

**ADVISORY COMMISSION ON CHILDHOOD VACCINES  
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March 3, 2016**

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***ADVISORY COMMISSION ON  
CHILDHOOD VACCINES***

***Agenda***

February 11, 2016

**ADVISORY COMMISSION ON CHILDHOOD VACCINES (ACCV)  
Teleconference and Adobe Connect**

March 3, 2016

(10:00 am – 3:15 pm Eastern Daylight Time)

Dial in: 1-800-779-3561

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<b>Time</b>	<b>Agenda Item</b>	<b>Presenter</b>
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 December 2015 Minutes	Dr. Kristen Feemster, Chair
10:20 AM	Presentation on Impact of Increased Claims Filed	Ms. Patricia E. Campbell-Smith Chief Judge United States Court of Federal Claims  Ms. Nora Beth Dorsey, Chief Special Master U.S. Court of Federal Claims
10:50 AM	Report from the Division of Injury Compensation Programs	Dr. Narayan Nair Acting Director, DICP
11:20 AM	Report from the Department of Justice	Mr. Vince Matanoski Assistant Director Torts Branch, DOJ
12:00 PM	<b>Lunch</b>	
1:00 PM	Review of Vaccine Information Statements	Skip Wolfe, CDC

<b>Time</b>	<b>Agenda Item</b>	<b>Presenter</b>
1:45 PM	Update on the Immunization Safety Office (ISO), Centers for Disease Control and Prevention (CDC) Vaccine Activities	Dr. Tom Shimbabukuro CDC
2:00 PM	Update on the National Institute of Allergy and Infectious diseases (NIAID), National Institutes of Health (NIH) Vaccine Activities	Dr. Barbara Mulach NIAID, NIH
2:15 PM	Update on the Center for Biologics, Evaluation and Research (CBER), Food and Drug Administration (FDA) Vaccine Activities	LCDR Valerie Marshall CBER, FDA
2:30PM	Update from the National Vaccine Program Office (NVPO)	Dr. Karin Bok NVPO
2:45PM	Public Comment (follows the preceding topic and may commence earlier or later than 2:45 pm)	Dr. Kristen Feemster, Chair
3:00 PM	Future Agenda Items/New Business <ul style="list-style-type: none"> <li>• Review previous Recommendations and discuss workgroup activities</li> </ul>	Dr. Kristen Feemster, Chair
3:15 PM	Adjournment of the December 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.





## **Roster**

**ADVISORY COMMISSION ON CHILDHOOD VACCINES (ACCV) ROSTER  
DIVISION OF INJURY COMPENSATION PROGRAMS (DICP)**

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**2016 Meeting Dates**

# **ADVISORY COMMISSION ON CHILDHOOD VACCINES**

## **2016 MEETING DATES**

March 3, 2016

June 2 & 3, 2016

September 1 & 2, 2016

December 1 & 2, 2016

**2**

**Advisory Commission on Childhood Vaccines  
December 3, 2015  
98th Meeting  
Teleconference and Adobe Connect**

**Members Present**

Kristen A. Feemster, M.D., ('15)  
Charlene Douglas, Ph.D. ('15)  
Edward Kraus, J.D. ('15)  
Karlen E. Luthy, ('18)  
Luisita dela Rosa, Ph.D. ('15)  
Jason Smith, J.D. ('15)  
Martha Toomey ('18)  
Alexandra Stewart, (18)  
Sylvia Fernandez Villarreal, M.D. ('15)

**Division of Injury Compensation Programs (DICP), Health Resources and Services Administration (HRSA), U.S. Department of Health and Human Services (HHS)**

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

**Welcome, Kristen A. Feemster, M.D., Chair**

Dr. Feemster invited commissioners to announce their presence on the phone after which she invited public comment on the meeting agenda.

**Public Comment on Agenda Items**

Janet Cakir noted that she was submitting a PowerPoint presentation to support of comments that she would be making during the public comment period. She requested that they be made available on the web during her presentation.

**Approval of September 3, 2015 minutes**

Dr. Feemster invited approval of the minutes of the September 3, 2015 ACCV meeting. On motion duly made by Ms. Douglas, seconded by Mr. Smith, the minutes of the September 3, 2015 meeting were approved without corrections or revisions. Dr. Feemster then turned to the agenda and invited Dr. Houston to provide her report.

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

Dr. Houston welcomed those present and briefly reviewed the agenda. The agenda includes an update from the Department of Justice (DOJ), a report from the ACCV Adult Immunization Workgroup, Presentations on Impact of Increased Claims Filed (DICP and DOJ) and finally updates from the ex officio members from the Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC), National Institutes of Health (NIH) and the National Vaccine Program Office (NVPO).

Looking at petitions and adjudications, Dr. Houston stated, as of November 5, 2015, the Division had received 133 petitions and the projection, based on that number is about 1,500 petitions may be filed before the end of this fiscal year (FY). The total adjudications for the current report period is 12, 75% of them were settled and 25% were due to concession. In the first month of FY 16, awards to petitioners totaled \$18.5 million and \$2 million to petitioners' attorneys for fees and costs. The Vaccine Injury Trust Fund stands at \$3.6 billion as of September 30, 2015. Of the \$3.6 billion \$275 million was derived from excise tax payments and \$59 million from interest on the Trust Fund balance.

Dr. Houston announced that the Revisions to the Vaccine Injury Table Notice of Proposed Rulemaking was published in the Federal Register on July 29, 2015, and the 180-day public period extends through January 25, 2016. There will also be a public hearing to provide further opportunity for public comment, and the date of that hearing will be published in the Federal Register. The commissioners will be informed when that date is known.

Dr. Houston described the National Vaccine Injury Compensation (VICP) outreach activities one of which is a partnership with the Food and Drug Administration, which distributes VICP materials at various meetings such as the November 18, 2015 meeting of 24 National Nurses Associations. In addition to meetings, an article written by the VICP was posted to the National Association of County & City Health Officials blog at <http://essentialelements.naccho.org/archives/1319> and went live on November 10, 2015.

Dr. Houston stated she attended the Advisory Committee on Immunization Practices (ACIP) in Atlanta on October 21, 2015. Information on ACCV meetings, including minutes and presentations, can be found on the web at <http://www.hrsa.gov/vaccinecompensation/commissionchildhoodvaccines.html>

## **Report from DOJ, Vince Matanoski, Assistant Director, Torts Branch**

Mr. Matanoski welcomed commissioners and referenced the Department of Justice Power Point materials (DOJ PP), as part of his presentation for the three-month period from August 16 - November 15, 2015. During this reporting period, 337 petitions were filed. Of those, 32 were filed on behalf of children and 305 were filed by adults. Last year there were about 800 petitions filed and this year the Department is expecting over a 1,000. He explained that, since flu accounts for the majority of vaccinations, and there is a seasonal effect on when vaccinations are given for flu, there is a concomitant seasonal fluctuation in claims filed for

vaccine injuries. There was also a notable increase in shoulder injuries related to vaccine administration (SIRVA).

With regard to total cases adjudicated, even though there were 337 claims filed, only 150 petitions were adjudicated, which indicates an increasing backlog. That issue will be discussed under a separate agenda item. A total of 116 cases were compensated, 34 cases conceded by HHS (nearly all by proffer), and 82 cases not conceded by HHS, all by settlement. Thirty-four were not compensated and seven claims were voluntarily withdrawn.

Mr. Matanoski discussed a number of cases now going through the appeals process

***Appeals by Petitioner in the U.S. Court of Appeals for the Federal Circuit:***

- A decision was handed down in *Hirmiz v. HHS* that the alleged injury occurred before the vaccination. That decision was affirmed by the U.S. Court of Appeals for the Federal Circuit (CAFC).
- In *Mora v. HHS*, one of five newly filed appeals, the petition was dismissed at the request of the petitioner in order to pursue a civil action. The claim was ineligible for that process under current regulations. The claimant then tried to return to the original claim process but was ineligible there as well.
- *D'Angiolini v. HHS*, involved a claim of ASIA (autoimmune syndrome induced by adjuvant), but the U.S. Court of Federal Claims (CFC) ruled against the petitioner after hearing evidence that ASIA was not the cause of the injury.
- In *Nutall v. HHS*, the CFC affirmed the Special Master's decision that the claimant failed to demonstrate that he had suffered an injury, specifically encephalitis.
- *Padmanabhan v. HHS* and *Greenberg v HHS* were both *pro se* cases in which the claimant represented himself, without engaging an attorney. *Padmanabhan* alleged that the child suffered from an underlying mitochondrial disease that was significantly aggravated by the vaccination. The claimant failed to submit court ordered medical information and ultimately failed to pursue the case for action and the special master dismissed the case for failure to prosecute. In *Greenberg* the issue related to the fact that the injury occurred after three years, past the statute of limitations for filing, as well as a ruling that, even if the claim had been timely filed, the claimant failed to prove causation. Review of that decision is pending at the CFC.

***Appeals by Petitioner in the U.S. CFC:***

Five cases were decided, three involving entitlement and two related to attorneys' fees and costs.

- In *Hodge v. HHS*, regarding timely filing of the claim, the CFC remanded the case to the special master to review whether the claimant had the mental capacity to properly file the claim in a timely manner. It is pending with the special master.
- *Greenberg v. HHS* was discussed above.
- In *Waterman v. HHS*, the claim involved a vaccination containing several vaccines and the issues of the claim revolve around proof of cause of death. The

CACF affirmed that there were insufficient facts to support the allegation in that case.

- In *Scharfenberger v. HHS*, the special master reduced the original award from \$100,000 to about \$80,000. An appeal to restore the original amount failed and the special master's decision was affirmed.
- In *Guerrero v. HHS*, the appeal was originally affirmed for the award handed down at the special master level, then reversed by the CFC so that the special master could review the circumstances (a small amount was added to the award).

***Five new appeals pending in the CF C:***

- In *Graham v. HHS*, the petitioner's attorneys filed a claim before fully developing the case and the claim was dismissed when it was clear the vaccine was not involved. Although attorneys are entitled to fees and costs whether the case is won or lost, in this case the special master deemed that there was no reasonable basis for filing the claim and the claim for fees and costs was rejected.
- In *Bloch v. HHS*, the special master determined that there was no evidence produced by the petitioner to show that the injury was aggravated by the vaccine, so the claim was dismissed.
- In *Tomberlin v. HHS*, the appeal was filed to cause a review of a decision, but the decision was actually an intermediate ruling on a particular damages issue. The question before the court is whether or not the ruling constitutes a final decision.
- *Kenzora v HHS* involved a settlement agreed on by the petitioner and respondent without requiring a finding that the vaccine in question actually caused the alleged injury. An award was made and the petitioner, deciding the award was not sufficient, petitioned the court to vacate the judgement in order to renegotiate the award. The special master denied the request, leading to this appeal.
- In *Krakov v. HHS*, the child involved suffered from a preexisting mitochondrial illness, which the petitioner believed was exacerbated by the vaccine such that the child suffered a subsequent neurological injury. After a lengthy hearing lasting more than a week, the special master found there was insufficient evidence to support the claim, resulting in this appeal.

Finally, Mr. Matanoski stated that one oral argument is scheduled in the CAFC on December 8 – *Moriarity v. HHS*.

***Adjudicated settlements***

Mr. Matanoski summarized the history of adjudicated settlements. Eighty-three cases were resolved by settlement in the period beginning August 16, 2015 through November 15, 2015. There were 72 adult cases and 11 cases involving minors. Flu vaccine was included in the alleged vaccines causing injury in 63 claims. The average time to process the claims was one year and ten months; the median processing time was 10 months. The percentage of cases resolved within one year was 43%; 75% within two years; and 85% within three years. Within the last few years the time to resolve cases has decreased, but in this time period that trend has ended, a cause for concern. Of course, Mr. Matanoski added that one instance is not sufficient to make conclusions about the future.

With regard to conceded cases, there were 33 such cases in this period, and the average processing time was 10 months, the median was eight months. Noting that this was an excellent result, Mr. Matanoski concluded his report.

### **Presentation on Impact of Increased Claims Filed, Dr. A. Melissa Houston, Director DICP, and Mr. Vince Matanoski, DOJ**

Dr. Houston introduced the discussion of the impact of the increasing number of claims being filed under the VICP. She noted that HRSA administers the program, reviews claims as they are filed, reviews medical and scientific literature as it applies to the types of claims made under the program, and determines if the claims meet the medical criteria for compensation. Finally, HRSA submits a preliminary recommendation on behalf of the Secretary of HHS to the Department of Justice. Once a claim has been adjudicated, HHS provides the logistical service of payments to petitioners and to their attorneys for fees and costs.

Historically, after a relatively stable rate of annual claims from 2002 through 2008, the number of claims began to increase at an exponential rate, climbing from an average of about 200 claims a year to 804 claims in fiscal year 2015. However, in the last three years HRSA VICP staffing levels responsible for processing those claims has remained stable (17 FTEs in 2013, and 18 FTEs in 2014 and 2015). Various strategies have eased the pressure on the staff, including the use of technology (in writing and distributing checks, for example), and a vacancy announcement was posted in late 2015 to recruit additional staff.

Mr. Matanoski commented on the situation at the DOJ where attorneys and paralegals work with HRSA medical officers, petitioners, expert witnesses, and others to develop the cases and reach an equitable outcome. The process involves conferences and hearings, a significant time requirement. Mr. Matanoski explained that the process is budget limited and that budget has remained flat since 2009. It was originally designed to accommodate about 400 claims per year, a number that increased to over 800 in FY 2015.

Noting that Omnibus Autism Proceeding cases were significantly reduced by March 2012, Mr. Matanoski also explained that a backlog of unresolved cases began to build by September of 2013. That backlog has grown to about 500 cases, which means that an unacceptable number of individuals are having to wait a longer time for resolution. There is also an added maintenance cost to a large backlog. There is an internal requirement for reports to update management about the delays, reports that take time to prepare, and there is an increased need to respond to petitioners' attorneys, who request clarification for the delays.

The resolution to the challenge is to increase the resources devoted to each case, which flies in the face of budget limitations, or to decrease the resources needed to resolve the cases, which speaks to making the process more efficient (e.g., relying on greater support from paralegals). It is also possible to increase support by "borrowing" attorneys from other federal offices, even to work on a part-time basis. Streamlining the way cases are processed is another way to reduce costs, such as defining cases that have similar medical issues, such that a single case can serve as a model to reduce the resources required to process other similar cases.

Looking ahead, the environment is changing. There are more adult claims now than before. Pertussis-related claims, common years ago, are being displaced by flu injury claims, and the complex neurological injuries, although still part of the claims profile, are giving way to more defined injuries like SIRVA. These changes may enable the development of more standard paradigms for awards and the determination of attorneys' fees. These kinds of changes could improve efficiencies that would reduce total costs.

Dr. Feemster expressed appreciation for the presentations and invited questions or comments. Ms. Toomey asked who is championing the effort on behalf of HRSA or ACCV for greater financial support for the program. She conceded that ACCV could not lobby for the cause and Ms. Douglas suggested identifying organizations, such as nonprofits, interested in the issues. Contacting those groups as a private citizen is one opportunity. Dr. Feemster suggested that there may be little understanding of the challenges related to the vaccine injury compensation program. Ms. Toomey asked if there were statistics about how many individuals may have died while waiting for results from a vaccine injury claim. Mr. Matanoski stated that those numbers were not well defined, but a consideration is the fact that flu-related vaccine injuries affect older adults more than children and those individuals may experience a higher rate of very negative outcomes.

Dr. Feemster asked if there were internal impediments to developing solutions for improving processing time for straightforward cases, such as SIRVA, versus the more complex neurological cases. Mr. Matanoski commented that SIRVA claims, in general, impose far fewer challenges and there should be few internal impediments to developing more efficient processes to resolve those cases within DOJ. But moving toward the paradigm model, including resolution of a model for attorneys' fees and costs, would require coordination among the players – DOJ, HRSA, petitioners and the CFC – which implies that the process would take time and funding to put together, even though it should have a positive outcome. Ms. Toomey commented that her impression of the process with her son was that the situation was adversarial, but that her participation in the ACCV discussion has demonstrated that the various players do seem to be interested in reaching a positive outcome, which she considered encouraging. Mr. Kraus agreed that there is a positive aspect to the discussion, but that the vaccine program was based on providing a litigation approach to achieving the best outcome for clients, which may not always be the most efficient route to ultimate resolution.

Mr. Matanoski concluded his comments by noting that, although the objective includes improving efficiency in attaining resolution, the focus of the process must always be on the interests of the individual involved, and not the aggregate of a 500 case backlog. He added a concern that, although there is an effort to identify simpler cases that can be fast tracked to resolution, that focus cannot or should not work to the detriment of the more complicated cases that, by their nature, take more time and resources to resolve. Two considerations related to the speed a case moves through the system are the petitioner's diligence in responding to requests for information, and the fact that, if the case must go to trial, it must also get in line to be heard, which can induce some delays.

Asked about whether it would be practical to have specialists on staff, both medical and legal, to address specific issues, such as SIRVA, both Dr. Houston and Mr. Matanoski said that the number of cases that must be addressed would make it impractical to reserve review of a specific injury to one or two staff members, although Mr. Matanoski commented that they had set up teams that were expert in certain issues (such as ASIA or complex award solutions).

### **Discussion of Petition to Add Food Allergies to the Vaccine Injury Table, Dr. Narayan Nair, Chief Medical Officer, DICP**

Dr. Feemster explained that this agenda item was the result of a request from a member of the public to add food allergies to the Vaccine Injury Table (Table).

Dr. Nair stated that his office had received an e-mail from a citizen requesting that food allergies be added to the Table based on the contention that food proteins present in vaccines may be able to cause the development of food allergies in the vaccinated individual on September 19, 2015. Dr. Nair briefly described the process by which an injury or a vaccine/vaccine component can be added to the Table, which includes a petition by a private citizen. Dr. Nair described the nature of food allergies, including the possibility of anaphylaxis.

The first exposure to a food allergen may or may not produce allergic symptoms, but the exposure can cause sensitization. Re-exposure can result in more specific symptoms, including hives, itching, nausea, vomiting, swelling of the mouth and throat and low blood pressure. Although rare, the most serious reaction was anaphylaxis.

The ACCV has established guiding principles for recommending changes to the Table. The first is that the proposal should be scientifically and medically credible, and the second, when such a proposal indicates a change, that change should be made for the benefit of petitioners. The request from the private citizen cited two studies, the 2012 Institute of Medicine (IOM) Report, “Adverse Effect of Vaccines: Evidence and Causality” and a 2002 paper by V. Pool et al, “Prevalence of anti-gelatin IgE antibodies in people with anaphylaxis after MMR vaccine in the United States”.

The IOM report reviewed 8 of the 12 vaccines covered by the VICP and provided 158 causality conclusions. It did not specifically evaluate evidence regarding a causal association between vaccination and food allergies. Therefore, the IOM did not recommend the addition of food allergies as an adverse event to the Table. The Pool study was a case controlled study relying on Vaccine Adverse Reporting System (VAERS) reports, comparing individuals who had anaphylaxis after vaccination. Fifty-seven individuals were identified as having anaphylaxis, 22 underwent IgE testing, and, although there was an indication that the gelatin in vaccines could cause anaphylaxis, the authors of the paper did not contend that the gelatin actually caused food allergies. The primary purpose of VAERS is not to develop causality conclusions.

Dr. Nair added that his office did an extensive literature search without finding any evidence of vaccines as a factor in causing food allergies. In the literature there are a number of papers related to food allergies, but there were no references to vaccines as a factor in causing food allergies. The National Institute of Allergy and Infectious Disease (NIAID) conducted an

expert panel to develop guidelines for diagnosing and managing food allergies, and vaccines were not mentioned as causative or even related to food allergies.

Dr. Nair articulated the recommendation options available to the ACCV: 1) add food allergies to the Table, or 2) do not add food allergies to the Table.

Dr. Feemster invited discussion. She noted that the Commission could choose either of the options, or propose alternative options. Ms. Stewart suggested a third option, to recommend additional study. If the government is not interested in sponsoring a study on causality, it might be appropriate for the ACCV to make such a recommendation. Dr. Houston conceded that the third option was viable, but she added that it should be considered apart from the two options presented. That is, the Commission should address the petition, which specifically asks for the addition of food allergies to the Table. The vote, either yes or no, should be based on currently available information.

Ms. Toomey noted that some families are reluctant to allow vaccination of their children because they are concerned about what is in the vaccine. Mr. Kraus commented that, based on the presentation, there is insufficient information to vote for either adding or not adding food allergies to the Table. He noted that if the second option prevails, an individual retains the right to file a claim under the VICP and show causation as with any other claim not supported on the Table. If the Commission must vote on the options immediately, he recommended Option rejecting addition of food allergies to the Table, but that perhaps under new business the Commission should look into the relationship between vaccines and food allergies.

Dr. Feemster suggested that the action should be to vote on the two options. Then the question of additional study could be addressed. Dr. Douglas commented that the serious adverse event of anaphylaxis is a rare event and it is difficult to design a study with sufficient power to make definitive conclusions. Dr. Feemster noted that the study presented looked at a different outcome – it is a different question as to whether receipt of a vaccine leads to food allergies versus developing anaphylaxis after vaccination. She suggested that the petition is based on developing food allergies after vaccination as the rationale for adding food allergies to the Table. Dr. dela Rosa commented that, if anaphylaxis a germane injury, it is already on the Table.

Concerning developing a third option that would include further study, Dr. Houston suggested that sufficient information to make that decision may not be available. She suggested that before making a recommendation for further study a more substantive rationale for further study should be developed as part of the recommendation.

On motion duly made and seconded, the Commission unanimously approved Option 2, not to add food allergies to the Table.

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

Dr. Villarreal reported that, at the December 2013 ACCV meeting, Dr. Steve Bende stated that an important area in immunization is among adults. He said that the NVPO supported

the objectives of the adult immunization plan. In March 2014 he announced that the NVPO intended to release the National Adult Vaccination Plan later in the year. In December 2014 the ACCV discussed whether recommended adult immunizations should be considered for inclusion in the National Vaccine Injury Program, and a working group was established to look at the issue.

The working group met monthly via teleconference from January to October 2015 to discuss issues related to vaccines recommended for adults only. The Workgroup asked the DICP to provide claims data for Zoster (Zostavax) vaccine, and the pneumococcal 23 vaccine (PPSV 23) vaccines. Because these vaccines are not routinely recommended for children and are not covered by the VICP, if claims are received for these vaccines, they are categorized as unqualified vaccines in the DICP information system. Therefore, there is not any specific data about claims filed for these two vaccines.

It is the conclusion of the workgroup that because of data limitations, claims limitations, and possible unintended consequences of allowing amendments to the National Childhood Vaccine Injury Act of 1986, neither vaccine should be recommended for coverage under the VICP. The rationale is that the risks to the program of any legislative change would outweigh any perceived benefit of modifying the legislation.

The workgroup strongly recommended that the Commission remain open to further discussion regarding amendments to the VICP in that new vaccines might be developed that would qualify for coverage. That could include vaccines routinely recommended for pregnant women solely for the benefit of a live born child. The workgroup also recommended a continued follow-up to the recommendations submitted to the Secretary regarding maternal immunizations.

Dr. Feemster expressed appreciation for the report. She invited comment. Dr. Douglas asked if there was a parallel advisory commission in HHS for adult vaccines. Dr. Feemster commented that the ACIP makes recommendations for both adults and children. Ms. Stewart commented that the adult vaccines under discussion were recently recommended and she felt there was a presumption that they would be included in the VICP. If not included, she asked if individuals alleging injury would have to seek redress by pursuing a tort lawsuit. Mr. Kraus clarified that the adults would not have recourse through the VICP, and would have to seek redress in the civil court system.

Mr. Smith commented that he had provided information to Biotechnology Industry Organization (BIO), a trade organization representing pharmaceutical manufacturers, about the deliberations of the Workgroup. BIO had responded that they felt the recommendations were acceptable, considering the risks that could be exposed if the original legislation was open to revision. There would be no way to limit legislative revisions to the specific recommendations that might be made by ACCV. All of the vaccine legislation would be open for review and revision, and special interest groups might be able to significantly change the Act. Mr. Smith added that earlier recommendations that might require legislative change (statute of limitations, limits on awards, etc.) were less vulnerable to unanticipated outcomes that could negatively impact the provisions of the program.

Asked about whether a recommendation should be formalized, Dr. Villarreal stated that the workgroup did not recommend any specific action. Dr. Houston added that the rationale for an adult vaccine commission, the National Vaccine Advisory Committee (NVAC) and ACIP makes recommendations for both children and adults. Dr. Feemster, noting that a vote on the report was not required, declared the discussion closed.

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

Mr. Wolfe noted that the Commission would complete the final review of the vaccine information statements (VIS) for hepatitis A and hepatitis B. He added that this final review followed several previous reviews when substantive changes were made. Therefore he did not anticipate significant revisions. He stated that the content of both VIS's has been vetted by the subject matter experts and reviewed by the FDA. Dr. Feemster announced that she would recuse herself from the discussion.

#### ***Hepatitis B***

Mr. Wolfe stated that FDA commented on Section 2, entitled "Why get vaccinated," that one drug company recommended a different schedule than other manufacturers as described in the first paragraph. He explained that no change in the wording would be made because the slightly different schedule was not relevant to the patient. Keeping the wording simple avoids having to reissue the VIS if a minor change is made. FDA also observed that the manufacturers recommend completing the series by six months of age if the series begins at birth, so that wording will be revised to reflect that schedule.

Finally, in that section, the FDA noted that the last sentence was not supported by research. However, Mr. Wolfe commented that there is a CDC recommendation that, with very few exceptions, all vaccines may be given simultaneously. Mr. Kraus suggested that the wording be changed to "currently there is no evidence that there are additional safety concerns caused by giving the hepatitis B vaccine at the same time as other vaccines."

In Section 3, FDA suggested mentioning latex when discussing allergic reactions.

In Sections 4 through 7, FDA had no comments.

Mr. Wolfe asked if risk should be quantified (e.g., one out of X people experience a risk event), or whether stating the fact that a risk exists is sufficient. He stated that the CDC's inclination is to make the latter the policy. He noted that additional risk information could be included in the provider guide. Mr. Krause felt that the quantified risk information might be helpful to the reader. Mr. Wolfe commented that since the quantified risk is usually included in the provider guide, a sentence advising the patient to ask his/her provider about specific risk numbers should suffice.

There was a brief discussion about the instance when a provider does not distribute the VIS as required, especially in non-medical environments (such as pharmacies like CVS). It was noted that this failure had nothing to do with wording in the VIS.

### *Hepatitis A*

The change in the hepatitis B VIS was also made in the Hepatitis A VIS – the wording in the last sentence in Section 2 changed to “currently there is no evidence that there are additional safety concerns caused by giving the hepatitis B vaccine at the same time as other vaccines.”

### **Update on the Immunization Safety Office (ISO), CDC Vaccine Activities, Dr. Mike McNeil**

Dr. McNeil explained that the one-day ACIP meeting held in October included a number of workgroup reports. The first, on meningococcal B vaccine, a permissive recommendation (allowing individual clinical decision-making), indicated that the vaccine may be administered to individuals aged 16 to 23 to provide short-term protection against meningococcal B disease. There is no recommendation for routine use since there is limited data and a low prevalence of disease.

The workgroup on influenza vaccine agreed there was limited activity in the US, and that the currently circulating viruses are similar to those in the 2015-2016 vaccines. A manufacturer made a presentation on cost effectiveness of high dose versus standard dose Fluzone, which revealed that high dose, even at three times the cost, is more cost effective than standard dose because of reductions in cardiovascular complications. Novartis discussed its new product, Flud, an adjuvanted trivalent flu vaccine that contains squalene, surfactants and citrate. It enhances the immune response with a safety profile similar to other flu vaccines.

The presentation on human papillomavirus (HPV) vaccine included the fact that coverage has increased (although still low) to 34% of girls and 21% of boys. Parents believe the vaccine is not needed for boys (not officially recommended) and possibly risky for girls (safety concerns). The CDC has sponsored a public campaign to increase coverage. Dr. McNeil stated that his office provided an update on HPV vaccine safety that showed no elevated risk of venous thromboembolism (VTE), fetal loss, spontaneous abortion or congenital abnormalities. There have been, however, recent safety concerns including primary ovarian insufficiency, complex regional pain syndrome, and postural orthostatic tachycardia syndrome.

Dr. McNeil concluded with four brief workgroup reports: Japanese encephalitis vaccine; a combination vaccine (pediatric hexavalent vaccine containing DTaP, IPV, Hib and Hep B); a new cholera vaccine (anticipated to be licensed in the US in 2016); and Ebola vaccine administered to 5,550 health care workers as of October 18, 2015 with no serious adverse events.

Dr. McNeil discussed several publications:

- Sukumaran et al, a study among women who received Tdap showed no increased risk of adverse events, and in those with recent tetanus-containing vaccinations also no increased risk of adverse events. JAMA Oct 2015

- McNeil et al, looked at data from the Vaccine Safety Data Link (VSD), and found a rare instance of anaphylaxis after any vaccine, two or less cases of anaphylaxis in children and adults. Journal of Allergy Clinical Immunology Sep 2015
- Sukumaran et al, a study that showed that concomitant administration of Tdap and flu vaccines during pregnancy did not result in increased risk of adverse events or negative birth outcomes compared with sequential vaccination. Journal of Obstetrics and Gynecology, Nov 2015
- Moro et al, in a CDC review of its public health response to ACIP's recommendation to study and monitor the safety of Tdap vaccines in pregnant women. Journal of Human Vaccine Immunotherapy Sep 2015
- Two studies looking at risk of venous thromboembolism. In Naleway et al, a study showed that the risk of developing VTE among individuals 9 to 26 was not elevated following HPV4 exposure. In Yuh et al, showed no increased risk of VTE in females 9 to 26 years of age. Vaccine 2015.

During discussion Dr. Villarreal asked if CDC had seen any adverse events from either HPV4 or HPV9 in a subpopulation of Native Americans. A parent in her clinic had indicated reports that sudden death syndrome had occurred after HPV vaccinations. Dr. McNeil responded that the Vaccine Safety Datalink (VSD) which follows more than 9 million people, should have good information of that kind of adverse events, and there is no association of that adverse event with childhood and adolescent vaccines. However, the Native American populations may not be well represented in the VSD.

Dr. Feemster asked about coverage of meningococcal B vaccine. Dr. Houston responded that meningococcal vaccines, as a group, are covered by the program, so the meningococcal B vaccine would be covered.

### **Update on the National Institute of Allergy and Infectious Diseases (NIAID), NIH Vaccine Activities, Dr. Barbara Mulach**

Dr. Mulach reported progress on the development of a vaccine for respiratory syncytial virus (RSV), which is the leading cause of respiratory disease in infants and young children. NIAID is supporting a candidate vaccine developed by Johns Hopkins Bloomberg School of Health researchers and Medimmune that has proven safe and effective in early Phase I clinical trials.

NIAID and National Institute of Child Health and Human Development (NICHD) are working together on a chickenpox vaccine dosing study of 432 HIV-infected children and 221 children exposed but not infected. The study showed that children who received two doses versus one dose had a stronger antibody response that lasted a longer period of time. The study also showed that there was greater effect if the first dose was given at least three months after initiating anti-HIV treatment.

Dr. Mulach noted that several candidate Ebola vaccines were being tested. One promising candidate is from Johnson and Johnson and Bavarian Nordic, a combined adenovirus/modified vaccinia Ankara. There were Phase I trials in the UK and the US, followed

by a Phase II trial in 2014. A Phase II immunogenicity study was begun in Sierra Leone, the first country with endemic Ebola.

NIAID is involved with the development of a malaria vaccine. Forty percent of the world's population lives in areas where exposure to malaria infection is a significant risk. Thus far the most advanced vaccine in terms of research is RTS/S vaccine, which has shown a 30%-50% efficacy in protecting children for about a year. The research question now is why it is only partially protective? Relying on genomic sequencing technology, it was discovered that there is variability in the surface protein that the vaccine targets, which drives the efficacy of the vaccine. In another study, changes in the protein in the vaccine provided a basis for further research into how to make the vaccine more effective.

The Commission may recall a briefing on a Phase I trial of a chikungunya vaccine. That trial of 25 subjects saw a robust immunity that encouraged development of a Phase II trial. That trial is underway in the Caribbean with 60 subjects at six sites. Since there were over 600,000 cases reported in 2015, the importance of this research is clear.

Finally, Dr. Mulach discussed the Precision Medicine Initiative, which will involve a research cohort of over a million subjects. There is more information on the web at [www.nih.gov/precision medicine](http://www.nih.gov/precision-medicine).

During discussion, Ms. Toomey, speaking from St. John in the Virgin Islands, commented that chikungunya is a serious problem there. An early response was to attempt mosquito control by spraying with methyl bromide. The chemical has a serious toxic effect in humans, which has affected all of the members of one family, who suffered severe neurological damage because of the pesticide.

#### **Update on the Center for Biologics, Evaluation and Research (CBER), FDA Vaccine Activities, LCDR Valerie Marshall**

Ms. Marshall reported that, on November 24, 2015, the FDA approved Fludax for individuals 65 years of age and older, the first seasonal flu vaccine containing an adjuvant. It is currently approved in 38 countries including Canada and 15 European countries.

Ms. Marshall commented that Biothrax is a vaccine indicated for post-exposure prophylaxis of disease resulting from bacillus anthracis exposure. It is approved for individuals 18 through 65 years of age.

In September 2015, FDA approved a supplement to the biologic license application to the hepatitis B vaccine to include safety and immunogenicity data for adults with type 2 diabetes mellitus in the Energix-B package insert prescribing information. The ACIP recommended vaccinating all adults with diabetes against hepatitis B. However, the efficacy of the vaccine had not been well defined, so the manufacturer initiated a study to assess the immunogenicity and safety of the vaccine in adults with or without type 2 diabetes. Protection rates were similar in both groups.

In November 2015, the Vaccine and Related Biological Products Advisory Committee (VRBPAC) discussed vaccines for pregnant women to protect the unborn infant. The VRBPAC considered various study designs for that purpose, safety end points and duration of follow-up for the infants.

FDA has a research component, developing an animal (baboon) model to compare three whole-cell pertussis vaccines, finding that these vaccines significantly improved clearance of B pertussis following challenge compare to no vaccine and A pertussis vaccine.

Finally, vaccination of African study participants increased serum bactericidal activity.

### **Update from the NVPO Vaccine Activities, Dr. Karin Bok**

Dr. Bok reported that NVPO is conducting a mid-course review of the 2010 National Vaccine Plan following five years of implementation. NVPO sent a survey to non-federal stakeholders between October 9 and November 9 and received 38 responses from a broad range of stakeholders including consumers. NVPO will continue to engage both federal and nonfederal stakeholders in the analysis process. NVPO is currently drafting the NVPO Vaccine Confidence Strategy document and a cooperative agreement to support the project. NVPO expects that the request will be published at the beginning of 2016. The early data from an NVPO-funded study of first-time mothers was published in November in the American Journal of Preventive Medicine. This study looked at vaccination-related intentions, knowledge, and confidence among 200 expectant mothers during their second trimester of pregnancy.

Finally, the National Adult Immunization Plan (similar to the National Vaccine Plan but focused on adults) is expected to launch in January 2016. The plan has four goals; strengthen the adult immunization infrastructure; improve access to adult vaccines; increase community demand for adult immunizations; and to foster innovation in adult vaccine development and vaccination-related technologies.

In response to the earlier question about whether there was a commission dedicated to adult vaccines, Dr. Bok stated that there is an Adult Immunization Task Force. NVAC will also issue adult immunization standards. Asked about whether there could be an ACCV-type commission for adults within the adult immunization plan, Dr. Bok stated that the ACIP and NVAC serve that function. The plan does not propose a new commission. Dr. Feemster suggested it would be helpful for the ACCV to work with those entities.

Dr. Feemster expressed appreciation for the presentations.

### **Public Comment**

#### ***Comments by Janet Cakir, parent of a child alleged to have been injured by a vaccine.***

Janet Cakir commented that the ACCV sent recommendations to the Secretary of HHS in December 2013 concerning extending the statute of limitations. Secretary Sebelius confirmed receipt of the recommendations, but subsequently resigned before taking action. Secretary

Burwell succeeded her in the position, but there has likewise been no action since she took office. The Senate committee responsible for health matters is also unaware of the recommendations and stated that there have been no communications with DHHS about the recommendation. Secretary Burwell's staff is unaware of the recommendations. An official in DHHS (Andrew Morris, policy analyst) confirmed that there is no intention to act on the recommendation. He said he was unaware of the recommendations. He added that it was not his responsibility to sponsor legislation. Ms. Cakir stated that the recommendation to extend the statute of limitations should be resubmitted to the Secretary, who can send a letter to the appropriate committees in the House and Senate articulating actions needed for DHHS programs.

Ms. Cakir explained that developmental milestones that would suggest a vaccine-related injury may take years to appear. Often vaccine injury is the last consideration, placing parents in a timeline well past the statute of limitations. She stated the opinion that parents will accept vaccination if there is a reasonable safety net to cover possible vaccine injury. She added that a reiteration of the original recommendation should be sent to the Secretary and it should include the fact that the appearance of injury in the very young can take a longer time than presently considered.

Ms. Cakir stated that the ACCV is the only advocate for American children and the recommendation to the Secretary should be to open the legislation to revision. To avoid the obstacle of legislative revision, HHS could add inflammation to the Vaccine Injury Table. She requested a discussion of the presentation before terminating her time on the agenda.

Dr. Feemster thanked Ms. Cakir for her comments and assured her that the points she made would be discussed as new business.

***Comments by Theresa Wrangham, Executive Director of the National Vaccine Information Center (NVIC)***

Ms. Wrangham commented that the materials posted on the web do not fully reflect the presentations, and there are instances when the presentation made at the meeting have been revised and do not reflect the content of the revised remarks in the presentation. Referring to an example presented of a petitioner who appealed the judgment award, NVIC points to the 2009 Altarum Report that surveyed VICP satisfaction. It emphasized inadequacy of settlement as a significant issue. Ms. Wrangham posed several questions: Why is there not an ongoing VICP survey process? Are settlements adequate to meet the need of those injured? Is there consistency in the award amounts? What progress has been made since the Altarum, Banyan and GAO reports to assess satisfaction with VICP?

Ms. Wrangham stated the opinion that the VICP process has become more adversarial for petitioners over the years. It is well known that there are risks associated with vaccines, and vaccines should not be exempt from informed consent. Non-medical vaccine exemptions are under attack. NVIC requests that actual presentations made at ACCV meeting, annotating what materials was actually presented, be published online. Conduct a review of the findings of the 2009 Altarum Report, 2010 Banyan Report and 2014 GAO report of the VICP, and issue a report including an analysis of what is needed to improve satisfaction and awareness of the VICP,

including an analysis of the impact to the VICP of vaccine safety deficits reported by the IOM, and how closing research gaps would improve the process.

A process should be created to inform the public when a scientific presentation is made by the government related to a public request for additions to the Vaccine Injury Table, and an equal opportunity for the public entity making the request to present information to the Commission.

The ACCV should affirm the fact that vaccines carries the risk for injury and death, and because of that the ACCV supports the right of every parent to make decisions about vaccination without prejudice.

### **Future Agenda Items**

Dr. Feemster invited discussion of future agenda items and new business. Since there was a public comment about the recommendations to the Secretary, she asked for comment about whether the recommendation should be re-submitted. Mr. Kraus commented that the Commission should ascertain where the recommendations already made stand. He suggested adding an agenda item for the next meeting to clarify the status of the statute of limitations recommendation.

Dr. Feemster suggested that the Commission revisit the issue of increasing resources for handling the increased caseload. Mr. Kraus agreed that an agenda item should be included in the next meeting to consider a recommendation to increase the budget for that purpose. Dr. Houston interjected that such action is a congressional prerogative and such a recommendation must be submitted to the Secretary.

Dr. Feemster recalled an issue that related to the addition of food allergy to the Vaccine Injury Table, and Mr. Kraus commented that if commissioners were interested it could be added as a discussion item. Dr. Feemster concluded that there was no interest in adding the food allergy issue to the agenda of the next meeting.

Mr. Kraus suggested that the Commission consider the importance of complying with the provision of information to the public, posted on the web by the time of the meeting. Ms. Herzog assured the Commission that every effort is made to provide all relevant information by the time the meeting begins.

Finally, there was a request that additional information be provided concerning the details of SIRVA claims (e.g., where the injections take place, the training of the vaccine administrators) and Dr. McNeil stated that he would pass that request on to Dr. Shimabukuro.

### **Adjournment**

There being no further business, on motion duly made and seconded, the Commission unanimously approved adjournment.

**3**

## Vaccine Injury Compensation Trust Fund

### **Balance as of January 31, 2015**

\$3,638,161,199.30

### **Figures for October 1, 2015 – January 31, 2016**

Excise Tax Revenue: \$91,542,000

Interest on Investments: \$18,434,234

Net Income: \$109,976,234

Interest as a Percentage of Net Income: 17%

*Source: U.S. Treasury, Bureau of Public Debt  
February 5, 2016*

**4**



## 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 petition for compensation.

### **What does it mean to be awarded compensation?**

Being awarded compensation for a petition 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.
- Attorneys are eligible for reasonable attorneys' fees, whether or not the petitioner is awarded compensation by the Court, if certain minimal requirements are met. In those circumstances, attorneys are paid by the VICP directly. By statute, attorneys may not charge any other fee, including a contingency fee, for his or her services in representing a petitioner in the VICP.

### **What reasons might a petition result in a negotiated settlement?**

- Consideration of prior U.S. Court of Federal Claims decisions, both parties decide to minimize risk of loss through settlement
- A desire to minimize the time and expense of litigating a case
- The desire to resolve a petition quickly

### **How many petitions have been awarded compensation?**

According to the CDC, from 2006 to 2014 over 2.5 billion doses of covered vaccines were distributed in the U.S. For petitions filed in this time period, 3,373 petitions were adjudicated by the Court, and of those 2,129 were compensated. This means for every 1 million doses of vaccine that were distributed, 1 individual was compensated.

Since 1988, over 16,729 petitions have been filed with the VICP. Over that 27 year time period, 14,397 petitions have been adjudicated, with 4,482 of those determined to be compensable, while 9,915 were dismissed. Total compensation paid over the life of the program is approximately \$3.3 billion.

### **The Latest Statistics**

[Read the current statistics report – updated as of February 3, 2016.](#)

This information reflects the current thinking of the United States Department of Health and Human Services on the topics addressed. This information is not legal advice and does not create or confer any rights for or on any person and does not operate to bind the Department or the public. The ultimate decision about the scope of the statutes authorizing the VICP is within the authority of the United States Court of Federal Petitions, which is responsible for resolving petitions for compensation under the VICP.

**VICP Adjudication Categories, by Alleged Vaccine,  
 For Petitions Filed Since the Inclusion of Influenza as an Eligible Vaccine for Filings 01/01/2006  
 Through 12/31/2014**

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 12/31/2014 (Source: CDC)	Compensable			Compensable Total	Dismissed/Non-Compensable Total	Grand Total
		Concession	Court Decision	Settlement			
DT	712,347	1		5	6	4	10
DTaP	83,052,184	13	20	87	120	80	200
DTaP-Hep B-IPV	51,305,397	4	7	21	32	38	70
DTaP-HIB	1,135,474					1	1
DTaP-IPV-HIB	46,401,211	1		7	8	13	21
DTap-IPV	15,490,820						
DTP	0	1	1	3	5	2	7
DTP-HIB	0			3	3	1	4
Hep A-Hep B	12,740,305			9	9	2	11
Hep B-HIB	4,787,457	1	1	1	3	1	4
Hepatitis A (Hep A)	136,935,713	6	3	24	33	22	55
Hepatitis B (Hep B)	143,946,953	2	11	48	61	39	100
HIB	93,160,376		1	4	5	5	10
HPV	77,506,945	11	4	74	89	92	181

National Vaccine Injury Compensation Program  
 Monthly Statistics Report

Influenza	1,078,000,000	95	95	1,095	1,285	195	1,480
IPV	62,344,612			4	4	2	6
Measles	135,660			1	1		1
Meningococcal	64,004,175	1	4	26	31	4	35
MMR	80,115,475	19	13	62	94	78	172
Mumps	110,749						
MMR-Varicella	14,403,057	8		8	16	8	24
Nonqualified	N/A			2	2	22	24
OPV	0	1			1	3	4
Pneumococcal Conjugate	150,497,243		1	5	6	14	20
Rotavirus	79,636,437	4	4	16	24	6	30
Rubella	422,548		1	1	2		2
Td	57,940,972	7	6	54	67	18	85
Tdap	177,160,298	30	7	117	154	17	171
Tetanus	3,836,052	4		23	27	11	38
Unspecified	N/A	1	2	3	6	556	562
Varicella	96,646,081	4	7	24	35	10	45
<b>Grand Total</b>	<b>2,532,428,541</b>	<b>214</b>	<b>188</b>	<b>1,727</b>	<b>2,129</b>	<b>1,244</b>	<b>3,373</b>

**Notes on the Adjudication Categories Table**

The date range of 01/01/2006 through 12/31/2014 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 conceded "unspecified" petition was for multiple unidentified vaccines that caused abscess formation at the vaccination site(s), and the "unspecified" settlements were for multiple vaccines later identified in the Special Masters' decisions

## Definitions

**Compensable** – The injured person who filed a petition 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 petition 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 petitions, 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. Petitions 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 petition was ultimately not paid money. Non-compensable Court decisions include the following:
    1. The Court determines that the person who filed the petition 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 petition 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 petition.

**Petitions Filed, Compensated and Dismissed, by Alleged Vaccine,  
 Since the Beginning of VICP, 10/01/1988 through 02/03/2016**

Vaccines	Filed			Compensated	Dismissed
	Injury	Death	Grand Total		
DTaP-IPV	5	0	5	0	0
DT	69	9	78	26	51
DTP	3,286	696	3,982	1,273	2,706
DTP-HIB	20	8	28	7	21
DTaP	393	79	472	195	207
DTaP-Hep B-IPV	65	27	92	31	34
DTaP-HIB	11	1	12	4	3
DTaP-IPV-HIB	36	17	53	7	12
Td	189	3	192	115	66
Tdap	314	1	315	165	16
Tetanus	105	2	107	51	37
Hepatitis A (Hep A)	81	6	87	34	22
Hepatitis B (Hep B)	629	55	684	253	364
Hep A-Hep B	25	0	25	9	2
Hep B-HIB	8	0	8	4	3
HIB	32	3	35	13	15
HPV	299	14	313	89	92
Influenza	2,369	100	2,469	1,366	169
IPV	264	14	278	8	267
OPV	282	28	310	158	150
Measles	143	19	162	55	107
Meningococcal	49	2	51	31	4
MMR	913	57	970	376	506
MMR-Varicella	34	1	35	16	8
MR	15	0	15	6	9
Mumps	10	0	10	1	9
Pertussis	4	3	7	2	5
Pneumococcal Conjugate	44	8	52	10	27
Rotavirus	71	1	72	44	17
Rubella	190	4	194	71	123
Varicella	82	8	90	55	20
Nonqualified1	91	9	100	2	87
Unspecified2	5,416	9	5,425	5	4,756
None	1	0	1	0	0
<b>Grand Total</b>	<b>15,545</b>	<b>1,184</b>	<b>16,729</b>	<b>4,482</b>	<b>9,915</b>

National Vaccine Injury Compensation Program  
Monthly Statistics Report

<sup>1</sup> Nonqualified petitions are those filed for vaccines not covered under the VICP.

<sup>2</sup> Unspecified petitions are those submitted with insufficient information to make a determination.

## Petitions Filed

<b>Fiscal Year</b>	<b>Total</b>
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	504
FY 2014	633
FY 2015	805
FY 2016	408
<b>Total</b>	<b>16,729</b>

## 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	232	294
FY 2005	60	121	181
FY 2006	69	191	260
FY 2007	82	123	205
FY 2008	147	132	279
FY 2009	134	231	365
FY 2010	180	293	473
FY 2011	266	1,371	1,637
FY 2012	263	2,439	2,702
FY 2013	367	628	995
FY 2014	371	166	537
FY 2015	512	79	591
FY 2016	142	2	144
<b>Total</b>	<b>4,482</b>	<b>9,915</b>	<b>14,397</b>

National Vaccine Injury Compensation Program  
 Monthly Statistics Report

**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	\$11,990,035.82	504	\$6,784,885.79	38	\$2,493,460.73	\$223,352,578.46
FY 2015	508	\$204,137,880.22	\$14,365,931.00	109	\$3,322,873.36	50	\$3,089,497.68	\$224,916,182.26
FY 2016	209	\$81,067,467.33	\$5,220,454.69	18	\$730,751.84	24	\$1,270,685.43	\$88,289,359.29

National Vaccine Injury Compensation Program  
 Monthly Statistics Report

<b>Total</b>	<b>4,481</b>	<b>\$3,087,176,862.08</b>	<b>\$136,764,203.84</b>	<b>5,006</b>	<b>\$68,145,199.93</b>	<b>279</b>	<b>\$22,067,956.22</b>	<b>\$3,314,154,222.07</b>
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"Compensated" are petitions 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/petitions 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 petition, whether or not the petition/petition 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.

Since influenza vaccines (vaccines administered to large numbers of adults each year) were added to the VICP in 2005, many adult petitions related to that vaccine have been filed, thus changing the proportion of children to adults receiving compensation.

# 5.1

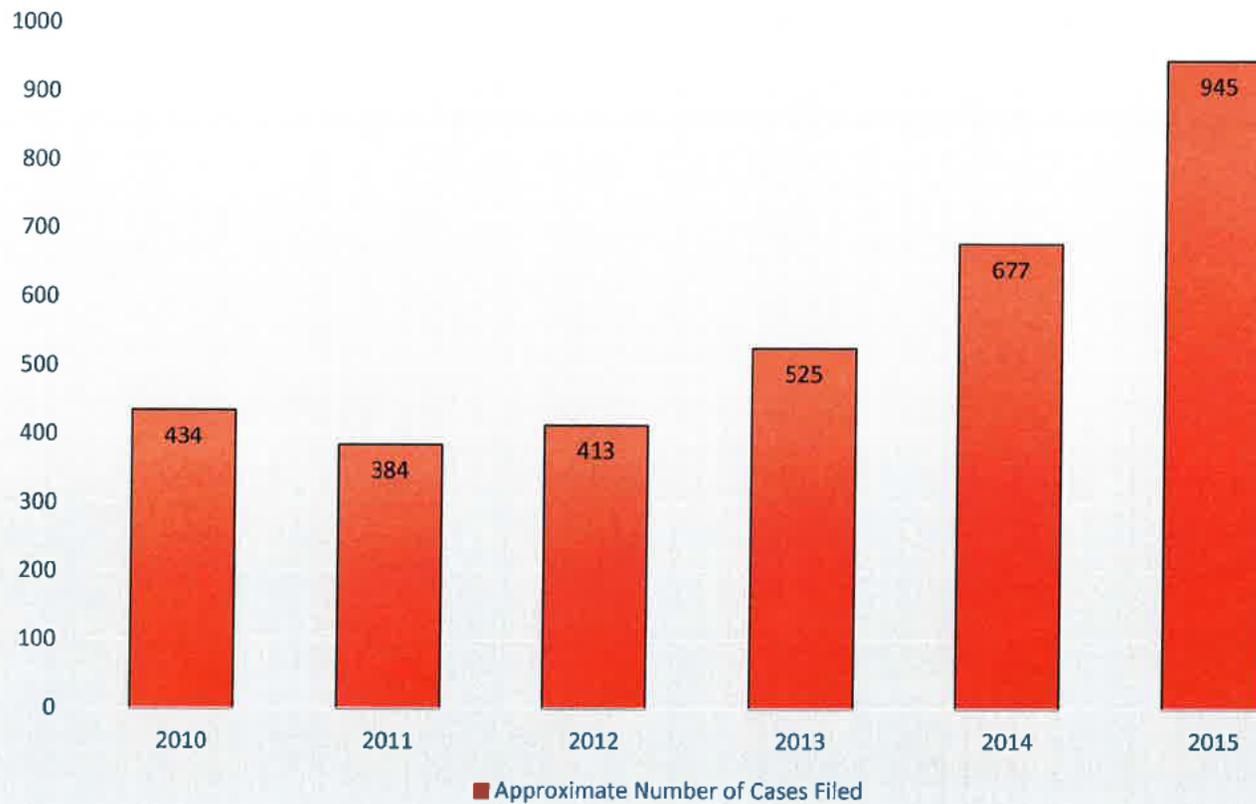


# Impact of the Increased Claims Filed on OSM

March 3, 2016, ACCV Meeting

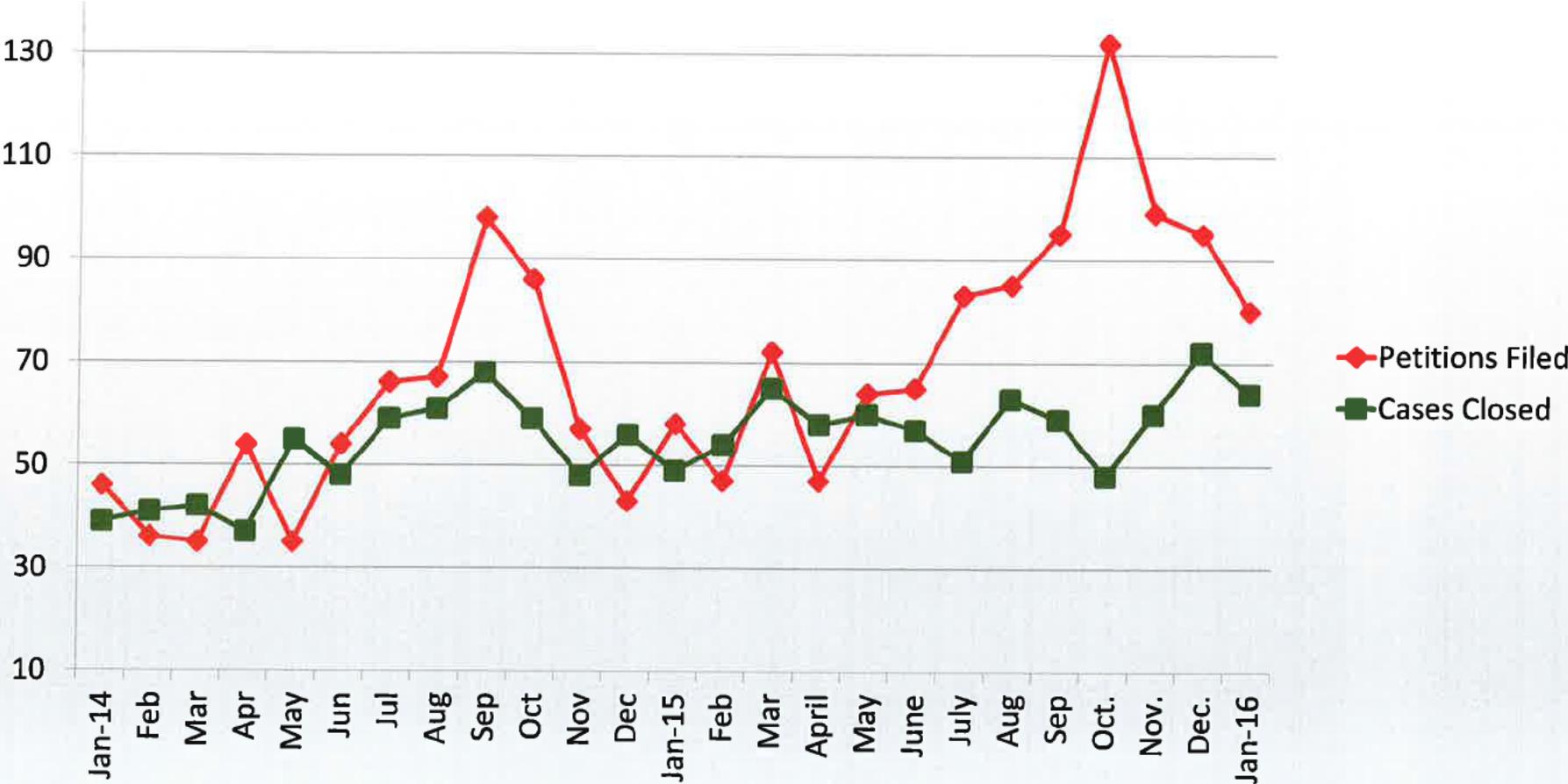
Chief Judge Patricia Campbell-Smith  
Chief Special Master Nora Beth Dorsey

## Total Cases Filed Per Year

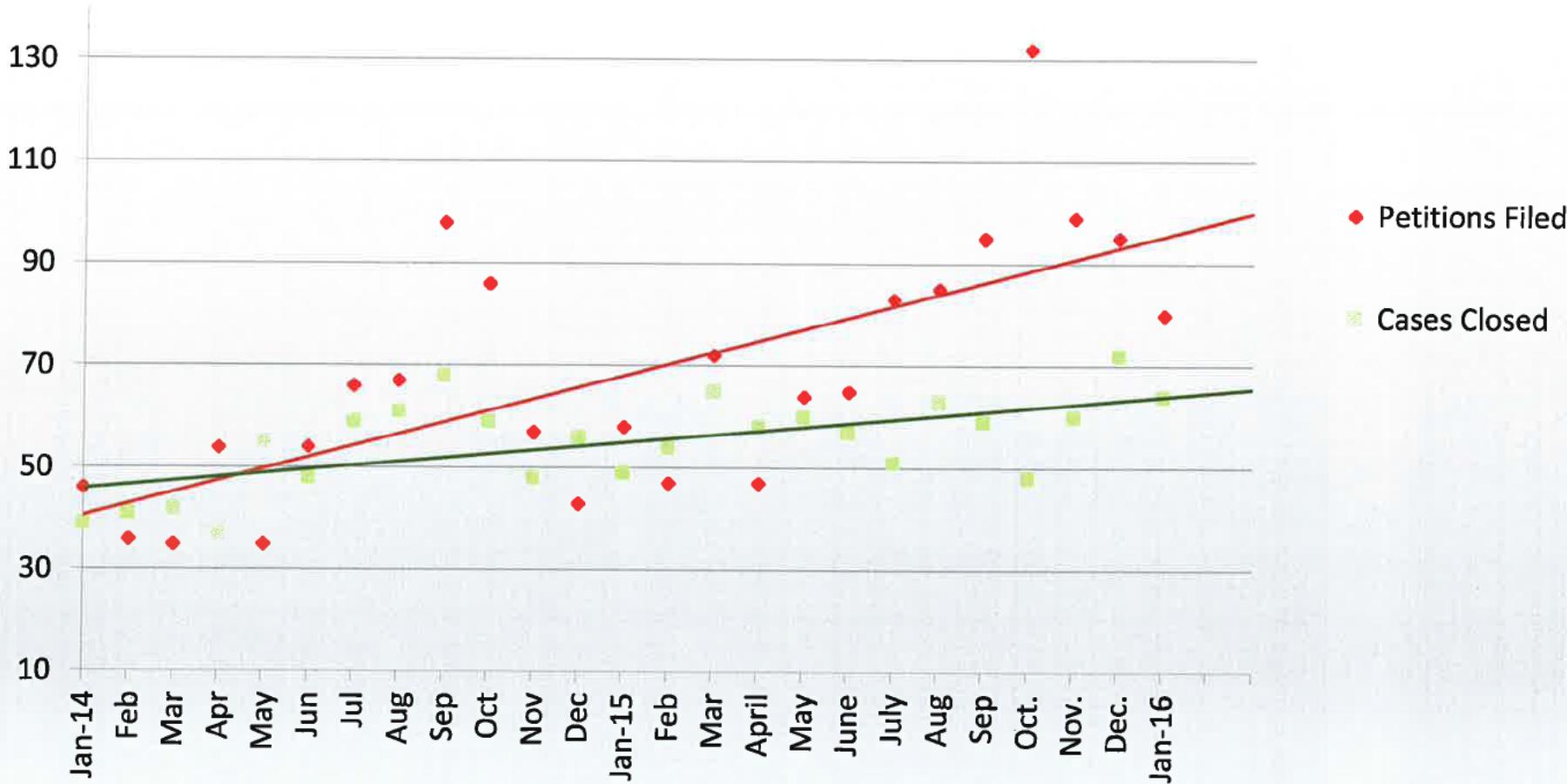




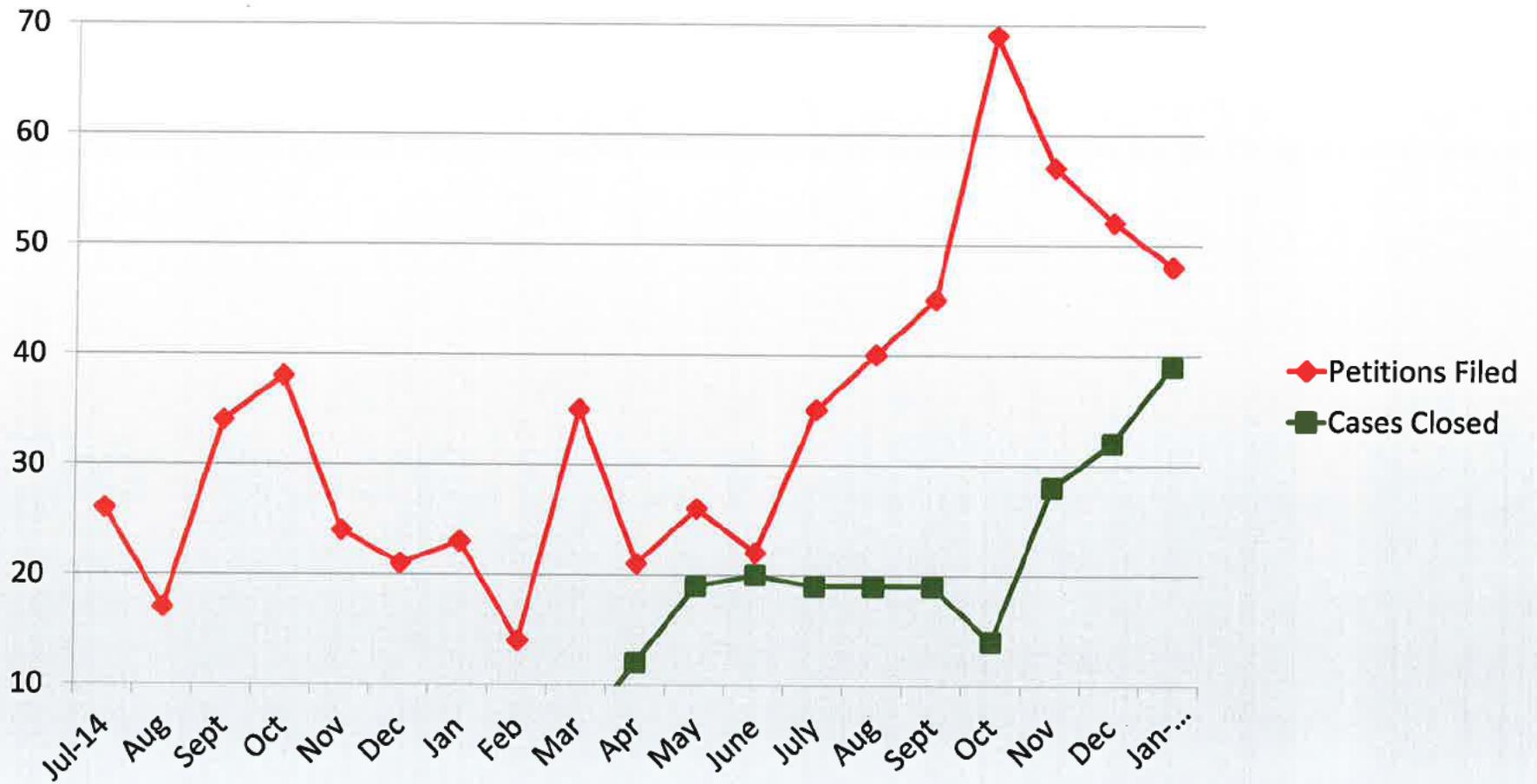
# OSM Activity by Month Jan. '14 - Jan. '16



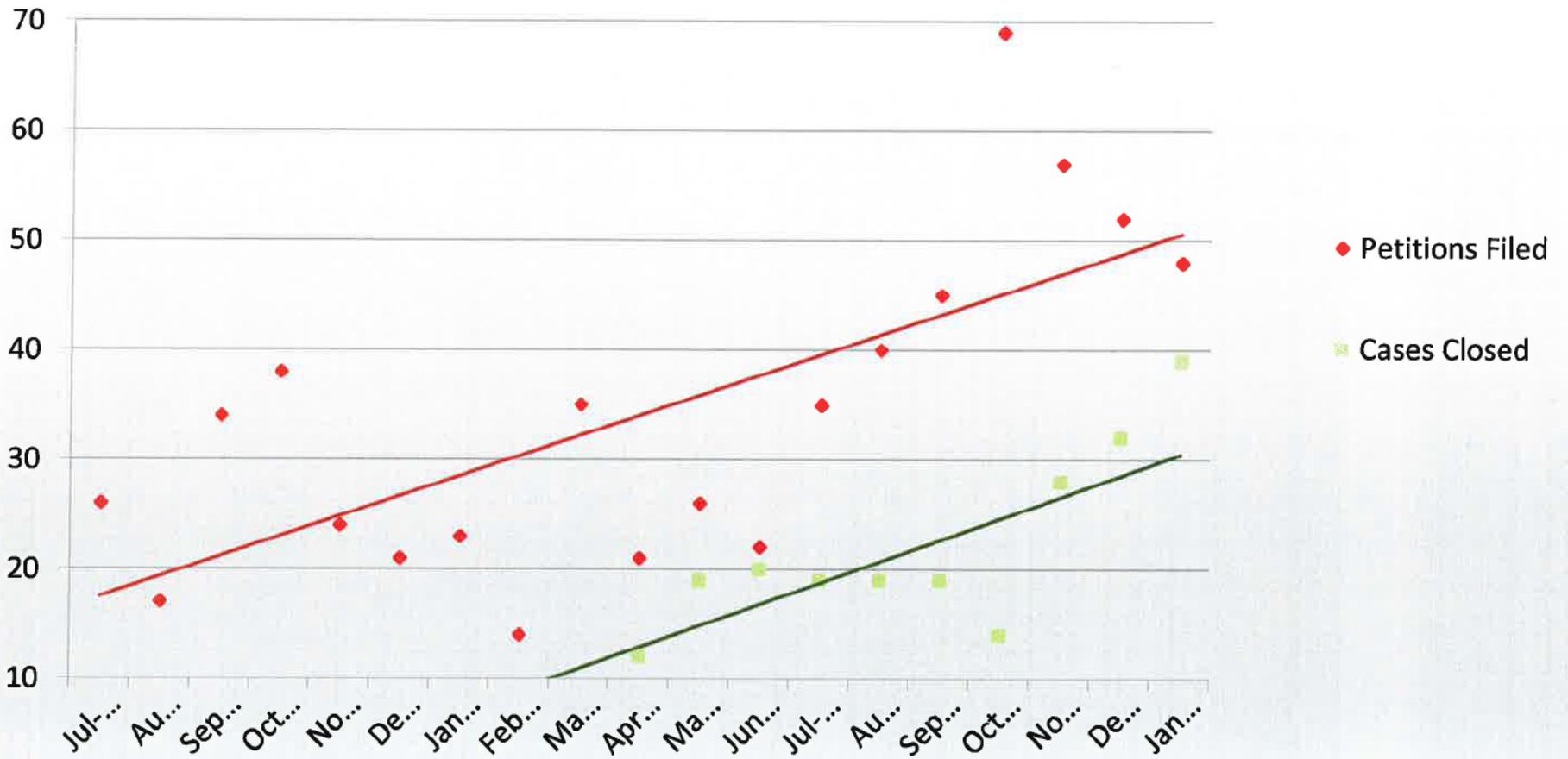
# OSM Activity by Month Jan. '14 - Jan. '16



## SPU Activity by Month July '14 – Jan. '16



## SPU Activity by Month July '14 – Jan. '16



# 5.2

# The National Vaccine Injury Compensation Program (VICP)

## Division of Injury Compensation Programs Update

Advisory Commission on Childhood Vaccines

March 3, 2016

CAPT Narayan Nair, MD

Department of Health and Human Services  
Health Resources and Services Administration



# ACCV Meeting Highlights

- Update from the Department of Justice Vaccine Litigation Office
- Presentation on Impact of Increased Claims Filed from the U.S. Court of Federal Claims, Office of the Special Master
- Review of Vaccine Information Statements
- Updates from ACCV Ex Officio Members – FDA, CDC, NIH, NVPO



# Number of Petitions Filed as of February 3, 2016

Average annual number of petitions filed during FY 2011-2015 = 546

Fiscal Year	Total
FY 2011	386
FY 2012	401
FY 2013	504
FY 2014	633
FY 2015	805
FY 2016	408



# Number of Adjudications as of February 3, 2016

Fiscal Year	Compensable	Dismissed	Total
FY 2011	266	1,371	1,637
FY 2012	263	2,439	2,702
FY 2013	367	628	995
FY 2014	371	166	537
FY 2015	512	79	591
FY 2016	142	2	144



# Adjudication Categories for Non-Autism Claims FY 2014 – FY 2016 as of February 8, 2016

Adjudication Category	FY 2014	FY 2015	FY 2016
<b>Compensable</b>	<b>371 (100%)</b>	<b>512 (100%)</b>	<b>146 (100%)</b>
❖ Concession	40 (11%)	90 (17%)	36 (25%)
❖ Court Decision (includes proffers)	35 (9%)	35 (7%)	18 (12%)
❖ Settlement	296 (80%)	387 (76%)	92 (63%)
<b>Not Compensable</b>	<b>122</b>	<b>65</b>	<b>2</b>
<b>Adjudication Total</b>	<b>493</b>	<b>577</b>	<b>148</b>



# Award Amounts Paid as of February 3, 2016

<u>Fiscal Year</u>	<u>Petitioners' Award</u>	<u>Attorneys' Fees &amp; Costs</u>
FY 2011	\$216,319,428	\$17,163,231
FY 2012	\$163,491,999	\$23,145,929
FY 2013	\$254,666,327	\$21,758,310
FY 2014	\$202,084,196	\$21,268,382
FY 2015	\$204,137,880	\$20,778,302
FY 2016	\$81,067,467	\$7,221,891



# Vaccine Injury Compensation Trust Fund

- Balance as of January 31, 2016
  - \$3,638,161,199.30
- Activity from October 1, 2015 to January 31, 2016
  - Excise Tax Revenue: \$91,542,000
  - Interest on Investments: \$18,434,234
  - Net Income: \$109,976,234
  - Interest as a Percentage of Net Income: 17%

Source: U.S. Treasury, Bureau of Public Debt (February 8, 2015)



# Significant Activities

- Status of Revisions to Vaccine Injury Table Notice of Proposed Rulemaking (NPRM)
  - Public hearing was held on January 14, 2016
  - Public comment period ended January 25, 2016
- Highlights of Recent Outreach Activities
  - Worked with HRSA's Office of Regional Operations to distribute information about VICP
  - Presented information about VICP to allied health students at Howard University in December 2015
  - Establishing new partners in FY 2016



# ACCV Information

- 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

5600 Fishers Lane, Room 08N146B

Rockville, Maryland 20857

Phone: 301-443-6634

Email: [aherzog@hrsa.gov](mailto:aherzog@hrsa.gov)



# 5.3

# 5.4

## Vaccine Information Statement

### **Polio Vaccine: What you need to know**

Many Vaccine Information Statements are available in Spanish and other languages. See [www.immunize.org/vis](http://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?**

Vaccination can protect people from **polio**. Polio is a disease caused by a virus.

Most people infected with polio have no symptoms. But sometimes people who get polio will develop paralysis (cannot move their arms or legs). Polio can result in permanent disability. Polio can also cause death, usually by paralyzing the muscles used for breathing.

Polio used to be very common in the United States. It paralyzed and killed thousands of people every year before polio vaccine was introduced in 1955.

Polio has been eliminated from the United States. But it can still occur in some parts of the world. It would only take one person infected with polio coming from another country to bring the disease back here if we were not protected by vaccine. If the effort to eliminate the disease from the world is successful, some day we won't need polio vaccine. Until then, we need to keep getting our children vaccinated.

#### **2. Polio vaccine**

Inactivated Polio Vaccine (**IPV**) can prevent polio.

##### **Children**

Most people should get IPV when they are children. 4 doses of IPV are usually given at 2, 4, 6 to 18 months, and 4 to 6 years of age.

A different vaccination schedule might be recommended for children traveling to areas where wild poliovirus has been reported in the last 12 months. Your health care provider can give you more information.

##### **Adults**

Most adults do not need IPV because they were already vaccinated as children. But some adults are at higher risk and should consider polio vaccination, including:

- people traveling to certain parts of the world,
- laboratory workers who might handle polio virus, and
- health care workers treating patients who could have polio.

These higher-risk adults could get anywhere from 1 to 3 doses of IPV, depending on how many doses they have had in the past.

IPV is given as an injection in the leg or arm, depending on age. It may be given at the same time as other vaccines.

### **3. Some people should not get this vaccine**

Anyone who has ever had a life-threatening allergic reaction to a dose of this vaccine should not get another dose of IPV.

Anyone with a severe allergy to any component of this vaccine, including the antibiotics neomycin, streptomycin or polymyxin B, should not get IPV. *Tell your immunization provider if the person being vaccinated has any severe allergies.*

If the person scheduled for vaccination is not feeling well, your health care provider might decide to reschedule the shot on another day.

### **4. Risks of a vaccine reaction**

With any medicine, including vaccines, there is a chance of reactions.

Some people who get IPV get a sore spot where the shot was given. IPV has not been known to cause serious problems, and most people don't have any problems at all with it.

#### **Problems that could happen after any injected 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 older children and adults 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 small 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/](http://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 or get the person to the nearest hospital. Otherwise, call your doctor.

Reactions 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](http://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](http://www.hrsa.gov/vaccinecompensation). There is a time limit to file a claim for compensation.

## 7. How can I learn more?

- Ask your healthcare 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](http://www.cdc.gov/vaccines)

Vaccine Information Statement

Polio Vaccine

[date]

42 U.S.C. § 300aa-26

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

Office Use Only

[barcode]

DRAFT

## Vaccine Information Statement

### **Chickenpox (Varicella) Vaccine: What you need to know**

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

#### **1. Why get vaccinated?**

Chickenpox (also called varicella) is a very contagious disease. It is caused by a virus called varicella-zoster. Chickenpox is usually mild, but it can be serious, especially in babies under 12 months of age, adolescents, adults, pregnant women, and people with weakened immune systems.

Chickenpox causes an itchy rash that usually lasts about a week. It can also cause:

- high fever
- tiredness
- loss of appetite
- headache

More serious complications can include:

- pneumonia
- infection or swelling of the brain
- skin infections
- blood stream, bone, or joint infections

Some people get so sick that they need to be hospitalized. It doesn't happen often, but people can die from chickenpox.

Children who get chickenpox usually miss 5 or 6 days of school or childcare.

People who get chickenpox often get a painful rash called shingles years later.

Chickenpox can spread easily from an infected person to anyone who has never had chickenpox or gotten chickenpox vaccine.

Chickenpox vaccine can prevent chickenpox.

#### **2. Chickenpox vaccine**

Chickenpox vaccine is a live-virus vaccine, meaning that the varicella-zoster virus has not been killed, but it has been weakened so it won't cause chickenpox.

You should get two doses of chickenpox vaccine.

For **children under 13 years of age**, these doses are recommended at:

- 12 through 15 months of age (first dose), and
- 4 through 6 years of age (second dose).

The second dose may be given earlier, but at least 3 months after the first dose.

**People 13 years of age or older** who didn't get the vaccine when they were younger, and have never had chickenpox, should get 2 doses at least 28 days apart.

For anyone who has gotten only 1 dose, it is never too late to get the second dose.

Chickenpox vaccine may be given at the same time as other vaccines.

This vaccine protects most people – but not everyone – from getting chickenpox. If someone who has been vaccinated does get chickenpox, it is usually very mild. They will have fewer blisters, are less likely to have a fever, and will recover faster.

### 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 ever had a life-threatening allergic reaction after a dose of chickenpox vaccine, or have a severe allergy to any part of this vaccine, you may be advised not to get vaccinated. Chickenpox vaccine contains gelatin and the antibiotic neomycin. *Tell your immunization provider if the person being vaccinated has any severe allergies.*
- **If you are pregnant.**  
Pregnant women should wait to get chickenpox vaccine until after they have given birth. Women should not get pregnant for 1 month after getting chickenpox vaccine.
- **If you have a weakened immune system because of**
  - HIV/AIDS or any other disease that affects the immune system
  - treatment with drugs that affect the immune system, such as steroids
  - cancer, or cancer treatment with x-rays or drugs
- **If you have recently had a transfusion or were given other blood products.**
- **If you have gotten another vaccine within the past 4 weeks.**  
Live vaccines given too close together might not work as well.
- **If you are not feeling well.**  
If the person scheduled for vaccination is not feeling well, your health care provider might decide to reschedule the shot on another day.

#### **4. Risks of a vaccine reaction**

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

Most people who get chickenpox vaccine do not have any problems with it.

**Minor problems** following chickenpox vaccine include:

- Sore arm from the shot
- Fever
- Mild rash
- Temporary pain and stiffness in the joints

If you get a rash after vaccination, you can spread the disease to others. But, this is extremely rare. If you have a rash, you should stay away from people with weakened immune systems until the rash goes away.

**More serious problems** following chickenpox vaccination are extremely rare. They can include:

- Seizures (jerking or staring spell), including seizures caused by fever
- Severe rash
- Infection of lungs or liver
- Meningitis (infection of the brain and spinal cord coverings)

**Problems that could happen after any injected 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/](http://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 the person to the nearest hospital. Otherwise, call your doctor.
- Reactions 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](http://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](http://www.hrsa.gov/vaccinecompensation). There is a time limit to file a claim for compensation.

## 7. How can I learn more?

- Ask your healthcare 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](http://www.cdc.gov/vaccines)

Vaccine Information Statement

Varicella Vaccine

[date]

42 U.S.C. § 300aa-26

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

Office Use Only

[barcode]

DRAFT

**5.5**

# 5.6

# Vaccine Activities Update

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

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

**March 2016**



National Institute of  
Allergy and  
Infectious Diseases



National Institute of  
Allergy and  
Infectious Diseases

# NIAID Zika Research

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- Basic research
  - How does Zika cause disease?
- Drug screening for activity against Zika virus
- Rapid diagnostics
- Vaccine candidates
  - DNA-based
  - Live-attenuated
  - Genetically engineered version of vesicular stomatitis virus



Credit: Pan American Health Organization



U.S. Department of Health and Human Services

**NIH News**  
National Institutes of Health

National Institute of Allergy and  
Infectious Diseases (NIAID)

<http://www.niaid.nih.gov>

Thursday, January 14, 2016

# Dengue Vaccine Enters Phase 3 Trial in Brazil



# Sequential Rotavirus Vaccine Schedules

---

- Rotavirus vaccines licensed in the U.S.: RotaTeq and Rotarix
  - Some children may receive mixture of products during vaccine series
- Does switching from one vaccine product to another work as well as using the same vaccine for all of the doses?
- Results:

Immunization with mixed series of rotavirus vaccines is safe and results in an immune response that is noninferior to that generated by immunization with any single product.
- Public health implications for use of mixed series in clinical settings



Credit: Andre Berro,  
CDC Division of Global Migration and Quarantine (DGMQ)

# Environmental Influences on Child Health Outcomes (ECHO) Program

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

<http://www.nih.gov>  
Monday, September 28, 2015

**NIH awards ~\$144 million in research on environmental influences on child health and development**



# Maternal Immunization

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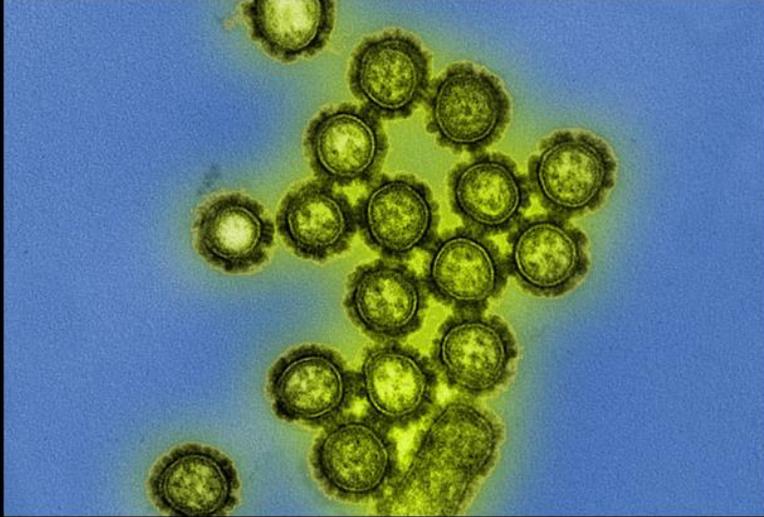


Advancing Maternal Immunization Programs Through  
Research in Low and Medium Income Countries  
(*Vaccine*. November 25, 2015)

# Selected NIAID Research Advances of 2015

**NIH** National Institute of Allergy and Infectious Diseases  
*Leading research to understand, treat, and prevent infectious, immunologic, and allergic diseases.*

## Selected NIAID Research Advances of 2015



**Advancing Toward a Universal Flu Vaccine**

Seasonal flu vaccines work by generating antibodies that target the head region of the lollipop-shaped viral protein hemagglutinin (HA), preventing the virus from entering and infecting cells. The HA head region frequently undergoes genetic changes as flu viruses evolve, making the antibodies produced against one strain ineffective against another. As a result, flu vaccines must be updated annually to best target the viruses predicted to spread and cause illness in a given year.

Scientists are working to develop a universal flu vaccine—one that confers durable protection against most influenza viruses. One possible approach is to create a vaccine that elicits antibodies targeting the HA stem. Unlike the head, the stem varies little among different influenza viruses.

NIAID scientists have developed a nanoparticle vaccine with a stabilized HA stem from an H1N1 influenza virus. Investigators immunized mice and

1 2 3 4 5 6 7 8 9 10

## Vaccine-related examples:

- Influenza
- HIV
- Ebola
- Epstein-Barr Virus Infection

**5.7**

**5.8**



# NATIONAL VACCINE PROGRAM OFFICE UPDATE



**ACCV, MARCH 2016**

**Dr. Karin Bok**



THE NATIONAL VACCINE PROGRAM OFFICE

# National Adult Immunization Plan Rollout

2

[www.hhs.gov/nvpo/](http://www.hhs.gov/nvpo/)



U.S. DEPARTMENT  
OF HEALTH AND  
HUMAN SERVICES

## NAIP OVERVIEW

- Outlines actions needed to be carried out by federal and nonfederal stakeholders to protect public health and achieve optimal prevention of infectious disease through immunization of adults
- Provides guidance through goals, objective and strategies aimed at strengthening infrastructure, improving access, increasing demand and fostering innovation for adult immunization



## GOAL 1: STRENGTHEN THE ADULT IMMUNIZATION INFRASTRUCTURE

### GOAL 1 INCLUDES SIX OBJECTIVES TO STRENGTHEN THE ADULT IMMUNIZATION INFRASTRUCTURE

GOAL 1 OBJECTIVE 1.1	GOAL 1 OBJECTIVE 1.2	GOAL 1 OBJECTIVE 1.3	GOAL 1 OBJECTIVE 1.4	GOAL 1 OBJECTIVE 1.5	GOAL 1 OBJECTIVE 1.6
Monitor and report trends in adult vaccine-preventable disease levels and vaccination coverage data for all ACIP/CDC-recommended vaccines. In cases where there are associated Healthy People 2020 goals, measure progress toward established targets.	Enhance current vaccine safety monitoring systems and develop new methods to accurately and more rapidly assess vaccine safety and effectiveness in adult subpopulations (e.g., pregnant women).	Continue to analyze claims filed as part of the National Vaccine Injury Compensation Program (VICP) to assess whether there was an association between vaccines that a claimant received and adverse events experienced.	Increase the use of electronic health records (EHRs) and immunization information systems (IIS) to collect and track adult immunization data.	Evaluate and advance targeted quality improvement initiatives.	Generate and disseminate evidence about the health and economic impact of adult immunization, including potential diseases averted and cost-effectiveness with the use of current vaccines.

# NVAC MATERNAL IMMUNIZATION WORKING GROUP

## CHARGE

**The Assistant Secretary for Health charges the NVAC to:**

Part 1:

- Review the current state of maternal immunization and existing best practices
- Identify programmatic barriers to the implementation of current recommendations related to maternal immunization and make recommendations to overcome these barriers <sup>1</sup>

**Part 2:**

- **Identify barriers to and opportunities for developing vaccines for pregnant women and make recommendations to overcome these barriers**

**5** <sup>1</sup> Reducing Patient and Provider Barriers to Maternal Immunizations, Public Health Reports, Jan-Feb 2015

# MATERNAL IMMUNIZATIONS: ETHICAL ISSUES

- **Consideration of development and articulation of broadly acceptable and applicable ethical framework that can be used at various venues**
- **Clarification on vulnerable populations: Unethical to describe pregnant women as a vulnerable population, they are rather a complex population**
- **Standardized definitions of minimal risk to aid IRB review process**

# MATERNAL IMMUNIZATIONS: REGULATORY ISSUES

- **Clearly define PLLR implementation concerning vaccinations**
- **New OHRP guidelines to include pregnant women in clinical trials**
- **Consideration of advocacy for models (similar to BPCA) that would effectively change from default to exclusion to default to inclusion, unless clear criteria given for why exclusion.**
- **Continued interface and dialogue between manufacturers and FDA on exact requirements for licensure/indication for existing and new vaccine products for use in pregnancy.**
- **Improve interaction and collaborations between manufacturers and government (DHHS) to encourage manufacturer investment in Maternal Immunization**
- **Continue to advocate to avoid liability issues, and to modify the VICP so maternal immunizations are fully covered**

# MATERNAL IMMUNIZATIONS: SAFETY MONITORING ISSUES

- **Development of standardized definitions of possible maternal and neonatal outcomes**
- **Work to align current safety systems for optimal output**
- **Create interface with international data systems**
- **Promote education of providers on maternal immunization safety research**
- **Clear guidance/consensus on acceptable newborn surveillance timeframe during trials and post-licensure**
- **Obtain data on the safety profile of individual antigen preparations, not only of a vaccine in general (especially for all the Flu and TDaP formulations)**

# MATERNAL IMMUNIZATIONS: PRE-CLINICAL AND CLINICAL RESEARCH

- Increase support of pre-clinical research to address barriers in developing maternal immunizations at this early stage
- Consider increasing research focus/network by creating a Maternal Immunization Research Network
- Focus on standardizing post-marketing surveillance for maternal immunization
- Encourage continuing studies of post-marketing effectiveness evaluation

# MATERNAL IMMUNIZATIONS: PROVIDER EDUCATION AND SUPPORT

- Professional societies should be a valuable partner encouraging and demanding that clinical research be conducted including pregnant women
- Obstetrician providers should be aware that currently there is little or no research during pregnancy, and become advocates for testing vaccines during pregnancy
- Obstetricians should also advocate for vaccination, and understand the importance of vaccine research during pregnancy
- Educate obstetricians on vaccination and interpretation of new labelling so they can make informed decisions



# NATIONAL VACCINE PROGRAM OFFICE VACCINE CONFIDENCE COOPERATIVE AGREEMENT

- Request for Cooperative Agreement related to vaccine confidence: this announcement is accepting applications, with the funding (\$250,000 for up to 18 months) supporting a project that is in line with the NVPO vaccine confidence strategy document and June 2015 NVAC Report on Vaccine Confidence.

THANK YOU



THE NATIONAL VACCINE PROGRAM OFFICE  
**NATIONAL ADULT  
IMMUNIZATION PLAN**



## EXECUTIVE SUMMARY

Vaccination is considered one of the most important public health achievements of the 20th century and continues to offer great promise in the 21st century. Vaccines save lives and improve the quality of life by preventing serious infectious diseases and their consequences. However, the benefits of vaccination are not realized equally across the U.S. population. Adult vaccination rates remain low in the United States, and significant racial and ethnic disparities also exist.

The U.S. Department of Health and Human Services National Vaccine Plan (NVP), released in 2010, is a road map for vaccines and immunization programs for the decade 2010–2020. While the NVP provides a vision for improving protection from vaccine-preventable diseases across the lifespan, vaccination coverage levels among adults are not on track to meet Healthy People 2020 targets. The National Vaccine Advisory Committee and numerous stakeholder groups have emphasized the need for focused attention on *adult vaccines and vaccination*.<sup>1</sup> The National Adult Immunization Plan (NAIP) outlined here results from the recognition that progress has been slow and that there is a need for a national adult immunization strategic plan.

As a national plan, the NAIP will require engagement from a wide range of stakeholders to achieve its full vision. The plan emphasizes collaboration and prioritization of efforts that will have the greatest impact. The NAIP also aims to leverage the unique opportunity presented by the implementation of the Affordable Care Act.

The NAIP is intended to facilitate coordinated action by federal and nonfederal partners to protect public health and achieve optimal prevention of infectious diseases and their consequences through vaccination of adults. The NAIP includes indicators to draw attention to and track progress against core goals. These indicators will measure progress against set standards and inform future implementation and quality improvement efforts. The plan establishes four key goals, each of which is supported by objectives and strategies to guide implementation through 2020:

Goal 1: Strengthen the adult immunization infrastructure.

Goal 2: Improve access to adult vaccines.

Goal 3: Increase community demand for adult immunizations.

Goal 4: Foster innovation in adult vaccine development and vaccination-related technologies.

Achieving the goals of the NAIP is facilitated by agreement on plan priorities and coordination of the wide range of programs that support them. The Assistant Secretary for Health serves as the director of the National Vaccine Program and will lead the NAIP and its implementation. In support of this mission, the National Vaccine Program Office will facilitate collaboration and coordinate the monitoring of progress for the NAIP.

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## ABBREVIATIONS

<b>Abbreviation</b>	<b>Definition</b>
ACF	Administration for Children and Families
ACIP	Advisory Committee on Immunization Practices
ACL	Administration for Community Living
AHRQ	Agency for Healthcare Research and Quality
AITF	Interagency Adult Immunization Task Force
ASH	Assistant Secretary for Health
ASPE	Assistant Secretary for Planning and Evaluation
ASPR	Assistant Secretary for Preparedness and Response
BARDA	Biomedical Advanced Research and Development Authority
CDC	Centers for Disease Control and Prevention
CMS	Centers for Medicare & Medicaid Services
DHS	U.S. Department of Homeland Security
DoD	U.S. Department of Defense
EHR	electronic health record
FDA	U.S. Food and Drug Administration
FOH	Federal Occupational Health
HHS	U.S. Department of Health and Human Services
HPV	human papilloma virus
HRSA	Health Resources and Services Administration
IHS	Indian Health Service
IID	Immunization and Infectious Diseases
IIS	immunization information systems
IT	information technology
NAIP	National Adult Immunization Plan
NIH	National Institutes of Health
NVAC	National Vaccine Advisory Committee
NVP	National Vaccine Plan
NVPO	National Vaccine Program Office
OASH	Office of the Assistant Secretary for Health
OMH	Office of Minority Health
ONC	Office of the National Coordinator for Health Information Technology
OWH	Office on Women's Health
RHA	Regional Health Administrator
Tdap	tetanus, diphtheria, and pertussis
VA	U.S. Department of Veterans Affairs
VAERS	Vaccine Adverse Event Reporting System
VFC	Vaccines for Children program
VICP	National Vaccine Injury Compensation Program

## INTRODUCTION

Despite the widespread availability of safe and effective vaccines, adult vaccination rates remain low in the United States and far below Healthy People 2020 targets.<sup>2,3</sup> Vaccine-preventable diseases take a heavy toll on adults age 18 and older. The health and productivity costs of influenza alone are estimated to be as high as \$87 billion per year.<sup>4</sup> The Centers for Disease Control and Prevention (CDC) estimates that, among U.S. adults, each year there are roughly 40,000 cases and 4,000 deaths attributable to invasive pneumococcal disease,<sup>5</sup> between 3,000 and 49,000 deaths due to seasonal influenza,<sup>6</sup> 9,000 reported cases of pertussis,<sup>7</sup> approximately 3,000 reported cases of acute hepatitis B,<sup>8</sup> and about one million cases of herpes zoster.<sup>9</sup> Adults have been directly affected in recent outbreaks of vaccine-preventable diseases, such as measles. Unvaccinated adults have also unknowingly spread vaccine-preventable diseases (e.g., to small children who are too young to be immunized); thus, limited vaccination of adults not only impacts adults directly but also has consequences for their families and communities. With the aging of the U.S. population, the public health impact of vaccine-preventable diseases and their complications in adults is likely to grow. The diminishing function of the aging immune system reduces the immune response to vaccination and underscores the need to develop more effective products for older adults.<sup>10</sup>

The CDC and its Advisory Committee on Immunization Practices (ACIP) currently recommend 13 different vaccines for adults age 18 and older to prevent a host of diseases (Appendix 1).<sup>10</sup> The adult vaccine schedule, which was first published in 2002, now includes vaccines that are universally recommended (e.g., influenza), those that are recommended for certain age groups (e.g., human papilloma virus [HPV]), and those that are targeted to individuals with specific risk factors (e.g., hepatitis A and B).<sup>1,10</sup> The adult schedule also includes catch-up vaccinations for those adults who never initiated or did not complete a multidose series when vaccination was first recommended during childhood. Catch-up vaccinations include such vaccines as measles, mumps, and rubella and varicella, which are routinely recommended for administration during childhood.

As shown in Table 1, despite the health benefits that result from implementation of ACIP/CDC recommendations, adults continue to be vaccinated at low and variable rates. In contrast, childhood vaccination rates in the United States typically exceed 90 percent. The success of childhood vaccination can be attributed to many factors unique to pediatric vaccination, such as state laws requiring vaccination for school entry and the coordinated public health infrastructure established by the Vaccines for Children program (VFC), a federally funded program to provide free vaccines to children who are

eligible for Medicaid, uninsured, underinsured, or American Indian or Alaska Native.<sup>11</sup> Another reason for the high rates of vaccination among children is that pediatricians and family physicians, the primary providers of health care and preventive health services for children, have long been committed to making immunization a core part of well-child care. For adults, chronic diseases and screenings for cancer, blood pressure, and cholesterol have historically been the primary focus of acute health care and preventive health services, respectively.<sup>1</sup> As a result, vaccinations are emphasized less and are underutilized in the adult population.

**TABLE 1. HEALTHY PEOPLE OBJECTIVES SPECIFIC TO ADULT VACCINATION, 2013 COVERAGE AND 2020 TARGETS**

<b>Objective IID-12: Increase the percentage of</b>	<b>2013 Percentage</b>	<b>2020 Target Percentage*</b>
Adults age >18 years	39 <sup>†</sup>	70
Health care personnel	62 <sup>‡</sup>	90
Pregnant women	52 <sup>§</sup>	No target, in development

<b>Objective IID-13: Increase the percentage of adults who are vaccinated against pneumococcal disease.</b>	<b>2013 Percentage</b>	<b>2020 Target Percentage**</b>
Noninstitutionalized adults age >65 years	60 <sup>††</sup>	90
Noninstitutionalized high-risk adults age 18– 64 years	21 <sup>‡‡</sup>	60

Healthy People 2020.<sup>2</sup>

† National Health Interview Survey, as reported by Healthy People 2020.<sup>2</sup>

‡ National Health Interview Survey, as reported by Healthy People 2020.<sup>2</sup>

§ Ding (2014).<sup>12</sup> The most recent published statistics are for the 2013–2014 influenza season; the estimate is from an Internet panel survey. The study sample did not include women without Internet access; results might not be generalizable to all pregnant women in the United States. Also, the estimate might be biased if the selection processes for entry into the Internet panel and a woman’s decision to participate in this survey were related to receipt of vaccination.

\*\* Healthy People 2020.<sup>2</sup>

†† National Health Interview Survey (2013).<sup>3</sup>

‡‡ National Health Interview Survey (2013).<sup>3</sup>

<b>Objective IID-13: Increase the percentage of adults who are vaccinated against pneumococcal disease.</b>	<b>2013 Percentage</b>	<b>2020 Target Percentage**</b>
Institutionalized adults age >18 years in long-term care or nursing homes	66§§	90

<b>Objective IID-14: Increase the percentage of adults age &gt;60 who are vaccinated against zoster (shingles).</b>	<b>2013 Percentage</b>	<b>2020 Target Percentage***</b>
Adults age >60 years	24†††	30

<b>Objective IID-15: Increase hepatitis B vaccine coverage among high-risk populations.</b>	<b>2013 Percentage</b>	<b>2020 Target Percentage†††</b>
Health care personnel age >19 years	64§§§	90

Notes: IID = Immunization and Infectious Diseases. The objective for influenza vaccination for pregnant women is developmental, and no target has been set. Some, but not all, of the ACIP/CDC-recommended vaccines are included in the Healthy People 2020 objectives.

In addition to achieving higher vaccination rates, the childhood vaccination program in the United States has been largely successful at reducing or eliminating racial and ethnic disparities in vaccination coverage. As a result of multiple interventions and programs implemented over the past two decades, including the VFC, disparities in vaccination coverage have dramatically declined between non-Hispanic white children and children of other racial and ethnic groups.<sup>11</sup> In contrast, various racial and ethnic minority adults (e.g., Blacks, Hispanics) receive recommended vaccinations at rates far below those of whites.<sup>13</sup> Appendix 2 shows the disparities in immunization rates for several racial and ethnic groups.

§§ Minimum Data Set data from 2005–2006, as reported by Healthy People 2020.<sup>2</sup>

\*\*\* Healthy People 2020.<sup>2</sup>

††† National Health Interview Survey (2013).<sup>3</sup>

††† Healthy People 2020.<sup>2</sup>

§§§ National Health Interview Survey data from 2008, as reported by Healthy People 2020.<sup>2</sup>

## Barriers to Adult Immunization

Numerous barriers must be addressed to make significant progress in adult vaccination, meet Healthy People 2020 objectives, and eliminate disparities. Barriers that are consistently highlighted by stakeholder groups and the research community include the following:

- Lack of coordination of adult immunization activities across all stakeholders, including multiple health care providers for adults<sup>1</sup>
- Lack of integration of vaccines into adult medical care<sup>1</sup>
- Lack or underuse of administrative systems (e.g., immunization information systems [IIS]) for documenting vaccination histories and identifying patients who are due for vaccinations in medical records<sup>14,15</sup>
- Skepticism regarding vaccine safety and effectiveness<sup>1</sup>
- Inability to pay for vaccination as a result of lack of insurance or variable coverage for recommended vaccinations across health plans<sup>1,14</sup>
- Provider concerns about reimbursement and vaccine administration fees paid by health insurers, which discourages some providers from stocking all adult vaccines<sup>14,16,17</sup>
- Lack of public knowledge regarding the adult immunization schedule and the risks and consequences of vaccine-preventable diseases; lack of awareness that adults are supposed to receive vaccines other than the influenza vaccine<sup>1</sup>
- Legal barriers at the state and federal levels (e.g., restricting which providers can administer vaccines)<sup>1</sup>
- Lack of and/or weak recommendations by health care providers<sup>1,14</sup>
- Limited use of evidence-based strategies to improve vaccine uptake, such as reminder-recall and related systems<sup>18</sup>
- Conflicting and inaccurate information about immunizations in mass media.<sup>1,19</sup>

The National Adult Immunization Plan (NAIP) was developed to help address these barriers, as well as other persistent challenges, through coordinated action.

## Opportunities in the Changing Policy Landscape

The NAIP builds on work that has been completed, or is under way, for adult immunization and advances priorities that reflect the changing landscape of health care and preventive health services as a result of Affordable Care Act implementation.

There have been several important developments in recent years that provide context for the development and implementation of the NAIP at this time.

In 2012, the National Vaccine Advisory Committee (NVAC) published *A Pathway to Leadership for Adult Immunization*, which outlined three recommendations to the Assistant Secretary for Health (ASH) to support a NAIP: national leadership, allocation of resources, and the development of a strategic plan for the adult immunization program.<sup>1</sup>

- In 2014, NVAC again served in an advisory capacity and published updated *Standards for Adult Immunization Practice* to emphasize that all providers who care for adults are responsible for assessing immunization needs at every clinical encounter, strongly recommending needed vaccines, administering recommended vaccines, and documenting receipt in a state immunization information system. The standards, which have been endorsed by the U.S. Department of Health and Human Services (HHS), also instruct providers who do not vaccinate to refer adult patients to providers who administer vaccinations.<sup>20</sup>
- In 2012, the first annual National Adult and Influenza Immunization Summit was convened. The summit brings together public and private stakeholders involved in adult immunization and provides a forum to share new ideas and information and identify actions to increase adult vaccination rates for ACIP/CDC-recommended vaccines.<sup>21</sup>

In addition, passage of the Affordable Care Act in 2010 was an important milestone for adult vaccination in the United States. The Affordable Care Act expanded access to health insurance to millions of previously uninsured or underinsured Americans and required that certain recommended clinical preventive services, including routine vaccines, be covered without cost-sharing to individuals enrolled in most private health insurance plans and those who obtained Medicaid coverage through Medicaid expansion. Coverage of vaccinations did not change for individuals enrolled in Medicare and traditional Medicaid plans. An estimated 17.6 million Americans have gained health insurance since the first open enrollment period in the fall of 2013.<sup>22</sup> Furthermore, about 137 million individuals have private insurance coverage of preventive services without cost-sharing.<sup>23</sup> At the state level, the Affordable Care Act also authorizes use of funds for purchase of vaccines for adults at federally negotiated prices. Although the full impact of the Affordable Care Act is yet to be determined, it is anticipated that it will eliminate some of the financial barriers to adult vaccination.

While the Affordable Care Act represents an important step forward for adult vaccination, some challenges remain. For example, people who continue to lack health insurance (e.g., uninsured non-U.S. citizens, low-income individuals in states that have not expanded Medicaid to cover people with annual incomes of up to 133 percent of the federal poverty level) may continue to have difficulty accessing and paying for recommended vaccinations.

Furthermore, some Medicare beneficiaries may encounter financial barriers when accessing vaccines covered by Medicare Part D (e.g., herpes zoster and tetanus, diphtheria, and pertussis [Tdap] vaccines). Medicare Part B covers three preventive vaccines without cost-sharing (influenza, pneumococcal, and hepatitis B vaccines), as well as select vaccines directly related to the treatment of an injury or disease exposure; however, cost-sharing for vaccines covered under Medicare Part D (e.g., herpes zoster) varies widely from plan to plan and may discourage uptake among some beneficiaries. In a 2011 report, the U.S. Government Accountability Office noted that some stakeholders have raised concerns about the administrative challenges associated with Part D and recommended actions to improve access to Part D vaccinations.<sup>24</sup> The Centers for Medicare & Medicaid Services (CMS) has issued guidance on a number of approaches to help address administrative challenges, but stakeholders report that additional steps are needed.

## PURPOSE AND LEADERSHIP OF THE NATIONAL ADULT IMMUNIZATION PLAN

To address ongoing barriers as well as new challenges, the NAIP is intended to promote coordinated planning and action across all stakeholder groups, including those within and outside the U.S. government. It provides direction by establishing a vision, four goals, 16 objectives, and numerous strategies to promote action through 2020.

*The vision for adult immunization is to protect the public health and achieve optimal prevention of infectious diseases and their consequences through vaccination of all adults.*

**The goals are as follows:**

- Goal 1:** Strengthen the adult immunization infrastructure.
- Goal 2:** Improve access to adult vaccines.
- Goal 3:** Increase community demand for adult immunizations.
- Goal 4:** Foster innovation in adult vaccine development and vaccination-related technologies.

Under each goal is a set of objectives to steer improvement efforts within functional areas critical to achieving each goal. Within these objectives, the NAIP identifies key strategies to guide implementation through 2020. The strategies encourage focused attention on areas that can have the greatest impact toward achieving the vision of a robust immunization system that will improve adult health by protecting adults against vaccine-preventable diseases and their complications. While the plan contains a list of strategies, it should be noted that many of the strategies are interdependent, and, as such, the appropriate sequencing of particular strategies is a key challenge for implementation. For example, before generating community-wide demand (Goal 3), it will be necessary to enhance the adult immunization infrastructure and remove access barriers (Goals 1–2) to ensure that the delivery system has sufficient capacity to serve a larger number of adults.

While there is recognition of the challenges facing adult vaccination, NAIP goals can be achieved through national leadership and collaboration among the many stakeholders who comprise the adult immunization system. National leadership is critical to focus our nation on disease prevention and to catalyze action to strengthen the vaccination delivery system across the country. The Office of the Assistant Secretary for Health

(OASH), within HHS, is a strong advocate for the importance of adult immunization. The ASH serves as the director of the National Vaccine Program and will lead the NAIP and its implementation. In support of this mission, the National Vaccine Program Office (NVPO) within HHS will facilitate collaboration and coordinate the monitoring of progress for the NAIP, which will be reviewed annually by the ASH and the National Vaccine Advisory Committee (NVAC).

While federal leadership and the alignment of federal activities are critical to implementing this plan, participation by diverse stakeholders is necessary for the NAIP to realize its potential. The NAIP is a national rather than federal plan and thus calls for the coordinated action of governmental and nongovernmental partners. The success of this plan depends on state, local, territorial, and tribal governments; health care providers; professional associations; advocacy groups; vaccine manufacturers; academia and research organizations; payers and health plans; employers; and the general public working together to overcome barriers and improve access to adult vaccinations. Table 2 outlines some of the stakeholder groups that will be a part of plan implementation.

**TABLE 2. NATIONAL ADULT IMMUNIZATION PLAN:  
FEDERAL AND NONFEDERAL STAKEHOLDERS**

Stakeholder Category	Agency/Entity
Federal government, HHS agencies	Administration for Community Living, Administration for Children and Families, Agency for Healthcare Research and Quality, Centers for Disease Control and Prevention, Centers for Medicare & Medicaid Services, U.S. Food and Drug Administration, Health Resources and Services Administration, Indian Health Service, National Institutes of Health, Office of the Assistant Secretary for Public Affairs, Office of the Assistant Secretary for Planning and Evaluation, Office of the Assistant Secretary for Preparedness and Response, Office of Global Affairs, Office of Minority Health, Office of the National Coordinator for Health Information Technology, Partnership Center, Office of the Assistant Secretary for Health, Office of Disease Prevention and Health Promotion, Office on Women's Health, Office of Adolescent Health, Regional Health Administrators
Federal government, other departments/agencies	Department of Defense, Department of Homeland Security, Department of Veterans Affairs, Department of Justice, Federal Occupational Health, Office of Personnel Management
Government, nonfederal	State, territorial, tribal, and local public health agencies and governments

Nongovernmental stakeholders	Academia/research organizations, health care providers, vaccine industry, health care systems, community immunizers, professional associations, payers and plans, employers, foundations, schools and training programs, community and patient advocacy organizations, philanthropic organizations, adult immunization coalitions, and the general public
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## DEVELOPMENT OF THE NATIONAL ADULT IMMUNIZATION PLAN

Lack of sufficient progress in increasing adult immunization rates coupled with the ASH's consideration of NVAC's recommendation led to the development of the NAIP.<sup>1</sup> The plan was drafted after deliberation, analysis, and input from a broad range of stakeholders, including health care providers; professional and advocacy organizations; federal, state, local, tribal, and territorial governments; researchers; health insurers; employers; vaccine manufacturers; and members of the general public. The RAND Corporation was enlisted to conduct an environmental scan, engage stakeholders, and collect data to identify plan priorities and key indicators.

### Environmental Scan

The first step in developing the plan was to develop a comprehensive environmental scan and review all prior recommendations and reports on adult vaccination from 2005 to 2015. Numerous stakeholder groups have issued reports in recent years calling for action to improve adult vaccination.<sup>14–16,25–31</sup> These reports inventory past successes, ongoing barriers, and potential opportunities to improve adult vaccination and recommend actions to be taken by government agencies, health insurers, community vaccinators, and others to raise adult vaccination rates. The environmental scan identified both best practices and potential actions for strengthening adult vaccination. These actions were assessed for continued relevance in the current policy environment, and the chosen actions were organized by plan goal and objective.

### Stakeholder Engagement

The second step in the process was robust stakeholder engagement. First, a survey was fielded to 96 respondents representing a range of stakeholder groups, such as health departments, payers, employers, research organizations, professional associations, and health care providers. Then, eight focus groups with a total of 90 participants were convened to review survey results. Lastly, in-depth interviews were conducted with dozens of governmental and nongovernmental subject matter experts. Stakeholders were asked to assess and prioritize actions identified in the environmental scan, as well as to identify any new actions.

## Measuring Progress: Indicator Development

Once a final set of actions was identified, stakeholders were also asked to identify and prioritize indicators to track progress on plan goals and objectives and set ambitious yet attainable milestones for 2020, using a target-setting method consistent with Healthy People 2020. If a target had already been set by an existing policy or program, that target was adopted. In cases in which no target existed, stakeholders discussed trend data and determined target levels by consensus.

Following a number of stakeholder engagements, a draft plan was released for public comment through a notice in the Federal Register. The final NAIP reflects the input of the full range of stakeholders in the adult vaccine system in the United States.

### *Alignment with Existing HHS Programs and Plans*

In developing the plan, care was taken to align with numerous HHS programs and plans, including the National Vaccine Plan (NVP), Healthy People 2020, the National Prevention Strategy, and the HHS Strategic Plan. These initiatives all contain specific objectives and indicators related to strengthening adult vaccination, including the following:

- Healthy People 2020: Healthy People 2020 includes four objectives related to improving vaccination coverage among adults within the topic of immunizations and infectious diseases and one within the topic of older adults. The NAIP supports the achievement of the adult vaccination targets specified in Healthy People 2020.
- National Prevention Strategy: The National Prevention Strategy emphasizes the importance of adult vaccination and other preventive services for increasing the number of Americans who are healthy at every stage of life.
- HHS Strategic Plan: One of the objectives of the HHS Strategic Plan is to reduce the occurrence of infectious diseases, including vaccine-preventable diseases. The HHS Strategic Plan includes a specific strategy to remove financial and other barriers to routine vaccination for adults, which is also a major focus of the NAIP.
- National Quality Strategy: Established as part of the Affordable Care Act, the National Quality Strategy focuses nationwide quality improvement and measurement efforts on six priorities, including working with communities to

promote wide use of best practices to enable healthy living. This priority encourages the adoption of recommended clinical preventive services for adults, such as vaccination.

- HHS Action Plan to Reduce Racial and Ethnic Health Disparities: The HHS Action Plan to Reduce Racial and Ethnic Health Disparities includes a measure to increase the percentage of racial and ethnic minority populations who receive the seasonal influenza vaccination.
- National Vaccine Plan: The 2010 NVP provides a guiding vision for vaccination for the decade 2010–2020 and strategic direction for coordination of the immunization system in the United States. The NAIP supports and can be described as being nested within the NVP, which is the road map for the broader set of efforts seeking to prevent serious infectious diseases and their complications through vaccination.

The NAIP was also designed to highlight areas of adult immunization that are addressed in a more focused and detailed manner by other efforts. While the NAIP provides a framework for approaching adult vaccination, there are unique issues for certain populations, such as pregnant women, that require focused attention:

- The NVAC Standards for Adult Immunization Practice, released in 2014, provide guidance for health care providers representing both traditional and complementary settings for vaccination of adults on how to implement many of the priorities in the plan.<sup>20</sup>
- The Community Guide to Preventive Services reviews the evidence for potential interventions and strategies to promote the use of screening, counseling, and other preventive services typically delivered in primary care settings. The Community Guide includes 13 recommendations on vaccination strategies and identifies five areas in which there is insufficient evidence.<sup>32</sup>
- NVAC also advises the ASH regarding strategies to improve vaccination for specific subgroups of adults, such as health care workers and pregnant women, by offering evidence-based strategies for overcoming patient and provider barriers that continue to hinder uptake of recommended vaccines in this population. In addition, NVAC provides forward-looking analyses to identify barriers and challenges to research and development of new vaccines specifically for pregnant women.<sup>33</sup> These analyses and resulting recommendations help guide efforts to expand the potential of vaccines to protect pregnant women and their infants.

## NAIP GOALS, OBJECTIVES, AND STRATEGIES

This section presents the goals, objectives, and strategies that compose the NAIP. The activities outlined here will guide federal adult immunization efforts in collaboration with nonfederal partners in the upcoming years to advance strategic goals and supporting objectives. For each objective, the key federal agencies and nonfederal partners with relevant roles and responsibilities are presented in Appendix 4.

While all of the goals, objectives, and strategies are important for advancing adult immunization, the NAIP's priorities are captured by the plan performance indicators in Table 3. In many cases, progress on the performance indicators (e.g., adult vaccination rates) requires action on multiple objectives and strategies; thus, the indicators serve as a barometer for what is happening across the adult immunization system.

# GOAL 1: STRENGTHEN THE ADULT IMMUNIZATION INFRASTRUCTURE

The adult immunization infrastructure in the United States is complex and multifaceted, consisting of numerous components with unique functions. While all the goals of the NAIP feature objectives that impact critical aspects of the infrastructure or interdependencies among system components, Goal 1 of the NAIP focuses on high level issues with the potential to have significant impact on adult vaccination rates in the next several years. One example is the increasing importance of health IT and the need for systems and providers to be able to exchange accurate, timely information. Goal 1 represents a commitment to strengthen the adult immunization infrastructure by improving and leveraging elements that already exist, rather than creating new systems, programs, and entities.

## GOAL 1 OBJECTIVES

GOAL 1 INCLUDES SIX OBJECTIVES TO STRENGTHEN THE ADULT IMMUNIZATION INFRASTRUCTURE:					
GOAL 1 OBJECTIVE 1.1	GOAL 1 OBJECTIVE 1.2	GOAL 1 OBJECTIVE 1.3	GOAL 1 OBJECTIVE 1.4	GOAL 1 OBJECTIVE 1.5	GOAL 1 OBJECTIVE 1.6
Monitor and report trends in adult vaccine-preventable disease levels and vaccination coverage data for all ACIP/CDC-recommended vaccines. In cases where there are associated Healthy People 2020 goals, measure progress toward established targets.	Enhance current vaccine safety monitoring systems and develop new methods to accurately and more rapidly assess vaccine safety and effectiveness in adult subpopulations (e.g., pregnant women).	Continue to analyze claims filed as part of the National Vaccine Injury Compensation Program (VICP) to assess whether there was an association between vaccines that a claimant received and adverse events experienced.	Increase the use of electronic health records (EHRs) and immunization information systems (IIS) to collect and track adult immunization data.	Evaluate and advance targeted quality improvement initiatives.	Generate and disseminate evidence about the health and economic impact of adult immunization, including potential diseases averted and cost-effectiveness with the use of current vaccines.

### Objective 1.1:

**Monitor and report trends in adult vaccine-preventable disease levels and vaccination coverage data for all ACIP/CDC-recommended vaccines. In cases where there are associated Healthy People 2020 goals, measure progress toward established targets.**

Translating vaccination policy into health outcomes depends on strong public health surveillance to evaluate the impact of adult vaccinations on vaccine-preventable diseases. Surveillance also provides needed data to assess progress on plan indicators, including the impact of activities on racial and ethnic disparities.

- 1.1.1** Evaluate the impact of adult vaccination on morbidity and mortality, with special emphasis on vulnerable populations (e.g., older adults and adults with chronic conditions, such as diabetes, heart disease, immune

compromising conditions, and stroke) where feasible.

- 1.1.2** Identify coverage gaps and disparities among racial and ethnic minorities and develop targeted strategies to reduce disparities.
- 1.1.3** Improve methods to verify vaccination coverage status.
- 1.1.4** Identify efficiencies to improve adult immunization delivery by encouraging greater use and increased functionality of existing systems (e.g., state and local IIS).

### **Objective 1.2:**

#### **Enhance current vaccine safety monitoring systems and develop new methods to accurately and more rapidly assess vaccine safety and effectiveness in adult subpopulations (e.g., pregnant women).**

Vaccines have a long track record of safety and effectiveness in adults, yet there is a need to ensure that, when recommended and used broadly, vaccines perform as would be expected from the clinical trials that led to their licensure. In addition, there is a need to closely monitor vaccine safety and effectiveness in adult populations after new vaccines are licensed, when licensed vaccines are recommended for new populations, or when vaccines are used as part of the response to a public health emergency (e.g., an influenza pandemic). Vaccine safety and effectiveness monitoring is important not only for public health, but also to ensure public confidence in vaccines.

The federal vaccine safety systems include, for example, the Vaccine Adverse Event Reporting System (VAERS) co-sponsored by CDC and the Food and Drug Administration (FDA), CDC's Vaccine Safety Datalink (VSD) and Clinical Immunization Safety Assessment, FDA's Post-Licensure Rapid Immunization Safety Monitoring System, and the Vaccine Injury Compensation Program and the Countermeasures Injury Compensation Program, which are administered by the Health Resources and Services Administration (HRSA). Vaccine safety monitoring is not limited to the federal government, however, and a variety of nonfederal entities, including manufacturers and academia, are active in this arena.

- 1.2.1** Increase awareness of the federal vaccine safety systems among adult health care providers who vaccinate the public.
- 1.2.2** Increase the percentage of adult vaccination providers and patients that report adverse events into VAERS.
- 1.2.3** Support improved online reporting interfaces (e.g., VAERS) to facilitate the electronic submission of adverse event reports that occur after the administration of vaccines.
- 1.2.4** Improve the timeliness and precision of vaccine effectiveness assessments.
- 1.2.5** Encourage use of clinical research and population-based epidemiologic studies for vaccine safety and effectiveness monitoring among vaccinated

adults.

- 1.2.6** Encourage greater use of EHRs and IIS to more rapidly identify persons who may be impacted when a safety concern has been raised about a particular vaccine or vaccine lot.
- 1.2.7** Determine the data needs to monitor vaccine safety and effectiveness in pregnant women and newborns and the ability of these systems to capture relevant data.

### **Objective 1.3:**

#### **Continue to analyze claims files as part of the National Vaccine Injury Compensation Program (VICP) to assess whether there was an association between vaccines that a claimant received and adverse events experienced.**

The VICP was established in 1988 to provide compensation to individuals, including adults, thought to have been injured or whose death was thought to have been related to receiving certain vaccines. While adverse events following vaccination are extremely rare, the VICP provides a no-fault alternative to the traditional tort system for resolving vaccine injury claims. This program is instrumental in helping to ensure an adequate supply of vaccines, encourage innovation, and stabilize vaccine costs by establishing and maintaining an accessible and efficient forum for individuals thought to be injured by select vaccines.

- 1.3.1** Review the latest medical and scientific literature for evidence of associations between vaccines and adverse events when reviewing claims.

### **Objective 1.4:**

#### **Increase the use of electronic health records (EHRs) and immunization information systems (IIS) to collect and track adult immunization data.**

While IIS have the potential to act as a centralized repository of adult vaccination records, the maturation of EHRs, IIS, and interoperability will also play a critical role in ensuring coordination of adult vaccination activities and improving coverage.<sup>34</sup> A centralized source of vaccination information is especially critical for adults who see variety of providers and receive vaccinations in a variety of settings (e.g., medical settings, workplaces, schools, colleges, universities, pharmacies).

Many adult vaccination improvements are dependent on or would be accelerated by better data exchange, and interoperability between EHRs and IIS facilitates better health outcomes.

In order to achieve these outcomes, EHRs must be able to electronically send data to IIS and to receive consolidated histories and forecasts from IIS in a secure manner.

EHRs also must be able to reconcile a patient’s history and forecast what might be needed to ensure that the appropriate vaccines are given at the right times. Information technology enhancements can lead to better recordkeeping and submission to IIS that addresses the barrier of unknown vaccination history, avoids the administration of duplicate doses of vaccine, and helps ensure that opportunities for vaccination are not missed. EHR and IIS-related strategies include the following:

- 1.4.1** Increase the ability of EHRs to generate a query using nationally accepted standards and accept a standardized immunization history and forecast, consistent with the objectives and measures set forth in rulemaking for the Medicare and Medicaid EHR Incentive Programs.
- 1.4.2** Increase the ability of IIS to accept a query using nationally accepted standards and respond with a standardized immunization history and forecast to inform providers of needed vaccinations, consistent with the objectives and measures set forth in rulemaking for the Medicare and Medicaid EHR Incentive Programs.
- 1.4.3** Increase adoption of standardized transport methods, including use of the CDC Web Services Definition Language (WSDL), by IIS and by EHRs to allow for more consistent information exchange across all in the health care system who provide vaccine services for adults.
- 1.4.4** Expand IIS and EHR functionality to facilitate interstate immunization data exchange through a centralized hub.
- 1.4.5** Develop and disseminate “model agreements” to address the documented legal and policy barriers that preclude data sharing between states and systems.
- 1.4.6** Expand consumers’ access to their own vaccination data through secure IIS and EHR consumer portals.
- 1.4.7** Develop and encourage adoption of standardized clinical decision support tools for adult vaccination.
- 1.4.8** Encourage evaluation of IIS and EHR usage for adult vaccinations among providers, facilities, and organizations delivering vaccines to adults.
- 1.4.9** Promote automation strategies for documenting adult vaccinations, such as the inclusion of 2D barcode data from vials and syringes, and by building IIS and EHR capacity to accept barcode data.
- 1.4.10** Encourage bidirectional exchange between EHRs and IIS for adult vaccinations among clinics and health systems already entering pediatric data (e.g., federally qualified health, center–funded clinics, health maintenance organizations).
- 1.4.11** Increase participation of federal agencies in IIS and the connectivity between IIS and EHR in these organizations (e.g., federal occupational health clinics, VA health systems, DoD-run clinics).
- 1.4.12** Promote the use of Clinical Decision Support for Immunizations (CDSi) resources by IIS and EHRs to standardize vaccine recommendations for

adult populations.

- 1.4.13** Increase the capability of IIS to onboard adult providers for bidirectional data exchange between the provider and IIS.

**Objective 1.5:**

**Evaluate and advance targeted quality improvement initiatives.**

Targeted quality improvement efforts, such as the development and use of clinical performance measures by providers and health plans, play an important role in helping providers set priorities and establish practice patterns and, thus, can motivate providers to improve adult vaccination rates. To ensure progress on plan goals and objectives, it is helpful to encourage and incentivize providers to recommend, provide, and maintain records of adult vaccinations. To date, there have been several efforts to assess current performance measures, identify measurement gaps, and make recommendations regarding the development and implementation of new measures. Most existing measures focus on uptake of select vaccines (e.g., the percentage of health care workers who receive an influenza vaccination); however, others also gather information about processes of care (e.g., the percentage of nursing home residents assessed and appropriately given the pneumococcal vaccine). Many future quality improvement projects will be facilitated by strengthening the IT tools outlined in objectives 1.3 and 1.4.

- 1.5.1** Evaluate impact of current adult vaccination quality measures and the feasibility of future quality measure development projects.
- 1.5.2** Disseminate best practices and lessons learned from successful and unsuccessful adult quality measure and adult quality improvement pilot projects.
- 1.5.3** Develop and validate new metrics to track progress on NAIP objectives.

**Objective 1.6:**

**Generate and disseminate evidence about the health and economic impact of adult immunization, including potential diseases averted and cost-effectiveness with the use of current vaccines.**

Generating information on the economic impact of adult immunization is a critically important element of the plan. While economic evaluations of the childhood immunization program in the United States have assessed the impact of all routinely recommended vaccines on direct and indirect costs, no parallel research has been published on adult immunization. Economic evaluations are critically important because they help to inform policymakers, health insurance plans, providers, employers, and the public about the value and importance of adult immunizations and can inform decisions

regarding promotion of and reimbursement for adult immunization services.

- 1.6.1** Encourage the development and evaluation of models to estimate the cost-effectiveness of adult immunization programs.
- 1.6.2** Encourage employers to offer and promote adult immunization using evidence on economic impact.

## GOAL 2: IMPROVE ACCESS TO ADULT VACCINES

The passage of the Affordable Care Act marked an important opportunity for adult vaccination, with more consumers having improved access to preventive services. However, despite the Affordable Care Act's impact, critical challenges remain in achieving access to low cost, high quality vaccination services. More than 17 million adults have gained health insurance coverage since the beginning of open enrollment in October 2013 through September 12, 2015. Over that period, the uninsured rate declined from 20.3 percent to 12.6 percent – a 38 percent (or 7.7 percentage point) reduction in the uninsured rate. Nonetheless, some adults will continue to be uninsured or underinsured.<sup>22</sup> The NAIP aims to leverage the full potential of the Affordable Care Act to improve access to adult vaccinations and to identify solutions to ongoing challenges.

## GOAL 2 OBJECTIVES

GOAL 2 INCLUDES FOUR OBJECTIVES TO IMPROVE ACCESS TO ADULT VACCINES:			
GOAL 2 OBJECTIVE 2.1	GOAL 2 OBJECTIVE 2.2	GOAL 2 OBJECTIVE 2.3	GOAL 2 OBJECTIVE 2.4
Reduce financial barriers for individuals who receive recommended adult vaccines.	Assess and improve understanding of providers' financial barriers to delivering vaccinations, including stocking and administering vaccines.	Expand the adult immunization provider network.	Ensure a reliable supply of vaccines and the ability to track vaccine inventories, including during public health emergencies.

### Objective 2.1:

#### Reduce financial barriers for individuals who receive recommended adult vaccines.

The inability of some individuals to pay for vaccines is a commonly cited barrier to increasing adult vaccination. There is no adult program comparable to the VFC, which offers free vaccines to eligible child populations and supports a robust delivery infrastructure, including provider education. While the Affordable Care Act has reduced financial barriers to vaccination for millions of Americans, certain segments of the population (e.g., the uninsured) will continue to have out-of-pocket costs for recommended vaccines. Thus, understanding and reducing financial barriers for these segments of the population is an important objective of the NAIP.

- 2.1.1** Evaluate the impact of financial barriers, such as co-pays, on adult vaccination uptake.
- 2.1.2** Advance efforts to have consistency in the individual state Medicaid benefit for ACIP/CDC-recommended vaccines for adults.
- 2.1.3** Evaluate the impact of state Medicaid program approaches to cost sharing for recommended adult vaccines on vaccination rates (e.g., compare programs that elect to offer the same benefits for traditional and expansion populations and those that maintain different benefits for these populations.)
- 2.1.4** Evaluate the advantages and disadvantages of novel state vaccine financing pilot programs that provide vaccines to adults, including health, economic, and innovation impacts.

**Objective 2.2:****Assess and improve understanding of providers' financial barriers to delivering vaccinations, including stocking and administering vaccines.**

Providers need to be educated about the importance of routinely assessing the vaccine needs of their patients, strongly recommending needed vaccines, and either vaccinating or referring patients to others who administer vaccinations. They also must be empowered to pursue these activities with tailored guidance, education, and tools.

Currently, many factors prevent providers from consistently vaccinating all patients who could benefit, and providers in underserved and minority communities may face unique challenges. The Affordable Care Act does not address providers' financial barriers to maintaining a vaccine inventory; thus, other policies and programs need to focus on understanding these issues and work toward improving providers' business practices when providing vaccination services.

- 2.2.1** Research the total costs of providing vaccination services in a provider setting to improve understanding of costs associated with the range of activities that are needed to ensure efficient and effective immunization services (e.g., ordering, handling, storage, administration, patient recall/reminders, and counseling).
- 2.2.2** Encourage the development of tools to improve immunization provider business practices and work flow (e.g., practice efficiency and inventory management), and assess the impact of these tools on adult vaccination rates at the practice level.
- 2.2.3** Encourage vaccine manufacturers and third-party vaccine distributors to build on existing work with providers to reduce the financial burden of maintaining vaccine inventories (e.g., permitting providers to purchase small quantities of vaccines).
- 2.2.4** Evaluate the impact of various methods to encourage and incentivize provider recommendations for, provision of, and recordkeeping related to adult vaccination (e.g., standing orders, IIS).
- 2.2.5** Evaluate the impact of various tools and other business models that address financial risks associated with providing adult vaccination services.

**Objective 2.3:****Expand the adult immunization provider network.**

To ensure that vaccines are available at convenient locations and to expand the capacity of the health care system to administer vaccines, the adult immunization provider network should be strengthened. Adults frequently obtain recommended vaccinations in complementary settings, such as workplaces, schools, community health centers and pharmacies, so it is especially important for these providers to have the capability to exchange information and document administration in collaboration with physicians and patients' medical homes. Pharmacists and others can play an even larger role in adult vaccine delivery if they can offer the full range of recommended vaccinations and bill for Medicare Part D vaccines. They are an important resource in the immunization system, as more than 250,000 pharmacists have been trained to administer vaccines in the United States, and nearly 95 percent of Americans live within five miles of a community pharmacy.

The Affordable Care Act established an immunization coverage standard that requires most new health plans to cover routine vaccines recommended by the ACIP/CDC without cost-sharing when administered by an in-network provider. This has led to questions about which providers are considered in and out of network and whether the network is adequate to meet demand in all geographic settings.<sup>1</sup> Therefore, the plan's goal of improving access to adult vaccination services includes an objective to collect data to better understand and evaluate reported insurance network provider adequacy concerns.

Another important element of the plan is to expand access through employers to improve employee health and wellness and create healthier workplaces. The most immediate impact from an employer perspective may be with seasonal influenza immunization campaigns, but such efforts may offer the possibility of expanding to other recommended adult vaccines.

- 2.3.1** Encourage in-network coverage of adult vaccinations administered in accessible health care delivery settings (e.g., public health clinics, pharmacies).
- 2.3.2** Identify and promote best practices related to collaborative models among physicians and complementary settings (e.g., streamlined referrals and information sharing).
- 2.3.3** Improve data collection efforts to support evaluation of reported in-network adequacy concerns.
- 2.3.4** Identify, promote, and disseminate effective practices for billing private health insurers (e.g., among health departments and others).
- 2.3.5** Continue to identify the barriers that prevent or discourage pharmacists and other providers in complementary settings from accessing and entering vaccinations into state and local IIS and reporting vaccinations to patients' primary care providers.
- 2.3.6** Identify legal, practical, and policy barriers that may impede expansion

of the adult immunization provider network and communicate challenges to policy makers.

- 2.3.7** Assess the impact of providing immunization services in complementary settings on vaccination coverage, cost-effectiveness, and health outcomes.
- 2.3.8** Increase the number of community health centers that routinely administer vaccinations to adults and report vaccinations to IIS and primary care providers.
- 2.3.9** Encourage on-site, occupational health vaccination clinics and involvement of employers to increase employee vaccination rates and reporting of vaccinations to IIS.
- 2.3.10** Conduct research on barriers and facilitators to delivering vaccines to adults in pediatric settings.

#### **Objective 2.4:**

#### **Ensure a reliable supply of vaccines and the ability to track vaccine inventories, including during public health emergencies.**

Many of the priorities described in the plan, if implemented, could result in increased demand for adult vaccines and vaccination services. Thus, a reliable and steady supply of adult vaccines is needed to realize the full benefit of the goals, objectives, and strategies described in the plan. In addition, ensuring the functioning of routine systems and engaging existing health care providers will be critical in monitoring the response to public health emergencies requiring vaccines, such as an influenza pandemic.

- 2.4.1** Increase the transparency of vaccine distribution strategies to public and private entities to facilitate equitable distribution of vaccines in times of shortage.
- 2.4.2** Develop and evaluate the impact of pilot projects designed to improve supply and innovative inventory management (e.g., the use of 2D bar coding on vaccine units of sale) to improve accuracy and timeliness of vaccine distribution tracking.
- 2.4.3** Evaluate strategies that encourage multiple suppliers of vaccines for adults.
- 2.4.4** Encourage manufacturers and public health authorities to work collaboratively to develop contingency plans for the timing and prioritization of vaccine supplies in case of shortages.

# GOAL 3: INCREASE COMMUNITY DEMAND FOR ADULT IMMUNIZATIONS

As described in the NVP, HHS is committed to providing accurate, timely, transparent, complete, and audience appropriate information about vaccinations. Furthermore, communication activities concerning vaccination should be strategic, evidence based, and culturally and linguistically appropriate and should reflect the health literacy, language proficiency, and functional and access needs of specific target populations. While the NVP includes a goal to support communications to enhance informed vaccine decision making more broadly, Goal 3 of the NAIP is intended to address the needs of adults and providers of adult vaccination services specifically. Further, because adults make decisions for their children regarding vaccination, education of adults and their health care providers is likely to have impacts beyond this population.

## GOAL 3 OBJECTIVES

GOAL 3 INCLUDES THREE OBJECTIVES TO INCREASE COMMUNITY		
GOAL 3 OBJECTIVE 3.1	GOAL 3 OBJECTIVE 3.2	GOAL 3 OBJECTIVE 3.3
Educate and encourage <i>individuals</i> to be aware of and receive recommended adult immunizations.	Educate and encourage <i>health care providers</i> to recommend and/or deliver adult vaccinations.	Educate and encourage <i>other groups</i> (e.g., community and faith-based groups, tribal organizations) to promote the importance of adult immunization.

### Objective 3.1:

#### Educate and encourage *individuals* to be aware of and receive recommended adult immunizations.

Communications and outreach to the public are critical to address a lack of knowledge, as well as common misconceptions and skepticism about adult vaccinations. Frequent outreach raises awareness that vaccination is recommended across the lifespan and helps establish vaccination as a routine part of preventive services and as a societal norm. Although education alone is insufficient to increase vaccination rates, it can have significant impact as a part of a number of broader, evidence-based strategies. Adults are often unaware of their potential risk of acquiring diseases that can be prevented by vaccination and of the availability of specific vaccines. This lack of knowledge may be particularly acute among populations with limited English proficiency and persons with disabilities.<sup>36–38</sup> While there are many existing materials that can be used to educate the public and health care providers about adult vaccination, innovative strategies are needed to address the lack of knowledge regarding the risk of vaccine-preventable diseases and their consequences and the benefits of vaccines in preventing these infections. In a digital age in which information travels rapidly and misinformation can reach millions, novel outreach strategies that take into account patients’ preferences, cognitive styles, literacy levels, preferred sources of information, and cultural backgrounds should be tested, deployed, and broadly disseminated. Furthermore, these strategies should recognize competing demands in providers’ office-based practices that limit the length of provider-patient interactions about vaccination.

- 3.1.1** Conduct research on public awareness and acceptance of adult vaccines (including vaccine financing, vaccine effectiveness, and vaccine safety concerns) among the public, with a focus on racial, ethnic, and economic disparities.

social media) for different adult subpopulations to inform communication efforts.

- 3.1.3** Develop and implement accessible and culturally and linguistically appropriate communications and outreach strategies in multiple formats for people with disabilities, including those who are deaf or hard of hearing, people with limited English proficiency, people with cognitive limitations, and people who do not use traditional media.
- 3.1.4** Increase the public's understanding of the presence and role of vaccine safety monitoring systems and the meaning of reported data and how it is used to assess vaccine safety.

### **Objective 3.2:**

#### **Educate and encourage *health care providers* to recommend and/or deliver adult vaccinations.**

Health care providers are a highly influential source of information and advice about vaccinations, and a strong recommendation about the importance of immunizations can exert a strong influence over the vaccination decisions of patients, including those patients who may have reservations about some or all vaccines.<sup>39,40</sup> However, adult immunization status is not routinely assessed, and the rationale for evidence-based vaccine recommendations is not always articulated from providers to patients. This is one reason why NVAC issued the updated Standards for Adult Immunization Practice to encourage assessment of vaccination needs at every patient encounter.

Many health care providers stock some, but not all, adult vaccines. Cost and reimbursement concerns; competing clinical priorities, such as the management of acute medical issues; and the complexities of vaccine storage and handling continue to be reported barriers to providing office-based immunization services. While educational outreach targeted at the public is important, health care providers also require the knowledge and tools to recommend and either deliver vaccinations or to refer their adult patients to others who administer vaccinations. Furthermore, increasing consumer demand without simultaneously addressing health care provider vaccination barriers could have a detrimental effect on efforts to improve adult immunization.

This NAIP objective focuses on activities that will have the most meaningful impact, while also recognizing the existence and importance of addressing provider barriers that may hinder uptake.

- 3.2.1** Encourage all providers, including providers in complementary settings, to implement the NVAC Standards for Adult Immunization Practice, which includes assessing patients' vaccination status at every clinical encounter, strongly recommending needed immunizations, and either administering

vaccines (including documentation in an IIS) or referring patients to others who administer vaccinations.

- 3.2.2** Encourage health care providers to request immunization records from patients to support vaccination status assessment and recommendations.
- 3.2.3** Encourage the incorporation of adult vaccine education into the training of health care providers (e.g., medical, nursing, and pharmacist education curricula; postgraduate training, certification, and board examinations; and required continuing education credits).
- 3.2.4** Encourage integration of vaccination into the provision of other adult preventive services and chronic disease management.
- 3.2.5** Encourage the incorporation of immunization status assessment into comprehensive medication reviews in medical therapy management programs.
- 3.2.6** Promote increased attention to vaccine-specific recommendations in disease-specific clinical practice guidelines (e.g., diabetes, heart disease, lung disease, and immunocompromising conditions).
- 3.2.7** Educate providers and health systems about evidence-based strategies and existing tools within EHRs and IIS to support adult immunization: standing orders, reminder and recall systems, clinical decision support for immunizations into EHRs, and other tools.
- 3.2.8** Reduce vaccine storage and handling errors by improving provider education and awareness of vaccine delivery best practices and the need for standardized vaccine management plans.
- 3.2.9** Improve provider awareness of the Affordable Care Act's impact on adult vaccine insurance coverage in Medicare, Medicaid, and private health insurance plans, both outside and inside the marketplaces.
- 3.2.10** Educate health care providers about the VICP.

**Objective 3.3:****Educate and encourage other groups (e.g., community and faith-based groups to promote the importance of adult immunization.**

While health care providers are critical to promoting vaccination, they are not the only influential source of vaccine-related information. Education through social and community networks may help to increase adults' knowledge of the risks of vaccine-preventable diseases and the benefits of vaccination. A variety of networks can be leveraged, including faith-based and community organizations, employers, and individual trusted leaders.

Prior research has shown that outreach on preventive services through faith-based organizations and individual faith communities is effective in increasing uptake of these services.<sup>1</sup> Community and faith-based organizations are likely to play an especially important role in reducing racial and ethnic disparities in adult immunization, as they can deliver education that is culturally sensitive, linguistically appropriate, and tailored to specific subpopulations.

- 3.3.1** Engage community leaders in reaching the public with information about the importance of adult vaccination.
- 3.3.2** Encourage the development of adult immunization champions across all sectors.

# GOAL 4: FOSTER INNOVATION IN ADULT VACCINE DEVELOPMENT AND RELATED TECHNOLOGIES

One of the five goals of the NVP is to develop new and improved vaccines. The NVP, as well as a myriad other policy documents, recognizes that vaccines have led to enormous reductions in the incidence and impact of several once widespread infectious diseases. Goals 1 through 3 in the NAIP focus on enhancing vaccine delivery. However, achieving these goals is dependent on the existence of safe and effective vaccines. Goal 4 recognizes that there are opportunities for the development of new vaccines, more effective versions of existing vaccines for adults, and technological advancements to improve vaccine delivery.

## GOAL 4 OBJECTIVES

<b>GOAL 4 INCLUDES TWO OBJECTIVES TO FOSTER INNOVATION AND</b>	
<b>GOAL 4 OBJECTIVE 4.1</b>	<b>GOAL 4 OBJECTIVE 4.2</b>
Develop new vaccines and improve the effectiveness of existing vaccines for adults.	Encourage new technologies to improve the distribution, storage, and delivery of adult vaccines.

### **Objective 4.1:**

#### **Develop new vaccines and improve the effectiveness of existing vaccines for adults.**

While most existing vaccines are highly effective in children, vaccines recommended for adults are generally less effective, especially older adults and those with immune systems compromised by underlying diseases or medications. In general, the immune response of currently recommended vaccines declines with advancing age and the onset of chronic diseases. The perception that vaccines may have limited effectiveness in some adults may, in turn, negatively influence demand and contribute to low vaccination rates. However, the changing demographics of an aging society highlight the importance of improving our understanding of the aging immune system and the development of next-generation vaccines that can protect against serious infections that occur in this population.

There are numerous challenges that must be overcome in developing new vaccines. Bringing a new product to market can take ten or more years in development and can require a significant financial investment on the part of manufacturers. The market is also limited for special populations that are smaller in size than the general population of adults, suggesting the need for targeted efforts to develop vaccines for use, for example, in pregnant women and in immunocompromised individuals.

- 4.1.1** Encourage ongoing efforts to develop and license new and improved vaccines, including support for research, development, and licensure of vaccines; improved effectiveness; and longer duration of immunity. Ensure that progress in these areas does not compromise the effectiveness of vaccines or the rigorous, scientific standards used to evaluate vaccines during the approval phase.
- 4.1.2** Encourage ongoing efforts to support the discovery, validation, development, standardization and distribution of specialized reagents, assays, technologies (i.e., genomic sequencing, bioinformatics, and systems biology tools), and animal models needed to facilitate basic, preclinical, and clinical research programs aimed at developing and testing vaccine candidates.
- 4.1.3** Continue ongoing efforts to support research and advanced development of vaccine adjuvants and formulations in order to enhance the immune response.
- 4.1.4** Develop and encourage use of internationally adopted standards for evaluating vaccine effectiveness that take into account diagnosis, study design, and correlates of protection.
- 4.1.5** Optimize predictive values of vaccine effectiveness in animal models, and develop and validate new analytical methods and biomarkers that will establish early-phase correlates of protection.
- 4.1.6** Evaluate existing and identify new incentives to accelerate vaccine development.

#### **Objective 4.2:**

#### **Encourage new technologies to improve the distribution, storage, and delivery of adult vaccines.**

Numerous studies have highlighted the challenges that health care providers face in storing and managing their vaccine inventories. New technologies are in development to address these challenges and reduce the administrative burden on providers. New technologies are also being developed to change the ways that vaccines are administered (e.g., jet injector for select products and populations). These

developments may further reduce barriers to adult immunization by offering new solutions that appeal to both providers and consumers. The NAIP encourages innovation in the realm of both new vaccine development and new technologies to facilitate the management and administration of vaccines.

- 4.2.1** Apply new distribution tools and methods to strengthen the supply chain.
- 4.2.2** Improve the storage and handling of vaccines through the application of new technologies.
- 4.2.3** Support and promote new technologies that improve the administration of vaccines.

## MONITORING AND EVALUATION

Achieving the goals of the NAIP requires the collaboration of partners around a shared vision and coordination of activities through focused implementation efforts. Meaningful progress will be achieved only if stakeholders are engaged in shared, sustained, focused, and coordinated actions. The strategies noted above operationalize the objectives and goals laid out in the plan. However, these strategies are not intended to be comprehensive; rather, they are focused on the areas of highest priority. The strategies described in the plan are conditional and are subject to engagement by all stakeholders and to the availability of resources to achieve them. To foster action and accountability, federal stakeholders with leading or supporting roles have been identified for each objective in the NAIP. Appendix 5 also offers recommendations regarding how nonfederal stakeholders can play a role. All stakeholders are invited to review these materials and identify novel ways that they can contribute.

An Adult Immunization Implementation Plan, which reflects available resources and federal priorities, will be developed by the Interagency Adult Immunization Task Force (AITF). The AITF was created to help improve coordination and collaboration across HHS agencies and other federal groups during the 2009 H1N1 pandemic. The AITF membership is composed entirely of HHS entities and representatives with a vested interest in adult immunization.

Implementing the NAIP will require not just federal action, but also national action. The success of the plan will require state, local, tribal, and territorial governments; components of the health care delivery system; communities; manufacturers; and other stakeholders to work together to ensure a coordinated and comprehensive adult immunization program. The strategies identified here are intended to serve as a catalyst for other stakeholders to develop their own plans for participation in adult immunization activities.

The implementation of this plan demands regular monitoring and documentation of progress, challenges, and opportunities—all of which provide transparency to policymakers and the public. NVPO, in partnership with the AITF, will regularly track and annually summarize progress on achieving the goals and priorities in the NAIP and present them to NVAC and the ASH in an effort to highlight the impact of the implementation of strategies outlined here, as well as to identify areas where progress is lagging and propose corrective action where needed. An update on plan progress also will be presented at an NVAC meeting, which is open to the public and is attended by many stakeholders.

A key feature of the NAIP is the indicators (Table 3) and accompanying milestones for specific improvements to be achieved by 2020. These indicators reflect the priorities within each goal of the plan. The indicators will be used to measure progress and inform future implementation and quality improvement efforts. While many things could be measured, a limited number of indicators—one or more for each plan goal—will be tracked to monitor progress on priority issues. Indicators were selected to draw attention to some of the most critical challenges within each goal of the plan and were drawn primarily from existing measurement and data collection efforts, such as Healthy People 2020 and annual national surveys. In most cases, required data are already being collected by partner agencies. A small number of developmental indicators have also been included to shed light on key aspects of adult vaccination programs where ongoing attention and improved data collection may be needed. NVPO has chosen to include the developmental indicators to draw attention to these important areas of opportunity. Research is planned to identify baseline levels for the developmental measures. The data sources for the full set of indicators are listed in Appendix 3.

Target milestones for most indicators were identified by subject matter experts or adapted from previously published goals. Certain developmental measures do not have target milestones because trend data are not available to inform the target-setting process. As data sources and indicators are developed or enhanced, the NAIP indicators and accompanying milestones will be updated.

**TABLE 3. PLAN PRIORITIES: INDICATORS FOR THE GOALS OF THE NAIP**

<b>Goal 1: Strengthen the Adult Immunization Infrastructure</b>			
<b>Key Indicator</b> ****	<b>Baseline (Year)</b> ††††	<b>2020 Milestone</b>	<b>Entity Responsible for Data Collection (Data Source)</b>
Adult vaccination coverage for Healthy People 2020 measures and racial/ethnic disparities in coverage			CDC (National Health Interview Survey, CMS Minimum Data Set, Internet panel surveys of pregnant women and health care providers)
Percentage of adults age >18 years who are vaccinated annually against seasonal influenza	39 (2013)	70	
Percentage of health care personnel who are vaccinated annually against seasonal influenza	62 (2013)	90	
Percentage of pregnant women who are vaccinated annually against influenza	52 (2013)	N/A	
Percentage of adults age >65 years who are vaccinated annually against pneumococcal disease	60 (2013)	90	
Percentage of noninstitutionalized high-risk adults age 18–64 years who are vaccinated annually against pneumococcal disease	21 (2013)	60	

\*\*\*\* Items in italics are developmental.

†††† The baseline year is 2012 unless otherwise specific

Percentage of institutionalized adults age >18 years in long-term care or nursing homes who are vaccinated annually against pneumococcal disease	66 (2006)	90	
Percentage of adults age >60 who are vaccinated against zoster	24 (2013)	30	
Percentage of health care personnel age >19 years who are vaccinated against hepatitis B	64 (2008)	90	
Percentage of surveyed primary care physicians who record information on adult vaccinations in state or regional IIS	8% of internists; 36% of family physicians	50%	CDC
Percentage of surveyed pharmacists who submit adult vaccination data to IIS	28% (2013)	60%	CDC
Percentage of adults age >19 with one or more immunizations recorded in an IIS	25% (2012)	50%	CDC (IIS Annual Report)
Developmental measure: (Among adult health care providers who have identified an adverse event following immunization) Percentage of providers who have reported one or more events to VAERS <sup>41</sup>	17%	In development	NVPO

<b>Goal 2: Improve Access to Adult Vaccines</b>			
<b>Key Indicator<sup>††††</sup></b>	<b>Baseline (Year)<sup>§§§§</sup></b>	<b>2020 Milestone</b>	<b>Entity Responsible for Data Collection (Data Source)</b>
Percentage of states and territories that allow pharmacists to administer all routinely recommended vaccines for adults >19 without a patient-specific prescription	85% (2013)	100%	American Pharmacists Association
Percentage of surveyed primary care providers who stock vaccines routinely recommended for adults <sup>*****</sup>	20% of internists; 31% of family physicians	60%	CDC
Percentage of state Medicaid programs that provide coverage of all ACIP/CDC-recommended vaccinations for adults and prohibit cost-sharing	20%	100%	CMS

<sup>††††</sup> Items in italics are developmental.

<sup>§§§§</sup> The baseline year is 2012 unless otherwise specified.

<sup>\*\*\*\*\*</sup> The survey will capture stocking behavior for different adult vaccines, as well as provider-reported rationale for not stocking some products.

<b>Goal 3: Increase Community Demand for Adult Vaccinations</b>			
<b>Key Indicator</b> <sup>++++</sup>	<b>Baseline (Year)</b> <sup>++++</sup>	<b>2020 Milestone</b>	<b>Entity Responsible for Data Collection (Data Source)</b>
Percentage of surveyed adults who believe that they are recommended to receive a flu vaccine	45%	75%	CDC
Percentage of surveyed adults who report receiving a provider recommendation for flu vaccine	45%	90%	CDC
Percentage of surveyed adult health care providers who report assessing vaccination status at every visit	29% of internists; 32% of family physicians	60%	CDC
<i>Developmental measure: Percentage of surveyed adults who are aware that certain vaccines are recommended for adults</i> <sup>§§§§</sup>	<i>In development</i>	<i>In development</i>	CDC
<i>Developmental measure: Percentage of pregnant women who reported receiving the following immunizations during pregnancy: 1) Influenza 2) Tdap</i>	<i>In development</i>	<i>In development</i>	CDC

++++  
Items in italics are developmental.

++++  
The baseline year is 2012 unless otherwise specified.

§§§§  
Research will capture data for selected adult subpopulations. However, this research is not meant to be inclusive of every group, but to provide an estimate of adult vaccine consumer awareness and areas of opportunity.

<b>Goal 4: Foster Innovation in Adult Vaccine Development and Vaccination-Related Technologies</b>			
<b>Key Indicator</b> *****	<b>Baseline (Year)</b> +++++	<b>2020 Milestone</b>	<b>Entity Responsible for Data Collection (Data Source)</b>
<i>Developmental measure: Number of vaccines in clinical development (Phase II or Phase III clinical trials) with an expected adult indication</i>	<i>In development</i>	<i>In development</i>	Biotechnology industry organization (publicly available data)
<i>Developmental measure: Number of vaccines on CDC-contracted vaccine pricelist that include a 2D barcode on unit of use or primary vaccine product (e.g., vials, syringes)</i>	<i>In development</i>	100%	CDC

\*\*\*\*\* Items in italics are developmental.

+++++ The baseline year is 2012 unless otherwise specified.

## APPENDIX 1: ADULT IMMUNIZATION SCHEDULE

Adult Immunization Schedule and Tools (CDC):

<http://www.cdc.gov/vaccines/schedules/easy-to-read/adult.html>

## APPENDIX 2: DISPARITIES IN ADULT IMMUNIZATION COVERAGE BY RACE/ETHNICITY

Vaccine and Age Group	White (%)	Black (%)	Hispanic (%)	Asian (%)	Other (%)
Pneumococcal vaccination, ever (age 19–64, high risk)††††††	22.3	21.2	17.9	11.0	19.8
Pneumococcal vaccination, ever (age ≥65)§§§§§§	63.6	48.7	39.2	45.3	54.6
Tetanus vaccination, past - 19–49)*****	69.0	54.1	52.5	52.7	66.0
Tetanus vaccination, past 10 years (age 50–64)†††††††	67.3	54.4	55.0	53.4	69.7
Tetanus vaccination, past 10 years (age ≥65)†††††††	59.6	40.3	45.3	42.8	72.4
Tetanus vaccination including pertussis vaccine, past 8 years (age ≥19)§§§§§§§	19.7	12.6	10.2	15.5	22.4
Hepatitis A vaccination (≥2 doses), ever (age 19–49)*****	12.6	11.0	10.6	16.1	15.2
Hepatitis B vaccination (≥3 doses), ever (age 19–49)††††††††	35.2	30.5	23.7	39.3	34.8
Herpes zoster (shingles) vaccination, ever (age ≥60)†††††††††	27.4	10.7	9.5	22.6	24.5
HPV vaccination among females (≥1 dose), ever (age 19–26)§§§§§§§§	41.7	30.6	30.3	19.8	43.1
Influenza vaccination, 2013–2014 season (age ≥18)*****	47.4	41.5	44.3	51.3	47.3

†††††† National Health Interview Survey (2013).<sup>3</sup>

§§§§§§ National Health Interview Survey (2013).<sup>3</sup>

\*\*\*\*\* National Health Interview Survey (2013).<sup>3</sup>

††††††† National Health Interview Survey (2013).<sup>3</sup>

†††††††† National Health Interview Survey (2013).<sup>3</sup>

§§§§§§§ National Health Interview Survey (2013).<sup>3</sup>

\*\*\*\*\* National Health Interview Survey (2013).<sup>3</sup>

††††††††† National Health Interview Survey (2013).<sup>3</sup>

††††††††† National Health Interview Survey (2013).<sup>3</sup>

§§§§§§§§ National Health Interview Survey (2013).<sup>3</sup>

\*\*\*\*\* National Immunization Survey—Flu and Behavioral Risk Factor Surveillance System (2013–2014).<sup>4</sup>

## APPENDIX 3: FEDERAL PARTNER EFFORTS

Agencies across HHS support a host of efforts that directly or indirectly support adult immunization. The table below lists just a small sampling of agency efforts. These select activities highlight how agencies across HHS advance adult immunization within their respective organizations.

Agency	Activities
Agency for Healthcare Research and Quality (AHRQ)	AHRQ has developed a data management tool, or dashboard, to depict Healthy People 2020 immunization data in a clear, easy-to-view format. This dashboard highlights ongoing racial and ethnic disparities in adult immunization and brings more attention to key gaps in coverage.
Assistant Secretary for Preparedness and Response (ASPR)	ASPR, in conjunction with DoD, has supported the development of Centers for Innovation in Advanced Development and Manufacturing. These centers help to bolster the nation's existing manufacturing surge capacity and flexible manufacturing of vaccines for pandemic influenza and other therapeutic products in a health emergency.
Centers for Disease Control and Prevention (CDC)	CDC has advanced new contracts with academic institutions and health systems for vaccine safety and ongoing surveillance; annually collects, analyzes, and disseminates influenza and adult vaccination coverage estimates and conducts economic evaluations for new vaccine recommendations; promotes immunization information system improvements; expands public and private sector partnerships; conducts research and disseminates materials to increase awareness of adult immunization; annually updates the adult immunization schedule; and works with state immunization programs to improve adult immunization infrastructure. CDC is also working with ONC and other partners to develop Clinical Decision Support for Immunizations (CDSi) tools.

Agency	Activities
Centers for Medicare & Medicaid Services (CMS)	<p>CMS has encouraged states to expand coverage of ACIP/CDC-recommended immunizations to all adults enrolled in the Medicaid program and has included the HEDIS measure—Flu Vaccinations for Adults Ages 18 to 64—in the core set of adult health care quality measures for the Medicaid program.</p> <p>Within the Medicare program, the CMS Quality Improvement Initiative includes a number of quality measures relating to immunizations for adults. In addition, CMS expanded coverage of the adult pneumococcal immunizations so that adults enrolled in Medicare can obtain them, as recommended by the ACIP.</p>
Health Resources and Services Administration (HRSA)	<p>HRSA has announced the Health Center Patient-Centered Medical Home and Quality Improvement Awards to recognize health centers that have focused on practice transformation and quality improvement, including efforts to strengthen adult immunization.</p> <p>HRSA also administers the VICP jointly with the Department of Justice and the U.S. Court of Federal Claims. The VICP provides compensation to individuals, including adults, thought to have been injured or whose death was thought to have been related to receiving certain vaccines covered by the program.</p>
Indian Health Service (IHS)	<p>IHS has implemented performance measures for adult immunizations and partnered with NVPO to evaluate the feasibility and usefulness of a composite adult immunization measure to facilitate monitoring of vaccine coverage.</p>

Agency	Activities
National Vaccine Program Office (NVPO)	<p>NVPO led the development of the NAIP and chairs (with CDC and the Immunization Action Coalition) the National Adult and Influenza Immunization Summit. NVPO collaborated on the advancement of a vaccine safety agenda, developed a tool kit to increase influenza vaccination among health care personnel in long- term care settings, published a report and recommendations on reducing barriers to increased uptake of recommended vaccines in pregnant women, co-authored an article on the Affordable Care Act and its impact on immunization insurance coverage for health care providers, and collaborated with CMS on the development of a Medicare claims data map for influenza.</p> <p>Through its support of NVAC, NVPO has supported publication of the 2011 report <i>A Pathway to Leadership for Adult Immunization: Recommendations of the National Vaccine Advisory Committee and NVAC's Standards for Adult Immunization Practice</i>.</p>
Office of Minority Health (OMH)	<p>OMH developed and maintains a co-sponsorship agreement between HHS and Walgreens Inc. that provides \$15 million in free seasonal influenza vaccine annually to uninsured individuals. Working with community and faith-based organizations, this initiative has successfully vaccinated over 800,000 individuals.</p>
Office of the National Coordinator for Health Information Technology (ONC)	<p>ONC continues to advance pilot projects designed to improve the exchange of vaccination data and improve access to vaccination data by consumers. This includes the “data hub” initiative that is being advanced in collaboration with NVPO, CDC, and state and local partners. The data hub enables state and local IIS to exchange data with each other through a centralized model utilizing existing standards. By connecting to the central hub, jurisdictions can then connect to any other jurisdiction also connected to the central hub. ONC is also working in close collaboration with CDC to specify CDC’s Clinical Decision Support for Immunizations tools into sharable clinical decision support artifacts.</p>
Department of Veterans Affairs (VA) National Institutes of Health (NIH) U.S. Food and Drug Administration (FDA)	<p>VA, NIH, and FDA have supported the development of new and improved vaccines. They have engaged in activities related to zoster vaccine research, maternal vaccination, and a host of other initiatives. These agencies and other stakeholders are working to advance adult vaccination safety, research, and development needs.</p>

## APPENDIX 4: FEDERAL ROLES AND RESPONSIBILITIES

GOAL AND OBJECTIVE	FEDERAL																			
	Department of Health and Human Services														DHS	DOD	VA	OPM		
	ACF	AHRQ	ASPR/BARDA	CDC	CMS	HRSA	IHS	NIH	NVPO	ONC	OWH	FDA	RHA	ACL					FOH	
<b>Goal 1: Strengthen the adult immunization infrastructure</b>																				
Objective 1.1: Monitor and report trends in adult vaccine preventable disease levels and vaccination coverage data for all ACIP/CDC recommended vaccines. In cases where there are associated Healthy People 2020 goals, measure progress toward established targets.		•		•			•							•	•	•		•	•	•
Objective 1.2: Enhance current vaccine safety monitoring systems and develop new methods to accurately and more rapidly assess vaccine safety and effectiveness in adult populations (e.g., pregnant women).		•	•	•	•	•	•	•			•	•						•	•	

GOAL AND OBJECTIVE	FEDERAL																		
	Department of Health and Human Services														DHS	DOD	VA	OPM	
	ACF	AHRQ	ASPR/BARDA	CDC	CMS	HRSA	IHS	NIH	NVPO	ONC	OWH	FDA	RHA	ACL					FOH
Objective 1.3: Continue to analyze claims filed as part of the National Vaccine Injury Compensation Program (VICP) to assess whether there was an association between vaccines that a claimant received and adverse events experienced.						.													
Objective 1.4: Increase the use of EHRs and IIS.				.	.	.	.	.	.	.	.	.	.				.		
Objective 1.5: Evaluate and advance targeted quality improvement initiatives.		.			.	.	.	.				.							

GOAL AND OBJECTIVE	FEDERAL																	
	Department of Health and Human Services														DHS	DOD	VA	OPM
	ACF	AHRQ	ASPR/BARDA	CDC	CMS	HRSA	IHS	NIH	NVPO	ONC	OWH	FDA	RHA	ACL				
Objective 1.6: Generate and disseminate evidence about the health and economic impact of adult immunization, including potential disease burden averted and cost effectiveness with the use of current vaccines.				.									.					
<b>Goal 2: Improve access to adult vaccines.</b>																		
Objective 2.1: Reduce financial barriers for individuals who receive recommended adult vaccines.				.	.	.	.		.				.	.	.		.	
Objective 2.2: Assess and improve understanding of providers' financial barriers to delivering vaccinations, including stocking and administering.				.	.	.	.		.			.						

GOAL AND OBJECTIVE	FEDERAL																	
	Department of Health and Human Services														DHS	DOD	VA	OPM
	ACF	AHRQ	ASPR/BARDA	CDC	CMS	HRSA	IHS	NIH	NVPO	ONC	OWH	FDA	RHA	ACL				
Objective 2.3: Expand the adult immunization provider network.	.			.	.	.		.		.		.			.			
Objective 2.4: Ensure a reliable supply of vaccines and the ability to track vaccine inventories, including during public health emergencies.			.	.				.			.	.			.	.		
<b>Goal 3: Increase community demand for adult immunizations.</b>																		
Objective 3.1: Educate and encourage <i>individuals</i> to be aware of and receive recommended adult immunizations.	.		.	.		.	.	.	.	.	.	.	.	.	.	.	.	.

GOAL AND OBJECTIVE	FEDERAL																		
	Department of Health and Human Services														DHS	DOD	VA	OPM	
	ACF	AHRQ	ASPR/BARDA	CDC	CMS	HRSA	IHS	NIH	NVPO	ONC	OWH	FDA	RHA	ACL					FOH
Objective 3.2: Educate and encourage <i>health care providers</i> to recommend and/or deliver adult vaccinations.			.	.		.	.		.		.		.	.	.		.	.	.
Objective 3.3: Educate and encourage <i>other groups</i> (e.g., community and faith based groups) to promote the importance of adult immunization.	.			.			.		.			.	.						
<b>Goal 4: Foster innovation in adult vaccine development and vaccination-related technologies.</b>																			
Objective 4.1: Develop new vaccines and improve the effectiveness of existing vaccines for adults.			.					.	.		.					.	.	.	
Objective 4.2: Encourage new technologies to improve distribution, storage, and delivery of adult vaccines.			.					.								.	.		

## APPENDIX 5: NONFEDERAL ROLES AND RESPONSIBILITIES

GOAL AND OBJECTIVE	Health Care Providers	Professional Organizations	Public and Private Health Care Payers and Plans	State, Local, Territorial, and Tribal Governments	Academia and Research Organizations	Advocacy Organizations	Employers	Vaccine Manufacturers
<b>Goal 1: Strengthen the adult immunization infrastructure</b>								
<p>Objective 1.1: Monitor and report trends in adult vaccine preventable disease levels and vaccination coverage data for all ACIP/CDC recommended vaccines. In cases where there are associated Healthy People 2020 goals, measure progress toward established targets.</p>	▪	▪		▪	▪			
<p>Objective 1.2: Enhance current vaccine safety monitoring systems and develop new methods to accurately and more rapidly assess vaccine safety and effectiveness in adult populations (e.g., pregnant women).</p>	▪			▪	▪			▪

GOAL AND OBJECTIVE	Health Care Providers	Professional Organizations	Public and Private Health Care Payers and Plans	State, Local, Territorial, and Tribal Governments	Academia and Research Organizations	Advocacy Organizations	Employers	Vaccine Manufacturers
Objective 1.3: Continue to analyze claims filed as part of the National Vaccine Injury Compensation Program (VICP) to assess whether there was an association between vaccines that a claimant received and adverse events experienced.								
Objective 1.4: Increase the use of EHRs and IIS to collect and track adult immunization data.	▪	▪	▪	▪	▪	▪	▪	
Objective 1.5: Evaluate and advance targeted quality improvement initiatives.	▪	▪	▪	▪	▪	▪	▪	▪

GOAL AND OBJECTIVE	Health Care Providers	Professional Organizations	Public and Private Health Care Payers and Plans	State, Local, Territorial, and Tribal Governments	Academia and Research Organizations	Advocacy Organizations	Employers	Vaccine Manufacturers
Objective 1.6: Generate and disseminate evidence about the health and economic impact of adult immunization, including potential disease burden averted and cost effectiveness with the use of current vaccines.		▪		▪	▪		▪	▪
<b>Goal 2: Improve access to adult vaccines.</b>								
Objective 2.1: Reduce financial barriers for individuals who receive recommended adult vaccines.	▪	▪	▪	▪	▪		▪	
Objective 2.2: Assess and improve understanding of providers' financial barriers to delivering vaccinations, including stocking and administering vaccines.	▪	▪	▪	▪	▪	▪		▪

GOAL AND OBJECTIVE	Health Care Providers	Professional Organizations	Public and Private Health Care Payers and Plans	State, Local, Territorial, and Tribal Governments	Academia and Research Organizations	Advocacy Organizations	Employers	Vaccine Manufacturers
Objective 2.3: Expand the adult immunization provider network.	▪	▪	▪	▪		▪	▪	
Objective 2.3: Expand the adult immunization provider network.	▪	▪	▪	▪		▪	▪	
Objective 2.4: Ensure a reliable supply of vaccines and the ability to track vaccine inventories, including during public health emergencies.	▪		▪	▪		▪		▪
<b>Goal 3: Increase community demand for adult immunizations.</b>								
Objective 3.1: Educate and encourage <i>individuals</i> to be aware of and receive recommended adult immunizations.	▪	▪	▪	▪	▪	▪	▪	▪

GOAL AND OBJECTIVE	Health Care Providers	Professional Organizations	Public and Private Health Care Payers and Plans	State, Local, Territorial, and Tribal Governments	Academia and Research Organizations	Advocacy Organizations	Employers	Vaccine Manufacturers
Objective 3.2: Educate, encourage, and motivate health care providers to recommend and/or deliver adult vaccinations.	▪	▪	▪	▪	▪	▪	▪	▪
Objective 3.3: Educate and encourage other groups (e.g., community and faith based groups, tribal organizations) to promote the importance of adult immunization.	▪	▪	▪	▪	▪	▪	▪	▪
<b>Goal 4: Foster innovation in adult vaccine development and vaccination-related technologies.</b>								
Objective 4.1: Develop new vaccines and improve the effectiveness of existing vaccines for adults.					▪			▪
Objective 4.2: Encourage new technologies to improve distribution, storage, and delivery of adult vaccines.		▪	▪		▪	▪		▪

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# 6.1

## Help Prevent Meningitis

Find Out About An Immunization For Meningococcal Group B.



**Tara Haelle** Contributor

*I offer straight talk on science, medicine, health and vaccines.*

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PHARMA & HEALTHCARE 7/15/2015 @ 8:00AM | 38,270 views

# Gardasil HPV Vaccine Safety Assessed In Most Comprehensive Study To Date

The largest review of the available evidence on the quadrivalent, or four-strain, HPV vaccine Gardasil, has found no evidence of any serious short-term or long-term safety issues. Bringing together the findings from clinical trials, post-licensure studies and data presented at scientific meetings but not yet published, the researchers focused particularly on autoimmune diseases, nervous system disorders, anaphylaxis, blood clots and stroke – but none of them is caused by the vaccine, they found.

“The big take home message for parents is that this is a reassuring study that supports what we already knew, that the HPV vaccine is a very safe vaccine,” said Michelle Berlin, M.D., the co-director of the Oregon Health and Science University Center for Women’s Health. “The most common side effects that we see are soreness at the injection site and that some children faint when they get the shot, but they do that with any other shot in adolescence too.”

Human papillomavirus, or HPV, is a common viral infection most often spread through sexual contact, though it can be spread by other intimate skin-to-skin contact methods or to a newborn during birth. Approximately 80 percent of sexually active individuals will eventually contract at least one of the 100 strains of HPV, and the vast number of infections go away on their own. Among the small proportion that don’t, however, some strains can develop into precancerous cervical lesions and, if not caught with a Pap smear, eventually cancer. The most effective way to reduce cervical cancer to date has

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been with [regular screenings](#). Adequate screenings for other types of cancers linked to HPV, such as penile, anal and oral cancers, are not available.

Two of the strains that Gardasil protects against, HPV 16 and HPV 18, are responsible for approximately 70 percent of all cervical, vaginal, vulvar and anal cancers. The other two strains the vaccine prevents, HPV 6 and HPV 11, cause genital warts. A more recent [formulation, Gardasil 9](#), includes five additional strains and, by preventing infection with those strains of HPV, theoretically expands prevention to [90 percent of HPV-related cancers](#). While the vaccine is too new to show in clinical trials that its use successfully reduces cancer incidence, researchers expect it to do so if the immunity it induces does not wane. If immunity does wane, researchers may consider a booster.

“This is an incredibly well studied vaccine, with huge data sets and huge populations, and nothing has panned out as being significant as far as major adverse events,” said Dr. Stanley Block, a pediatrician in private practice in Bardstown, Kentucky, and a coauthor of the study [recently published](#) in the *Pediatric Infectious Disease Journal*. “We know the reality is that it protects against a tremendous number of deaths, cancers and chemotherapies for your daughters and your sons somewhat too.



University of Miami pediatrician Judith L. Schachter, M.D. gives an HPV vaccination to a 13-year-old girl in her office at the Miller School of Medicine on September 21, 2011 in Miami, Florida. (Photo by Joe Raedle/Getty Images)

Among the studies Block and his colleagues reviewed were the five clinical trials, involving 29,364 male and female participants, used to seek approval for the vaccine from the FDA, licensed in 2006 for girls and women and then in

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2009 for boys and men. They also looked at studies evaluating the vaccine in pregnant women, those with HIV and those with lupus.

“In the 8 years of post-licensure vaccine safety monitoring and evaluation conducted following the initial licensure of HPV4 in the U.S., no serious safety concerns have been identified in any study conducted worldwide,” the researchers found. By the time the long-term arm of the clinical trials concludes, researchers will have 14 years of follow-up data.

One of the most important ways researchers investigate possible severe side effects of a vaccine is to use the Vaccine Safety Datalink. Usually, the researchers first look at what has been reported to the Vaccine Adverse Event Reporting System (VAERS), a passive surveillance system to which anyone can make a report about something happening after getting a vaccine (whether it’s related or not). There is no evidence that the incidents reported to VAERS are caused by the vaccine, but when reports show up in VAERS, especially multiple times, researchers can use the Vaccine Safety Datalink to investigate whether those conditions might be related to the vaccine. The VSD includes more than 9 million participants from seven healthcare systems across the U.S.

The researchers compared how many cases of Guillain-Barre syndrome, blood clots, stroke, appendicitis, allergic reactions, seizures and fainting occurred to those who received the vaccine to the number of these cases in those who never received the vaccine. The VSD studies for the HPV vaccine included than 600,000 doses of the vaccine. The only condition that appeared more often among those receiving the vaccine was blood clots, but close examination of those cases showed that all the girls with blood clots had other risk factors that increased their likelihood of a blood clot – using birth control pills, smoking, obesity, a long-term hospitalization or an underlying blood clotting disorder.

The researchers also reviewed the three studies of HPV safety conducted in Denmark and Sweden. One of these, involving [nearly 1 million girls](#), looked for 53 different conditions, including blood clots and autoimmune and neurological disorders, and found no link

between the vaccine and serious conditions. Another [Danish study](#) of more than 1.6 million girls and women similarly found no risk for blood clots, and the third, involving [nearly 4 million females](#), found no link between the [HPV vaccine and multiple sclerosis](#) or [any similar disease](#).

Finally, several large studies involving the patient population of Kaiser Permanente Southern California looked for possible links between the HPV vaccine and 50 different conditions, including multiple nervous system and autoimmune disorders. Again, no dice.

Despite these reassuring findings, however, some parents still [express hesitancy](#) about the vaccine, owing largely to [misinformation](#) and [irresponsible media coverage](#). Part of the fault lay with how the vaccine has been presented to parents and families, suggested Berlin. “It was not promoted as a cancer prevention vaccine,” she said. “That’s how it should have been framed.”

She points out that all the data so far supports the vaccine as being “very, very safe,” and researchers are continuing to follow the initial populations who received the vaccine, just as has happened with all past vaccines. The path Gardasil took to FDA approval was similar to the path every other vaccine has taken for the past half century.

The effects of cervical cancer are huge,” Berlin said. “No woman in the United States should die of cervical cancer in this day and age. If we can get everyone who needs to be, vaccinated, we can dramatically reduce the number of women who die of this preventable cancer.”

*This post has been updated to include the importance of screenings to cervical cancer prevention.*

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# 6.2

# As Antibiotics Fail, We Need More Vaccines

[phenomena.nationalgeographic.com/2016/02/10/amr-review-vax/](http://phenomena.nationalgeographic.com/2016/02/10/amr-review-vax/)

The global problem of antibiotic misuse that allows bacteria to become resistant can be solved in part by *more* use—not of antibiotics, but of vaccines and other compounds, which could reduce the occurrence of diseases that antibiotics are otherwise used to treat.



A patient receives a vaccination injection at Gorkha district hospital in Nepal. Photograph by Alex Treadway, National Geographic Creative

That is the [latest piece of analysis](#) of the worldwide resistance problem from the [Review on AMR](#), the British project that is conducting a two-year examination of antibiotic resistance at the request of UK Prime Minister David Cameron. The group, which is supported by the Wellcome Trust, is closing in on its deadline of May 2016 for presenting comprehensive recommendations to ameliorate resistance. On the way, it has examined reducing [agricultural use](#) of antibiotics, funding [drug development](#), promoting increased use of [diagnostic devices](#), combatting [over-the-counter sales](#) and counterfeits, and achieving better data on the [occurrence](#) and [cost](#) of resistance.

“This year, 2016, is a critical year for action on the wider issue of drug-resistant infections, and both vaccines and alternative therapies have a crucial role to play as part of the strategy to tackle this threat. Internationally there will be focus on this issue at the World Health Assembly, the G7, G20 and UN General Assembly,” the report says. “This is a crucial time for the world to make significant progress – a moment that needs to be seized.”

The project is chaired by Lord Jim O’Neill, the former chief economist for Goldman Sachs, who is also [Commercial Secretary to the Treasury](#) in Cameron’s government. “Drug resistant infections could be compared to a slow-motion

car crash,” he said. “Antibiotics are important to tackle this threat, but if we can encourage the development and use of vaccines and other alternatives we give the world a better chance of beating drug resistance.”

In the newest report, the Review proposes that better use of vaccines, along with development of new vaccines and other non-antibiotic compounds, could reduce the need for antibiotic use. But what stands in the way, it says, is a lack of funding both for getting existing vaccines to vulnerable populations, and also for developing crucially needed new vaccines.

Vaccines, it says, can reduce the occurrence of bacterial infections for which antibiotics are used; viral infections, for which the drugs are often given in error, increasing resistance; infections that occur in hospitals, a setting in which bacteria often become multi-drug resistant; and infections in farm animals, forestalling the huge use of antibiotics on farms.

The report finds that existing vaccines are not being used as much as they might be: globally, pneumococcal and rotavirus vaccines reach only 31 percent, and 18 percent, of children eligible for them. If pneumococcal vaccine were fully deployed, it says, the lives of 800,000 children younger than 5 could be saved every year—and in addition, 11.4 million days of antibiotic consumption, almost half the global usage for that disease, could be prevented.

But there is also a need for new vaccines to address specific diseases which antibiotic resistance makes worse. In 2013, the US Centers for Disease Control and Prevention compiled a long list of the resistant bacteria that it considers the most serious threats to health. There are no vaccines for the problems that it ranked as most urgent: resistant gonorrhea, *Clostridium difficile*, and bacteria such as *E. coli* and *Klebsiella* that have become resistant to the last-resort antibiotic class carbapenems and collectively are known as CRE.

Unlike antibiotics, vaccines can be attractive moneymakers for pharma companies, but the size of the clinical trials needed to get them to market means that many candidates stall in development, the report notes. To improve vaccine's prospects in the market, it proposes additional funding to buy existing vaccines for low-income countries and to support early-stage research, and the creation of reward commitments (also known as advance market commitments or market entry rewards) for vaccines that make it through the development pipeline and reach the market.

Elizabeth Jungman, director of public health at The Pew Charitable Trusts, said about the proposals: “This report highlights the need to take a multifaceted approach to addressing antibiotic resistance. Vaccines and some alternatives can play a critical role in the fight against antibiotic resistance by preventing infections, and other alternatives can make antibiotics more effective or even replace them for treatment.”

The new report is being released just after midnight in Britain, and a number of experts gave the Review their comments to release at the time of publication.

Dr. Jeremy Farrar, Director of the Wellcome Trust, said: “Our own analysis on how we might use vaccines and other



alternatives to tackle this crisis supports the O'Neill team's report, and suggests they will be an important way we can reduce – but not replace – our need for antibiotics. Vaccines are also critical for controlling epidemics, like Ebola, and endemic diseases such as TB and dengue fever, and how we incentivise developing new ones must take the whole picture into account.”

Dr. Seth Berkley, CEO of Gavi, the Vaccine Alliance—which is praised in the report for innovative funding strategies that allow vaccines to flow to poor countries—said: “It is exciting to see such a powerful argument on the important roles vaccines play, not just in preventing diseases and therefore reducing antibiotic usage, but also in directly reducing antimicrobial resistance. New incentives are needed to further accelerate their development.”



Vaccine syringes.  
Photograph by Debora Cartagena, [CDC.gov](http://www.cdc.gov).

*Previous posts in this series:*

- Jan. 20, 2016: “[Pharma Industry Calls on Governments to Fund New Antibiotics](#)“
- Dec. 7, 2015: “[Proposal: Set International Targets for Farm Antibiotic Use](#)“
- Sept. 9, 2015: “[Can Offering a \\$12 Million Prize Make a Difference to Drug Resistance?](#)“
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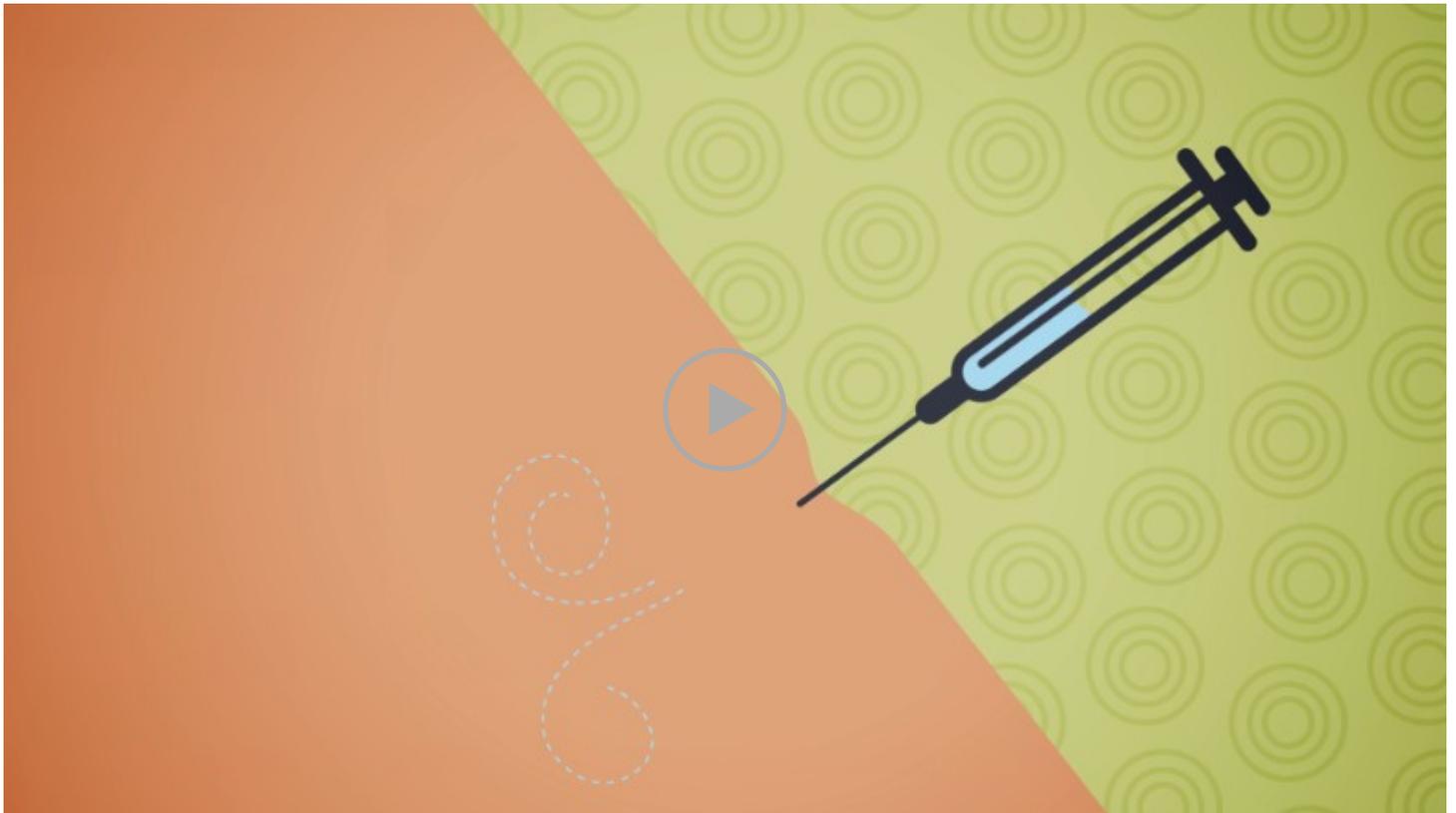
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# 6.3

# New vaccines for HPV, meningitis recommended for kids and adults

By Carina Storrs, Special to CNN

🕒 Updated 12:29 AM ET, Thu February 4, 2016



How vaccines stop diseases like measles 01:26

## Story highlights

A CDC committee released its annual updates for childhood and adult vaccinations

A new vaccine against meningococcal type B is recommended for certain groups

A new HPV vaccine is available that offers better protection against associated cancers

including hearing loss and loss of limbs.

"Parents need to know about it. ... It strikes quickly, it's unforgiving and it's often deadly," said Dr. Sandra Fryhofer, the American College of Physicians liaison to the ACIP. Parents and young adults should talk with their doctor about whether they should get the vaccine, she added.



**Related Article:** White, wealthy and unvaccinated

**(CNN)**—New vaccines for meningococcal type B and HPV and are among the updates to the immunization schedule published for children and adults.

The Advisory Committee on Immunization Practices, known as ACIP, makes the updates every year. ACIP is a part of the Centers for Disease Control and Prevention.

A number of medical groups, including the American College of Obstetricians and Gynecologists and the American Academy of Family Physicians, have endorsed the new schedules.

One of the biggest changes this year is a new recommendation for MenB, a vaccine that protects against meningococcal serotype B infections, said Dr. Candice Robinson, a member of the childhood and adolescent working group for the ACIP.

Meningococcal serotype B infections are responsible for about [one-third of U.S. cases of meningitis](#), an infection that attacks the lining of the brain and spinal cord. It is fatal in 10% to 14% of cases and can lead to [permanent disability](#),

For the first time, the schedule includes advice about MenB vaccination even for those who are not at high risk of disease. It applies to certain groups of young people, generally 16 to 23, who might face elevated risk because they will be moving into college dormitories or military barracks.

The immunization schedule recommends one of the new MenB vaccines, Bexsero or Trumenba, for anyone older than 10 who is at increased risk of developing serious meningococcal disease, such as those with sickle cell disease or other conditions that damage the spleen and those with immune problems that could affect their ability to fight off the meningitidis bacteria.

"Providers should discuss with the family the circumstances for that individual child," Robinson said.

Last year's recommendation that all children and adults at elevated risk receive the MenACWY vaccine still stands.

"Getting one does not mean they don't need the other," Robinson said.

## New HPV vaccine

Another big change in this year's schedule is that individuals getting the human papillomavirus (HPV) vaccine, which is recommended for girls and boys ages 11 to 12, have another option. A new vaccine product called 9vHPV protects against nine types of the virus.

The other HPV vaccines, 2vHPV and 4vHPV, protect against two and four different HPV types, respectively. All three vaccines prevent infection with types 16 and 18, which are responsible for **66% of cases of cervical cancer**. The additional types covered in 9vHPV are responsible for about 14% of HPV cancers in females and 4% in males.



**Related Article:** Cancer on the rise, and HPV vaccine too late for Gen X

The type of HPV vaccine that people receive could depend on what is available in their doctor's office, Robinson said.

Parents might also notice a change in the timing of the HPV vaccine in [the full immunization chart](#), which captures this year's immunization schedule for children from birth to 18.

Children who have been victims of sexual abuse should receive the vaccine at 9 or 10 instead of 11 or 12 because they have a higher risk of HPV. This modification was actually included in the 2015 recommendations but was not represented on the chart, Robinson said. It would actually be fine for children starting at 9 to receive the HPV vaccine if the parents would like them to get it a little earlier, Robinson said.

Although Robinson does not foresee changes in this year's childhood immunization schedule that would be contested by parents, she said, "If a parent has a concern about a vaccine, they should always talk with their provider and they can provide the best information."

Parents who want all the information in this year's childhood immunization schedule can refer to [CDC.gov/vaccines](http://CDC.gov/vaccines) for the full chart online, which includes specific recommendations for children in high-risk groups, which are depicted in purple.

However, "if your child is otherwise healthy, the [easy-to-read version](#) is a good place to start to see which vaccinations they need," Robinson said. It summarizes recommendations for children from birth to 6 years of age.

## Vaccines aren't just for kids

There's also a chart that summarizes the new adult immunization schedule. It is available in an article published in the [Annals of Internal Medicine](#) on Monday about the changes, but will soon be on the CDC website.

"It's a neat cheat for patients, nurses, physicians, everyone to refer to," Fryhofer said. "As time has gone on, adult immunization has got more complicated as we have more vaccines for adults."



**Related Article:** 5 myths about vaccines

Some of the changes for adults are similar to the ones for children and adolescents. Adults at high risk of meningococcal B infection are also candidates for the new MenB vaccine, including those with spleen damage or traveling to areas where there are meningococcal outbreaks.

In addition, the HPV vaccine is recommended for women between 19 and 26 and men between 19 and 21, or up to 26 years old among men having sex with men. Now those groups have the option of the 9vHPV product. Even those who have already finished the full three-dose course of 2vHPV or 4vHPV may want to talk with their doctor about whether to get 9vHPV, Fryhofer said.

There is also a change to the timing of the pneumococcal vaccines.

In 2015, it was recommended that all adults 65 get PCV13 (Prevnar 13) and PPSV23 (Pneumovax), which protect against different types of Streptococcus pneumonia bacteria, between 6 and 12 months apart from each other. The new schedule changes the spacing to at least one year, because research has found it is associated with a better immune response.

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lung disease. The inclusion of these groups has not changed since last year.

The article describing the new adult immunization schedule calls out the low rates of vaccination, particularly among groups of people who stand to benefit the most from getting vaccinated. During the 2012-2013 flu season, only 46% of patients with lung disease and 50% of patients with heart disease received the flu vaccine. The article reminds physicians to assess their patients' vaccination status and urge them to get the appropriate immunizations.

"Vaccination is important, and vaccines are not just for kids, adults need them, too," Fryhofer said.

There is information on the CDC website about [additional vaccines that are not included in the general immunization schedules](#) but are recommended for certain groups of people, such as yellow fever for travelers and anthrax for members of the military.

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Sources: Syrian hospitals struck; at least 22 killed

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A glove could block Parkinson's tremors

# 6.4



**Tara Haelle** Contributor

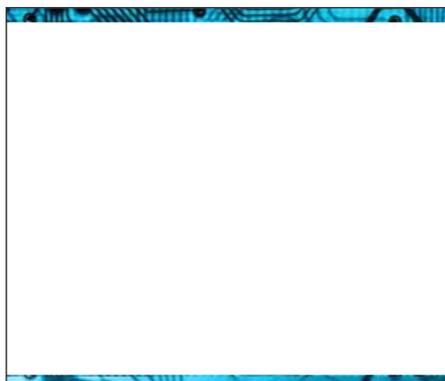
*I offer straight talk on science, medicine, health and vaccines.*

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## Is It Time To Ditch Tdap As A Routinely Recommended Teen Vaccination?

It's not news that we need a [better pertussis vaccine](#). Scientists have known [for several years](#) that protection against whooping cough wanes much faster than expected in children and adolescents. A cursory skim of [cases over the past century](#) makes it clear that the increase in cases beginning in the early 2000s correlates with children who received the current vaccine (introduced in the early 90s) reaching school-age. Increases in outbreaks have also resulted from [clustering of vaccine refusers](#) and improvements in [testing](#) and detection. However, replacing the older whole-cell vaccine—which could cause frightening [fever-induced seizures](#) but with no long-term effect—with an acellular vaccine shoulders the lion's share of blame for increasing cases.



Now the same researchers who [initially reported waning](#) in acellular vaccines have reported in a [new study in Pediatrics](#) that the Tdap, the booster vaccine dose against tetanus, diphtheria and pertussis, wanes after just one year—and that hasn't helped with the disease in California.

“Routine immunization with Tdap did not prevent pertussis outbreaks among this highly vaccinated population,” wrote Nicola Klein and her colleagues from Kaiser Permanente North California. “We expect future pertussis epidemics to be larger as the cohort that has only received acellular pertussis vaccines ages. The results in



this study raise serious questions regarding the benefits of routinely administering a single dose of Tdap to every adolescent aged 11 or 12 years.”

That last sentence is pretty bold. An FDA [study in baboons](#) two years ago already revealed that pertussis can be transmitted even among those immunized with the acellular vaccine, and a recently reported [outbreak in Florida](#) bears that out in humans. (The vaccine absolutely cannot, however, give someone pertussis because it is inactivated and only contains a few proteins of the bacterium.)

Looking at the findings of this study, though, it becomes clearer why the researchers make such a striking declaration. The effectiveness of the vaccine against whooping cough doesn't just wane—it plunges to almost nothing after just a few years. Using medical records from January 2006 to March 2015, the researchers tracked over a quarter million children who had only received the acellular DTaP vaccine in infancy and childhood. The researchers started following the kids at age 10, the earliest age the Tdap booster is licensed for, and by their 14<sup>th</sup> birthday, nearly all the kids (96.5%) had received the booster. But those intervening four years gave the researchers a chance to compare pertussis cases among those who had gotten the vaccine and those who hadn't yet.



*Students leave the school nurse office after receiving a vaccine against whooping cough before giving it to students at Mark Twain Middle School August 7, 2012 in Los Angeles, California. (Photo by Kevork Djansezian/Getty Images)*

Over that time, 1,207 pertussis cases occurred in the Kaiser Permanente Northern California network. Just a half percent of these cases occurred among teens ages 17-19, the same teens who would have received the whole-cell vaccine as children. But 85% of the cases occurred among 10- to 13-year-olds, and 15% occurred in 14- to

16-year-olds, which matches up with the generations who would have received part or only the acellular vaccine.

With the researchers' investigation of which age groups had the most cases, particularly during the 2010 and 2014 epidemics, the role of the weaker vaccine in contributing to outbreaks emerges pretty clearly. And the vaccine effectiveness the authors calculated underscores that contribution: Throughout the first year after vaccination, the Tdap was about 69% effective, which drops to 57% the next year. But that's halved to 25% in the third year. And it's just over a third of that, at 9%, the fourth year after vaccination.

Klein's team calculated that adolescents' risk of pertussis increases by 35% each year after getting the booster. Further, contrary to previous evidence showing cases to be milder in vaccinated individuals, the severity of cases among those vaccinated and unvaccinated did not appear to differ. Similar proportions of antibiotic prescriptions and emergency room visits existed among both groups.

But this does not mean the vaccine strategy with acellular pertussis vaccines has failed, pointed out [Mark Schleiss, MD](#), director of pediatric infectious diseases at the University of Minnesota in Minneapolis.

"We have saved lives with pertussis vaccine and changed the disease from a ubiquitous and tragically sometimes fatal disease in infants to an annoying but controllable disease in adolescents and young adults," Schleiss said. "We can't do anything that would compromise that kind of progress."

He noted that other vaccine strategies, such as influenza, also need improvement, but that doesn't mean tossing what we have. "We need improved vaccines with longer duration of protection and this will only come from research, but until then we should continue with our current pertussis vaccine strategy because, although imperfect, it saves lives," he said.

Despite the rapid waning, the vaccine offers significant protection in the year after vaccination. The authors therefore note in their conclusion, "Because Tdap provides reasonable

short-term protection against pertussis, Tdap may more effectively contain pertussis if it is administered to adolescents in anticipation of a local pertussis outbreak rather than on a routine basis.” In other words, they suggest, wait until cases start popping up, and then immunize those geographically near the outbreaks.

This study also supports the importance of pregnant women receiving the Tdap in their third trimester. The effectiveness is high enough that the maternal antibodies can cross the placenta and provide newborns [enough protection to make it](#) to their first round of vaccines at 2 months. Previous [research has already shown](#) the [safety and](#) the [value of prenatal Tdap](#) boosters. And the acellular vaccine, disappointing though it is, is still the [best defense](#) against death from whooping cough, as [very recent research](#) has shown.

And for teens in the meantime? “While awaiting development of new vaccines that will provide long-lasting protection against pertussis,” the authors write—and there are [vaccines in development](#)—“we should consider alternate Tdap immunization strategies for adolescents.”

But Schleiss disagrees with this suggestion. “Pertussis disease persists long after the bacteria have ‘disappeared’ — a non-intuitive situation that we really don’t understand scientifically,” he explained. “Tdap may have epidemiological benefits by impacting on circulation or spread of bacteria even if coughing illness develops.”

He also points out that the Tdap provides protection against more than just pertussis. Adolescents need boosters to maintain their protection against tetanus and diphtheria as well. He proposes something different.

“The study does suggest two possible solutions: first, to increase the amount of pertussis antigen in Tdap since there’s less pertussis antigen in Tdap than DTaP, and, secondly, to add additional doses of Tdap in adolescence and young adulthood,” Schleiss said. “Already we recognize and recommend that women receive a Tdap booster with each pregnancy.”

*NOTE: This post has been updated to add comments from Dr. Schleiss.*

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