	450	(26)
30–39 yrs	331	(2)	3,866	(7)	169	(10)
≥40 yrs	102	(1)	482	(1)	23	(1)
No data	507	(4)	62	(0)	2	(0)
Total	**14,142**	**(100)**	**58,700**	**(100)**	**1,719**	**(100)**

* Includes reported measles cases that were laboratory confirmed, epidemiologically linked, and either clinically confirmed (2007–2012) or clinically compatible (2013–2014). Both clinically confirmed and clinically compatible cases were suspected cases with fever and maculopapular (nonvesicular) rash and one of cough, coryza, or conjunctivitis for which no adequate clinical specimens were taken and that were not linked epidemiologically to laboratory-confirmed cases of measles.
† SIAs were implemented in October 2007 (nationwide) targeting children aged 9–48 months, during April–May 2011 (nationwide) for children aged 9–95 months, during January–February 2014 (in Regions 3 and 4A and in the National Capital Region) for children aged 6–59 months, and in September 2014 (nationwide) for children aged 9–59 months.

FIGURE 2. Number* of reported confirmed measles cases, by month of rash onset — Philippines, 2013–2014



Source: As reported in monthly reports to the World Health Organization Western Pacific Regional Office by December 20, 2014.
* N = 58,389.
† Outbreak response immunization activities using measles vaccine during January–February 2014 targeting children aged 6–59 months in Calabarzon, Central Luzon, and the National Capital Region.
§ Nationwide supplementary immunization activity using measles-rubella vaccine implemented during September 2014 for children aged 9–59 months.

sustained measles virus transmission (*7*). In August 2015, the government will implement a nationwide public school-based measles-rubella-tetanus-diphtheria vaccination of 7th-grade students and establish a school entry immunization check in all public and private schools. Children with incomplete vaccination records at the time of school entry immunization

What is already known on this topic?

In 2005, the World Health Organization (WHO) Regional Committee for the Western Pacific Region (WPR) resolved to eliminate measles by 2012. In the WPR, the Philippines set a national goal in 1998 to eliminate measles by 2008.

What is added by this report?

WHO-UNICEF–estimated coverage with the routine first dose of a measles-containing vaccine (MCV1) increased from 80% in 1998 to 90% in 2013. The estimated coverage with the routine second dose (MCV2) increased from 10% after introduction in 2010 to 53% in 2013. After nationwide supplementary immunization activities (SIAs) in 1998 and 2004, historic lows in numbers and incidence of reported measles cases occurred in 2006. Despite nationwide SIAs in 2007 and 2011, reported cases and incidence generally increased during 2007–2012. During 2013–2014, nationwide measles resurgence occurred, including cases among older children and young adults, because of persistent MCV1 coverage <95%, low MCV2 coverage, and suboptimal MCV coverage in several regions of the country by SIAs conducted during 1998–2011.

What are the implications for public health practice?

Resuming progress toward measles elimination in the Philippines requires sustained investments to strengthen health systems and implement the recommended national and subnational strategies, including achieving and maintaining >95% 2-dose MCV coverage, implementing additional strategies for reducing accumulated measles susceptibility among older children and adults, and strengthening surveillance and outbreak response.

check will be referred to either the school clinic or the nearest health center to receive missed vaccinations.

The findings in this report are subject to at least two limitations. First, administrative coverage data might be unreliable because of inaccurate estimates of the size of target populations and the reported number of doses delivered. Second, surveillance data underestimate the likely number of cases that occurred because not all persons with measles sought care and were reported through surveillance.

In 2013, the WPR Regional Verification Committee for Measles Elimination[¶¶] verified that endemic measles virus transmission had been interrupted for a period of at least 36 months in Australia, Macao [China], Mongolia, and the Republic of Korea. However, during 2013–2014, the measles resurgence in the Philippines led to measles virus importations and increased incidence in several WPR countries including Australia and the Republic of Korea and in countries in other WHO regions[***] (*8–10*). Resuming progress toward regional measles elimination goals requires sustained investments, including strengthening health systems and implementing the recommended strategies in the Philippines.

[¶¶] In 2005, the Regional Committee for the WHO WPR established a goal for measles elimination by 2012, and a Regional Verification Committee (RVC) was established in 2013. In March 2015, the RVC verified that endemic measles virus transmission had been interrupted for a period of at least 36 months in Brunei Darussalam, Cambodia, and Japan.

[***] During 2013–2014, a total of 17 countries in four WHO regions reported measles virus genotype B3 in persons who had a history of recent travel to the Philippines.

[1]Expanded Programme on Immunization, World Health Organization Western Pacific Regional Office, Manila, Philippines; [2]World Health Organization Representative's Office, Manila, Philippines; [3]National Center for Disease Prevention and Control, Department of Health, Manila, Philippines; [4]Department of Immunization, Vaccines, and Biologicals, World Health Organization, Geneva, Switzerland; [5]Division of Viral Diseases, National Center for Immunization and Respiratory Diseases; [6]Global Immunization Division, Center for Global Health, CDC (Corresponding author: James L. Goodson, jgoodson@cdc.gov, 404-639-8170)

References

1. World Health Organization, Regional Committee for the Western Pacific. Resolution WPR/RC56.R8: measles elimination, hepatitis B control, and poliomyelitis eradication. Manila, Philippines: World Health Organization; 2005. Available at http://www2.wpro.who.int/rcm/en/archives/rc56/rc_resolutions/wpr_rc56_r08.htm.
2. World Health Organization, Regional Office for the Western Pacific. Western Pacific Region measles elimination field guide. Manila, Philippines: World Health Organization; 2013.
3. Office of the Secretary, Department of Health, Republic of the Philippines. Administrative order No.5S. 1998: implementing guidelines for the Philippines Measles Elimination Campaign. Manila, Philippines: Department of Health, Republic of the Philippines; 1998.
4. Fuji N, Suzuki A, Saito M, et al. Interruption of the circulation of an indigenous measles genotype and the introduction of other genotypes after a mass vaccination campaign in the Philippines. J Med Virol 2011;83:1424–7.
5. World Health Organization, Regional Office for the Western Pacific. Twenty fourth meeting of the Technical Advisory Group (TAG) on immunization and vaccine preventable diseases in the Western Pacific Region. Manila, Philippines: World Health Organization; 2015 (in press).
6. Department of Health, Republic of the Philippines. The Philippines Immunization Programme Strategic Plan for 2015–2019 (draft). Manila, Philippines: Department of Health, Republic of the Philippines.
7. Office of the Secretary, Department of Health, Republic of the Philippines. Administrative Order No. 2014-0039: Strengthening the capacity of LGUs in identifying potential measles outbreak and planning for appropriate response. Manila, Philippines: Department of Health, Republic of the Philippines; 2014.
8. Takahashi T, Arima Y, Kinoshita H, et al. Ongoing increase in measles cases following importations, Japan, March 2014: times of challenge and opportunity. Western Pac Surveill Response J 2014;5:31–3.
9. Yang TU, Kim JW, Eom HE, et al. Resurgence of measles in a country of elimination: interim assessment and current control measures in the Republic of Korea in early 2014. Int J Infect Dis 2014;33:12–4.
10. Rota PA, Brown K, Mankertz A, et al. Global distribution of measles genotypes and measles molecular epidemiology. J Infect Dis 2011; 204(Suppl 1):S514–23.

Vital Signs: Trends in Use of Long-Acting Reversible Contraception Among Teens Aged 15–19 Years Seeking Contraceptive Services — United States, 2005–2013

Lisa Romero, DrPH[1], Karen Pazol, PhD[1], Lee Warner, PhD[1], Lorrie Gavin, PhD[2], Susan Moskosky, MS[2], Ghenet Besera, MPH[1], Ana Carolina Loyola Briceno, MPH[2], Tara Jatlaoui, MD[1], Wanda Barfield, MD[1] (Author affiliations at end of text)

On April 7, 2015, this report was posted as an MMWR *Early Release on the* MMWR *website (http://www.cdc.gov/mmwr).*

Abstract

Background: Nationally, the use of long-acting reversible contraception (LARC), specifically intrauterine devices (IUDs) and implants, by teens remains low, despite their effectiveness, safety, and ease of use.

Methods: To examine patterns in use of LARC among females aged 15–19 years seeking contraceptive services, CDC and the U.S. Department of Health and Human Services' Office of Population Affairs analyzed 2005–2013 data from the Title X National Family Planning Program. Title X serves approximately 1 million teens each year and provides family planning and related preventive health services for low-income persons.

Results: Use of LARC among teens* seeking contraceptive services at Title X service sites increased from 0.4% in 2005 to 7.1% in 2013 (p-value for trend <0.001). Of the 616,148 female teens seeking contraceptive services in 2013, 17,349 (2.8%) used IUDs, and 26,347 (4.3%) used implants. Use of LARC was higher among teens aged 18–19 years (7.6%) versus 15–17 years (6.5%) (p<0.001). The percentage of teens aged 15–19 years who used LARC varied widely by state, from 0.7% (Mississippi) to 25.8% (Colorado).

Conclusions: Although use of LARC by teens remains low nationwide, efforts to improve access to LARC among teens seeking contraception at Title X service sites have increased use of these methods.

Implications for public health practice: Health centers that provide quality contraceptive services can facilitate use of LARC among teens seeking contraception. Strategies to address provider barriers to offering LARC include: 1) educating providers that LARC is safe for teens; 2) training providers on LARC insertion and a client-centered counseling approach that includes discussing the most effective contraceptive methods first; and 3) providing contraception at reduced or no cost to the client.

Introduction

The teen birth rate in the United States has continued to decline during the past two decades, from 61.8 births per 1,000 teens aged 15–19 years in 1991 to an all-time low of 26.5 births per 1,000 teens in 2013 (*1*). Improved contraceptive use has contributed substantially to this decline (*2*); however, there were approximately 273,000 births to teens in 2013 (*1*), and the U.S. teen pregnancy rate remains up to seven times higher than in some developed countries (*3*). Teen childbearing has potential negative health, economic, and social consequences for mothers and their children (*4*), and each year costs the United States approximately $9.4 billion (*5*).

A key strategy for further reducing teen pregnancy is increasing awareness, access, and availability of long-acting reversible contraception (LARC), specifically intrauterine devices (IUDs) and implants. IUD use was more common among U.S. women in the 1970s before concerns about safety led to a decline; however, with approval of redesigned IUDs and implants, there has been growing interest in the use of LARC (*6*). LARC requires no effort after insertion, and can prevent unintended pregnancy for at least 3 to 10 years, depending on the type of LARC (*7*). During the first year of typical use, both IUDs and implants have lower failure rates (<1%) than oral contraceptives (9%) and condoms (18%) (*8*), the two methods teens use most often (*9*). Among teens, LARC also has high acceptability (*10*) and higher continuation rates than shorter-acting methods (*11*). Further, LARC is safe and appropriate for teens (*12*): major professional societies, including the American College of Obstetricians and Gynecologists and the American Academy of Pediatrics, have endorsed LARC as a first-line contraceptive

* For this study, teens are defined as persons aged 15–19 years.

Key Points

- Intrauterine devices (IUDs) and implants, known as Long-Acting Reversible Contraception (LARC), are the most effective types of birth control for teens. With use of LARC, less than 1% of users become pregnant during the first year of use.
- LARC is safe for teens, requires no effort after insertion, and can prevent pregnancy for 3 to 10 years.
- Nationally, use of LARC among teens has increased but still remains low (<5%).
- Strategies for removing barriers to LARC include: 1) educating providers that LARC is safe for teens, 2) training providers on LARC insertion and use of a client-centered counseling approach that includes discussing the most effective contraceptive methods first, and 3) providing contraception at reduced or no cost to the client.
- Efforts to address barriers at Title X service sites have increased the percentage of teens selecting LARC as their preferred contraceptive option from 0.4% in 2005 to 7.1% in 2013.
- Additional information is available at http://www.cdc.gov/vitalsigns.

choice for teens that can be combined with condoms to provide the best protection against pregnancy and sexually transmitted diseases (*13,14*).

National estimates suggest use of LARC among teens has increased but still remains low (<5%) (*15,16*). Common barriers to LARC use by teens include unfounded concerns about safety, high upfront costs, and lack of awareness about LARC (*17,18*). For example, in a nationally representative sample of U.S. publicly funded family planning clinics, LARC was discussed with teen clients at fewer than half of these clinics (*18*). Common challenges reported by clinic directors included cost (60%), staff concerns about IUD use among teens (47%), and lack of training on insertion of implants (47%) and IUDs (38%) (*18*).

The reported barriers to use of LARC prompted CDC and the U.S. Department of Health and Human Services' Office of Population Affairs to analyze clinic data from the Title X National Family Planning Program. Since 1970, this program has provided cost-effective and confidential family planning and related preventive health services for low-income women and men; it serves approximately 1 million teens each year (*19*). The Title X National Family Planning Program encourages health care providers to offer LARC as an option for teens by increasing awareness of clinical guidelines on LARC for teens, training providers on LARC insertion and client-centered contraceptive counseling, and supporting community education and outreach. The Title X Program also helps its service sites to reduce financial barriers to LARC (e.g., by building capacity to bill third-party payers).

Methods

To examine use of LARC among female teens aged 15–19 years attending service sites funded under the Title X National Family Planning Program, data from the 2005–2013 Family Planning Annual Report† were analyzed. These years include the period during which modern IUDs and implants were available for use by women of all ages, including teens. The Family Planning Annual Report contains data from all entities that receive Title X grants to support delivery of family planning and related preventive health services through approximately 4,200 service sites. This report includes data on the number and percentage of female family planning users aged 15–19 years by primary contraceptive method and age.

A family planning user was defined as a person who had at least one family planning encounter at a Title X service site in a calendar year. The primary contraceptive method was defined as the method adopted or continued at exit from the last encounter of that year. If a user reported more than one method, only the most effective method was recorded as the primary method. Female clients were excluded from analyses if they were pregnant or seeking pregnancy; they or their partner were sterile by means other than surgical sterilization; or they reported refraining from sexual intercourse. A small percentage of clients (range = 1.8%–5.3% by year) was excluded because the primary contraceptive method at their last encounter was unknown.

Reversible contraceptive methods were placed in three tiers based on the percentage of users who experience pregnancy during the first year of typical use: most effective (<1%), moderately effective (6%–12%), and least effective (≥18%) (*8*). The most effective methods included IUDs and implants; moderately effective methods included oral contraceptives, injectables (e.g., Depo-Provera), the contraceptive patch, the vaginal ring, and diaphragms; and least effective methods included condoms, contraceptive sponges, spermicides, fertility awareness-based methods, and other methods, including withdrawal. Trends over time and by age, region, and type of service site were evaluated using the Cochran-Mantel-Haenszel test statistic.

† Available at http://www.hhs.gov/opa/title-x-family-planning/research-and-data/fp-annual-reports.

Results

Among approximately 7.5 million female clients aged 15–19 years who sought contraceptive services during 2005–2013 from Title X service sites in the United States, the percentage who adopted or continued use of LARC at their last visit increased from 0.4% (2005) to 7.1% (2013) (p-value for trend <0.001); the number of LARC users increased from 4,112 (2005) to 43,696 (2013). During this time, the percentage that used moderately effective methods decreased from 76.9% to 73.4%, and the percentage that used least effective methods decreased from 22.7% to 19.5% (Figure 1).

By type of LARC, use of IUDs for teens aged 15–19 years increased from 3,685 (0.4%) to 17,349 (2.8%), and use of implants increased from 427 (0.04%) to 26,347 (4.3%) (Figure 2). Use of IUDs was more prevalent than use of implants during 2005–2011 but was surpassed by implants in 2012 and 2013.

By age, overall use of LARC during 2005–2013 was higher each year among teens aged 18–19 versus 15–17 years (p<0.001 for each year). Use of LARC increased from 0.6% to 7.6% among teens aged 18–19 years, and from 0.3% to 6.5% among teens aged 15–17 years. For both age groups, the increase in use of implants exceeded the increase in use of IUDs (teens 15–17 years: 0.05% to 4.5% for implants, and 0.2% to 2.0% for IUDs; teens 18–19 years: 0.04% to 4.1% for implants, and 0.5% to 3.4% for IUDs).

In 2013, among 616,148 female clients aged 15–19 years seeking contraception at Title X service sites, the use of LARC varied markedly by region (Table). Use was highest in the West (9.5%), followed by the Northeast and Midwest (both 6.4%), and lowest in the South (5.3%) (p<0.001). By state, Colorado had the highest percentage of teen clients using LARC (25.8%), followed by Alaska (19.6%), District of Columbia (17.9%), Iowa (16.6%), Hawaii (14.4%), and Vermont (13.8%); conversely, the lowest percentage of teen clients using LARC was in West Virginia (2.0%), Indiana (1.5%), and Mississippi (0.7%) (Figure 3). By type of LARC, use of IUDs was highest in Colorado (8.2%), Rhode Island (5.4%), New Hampshire (5.2%), and Washington (5.2%), and use of implants was highest in Colorado (17.6%), Alaska (15.4%), Iowa (13.4%), District of Columbia (12.9%), and Hawaii (12.2%) (Table).

Use of LARC among teens aged 15–19 years seeking contraception at Title X service sites also varied by type of facility. Service sites that focused primarily on delivering family planning services, as opposed to primary care services, had the highest percentage of teen clients using LARC (7.5%), followed by health departments (6.7%), other types of service sites (5.7%), and Federally Qualified Health Centers[§] (5.6%) (p<0.001) (Table). By type of LARC, use of IUDs was highest at service sites that focused primarily on family planning services (3.3%), whereas use of implants was equally high (4.3%) at health departments and services sites that focused primarily on family planning services.

FIGURE 1. Percentage of female teens aged 15–19 years using moderately effective and least effective contraceptive methods, compared with long-acting reversible contraception (LARC), among those seeking contraceptive services at Title X service sites — United States, 2005–2013

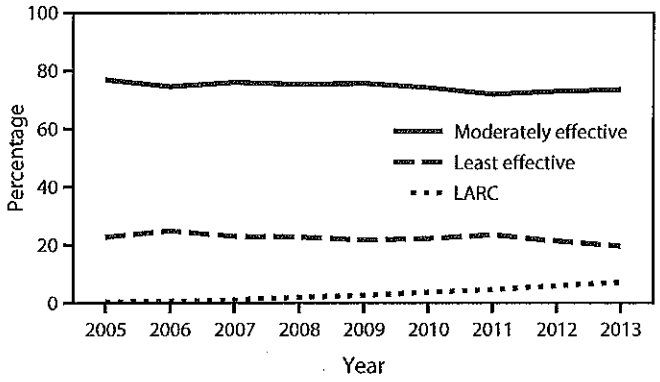
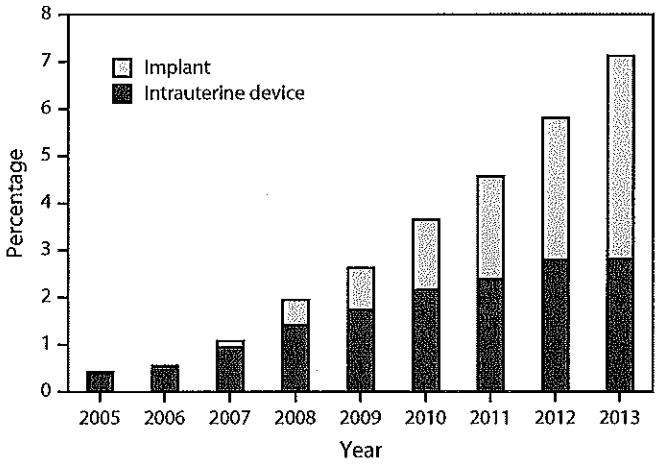


FIGURE 2. Percentage of female teens aged 15–19 years using long-acting reversible contraception (LARC) among those seeking contraceptive services at Title X service sites, by LARC type — United States, 2005–2013



Conclusions and Comment

These data show efforts to improve access to LARC among teens seeking contraception at Title X service sites have increased use of these methods more than 15-fold from 0.4% in 2005 to 7.1% in 2013, with a marked increase in use of implants. Concurrently, use of moderately effective and least

[§] Federally Qualified Health Centers are "safety net" providers such as community health centers, public housing centers, outpatient health programs funded by the Indian Health Service, and programs serving migrants and the homeless. The main purpose of these centers is to enhance the provision of primary care services in underserved urban and rural communities.

TABLE. Percentage of female Title X clients aged 15–19 years using long-acting reversible contraception (LARC), by age group, type of service site, region, and state — Family Planning Annual Report, United States, 2013

Characteristic	No.	% using LARC								
		15–19 yrs			15–17 yrs			18–19 yrs		
		Total	IUD	Implant	Total	IUD	Implant	Total	IUD	Implant
Total	**616,148**	**7.1**	**2.8**	**4.3**	**6.5**	**2.0**	**4.5**	**7.6**	**3.4**	**4.1**
Type of service site										
Health department	333,203	6.7	2.5	4.3	6.4	1.8	4.6	7.0	3.0	4.0
Family planning	277,000	7.5	3.3	4.3	6.6	2.2	4.4	8.2	4.0	4.2
FQHC	1,738	5.6	1.8	3.8	4.5	0.7	3.8	6.7	3.0	3.8
Other	4,207	5.7	1.9	3.9	4.8	0.8	4.0	6.4	2.7	3.8
Region*										
Northeast	115,850	6.4	3.2	3.2	5.8	2.4	3.4	6.9	3.9	3.1
Midwest	89,359	6.4	2.0	4.4	6.3	1.3	5.0	6.5	2.5	4.0
South	199,619	5.3	1.6	3.6	4.9	1.1	3.8	5.5	2.1	3.5
West	211,320	9.5	4.1	5.4	8.6	2.9	5.6	10.1	4.8	5.3
State										
Alabama	16,677	3.7	0.3	3.4	3.3	0.1	3.2	4.0	0.5	3.5
Alaska	1,207	19.6	4.1	15.4	18.6	2.9	15.8	20.3	5.1	15.1
Arizona	5,307	5.8	3.8	2.0	4.6	2.3	2.3	6.7	4.8	1.8
Arkansas	9,734	2.5	2.3	0.2	1.7	1.5	0.1	3.2	3.0	0.3
California	144,157	9.0	4.1	4.9	7.9	2.9	5.0	9.7	4.7	4.9
Colorado	9,211	25.8	8.2	17.6	24.8	6.3	18.6	26.6	9.8	16.8
Connecticut	5,556	6.9	2.4	4.4	6.4	1.7	4.8	7.2	3.0	4.2
Delaware	1,660	3.9	1.8	2.0	3.3	1.0	2.3	4.2	2.4	1.9
District of Columbia	2,116	17.9	5.0	12.9	14.9	2.7	12.2	20.3	6.9	13.4
Florida	22,027	2.5	2.0	0.5	1.8	1.3	0.6	3.1	2.6	0.5
Georgia	18,016	4.1	1.2	2.9	3.6	0.7	3.0	4.5	1.7	2.8
Hawaii	2,787	14.4	2.2	12.2	13.0	1.1	11.9	16.0	3.5	12.5
Idaho	3,539	3.6	2.9	0.7	1.9	1.5	0.4	5.3	4.3	0.9
Illinois	13,613	7.7	2.9	4.8	6.6	1.8	4.9	8.4	3.8	4.7
Indiana	4,539	1.5	0.7	0.9	1.1	0.6	0.5	1.8	0.7	1.1
Iowa	9,402	16.6	3.2	13.4	17.7	2.2	15.5	15.7	4.0	11.7
Kansas	3,890	3.1	1.8	1.3	2.8	1.5	1.4	3.3	2.0	1.3
Kentucky	8,787	2.6	0.5	2.1	2.9	0.1	2.8	2.4	0.7	1.7
Louisiana	5,708	3.7	0.6	3.1	3.6	0.2	3.5	3.7	0.9	2.9
Maine	3,673	9.5	4.6	4.8	9.0	3.3	5.7	9.9	5.9	4.0
Maryland	8,436	8.3	3.3	5.0	7.5	2.1	5.5	9.0	4.4	4.6
Massachusetts	8,905	9.0	3.5	5.4	7.0	2.1	4.9	10.7	4.8	5.9
Michigan	15,165	3.3	1.2	2.1	3.2	0.9	2.4	3.4	1.5	1.9
Minnesota	8,258	8.8	2.5	6.3	9.5	1.4	8.2	8.4	3.1	5.3
Mississippi	12,089	0.7	0.5	0.2	0.4	0.3	0.1	0.9	0.7	0.3
Missouri	9,146	3.8	0.9	2.9	4.2	0.7	3.5	3.4	1.1	2.2
Montana	4,382	3.0	1.5	1.5	2.7	1.0	1.7	3.2	1.9	1.2
Nebraska	2,887	7.2	3.1	4.1	6.2	2.0	4.2	7.8	3.8	4.0
Nevada	2,747	3.8	2.1	1.7	2.4	1.2	1.3	5.0	2.9	2.0
New Hampshire	2,982	10.6	5.2	5.4	10.1	3.7	6.4	11.0	6.4	4.6
New Jersey	10,519	2.1	1.6	0.5	1.4	1.0	0.5	2.5	2.0	0.5
New Mexico	5,064	7.4	2.2	5.3	5.0	1.2	3.8	9.5	3.0	6.5
New York	43,748	8.5	4.8	3.7	8.0	3.8	4.1	8.9	5.5	3.4
North Carolina	16,584	7.4	2.8	4.6	7.0	1.8	5.2	7.7	3.5	4.2
North Dakota	1,661	3.5	1.2	2.3	4.4	0.9	3.4	2.9	1.4	1.6
Ohio	12,599	5.2	1.7	3.5	5.3	1.2	4.1	5.2	2.2	3.0
Oklahoma	10,438	10.0	1.4	8.6	10.1	0.9	9.1	10.0	1.9	8.1
Oregon	9,949	11.0	4.5	6.5	10.4	3.3	7.1	11.5	5.7	5.8
Pennsylvania	36,229	3.1	1.2	1.9	2.8	1.0	1.8	3.4	1.4	2.0
Rhode Island	2,706	11.6	5.4	6.2	10.8	3.3	7.5	12.2	6.9	5.4
South Carolina	10,316	6.5	1.8	4.7	6.8	1.5	5.3	6.4	1.9	4.5
South Dakota	1,564	2.2	1.5	0.8	1.6	0.9	0.7	2.6	1.8	0.8
Tennessee	17,370	5.8	1.2	4.5	6.2	0.7	5.5	5.4	1.6	3.8
Texas	18,583	9.1	2.6	6.5	8.2	1.8	6.4	9.7	3.2	6.5
Utah	6,679	3.5	2.5	1.0	2.8	1.6	1.2	3.9	3.0	0.9
Vermont	1,532	13.8	4.2	9.5	13.4	2.3	11.1	14.1	5.9	8.3
Virginia	11,620	7.3	1.7	5.6	7.7	1.9	5.8	7.1	1.6	5.5
Washington	14,457	11.2	5.2	6.1	10.6	4.2	6.4	11.7	5.9	5.8

See table footnotes on next page.

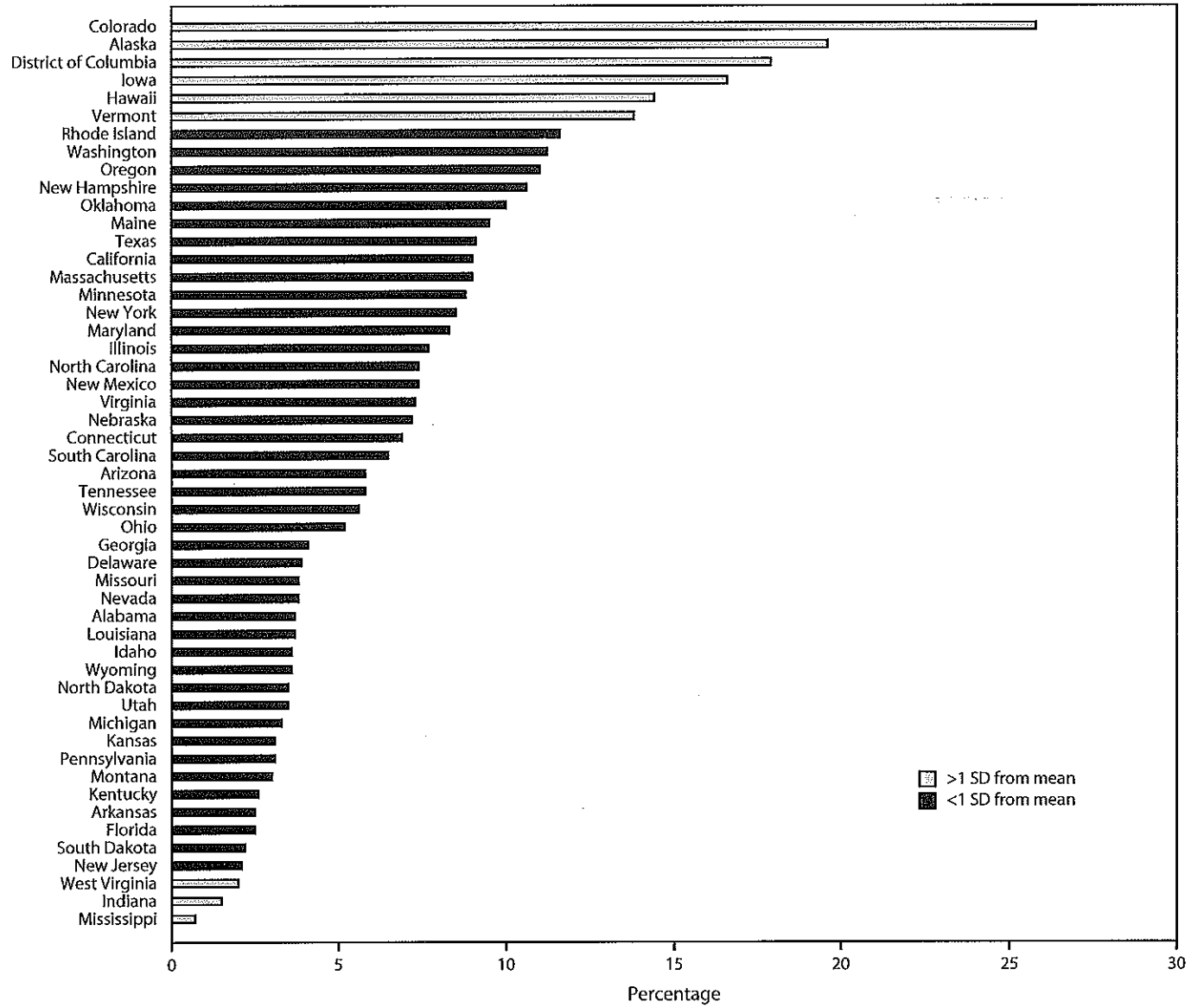
TABLE. (*Continued*) Percentage of female Title X clients aged 15–19 years using long-acting reversible contraception (LARC), by age group, type of service site, region, and state — Family Planning Annual Report, United States, 2013

Characteristic	No.	% using LARC								
		15–19 yrs			15–17 yrs			18–19 yrs		
		Total	IUD	Implant	Total	IUD	Implant	Total	IUD	Implant
West Virginia	9,458	2.0	1.0	1.0	1.8	0.7	1.1	2.2	1.3	0.9
Wisconsin	6,635	5.6	2.0	3.6	4.7	0.9	3.8	6.1	2.6	3.5
Wyoming	1,834	3.6	0.8	2.8	3.0	0.4	2.6	4.1	1.2	2.9

Abbreviations: IUD = intrauterine device; FQHC = federally qualified health center.

* *Northeast:* Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont. *Midwest:* Illinois, Iowa, Indiana, Kansas, Michigan, Minnesota, Missouri, Nebraska, North Dakota, Ohio, South Dakota, Wisconsin. *South:* Alabama, Arkansas, Delaware, District of Columbia, Florida, Georgia, Kentucky, Louisiana, Maryland, Mississippi, North Carolina, Oklahoma, South Carolina, Texas, Tennessee, Virginia, West Virginia. *West:* Alaska, Arizona, California, Colorado, Hawaii, Idaho, Montana, Nevada, New Mexico, Oregon, Utah, Washington, Wyoming.

FIGURE 3. Percentage of female teens aged 15–19 years using long-acting reversible contraception (LARC) among those seeking contraceptive services at Title X service sites, by state — United States, 2013



Abbreviation: SD = standard deviation.

effective methods among teens seeking contraceptive services declined. Given the estimated 4.4 million sexually experienced female teens in the United States (*9*), and the high effectiveness, safety and ease of using LARC, continued efforts are needed to increase access and availability of these methods for teens.

CDC, in partnership with the U.S. Department of Health and Human Services' Office of Population Affairs, recently issued recommendations for providing quality family planning services, based on the Title X program's guidance for direct service delivery (*20*). These recommendations outline a client-centered approach for contraceptive counseling, in which a client's reproductive life plan, social needs, and contraceptive preferences are discussed along with medical information to identify acceptable methods for the client. By recommending that the most effective methods be discussed first, these recommendations promote increased awareness of LARC. In concurrence with statements from the American College of Obstetricians and Gynecologists and the American Academy of Pediatrics, these recommendations also emphasize the need to include information on the use of condoms for teens to reduce the risk for sexually transmitted diseases (*13,14*). Despite the long-term protection provided by LARC, it is important that teens have frequent follow-up to reinforce healthy decision-making, promote problem-solving regarding contraceptive continuation and sexually transmitted disease prevention, and receive other preventive health services (*13*).

Three other initiatives (*21–23*) have facilitated use of LARC among reproductive aged women, including teens, by underscoring the importance of educating providers that LARC is medically safe for teens (*12*), training providers on LARC insertion and use of a client-centered counseling approach that includes discussing the most effective contraceptive methods first (*20*), and providing contraception at reduced or no cost to the client. These efforts have increased the percentage of teens and young women selecting LARC as their preferred option for contraception and have been associated with declines in teen pregnancies, births, and abortions (*21,22*).

The findings of this report suggest that implants, as compared with IUDs, accounted for a greater proportion of the increase in use of LARC among teens seeking contraceptive services at Title X service sites. However, national surveys indicate that more service sites, whether privately or publicly funded, offer IUDs than implants on-site (*24–26*). To meet the increasing demand for implants by teens, providers should consider increasing on-site availability and affordability of implants.

This report documents that use of LARC among females aged 15–19 years seeking contraception through Title X was highest at services sites that focused primarily on delivering family planning services. This finding is consistent with a recent study of publicly funded clinics, in which those primarily focusing on family planning (compared with those focusing on primary care) offered more methods on-site, including IUDs and implants (*24*). Additionally, a 2011 survey of Federally Qualified Health Centers found that a higher percentage of centers receiving Title X funding (compared with those not receiving funding) offered IUDs and implants on-site (*25*). Together, these findings suggest the importance of providing quality contraceptive services, regardless of setting, to ensure that the contraceptive needs of teens are met.

The considerable state-specific variation observed in the prevalence of LARC use suggests that state-based policies and programs might also influence teen use of LARC. Over the past two decades, many states have expanded eligibility for Medicaid coverage of family planning services. Currently 25 states grant coverage solely on the basis of income, and in 20 states this expansion includes persons aged <19 years (*27*). Recent surveys have found that Title X service sites in states with Medicaid family planning expansions (compared with those without such expansions) are more likely to provide LARC on-site, report fewer cost-related difficulties obtaining LARC, have extended weekend and evening hours, have a higher percentage of clients paying for services with Medicaid, and assist clients with Medicaid enrollment (*24*).

The findings in this report are subject to at least three limitations. First, to minimize data collection burden for Title X grantees, only summary information on a limited number of client characteristics is requested for the Family Planning Annual Report. This limits the type of questions than can be addressed. For example, it is currently not possible to examine the use of the primary contraceptive method, including LARC, by factors such as race or ethnicity. Second, the use of existing clinic records might have been subject to error regarding the primary contraceptive method provided to teens; however, such records circumvent many of the biases associated with relying on self-report for sensitive behaviors. Finally, the Title X service sites provide care to those from underserved, primarily low-income communities nationwide, including teens, and might not be generalizable to the population of teens nationally. However, given the higher rates of unintended pregnancy among teens and low-income women (*28*), Title X data offer important information on a population with a high need for increased access to contraceptive services, including LARC.

This report documents increasing use of LARC among teens seeking contraceptive services at Title X service sites during the past decade. Approximately one out of every 14 teen clients seeking contraceptive services chose LARC as their preferred method. The type of data presented in this report can help identify areas where barriers remain and guide interventions to increase access to and awareness of LARC among teens. Removing barriers to LARC by educating providers that LARC

is medically safe for teens, training providers on LARC insertion and a client-centered counseling approach that includes discussing the most effective contraceptive methods first, and providing contraception at reduced or no cost to the client, can increase the array of options available to teens and may contribute to the continuing declines in teen pregnancy in the United States.

[1]Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion, CDC; [2]Office of Family Planning, Office of Population Affairs, US Department of Health and Human Services (Corresponding author: Lisa Romero, eon1@cdc.gov, 770-488-5200)

References

1. Martin JA, Hamilton BE, Osterman MJK, Curtin SC, Matthews TJ. Births: final data for 2013. Natl Vital Stat Rep 2015;64:1–65.
2. Santelli JS, Lindberg LD, Finer LB, Singh S. Explaining recent declines in adolescent pregnancy in the United States: the contribution of abstinence and improved contraceptive use. Am J Public Health 2007;97:150–6.
3. Sedgh G, Finer LB, Bankole A, Eilers MA, Singh S. Adolescent pregnancy, birth, and abortion rates across countries: levels and recent trends. J Adolesc Health 2015;56:223–30.
4. Hoffman SD. Updated estimates of the consequences of teen childbearing for mothers. In: Hoffman S, Maynard R, eds. Kids having kids: economic costs and social consequences of teen pregnancy. Washington, DC: The Urban Institute Press; 2008.
5. National Campaign to Prevent Teen and Unplanned Pregnancy. Counting it up: the public costs of teen childbearing. Washington, DC: National Campaign to Prevent Teen and Unplanned Pregnancy; 2013. Available at http://thenationalcampaign.org/why-it-matters/public-cost.
6. Dean G, Schwarz EB. Intrauterine Contraceptives (IUCs). In: Hatcher RA, Trussell J, Nelson AL, Cates W, Kowal D, Policar MS, eds. Contraceptive technology, 20th edition. New York, NY: Ardent Media, Inc; 2011:147–91.
7. American College of Obstetricians and Gynecologists. ACOG Practice Bulletin No. 121: Long-acting reversible contraception: Implants and intrauterine devices. Obstet Gynecol 2011;118:184–96.
8. Trussell J. Contraceptive failure in the United States. Contraception 2011;83:397–404.
9. Martinez G, Copen CE, Abma JC. Teenagers in the United States: sexual activity, contraceptive use, and childbearing, 2006–2010 National Survey of Family Growth. Vital Health Stat 2011;23(31).
10. Mestad R, Secura G, Allsworth JE, Madden T, Zhao Q, Peipert JF. Acceptance of long-acting reversible contraceptive methods by adolescent participants in the Contraceptive CHOICE Project. Contraception 2011;84:493–8.
11. O'Neil-Callahan M, Peipert JF, Zhao Q, Madden T, Secura G. Twenty-four-month continuation of reversible contraception. Obstet Gynecol 2013;122:1083–91.
12. CDC. U.S. medical eligibility criteria for contraceptive use, 2010. MMWR Recomm Rep 2010;59(No. RR-4):1–86.
13. Committee on Adolescence. Contraception for adolescents. Pediatrics 2014;134:e1244–56.
14. American College of Obstetricians and Gynecologists. Adolescents and long-acting reversible contraception: implants and intrauterine devices. Committee Opinion No. 539. Obstet Gynecol 2012;120:983–8.
15. Finer LB, Jerman J, Kavanaugh ML. Changes in use of long-acting contraceptive methods in the United States, 2007-2009. Fertil Steril 2012;98:893–7.
16. Kann L, Kinchen S, Shanklin SL, et al. Youth risk behavior surveillance—United States, 2013. MMWR Surveill Summ 2014;63(Suppl 4).
17. Kavanaugh ML, Frohwirth L, Jerman J, Popkin R, Ethier K. Long-acting reversible contraception for adolescents and young adults: patient and provider perspectives. J Pediatr Adolesc Gynecol 2013;26:86–95.
18. Kavanaugh ML, Jerman J, Ethier K, Moskosky S. Meeting the contraceptive needs of teens and young adults: youth-friendly and long-acting reversible contraceptive services in U.S. family planning facilities. J Adolesc Health 2013;52:284–92.
19. Title X National Family Planning Program. Title X National Family Planning Program overview. Washington, DC: US Department of Health and Human Services, Office of Population Affairs; 2014. Available at http://www.hhs.gov/opa/title-x-family-planning.
20. Gavin L, Moskosky S, Carter M, et al.; CDC. Providing quality family planning services: Recommendations of CDC and the U.S. Office of Population Affairs. MMWR Recomm Rep 2014;63(No. RR-4):1–54.
21. Secura GM, Madden T, McNicholas C, et al. Provision of no-cost, long-acting contraception and teenage pregnancy. N Engl J Med 2014; 371:1316–23.
22. Ricketts S, Klingler G, Schwalberg R. Game change in Colorado: widespread use of long-acting reversible contraceptives and rapid decline in births among young, low-income women. Perspect Sex Reprod Health 2014;46:125–32.
23. Biggs MA, Rocca CH, Brindis CD, Hirsch H, Grossman D. Did increasing use of highly effective contraception contribute to declining abortions in Iowa? Contraception 2015;91:167–73.
24. Frost JJ, Gold RB, Frohwirth L, Blades N. Variation in service delivery practices among clinics providing publicly funded family planning services in 2010. New York, NY: Guttmacher Institute; 2012. Available at http://www.guttmacher.org/pubs/clinic-survey-2010.pdf.
25. Beeson T, Wood S, Bruen B, Goldberg DG, Mead H, Rosenbaum S. Accessibility of long-acting reversible contraceptives (LARCs) in Federally Qualified Health Centers (FQHCs). Contraception 2014;89:91–6.
26. CDC. Contraceptive methods available to patients of office-based physicians and title X clinics — United States, 2009-2010. MMWR Morb Mortal Wkly Rep 2011;60:1–4.
27. Guttmacher Institute. State policies in brief (as of April 1, 2015): Medicaid family planning eligibility expansions. New York, NY: Guttmacher Institute; 2015. Available at http://www.guttmacher.org/statecenter/spibs/spib_SMFPE.pdf.
28. Finer LB, Zolna MR. Shifts in intended and unintended pregnancies in the United States, 2001-2008. Am J Public Health 2014;104(Suppl 1):S43–8.

Announcements

National Public Health Week — April 6–12, 2015

Every year since 1995, the American Public Health Association has led the observation of National Public Health Week in the United States during the first full week of April. The goal of National Public Health Week is to acknowledge contributions made by public health and to raise awareness of issues important to improving the nation's health. This year's observance (April 6–12) focuses on making the United States the Healthiest Nation in One Generation by 2030. Additional information about this year's observance is available at http://www.nphw.org.

In conjunction with this year's observance, CDC is partnering with the American Public Health Association to promote daily themes for National Public Health Week, by sharing information on CDC topics that align with each day's theme. Additional information available at http://www.cdc.gov/features/public-health-week/.

National Infant Immunization Week — April 18–25, 2015

National Infant Immunization Week (NIIW) is April 18–25, 2015. This annual observance promotes the benefits of childhood immunizations and their role in improving the health of children aged ≤2 years. Since 1994, local and state health departments, immunization partners, health care professionals, community leaders, clinicians from across the United States, and CDC have come together to highlight the importance of vaccination in the lives of infants and children.

Although immunization coverage among children remains at high levels, recent outbreaks of measles in the United States highlight the importance of maintaining high immunization rates. NIIW provides an opportunity to celebrate immunization achievements, recognize partners and volunteers dedicated to childhood immunization, and revitalize community efforts to maintain high vaccination levels.

During NIIW, local and state health departments, national immunization partners, and health care professionals will host events and educational activities for parents and clinicians. To help with planning these activities, various promotional and educational materials are available from CDC on the NIIW website.* Also available are materials from CDC's new *Born with Protection* campaign,† which promotes whooping cough vaccination during the third trimester of each pregnancy to help protect babies during their first few months of life when they are most vulnerable.

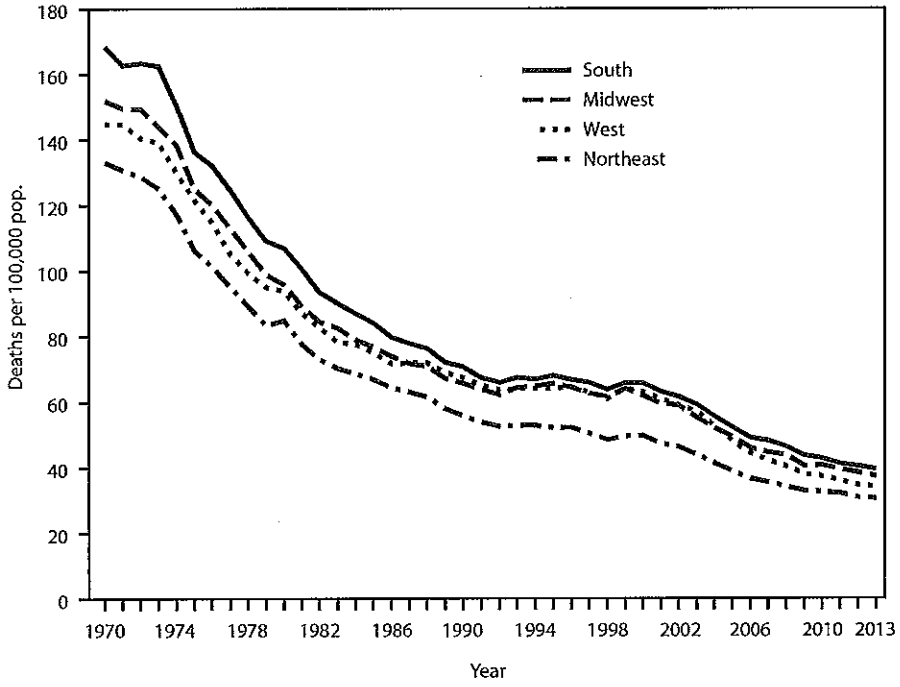
* Additional information available at http://www.cdc.gov/vaccines/events/niiw/index.html.

† Additional information available at http://www.cdc.gov/pertussis/pregnant/index.html.

QuickStats

FROM THE NATIONAL CENTER FOR HEALTH STATISTICS

Age–Adjusted Death Rates* for Stroke,† by U.S. Census Region§ — United States, 1970–2013



* Per 100,000 standard population.

† Stroke cases are identified using underlying cause of death with codes 430-438 (1970–1998), and I60–I69 (1999–2013) in the *International Classification of Diseases, Eighth, Ninth and Tenth Revisions*. ICD-10 replaced ICD-9 in 1999, and its new classification scheme has had a net effect of increasing counts of stroke as an underlying cause of death by about 6% starting that year.

§ *Northeast:* Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, New Jersey, New York, Pennsylvania, and Vermont; *Midwest:* Illinois, Indiana, Iowa, Kansas, Michigan, Minnesota, Missouri, Nebraska, North Dakota, Ohio, South Dakota, and Wisconsin; *South:* Alabama, Arkansas, Delaware, Florida, Georgia, Kentucky, Louisiana, Mississippi, Maryland, North Carolina, Oklahoma, South Carolina, Virginia, Tennessee, Texas, West Virginia, and District of Columbia; *West:* Alaska, Arizona, California, Colorado, Hawaii, Idaho, Montana, Nevada, New Mexico, Oregon, Utah, Washington, and Wyoming.

The age-adjusted death rates for stroke in all U.S. Census regions in the United States generally decreased from 1970 to 2013, although the rates in all regions were relatively stable from 1992 to 1999. From 1970 to 2013, the rate decreased an average of 3.3% per year in the South, 3.2% in the Midwest, 3.3% in the West, and 3.4% in the Northeast. Throughout the period, the rate was the highest in the South and lowest in the Northeast region.

Source: National Vital Statistics System. Mortality public use data files, 1970–2013. Available at http://www.cdc.gov/nchs/data_access/vitalstatsonline.htm.

Reported by: Jiaquan Xu, MD, jax4@cdc.gov, 301-458-4086.

The *Morbidity and Mortality Weekly Report (MMWR)* Series is prepared by the Centers for Disease Control and Prevention (CDC) and is available free of charge in electronic format. To receive an electronic copy each week, visit *MMWR*'s free subscription page at *http://www.cdc.gov/mmwr/mmwrsubscribe.html*. Paper copy subscriptions are available through the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402; telephone 202-512-1800.

Readers who have difficulty accessing this PDF file may access the HTML file at *http://www.cdc.gov/mmwr/index2015.html*. Address all inquiries about the *MMWR* Series, including material to be considered for publication, to Executive Editor, *MMWR* Series, Mailstop E-90, CDC, 1600 Clifton Rd., N.E., Atlanta, GA 30329-4027 or to mmwrq@cdc.gov.

ISSN: 0149-2195

8.3

First Use of a Serogroup B Meningococcal Vaccine in the US in Response to a University Outbreak

Lucy A. McNamara, PhD, MS[a,b], Alice M. Shumate, PhD[a,c], Peter Johnsen, MD[d], Jessica R. MacNeil, MPH[b], Manisha Patel, MD[b], Tina Bhavsar, PharmD[e], Amanda C. Cohn, MD[b], Jill Dinitz-Sklar, MPH[e,f], Jonathan Duffy, MD, MPH[g], Janet Finnie, MBA, LSW[d], Denise Garon, MS[e], Robert Hary, MA, MBA[h], Fang Hu, PhD[b], Hajime Kamiya, MD, PhD, MPH[a,b], Hye-Joo Kim, PharmD[e], John Kolligian Jr, PhD[d], Janet Neglia, MD[d], Judith Oakley[d], Jacqueline Wagner, MS[d], Kathy Wagner, MPH[d], Xin Wang, PhD[b], Yon Yu, PharmD[e], Barbara Montana, MD, MPH[e], Christina Tan, MD, MPH[e], Robin Izzo, MS[d], Thomas A. Clark, MD, MPH[b]

abstract

BACKGROUND: In 2013–2014, an outbreak of serogroup B meningococcal disease occurred among persons linked to a New Jersey university (University A). In the absence of a licensed serogroup B meningococcal (MenB) vaccine in the United States, the Food and Drug Administration authorized use of an investigational MenB vaccine to control the outbreak. An investigation of the outbreak and response was undertaken to determine the population at risk and assess vaccination coverage.

METHODS: The epidemiologic investigation relied on compilation and review of case and population data, laboratory typing of meningococcal isolates, and unstructured interviews with university staff. Vaccination coverage data were collected during the vaccination campaign held under an expanded-access Investigational New Drug protocol.

RESULTS: Between March 25, 2013, and March 10, 2014, 9 cases of serogroup B meningococcal disease occurred in persons linked to University A. Laboratory typing results were identical for all 8 isolates available. Through May 14, 2014, 89.1% coverage with the 2-dose vaccination series was achieved in the target population. From the initiation of MenB vaccination through February 1, 2015, no additional cases of serogroup B meningococcal disease occurred in University A students. However, the ninth case occurred in March 2014 in an unvaccinated close contact of University A students.

CONCLUSIONS: No serogroup B meningococcal disease cases occurred in persons who received 1 or more doses of 4CMenB vaccine, suggesting 4CMenB may have protected vaccinated individuals from disease. However, the ninth case demonstrates that carriage of serogroup B *Neisseria meningitidis* among vaccinated persons was not eliminated.

WHAT'S KNOWN ON THIS SUBJECT: Outbreaks of serogroup B meningococcal disease occur at universities and other organizations. Until October 2014, options for control of serogroup B outbreaks were limited by the absence of a licensed vaccine for serogroup B meningococcal disease in the United States.

WHAT THIS STUDY ADDS: We describe a serogroup B outbreak at a university in 2013 and the campaign with investigational serogroup B vaccine held in response. This was the first use of a serogroup B vaccine as an outbreak response in the United States.

[a]*Epidemic Intelligence Service Program, Division of Scientific Education and Professional Development, Center for Surveillance, Epidemiology, and Laboratory Services,* [b]*Division of Bacterial Diseases, National Center for Immunization and Respiratory Diseases,* [c]*Regulatory Affairs, Office of the Director, and* [g]*Immunization Safety Office, National Center for Emerging and Zoonotic Infectious Diseases, Centers for Disease Control and Prevention, Atlanta, Georgia;* [e]*New Jersey Department of Health, Trenton, New Jersey;* [d]*Princeton University, Princeton, New Jersey;* [f]*Mercer County Division of Public Health, Trenton, New Jersey; and* [h]*Princeton Health Department, Princeton, New Jersey*

Dr McNamara participated in collection and analysis of epidemiologic data on the cases and population at risk, contributed to the conception and design of the epidemiologic investigation and analysis, contributed to the conception and design of the vaccination campaign and vaccination coverage and safety data collection, contributed to collection and analysis of vaccination coverage and safety data, and drafted the initial manuscript; Dr Shumate participated in collection and analysis of epidemiologic data on the cases and population at risk, contributed to the conception and design of the epidemiologic investigation and analysis, contributed to the conception and design of the vaccination campaign and vaccination coverage and safety data collection, contributed to collection of vaccination coverage and safety data, and critically reviewed the manuscript;

ARTICLE

Between March 25, 2013 and March 10, 2014, 9 cases of serogroup B meningococcal disease were reported in persons linked to a New Jersey university (University A). During this time, options for control of serogroup B meningococcal disease outbreaks were limited by the absence of a licensed serogroup B (MenB) vaccine in the United States. However, in 2013, 2 recombinant MenB vaccines were under prelicensure review in the United States: the 3-dose vaccine rLP2086 (Trumenba; Wyeth Pharmaceuticals, Inc., a subsidiary of Pfizer, Inc., Philadelphia, PA) and the 2-dose vaccine 4CMenB (Bexsero; Novartis Vaccines and Diagnostics, Siena, Italy). Because 4CMenB had already been licensed in Europe and Australia in 2013, whereas rLP2086 was not yet licensed in any country, we thought 4CMenB would be more acceptable in the target population. The Centers for Disease Control and Prevention (CDC) therefore submitted an expanded access Investigational New Drug (IND) application to the Food and Drug Administration to allow use of 4CMenB to control the outbreak at University A. The CDC, New Jersey Department of Health (NJDOH), Princeton Health Department, and University A collaborated to provide the 2-dose vaccination series to the population at risk in the outbreak beginning in December 2013.

Here, we describe the epidemiologic investigation of the outbreak that led to the decision to vaccinate and the implementation of the vaccination campaign with investigational 4CMenB vaccine.

METHODS

Case Investigation

Meningococcal disease is nationally notifiable and suspected cases are reported directly to state or local public health authorities. The current Advisory Committee on Immunization Practices guidelines define an organization-based meningococcal disease outbreak as the occurrence of 3 or more cases in 3 months in persons with a common organizational affiliation but without direct close contact and a resulting attack rate of >10 per 100 000.[1] An outbreak case was defined as a case of serogroup B meningococcal disease with laboratory results consistent with the outbreak strain that occurred in a University A student or close contact of University A students. Cases were reported in New Jersey, Texas, Massachusetts, and Pennsylvania in the United States, as well as in Greece, and were investigated by university and local and state health department staff to identify close contacts for antibiotic chemoprophylaxis. The case-patient who became ill in Greece had been traveling with a group of University A students in Europe for 3 weeks before illness onset; no air travel contacts of this patient required chemoprophylaxis. NJDOH compiled data on all outbreak cases, including those initially reported elsewhere.

Molecular Characterization

For 8 cases, *Neisseria meningitidis* serogroup was determined by slide agglutination at the state public health laboratory and confirmed by real-time polymerase chain reaction at CDC.[2–4] Serogroup determination and Porin A (PorA) typing for 1 case was performed in Greece by using polymerase chain reaction.

At CDC, isolates were characterized by using pulsed-field gel electrophoresis, multilocus sequence typing, and molecular typing of factor H binding protein (fHbp), Neisserial heparin binding antigen (NhbA), *Neisseria meningitidis* adhesin A (NadA), and PorA, as previously described.[5–8] Novartis assessed whether 4CMenB vaccine was expected to protect against the outbreak strain by using human serum bactericidal assay (hSBA) and meningococcal antigen typing system (MATS).[9,10]

Epidemiologic Investigation

After the sixth outbreak case in October 2013, NJDOH invited CDC to assist with an on-site investigation to determine the target population for potential vaccination. To understand whether cases shared epidemiologic links, case information gathered by NJDOH, the Princeton Health Department, and University A was compiled and reviewed. The population at risk[1] was characterized through interviews with University A staff and students and review of university data on student ages, living arrangements, and social interactions.

Vaccination Clinic

In November 2013, use of 4CMenB vaccine was authorized per the Food and Drug Administration under the expanded access IND regulations (21 CFR 312.320). The primary goal of the expanded-access IND was to make vaccine available to the population at risk for serogroup B meningococcal disease during the outbreak, given the lack of an adequate, approved alternative for prevention of this potentially life-threatening condition in the United States. The primary purpose of an expanded-access IND is to provide access to a vaccine or treatment; it is not intended to establish safety and efficacy of the product.

CDC's Institutional Review Board (IRB) served as the IRB for this IND protocol; the university's IRB deferred to CDC. Written informed consent was obtained from all vaccine recipients and parental consent and written assent were obtained for recipients <18 years.

University A and CDC collaborated to provide students, parents, faculty, and staff with accurate and timely information about the 4CMenB vaccination program, implement the vaccination campaign, and monitor adverse events after vaccination.

Potential vaccine recipients were notified of the clinic through multiple mechanisms, including e-mail, posters, and text messages. At the clinic, precautions and contraindications for vaccination were assessed through a screening questionnaire for each recipient; those with questions about the vaccine or medical conditions received further evaluation from a clinical team composed of medical doctors from CDC and University A. Vaccination coverage was monitored through real-time entry of vaccination into recipients' electronic health records or, for nonstudents, by collecting copies of the informed consent paperwork. Reports of adverse events after vaccination are being collected passively via phone and student health clinic visits and actively via surveys administered at the time of second dose administration and 30 days after receipt of the second dose.

RESULTS

Case Ascertainment

Between March and November 2013, 7 cases occurred in University A undergraduates and 1 additional case occurred in a high school student who became ill after staying in an undergraduate dormitory at University A. Excluding the 1 case that occurred during the university's summer break, case-patients lived or stayed in 6 of the 50 undergraduate dormitories at University A immediately before disease onset. No cases occurred in graduate students, faculty, staff, local community members, or family members of case-patients. The median time between cases was 26 days (range 12–94).

All 8 of these case-patients experienced headache and fever and 7 of the 8 developed a rash. Seven case-patients had meningitis, whereas 1 had bloodstream infection only. All case-patients were hospitalized; the median length of stay was 7 days (range 5–10 days). None of these 8 cases was fatal, but 3 case-patients had long-term sequelae (unilateral hearing loss [n = 1], neurocognitive deficits [n = 1], and chronic headaches [n = 1]).

The ninth case occurred in March 2014, after the 4CMenB vaccination campaigns and 109 days after the eighth case. This case occurred in a student at a different university who had close contact with University A undergraduates at an off-campus social event 8 days before disease onset. The ninth case-patient exhibited a petechial rash but did not have evidence of meningitis. The ninth case was fatal, bringing the overall outbreak case-fatality ratio to 11%.

Outbreak case-patient ages ranged from 17 to 21 years (median 19); cases occurred in both male (56%) and female individuals and across 4 undergraduate classes (Fig 1). No case-patients had a previous diagnosis of a medical condition that increases risk of meningococcal disease (ie, functional or anatomic asplenia or persistent complement component deficiency).[1] The annualized attack rate of serogroup B meningococcal disease among University A undergraduates was 134 per 100 000.

Immediately on identification of each case, close contacts of case-patients were identified by University A, NJDOH, the Princeton Health Department, and other state and local health departments and were recommended antibiotic chemoprophylaxis. Close contacts include household contacts (including roommates), child care center contacts, and anyone else with a direct exposure to a case-patient's oral secretions.[1] No secondary cases occurred in close contacts of case-patients. In addition to chemoprophylaxis for close contacts, in May 2013 the university issued recommendations for students to reduce sharing of eating and drinking materials and other activities that could result in contact with oral secretions.

Molecular Characterization

All cases were confirmed as serogroup B meningococcal disease and had the same PorA type (P1.5-1,2-2). Isolates from the 8 cases identified in the United States were characterized further; all were sequence type 409 (ST-409) of clonal complex 41/44/Lineage 3 and had the same pulsed-field gel electrophoresis pattern (429) and antigen types (fHbp 1.276, NhbA p0002, and NadA negative by Novartis nomenclature). The fHbp and NhbA antigens in the outbreak strain demonstrated cross-reactivity with 4CMenB vaccine antigens by MATS; hSBA testing showed that serum from people vaccinated with 4CMenB was able to kill the outbreak strain.

Epidemiologic Investigation

The outbreak spanned 2 academic years. Only 1 person was identified as a close contact of more than 1 case (cases 4 and 7); however, these cases occurred nearly 6 months apart and the contact in question received chemoprophylaxis immediately after the identification of each case. No case-patients were found to share common extracurricular activities and no cases occurred in the same dormitory within an academic year.

In the 2013–2014 academic year, 5241 undergraduate and 2666 graduate students were enrolled at University A. More than 98% of undergraduates and 20% of graduate students lived in on-campus dormitories. For undergraduates, the mean age was 21 years (range 16–31) and vaccination coverage with quadrivalent meningococcal conjugate vaccine (MenACWY) was >99.9%. Graduate students living in the graduate student dormitory were significantly younger than graduate students living in university-owned apartments, with mean ages of 24.1 and 26.4 years, respectively (t test,

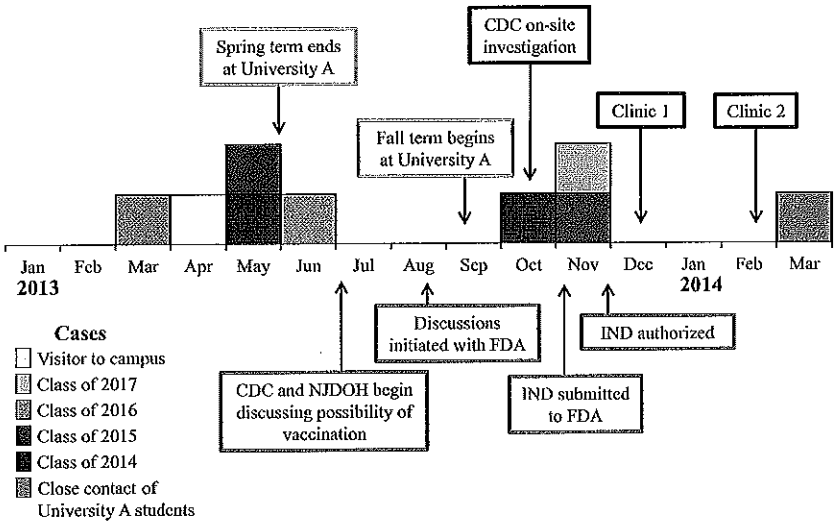


FIGURE 1
Timeline of outbreak cases and response activities.

$t = 13$, $P < .0001$). Social mixing between undergraduate and graduate students was reported to be uncommon but extant; however, the degree of social mixing could not be quantified.

Based on this investigation, the target population for vaccination included University A undergraduate students ($n = 5241$); graduate students living in undergraduate and graduate student dormitories ($n = 541$); graduate students, faculty, and staff with a medical condition that increases risk of meningococcal disease ($n = 11$); and spouses and caregivers of undergraduate and graduate students living in a dormitory with the students ($n = 6$).

Vaccination Campaign

The first-dose vaccination clinic was held December 9 to 12, 2013, and the second-dose clinic was held February 17 to 20, 2014. Additional small clinics were held for persons unable to attend the larger clinics. Through May 14, 2014, 94.9% of the target population had received at least 1 dose of the vaccine and 89.1% had received both doses (Table 1). Within this target population, coverage was highest among undergraduate students, of whom 96.6% received the first dose and 91.4% received both doses (Table 1). As of February 1, 2015, 1 serious adverse event was deemed possibly related to the vaccine (a case of rhabdomyolysis with onset 1 day after the second dose), but no concerning patterns of adverse events after vaccination have been observed. Monitoring for adverse events is ongoing.

Through February 1, 2015, no cases of serogroup B meningococcal disease have been reported in individuals who received the 4CMenB vaccine. However, as noted previously, the ninth case did occur after the vaccination campaigns. The ninth case-patient was a student at another university who had close contact with several University A students, most of whom had received 2 doses of 4CMenB, before disease onset. The student body of the second university was not considered to be at increased risk for meningococcal disease due to this incident.

DISCUSSION

In this report, we describe the first time an expanded-access IND program for an investigational vaccine has been implemented in response to a serogroup B meningococcal disease outbreak in the United States. The attack rate among undergraduate students at University A, 134 per 100 000, was more than 1400 times greater than the national incidence in this age group (1, CDC, unpublished data). Before routine MenACWY vaccination, most meningococcal disease outbreaks on college campuses were caused by serogroup C.[11,12] However, serogroup C outbreaks have declined with high MenACWY coverage in adolescents,[13] leaving serogroup B as the cause of recent meningococcal outbreaks on college campuses.

The sequence type of the bacterial strain isolated in this outbreak, ST-409, is uncommon in the United States. Aside from the samples received from this outbreak, CDC has received only 9 (0.25%) serogroup B ST-409 isolates of 3595 unique case isolates that have been characterized by multilocus sequence typing (isolates collected 1911–2014). None of these other ST-409 isolates had the same antigen profile as the University A outbreak strain. To our knowledge, no other outbreaks associated with ST-409 have been reported in the United States or elsewhere. Little is known about the clinical presentation of meningococcal disease caused by ST-409, but in this outbreak, the case-fatality ratio and proportion of case-patients with meningitis were consistent with those from meningococcal disease surveillance data for the United States.[14]

It is not clear why this strain caused an outbreak at University A. This strain might be more invasive than other *N meningitidis* sequence types and indeed it is part of the ST-41/44 clonal complex, which is thought to be hypervirulent.[15] Alternatively, the undergraduate population may have had low baseline immunity to this novel bacterial strain, leading to a high attack rate once it was introduced into the student population.

Defining the population at risk in meningococcal disease outbreaks can be challenging. In this outbreak, cases occurred in students of 4 undergraduate class years, and

TABLE 1 Coverage of 4CMenB Vaccine in Targeted Populations at University A, December 9, 2013–May 14, 2014

Constituency	No. in Target Population	No. First Doses Given	Coverage with First Dose, %	No. Second Doses Given	Coverage with 2-Dose Series, %
Undergraduate students	5241	5062	96.6	4791	91.4
Class of 2017	1292	1260	97.5	1214	94.0
Class of 2016	1349	1296	96.1	1232	91.3
Class of 2015	1320	1274	96.5	1178	89.2
Class of 2014	1280	1232	96.3	1167	91.2
Graduate students	541	424	78.4	361	66.7
Other[a]	17	16	94.1	13	76.5
Total	5799	5502	94.9	5165	89.1

[a] Category includes faculty, staff, and graduate students with medical conditions that increase risk of meningococcal disease, and spouses and caregivers of graduate and undergraduate students living in a dormitory with the students.

therefore the entire undergraduate population was targeted for vaccination. Although no cases occurred in graduate students, graduate students living in on-campus dormitories were targeted for vaccination because the increased risk of meningococcal disease for college freshmen living in dormitories[16–19] raised concerns that dormitory living might also increase risk for other populations. Furthermore, most outbreak-associated cases of meningococcal disease in the United States occur in persons aged <25 years and the mean age of the graduate students living in dormitories was <25 years.[11] Although the population at risk must be determined separately for each outbreak of meningococcal disease, we hope the process used to define the population at risk at University A can inform this determination in future outbreaks.

More than 5000 students received 4CMenB vaccine during the 4-day first-dose vaccination campaign. Several factors likely contributed to the campaign's success. First, the university provided information about meningitis and the vaccination clinics to students and parents through multiple mechanisms, including e-mails, posters, text messages, a student-created video, and town hall meetings featuring University A and CDC staff. In addition, efficient clinic management and short wait times for participants resulted in high throughput. Finally, the high attack rate of meningococcal disease and the occurrence of cases shortly before the vaccination campaign likely motivated students to receive the vaccine. This highly successful vaccination campaign provides a model for future vaccination campaigns in response to outbreaks on college campuses.

As of February 1, 2015, no additional serogroup B meningococcal disease cases occurred at University A. Although 2 doses of the vaccine are critical for a sustained immune response,[20] 1 study demonstrated that adolescents also have a strong initial immune response after a single dose.[21] This fact might have contributed to the absence of cases between the first and second vaccination campaigns. However, a case did occur in a close contact of University A students in March 2014. Most of the students with whom the last case-patient had contact had received 2 doses of 4CMenB vaccine. The occurrence of this case demonstrates that the vaccination campaign had not eliminated carriage from the University A population by this time and that transmission of the outbreak strain was ongoing. This finding is consistent with a recent study demonstrating that 4CMenB has at most a modest impact on prevalence of meningococcal carriage in vaccinated people.[22] Ultimately, it is unknown whether additional cases would have occurred in University A students in the absence of the vaccination campaign, but the lack of cases in vaccinated persons combined with the evidence of ongoing transmission in the population suggests the campaign did succeed in providing primary protection to the student population.

The first vaccine for serogroup B meningococcal disease, rLP2086, was licensed for use in individuals 10 to 25 years old on October 29, 2014, and 4CMenB was approved for use in the same age group on January 23, 2015. Although the Advisory Committee on Immunization Practices has not yet developed recommendations for the use of either vaccine, CDC formed a meningitis outbreak working group to provide interim guidance for responding to outbreaks of serogroup B meningococcal disease. These guidelines are available online at http://www.cdc.gov/meningococcal/outbreaks/vaccine-serogroupb.html. Although the number of sporadic cases of serogroup B meningococcal disease occurring in adolescents each year is at historic lows, the potential impact of MenB vaccines on both sporadic disease and outbreaks will be important to consider in the development of recommendations for use of licensed MenB vaccines in the United States.

CONCLUSIONS

No serogroup B meningococcal disease cases occurred in students who had received 1 or more doses of 4CMenB vaccine, suggesting 4CMenB was effective in protecting vaccinated individuals from disease. However, the ninth case demonstrates that carriage of serogroup B *N meningitidis* among vaccinated persons was not eliminated. The outbreak investigation and highly successful vaccination campaign described here can serve as a model for how to approach similar outbreaks in the future.

ACKNOWLEDGMENTS

We thank Evangeline Reynolds and Wendy Chung of Dallas County Health and Human Services, Dallas; Tamara Baldwin and Grace Kubin, Texas

Department of State Health Services, Austin; Johanna Vostok, Massachusetts Department of Public Health, Boston; Ami Patel, Office of Public Health Preparedness and Response, CDC, Atlanta, and Philadelphia Department of Public Health; Lauren Finn, Philadelphia Department of Public Health; Lisa Dettinger and Christina Russell, Pennsylvania Department of Health, Exton; Maria Orsini and Howard Sarubin, NJDOH, Trenton; and the staff of the Princeton Health Department, Princeton, the Mercer County Division of Public Health, Trenton, Papageorgiou General Hospital, Thessaloniki, the American Hospital of Paris, Neuilly-sur-Seine, Drexel University, and the Presbyterian University Hospital for assistance with case investigations, contact tracing, and meningococcal testing. We are grateful to the staff of Novartis Vaccines and Diagnostics, Siena, Italy, for coordinating MATS and hSBA testing of patient isolates and vaccine procurement as well as for providing information about the 4CMenB vaccine. We thank Chad Myers and the New Jersey staff of Maxim Healthcare Services, Columbia, MD; Sarah Meyer and Tejpratap Tiwari, Division of Bacterial Diseases, National Center for Immunization and Respiratory Diseases, CDC, Atlanta; Natalie Kratz, CDC/Council of State and Territorial Epidemiologists Applied Epidemiology Fellow assigned to the NJDOH, Trenton; and the staff and students of University A for their work implementing and supporting the vaccination campaigns.

Dr Johnsen participated in collection of epidemiologic data on the cases and population at risk, contributed to the conception and design of the vaccination campaign and vaccination coverage and safety data collection, contributed to collection of vaccination coverage and safety data, and critically reviewed the manuscript; Ms MacNeil participated in collection and analysis of epidemiologic data on the cases and population at risk, contributed to the conception and design of the epidemiologic investigation and analysis, contributed to the conception and design of the vaccination campaign and vaccination coverage and safety data collection, and critically reviewed the manuscript; Dr Patel contributed to the conception and design of the vaccination campaign and vaccination coverage and safety data collection, contributed to collection and analysis of vaccination coverage and safety data, and critically reviewed the manuscript; Dr Bhavsar and Ms Finnie contributed to the conception and design of the vaccination campaign and vaccination coverage and safety data collection, and critically reviewed the manuscript; Dr Cohn contributed to the conception and design of the epidemiologic investigation and analysis, and critically reviewed the manuscript; Ms Dinitz-Sklar and Dr Neglia participated in collection of epidemiologic data on the cases and population at risk, and critically reviewed the manuscript; Dr Duffy contributed to the conception and design of the vaccination campaign and vaccination coverage and safety data collection, contributed to collection and analysis of vaccination safety data, and critically reviewed the manuscript; Ms Garon and Mr Hary participated in collection of epidemiologic data on the cases and population at risk, and critically reviewed the manuscript; Drs Hu and Wang collected and analyzed laboratory data, and critically reviewed the manuscript; Dr Kamiya participated in collection and analysis of epidemiologic data on the cases and population at risk, contributed to collection of vaccination safety data, and critically reviewed the manuscript; Drs Kim, Kolligian, and Yu contributed to the conception and design of the vaccination campaign and vaccination coverage and safety data collection, and critically reviewed the manuscript; Ms Oakley contributed to collection and analysis of vaccination coverage data, and critically reviewed the manuscript; Ms J. Wagner and Ms K Wagner contributed to the conception and design of the vaccination campaign and vaccination coverage and safety data collection, contributed to collection of vaccination coverage data, and critically reviewed the manuscript; Drs Montana, Tan, and Clark and Ms Izzo contributed to the conception and design of the epidemiologic investigation and analysis, and critically reviewed the manuscript; and all authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

www.pediatrics.org/cgi/doi/10.1542/peds.2014-4015

DOI: 10.1542/peds.2014-4015

Accepted for publication Feb 19, 2015

Address correspondence to Lucy McNamara, PhD, Division of Bacterial Diseases, National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention, 1600 Clifton Rd, MS C-25, Atlanta, GA 30333. E-mail: xdf4@cdc.gov

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

FINANCIAL DISCLOSURE: The authors have indicated they have no financial relationships relevant to this article to disclose.

FUNDING: Supported in part by an appointment to the Applied Epidemiology Fellowship Program administered by the Council of State and Territorial Epidemiologists (CSTE) and funded by the Centers for Disease Control and Prevention Cooperative Agreement 5U38HM000414-5.

POTENTIAL CONFLICT OF INTEREST: Dr Johnsen was invited by Pfizer (manufacturer of rLP2086, Trumenba) to speak to their vaccine group and at 3 national conferences. Pfizer paid for Dr Johnsen's airfare and lodging to attend these events; he did not receive an honorarium or other reimbursements. Dr Johnsen was also invited by the National Meningitis Association to participate in a round table at another conference. The National Meningitis Association paid for Dr Johnsen's lodging but did not provide any honorarium or other reimbursements. The other authors have indicated they have no potential conflicts of interest to disclose.

REFERENCES

1. Cohn AC, MacNeil JR, Clark TA, et al; Centers for Disease Control and Prevention (CDC). Prevention and control of meningococcal disease: recommendations of the Advisory Committee on Immunization Practices

(ACIP). *MMWR Recomm Rep.* 2013;62(RR-2):1–28

2. Dolan Thomas J, Hatcher CP, Satterfield DA, et al. *sodC*-based real-time PCR for detection of *Neisseria meningitidis*. *PLoS ONE.* 2011;6(5):e19361
3. Mothershed EA, Sacchi CT, Whitney AM, et al. Use of real-time PCR to resolve slide agglutination discrepancies in serogroup identification of *Neisseria meningitidis*. *J Clin Microbiol.* 2004;42(1):320–328
4. Wang X, Theodore MJ, Mair R, et al. Clinical validation of multiplex real-time PCR assays for detection of bacterial meningitis pathogens. *J Clin Microbiol.* 2012;50(3):702–708
5. Maiden MCJ, Bygraves JA, Feil E, et al. Multilocus sequence typing: a portable approach to the identification of clones within populations of pathogenic microorganisms. *Proc Natl Acad Sci U S A.* 1998;95(6):3140–3145
6. Popovic T, Schmink S, Rosenstein NA, et al. Evaluation of pulsed-field gel electrophoresis in epidemiological investigations of meningococcal disease outbreaks caused by *Neisseria meningitidis* serogroup C. *J Clin Microbiol.* 2001;39(1):75–85
7. Sacchi CT, Whitney AM, Popovic T, et al. Diversity and prevalence of PorA types in *Neisseria meningitidis* serogroup B in the United States, 1992-1998. *J Infect Dis.* 2000;182(4):1169–1176
8. Wang X, Cohn A, Comanducci M, et al. Prevalence and genetic diversity of candidate vaccine antigens among invasive *Neisseria meningitidis* isolates in the United States. *Vaccine.* 2011;29(29-30):4739–4744
9. Donnelly J, Medini D, Boccadifuoco G, et al. Qualitative and quantitative assessment of meningococcal antigens to evaluate the potential strain coverage of protein-based vaccines. *Proc Natl Acad Sci U S A.* 2010;107(45):19490–19495
10. Giuliani MM, Biolchi A, Serruto D, et al. Measuring antigen-specific bactericidal responses to a multicomponent vaccine against serogroup B meningococcus. *Vaccine.* 2010;28(31):5023–5030
11. Jackson LA, Schuchat A, Reeves MW, Wenger JD. Serogroup C meningococcal outbreaks in the United States. An emerging threat. *JAMA.* 1995;273(5):383–389
12. Centers for Disease Control and Prevention. Meningococcal disease and college students: recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR Recomm Rep.* 2000;49(RR-7):13–20
13. Curtis CR, Yankey D, Jeyarajah J, et al; Centers for Disease Control and Prevention (CDC). National and state vaccination coverage among adolescents aged 13-17 years—United States, 2012. *MMWR Morb Mortal Wkly Rep.* 2013;62(34):685–693
14. Cohn AC, MacNeil JR, Harrison LH, et al. Changes in *Neisseria meningitidis* disease epidemiology in the United States, 1998-2007: implications for prevention of meningococcal disease. *Clin Infect Dis.* 2010;50(2):184–191
15. Climent Y, Yero D, Martinez I, et al. Clonal distribution of disease-associated and healthy carrier isolates of *Neisseria meningitidis* between 1983 and 2005 in Cuba. *J Clin Microbiol.* 2010;48(3):802–810
16. Bruce MG, Rosenstein NE, Capparella JM, Shutt KA, Perkins BA, Collins M. Risk factors for meningococcal disease in college students. *JAMA.* 2001;286(6):688–693
17. Froeschle JE. Meningococcal disease in college students. *Clin Infect Dis.* 1999;29(1):215–216
18. Harrison LH, Dwyer DM, Maples CT, Billmann L. Risk of meningococcal infection in college students. *JAMA.* 1999;281(20):1906–1910
19. Neal KR, Nguyen-Van-Tam J, Monk P, O'Brien SJ, Stuart J, Ramsay M. Invasive meningococcal disease among university undergraduates: association with universities providing relatively large amounts of catered hall accommodation. *Epidemiol Infect.* 1999;122(3):351–357
20. Santolaya ME, O'Ryan M, Valenzuela MT, et al. Persistence of antibodies in adolescents 18-24 months after immunization with one, two, or three doses of 4CMenB meningococcal serogroup B vaccine. *Hum Vaccin Immunother.* 2013;9(11):2304–2310
21. Santolaya ME, O'Ryan ML, Valenzuela MT, et al; V72P10 Meningococcal B Adolescent Vaccine Study Group. Immunogenicity and tolerability of a multicomponent meningococcal serogroup B (4CMenB) vaccine in healthy adolescents in Chile: a phase 2b/3 randomised, observer-blind, placebo-controlled study. *Lancet.* 2012;379(9816):617–624
22. Read RC, Baxter D, Chadwick DR, et al. Effect of a quadrivalent meningococcal ACWY glycoconjugate or a serogroup B meningococcal vaccine on meningococcal carriage: an observer-blind, phase 3 randomised clinical trial. *Lancet.* 2014;384(9960):2123–2131

8.4

UO to resume mass clinics for meningitis vaccination

registerguard.com/rg/news/local/33066680-75/uo-parents-urged-to-get-their-students-meningococcal-vaccination.html.csp

Public health officials again are seeking the help of parents of University of Oregon students to encourage their children to get vaccinated against a contagious and potentially fatal bacteria.

They say Mother's Day weekend is a good time for parents to urge students ahead of a second mass vaccination clinic to get inoculated against meningococcal disease. The clinic starts Tuesday at Matthew Knight Arena.

The UO outbreak of type B meningococcal disease that began in January killed Lauren Jones, an 18-year-old member of the UO's acrobatics and tumbling team, in February and sickened five other students. The last reported case was seven weeks ago.

Public health officials maintain that vaccination is the best way to prevent more students from falling ill.

Slightly fewer than 10,000 students have been vaccinated so far, Lane County Public Health reported.

The U.S. Centers for Disease Control and Prevention recommended the university vaccinate nearly 22,000 people: all undergraduates as well as graduate students and faculty who live on campus or have compromised immune systems.

Public health officials had made an initial plea to parents when they confirmed the sixth case of the disease right before spring break.

The UO held the first mass clinic in March, making available one of two newly approved vaccines. It requires three doses to allow the body to develop a full immunity.

Students can also receive a two-dose vaccine, known under the brand name Bexsero, at local pharmacies.

Students will be able to get their first or second dose of the three-dose vaccine, known under the brand name Trumenba, at the mass clinic that runs Tuesday through Thursday. Insurers are covering the cost of the vaccine.

To avoid confusion, as UO students got different vaccines with different dosage schedules at different times, students can visit

https://healthcenter.uoregon.edu/getthevax.aspx to figure out the best way to keep up-to-date on their vaccination schedule.

"I really want to drill home the fact that each dose matters," Dr. Patrick Luedtke, the county's chief health officer, said in a statement. "For all the students who received the first dose, they need to know that completing the vaccine series by receiving subsequent doses is the absolute best way to receive the maximum immunity possible."

Public health officials have sent out reminders that students are due for their next dose. Jason Davis, the department's spokesman, has heard from parents who have threatened to withhold money unless their child receives the dose.

"When you put dollars and cents to the motivation, it tends to work," he said. "Unfortunately, we can't do that."

Meningococcal disease occurs when a bacteria that lodges in the nose and throat begins to attack the body. It can infect the blood, causing meningococcemia, or the membranes protecting the brain and spinal cord, resulting in meningitis.

The bacteria can pass through kissing, sharing cups or utensils or remaining in close contact with a person carrying the bacteria for a prolonged period. The disease is rare — some people can carry the bacteria without becoming ill — but the infection can spread rapidly once it begins, requiring a person to seek immediate medical attention.

The disease can be fatal, and survivors can suffer lifelong complications, including amputated limbs and brain damage.

Correction: A previous version of this story stated that the vaccination clinic would run Monday through Wednesday. The clinic runs Tuesday through Thursday.

9

Herzog, Andrea (HRSA)

From: jean public <jeanpublic1@gmail.com>
Sent: Monday, May 11, 2015 6:50 PM
To: Herzog, Andrea (HRSA); vicepresident@whitehouse.gov; AMERICANVOICES@MAI.HOUSE.GOV; INFO; media; jungaro
Subject: Re: pushsers at feds wnt to push more vaccines into babies to kill them

PUBLIC COMMENT ON FEDERAL REGISTER

THIS GROUP IS ALL ABOUT SEIZING POWER OVER EVERYBODYS BODY IN THE ENTIRE \USA. THESE PEOPLE ARE PROFITEERS AND DRUG PUSHERS WITH VACCINES. THEIR VACCINES KILL AND INJURE MANY. WE JUST HAD 2 BABIES DIE IN MEXICO AND 27 INJURED INT HE HOSPITAL FROM VACCINES. ITS CLEAR THEY ARE PUSHING APRODUCT THATKILLS AND INJURES SOME PEOPLE. THAT MEANS THEY WANT TO STILL WANT THE RIGHT TO OWN EVERYBODY'S BODY. THEY ARE LIKE THE NAZIS. THIS COMMENT IS FOR TH EPUBLIC RECORD. THE PUBLIC NEVER ASKED THIS AGENCY TO MAKE EVERYBODY PUT THIS CRAP POSION INTO EVERYBODY'S BODY. THISIS THE POWER MAD DECISION OF THIS INSIDERS GROUP FILLED WITH BIG PHARMA MONEY. THIS EVIL GROUP IS NOT HELPING AMERICA. I WANT THE BUDGET FORO THIS GROUP TO BE REDUCED BY 50%.I DO NOT THIN THEIR ACTIONS ARE GOOD FOR AMERICA OR THE AMERCAN PEOPLE. THEY DONT OWN US. THEY WANT TO OWN US COMPLETELY INCLUDING OUR BODIES AND MINDS. THIS COMMENT IS FOR THE PUBLIC RECORD. THIS IS AN EVIL, VICIOUS GROUP TAKING AWAY ALL INDEPENDENCE. THEY PICKED ON BABIES FIRST, WHO HAVE NO VOICE. JUST LIKE ANIMALS WHO HAVE NO VOICE. NOW THEY ARE AFTER ALLOF US. ITS A NAZI TACTIC. PLEASE RECEITP. JEAN PUBLI JEANPUBLIC1@GMAIL.COM

On Sat, May 9, 2015 at 3:13 PM, jean public <jeanpublic1@gmail.com> wrote:
[Federal Register Volume 80, Number 89 (Friday, May 8, 2015)]
[Notices]
[Pages 26568-26569]
From the Federal Register Online via the Government Publishing Office [www.gpo.gov]
[FR Doc No: 2015-11097]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Commission on Childhood Vaccines; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), notice is hereby given of the following meeting:

Name: Advisory Commission on Childhood Vaccines (ACCV).
Date and Time: June 4, 2015, 10:00 a.m. to 4:30 p.m. EDT.
Place: Audio Conference Call and Adobe Connect Pro.

The ACCV will meet on Thursday, June 4, 2015, from 10:00 a.m. to 4:30 p.m. (EDT). The public can join the meeting by:

1. (Audio Portion) Calling the conference Phone Number 877-917-4913 and providing the following information:

Leaders Name: Dr. A. Melissa Houston.

Password: ACCV.

2. (Visual Portion) Connecting to the ACCV Adobe Connect Pro Meeting using the following URL: https://hrsa.connectsolutions.com/accv/ (copy and paste the link into your browser if it does not work directly, and enter as a guest). Participants should call and connect 15 minutes prior to the meeting in order for logistics to be set up. If you have never attended an Adobe Connect meeting, please test your connection using the following URL: https://hrsa.connectsolutions.com/common/help/en/support/meeting_test.htm and get a quick overview by following URL: http://www.adobe.com/go/connectpro_overview.

Call (301) 443-6634 or send an email to aherzog@hrsa.gov if you are having trouble connecting to the meeting site.

[[Page 26569]]

Agenda: The agenda items for the June 2015 meeting will include, but are not limited to: Updates from ACCV Adult Immunization Workgroup, the Division of Injury Compensation Programs (DICP), Department of Justice (DOJ), National Vaccine Program Office (NVPO), Immunization Safety Office (Centers for Disease Control and Prevention), National Institute of Allergy and Infectious Diseases (National Institutes of Health), and Center for Biologics, Evaluation and Research (Food and Drug Administration). A draft agenda and additional meeting materials will be posted on the ACCV Web site (http://www.hrsa.gov/vaccinecompensation/accv.htm) prior to the meeting. Agenda items are subject to change as priorities dictate.

Public Comment: Persons interested in providing an oral presentation should submit a written request, along with a copy of their presentation to: Annie Herzog, Division of Injury Compensation Programs (DICP), Healthcare Systems Bureau (HSB), Health Resources and Services Administration (HRSA), Room 11C-26, 5600 Fishers Lane, Rockville, Maryland 20857 or email: aherzog@hrsa.gov. Requests should contain the name, address, telephone number, email address, and any business or professional affiliation of the person desiring to make an oral presentation. Groups having similar interests are requested to combine their comments and present them through a single representative. The allocation of time may be adjusted to accommodate the level of expressed interest. DICP will notify each presenter by email, mail, or telephone of their assigned presentation time. Persons who do not file an advance request for a presentation, but desire to make an oral statement, may announce it at the time of the public comment period. Public participation and ability to comment will be limited to space and time as it permits.

For Further Information Contact: Anyone requiring information regarding the ACCV should contact Annie Herzog, DICP, HSB, HRSA,

Room 11C-26, 5600 Fishers Lane, Rockville, Maryland 20857; telephone (301) 443-6593, or email: aherzog@hrsa.gov.

Jackie Painter,
Director, Division of the Executive Secretariat.
[FR Doc. 2015-11097 Filed 5-7-15; 8:45 am]
BILLING CODE 4165-15-P