ADVISORY COMMISSION ON CHILDHOOD VACCINES
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March 6 & 7, 2014

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ADVISORY COMMISSION ON CHILDHOOD VACCINES

Agenda

March 04, 2014

ADVISORY COMMISSION ON CHILDHOOD VACCINES (ACCV)
Parklawn Building, 5600 Fishers Lane, Rockville, Maryland
Conference Room 10-65
March 06 & 07, 2014
(1:00pm – 4:15 pm Eastern Daylight Time)
(9:00 am – 12:00 pm Eastern Daylight Time)
Dial: 1-877-917-4913
Passcode: ACCV

Thursday, March 06, 2014

Time	Agenda Item	Presenter
1:00 PM	Welcome and Chair Report	Mr. David King, Chair
1:10 PM	Public Comment on Agenda Items	
1:15 PM	Approval of December 2013 Minutes	Mr. David King, Chair
1:20 PM	Report from the Division of Vaccine Injury Compensation	Dr. Vito Caserta Acting Director, DVIC
1:50 PM	Report from the Department of Justice	Mr. Vince Matanoski, Deputy Director, Torts Branch, DOJ
2:30 PM	Break	
2:45 PM	Report from the Process Workgroup	Ms. Luisita dela Rosa, ACCV Member
4:00 PM	Public Comment (follows the preceding topic and may commence earlier or later than 4:00 pm)	
4:15 PM	Adjourn	

Friday, March 07, 2014

Time	Agenda Item	Presenter
9:00 AM	Welcome & Unfinished Business from Day 1	Mr. David King, Chair
9:15 AM	Review of Vaccine Information Statements	Mr. Skip Wolfe, CDC
10:00 AM	Update on the Immunization Safety Office (ISO), Centers for Disease Control and Prevention (CDC) Vaccine Activities	Dr. Tom Shimabukuro CDC
10:15 AM	Pneumococcal Polysaccharide (Pneumovax 23) Vaccine Safety Review	Ms. Elaine Miller, R.N., MPH CDC
10:45 AM	Update on the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH) Vaccine Activities	Dr. Barbara Mulach NIAID, NIH
11:00 AM	Update on the Center for Biologics, Evaluation and Research (CBER), Food and Drug Administration (FDA) Vaccine Activities	Ms. Theresa M. Finn, Ph.D CBER, FDA
11:15 AM	Update from the National Vaccine Program Office (NVPO)	Dr. Steve Bende, NVPO
11:30 AM	Public Comment (follows the preceding topic and may commence earlier or later than 11:30 am)	Mr. David King, Chair
11:45 AM	Future Agenda Items/New Business	Mr. David King, Chair
12:00 PM	Adjournment of the ACCV March Quarterly Meeting	

Charter

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Rockville, MD 20857

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 on Childhood Vaccines 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 $84,685. The estimate of annual person-years of staff support required is 1.5 at an estimated annual cost of $257,582.

Designated Federal Officer

HRSA will select a full-time or permanent part-time Federal employee to serve as the Designated Federal Officer (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, call 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 4 times per year and at the call of the DFO. 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. Members may serve after the expiration of their term until their successors have taken office.

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 nonvoting 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 committee, formally and informally established subcommittees, or other subgroups of the committee, 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.

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Filing Date
July 21, 2012

Approved:

July 17, 2012
Date

for Jennifer Rigsby
Wendy Ponton
Director, Office of Management

Roster

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2014 Meeting Dates

ADVISORY COMMISSION ON CHILDHOOD VACCINES

2014 MEETING DATES

March 6 & 7, 2014
June 5 & 6, 2014
September 4 & 5, 2014
December 4 & 5, 2014

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Advisory Commission on Childhood Vaccines

December 5, 2013

90th Meeting

Teleconference Minutes

Members Present

David King, Chair
Charlene Douglas, Ph.D.
Kristen Feemster, M.D.
Edward Kraus, J.D.
Ann Linguiti Pron, DNP, CRNP, RN
Luisita dela Rosa, Ph.D.
Jason Smith, J.D.
Sylvia Fernandez Villareal, M.D.
Michelle Williams, J.D.

Division of Vaccine Injury Compensation

Vito Caserta, M.D., Acting Director, DVIC
Tamara Overby, Acting Deputy Director, DVIC
Avril Melissa Houston, Chief Medical Officer, DVIC
Andrea Herzog, Staff Liaison

Office of the General Counsel
Andrea Davey, J.D.

Department of Justice
Vince Matanowski, J.D.
Julia McInerny, J.D.

Welcome, Report of the Chair and Approval of Minutes
Mr. David King, ACCV Chair

Noting a quorum present, Mr. King called the meeting to order and, after introductions, reminded the members that in its deliberations the Commissioners should keep in mind, in an empathetic way, the significant challenges that an individual or family faces when a sudden, unexpected and serious vaccine injury occurs. It is a whole new experience with health care issues, insurance and treatment financing challenges, dealing with the provisions of the Vaccine Injury Compensation Program (VICP). The decisions of the Commissioners should be made in favor of supporting those individuals and families in what is a significant ordeal in their lives.

Public Comment on Agenda

Mr. King invited public comment specifically on the agenda.

Theresa Wrangham, Executive Director of the National Vaccine Information Center, spoke to the agenda item entitled, Discussion regarding in-person meetings. She noted that the other federal committees responsible for vaccine-related issues usually meet in a face-to-face environment, and for the ACCV that venue would be more appropriate with regard to the objective of outreach and informing parents of the benefits of the VICP.

Approval of June 2013 ACCV Meeting Minutes

Noting no further comment from the public, Mr. King invited approval of the minutes of the September 5, 2013 meeting. Ms. Herzog stated that the minutes would be corrected to reflect that the meeting was the 89th, and not the 88th ACCV meeting,

Mr. King noted that on page 8, his name was preceded by the title Dr. and not Mr., which should be corrected in the final version.

Ms. dela Rosa stated that she had not received the meeting documents in advance. Ms. Herzog agreed to e-mail the material to her and Mr. King decided that the approval of the minutes would be delayed until later in the meeting to allow Ms. dela Rosa time to review those minutes.

Report from the Division of Vaccine Injury Compensation, Dr. Vito Caserta, Acting Director, DVIC

Dr. Caserta briefly reviewed the day's agenda, noting that the Commission would participate in a discussion about making the ACCV more effective, followed by a discussion about holding in-person meetings, after which the usual agenda items would be addressed – a report from the Process Workgroup, the report from the Department of Justice, a review of selected Vaccine Information Statements, and reports from the National Institute of Allergy and Infectious Diseases (NIAID), the Immunization Safety Office (ISO), and the National Vaccine Program Office (NVPO).

Dr. Caserta reported that in the first 37 days of FY 2014, 54 petitions had been filed. That would extrapolate to about 530 for the full year, which would follow the increasing number of petitions filed annually over the past several years. However, the impact of the federal shutdown has not been assessed. In terms of adjudications, there has been a slow start with 15 adjudicated cases that, if also extrapolated, would suggest only 150 cases, a number which is probably low. The same is true of actual awards for petitioners (about $7 million) and attorney's fees (about $3 million) – it is too early to project final amounts. Finally, the Vaccine Injury Compensation Trust Fund (Trust Fund) balance is about $3.4 billion, and in the past fiscal year net income was $266 million. In that year, awards to petitioners and attorney's fees slightly exceeded the net income. In previous years income exceeded what was paid from the Trust Fund.

In terms of significant activities, the public hearing on the rotavirus notice of proposed rulemaking (NPRM) will be in December, specific date to be announced. A notice about adding seasonal quadrivalent flu vaccine to the Vaccine Injury Table was published in the Federal Register. The effective date for coverage of this vaccine is November 12, which is the date that starts the 8-year look-back period. Petitions must be filed within two years of that date. The effective date for trivalent vaccine remains July 1, 2005. Finally, the federal shutdown delayed the progress of the Vaccine Injury Table NPRM, but it is back on track and should be sent to the Department for clearance within a month.

Dr. Caserta explained that an outbreak of serogroup B meningococcal disease occurred at Princeton University and to a lesser extent at UC Santa Barbara, and Centers for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA) worked with university officials and health departments to obtain authorization to distribute a vaccine under a formal protocol as an investigational new drug (IND). The vaccine is unlicensed in the U.S. because group B disease is relatively rare compared to the other serogroups in the US licensed vaccine, but used widely in Europe with a good safety record. It is a dangerous disease with serious morbidity. The Secretary confirmed that the vaccine would be covered by the VICP since all types of meningococcal vaccines are covered.

Dr. Shimabukuro added that the vaccination program will begin at Princeton the week after the ACCV meeting, with an initial vaccination, followed by a second vaccination in February. The CDC is the IND sponsor, which is approved by the FDA and includes a safety monitoring plan and a detailed consent process. The European vaccine was only recently licensed. He added, for clarification, that the outbreak at UC Santa Barbara involved a different strain and was not caused by exposure to Princeton students.

Dr. Caserta continued with his report, announcing that VICP and the Department of Justice (DOJ) separately briefed the staff of Congressman Issa (R-CA) and Congressman Cummings (D-MD) to familiarize them with the VICP. Mr. Matanoski commented that his Office of Legislative Affairs had advised him of a request by the Health Government Oversight Committee for a briefing, and it was held with congressional staff on November 7. Mr. King requested that staff provide the names of congressional staff who may have attended the briefings. There was a brief discussion about an information item in the meeting book referring to a video entitled "The Injustice of the Vaccine Injury Program" by the Canary Party. A congressional hearing that was mentioned in that video has not been scheduled.

Dr. Caserta noted that there had been a discussion at the last meeting about adding Guillain-Barre Syndrome (GBS) to the Vaccine Injury Table (Table) for influenza, which was approved by the Commission at that meeting. Final language for the Table was provided to the Commission for review and comment. Mr. Kraus questioned why chronic inflammatory demyelinating polyneuropathy (CIDP) was considered an exclusion criteria when the symptoms are very similar to GBS. Dr. Caserta explained that the Secretary based the determination on the fact that there is consensus in the neurology community that the two conditions respond to different therapies, demonstrate different pathologies and have different disease courses. He added that that determination does not prevent a petition from being filed as a non-Table injury. He also explained that the Qualifications and Aids to Interpretation go through a number of

federal departments, including OMB, which may consult other departments (like Defense and Justice) before the final regulation is written into an NPRM. Dr. Caserta finally stated that the Commission should reach a consensus on the language of the NPRM. Although the Commission had reached consensus on the language, Mr. Kraus recommended reaching out to non-federal health experts, such as medical societies concerned with neurological issues, to proactively invite them to comment on the NPRM.

Dr. Caserta noted that nothing of significance to the VICP was discussed at either the National Vaccine Advisory Committee meeting in late September or the Advisory Committee on Immunization Practices in late October.

Dr. Caserta closed with the announcement that Amber Berrian, who was introduced at the last meeting, had moved on to another federal position within the agency and that Ms. Herzog would continue as staff liaison to the Commission.

Presentation: Making the ACCV Most Effective, Dr. Vito Caserta, DVIC; Mr. Vince Matanoski, DOJ; Chief Special Master Denise Vowell

Chief Special Master Vowell introduced the presentation with an announcement that Chief Special Master Campbell Smith had been appointed to the U.S. Court of Federal Claims on September 19th, and shortly thereafter President Obama had appointed her chief judge of that court. That loss and the retirement of one of the special masters had put the Office of Special Masters (OSM) below the legislated allotment by 25%. Those vacancies will shortly be filled by two new appointees now undergoing clearance and approval.

Chief Special Master Vowell commented that the upward trend of filings continues, about 20% higher than last year, partly because of new vaccines added to the Vaccine Injury Table. She commended the efforts to examine the most effective way for the Commission to fulfill its mission, adding that focusing on moving the proposed changes to the Vaccine Injury Table is an appropriate agenda. Although the GBS claims have been efficiently processed on the basis of causation, adding GBS as a factor in flu vaccines will expedite the process to the damage phase, which should reduce the workload on the court and speed up the resolution of the claims.

Chief Special Master Vowell noted that, in contested cases, the special masters hear expert testimony and thoroughly review relevant medical literature and, although not scientists, that experience is very valuable in reaching conclusions about claims. She encouraged the Commission to consider the resolution of such contested claims with an eye toward improving the value of the Vaccine Injury Table and advocating further research.

Although the funding for the OSM operations comes from the Trust Fund, there are financial issues that impact operations, such as the limitations of sequestration (even though the funds come from the Trust Fund, use of the funds must be approved by Congress). OSM has restricted travel because of that and hopes to ease that restriction in early 2014 so that special masters may travel to venues more convenient to petitioners.

Another issue has been the loss at HHS of an individual who worked with the state Medicaid agencies to resolve lien issues that would delay final payments. Those liens would have to be resolved before the program could make payment. Since the individual is no longer at HHS to guide that resolution, the challenges of defining the lien amount and negotiating a resolution is left to the parties of the claim.

Chief Special Master Vowell encouraged the Commissioners to review decisions on the OSM web site, visit the office when convenient, attend the upcoming Judicial Conference (February 25), and attend an entitlement hearing when possible. In conclusion, she expressed appreciation for the Commission's dedication.

Dr. Caserta reviewed the Commission responsibilities contained in the ACCV charter:

* Advise the Secretary on the implementation of the Program
* Advise the Secretary on making changes to the Vaccine Injury Table
* Advise the Secretary regarding the need for childhood vaccination products that result in fewer significant adverse reactions
* Survey programs that gather vaccine adverse event information
* Advise the Secretary on the means to obtain, compile, publish and use credible data related to the frequency and severity of childhood vaccine adverse reactions
* Recommend vaccine injury research to the NVPO Director
* Consult on the development and revision of Vaccine Information Statements

Based on this charge, Dr. Caserta indicated that he and Mr. Matanoski had reviewed the current literature to recommend strategies to help the ACCV achieve its mission and support development of more effective responses to that mission. He suggested the following:

* To request, on an annual basis, that the Secretary define the highest priority public health issues related to the Vaccine Program and the provisions of the ACCV charter. That information would serve to guide the Commission towards activities that the Department considers most important and that would therefore be more valuable in terms of ACCV effectiveness.
* Request that the Secretary apprise the Commission of new priorities that might emerge during the year. Perhaps the DVIC staff could work with the Assistant Secretary for Health, under whose aegis the NVPO operates, to ensure that those new issues are addressed by the Commission (as well as to continue addressing current priorities that include adult immunizations, immunizations for pregnant women and their unborn or newly born children, and focusing on vaccine safety research). This should make the Commission's policy recommendations more relevant to the Department's needs.

This should help ACCV provide policy input where HHS needs it most. Then ACCV should request that the Department provide feedback, perhaps at the first calendar year ACCV meeting, on actions taken with regard to ACCV recommendations, including a rationale for

either accepting or rejecting those recommendations. The Commission should consider how to communicate with interested audiences and stakeholders about what the ACCV is doing. Dr. Caserta suggested that the Commission should focus on a small number of higher priority objectives, and provide information to stakeholders on how to support those objectives. ACCV has a diverse representation among its membership and with interested stakeholders, and that should serve to promote consensus support for the Commission's goals. Part of that would be improving coordination with other federal groups, such as Advisory Committee on Immunization Practices (ACIP), National Vaccine Advisory Committee (NVAC), etc.

Dr. Caserta recommended that the Commission develop recommendations with regard to what actions are needed and why they are needed, and who should take action and when, including the degree of support needed from each interest group or stakeholder. In addition, issues that affect the program, if adopted, should be identified --cost implications, improving processing time, casting a wider net for compensation, and streamlining the program. Dr. Caserta invited discussion.

Asked about the relationship with the other federal groups that were mentioned, Dr. Caserta stated that ACCV is represented on NVAC, and provides updates to ACIP. NVAC provides an insight into the priorities of the Department and Dr. Douglas, as the Commission representative to NVAC, could bring back that information to the Commission. Dr. Bende commented that all of the meeting information, the meeting book and presentations, are available on the NVPO web site shortly after the meeting. Dr. Douglas suggested that Commission members should be provided with the NVPO web link. Dr. Feemster agreed that the Commission could identify topics of common interest with NVAC and perhaps provide space on the Commission agenda for a brief discussion or presentation.

Mr. King suggested suspending the discussion until the afternoon session in order to recess for lunch.

(Recess for lunch)

Report from the Process Workgroup, Luisita dela Rosa

Mr. King called the meeting back to order and stated that, in deference to the guest speaker, Cheryl Dammons, who would join the discussion about in-person Commission meetings, Ms. dela Rosa, chair of the Process Working Group, would report on that segment of the meeting and complete her report after the discussion.

This summary pertained to the Process Working Group meeting held on November 20, 2013.

Ms. dela Rosa commented that one face-to-face meeting per year had been authorized, presuming that the matters to be discussed at the meeting justified the expense of that meeting format. Dr. Caserta suggested requesting approval from the Secretary to hold the March meeting in that manner, with the proviso that there could be no additional in-person meetings in FY 2014. Mr. King requested a rationale

from the Secretary as to why the NVAC continued to hold in-person meetings, since both ACCV and NVAC were created by the same legislation. Dr. Caserta noted that a representative from the Secretary's office or HRSA should attend the December meeting, where the issue could be discussed. He agreed that the issue of travel could also be discussed at the December meeting.

Dr. Caserta introduced Cheryl Dammons, HRSA Associate Administrator and head of the Healthcare Systems Bureau. She expressed her appreciation for being able to speak to the ACCV. Concerning the ability of NVAC to hold in person meetings, while ACCV is restricted in that area, Ms. Dammons explained that appropriations are different for each Department of Health and Human (DHHS) activity and that she could not address the funding decisions of the Office of the Assistant Secretary for Health (OASH), under which NVAC falls. There was a brief discussion about the mechanics of funding the ACCV, in light of the fact that the ACCV receives its funding from the Trust Fund, although HRSA must approve how the funds are used. HRSAestablished a limited travel policy during FY 2013. Mr. King made the point that there is a logical disconnect between the facts that funds for ACCV come from the Trust Fund, which is unrelated to HRSA appropriations. Ms. Dammons announced that during FY 2014 the ACCV is authorized to hold two in-person meetings, with the caveat that one would be held in conjunction with new member orientation.

Mr. King invited Ms. dela Rosa to continue her report. She reported that the working group had approved three recommendations at the last meeting. The first, already submitted to the Secretary, recommended adding a vaccine-injured individual to the Commission; the second, to extend the statute of limitations for filing claims; and the third, to increase the cap for pain and suffering. Those two would be forwarded to the Secretary after the December meeting and a copy of each would be sent to each Commissioner. Ms. dela Rosa stated that the working group had approved a recommendation that the third attorney on the Commission represent vaccine-injured individuals and be familiar with the mechanics of the VICP. Then there would be two attorneys who represent vaccine injury petitions and one who represents vaccine manufacturers. Since there is a vacancy in the near future, the Vaccine Injured Petitioners Bar indicated that it would submit a proposal for that appointment.

Considering the agenda for future working group meetings, there was agreement to focus on support for the three recommendations already approved. However, there could still be consideration of the fourth proposed recommendation, that affecting derivative claims. Dr. Caserta advised the working group to limit the number of recommendations to those of highest priority so as not to dilute the impact of the working group.

Mr. Kraus made a motion, duly seconded, that the ACCV recommend to the Secretary the appointment, as the third member of the legal counsel segment of the Commission, of an attorney who has experience with the Vaccine Injury Compensation Program. During discussion, Ms. Williams suggested that the motion would eliminate the position she now holds as unaffiliated lawyer, which she felt was a valuable resource person to be on the Commission. Mr. Smith agreed, noting that the unaffiliated attorney provides a different perspective than one who is dedicated to representing vaccine-injured individuals. He noted that, if approved, the

motion would dictate that Ms. Williams slot be filled by an attorney representing vaccine injured individuals, but felt that the change would not require that in perpetuity.

Mr. King noted that the charter designates the need to appoint an attorney who represents the vaccine manufacturing industry and one who represents vaccine injured individuals. The third is not specified in the charter. However, the Commission should see the vaccine-injured individuals as most important in the consideration. Dr. Caserta observed that a second attorney associated with vaccine-injured parties, although worthwhile in that obligation, does not add to the diversity of experience that is valuable in the Commission's work. Mr. Smith observed that Mr. Kraus had done an excellent job maintaining the Commission's awareness of the needs of the vaccine-injured, and he was not sure a second attorney with similar experience would make a significant difference. Although he stated his support for the motion, he felt it would be inappropriate to interpret the motion to mean that the third attorney would always be an attorney who represents petitioners. There was also an observation that the wording could be broadly interpreted to mean any attorney, even one for a vaccine manufacturer, could qualify if he or she could demonstrate experience with the Program.

A voice vote was taken and the Commission unanimously approved the motion to recommend that the third attorney on the Commission have experience with the VICP.

Concluding the Process Workgroup report, Ms. dela Rosa suggested discussing several issues, including the Chief Special Master's recommendation for the Commission to review entitlement decisions in order to identify future research. Other issues that could be included in the discussion would be the need to improve the process to resolve the burden of Medicaid obligations that must be eliminated to facilitate payment of awards, establishing a URL link on the Commission web site to NVAC, future uses of Trust Fund monies, and providing information to stakeholder groups related to ACCV recommendations that might be helpful to those groups in pursuing their own goals and objectives that are related to ACCV goals and objectives. Mr. King asked if specific topics could be included in the ACCV meeting agenda, such as increasing the cap for pain and suffering, and inviting outside witnesses to attend and comment in a public hearing type of venue.

Dr. Caserta stated that the idea would be acceptable if the Commission felt that it would promote the goal of greater effectiveness. Mr. Matanoski agreed that, in providing advice and counsel to the Secretary regarding childhood vaccines, there is value in hearing from diverse stakeholders who are part of the ACCV process, as long as the Commission is able to crystalize the information gleaned into an appropriate recommendation to the Secretary. Mr. Kraus added that the ACCV is unlike the other vaccine advisory committees, whose purview is the overall, broad vaccine arena. The ACCV focuses on vaccine-injured individuals, and the Commission's agenda should be in consonance with that difference.

Approval of June 2013 ACCV Meeting Minutes (continued)

Mr. King moved on to the deferred approval of the minutes of the June 2013 meeting and, on motion duly made and seconded, the minutes were unanimously approved by voice vote.

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

Mr. Matanoski referenced the DOJ Power Point materials (DOJ PP), dated December 5, 2013, as part of his presentation. He reported that there were 202 claims filed in the three-month reporting period, an increase in the number reported last year. (DOJ PP at 2) Adults represented 85% of the claims (up from 75% in last reporting period). Mr. Matanoski projected filings for 2014 to reach 500. This reflects a continued increase consistent with distribution of influenza vaccine. These trends are expected to continue, although there are no plans to increase the staff at DOJ. Responding to a question about the effect of potential changes to the Vaccine Injury Table on case processing, Mr. Matanoski said that while Table changes could result in more concessions by HHS, the amount of damages would still need to be resolved on a case by case basis.

With regard to adjudications, more than half of the petitions in the reporting period were compensated (75 of 139 cases), and all but one of the compensated cases were resolved by settlement. (DOJ PP at 3). Three cases were voluntarily withdrawn. (DOJ PP at 4).
Mr. Matanoski identified the glossary of terms (DOJ PP at 5-7) together with the wire diagram depicting case processing (DOJ PP at 8) and the appeals chart (DOJ PP at 9-10). These have been presented at past meetings.

Turning to appeals in the U.S. Court of Appeals for the Federal Circuit (CAFC), Mr. Matanoski briefly discussed three recently decided cases by the CAFC. In *Isaac v. HHS,* petitioner claimed that a tetanus toxoid vaccine caused Guillain-Barre Syndrome, and relied on a theory of challenge/rechallenge based on a single case report. The Special Master denied compensation and the CAFC affirmed that decision. (DOJ PP at 11). In *Carson v. HHS*, the special master dismissed petitioner's claim as untimely. On appeal, the CAFC affirmed dismissal finding the claim untimely and equitable tolling inapplicable. (DOJ PP at 11). *Tembenis v. HHS,* involved a question of future lost earnings available to an estate following the death of a child. The special master held that the child's estate was entitled to lost future damages based on the expected lifetime earnings of the child. The U.S. Court of Federal Claims (CFC) affirmed the special master's decision. On appeal by respondent, the CAFC reversed, finding that the estate could not recover future lost earnings, and that the estate was entitled to damages calculated up to the date of death. (DOJ PP at 11). There is one pending case filed by petitioner and three pending cases filed by respondent. (DOJ PP at 12).

Turning to the CFC, there was one case was recently decided. (DOJ PP at 13). There were four new cases filed by petitioner and none by respondent. (DOJ PP at 14). Of those, Mr. Matanoski discussed *Scanlon v. HHS.* In *Scanlon*, petitioner alleged an injury caused by the shingles vaccine (which is administered to adults) based on the vaccine's similarity to varicella vaccine. In dismissing the petition, the special master found that the shingles vaccine is not listed on the Vaccine Injury Table, and no excise tax is levied on the vaccine, which is a prerequisite to being covered under the Act. Mr. Matanoski noted three upcoming scheduled oral arguments: one at the CAFC and two at the CFC. (DOJ PP at 15). Turning to the slides entitled Adjudicated Settlements (DOJ PP at 16-24); Mr. Matanoski noted that 70 cases were settled during the current reporting period. Of those, it appeared that 60 were for adults and 10 for minors. More than half of the settlements (42 cases) involved the flu vaccine. During this reporting period, the

average time to resolve all of the cases, from filing a petition to judgment, was one year and nine months. Of the 70 cases settled, 27% settled within the first year; 44% within two years; and 20% in the third year. A total of 91% of cases were resolved within three years, an improvement over the last reporting period. Mr. Matanoski added that, for comparison, although not necessarily indicative of a trend, 84% of cases in the last reporting period were resolved in less than three years, and 40% of cases were resolved in the first year.

Finally, Mr. Matanoski commented that the budget issues have had an impact on case processing, although it is not clear whether the federal government shutdown adversely impacted case processing. He added that DOJ would work to resolve Medicaid liens in a timely manner to ensure that those who are entitled to compensation receive it without significant delays.

Review of Vaccine Information Statements, Skip Wolfe, CDC

Td (Tetanus, Diphtheria) Vaccine

Mr. Wolfe began with the Td (tetanus/diphtheria) Vaccine Information Statement (VIS), Section 1, noting that FDA had requested that information about how tetanus is acquired be placed early in the discussion. Therefore the paragraph that follows the diphtheria description (beginning "Both diseases are caused by bacteria) has been moved to the first introductory paragraph under Section 1.

In Section 2, about Td vaccine, there was a recommendation to delete the second paragraph (beginning "A similar vaccine") because Tdap is often given off label as a booster to the first tetanus vaccination, and because there is a separate VIS for Tdap. The ensuing sentence about receiving more information from your doctor would be revised to delete the words "about both vaccines."

In Section 3, there was a brief discussion about the warning to reschedule if the individual is "not feeling well." Mr. Wolfe explained that the wording previously had suggested that the individual make a judgment about the severity of the individual's health at the time of the appointment, but there was a decision to simplify the wording and rely on the caregiver's advice about rescheduling.

In Section 4, listing adverse events, Mr. Wolfe explained that, on the advice of the subject matter experts, the list was taken from the Tdap VIS because there is no separate list of adverse effects for the Td vaccine. And on the advice of FDA, under moderate problems, the last item (swelling of the entire arm) was removed because it is not a risk. However, the swelling and severe pain is a potential adverse event following Td and it is retained as the only severe problem. There was a brief discussion about whether the "bleeding" mentioned in the Severe Problems paragraph was actually bleeding or bruising, and Mr. Wolfe indicated he would ascertain the proper word to use. Finally, inadvertently, the standard warning in all VIS about syncope and deltoid was left out and will replace the second paragraph in Section 4.

Haemophilus influenza type b (Hib) Vaccine

Mr. Wolfe commented that FDA had indicated that the paragraph in Section 1 describing incidence and mortality should be revised, since it is not clear if the fatalities are among the children or could include adults. He suggested rewording the sentence to retain the total incidence of 20,000, but describe the fatalities in terms of a percentage range, perhaps 3% to 5%. Mr. King commented that, if the numbers are used, there should be citations that support the numbers. Mr. Wolfe stated that FDA also recommended changing the term "spinal cord coverings" to "spinal cord linings." There was a suggestion that the term "invasive Hib disease" may not be easily understood by the general public and that the term "severe Hib disease" or "life-threatening Hib disease" might be more appropriate.

There were no comments regarding changes in the content of Sections 2 and 3. There was an observation; however, that in the last paragraph there is no explanation of the increased benefit of the vaccination before, not after, spleen removal. Mr. Wolfe indicated he would work on the wording of that paragraph.

Finally, Mr. Wolfe referred to the combination vaccine MenHibrix (Hib and bivalent meningococcal vaccine), commenting that a VIS is not usually created for combination vaccines and perhaps a short discussion could be appended to the Hib VIS, since it can be used for Hib immunization. He invited comments from the Commission. It was noted that there is a sentence that indicates that Hib vaccine may be given as part of a combination vaccine (in Section 2). There was a brief discussion about whether or not the vaccine would be covered. Dr. Villareal felt the reference to combination vaccines in the VIS should be sufficient.

Mr. Wolfe expressed appreciation for the comments and recommendations of the commission.

Update on the National Institute of Allergy and Infectious Diseases (NIAID) Activities, Barbara Mulach, NIH

Ms. Mulach noted two recent publications that might be of interest to the Commissioners. The first was an announcement by University of Pittsburgh researchers of release of an extensive database of 56 infectious diseases going back 125 years. Development of the database was supported by the Bill and Melinda Gates Foundation and NIH, and it is a searchable database that will allow extensive data mining.

The second is a research program at NIH to investigate the potential of a vaccine for respiratory syncytial virus that affects infants, very young children, older adults and immune compromised individuals.

The third involves development of research relying on a baboon model to look at the mechanism of action of both whole cell and acellular pertussis vaccines. Recent FDA-NIH collaborative research has shown that baboons vaccinated with acellular vaccine are able to resist infection, but may transmit the infection to other animals.

The fourth study focuses on the possibility that eye contact in infant's offers a clue to subsequent autism diagnosis. Using eye-tracking equipment, some evidence has been developed

that infants between two months and three years who have reduced eye contact, also have a high probability of an autism diagnosis.

Update on the Center for Biologics Evaluation and Research (CBER) - LCDR Valerie Marshall, FDA

LCDR Marshall reported that on November 19-20, the Center for Biologics Evaluation and Research (CBER) met with the Biotechnology Industry Organization (BIO) to discuss expedited review programs, pregnancy registries, pediatric review plans and revising the IND managed review process. On November 22, 2013, the FDA approved the first adjuvanted vaccine for the prevention of H5N1 influenza, commonly known as avian or "bird flu." The vaccine, Influenza A (H5N1) Virus Monovalent Vaccine, Adjuvanted, is approved for use in adults 18 years of age and older who are at increased risk of exposure to the H5N1 influenza virus. The H5N1 avian influenza vaccine is not intended for commercial availability but has been purchased by DHHS for inclusion in the National Stockpile for distribution by public health officials if needed.

Update on the Immunization Safety Office, Tom Shimabukuro, CDC

Dr. Shimabukuro reviewed presentations made at the October 2013 Advisory Committee on Immunization Practices (ACIP) meeting. Meningococcal vaccine, MenACWY-CRM (Menveo) can be used for protection against serogroups A, C, W, and Y in increased risk infants aged 2 through 23 months. Infants aged 2 through 8 months who travel to or reside in countries in which meningococcal disease is hyperendemic or epidemic are recommended to receive MenACWY-CRM prior to travel to provide protection against meningococcal serogroups A and W. MenACWY-CRM may be co-administered with PCV13, including in asplenic children.

During the session on pneumococcal conjugate vaccine (PCV), the ACIP discussed a possible reduced 3-dose PCV13 schedule. The 3-dose schedule has been approved by the European Medical Agency, but not the FDA. There is evidence supporting a 3-dose PCV series as effective against invasive pneumococcal disease, pneumonia and otitis media and strong direct and indirect (herd) effects observed in countries using 3-dose PCV schedules. However, programs may not always deliver high coverage rates. Dr. Shimabukuro commented that this presentation was for information only, and no recommendations or votes on any change were proposed.

During the human papillomavirus vaccine session, the manufacturer of a 9-valent vaccine gave a presentation. The 9-valent vaccine includes 5 additional cancer-causing HPV types (compared to the current quadrivalent vaccine) and has the potential to prevent ~90% of cervical cancers and ~80% of high grade disease (CIN 2 or worse). Six Phase III trials have been completed that included more than 13,000 subjects. A preliminary report was made at a recent EUROGIN conference, and further details of the studies will be available soon.

In the Influenza session, the manufacturer of high-dose inactivated influenza vaccine discussed a randomized control trial involving 32,000 subjects over 65 years of age, who received either standard Fluzone or Fluzone High-Dose (which contains three times the amount

of antigen than the standard version). Both are approved for administration to adults 65 and over with no vaccine type preference indicated in the recommendations. The result of the trial indicated that Fluzone High-Dose was 24% more effective in preventing influenza of any strain in adults aged ≥65 relative to Fluzone.

Dr. Shimabukuro reported that the Frequently Asked Questions (FAQ's) on the CDC website had been updated concerning HPV vaccines to address the question of whether or not those vaccines are associated with ovarian failure -- there is no evidence to indicate this. There is also a CDC Expert Commentary available that discusses rotavirus and intussusception, a subject that was covered at the last ACCV meeting. The conclusion is that there is a small increased risk of intussusception after receiving rotavirus vaccine, but the benefits of the immunization continue to outweigh those risks.

Dr. Shimabukuro commented on four recent publications:

- Glanz et al., reported in the *Journal of the American Medical Association Pediatrics* that under vaccination with DTaP vaccine increases the risk of pertussis in children 3 to 36 months of age.

- Rohani-Rahbar et al., also in *JAMA Pediatrics*, reported that measles-containing vaccines are associated with a lower increased risk of seizures when administered at 12 to 15 months of age (compared to children aged >15 months).

- McCarthy et al., in *Vaccine*, looking at claims data, found no increased outcome risk (included GBS and seizures) following administration of 998,881 trivalent inactivated vaccine (TIV) and 538,257 H1N1 vaccine doses in the 2009-2010 season, and 1,158,932 TIV doses in the 2010-2011 season.

- Moro et al. reported in the *American Journal of Obstetrics and Gynecology* that rates of spontaneous abortion, preterm birth, and major birth defects in pregnant women who received live H1N1 vaccine were similar to or lower than published background rates. No concerning patterns of medical conditions in infants were identified.

Finally, Dr. Shimabukuro commented on two vaccines not on the Vaccine Injury Table. He announced that his office is working on presentations that review the safety of zoster vaccine (for adults) and 23-valent polysaccharide vaccine (for adults mainly and for some high risk children), which will be presented to the Commission at a future meeting.

Update from the National Vaccine Program Office, Dr. Steve Bende, NVPO

Dr. Bende summarized the agenda for the September NVAC meeting, noting that there was a discussion of the Healthy People 2020 immunization goals, and update on the Affordable Care Act as it relates to immunization, an update on adult immunization standards of practice (approved at the meeting), a panel on adult immunization registries, and a briefing by the CDC on the communications plan for the upcoming flu season. On the second there were several updates by the Vaccine Hesitancy Workgroup (confidence impacts parents' acceptance of

immunization), the Maternal Immunization Workgroup, and the HPV Workgroup. The Pan American Health Organization presented a discussion on challenges to sustaining immunization programs, and the NVAC Global Immunization Workgroup made a final report and recommendations, which were unanimously approved. Finally, there was a discussion about vaccine storage and handling.

Dr. Bende commented on one area of importance in adult immunizations, which are the plans to update standards and practices such that healthcare providers, and specifically providers of immunization services, increase vaccine access and coverage. There is an adult immunization task force focused on enhancing the HHS response to that objective, and Dr. Bende discussed the activities in NVPO that are under way to support the objectives of the adult immunization strategy and plan, which are a significant part of the NVPO effort.

Dr. Bende stated that the annual report on the National Vaccine Plan will be presented at the February NVAC meeting. He also noted that a contract negotiated by AHRQ with Rand Corporation to conduct a literature search of reports of safety for all vaccines not assessed by the IOM report, should be received before the end of the year. It will be an important resource to support the NVPO's charge to develop a cohesive pan-federal vaccine research agenda. Finally, Dr. Bende commented that the NVPO was working on the development of a plan for sustained maternal safety monitoring, which will be submitted to the Assistant Secretary for Health.

Public Comment

Mr. King invited comment from members of the public.

Ms. Theresa Wrangham, representing the National Vaccine Information Center

Mr. Wrangham commented on the lack of public awareness of the VICP as evidenced by the number of claims that fail because of the statute of limitations. She commended the Commission for its interest in extending the statute, but commented that greater outreach is needed to make the public more aware of the program. She noted that media announcements and press releases by other federal groups, such as ACIP, could serve as an example. Ms. Wrangham commented that face-to-face meetings, such as those held by other vaccine advisory groups, should be encouraged, since they would provide a better vehicle for outreach.

Concerning the use of Trust Fund monies, Ms. Wrangham was not in favor of the proposal by some on the Commission that the Trust Fund financially support immunization research. She requested that the Commission recommend funding sources other than the Trust Fund, which should be reserved for compensation of vaccine-injured individuals.

Ms. Wrangham commended the Commission staff for posting the Commission meeting materials on the ACCV web site in a timely manner, unlike most of the other federal vaccine advisory committees. She also recommended that correspondence from the Secretary in response to ACCV recommendations be posted, and that a spreadsheet be developed to provide a chronological presentation of ACCV recommendations and responses to those recommendations.

Mr. Louis Conte, A Parent

Mr. Conte commented that the director of the advocacy organization, Every Child by Two, published a letter that stated that "remedies to the current program can be remedied through the Advisory Commission on Childhood Vaccines." The letter stated that the outcome of the Omnibus Autism Proceeding determined that vaccines do not cause autism. However, in a paper published in 2011, "Unanswered Cases," Mr. Conte (one of the authors) stated that 83 cases of vaccine-induced brain damage were identified that could be related to autism. Mr. Conte described the specific case of Bailey Banks, who was awarded compensation through the VICP based on the Special Master's ruling that the vaccine caused acute disseminated encephalomyelitis, a neurological condition that Mr. Conte stated was associated with autism spectrum disorder. Mr. Conte recommended that the Commission recommend to the Secretary of HHS that the Vaccine Injury Table should include acute disseminated encephalomyelitis as a precursor to autism spectrum disorder and that appropriate warnings should be added to the Vaccine Injury Statements.

Future Agenda Items/New Business

There being no further comments from the public, Mr. King invited discussion on new business and proposed future agenda items.

Mr. King suggested that the Commission begin to consider the retirement of Commissioners who have reached the end of their terms, the introduction of new members, elections leading to the next chair and co-chair – all of which should be included for consideration on the March meeting agenda. Other possible agenda items could include appropriations, the Medicaid issue, continued discussion of the virtual meeting, and research funding and the Trust Find. Mr. Kraus suggested forming an ad hoc transition workgroup to develop the agenda. Ms. Williams and Dr. Pron agreed to co-chair the ad hoc workgroup and coordinate its scheduling.

Mr. King invited a motion to adjourn and, on motion duly made and seconded, there was unanimous approval to adjourn the meeting.

3

Vaccine Injury Compensation Trust Fund

Balance as of December 31, 2013

$3,485,591,623.37

Figures for October 1, 2013 – December 31, 2013

Excise Tax Revenue: $48,558,000
Interest on Investments: $15,163,853
Net Income: $63,721,853
Interest as a Percentage of Income: 31%

Source: U.S. Treasury, Bureau of Public Debt
February 3, 2014

4

4.1

NATIONAL VACCINE INJURY COMPENSATION PROGRAM[1]

PROGRAM STATISTICS REPORT

As of Monday, February 03, 2014

I. PETITIONS FILED	
Fiscal Year	**Totals**
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	216
FY 2002	957
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	449
FY 2011	386
FY 2012	400
FY 2013	502
FY 2014	174
Totals:	**15,055**

NATIONAL VACCINE INJURY COMPENSATION PROGRAM[1]

PROGRAM STATISTICS REPORT

As of Monday, February 03, 2014

II. ADJUDICATIONS[2]

Fiscal Year	Compensable	Dismissed	Totals
FY 1989	9	12	21
FY 1990	100	33	133
FY 1991	141	447	588
FY 1992	166	487	653
FY 1993	125	588	713
FY 1994	162	446	608
FY 1995	160	575	735
FY 1996	162	408	570
FY 1997	189	198	387
FY 1998	144	181	325
FY 1999	98	139	237
FY 2000	125	104	229
FY 2001	86	87	173
FY 2002	104	103	207
FY 2003	56	99	155
FY 2004	62	233	295
FY 2005	60	121	181
FY 2006	69	191	260
FY 2007	83	120	203
FY 2008	147	134	281
FY 2009	134	231	365
FY 2010	181	292	473
FY 2011	261	1,371	1,632
FY 2012	259	2,440	2,699
FY 2013	365	628	993
FY 2014	69	61	130
Totals:	**3,517**	**9,729**	**13,246**

NATIONAL VACCINE INJURY COMPENSATION PROGRAM[1]

PROGRAM STATISTICS REPORT

As of Monday, February 03, 2014

III. AWARDS PAID[3]

	Compensated			Dismissed		Interim Fees		
Fiscal Year	No. of Awards	Petitioners' Award Amounts	Attorneys' Fees/Costs Payments	No. of Payments to Attorneys	Attorneys' Fees/Costs Payments	No. of Payments	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	$3,098,231.96	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	$5,270,237.04	72	$2,432,847.05	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	$9,736,216.87	402	$5,425,243.19	28	$2,001,770.91	$233,482,659.44
FY 2012	250	$163,511,998.82	$9,104,488.60	1,017	$8,621,182.32	37	$5,420,257.99	$186,657,927.73
FY 2013	375	$254,666,326.70	$13,250,679.53	704	$7,052,778.84	50	$1,454,851.74	$276,424,636.81
FY 2014	111	$66,154,621.10	$3,256,548.28	332	$3,387,189.79	12	$824,704.08	$73,623,063.25
Totals:	**3,511**	**$2,666,061,939.51**	**$108,604,470.82**	**4,706**	**$60,533,738.52**	**179**	**$16,039,016.46**	**$2,851,239,165.31**

1. Fiscal year statistics for petitions/claims alleging injuries or deaths resulting from vaccines administered on or after 10/1/1988.

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

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

4.2

National Vaccine Injury Compensation Program (VICP) Adjudication Categories by Vaccine for Claims Filed Calendar Year 2006 to Present (as of February 3, 2014)[1]

		Compensable			Compensable Total	Dismissed/Non-Compensable Total	Grand Total
Vaccine Alleged by Petitioner[2]	No. of Doses Distributed US CY 2006 - CY 2012 (Source: CDC)[3]	Concession	Court Decision	Settlement			
DT	592,707	1	0	3	4	3	7
DTaP	68,113,573	10	16	69	95	64	159
DTaP-Hep B-IPV	38,347,667	4	6	18	28	31	59
DTaP-HIB	1,135,474	0	0	0	0	1	1
DTaP-IPV-HIB	46,633,881	0	0	4	4	7	11
DTP	0[4]	0	1	2	3	1	4
Hep A-Hep B	10,405,325	0	0	8	8	0	8
Hep B-HIB	4,621,999	0	1	1	3	1	4
Hepatitis A (Hep A)	110,596,300	1	5	17	23	16	39
Hepatitis B (Hep B)	116,853,062	2	10	33	45	29	74
HIB	70,755,674	0	1	4	5	4	9
HPV	55,168,454	10	0	59	69	70	139
Influenza[5]	809,000,000	17	67	604	688	134	822
IPV	52,439,162	0	0	3	3	2	5
Measles	135,660	0	0	1	1	0	1
Meningococcal	51,173,032	1	1	19	21	3	24
MMR	65,864,745	15	13	48	76	62	138
MMR-Varicella	8,073,618	7	0	6	13	7	20

[1] The date range for this table was selected to reflect the status of the current Program since the inclusion of influenza in July 2005, which now constitutes the majority of all VICP claims.

[2] This is the first vaccine listed by the petitioner in the claim, and other vaccines may be alleged or may form the basis of compensation.

[3] 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.

[4] Whole cell pertussis vaccines were not distributed during this time period.

[5] 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.

Nonqualified[6]	N/A	0	0	0	0	20	20
OPV	0	1	0	0	1	3	4
Pneumococcal Conjugate	123,606,306	0	1	5	6	12	18
Rotavirus	61,336,583	0	2	14	16	5	21
Rubella	422,548	0	1	0	1	0	1
Td	53,009,015	4	5	47	56	15	71
Tdap	133,744,203	6	5	58	69	7	76
TETANUS	3,836,052	2	0	14	16	9	25
Unspecified[7]	N/A	1	0	2	3	536	539
Varicella	82,534,257	3	5	17	25	10	35
Grand Total	**1,968,399,297**	**86**	**140**	**1,056**	**1,282**	**1,052**	**2,334**

DEFINITIONS:

1. Compensable – The injured person who filed a claim was paid money by the VICP. Compensation can be achieved through a concession by the Department of Health and Human Services (HHS), a decision on the merits of the claim by a special master or a judge of the United States Court of Federal Claims (Court), or a settlement between the parties.
    a. 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.
    b. 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).
        i. For injury claims, compensable court decisions are based in part on one of the following determinations by the court:
            1. The evidence is legally sufficient to show that the vaccine more likely than not caused (or significantly aggravated) the injury; or

[6] Claims filed for vaccines which are not covered under the VICP.

[7] Insufficient information submitted by petitioner to make an initial determination. The concession was for multiple unidentified vaccines that caused abscess formation at the vaccination site(s), and the settlements were for multiple vaccines later identified in the Special Master's Decisions.

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.

c. Settlement: The petition is resolved via a negotiated settlement between the parties. This settlement is not an admission by the United States or the Secretary of Health and Human Services that the vaccine caused the petitioner's alleged injuries, and, in settled cases, the Court does not determine that the vaccine caused the injury. A settlement therefore cannot be characterized as a decision by HHS or by the Court that the vaccine caused an injury. Claims may be resolved by settlement for many reasons, including consideration of prior court decisions; a recognition by both parties that there is a risk of loss in proceeding to a decision by the Court making the certainty of settlement more desirable; a desire by both parties to minimize the time and expense associated with litigating a case to conclusion; and a desire by both parties to resolve a case quickly and efficiently.

2. Non-compensable/Dismissed – The injured person who filed a claim was ultimately not paid money.

a. Non-compensable Court decisions include the following:

i. The Court determines that the person who filed the claim did not demonstrate that the injury was caused (or significantly aggravated) by a covered vaccine or meet the requirements of the Table (for injuries listed on the Table).

ii. The claim was dismissed for not meeting other statutory requirements (such as not meeting the filing deadline, not receiving a covered vaccine, and not meeting the statute's severity requirement).

iii. The injured person voluntarily withdrew his or her claim.

5

5.1

Vaccine Information Statement

Hepatitis A Vaccine: What You Need to Know

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

1. Why get vaccinated?

Hepatitis A is a serious disease that affects the liver. It is caused by the hepatitis A virus (HAV). HAV is found in the stool of persons with hepatitis A.

It is usually spread by close personal contact and sometimes by eating food or drinking water containing HAV. A person who has hepatitis A can easily pass the disease to others, especially within the same household

Hepatitis A can cause:
- "flu-like" illness
- jaundice (yellow skin or eyes, dark urine)
- severe stomach pains and diarrhea (children)

Adults with hepatitis A can be too ill to work.

Up to 1 person in 5 with hepatitis A has to be hospitalized, and some (between about 1 in 350 and 1 in 160) die.

Hepatitis A vaccine can prevent hepatitis A. Since vaccines were licensed in 1995-96, the number of cases of hepatitis A reported each year has dropped from 22,000 – 36,000 to under 2,000.

2. Hepatitis A vaccine

Hepatitis A vaccine is an inactivated (killed) vaccine. **Two doses** are needed for lasting protection. These doses should be given at least 6 months apart.

- Children are routinely vaccinated between their first and second birthdays (12 through 23 months of age).

- Others who should be vaccinated include:
  - Older children and adolescents living in areas with high rates of hepatitis A
  - Travelers to certain countries (best at least a month before travel)
  - Men who have sex with men
  - People who use street drugs
  - People with chronic liver disease
  - Some lab workers
  - People planning to adopt or care for children from certain countries

- People treated with clotting factor concentrates

- Anyone who wants to be protected from hepatitis A may be vaccinated.

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

3. Some people should not get this vaccine

- Babies younger than 12 months of age.

- Anyone who has ever had a severe (life threatening) allergic reaction to a previous dose of hepatitis A vaccine should not get another dose.

- Anyone who has a severe (life threatening) allergy to any part of this vaccine should not get the vaccine. **Tell your doctor if you have any severe allergies.**

Tell your doctor:
- **If you are not feeling well**. Your doctor might suggest waiting until you feel better. But you should come back.
- **If you are pregnant**. Your doctor can discuss the very low risk from vaccination compared with the need for protection.

4. Risks of a vaccine reaction

With a vaccine, like any medicine, there is a chance of side effects. These are usually mild and go away on their own.

Serious side effects are also possible, but are very rare.

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

Mild problems

- soreness where the shot was given (about 1 out of 2 adults, and up to 1 out of 6 children)

- headache (about 1 out of 6 adults and 1 out of 25 children)

- loss of appetite (about 1 out of 12 children)

- tiredness (about 1 out of 14 adults)

If these problems occur, they usually last 1 or 2 days.

Problems that could happen after any vaccine

- Brief fainting spells can happen after any 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.

- Severe shoulder pain and temporary loss of range of motion in the arm where a shot was given can happen, very rarely, after a vaccination.

- Severe allergic reactions from a vaccine are very rare, estimated at less than 1 in a million doses. If one were to occur, it would be within a few minutes to a few hours after the vaccination.

5. What if there is a serious problem?

What should I look for?

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

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

What should I do?

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

VAERS is only for reporting reactions. They do 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**.

7. How can I learn more?

- Ask your doctor.
- 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)**
  - Visit CDC websites at or **www.cdc.gov/vaccines**

Vaccine Information Statement (Interim)
Hepatitis A Vaccine
(DATE)
42 U.S.C. § 300aa-26

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

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5.2

Vaccine Information Statement

Hepatitis B Vaccine: What You Need to Know

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Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.immunize.org/vis

1. Why get vaccinated?

Hepatitis B is a serious disease that affects the liver. It is caused by the hepatitis B virus.

- In 2009, about 38,000 people became infected with hepatitis B.

Hepatitis B causes two types of infection:

1. ***Acute (short-term) illness.***
   This can lead to:
   - loss of appetite
   - diarrhea and vomiting
   - tiredness
   - jaundice (yellow skin or eyes)
   - pain in muscles, joints, and stomach

2. ***Chronic (long-term) infection.***
   Some people go on to develop chronic infection. Most of them don't have symptoms, but it is still very serious, and can lead to:
   - liver damage (cirrhosis)
   - liver cancer
   - death

   Chronically infected people can spread hepatitis B virus to others, even if they don't feel sick themselves. Up to 1.4 million people in the United States may have chronic hepatitis B infection.

- You can become infected with hepatitis B by:
  - contact with blood or other body fluids through breaks in the skin such as bites, cuts, or sores;
  - contact with objects that have blood or body fluids on them such as toothbrushes, razors, or monitoring and treatment devices for diabetes;
  - having unprotected sex with an infected person;
  - sharing needles when injecting drugs;
  - being stuck with a used needle.
- A baby whose mother is infected can be infected at birth.

Each year about 2,000 to 4,000 people die from cirrhosis or liver cancer caused by hepatitis B.

Hepatitis B vaccine can prevent hepatitis B and its consequences, including liver cancer and cirrhosis.

Since hepatitis B vaccine was recommended for children in 1991, infections among children and adolescents have dropped by more than 95% – and by 75% in other age groups.

2. Hepatitis B vaccine

Hepatitis B vaccine is made from parts of the hepatitis B virus. It cannot cause hepatitis B infection. The vaccine is given as a 3-dose series.

- **Babies** normally get hepatitis B vaccine at these ages:
  1st Dose: Birth
  2nd Dose: 1-2 months of age
  3rd Dose: 6-18 months of age

  Some "combination" vaccines (several different vaccines in the same shot) contain hepatitis B. Children who get these vaccines may get an extra (4th) dose. This is not a problem.

- **Older children and adolescents** who didn't get the vaccine when they were younger should also be vaccinated.

- **Adults** at risk for hepatitis B infection should be vaccinated. They include:
  - sex partners of people with hepatitis B,
  - people with more than one sex partner,
  - men who have sex with men,
  - household contacts of people infected with hepatitis B,
  - people who inject street drugs,
  - people with chronic liver or kidney disease,
  - people under 60 years of age with diabetes,
  - people with HIV infection,
  - kidney dialysis patients,
  - people whose jobs expose them to human blood or other body fluids,
  - residents and staff in institutions for the developmentally disabled,
  - people who travel to countries where hepatitis B is common.

- Anyone else who wants to be protected from hepatitis B infection can get the vaccine.

- Pregnant women may be vaccinated.

- Hepatitis B vaccine may be safely given with other vaccines.

3. Some people should not this vaccine.

- Anyone who has ever had a severe (life threatening) allergic reaction to a previous dose of hepatitis B vaccine should not get another dose.

- Anyone who has a severe (life threatening) allergy to any part of this vaccine, including yeast, should not get the vaccine. **Tell your doctor if the person being vaccinated has any severe allergies.**

- If the person getting the vaccine is not feeling well, the doctor might suggest waiting until they feel better. But they should come back.

Ask your doctor for more information.

Note: You might be asked to wait 4 weeks before donating blood after getting hepatitis B vaccine. This is because the screening test could mistake vaccine in the blood for hepatitis B infection.

4. Risks of a vaccine reaction

With a vaccine, like any medicine, there is a chance of side effects. These are usually mild and go away on their own.

Serious side effects are also possible, but are very rare.

Hepatitis B is a very safe vaccine. Most people don't have any problems with it. More than 100 million people in the United States have been vaccinated with hepatitis B vaccine.

Some mild problems have been reported:

- Soreness where the shot was given (up to about 1 person in 4).
- Temperature of 99.9°F or higher (up to about 1 person in 15).

Problems that could happen after any vaccine

- Brief fainting spells can happen after any 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.

- Severe shoulder pain and temporary loss of range of motion in the arm where a shot was given can happen, very rarely, after a vaccination.

- Severe allergic reactions from a vaccine are very rare, estimated at less than 1 in a million doses. If one were to occur, it would be within a few minutes to a few hours after the vaccination.

5. What if there is a serious problem?

What should I look for?

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

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

What should I do?

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

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

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6

6.1

It's *Still* Not Too Late to Get Your Flu Vaccine

Meant to get vaccinated in the fall to ward off the flu, but somehow didn't get around to it? Think it's too late to get vaccinated now?

Not so. According to the Food and Drug Administration (FDA), vaccinations can be protective as long as flu viruses are circulating. And while seasonal flu outbreaks can happen as early as October, flu activity usually peaks in January or February, and can last well into May.

FDA plays a key role in ensuring that safe and effective influenza vaccines are available every flu season. In fact, the task of producing a new vaccine for the next flu season starts well before the current flu season ends. For FDA, it's a year-round initiative.

Why a new vaccine?

According to Marion Gruber, Ph.D., director of FDA's Office of Vaccine Research and Review, there are several reasons that new vaccines must be manufactured each year.

"Influenza viruses can change from year to year, due to different subtypes and strains that circulate each year," says Gruber. A vaccine is needed that includes virus strains that most closely match those in circulation, and the protection provided by the previous year's vaccine will diminish over time.

Identifying Likely Virus Strains

Each February, before that year's flu season ends, FDA, the World Health Organization (*www.who.int/influenza/en/*), the Centers for Disease Control and Prevention (CDC) and other public health experts collaborate on collecting and reviewing data from around the world to identify the flu viruses likely to cause the most illnesses in the next flu season. Based on that information and the recommendations of an FDA advisory committee, the agency selects the virus strains for FDA-licensed manufacturers to include in their vaccines for use in the United States.

"The closer the match between the circulating strains causing disease and the virus strains in the vaccine, the better the protection against influenza," Gruber says.

In addition, FDA inspects the manufacturing facilities on a regular basis, and prepares and provides reagents (necessary test components

"Influenza seasons and severity are often unpredictable. Annual influenza vaccination is the best way to prevent influenza among people 6 months of age and older."

to standardize vaccines) that vaccine manufacturers need to make their vaccine and to verify its identity and strength. FDA also evaluates each manufacturer's vaccine each year for approval purposes, conducts lot release (that is, performs certain tests and reviews the results of the manufacturers' tests on each lot of vaccine prior to distribution), and continues to monitor the safety of the vaccines once they are approved for use and in distribution.

FDA and CDC scientists routinely evaluate reports to the Vaccine Adverse Event Reporting System (VAERS) of health problems that may be associated with a vaccine (*www.fda.gov/biologicsbloodvaccines/safetyavailability/reportaproblem/vaccineadverseevents/overview/default.htm*).

FDA conducts yearly surveillance for Guillain-Barre syndrome, a rare neurological condition associated with the 1976 flu vaccine, in collaboration with the Centers for Medicare and Medicaid Services. And the agency is now testing influenza surveillance in the new Mini-Sentinel Post Licensure Rapid Immunization Safety Monitoring (PRISM) system (*www.mini-sentinel.org*). If testing proves successful, FDA will be able to monitor rates of health problems after influenza vaccination among members of multiple health plans that serve the general U.S. population.

CDC also monitors the safety of annual influenza and other vaccines through the Vaccine Safety Datalink (VSD) (*www.cdc.gov/vaccinesafety/Activities/VSD.html*) by almost real-time observation of the health of people who are vaccinated, in collaboration with nine integrated health care organizations.

Who's Most Affected So Far?

CDC tracks influenza activity year round in the U.S. and typically children and seniors are most at risk for influenza, but occasionally a flu virus will circulate that disproportionately affects young and middle-aged adults. So far, data reported by CDC suggest that 2013-2014 could be such a flu season.

CDC received an unusually high number of reports of severe respiratory illness among young and middle-aged adults in the last two months of 2013. Many of the cases were associated with the H1N1 strain of influenza that affected children and young adults compared to older adults during the 2009 influenza pandemic. The 2009 H1N1 virus has circulated each year since the pandemic. It is not known if those most severely affected received a vaccine, but this particular strain is included in this year's vaccine and will help provide protection.

"Influenza seasons and severity are often unpredictable. Annual influenza vaccination is the best way to prevent influenza among people 6 months of age and older," says Gruber. "However, taking such practical measures as washing hands, covering coughs and sneezes and staying home when sick can also help to decrease the spread and minimize the effects of flu."

In addition, while antiviral drugs are not a substitute for vaccine, they can help to treat influenza. Tamiflu (oseltamivir phosphate) and Relenza (zanamivir) are the two FDA-approved influenza antiviral drugs recommended by CDC for use against recently circulating influenza viruses. FDA

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6.2

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Contact: Tom Abate
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Stanford School of Engineering

Stanford researchers take a step toward developing a 'universal' flu vaccine

Targeting the stem rather than the head of a critical protein is the challenging but promising tactic of a new study

Every year the approach of flu season sets off a medical guessing game with life or death consequences. There are many different strains of flu and they vary from year to year. So each season authorities must make an educated guess and tell manufacturers which variants of the flu they should produce vaccines against.

Even when this system works, flu-related illnesses can kill 3,000 to 49,000 Americans annually, according to the Centers for Disease Control and Prevention. A bad guess or the unexpected emergence of a virulent strain could send the death toll higher.

Against this backdrop Stanford researchers report promising steps toward the creation of a universal flu vaccine, one that could be produced more quickly and offer broader protection than the virus-specific inoculants available today.

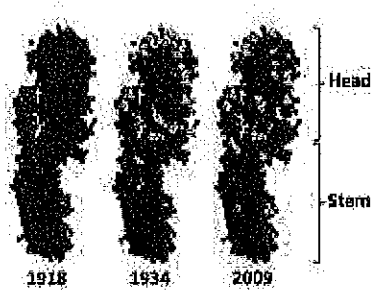

IMAGE: The flu virus changes each year. Today's vaccines target specific strains of flu prevalent in a given year. This image shows the HA protein from three flu strains. The HA...

Click here for more information.

The researchers detail their work in the current edition of the *Proceedings of the National Academy of Sciences*. The team was led by chemical and bioengineer James R. Swartz, who is the James H. Clark Professor in the School of Engineering.

Their approach arises from a better understanding of the structure of a key protein on the surface of the flu virus, and a new process for making vaccines based on that understanding.

A flu virus is made up of different proteins. Protruding from the surface of the virus are hundreds of copies of a protein called Hemagglutinin (HA). Each copy of HA resembles a mushroom, with a head and a stem. The head of HA helps determine the virulence of a given strain of flu.

Today's vaccines are based on inactivated viruses that contain the heads of HA proteins. When a flu shot is injected into our blood stream, our immune system sees the HA head as a target, and creates antibodies to fight what appears to be an infection.

Teaching the immune system to recognize a target is the essence of vaccination. If we are exposed to the flu after getting vaccinated, our immune system is primed to recognize and eradicate the invading virus before it can replicate sufficient copies to make us sick.

Swartz and his colleagues base their new vaccine approach on the understanding that, whereas the head of the flu virus varies from year to year, the protein stem remains more constant over time.

Theoretically, a vaccine based on the stem should be more broadly protective against different strains of flu, and perhaps offer universal protection. Moreover, since the stem remains relatively constant from year to year, once our immune systems produces antibodies against that antigen, multi-season protection might be possible.

But this approach remains experimental and has not yet been tested on patients.

The Stanford paper focused on the first step in developing such a universal vaccine: creating a protein stem fragment that could be injected into the blood stream, in short, creating a target, or antigen, to attract the attention of our immune system and trigger an effective defense.

Yuan Lu, a postdoctoral scholar in Swartz's lab and member of the research team, outlined the process detailed in the PNAS paper.

The researchers began with a section of DNA that contained the instructions for making the protein structure for one important strain of flu, the H1N1 virus that caused the pandemic of 1918 and recurred in milder form in 2009.

The researchers started with the DNA sequence that defines the entire HA protein, both head and stem.

They then subtracted the DNA coding for the head. Thus, their edited DNA strand only contained the instructions for making the protein stem.

The Stanford team used a relatively new and experimental process to manufacture the viral stem. This process is called cell free protein synthesis (CFPS).

To understand how CFPS works let's review how proteins are made in nature.

Inside all cells there are molecular machines called RNA polymerases and ribosomes. These RNA polymerases and ribosomes "read" DNA to manufacture proteins based on the instructions in the genetic code.

In cell free protein synthesis, scientists bust open bacterial cells to create a molecular goop that contains a lot of these ribosomes. Scientists know how to transmit their DNA instructions directly to these protein factories.

The advantage of CFPS is that it can produce proteins in a few hours versus a couple of weeks or even a couple of months, which is how long it takes to make proteins for flu vaccines using the practices that are approved for medical use today.

The Stanford researchers used this CFPS process to create and refine a viral protein stem that would be useful as an experimental vaccine antigen.

To do this they had to solve two fundamental problems.

First, the CFPS process produced a single-strand protein, or monomer. But the HA stem is a trimer, or three identical monomers braided together.

Second, their bioengineered antigen was not initially soluble. In other words, it could not be made into a liquid vaccine form.

Remember that everything started with a DNA sequence. Making the antigen involved feeding a DNA sequence into the molecular goop containing RNA polymerases and ribosomes, extracting the viral protein stems, and determining whether they had created soluble trimers that had at least the potential to be injectable antigens.

The researchers went though dozens of experiments to produce monomers that could fold into soluble trimers. Proteins are made of smaller building blocks called amino acids. Changing the structure of the protein stem therefore involved editing the DNA to change specific amino acids, running these new instructions back through the ribosome factories, extracting the finished product and testing the results.

It took dozens of tries over two years but eventually the researchers fed a DNA snippet into the CFPS process and created a soluble viral stem protein that could be a good antigen. That is what they report in the PNAS paper.

"This has been a tough process," Swartz said. "Many labs have been trying to develop an HA stem vaccine and we're glad to have made these contributions."

Many steps remain before the research community knows whether this viral stem approach yields a better flu vaccine. Next, Swartz and his team will attach their stem protein to a virus-like particle. The idea will be to create a bigger, better target with which to elicit an immune system response.

Should that prove successful, the new vaccine candidate would have to undergo safety and efficacy tests in animals, and eventually, large scale human clinical trials.

Much is at stake. Recent estimates put the worldwide death toll from flu-related illnesses at between 250,000 and 500,000 persons per year.

"This is an important project for world health," Swartz said, noting that the vaccine must not only be broadly effective against different strains of flu but cheap to produce so that it can be widely distributed. "These are big challenges but we are committed to the effort."

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650-736-2245, tabate@stanford

6.3

dsn Rx DRUG STORE NEWS

Study: Pharmacist intervention improves shingles vaccine rate

By Michael Johnsen

COLUMBUS, Ohio - A new study from researchers at Ohio State University is reporting that older patients who receive written information on shingles were almost three times more likely to get vaccinated than those that didn't receive a similar communication. The study is also one of the first to show that using a patient's electronic medical record coupled with pharmacist intervention markedly improves preventative care of shingles over the current standard.

While people over the age of 60 account for more than half of all shingles cases, less than 15% get the vaccination that helps prevent the blistering skin rash, which can cause lingering nerve pain, researchers noted.

The research team, led by Stuart Beatty, a pharmacist with Ohio State's College of Pharmacy, says that the low vaccination rate is due to a combination of factors including lack of awareness, cost, access to clinics able to store the fragile vaccine and the fact that face-to-face appointments don't offer enough time to discuss shingles, also known as herpes zoster.

"With older patients, there are usually more pressing health issues to discuss during routine appointments, so herpes zoster falls off the list," Beatty said. "Plus, as a live vaccine, it's not appropriate for people with certain illnesses. There usually isn't time to figure all that out in a regular office visit."

Neeraj Tayal, an Ohio State Wexner Medical Center general internist on the research team, noted that while the numbers of patients vaccinated may seem small, the study was conducted from 2010 to 2011, a time when the national vaccination average was actually 6%, far lower than today's average of 15%. Tayal also suggested that despite the overall low vaccination rate, the results challenge the notion that there are too many logistical barriers to this type of effort.

"It took pharmacists a matter of minutes to review the chart and mail out a prescription. This saved the physician time, the patient time, and improved the overall health of our patients," Tayal said. "By utilizing pharmacists as members of a care team, many perceived logistical barriers were managed and overcome."

For the six-month study, which was supported by the Ohio State Center for Clinical and Translational Science, Beatty and his team used electronic medical record data to identify more than 2,500 patients over the age of 60 without a documented herpes zoster vaccination. Some were randomized to receive information about shingles via a secure email linked to their online personal health record or a mailed postcard, while others received no information outside what they may have gotten in a routine doctor visit.

Pharmacists reviewed the EMRs of patients who had received emails or mailed information to identify eligible vaccine candidates, and then sent them a vaccination prescription via standard mail, along with a list of local pharmacies that offered the vaccine. Vaccine fulfillment was tracked by reports submitted to the team by local pharmacists.

Patients with an active PHR that received email information on shingles had the highest vaccination rate of 13.2% compared to a rate of 5% for patients with an active PHR that did not receive the email information. For patients that did not have an active PHR but did receive mailed information, the vaccination rate was 5.2% compared to a rate of 1.8% for patients without an active PHR and received no information.

The study was published in *The American Journal of Medicine*.

Source URL: http://drugstorenews.com/article/study-pharmacist-intervention-improves-shingles-vaccine-rate

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U.S. Department of Health & Human Services

2010 National Vaccine Plan

Protecting the Nation's Health through Immunization

Table of Contents

1. Please note that the Appendices can be found on the National Vaccine Plan website at www.hhs.gov/nvpo/vacc_plan/index. As the Plan is a "living document," the Appendices will be updated on an ongoing basis.

Acronyms and Abbreviations

ACA	Affordable Care Act (comprised of the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010)
ACF	Administration for Children and Families
ACIP	Advisory Committee on Immunization Practices
AEFI	Adverse Event Following Immunization
AIDS	Acquired Immune Deficiency Syndrome
AHRQ	Agency for Healthcare Research and Quality
ASPR	Assistant Secretary for Preparedness and Response
BARDA	Biomedical Advanced Research and Development Authority
CDC	Centers for Disease Control and Prevention
CICP	Countermeasures Injury Compensation Program
CMS	Centers for Medicare and Medicaid Services
DoD	Department of Defense
DHS	Department of Homeland Security
DoJ	Department of Justice
EHR	Electronic Health Records
FDA	Food and Drug Administration
GAVI	Global Alliance for Vaccines and Immunizations
GHI	Global Health Initiative
HBV	Hepatitis B Virus
HHS	U.S. Department of Health and Human Services
Hib	*Haemophilus influenzae* type b
HIV	Human Immunodeficiency Virus
HP	Healthy People
HPV	Human papillomavirus
HRSA	Health Resources and Services Administration

IHS	Indian Health Service
IIS	Immunization Information Systems
IOM	Institute of Medicine
NGO	Non-Governmental Organization
NIH	National Institutes of Health
NVAC	National Vaccine Advisory Committee
NVP	National Vaccine Program
NVPO	National Vaccine Program Office
ONC	Office of the National Coordinator for Health Information Technology
P.L.	Public Law
TB	Tuberculosis
UNICEF	United Nation's Children's Fund (formerly United Nations International Children's Emergency Fund)
USAID	U.S. Agency for International Development
VA	Department of Veterans Affairs
VICP	National Vaccine Injury Compensation Program
VPD	Vaccine-Preventable Disease
WHO	World Health Organization

"To raise new questions, new possibilities, to regard old problems from a new angle, requires creative imagination and marks real advance in science."

- Albert Einstein

Executive Summary

The 20th century could be considered the century of vaccines. The life spans of Americans increased by more than thirty years in large part because of vaccines, and mortality from infectious diseases in the United States decreased 14-fold.[2] Death or disability from many once-common diseases is now rare in the U.S. A child born in the U.S. today can now be protected against 17 serious diseases and conditions through immunization. The widespread use of vaccines has helped to eradicate smallpox worldwide and eliminate polio, measles and rubella in the U.S. Globally, vaccination saves 2 to 3 million lives per year.[3]

Vaccines have the unique quality of protecting both individuals and communities. However, they have been so effective for many years in preventing and eliminating a number of serious infectious diseases that the significant contributions that vaccines make to our society and its health may have faded from public consciousness. Before the development and widespread use of safe and effective vaccines, infectious diseases threatened the lives of millions of children and adults in this country and abroad. What were once referred to as the common diseases of childhood are now vaccine-preventable diseases (VPDs). In the U.S., children are no longer crippled cases by polio nor killed by infections such as diphtheria or *Haemophilus influenzae* type B (Hib). Vaccines also help prevent cancers caused by human papillomavirus (HPV) and hepatitis B virus (HBV).

The 2010 National Vaccine Plan provides a vision for the U.S. vaccine and immunization enterprise for the next decade. The Plan articulates a comprehensive strategy to enhance all aspects of vaccines and vaccination including: research and development, supply, financing, distribution, safety, informed decision making by consumers and health care providers, VPD surveillance, vaccine effectiveness and use monitoring, and global cooperation. The actions contained in the strategies of the Plan are conditional and are subject to the availability of resources.

The scope of the Plan is broad and addresses vaccines and key vaccine-related issues for the U.S. and its global partners. It provides a strategic approach for preventing infectious diseases and improving the public's health through vaccination for the coming decade. Although vaccines are being developed to treat diseases and conditions (therapeutic vaccines) and for non-infectious diseases, the focus of this Plan is on vaccines for the prevention of infectious diseases as guided by the law that established the National Vaccine Program (NVP).[4]

2. American Academy of Pediatrics. Prologue. In: Pickering LK, ed. Red Book: 2009 Report of the Committee on Infectious Diseases. 28th ed. Elk Grove Village, IL: American Academy of Pediatrics; 2009:1-2.

3. World Health Organization and United Nations Children's Fund. Global Immunization Vision and Strategy, 2006--2015. Geneva, Switzerland: World Health Organization and United Nations Children's Fund; 2005. Available at www.who.int/vaccines/GIVS/english/GIVS_Final_17Oct05.pdf.

4. Public Law (P.L.) 99-660 established the National Vaccine Program, and required the National Vaccine Program to focus on prevention of infectious diseases and adverse reactions to vaccines.

The Plan has five broad goals:

Goal 1:
Develop new and improved vaccines.

Goal 2:
Enhance the vaccine safety system.

Goal 3:
Support communications to enhance informed vaccine decision-making.

Goal 4:
Ensure a stable supply of, access to, and better use of recommended vaccines in the United States.

Goal 5:
Increase global prevention of death and disease through safe and effective vaccination.

Existing national and global vaccine-related initiatives, such as improvements in regulatory science, the development of medical countermeasures for emergencies, and global health partnerships are embedded within the Plan. Strategies of this Plan will also be coordinated with those developed through other federal efforts. One example is the National Prevention, Health Promotion and Public Health Council, established in the 2010 Affordable Care Act (ACA). The Council will coordinate federal prevention, wellness, and public health activities, and develop a national strategy to improve the nation's health.

In conjunction with other federal efforts like the National Prevention and Health Promotion Strategy, Healthy People (HP) 2020, and the Public Health Emergency Medical Countermeasures Enterprise Review, the 2010 National Vaccine Plan provides the strategic guidance to build a stronger preventive health system. It will help bridge disparities in use of, and access to vaccines, and will provide innovative strategies to guide the nation's vaccine enterprise across the next decade and beyond.

Purpose and Background

The purpose of the 2010 National Vaccine Plan is to provide strategic direction for the coordination of the vaccine and immunization enterprise for the NVP. The Program's goals are to prevent infectious diseases and their sequelae and reduce adverse reactions to vaccines in the U.S. The Plan will achieve this through coordinated implementation of a strategic vision implemented by vaccine and immunization stakeholders across and outside of the federal government.

Background

Federal involvement in vaccination programs targeting civilian and military populations has a rich history that includes research and development, assuring safety and effectiveness, supporting delivery, and developing mechanisms for reporting adverse events following immunization. Recognizing the need for increased coordination of these activities, the NVP was established by Congress in 1986.[5] Congress called for the development of a National Vaccine Plan to guide activities in pursuit of program goals. The initial Plan, completed in 1994, defined activities to achieve the program's mission through coordinated action by federal agencies, state and local governments, and private sector partners including manufacturers and health care providers.

The nation's vaccine enterprise has made considerable progress since the first National Vaccine Plan. Through routine vaccination, a child born today can be protected against 17 diseases and conditions while one born in 1995 could be protected against only nine. Growing scientific knowledge coupled with advances in biotechnology provides possibilities for new and improved vaccines. Many of the financial barriers that once limited widespread use of vaccines have been overcome. A myriad of enhanced tools are available for communicating accurate information about vaccines and for ensuring that vaccines are safe and effective. A broad range of public and private stakeholders have become essential to the vaccine enterprise.

Ironically, the public health victory witnessed from the use of vaccines has created a public health challenge: because vaccines have reduced the impact and awareness of many infectious diseases, some have begun to question the value and need for vaccines. In addition, the long-term effects (e.g., cancer) of some VPDs (e.g., HBV and HPV) may not be visible to the public, thus diminishing the perceived value of vaccination. Thus, this Plan comes at a critical time for this nation and its health as it engages on these issues and as there is an increased focus on the importance of preventive health for the U.S. and its citizens.

5. P.L. 99-660

Mission, Perspective, and Scope

The 2010 National Vaccine Plan provides a strategic approach for preventing infectious diseases and improving the public's health through vaccination.

The scope of the Plan is broad, including vaccines and vaccine-related issues for the U.S. and global communities. As guided by the statute that established the NVP, the focus for this Plan is prevention of infectious diseases and adverse reactions to vaccines.[6] The Plan incorporates current initiatives, such as the long recognized need to develop vaccines against human immunodeficiency virus/acquired immune deficiency syndrome (HIV/AIDS), tuberculosis (TB), and malaria, and programs to enhance medical countermeasures, regulatory science, and vaccine production. A ten-year horizon was set for the Plan to align with HP 2020 goals (see Appendix 1 for more details[7]).

2010 National Vaccine Plan Structure

The 2010 National Vaccine Plan provides a comprehensive approach to reduce infectious diseases and their sequelae and reduce adverse reactions to vaccines through coordinated efforts of federal, state, local, multinational and non-governmental stakeholders. Recognizing that success is facilitated by careful planning that includes defining specific activities, milestones and measurable outcomes, an implementation plan will be developed based on this plan and released in 2011. With a ten-year horizon, this framework recognizes and anticipates that emerging science, new opportunities, and changing circumstances will guide the course of the Plan. Annual monitoring of progress and a mid-course review will promote both accountability and flexibility.

The Plan is built around five broad goals:

Goal 1:
Develop new and improved vaccines.

Goal 2:
Enhance the vaccine safety system.

Goal 3:
Support communications to enhance informed vaccine decision-making.

Goal 4:
Ensure a stable supply of, access to, and better use of recommended vaccines in the United States.

Goal 5:
Increase global prevention of death and disease through safe and effective vaccination.

Each goal is supported by objectives that will be pursued through a defined set of strategies. Reaching goals and objectives generally requires action by many stakeholders in the vaccine and immunization enterprise. The Implementation Plan, to be written during 2011, will describe the action steps and measurable indicators for key Plan objectives and strategies.

6. P.L. 99-660

7. Please note that the Appendices can be found on the National Vaccine Plan website at www.hhs.gov/nvpo/vacc_plan/index. As the Plan is a "living document," the Appendices will be updated on an ongoing basis.

Progress Since the 1994 Plan

The 2010 National Vaccine Plan builds on the many achievements of the vaccine and immunization enterprise prior to and since the establishment of the NVP in 1986 and the completion of the first National Vaccine Plan in 1994. New vaccines have been licensed to expand the number of infections that can be prevented, and more effectively and safely prevent some diseases for which earlier generation vaccines already existed. In addition, federal immunization financing programs have reduced or eliminated many financial barriers to vaccination, particularly for children. The number of infections caused by VPDs has decreased significantly while vaccination coverage in the U.S. has increased, and coverage for many vaccines has reached record levels. More robust systems have been developed to identify adverse events following immunization and to assess potential associations of those events with vaccination. Globally, the U.S. has worked with multilateral and bilateral partners and non-governmental organizations (NGOs) in contributing to improvements in child health status and the prevention of hundreds of thousands of child deaths each year through improved vaccine coverage and introduction of new vaccines. Of the fourteen anticipated outcomes included in the 1994 National Vaccine Plan, most were substantially or fully achieved (see Appendix 2).

Unfortunately, many of the challenges that stimulated establishment of the NVP and the development of the 1994 National Vaccine Plan remain relevant today. Vaccine shortages and interruptions have occurred for many routinely recommended vaccines. Despite improved vaccination coverage among children, recent VPD outbreaks in the U.S. serve as reminders that these diseases still occur. Among older adults both vaccination coverage and the effectiveness of some routinely recommended vaccines remain sub-optimal. Disparities exist in adult vaccination rates between racial and ethnic groups. As the cost of vaccination has increased, financial barriers to vaccination have emerged for health departments, health care providers, and the public. Significant scientific challenges remain in the development of safe and effective vaccines against existing global health threats, such as HIV, TB and malaria. Vaccines that have been developed and are in use in industrialized countries have the potential to make major contributions to health in developing countries, but are currently underused in many places. Additionally, emerging infections and the persistent threat of natural and intentional infectious disease pose new challenges for vaccine development and regulation, manufacturing, vaccine delivery and access in the U.S. and abroad.

U.S. Immunization Framework

Disease prevention and enhanced vaccine safety are ultimate outcomes of a successful vaccination program. Identifying objectives and strategies that lead to and sustain these outcomes is facilitated by understanding the many processes or determinants of these outcomes.

To protect individuals and communities from VPDs, vaccines must be administered to the public. Vaccination begins with the identification of public health priorities, which are informed by disease surveillance data and information on the public health burden of the diseases that vaccines can effectively and safely prevent. Vaccine research and licensure follows. After the licensure of a vaccine and the Advisory Committee on Immunization Practices (ACIP) and medical organizations' recommendation for its use, a vaccine must be distributed, stored, and handled appropriately. Vaccine payment and reimbursement policies are important for ensuring receipt and use of the vaccine. Communications and public and provider outreach help support informed decision-making about vaccination. Attitudes, vaccination coverage and the effectiveness of disease prevention also are influenced by issues related to vaccine safety and effectiveness.

Development of the 2010 National Vaccine Plan

The 2010 National Vaccine Plan, under the coordination of the U.S. Department of Health and Human Services (HHS) National Vaccine Program Office (NVPO), is the product of deliberation, analysis, and input from multiple federal agencies, and it incorporates broad public and stakeholder input. NVPO is the principal coordinating office for the NVP and is responsible for providing leadership, facilitating coordination, and monitoring progress of the 2010 National Vaccine Plan during implementation.

Relevant federal government agencies (see Appendix 3) identified key objectives and strategies as pathways to success for each of the five goals. NVPO consulted with the National Vaccine Advisory Committee (NVAC), federal agencies, domestic and international stakeholders, and the public regularly about the development of the Plan. A national stakeholder meeting was convened to discuss the first draft of the Plan. In addition to the national stakeholder meeting, NVPO obtained input through several mechanisms:

- Comments gathered by an Institute of Medicine (IOM) committee[8] at five public meetings that focused on the different goals in the Plan;
- The IOM committee's final report;[9]
- Input from federal vaccine advisory committee members;
- Meetings with domestic and international stakeholders; and
- Input from the public in three public meetings and through public comment in response to a notice in the Federal Register.

Additional information about the development of the National Vaccine Plan is available at *www.hhs.gov/nvpo/vacc_plan/index.*

Coordination with Other Federal Initiatives

The 2010 National Vaccine Plan will support relevant strategic health priorities and key interagency collaborations for the nation issued by the Secretary of HHS, which include the following: to promote early childhood health and development, to accelerate the process of scientific discovery to improve patient care, and to improve global health.[10] Global health plays an important role in the national security of the U.S. population and populations worldwide, and as such the Plan is of import to all agencies involved in global health activities, including the Department of State and the U.S. Agency for International Development (USAID). U.S. involvement in global vaccine issues can reduce worldwide transmission of VPDs, strengthen health systems, and foster bilateral and international partnerships.

In addition, the 2010 National Vaccine Plan has direct relevance to the goals of the ACA, the comprehensive health care reform law enacted in March 2010, which expands access to preventive care, including vaccines, by requiring health plans to cover preventive services without charging a deductible, copayment, or coinsurance. Individuals enrolled in these new group or individual health plans will have access to the vaccines recommended by the ACIP prior to

8. HHS requested the formation of an IOM committee specifically to gather public input and provide recommendations on priorities for the 2010 National Vaccine Plan.
9. Available at www.iom.edu/Reports/2009/Priorities-for-the-National-Vaccine-Plan.
10. U.S. Department of Health and Human Services. Secretary's Strategic Initiatives & Key Inter-Agency Collaborations. Available at www.hhs.gov/secretary/about/priorities.

September 2009 with no co-payments or other cost-sharing requirements when those services are delivered by an in-network provider. These new health plans will be required to cover new ACIP recommendations made after September 2009 without cost-sharing in the next plan year that occurs one year after the date of the recommendation. In addition to expanding access to immunization under the preventive services rules, the ACA includes the following immunization-related provisions:

- Provides authority to states to purchase adult vaccines with state funds from federally-negotiated contracts.
- Reauthorizes the Section 317 Immunization Grant Program, which makes available federally purchased vaccines and grants to all 50 states, the District of Columbia, five large urban areas, and territories and protectorates to provide immunization services to priority populations.
- Requires a General Accountability Office study and report to Congress about Medicare beneficiary access to recommended vaccines under the Medicare Part D benefit.

More information about the new preventive services requirements can be found at: *www.healthcare.gov/center/regulations/prevention/recommendations.*

Strategies identified in the Plan will be coordinated with those in the National Health Security Strategy, the Global Health Initiative (GHI), the National Strategy for Pandemic Influenza, and other national strategic plans that relate to immunization and vaccines. In particular, this work will be coordinated with the National Prevention, Health Promotion and Public Health Council's priorities, which will integrate federal prevention, wellness, and public health activities, and develop the National Prevention and Health Promotion Strategy to improve the nation's health. All of these efforts will complement the National Strategy for Quality Improvement in Health Care, also described in the ACA.

The Plan aligns with quality of care improvement initiatives under the Children's Health Insurance Program Reauthorization Act and complements the Centers for Medicare and Medicaid (CMS)'s work to improve access to and measurement of mandatory health care services delivered children enrolled in Medicaid through the Early and Periodic Screening, Diagnostic, and Treatment Program. The Plan also supports the GHI, which focuses on improving the health of women, newborns, and children worldwide through strengthened health systems and through coordinated, results-oriented, country-led approaches. Additionally, the Plan complements other initiatives including the U.S. President's Emergency Plan For AIDS Relief, which assists countries in strengthening their health systems and providing comprehensive prevention, care, and treatment to combat the global epidemic of HIV/AIDS and diplomatic efforts to build global partnerships in preparation for pandemic influenza and other pandemic diseases. For a full list of relevant plans please see Appendix 4.

Understanding the extensive scope of the vaccine and immunization enterprise, the Plan also encompasses relevant strategic visions within other federal agencies. These include the HP 2020 objectives as well as the full spectrum of strategies articulated in the effort to develop medical countermeasures against bioterrorist threats, the threat of pandemics, and new and emerging infectious disease threats.[11]

11. For example, see BARDA strategic plan at www.hhs.gov/aspr/barda/phemce/enterprise/strategy/index.

Implementation Opportunities and Challenges

Many factors may affect achievement of the 2010 National Vaccine Plan. Opportunities may emerge that facilitate rapid progress and achievement of objectives sooner than anticipated. Scientific, technological, health care financing, or communications advances also could emerge, enabling rapid achievement of the vision laid forth by the Plan, superseding its objectives and goals. Conversely, existing challenges and barriers may be more difficult to overcome than anticipated and new challenges may surface.

The 2010 National Vaccine Plan will rely on sound science and includes measurable goals, timelines, and accountability measures for the elements that have been identified as highest priority as noted in Table 1. These priorities take into account the suggestions of the IOM, the NVAC, and the agencies involved in developing, implementing and evaluating the 2010 National Vaccine Plan. These priorities also provide strategic action steps to ensure that the nation has a robust immunization program; they are not however intended to be a comprehensive list of all activities related to vaccines and immunizations. The actions described in the Plan are conditional, serve as a guideline for future development, and are subject to the availability of resources.

Indicators for tracking progress in meeting each of these priorities are under development and will be included in an Implementation Plan to be released in 2011. These indicators will represent the federal government's plan for measuring progress toward meeting the Plan's goals and include immediate, short-term, and longer-term actions. In 2011, NVPO will consult with federal agencies to implement these priorities and develop indicators for 2012 and beyond and update them as necessary. Additionally, as federal agencies begin to implement the Plan and as discussions continue with stakeholders, new indicators may also be developed.

Implementing the 2010 National Vaccine Plan does not fall to the federal government alone. The success of this plan will require states, tribal and local governments, components of the health care delivery system, communities and other stakeholders to work together to ensure a coordinated and comprehensive immunization program. See Appendix 5 for a list of immunization stakeholders. The priorities and the Plan are intended to serve as a catalyst for all stakeholders to develop their own implementation plans for achieving the goals of the 2010 National Vaccine Plan.

Table 1:
National Vaccine Plan Priorities for Implementation

A.	Develop a catalogue of priority vaccine targets of domestic and global health importance (**Goal 1**).
B.	Strengthen the science base for the development and licensure of new vaccines (**Goals 1 and 2**).
C.	Enhance timely detection and verification of vaccine safety signals and develop a vaccine safety scientific agenda (**Goal 2**).
D.	Increase awareness of vaccines, vaccine-preventable diseases, and the benefits/risks of immunization among the public, providers, and other stakeholders (**Goal 3**).
E.	Use evidence-based science to enhance vaccine-preventable disease surveillance, measurement of vaccine coverage, and measurement of vaccine effectiveness (**Goal 4**).
F.	Eliminate financial barriers for providers and consumers to facilitate access to routinely recommended vaccines (**Goal 4**).
G.	Create an adequate and stable supply of routinely recommended vaccines and vaccines for public health preparedness (**Goal 4**).
H.	Increase and improve the use of interoperable health information technology and electronic health records (**Goal 4**).
I.	Improve global surveillance for vaccine-preventable diseases and strengthen global health information systems to monitor vaccine coverage, effectiveness, and safety (**Goal 5**).
J.	Support global introduction and availability of new and under-utilized vaccines to prevent diseases of public health importance (**Goal 5**).

Goal 1:
Develop new and improved vaccines

Introduction

The greatest and most rapid changes in health occurred during the last century, primarily attributed to a higher standard of living, improved public health measures, and the application of science-based medicine. In addition to clean water, sanitation, and the use of antibiotics, vaccines are an essential part of these public health achievements. Vaccine research and development as well as the implementation of effective vaccine delivery programs has led to the eradication and elimination of several once-common serious infectious diseases.

Discovery begins with the recognition of an infectious disease burden and the opportunity to prevent it through immunization. Basic scientific research brings ideas forward into the product development pathway toward the ultimate goal of translating these ideas into safe and effective medical products. Safety and efficacy testing are conducted at every step of this product development pathway. Both basic and targeted research is the basis for the development of vaccine candidates and new vaccine platforms that offer greater flexibility in vaccine development and production. New tools, such as efficient antigen identification techniques, coupled with a profoundly greater understanding of the immune response are available to define basic mechanisms of disease to support design and development of novel and improved vaccines. Determining "proof of concept" regarding immunogenicity and safety follows – initially in pre-clinical studies in animals and then in humans to further evaluate safety and efficacy. Finally, researchers conduct scientific characterization of the vaccine and the process for producing it, including scaling the manufacturing process to commercial levels before vaccines are moved into human testing.

Vaccines are developed through public-private partnerships – including researchers, government, manufacturers, purchasers, and policy-makers -- who have been successful at bringing new vaccines to licensure for broad use. These partnerships are central to the success of vaccine innovations. Through targeted investments in science and technology, such partnerships have led to the development of hundreds of vaccine candidates at various stages of maturity in the development pipeline. The Global HIV Enterprise is an example of unprecedented collaboration among organizations worldwide, including the National Institutes of Health (NIH), the International AIDS Vaccine Initiative, USAID, the Bill and Melinda Gates Foundation, and many others working together to accelerate the development of a preventive HIV vaccine.

Because vaccine development is time- and resource-intensive, establishing and understanding priorities for development and encouraging collaboration between stakeholders is essential in addressing the challenges of developing new and improved vaccines. Fostering continued investment from all sectors is critical as technological approaches and disease threats expand amid increasing costs to develop, license, and deliver vaccines.

The aim of Goal 1 is to develop new and improved vaccines and to address the upstream research and development aspects of vaccines for domestic and global health priorities. The research needs of other aspects of the vaccine enterprise (e.g., program implementation, distribution logistics, communication) are included within other goals in the Plan.

Objectives

Objective 1.1
Prioritize new vaccine targets of domestic and global public health importance.

Strategies:

1.1.1
Develop and implement a process for prioritizing and evaluating new vaccine targets of domestic and global public health importance. This catalogue of vaccine targets (including improved vaccines) should include an analysis of barriers to development.

1.1.2
Conduct and improve disease surveillance of existing pathogens and optimize methods to detect new pathogens to continuously inform the priorities for potential new vaccines.

Objective 1.2
Support research to develop and manufacture new vaccine candidates and improve current vaccines to prevent infectious diseases.

Strategies:

1.2.1
Conduct and support expanded vaccine research to meet medical and public health needs. Establish surveillance systems or studies to better assess disease burden in specific target populations including neonates, infants, children, older adults, pregnant women, immunocompromised individuals, and other at-risk individuals.

1.2.2
Advance research and development toward new and/or improved vaccines that prevent infectious diseases and their sequelae, including those that protect against emerging, re-emerging, and important biodefense-related pathogens.

1.2.3
Advance the science of neonatal and maternal immunity including immunization and the development of immunological models to study maternal immunization and effects on offspring.

1.2.4
Develop a process that identifies current vaccines that would benefit from improved performance characteristics (e.g., effectiveness, safety, number of doses, stability, and/or vaccine administration characteristics) that can be used in the evaluation and licensure process.

1.2.5
Develop new approaches to vaccine manufacturing (e.g., rapid, flexible, and cost-effective) to meet demands for efficient, expandable vaccine production capacity while also meeting needs related to other public health emergency threats such as international emerging diseases.

Objective 1.3
Support research on novel and improved vaccine delivery methods.

Strategies:

1.3.1
Develop and evaluate new and improved alternate delivery methods of vaccine administration to optimize the protective immune response, safety, effectiveness, and/or efficiency (e.g., number of doses).

1.3.2
Expand knowledge regarding the induction and maintenance of vaccine immune responses via different routes of administration (e.g., mucosal surfaces).

Objective 1.4
Increase understanding of the host immune system.

Strategies

1.4.1
Define the capacity and quality of innate and adaptive human immune response to infections among diverse gender, ethnic, racial, age (childhood, adolescence, and adulthood), and health condition status (e.g., autoimmune compromised individuals) populations in order to advance the understanding of immune protection.

1.4.2
Gain a better understanding of how induction and recall of immune memory may inform the development of vaccines that provide life-long protection.

1.4.3
Support development of immunomodulators including vaccine adjuvants that facilitate the appropriate cell-mediated and antibody responses for protection against pathogens with distinct effector requirements.

1.4.4
Expand knowledge of host-related factors that impact severity of disease and vaccine-induced host immune response, and use this information to inform vaccine development.

1.4.5
Develop a database of gene-expression and immunologic responses to selected currently licensed vaccines with a focus on signals that correlate with mechanism of action, protection, safety, and adverse events. Utilize this compendium to inform development of new candidate vaccines and adjuvants.

1.4.6
Study mucosal immunity following vaccination in order to better understand vaccine mechanisms and to provide new, potentially more relevant, correlates of protection against respiratory, enteric, genital, and urinary pathogens.

Objective 1.5
Support product development, evaluation, and production techniques of vaccine candidates and the scientific tools needed for their evaluation.

Strategies
1.5.1
Support applied research to develop rapid and cost-efficient production, and optimize formulations and stability profiles of currently available vaccines.

1.5.2
Support research on and development of more flexible and agile approaches to product development, manufacturing production techniques including multi-use technologies such as platforms, and quality testing procedures (e.g., potency and safety testing).

1.5.3
Improve access to pilot lot manufacturing facilities that produce clinical grade material for evaluating promising vaccine candidates.

1.5.4
Support translational research that accelerates the development of information that can be used in the evaluation and licensure process.

1.5.5
Establish and strengthen public and private partnerships to address urgent needs in vaccine research and development.

Objective 1.6
Improve the tools, standards, and approaches to assess the safety, efficacy, and quality of vaccines.

Strategies
1.6.1
Improve assay development for characterization of novel cell substrates.

1.6.2
Improve efforts to develop, refine, and validate new biomarkers and correlates of immunity.

1.6.3
Develop and improve methods to better assess vaccine efficacy and safety including assessment of new technologies and development of better animal models.

1.6.4
Improve methods for assessing and evaluating vaccine quality, potency, safety, and effectiveness.

Goal 2:
Enhance the vaccine safety system

Introduction

The U.S. has a robust vaccine safety system. The goal of this system is to identify in a timely manner and minimize the occurrence of adverse events from vaccines. Past successes and challenges offer insights into areas where the existing vaccine safety system can be enhanced. Advances in information technology enhance the ability to conduct active surveillance. Improvements in understanding of immunology and genomics create opportunities to better comprehend the immune response and biological mechanisms important for understanding the safety of vaccines.

Vaccine safety is a key element of any immunization program. The vision of Goal 2 is to specifically address safety-related issues, strengthen the system that monitors the safety of vaccines throughout production and use, and advance the safety profile of vaccines.[12] Specifically, this goal aims to prevent adverse events and fully characterize the safety profile of vaccines in a timely manner.

Vaccine safety science is often challenging because it may require studying very rare outcomes. However, tools have been developed that help detect and quantify exceedingly rare events. Importantly, a vaccine safety monitoring system should have the capacity to distinguish a potential increased risk of a vaccine adverse reaction from an adverse event following immunization[13] that is occurring because of other diseases or exposures. Every day, people suffer from heart attacks, severe headaches and other health problems and some of these will naturally coincide with vaccination. Moreover, as the ability of epidemiology to rule out a very rare event is difficult, new technologies and multi-disciplinary research can help elucidate biological mechanisms and subpopulations at increased risk for adverse events and help address these scientific challenges.

Several important vaccine safety issues are addressed in other goals of the 2010 National Vaccine Plan. For example, Goal 1 addresses vaccine research and development that includes the importance of safety assessments in pre-clinical and clinical vaccine evaluation. Issues related to education, risk communications, behavioral science research, and stakeholder engagement on vaccine safety are included in Goal 3. Because vaccine safety is an important component of every immunization program, whether in the U.S. or globally, it is also featured in Goals 4 and 5.

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12. Throughout Goal 2, the following terms are frequently used: "signal" and "vaccine adverse reaction." These terms as are defined as:

    Signal: While there are multiple definitions of signals, in this document a signal refers to a concern that a vaccine adverse event could be temporally occurring more often than anticipated based on chance alone (i.e., that the event could be related to the receipt of the vaccine). A signal is not proof of causation; rather it represents the need for further evaluation. Signals may arise from a variety of sources, including from pre-licensure clinical trials, case series, surveillance, clinical experience, the literature, expert committee reviews, the media and/or the public.

    Vaccine adverse reaction is an adverse event caused by a vaccine. Vaccine adverse reactions are defined as minor, such as a sore arm or low grade fever, or can be more severe such as anaphylaxis. Vaccine adverse reactions are dichotomized as local (e.g., sore arm, swelling at site of injection) or systemic (e.g., fever, irritability).

13. *Adverse event following immunization* (AEFI) is an adverse event temporally associated with an immunization that may or may not be causally related to the immunization. The term "vaccine adverse event" is also commonly used to convey the same meaning.

Objectives

Objective 2.1
Ensure a robust vaccine safety scientific system that focuses on high priority areas.

Strategies:

2.1.1
Develop, prioritize, and regularly update a national vaccine safety scientific agenda.

2.1.2
Retain current and recruit additional highly trained vaccine safety scientists and clinicians.

2.1.3
Improve laboratory, epidemiological, and statistical methods used in vaccine safety research.

Objective 2.2
Facilitate the timely integration of advances in manufacturing sciences and regulatory approaches relevant to manufacturing, inspection, and oversight to enhance product quality and patient safety.

Strategies:

2.2.1
Facilitate the enhancement of vaccine manufacturing sciences and quality systems, including production technologies, in-process controls and testing, and identification of best practices in preventive quality systems and oversight.

2.2.2
Develop, implement, and periodically reassess risk-based scientific approaches to identify inspectional priorities and best practices.

2.2.3
Develop new scientific methods for both industry and the Food and Drug Administration (FDA) for product quality testing.

2.2.4
Assure that regulations, guidance documents, policies, and procedures that are relevant to vaccine manufacturing, laboratory testing, and quality control incorporate the most current relevant scientific information to promote and enhance product safety.

Objective 2.3
Enhance timely detection and verification of vaccine safety signals.

Strategies

2.3.1
Improve the effectiveness and timeliness of signal identification and assessment through coordinated use of passive and active surveillance systems, and from providers and the public.

2.3.2
Improve the process for assessing AEFI signals to determine which signals should be evaluated further in epidemiological and clinical studies.

Objective 2.4:
Improve timeliness of the evaluation of vaccine safety signals, especially when 1) a high-priority new vaccine safety concern emerges or 2) when a new vaccine is recommended, vaccination recommendations are expanded, or during public health emergencies such as in an influenza pandemic or other mass vaccination campaign.

Strategies
2.4.1
Expand collaboration with clinical, laboratory, genetic, statistical, and bioinformatics experts to conduct clinical research studies to investigate the role of host genetics in AEFIs.

2.4.2
Increase the size, representativeness, and utility of the population under active surveillance for serious AEFIs that can be included in timely, high quality, rigorously conducted epidemiological studies to assess vaccine safety questions.

Objective 2.5
Improve causality assessments of vaccines and related AEFIs.

Strategies
2.5.1
Build upon new scientific developments in areas such as genetics, systems biology and bioinformatics, and immunology to develop and validate tools which aid in (or enable) the identification of individual risk factors for AEFIs for which a causal relationship has been established.

2.5.2
Assess the evidence for a causal relationship between certain vaccines and specific clinically important AEFIs and, as the need arises, conduct an independent review of available evidence.

Objective 2.6
Improve scientific knowledge about why and among whom vaccine adverse reactions occur.

Strategies
2.6.1
Identify host risk factors that may be associated with increased risk for specific vaccine adverse reactions through basic, clinical, or epidemiological research.

2.6.2
Identify the biological mechanism(s) for vaccine adverse reactions.

2.6.3
Assess whether the risk of specific AEFIs is increased in specific populations such as pregnant women, premature infants, older adults, those with immunocompromising or other medical conditions, based on gender or race/ethnicity, or other at-risk individuals.

2.6.4
Develop a robust system to enhance collection of medical histories and biological specimens from selected persons experiencing serious AEFIs to enhance study of biological mechanisms and individual risk factors.

Objective 2.7
Improve clinical practice to prevent, identify and manage vaccine adverse reactions.

Strategies

2.7.1
Improve training, availability of, and access to vaccine safety clinical and communication experts to provide consultation to health care providers and public health practitioners.

2.7.2
Develop and disseminate evidence-based guidelines for vaccination or revaccination, as appropriate, especially for persons who may be at increased risk for vaccine adverse events. Use this information to clarify contraindications and precautions to vaccination.

Objective 2.8
Enhance collaboration of vaccine safety activities.

Strategies

2.8.1
Improve collaboration, such as data sharing arrangements, across federal agencies, departments, and with non-federal partners.

2.8.2
Improve information and data sharing with international partners (e.g., national vaccine safety programs) consistent with ethical and human subjects protections and applicable law, including confidentiality protections.

2.8.3
Develop additional standard case definitions for AEFIs for use in immunization safety surveillance and research, vaccine safety standards such as concept definitions, standardized abbreviations, and standardized study designs.

Goal 3:
Support communications to enhance informed vaccine decision-making

Introduction

HHS is committed to providing accurate, timely, transparent, complete, and audience-appropriate information about immunizations and vaccines. This information is designed for parents making vaccination decisions for their children (birth through age 18); adults considering vaccines for themselves; public health partners; providers; policy-makers and others.

Communication tools and channels used to disseminate immunization and vaccine information span a broad spectrum: publication of evidence-based recommendations; use of mass media and new media; provider education and training; and support of partner organizations and state immunization programs through provision of resources, trainings, updates, and announcements.

Current communication efforts are informed by research as well as the principles of effective risk communication, social marketing, and social mobilization. Research should be enhanced to better understand the nature of informed decision-making and the elements that support such decisions. Improved communications research can facilitate development of more targeted messages and methods for clearly and effectively communicating about the benefits and risks of vaccines, and to address information needs unique to various audiences. The combined efforts of communication scientists, health services researchers, and others can enhance the development and implementation of long-term, sustainable plans for gathering reliable real-time data about facilitators of and barriers to vaccine acceptance, translating those data into practical solutions. This research also enhances efforts to promote the adoption of vaccine recommendations to prevent disease and improve the public's health.

The 2010 National Vaccine Plan recognizes the importance of communication activities that are strategic, science-based, transparent, and culturally appropriate. Communication strategies should reflect the health literacy level and English proficiency of specific target population groups, as well as considerations of the accessibility of information to individuals with hearing, visual, cognitive, or other limitations. Related to these goals are the roles and responsibilities of various stakeholders engaged in vaccine communications and education. Policy-makers, such as federal, state, and local legislators; health departments; employers; third-party payors and others, are critical stakeholders in the vaccine enterprise. Collaborating with public health decision makers across the health sector is critical to realizing the full vision of the plan. Health care providers, advocacy groups, the public health community, and community and faith-based organizations can serve as strong and credible immunization advocates about the risk of VPDs, the benefits of vaccination, recommended schedules, the supply and financing of vaccines, and the possible risks associated with vaccination. Public-private collaboration on communication and education activities will be critical to achieving the goal and objectives set forth by the Plan.

While the focus of Goal 3 is on communication and education issues relevant to informed decision-making, these issues are also relevant to each of the other goals of the 2010 National Vaccine Plan. Topic-specific communications and education activities are described in Goals 2, 4, and 5.

Objectives

Objective 3.1
Utilize communication approaches that are based on ongoing research.

Strategies
3.1.1
Conduct research regularly to understand the public's knowledge, beliefs, and concerns about vaccines and VPDs.

3.1.2
Conduct research on factors that affect decision-making about vaccination for individuals and families, providers, and policy-makers.

3.1.3
Identify, develop, and test educational strategies that better enable policy-makers to read, understand, and use information about vaccine benefits and risks.

3.1.4
Evaluate the effectiveness of messages and materials in addressing the information needs and concerns of the public and under-immunized populations.

3.1.5
Develop evidence-based tools to assist individuals, parents, and providers with relevant information to make informed decisions regarding vaccination.

Objective 3.2:
Build and enhance collaborations and partnerships for communication efforts.

Strategies
3.2.1
Strengthen existing partnerships and coalitions and build relationships with new partners to support relevant immunizations across the lifespan.

3.2.2
Use cross-agency and intra-agency collaboration to inform development of communication research agendas, protocols, campaigns and messages.

3.2.3
Collaborate with partners and stakeholders to communicate vaccine benefits, risks, and recommendations in accessible formats and in culturally appropriate languages, methods, and literacy levels.

3.2.4
Utilize state and local venues to educate on vaccine and immunization issues to expand the reach of messages outside of the traditional clinical setting.

Objective 3.3
Enhance delivery of timely, accurate, and transparent information to public audiences and key intermediaries (such as media, providers, and public health officials) about what is known and unknown about the benefits and risks of vaccines.

Strategies

3.3.1
Enhance communication of new findings about vaccine effectiveness, safety, and administration studies to the public, partners and providers in a clear, transparent and timely manner.

3.3.2
Respond in a rapid, coordinated, consistent, and effective manner to emerging vaccine issues and concerns (e.g., supply, safety, or public health emergencies).

3.3.3
Rapidly and effectively disseminate communications research findings through peer-reviewed journals, conferences, media, and partner communications to facilitate implementation of evidence-based strategies.

Objective 3.4
Increase public awareness of the benefits and risks of vaccines and immunization, especially among populations at risk of under-immunization.

Strategies

3.4.1
Develop, implement, and evaluate a long-term strategic communications plan and program aimed at educating parents, caregivers of children, adolescents, and adults about VPDs; the benefits and risks of vaccines; and vaccine recommendations.

3.4.2
Maintain current, easily accessible, evidence-based online information on VPDs and vaccines, including benefits and risks and the basis of immunization recommendations, for all audience groups.

3.4.3
Evaluate new media (such as mobile technologies and social media) and utilize it appropriately to reach target audiences with accurate and timely information about vaccines and to respond to emerging concerns and issues.

3.4.4
Enhance awareness of the importance of immunization as part of preventive health care among parents, adolescents, and adults.

3.4.5
Collaborate with the education community to assess opportunities to integrate information on VPDs, recommended vaccines, preventive health care, and public health in existing educational curricula.

3.4.6
Develop and disseminate vaccine communication tools/materials that are accessible and culturally and literacy-level appropriate for groups at risk of under-immunization.

Objective 3.5:

Assure that key decision- and policy-makers (e.g., third-party payers, employers, legislators, community leaders, hospital administrators, health departments) receive accurate and timely information on vaccine benefits and risks; economics; and public and stakeholder knowledge, attitudes, and beliefs.

Strategies

3.5.1

Develop, disseminate, and evaluate broad-based education tools for key groups on the value, risks, and cost-effectiveness of vaccines; the basis of immunization recommendations; business case evidence and guidance; vaccine policy development; the standards of immunization practice and administration; and vaccines as a component of preventive health care.

3.5.2

Select and implement a model for sustained community engagement to inform vaccine policy and program activities.

3.5.3

Provide vaccine program managers and policy-makers information on the direct and indirect costs and benefits of vaccination. This includes, but is not limited to, information on federal and state programs that offer low-cost vaccines.

3.5.4

Provide policy-makers with data necessary to make informed decisions on the utilization of vaccines in mass vaccination programs for public health emergencies.

Goal 4:
Ensure a stable supply of, access to, and better use of recommended vaccines in the United States

Introduction

VPD incidence in the U.S. is at or near record-low levels for most diseases against which children are routinely immunized; infant and child vaccination rates are approaching or meet record levels. However, coverage levels are below HP 2020 targets for many vaccines targeted to adolescents and adults, and substantial disparities exist among racial and ethnic groups in adult and adolescent vaccination levels. Limited knowledge about recommended vaccines and attitudes towards vaccines exist among the public, health care professionals, and health policy- and decision-makers. Lack of health care access and financial barriers also contribute to these disparities and need to be addressed in strategies moving forward. Research on how best to overcome such barriers will dictate strategies and practices. Ongoing partnerships among national, state, local, tribal, private, and public entities are needed to sustain and improve vaccine use and the concomitant individual and public health benefits.

Ensuring a reliable and steady supply of all vaccines is critical in the U.S., where shortages of several commonly used vaccines have occurred since 2000 (e.g., Hib, hepatitis A, and influenza). New 21st-century vaccine supply concerns, such as vaccines for pandemic influenza, emerging diseases and bioterrorism threats, present different challenges for sustainability and may require surge manufacturing capacity compared with traditional vaccine pathways.

Immunization information systems (IIS) and electronic health records (EHR) may become increasingly important components of immunization programs. Jointly they can lead to much better immunization recordkeeping for children and adults, thereby reducing the barrier of unknown immunization status and the receipt of additional unneeded doses of vaccines and enhancing efficiency and cost-effectiveness of national immunization efforts.

Strong public health surveillance to monitor and evaluate VPDs and the effectiveness of licensed vaccines provides the link between vaccination policy and health outcomes. Such public health surveillance is a key component of strategies to overcome barriers and improve use of existing vaccines.

Challenges persist to improve vaccination rates and to incorporate new vaccines into child and adolescent vaccination schedules. Between 2005 and 2010, six new vaccines or vaccine recommendations were added for children and adolescents by the ACIP and the Centers for Disease Control and Prevention (CDC):

- meningococcal conjugate vaccine
- tetanus, diphtheria, acellular pertussis vaccine
- HPV vaccine
- rotavirus vaccine
- universal influenza vaccination
- 13-valent pneumococcal conjugate vaccine.

Barriers to improved vaccine uptake include persistent cost, awareness and access problems; lack of knowledge of necessary vaccines; and limited use of evidence-based strategies to improve vaccine uptake, such as reminder-recall systems. Community health centers, other community immunization sites (e.g., pharmacies and stores) and school-located clinics offer venues for improving vaccine uptake, in addition to traditional provider sites.

Goal 4 identifies nine objectives and related strategies to strengthen our nation's vaccination program and overcome barriers. Enhancing communication and education activities about vaccination is a key approach to overcome many of the current challenges identified in Goal 4, and is addressed in detail in Goal 3.

Objectives

Objective 4.1
Ensure consistent and adequate supply of vaccines for the U.S.

Strategies
4.1.1
Determine barriers to having multiple suppliers for each vaccine licensed and recommended for routine use in the U.S.

4.1.2
Promote harmonization of international vaccine regulatory standards for licensure.

4.1.3
Improve vaccine quality and availability through better manufacturing and production oversight.

4.1.4
Optimize use, content, and distribution of vaccine stockpiles and ancillary supplies.

4.1.5
Improve the development of, communication of, and tracking of adherence to recommended changes in vaccine use during national vaccine shortages.

Objective 4.2
Ensure consistent and stable delivery of vaccines for the U.S.

Strategies
4.2.1
Improve vaccine ordering, distribution and tracking systems for routine use, for public health emergencies, and for management of delivery disruptions.

4.2.2
Enhance public sector infrastructure to support and sustain adult immunization activities, including addressing disparities in vaccination rates among racial and ethnic minorities and unvaccinated refugees resettling to the U.S.

4.2.3
Expand access to vaccination at medical care sites for children, adolescents, and adults, such as by increasing hours of operation and establishing specific vaccination clinics at selected times of the year (e.g., "back to school" campaigns).

4.2.4
Expand access to vaccination in non-health care settings, such as retail outlets, schools, workplaces, and community centers.

4.2.5
Develop, monitor, and evaluate policies promoting vaccination for patients in long-term care facilities and hospitals.

4.2.6
Develop, implement, and evaluate employer-based immunization programs, which should include free vaccines, convenient access, education, and compliance monitoring, to increase the coverage of employees, including health care workers, with recommended vaccines.

4.2.7
Implement, monitor, and evaluate evidence-based interventions designed to raise and sustain high vaccination coverage across the lifespan.

4.2.8
Monitor and evaluate the impact of state immunization laws and regulations on vaccine coverage, including childcare, pre-school, school, college prematriculation requirements, employer requirements, and the role of exemptions, insurance mandates, and immunization information systems requirements.

4.2.9
Prepare, practice, and evaluate mass vaccination activities, including vaccine administration, for scenarios such as an outbreak of a VPD, for a biological attack, for the critical workforce in advance of an influenza pandemic, and for the entire population, prior to and during, an influenza pandemic.

Objective 4.3
Reduce financial barriers to vaccination.

Strategies
4.3.1
Identify and regularly monitor financial barriers to receipt of ACIP-recommended and CDC-adopted vaccines.

4.3.2
Ensure that out-of-pocket costs for purchase and administration of ACIP-recommended and CDC-adopted vaccines do not represent a significant financial barrier.

4.3.3
Strengthen the ability of states to purchase, and expand access to, ACIP-recommended and CDC-adopted vaccines for those who qualify for publicly supported vaccinations.

4.3.4
Develop, implement, and evaluate strategies to reduce the financial burden on vaccination providers for purchase of initial and ongoing vaccine inventories.

Objective 4.4
Maintain and enhance the capacity to monitor immunization coverage for vaccines routinely administered to all age groups.

Strategies
4.4.1
Identify, implement, and evaluate cost-effective and rapid methods, such as the use of IIS or internet panel surveys, for assessing vaccination coverage by categories, including age groups, groups at risk of under immunization, by type of vaccine, and type of financing.

4.4.2
Improve the completeness of, use of, and communication between, IIS and EHR to monitor vaccination coverage.

4.4.3
Support the adoption of national certified, interoperable health information technology and EHR for immunization.

4.4.4
Support and improve existing surveys assessing immunization coverage (e.g., the National Immunization Survey and the Behavioral Risk Factor Surveillance System), to include more representative samples and timely reporting of data.

Objective 4.5
Enhance tracking of VPDs and monitoring of the effectiveness of licensed vaccines.

Strategies
4.5.1
Strengthen epidemiologic and laboratory methods and tools to diagnose VPDs, assess population susceptibility, and characterize vaccine effectiveness and the impact of vaccination coverage on clinical and public health outcomes.

4.5.2
Monitor circulating strains of relevant vaccine-preventable and potentially vaccine-preventable pathogens, including emerging and re-emerging diseases.

4.5.3
Improve monitoring of disease burden and determine epidemiologic and clinical characteristics of cases of VPDs and potential VPDs by supporting traditional surveillance and use of health information technology, interoperable data standards, and new data resources.

4.5.4
Develop and maintain capacity to rapidly estimate the effectiveness of new vaccines, such as pandemic and pre-pandemic influenza vaccines.

4.5.5
Assure rapid and comprehensive identification, investigation, and response to vaccine-preventable disease outbreaks.

4.5.6
Assure timely evaluation to assess vaccine effectiveness, duration of protection, and indirect (community and herd) protection by current and newly recommended vaccines.

Objective 4.6
Educate and support health care providers in vaccination counseling and vaccine delivery for their patients and themselves.

Strategies
4.6.1
Expand and implement training and education of health care providers on VPDs, including diagnosis, modes of transmission, prevention and control, and reporting requirements.

4.6.2
Expand and implement training and education of immunization providers at all levels of their education on the proper use and administration of vaccines; the proper storage and handling of vaccines; the basis of immunization recommendations; the safety of vaccines; reporting of AEFIs; understanding of the vaccine safety system; and on the standards of immunization practice (e.g., vaccine education modules in primary care and continuing medical education programs).

4.6.3
Develop a plan to reduce and ultimately eliminate errors in vaccine administration (e.g., wrong vaccine, dose, injection site, or timing).

4.6.4
Promote and support educational and technical assistance to improve business practices associated with providing immunizations, such as educating providers and enrolling new providers into the Vaccines for Children program, including non-traditional providers.

4.6.5
Expand the incorporation of vaccinations and the use of IIS into quality improvement programs such as the Healthcare Effectiveness Data and Information Set.

4.6.6
Support adequate reimbursement for vaccine counseling, administration, storage and handling by providers under public sector and private health plans.

4.6.7
Support research to evaluate the capacity (accommodating the increased number of patient visits required to receive recommended vaccines) of health care providers to implement vaccine recommendations for all age groups.

4.6.8
Develop, implement, and evaluate comprehensive programs to ensure health care professionals are appropriately immunized with recommended vaccines.

Objective 4.7
Maintain a strong, science-based, transparent process for developing and evaluating immunization recommendations.

Strategies
4.7.1
Obtain broad-based input from the public and stakeholders contributing to new immunization policies and the assessment of existing policies.

4.7.2
Assess the impact of new vaccines and vaccine recommendations on the overall immunization schedule, including programmatic implementation, safety, and efficacy.

4.7.3
Evaluate the cost-effectiveness and comparative effectiveness of proposed and existing immunization recommendations.

Objective 4.8
Strengthen the National Vaccine Injury Compensation Program (VICP) and Countermeasures Injury Compensation Program (CICP).

Strategies
4.8.1
Increase knowledge about the VICP and CICP among all stakeholders.

4.8.2
Assure the programs are responsive to evolving science, including regularly updating their Vaccine Injury Tables.

4.8.3
Continue to ensure fair and efficient compensation for vaccine-related injuries.

4.8.4
Examine alternative approaches, and evaluate and implement those deemed optimal, for adjudication of VICP claims for illnesses not included in the Vaccine Injury Table to the extent permitted by applicable law.

Objective 4.9
Enhance immunization coverage for travelers.

Strategies
4.9.1
Define the populations at risk for acquiring international travel-related VPDs, and identify and address barriers to their receiving immunizations.

4.9.2
Assess overall immunization status during travel-related immunization clinics.

Goal 5:
Increase global prevention of death and disease through safe and effective vaccination

Introduction

Infectious diseases are the leading cause of death among children globally and contribute substantially to disease and disability among persons of all ages. Immunization programs have been remarkably successful in preventing millions of childhood deaths, eradicating smallpox, and eliminating circulation of polio and measles from many countries around the world. However, substantial challenges remain. Many diseases for which safe and effective vaccines are available pose a continued burden, as does the underutilization of vaccines in most countries (e.g., pneumococcal, rotavirus and HPV) and diseases for which vaccines are being developed (e.g., HIV, TB, and malaria). Globally mobile populations including refugees, and stateless and internally displaced persons are often difficult to reach and may not be included in national immunization programs. Achieving the United Nations' Millennium Development Goals of reducing the under-five year mortality rate by two thirds by 2015 will require substantive action, including increasing the proportion of one year-old children immunized against measles.

The goals of global vaccination are to control, eliminate, or eradicate infectious diseases in a way that strengthens health systems and is sustainable as new vaccines are introduced. Success in global immunization requires action by the full range of stakeholders involved in the vaccine and immunization enterprise: research and development, regulation and manufacturing, and program implementation and monitoring. New partnerships such as the Global Alliance for Vaccines and Immunizations (GAVI) have led to increased support for immunization worldwide, spurring introduction of new vaccines in low income countries and expanded vaccination coverage. U.S. governmental and NGOs have contributed to progress through vaccine research and development, participation in multilateral and bilateral partnerships, technical assistance, and program support.

Given the breadth of global immunization activities in Goal 5, some of the objectives and strategies relevant to this topic are included elsewhere in this Plan. For example, all vaccine research and development issues are included under Goal 1 because the approach and stakeholders necessary to achieve these objectives are largely the same in the U.S. and the rest of the world. Similarly, issues related to vaccine safety, communications and program implementation are included under this goal, as well as under other goals of the Plan, as there are unique intellectual perspectives for them. While many of the objectives in these areas are similar for the U.S. and abroad, the strategies differ internationally because U.S. stakeholders focus on partnerships and providing assistance rather than on direct implementation.

In the era of global pandemics and mass travel, the public health of U.S. citizens is closely related to diseases occurring in other countries. Even though many VPDs such as polio, measles, and rubella have been eliminated in this country, the U.S. remains vulnerable to importations as long as these diseases continue to persist elsewhere. Support for overseas (pre-departure) vaccination of mobile populations, including refugees and immigrants migrating to the U.S., will reduce the likelihood of importation. Support for developing and introducing new vaccines to address diseases in other countries and assisting with strengthening and enhancing capacity of their immunization programs contributes toward providing an "umbrella of protection" for the U.S. and fulfilling the U.S. government's broader commitment to global public health.

Meeting this commitment to support global immunization is also reflected in other federal public health initiatives and development initiatives beyond the Plan. The GHI – currently led by the U.S.

Department of State, USAID, and the CDC, with active engagement of other agencies, including the Department of Defense (DoD), NIH, and the Health Resources Services Administration (HRSA) – and FDA's global vaccine regulatory capacity building efforts through the World Health Organization (WHO) are two examples of federal initiatives that incorporate immunization as a component of a broad U.S. interest to improve maternal and child health. Additionally, the CDC has a Global Immunization Strategic Framework that focuses on how the agency will support immunization programs around the world. These and other initiatives are consistent with the objectives outlined in the Plan.

Objectives

Objective 5.1

Support international organizations and countries to improve global surveillance for VPDs and strengthen health information systems to monitor vaccine coverage, effectiveness, and safety.

Strategies

5.1.1

Achieve sustainable WHO certification quality surveillance for eradication of targeted VPDs.

5.1.2

Expand and improve sustainable surveillance systems for all diseases having WHO-recommended vaccines and diseases for which vaccine introduction is being considered.

5.1.3

Strengthen all levels of global laboratory networks (including national, regional, and global reference laboratories) to sustain and improve VPD diagnosis in order to establish baseline disease burden, detect outbreaks, detect newly emerging variants of VPDs, and monitor the impact of new vaccines. This laboratory capacity should also be developed for surveillance of potential public health emergencies of international concern.

5.1.4

Enhance assessments of emerging variants or strains of VPD agents.

5.1.5

Develop new diagnostic tests, tools and procedures to improve both field-based and laboratory confirmation of diagnoses.

Objective 5.2

Support international organizations and countries to improve and sustain immunization programs as a component of health care delivery systems and promote opportunities to link immunization delivery with other priority health interventions, where appropriate.

Strategies

5.2.1

Provide technical support to countries, multilateral institutions, and other partners to strengthen key components of immunization program management and implementation, including epidemiological analysis, comprehensive planning, vaccine distribution and safe administration, monitoring, information systems, and program evaluation.

5.2.2
Provide technical support to countries and multilateral institutions as appropriate to introduce, sustain, and monitor recommended safe injection practices for all vaccinations, including the use of auto disable syringes or needle-free devices.

5.2.3
Improve coverage monitoring of vaccines and other health services linked with the vaccination program and the use of information at district and local levels.

5.2.4
Introduce and improve programs that evaluate AEFIs.

5.2.5
Develop standardized methods for monitoring and evaluating the efficiency, effectiveness and impact of combined interventions to improve coverage, and support linking delivery of immunization and other health services in ways that do not jeopardize immunization coverage.

5.2.6
Encourage establishment of programs, as appropriate, for vaccination beyond the traditional infant target age groups (e.g., among older children, adolescents, adults, and health care providers), including unvaccinated mobile populations of various age groups since the epidemiology in some mobile populations may differ from other populations where the diseases are normally spreading in certain age-groups.

5.2.7
Provide technical support to countries, multilateral institutions as appropriate, and other partners to develop sustainable vaccine financing mechanisms and adequate global supplies of vaccines, including through economic and supply and demand analyses.

Objective 5.3
Support international organizations and countries to introduce and make available new and underutilized vaccines to prevent diseases of public health importance.

Strategies
5.3.1
Strengthen capacity at the country level, and in multilateral institutions as appropriate, to make informed decisions on introduction of new vaccines based on evaluation of epidemiology, financial sustainability, safety, and programmatic considerations, including support to national advisory committees.

5.3.2
Collaborate with global organizations and partners to accelerate clinical testing and licensure in developing countries of vaccines already licensed in developed countries, where appropriate.

5.3.3
Support the integration of new and underutilized vaccines into each GAVI-eligible country's multi-year national plan of action and provide training and logistical support necessary to successfully incorporate new vaccines into routine programs.

5.3.4
Support post-licensure evaluations of new vaccines with regard to immunization programs, disease patterns, and vaccine safety.

5.3.5
Work with global partners to establish an international system that facilitates rapid response to emerging infections through the development of vaccine reference strains and candidate vaccines.

5.3.6
Work with global partners to secure and maintain adequate stockpiles/strategic reserves of vaccines to maintain uninterrupted supply and for emergency response to outbreaks.

5.3.7
Support and develop mechanisms for rapidly making vaccines available to developing countries for public health emergencies such as pandemic influenza, including exploring options for sharing of vaccines and tiered pricing.

Objective 5.4
Support international organizations and countries to improve communication of evidence-based and culturally and linguistically appropriate information about the benefits and risks of vaccines to the public, providers, and policy-makers.

Strategies
5.4.1
Support appropriate economic studies to inform key decision- and policy-makers' understanding of the benefits and costs of immunization.

5.4.2
Support the development of capabilities to communicate vaccine benefits and risks and to respond to emerging vaccine safety issues.

5.4.3
Support national systems to improve reporting of adverse events.

5.4.4
Assist countries to develop and implement sustainable communication research to gather timely and reliable data from the public and providers on knowledge, attitudes and beliefs about the benefits and risks of vaccines.

5.4.5
Assist countries to develop communication plans to increase provider and public awareness of VPDs and promote immunization recommendations, especially among populations at risk of under-immunization.

5.4.6
Provide technical assistance and training to behavioral and communications scientists and promote their participation on Technical Advisory Groups.

5.4.7
Support and participate with partners to create and implement a global vaccine advocacy strategy.

Objective 5.5
Support the development of regulatory environments and manufacturing capabilities that facilitate access to safe and effective vaccines in all countries.

Strategies
5.5.1
Promote and support the efforts of WHO and other global partners to develop and harmonize international standards for vaccine development and licensure.

5.5.2
Promote and support the efforts of WHO and others to improve regulatory capacity in countries with limited infrastructures to assure vaccine quality, evaluate new vaccines when appropriate, and assure that clinical trials are conducted in accordance with Good Clinical Practices.

5.5.3
Provide technical assistance to developing country vaccine manufacturers to support development and production of safe and effective vaccines.

Objective 5.6
Build and strengthen multilateral and bilateral partnerships and other collaborative efforts to support global immunization and eradication programs.

Strategies
5.6.1
Participate in establishing global immunization priorities, goals and objectives and provide technical assistance at global, regional, and national levels.

5.6.2
Strengthen international collaborations for basic and applied research and related training of next generation researchers, especially in disease endemic areas, to include improving the stability and performance of current vaccines.

5.6.3
Contribute to development and implementation of a plan establishing the scientific basis for VPD eradication/elimination, identifying optimal vaccination approaches, and developing strategies to minimize risks in the post-eradication period.

5.6.4
Participate in regional immunization initiatives, such as those adopted by the Pan American Health Organization and other WHO regions.

5.6.5
Strengthen vaccination of globally mobile populations through targeted programs (e.g., pre-departure vaccination of US bound refugees).

Monitoring and Evaluation

NVPO will be responsible for assuring coordination and for monitoring federal actions and accomplishments on the 2010 National Vaccine Plan on an ongoing basis. NVPO and NVAC will report their findings to the Assistant Secretary for Health annually. This report will include a summary of progress, identify areas where progress is lagging, and propose corrective action where needed. The report also will be presented at an NVAC meeting, which is open to the public and is attended by many stakeholders not represented directly on the Committee.

Key federal stakeholders in global immunization include CDC, the Department of State and USAID. Many of the global immunization targets included in the Plan were established by international organizations (e.g., WHO) in consultation with U.S. stakeholders. However, the role of those stakeholders in achieving these targets most often involves providing technical assistance and support rather than direct implementation.

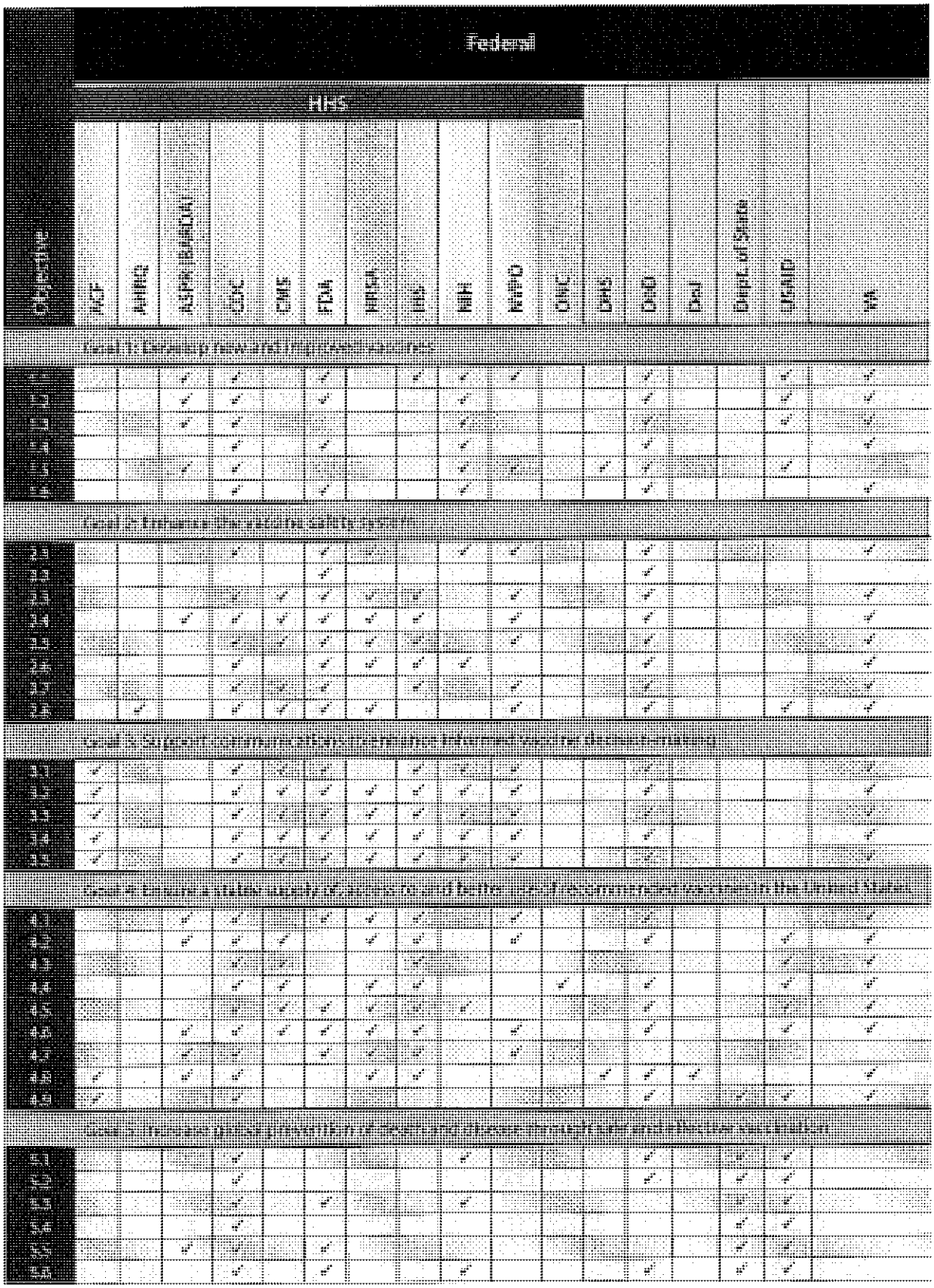
Many factors may affect the ability to achieve National Vaccine Plan objectives. Opportunities may emerge that facilitate rapid progress and achievement of objectives sooner than anticipated. Scientific, technological, health care financing, or communications advances also could emerge and enable rapid achievement of the vision laid forth by the Plan, superseding its objectives and goals. On the other hand, existing challenges and barriers may be more difficult to overcome than anticipated and new challenges may emerge. For example, a range of scientific and technical issues may delay development and licensure of new vaccines; safety concerns may affect vaccine uptake; financial constraints may affect vaccination delivery. Recognizing these uncertainties, NVPO will coordinate a mid-course review of the Plan after five years allowing changes to be made which respond to the reality of the environment. Modified indicators, strategies, actions, and milestones will guide subsequent annual evaluation through the overall ten-year horizon of the Plan.

Conclusion

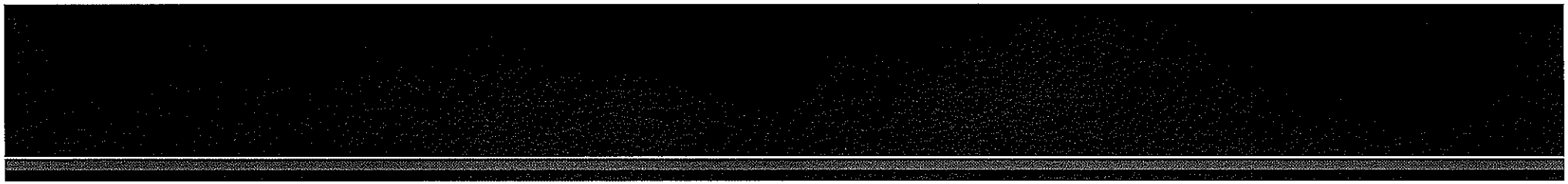
The overriding goal of this plan is to invigorate national coordination and planning on vaccines and immunizations. HHS will lead this national effort, leveraging existing resources and expertise, to maximize the control of VPDs in this country and with global partners. Given that this is intended to be not just a federal plan but represent a national strategy, it will require the partnership of stakeholders involved in all aspects of the vaccine enterprise. The goals, objectives, and strategies outlined in this document, when fully implemented, will markedly enhance the control of VPDs and the health of the public in this nation.

Table 2:

National Vacancy Plan Objectives: Responsible Stakeholders



Objective	Non-federal									
	Health care providers	Health care system	Public and private health care plans	State, local, and tribal governments	Academia	Advocacy organizations	Philanthropic organizations	Vaccine manufacturers	UNICEF	WHO
Goal 1: Develop new and improved vaccines										
1.1	✓			✓	✓		✓	✓		✓
1.2					✓		✓	✓		
1.3					✓		✓	✓		
1.4					✓		✓	✓		
1.5					✓		✓	✓		
1.6					✓			✓		
Goal 2: Enhance the vaccine safety system										
2.1				✓	✓	✓		✓		
2.2					✓			✓		
2.3		✓	✓	✓	✓			✓		
2.4		✓	✓	✓	✓			✓		
2.5		✓	✓	✓	✓			✓		
2.6					✓			✓		
2.7		✓	✓	✓	✓			✓		
2.8			✓		✓			✓		✓
Goal 3: Support communications to enhance informed vaccine decision-making										
3.1		✓	✓	✓	✓			✓		
3.2	✓	✓	✓	✓	✓	✓		✓		
3.3	✓	✓	✓	✓	✓	✓		✓		
3.4	✓	✓	✓	✓		✓		✓		
3.5		✓	✓	✓	✓	✓		✓		
Goal 4: Ensure a stable supply of, access to and better use of recommended vaccines in the United States										
4.1	✓	✓	✓	✓				✓		
4.2	✓	✓	✓	✓				✓		
4.3		✓	✓	✓				✓		
4.4	✓	✓	✓	✓	✓	✓	✓	✓		
4.5		✓	✓	✓			✓	✓		
4.6	✓	✓		✓	✓	✓		✓		
4.7		✓		✓	✓	✓		✓		
4.8		✓	✓	✓		✓	✓	✓		
4.9	✓	✓	✓	✓				✓		
Goal 5: Increase global prevention of death and disease through safe and effective vaccination										
5.1					✓	✓	✓		✓	✓
5.2					✓	✓	✓		✓	✓
5.3					✓	✓	✓		✓	✓
5.4					✓	✓	✓		✓	✓
5.5					✓	✓	✓	✓		✓
5.6					✓	✓	✓		✓	✓



7.2

The State of the

National Vaccine Plan

2013 Annual Report

U.S Department of Health & Human Services

Protecting the Nation's Health through Immunization

U.S. Department of Health and Human Services

The State of the National Vaccine Plan
2013 Annual Report

Protecting the Nation's Health through Immunization

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Acronyms and Abbreviations

ACCV – Advisory Commission on Childhood Vaccines
ACF – Administration for Children and Families
ACIP – Advisory Committee on Immunization Practices
AFENET – African Field Epidemiology Network
AHRQ – Agency for Healthcare Research and Quality
AIDS – Acquired immunodeficiency syndrome
AITF – Adult Immunization Task Force
ASH – Assistant Secretary for Health
ASPR – Assistant Secretary for Preparedness and Response
AVMI – African Vaccine Manufacturing Initiative
BARDA – Biomedical Advanced Research and Development Authority (within the Office of the Assistant Secretary for Preparedness and Response)
BSL – Biosafety Level
CBER – Center for Biologics Evaluation and Research (of the Food and Drug Administration)
CDC – Centers for Disease Control and Prevention
CMS – Centers for Medicare and Medicaid Services
CRS – Congenital rubella syndrome
DHS – U.S. Department of Homeland Security
DoD – U.S. Department of Defense
DoJ – U.S. Department of Justice
DPT – Diphtheria-pertussis-tetanus vaccine
DTaP – Diphtheria-tetanus-pertussis vaccine
EHR – Electronic health record
FDA – Food and Drug Administration
FELTP – Field Epidemiology and Laboratory Training Program (of the Centers for Disease Control and Prevention)
FY – Fiscal Year
GAP – Global Action Plan for Influenza Vaccines
GAVI – The GAVI Alliance
GBS – Guillain-Barré syndrome
GPEI – Global Polio Eradication Initiative
HepA – Hepatitis A
HepB – Hepatitis B
HepC – Hepatitis C
HHS – U.S. Department of Health and Human Services
Hib – *Haemophilus influenzae* type b
HIV – Human immunodeficiency virus
HPV – Human papillomavirus
HRSA – Health Resources and Services Administration
ICT – Information and communication technologies
IHS – Indian Health Service

IIS – Immunization information systems
IOM – Institute of Medicine
ISTF – Federal Immunization Safety Task Force
JE – Japanese encephalitis
MD – Medical Doctor
MMR – Measles, mumps, and rubella vaccine
MPH – Master of Public Health
MSM – Men who have sex with men
MVP – Meningitis Vaccine Project
NAIIS – National Adult and Influenza Immunization Summit
NCIRD – National Center for Immunization and Respiratory Diseases (within the Centers for Disease Control and Prevention)
NIAID – National Institute of Allergy and Infectious Diseases (within the National Institutes of Health)
NIH – National Institutes of Health
NNDSS – National Notifiable Disease Surveillance System
NUVI – New and Underutilized Vaccines Implementation
NVAC – National Vaccine Advisory Committee
NVPO – National Vaccine Program Office
OGA – Office of Global Affairs
ONC – Office of the National Coordinator for Health Information Technology
OPV – Oral polio vaccine
PAHO – Pan American Health Organization
PCV – Pneumococcal conjugate vaccine
PhD – Doctor of Philosophy
PRISM – Post-Licensure Rapid Immunization Safety Monitoring (a component of the Food and Drug Administration's Sentinel Initiative)
RECs – Regional Extension Centers
RePORT – Research Portfolio Online Reporting Tools (of the National Institutes of Health)
SMART Vaccines – Strategic Multi-Attribute Ranking Tool for Vaccines
TB – Tuberculosis
Td – Tetanus-diphtheria vaccine
Tdap – Tetanus-diphtheria-pertussis vaccine
UNICEF – United Nations Children's Fund
U.S. – United States
USAID – U.S. Agency for International Development
VA – U.S. Department of Veterans Affairs
VAERS – Vaccine Adverse Event Reporting System
VAMPSS – Vaccines and Medications in Pregnancy Surveillance System
VFC – Vaccines for Children program
VIS – Vaccine Information Statement
VSD – Vaccine Safety Datalink
VTrckS – Vaccine Tracking System
WHO – World Health Organization

Introduction

Vaccines have been hailed as one of the most important public health advances in human history. Vaccines save lives by preventing the transmission and consequences of infectious diseases, and are unique among medical products in that they protect health at both the individual and the community level. Thus, vaccines are not only the model of prevention, but also best represent the convergence of medicine and public health. During the 20th century, the life span of Americans increased by more than 30 years in part because of the use of vaccines, and mortality from infectious diseases in the United States has been reduced 14-fold through the use of vaccines.[1] Children born in the United States today are routinely protected against 17 serious diseases and conditions through immunization. The benefits of this routine preventive care are astonishing: for each birth cohort vaccinated using the routine immunization schedule, approximately 33,000 lives are saved, 14 million cases of disease are prevented, $9.9 billion in direct health care costs savings are achieved, and $33.4 billion are saved in indirect health care costs.[2,3]

The initial National Vaccine Plan was created in 1994 [4] to provide a strategic approach for maximizing the impact of vaccines on the health of United States (U.S.) populations. In 2010, the National Vaccine Plan was updated[5] to reflect the priorities, opportunities, and challenges of today's science and our national immunization program, and it provides a guiding vision for vaccines and immunization in the United States for the decade 2010–2020. It includes strategies for advancing vaccine research and development, financing, supply, distribution, safety, global cooperation, and informed vaccine decision-making among consumers and health care providers. This report on the State of the National Vaccine Plan, the first of what will be an annual report, provides an overview of recent accomplishments and progress that fall under the five goals of the National Vaccine Plan:

- Goal 1: Develop new and improved vaccines.
- Goal 2: Enhance the vaccine safety system.
- Goal 3: Support communications to enhance informed vaccine decision-making.

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[1] American Academy of Pediatrics. (2009). Prologue. In L. K. Pickering (Ed.), *Red Book: 2009 Report of the Committee on Infectious Diseases* (28th ed.). Elk Grove Village, IL: American Academy of Pediatrics.

[2] Zhou, F., Santoli, J., Messonnier, M. L., Yusuf, H. R., Shefer, A., Chu, S. Y., Rodewald, L., & Harpaz, R. (2005). Economic evaluation of the 7-vaccine routine childhood immunization schedule in the United States, 2001. *Archives of Pediatric and Adolescent Medicine, 159*(12), 1136–1144. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/16330737

[3] Schuchat, A. (2011). Human vaccines and their importance to public health. *Procedia in Vaccinology, 5*,120–126. Retrieved from http://www.sciencedirect.com/science/article/pii/S1877282X11000269# (exit link disclaimer)

[4] U.S. Department of Health and Human Services. (1994). *Disease prevention through vaccine development and immunization: The U.S. National Vaccine Plan – 1994.* Retrieved from http://archive.hhs.gov/nvpo/vacc_plan/1994plan/

[5] U.S. Department of Health and Human Services. (2010). *2010 National Vaccine Plan: Protecting the nation's health through immunization.* Retrieved from http://www.hhs.gov/nvpo/vacc_plan/2010%20Plan/nationalvaccineplan.pdf

- Goal 4: Ensure a stable supply of, access to, and better use of recommended vaccines in the United States.
- Goal 5: Increase global prevention of death and disease through safe and effective vaccination.

As shown in Figure 1, the National Vaccine Plan is led and coordinated by the National Vaccine Program Office (NVPO) under the direction of the Assistant Secretary for Health (ASH) within the U.S. Department of Health and Human Services (HHS), with guidance from the National Vaccine Advisory Committee. The National Vaccine Plan is a national and not a federal plan, emphasizing that many partners are needed to achieve the full promise of vaccines and immunization. These partners include federal, state, and local governments, academia, health care providers, public health organizations, health insurance providers, advocacy organizations, vaccine manufacturers and distributors, and the general public, among others. Leaders from several of these stakeholder organizations, such as the World Health Organization (WHO), the Institute of Medicine (IOM), the GAVI Alliance (GAVI), and the Bill and Melinda Gates Foundation, are among those who have provided commentaries on this report, demonstrating their commitment to the National Vaccine Plan and the contributions their organizations make to advancing the goals of the Plan. Although many partners work to achieve the goals of the National Vaccine Plan, this report focuses on the advances and accomplishments made by HHS and its agencies in collaboration with its partners, including the U.S. Agency for International Development (USAID), the Department of Veterans Affairs (VA), and the Department of Defense (DoD). The highlighted accomplishments provided in this report are reflective of (1) the extensive and ongoing coordination undertaken by NVPO in fulfillment of its mission, as laid out in the Public Health Service Act,[6] and (2) the breadth and scope of the vaccine-related activities of HHS agencies that represent just some of the extraordinary work carried out during their daily operations.

The State of the National Vaccine Plan Annual Report in Context

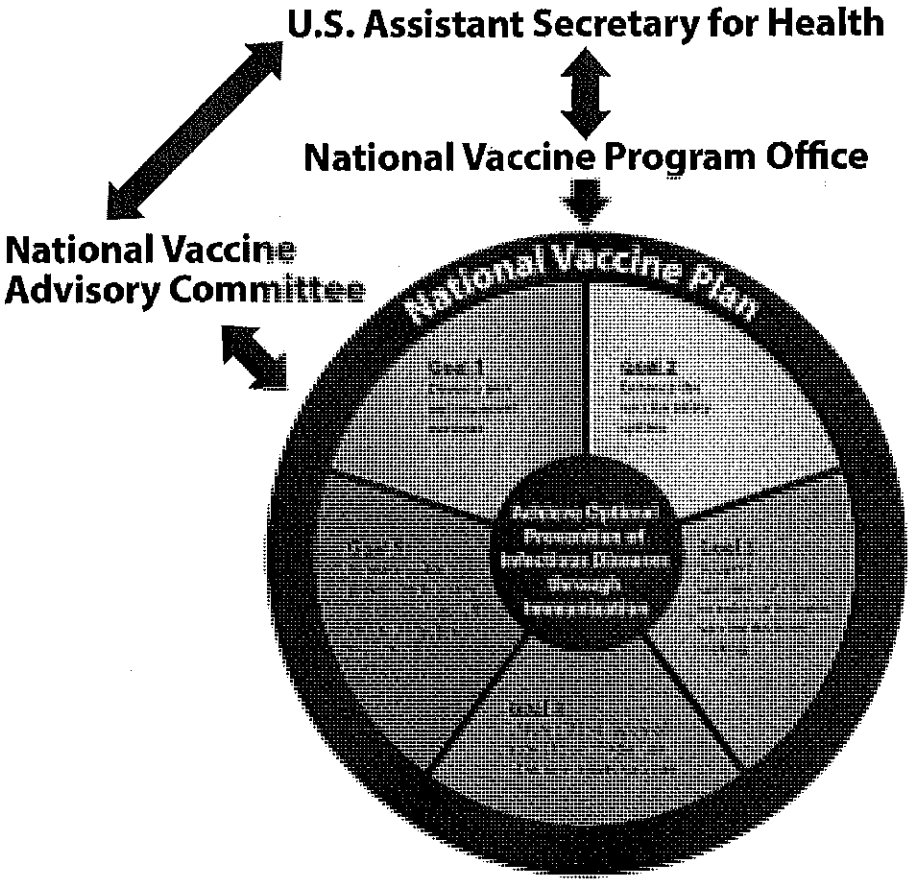
The 2010 National Vaccine Plan aligns with a number of HHS goals and objectives to reduce the occurrence of vaccine preventable diseases by focusing on strategies to improve the quality of all aspects of the immunization system, from vaccine research to vaccine delivery. As part of these efforts, the Healthy People 2020 goals for immunization and infectious diseases[7] complement the National Vaccine Plan. They set measurable targets to reduce vaccine preventable diseases by increasing vaccine coverage rates. An update on progress toward achieving Healthy People 2020 goals for infectious disease and immunization is included in this report.

The National Vaccine Plan also aligns with the 2010 Affordable Care Act's focus on prevention, and the 2010–2015 HHS Strategic Plan,[8] which highlights the importance of

[6] Public Health Service Act, 42 U.S.C. § 300aa1. Retrieved from http://www.hhs.gov/nvpo/about/legislation.pdf
[7] Healthy People 2020. (2013). *Immunization and infectious diseases topic area.* Retrieved from http://www.healthypeople.gov/2020/topicsobjectives2020/overview.aspx?topicId=23
[8] U.S. Department of Health and Human Services. (2010). *Strategic Plan 2010–2015.* Retrieved from http://www.hhs.gov/secretary/about/priorities/priorities.html

advancing the health, safety, and well-being of the American people. One of the main objectives of the HHS Strategic Plan is to reduce the occurrence of infectious diseases, which include vaccine preventable diseases. The HHS Strategic Plan names the National Vaccine Plan as the roadmap for pursuing the prevention of infectious diseases through immunizations. In addition to aligning with the overall HHS Strategic Plan, the National Vaccine Plan harmonizes with and strengthens other HHS-led strategic plans that include a focus on infectious disease prevention, such as the National Prevention Strategy,[9] the HHS Action Plan to Reduce Racial and Ethnic Disparities,[10] the National Health Security Strategy of the United States of America,[11] and a number of other strategic initiatives that promote a culture of prevention.

Figure 1: Organizational Structure of the National Vaccine Plan



[9] U.S. Department of Health and Human Services. (2011). *National Prevention Strategy.* Retrieved from http://www.surgeongeneral.gov/initiatives/prevention/strategy/

[10] U.S. Department of Health and Human Services. (2011). *HHS Action Plan to Reduce Racial and Ethnic Disparities: A nation free of disparities in health and health care.* Retrieved from http://minorityhealth.hhs.gov/npa/files/Plans/HHS/HHS_Plan_complete.pdf

[11] U.S. Department of Health and Human Services. (2009). *National Health Security Strategy of the United States of America.* Retrieved from http://www.phe.gov/Preparedness/planning/authority/nhss/Pages/default.aspx

Progress and Opportunities: Implementing the 2010 National Vaccine Plan

By Howard K. Koh, MD, MPH
Assistant Secretary for Health
U.S. Department of Health and Human Services

The future of public health depends on creating and sustaining strong systems of prevention. A commitment to better prevention, in addition to treatment, can promote longer, healthier lives for all. Of all of our prevention tools, vaccination represents the foundation for public health. Despite great progress toward ensuring the availability, safety, and widespread use of vaccines over the years, we are still far from fulfilling their full potential.

Passage of the 2010 Affordable Care Act reset the stage for making prevention through immunization come alive. The beginning of open enrollment into the Health Insurance Marketplace in every state on October 1, 2013, gives millions of Americans who need or want health insurance coverage access to it. In addition, the Affordable Care Act offers new opportunities to build prevention and public health at the individual, state, and national levels.[12] Already, since passage of the Affordable Care Act, more than 71 million individuals in private plans have better access to immunizations and other high-value preventive services, without cost sharing. At the state level, the Affordable Care Act authorizes use of funds for purchase of vaccines for adults at federally negotiated prices. And at the national level, the National Prevention, Health Promotion, and Public Health Council has elevated immunization and other preventive services as a priority, in order to increase the number of Americans who are healthy at every stage of life. By building on the time-honored Healthy People initiative,[13] which has framed the country's health promotion and disease prevention agenda for the past 30 years, the Council created a new National Prevention Strategy. It prioritizes themes of empowered individuals, healthy and safe communities, clinical and community preventive services, and the elimination of health disparities. And the Prevention and Public Health Fund, now entering its fifth year, has invested in a host of critical efforts that strengthen public health infrastructure, promote prevention research, and improve data collection on health disparities.

It is within this context that we now unveil the first annual progress report of the 2010 National Vaccine Plan. First established in 1994, the National Vaccine Plan then represented an initial blueprint to set goals and align national efforts for immunization in the country. The updated 2010 National Vaccine Plan, designed to provide a 10-year vision of national priorities for the 21st century, has broadened the vision and goals.

[12] Koh, H. K, & Sebelius, K. G. (2010). Promoting prevention through the Affordable Care Act. *The New England Journal of Medicine, 363*(14), 1296–1299. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/20879876

[13] Koh, H. K. (2010). A 2020 vision for healthy people. *The New England Journal of Medicine* 362(18):1653–1656. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/20445177

Special attention now addresses the critical dimension of global health, especially since health leaders have committed to a common vision of a Decade of Vaccines to extend the full benefits of immunization to all people. Overall, the 2010 National Vaccine Plan represents a heightened commitment to systems of vaccination that strengthen public health, reduce disparities, and improve global health. Hence, every effort was made to align with key elements of Healthy People 2020, the National Prevention Strategy, the HHS Strategic Plan, the HHS Action Plan to Reduce Racial and Ethnic Disparities, and the HHS Global Health Strategy. This first annual progress report illustrates the achievements and ongoing efforts of many stakeholders in the vaccine and immunization enterprise. Table 1 lists some of the key accomplishments to date as well as opportunities on the horizon.

Of course, implementing strategy requires regular monitoring and documentation of progress, challenges, and opportunities which provide transparency to policymakers and the public alike. Readers will be intrigued to see progress in areas such as adult immunization, decision-making about new vaccine development, vaccine coverage, and risk communication. We envision future reports will also document further substantial developments in results, lessons learned, and areas for improvement.

We hope the end product of these aligned efforts will be a healthier society where true prevention systems are attained, maintained, and sustained. Only then can everyone have the chance to lead vibrant lives free from vaccine preventable illness and have a chance to reach their full potential for health.

Table 1: The State of the National Vaccine Plan – A Quick Glance

Goal	Key accomplishments	The coming years
1. Develop new and improved vaccines.	• A new framework and open-source software for determining vaccine development priorities. • A new generation of influenza vaccines. • Advances in scientific understanding of diseases and vaccine responses, especially for pertussis, pneumococcal disease, dengue and hepatitis C. • New vaccine production techniques and technologies. • Licensure of the first cell- and recombinant-based influenza vaccines in the United States to improve response time and capacity for influenza pandemics.	• Research on currently licensed, safe, and effective vaccines that further informs their use. • Research contributing to the development of new vaccines and improvement of existing vaccines, particularly for diseases like human immunodeficiency virus (HIV) and influenza. • Continued advances in vaccine production technologies and testing, including those that foster manufacturing efficiencies and lower costs (which can enable greater use in developing countries).
2. Enhance the vaccine safety system.	• Vaccines and Medications in Pregnancy Surveillance System established with HHS support, which helps monitor the safety of vaccines and medications administered during pregnancy. • The Food and Drug Administration's Post-licensure Rapid Immunization Safety Monitoring covered >100 million patients. • Continued support of the Centers for Disease Control and Prevention's Vaccine Safety Datalink. • The Indian Health Service's Influenza Awareness System, which helps monitor influenza vaccine safety, was created. • IOM reviews that focus on key vaccine safety concerns, including the safety of the childhood immunization schedule. • Advances in using electronic health data to monitor vaccine safety.	• Continued use of safety monitoring systems to monitor and assess vaccine safety, and identification of potential vaccine side effects or rare adverse reactions. • Continued identification and assessment of whether rare health outcomes have any association or link to vaccines or vaccination. • Continued development of more precise vaccine safety risk estimates and assessments. • Extension of efforts to monitor, assess, and identify vaccine safety issues in specific populations (e.g., pregnant women). • Continued investment in laboratory and other research methods that can foster vaccine safety assessments.

Goal	Key accomplishments	The coming years
3. Support communications to enhance informed vaccine decision-making.	• Research on adults' knowledge, attitudes and beliefs with respect to recommended adult immunizations. • Establishment of Vaccines.gov website in English and Spanish. • Research and efforts to foster human papillomavirus (HPV) vaccination among adolescents, including the National Institutes of Health's Go Healthy Girls web-based intervention. • Materials developed by the Food and Drug Administration for consumers and health care providers, including "Vaccines for Children: A Guide for Parents and Caregivers." • The National Vaccine Program Office's support of communication materials to promote adult immunization. • Collaboration with the new Adult Immunization Task Force, and National Adult and Influenza Immunization Summit.	• Continued research into adult, public, and parent knowledge, attitudes, beliefs, intentions, and behaviors related to vaccines and immunization recommendations. This includes better understanding of vaccine confidence and acceptance and how to foster informed vaccine decision-making. • Continued publicity of the Vaccines.gov website so it becomes a widely used resource and tool for vaccine decision-making. • Efforts to understand how best to use new information and communication technologies to provide access to disease and vaccine information. This includes efforts to target and serve the needs of different population groups.

Goal	Key accomplishments	The coming years
4. Ensure a stable supply of, access to, and better use of recommended vaccines in the United States.	• Contracts awarded, through the Assistant Secretary for Preparedness and Response's Biomedical Advanced Research and Development Authority, to five vaccine manufacturers to produce master seed stocks for influenza viruses with pandemic potential. • Establishment of an International Society for Pharmaceutical Engineering award-winning cell-based influenza vaccine manufacturing facility in the United States to increase the domestic supply of seasonal and pandemic influenza vaccines. • Partnerships with nongovernment organizations to make influenza vaccination more financially accessible. • Accurate tracking of vaccine preventable diseases and disease rates, including supporting specialized systems (e.g., those for pertussis tracking). • New mapping tool to track influenza vaccination claims rates by Medicare beneficiaries. • Identification of health care system and provider barriers and facilitators of immunization. • Expansion of access to vaccines via partnerships with pharmacists and other immunization providers. • Broadening of access to vaccines without cost-sharing through the Affordable Care Act. • Working to foster use of health information technology for vaccine and immunization tracking.	• Continued support of efforts that reduce the number of "missed vaccination opportunities" (e.g., those related to HPV and adolescent and adult vaccinations), including systems and services that support physicians and other immunization providers, such as Immunization Information Systems for all age groups. • Continued support and encouragement of the adoption of health information technology – such as 2D barcoding and interactive vaccine finder services – to make it easy for individuals and parents to access recommended vaccines. • Identification and encouragement of expansion and adoption of "best practices" in childhood, adolescent, and adult immunization. • Work with providers and consumers to increase awareness that all Advisory Committee on Immunization Practices-recommended vaccines are accessible with no cost sharing to many more in the United States, effective January 2014. • Work to strengthen the existing immunization "infrastructure" – the system and components that exist, in both the public and private sectors, to provide access to recommended vaccines and foster high vaccination rates.

Goal	Key accomplishments	The coming years
5. **Increase global prevention of death and disease through safe and effective vaccination.**	• A strengthened commitment to global polio eradication. • Continued strong support and engagement in global disease surveillance and immunization efforts, including measles elimination and expanded use of high impact vaccines including pneumococcal and rotavirus. • Development and use of new vaccines tailored for global populations, such as MenAfriVac. • Greater and more widespread use of influenza vaccines, and development of influenza manufacturing capacity. • Improved global pandemic preparedness by increasing vaccine manufacturing capacity in developing and under-resourced countries by over 280 million doses through infrastructure-building and technical training to the workforce to ensure high quality vaccine production. • A continued commitment to reducing the global threat of influenza by building and strengthening capacity for developing and under-resourced countries to produce seasonal and pandemic influenza vaccine.	• Eradication of polio and successful implementation of the polio endgame strategy (i.e., a worldwide transition from oral polio vaccines to inactivated polio vaccines). • Continued efforts to use MenAfriVac to prevent meningitis in Africa and other regions of the world. • Continued efforts to expand global access to pneumococcal conjugate, rotavirus, influenza, HPV, hepatitis and other new and underutilized life-saving vaccines. • Collaborations that foster public and health care provider understanding of vaccines and immunization globally, including vaccine benefits and risks. • Continued collaboration between HHS and international organizations to expand pandemic influenza vaccine manufacturing capacity in developing countries.

Success through Collaboration: The National Vaccine Plan

By Bruce Gellin, MD, MPH
Deputy Assistant Secretary for Health
Director, National Vaccine Program Office
U.S. Department of Health and Human Services

"To raise new questions, new possibilities, to regard old problems from a new angle, requires creative imagination and marks real advance in science." This quotation from Albert Einstein set the tone of the 2010 National Vaccine Plan—and is a timely reminder for this first report on progress toward accomplishing the goals and objectives of the 2010 National Vaccine Plan. The National Vaccine Plan is the strategy guiding the National Vaccine Program, which was created in 1988 by the Public Health Service Act. The first National Vaccine Plan was issued in 1994 and updated in 2010 to reflect the new opportunities and challenges of the 21st century immunization landscape. In this first State of the National Vaccine Plan Report, you'll find highlights of work done by HHS agencies and their partners to implement the 2010 National Vaccine Plan.

The accomplishments of each HHS agency are truly remarkable when considered individually. However, as President Lyndon B. Johnson noted, "There are no problems we cannot solve together, and very few that we can solve by ourselves." The many examples of collaboration provided in this report demonstrate the necessity for a synergistic approach to maintaining and enhancing the immunization system of the United States. There are many stakeholders, both federal and nonfederal, that contribute to the successful functioning of our national vaccine program, all performing their specialized functions in concert. Table 2 provides an overview of these stakeholders and their respective roles in achieving the objectives of the 2010 National Vaccine Plan. When the work of these stakeholders is considered as a whole, it becomes clear that by working together it is possible to achieve truly great successes. This report also highlights and demonstrates the integrative mission of NVPO: to bring these stakeholders together and facilitate their collaboration to develop strategies to strengthen our national immunization system, and solve emerging and ongoing problems confronting the U.S. vaccine enterprise. Part of this coordination involves a continuous feedback process, where stakeholders share information about their respective activities that contribute to the achievement of the five goals of the National Vaccine Plan. In this way, NVPO ensures that all involved parties are included in the ongoing national strategic dialogue on vaccines and immunization.

The accomplishments and progress highlighted in this report were achieved through the contributions of many organizations, both federal and nonfederal, working together toward common goals. Included are updates on the actions currently being carried out by HHS and other federal partner agencies to implement the National Vaccine Plan. The report also provides an overview of work identified by HHS and its agencies that feature our collective

efforts to achieve the five goals of the National Vaccine Plan, as well as ongoing relevant challenges and opportunities.

Input and guidance from nonfederal experts have been essential to HHS's work over the years to strengthen and support our National Vaccine Program. The role and impact of our National Vaccine Advisory Committee (NVAC) are featured in this report. NVAC is a chartered federal advisory committee comprising experts from stakeholder organizations involved in implementing the National Vaccine Plan. NVAC has provided essential expertise and guidance on HHS's work to improve the nation's immunization system for the last 25 years. Also accompanying the report are commentaries provided by leaders in the field of vaccines and immunization. These experts have kindly contributed their perspectives on issues that need continued attention moving forward.

This report not only highlights accomplishments that have been made during the last few years, it also provides an opportunity to take stock of our progress and ensure that we're sufficiently focused on areas that need our attention and support. Through continued collaboration, HHS and its partners will keep seeking out solutions to new and emerging challenges that prevent those in the United States, and around the world, from experiencing the full benefits of immunization.

Table 2: The 2010 National Vaccine Plan: Responsible Stakeholders

Goal	HHS-ACF^	HHS-AHRQ^	HHS-ASPR (BARDA) ^	HHS-CDC^	HHS-CMS^	HHS-FDA^	HHS-HRSA^	HHS-IHS^	HHS-NIH^	HHS-NVPO^	HHS-ONC^	DHS^	DoD^	DoJ^	Dept. of State^	USAID^	VA^	Health care providers*	Health care system*	Public and private health care plans*	State, local, and tribal governments*	Academia*	Advocacy organizations*	Philanthropic organizations*	Vaccine manufacturers*	The GAVI Alliance*	UNICEF*	WHO*
1			X	X		X			X	X		X	X			X	X	X			X	X		X	X	X		X
2		X	X	X	X	X	X	X	X	X			X			X	X		X	X	X	X	X		X	X		X
3	X			X	X	X	X	X	X	X			X			X	X	X	X	X	X	X	X		X	X	X	
4	X		X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X			
5			X	X		X			X				X		X	X						X	X	X	X	X	X	X

^=Federal

*=Non-federal

Goal 1: Develop New and Improved Vaccines

In this section:

- The Next Generation of Influenza Vaccines
- Selected Advances in Vaccine Research and Development
- New Vaccine Production Techniques and Vaccine Technologies
- Feature: SMART Vaccines
- Commentary: *Vaccine Research and Development: Doing Better than Nature*, by Dr. Anthony Fauci
- Commentary: *New Business Models for Vaccines Targeting Diseases in Low-income Countries,* by Dr. Marie-Paule Kieny
- Commentary: *Overcoming the Complexity of Vaccine Development for Global Health,* by Dr. Trevor Mundel

Background

Vaccine research and development are the foundation of successful immunization programs. Through scientific discoveries and breakthroughs, researchers develop vaccines that protect the health of the world's population in new and more efficient ways. Research to improve existing vaccines also provides opportunities to improve on a range of vaccine characteristics such as efficacy, safety, and vaccine delivery. By developing and using new and improved vaccines, we are better prepared to meet our overall goals to prevent serious infectious diseases and their complications.

Several agencies within HHS and across the federal government are actively involved in vaccine development. These agencies conduct research, often partnering with other agencies and other sectors, such as vaccine manufacturers and vaccine purchasers, to develop new vaccines and improve existing vaccines. NVPO plays an essential role in facilitating communication between the entities involved in vaccine development, thereby providing enhanced opportunities for collaboration and information sharing. Examples of important vaccine research and development work are provided below. This sampling of achievements from the past two years demonstrates the commitment of HHS and its partners to improving the health of people in the United States, as well as people around the world, through new and improved vaccines.

Recent Accomplishments and Progress

The Next Generation of Influenza Vaccines

Influenza is a major public health concern in the United States. Between 5 and 20 percent of U.S. residents become infected with influenza each year, resulting in more than 200,000 individuals hospitalized with influenza-related complications.[14] Annually there are between 3,000 and 49,000 influenza-related deaths, of which approximately 90 percent occur in those over 65 years of age. To better prevent seasonal influenza and better prepare for an influenza pandemic, HHS is working to support the research, development, and licensure necessary to create a diverse variety of influenza vaccines, with the ultimate goal of offering influenza vaccines that provide better, broader, and longer-term protection and that can ultimately remove the threat of an influenza pandemic. In recent years, several new influenza vaccines have been licensed that are produced using new techniques, including ones that do not involve eggs. New vaccine production technologies can also shorten manufacturing timelines, which is especially important when a novel influenza strain with pandemic potential emerges.

In 2012 and 2013, six new vaccines, including four quadrivalent vaccines, were licensed by the U.S. Food and Drug Administration (FDA) to prevent seasonal influenza—Flucelvax, Flublok, Fluarix Quadrivalent, FluLaval Quadrivalent, FluMist Quadrivalent, and Fluzone Quadrivalent. The National Institutes of Health (NIH), the Biomedical Advanced Research and Development

[14] U.S. Centers for Disease Control and Prevention. (2013). *Seasonal influenza Q&A*. Retrieved from http://www.cdc.gov/flu/about/qa/disease.htm

Authority (BARDA) within the Office of the Assistant Secretary for Preparedness and Response (ASPR), the FDA, and vaccine manufacturers each played critical roles in the development of these vaccines.

Two types of influenza viruses—influenza A and influenza B—cause illness and death in people. Seasonal influenza vaccines have traditionally included three strains of influenza virus: two strains of influenza A and one of influenza B. **Quadrivalent influenza vaccines** contain four strains of the influenza virus: two influenza A strains and two influenza B strains. During some influenza seasons, two different influenza B strains may be circulating, or the B strain selected for inclusion in the trivalent influenza vaccine may not be the influenza B strain that eventually circulates causing illness. The inclusion of a second B strain increases the likelihood of adequate protection against circulating influenza B

Additionally, scientists at NIH's National Institute of Allergy and Infectious Diseases (NIAID) have recently devised a new strategy for the development of more broadly protective vaccines for influenza, an approach that represents a promising step forward toward a universal influenza vaccine.[15] Since influenza viruses change rapidly, influenza vaccines are updated and produced annually to protect against the virus strains that will be most common that year. In animal studies, researchers at NIH/NIAID were able to elicit an immune response to sites within influenza viruses that are shared across different influenza strains and that typically don't change very much over time, despite ongoing mutations in the virus. This is one of the many strategies that NIH/NIAID is pursuing toward the development of a safe and effective universal influenza vaccine, which would potentially eliminate the need for a new seasonal influenza vaccine each year and could remove the threat of an influenza pandemic.

Selected Advances in Vaccine Research and Development

Investments in basic biology, immunology, and pathogenesis have provided key insights that will inform advances in understanding how vaccines work and can be better used to prevent disease, and in some cases, will inform the creation of new and improved vaccines. The examples of this research provided below focus on pertussis, pneumococcal, dengue, smallpox, anthrax, hepatitis C, and adenovirus diseases, and represent just some of the progress being made in vaccine research and development:

- FDA is conducting research to better understand pertussis disease and the response to vaccination. Animal models help researchers study the disease, but the current models do not adequately reproduce the full spectrum of pertussis seen in people. In 2012, FDA scientists reported results demonstrating that the baboon provides an excellent model of clinical pertussis that will allow researchers to investigate how *Bordetella pertussis* bacteria cause disease, how pertussis spreads in a population, how it is prevented by existing vaccines, and how those vaccines may be improved in the future.[16] This work was funded by both FDA and NIH.

[15] U.S. National Institute of Allergy and Infectious Diseases (NIAID). (2013). *Novel approach for influenza vaccination shows promise in early animal testing.* Retrieved from http://www.niaid.nih.gov/news/newsreleases/2013/Pages/FluSelfAssemble.aspx

[16] Warfel, J. M., Beren, J., & Merkel, T. J. (2012). Airborne transmission of Bordatella pertussis. *The Journal of Infectious Diseases, 206*(6), 902–906. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/22807521

- Pneumococcal disease causes hundreds of thousands of cases each year of pneumonia, meningitis, and blood infections. In an effort to better protect older adults from pneumococcal disease, NIH/NIAID began a study at the end of 2012 to see whether a dose of a pneumococcal conjugate vaccine higher than what is currently routinely administered will create a stronger immune response in that age group.[17] The Phase IIb study continued into 2013.
- Dengue viruses, which are transmitted by mosquitoes, cause 50–100 million illnesses around the world each year. Although dengue is not commonly perceived as a disease that affects the United States, 357 cases of dengue were reported in the continental United States in 2012, a 70 percent increase from 2011. Most cases were identified in Florida, California, and New York. In 2012, NIH/NIAID evaluated a candidate tetravalent vaccine for dengue and determined that this vaccine elicits protective antibodies against all four types of dengue, and could cost less than $1 per dose to produce. Phase II trials to evaluate the safety and immunogenicity of the vaccine have begun in Brazil and will begin soon in Thailand.
- Though smallpox has been eradicated globally, the United States maintains a stockpile of vaccine as a precaution against a potential outbreak due to intentional or unintentional release of smallpox virus, as a matter of national security. A collaboration between NIH/NIAID, ASPR/BARDA, the DoD, and vaccine manufacturer Bavarian Nordic led to the production and testing of a next generation smallpox vaccine, Imvamune. Imvamune is designed to be safer than previous smallpox vaccines as it does not replicate in human cells. In addition, Imvamune is in the Strategic National Stockpile and has the potential to be used during a declared emergency under Emergency Use Authorization in individuals with human immunodeficiency virus (HIV) or atopic dermatitis, all age ranges including pregnant and nursing mothers.
- To facilitate development of the next generation of anthrax vaccines, ASPR/BARDA is supporting studies to expand the use of the currently licensed anthrax vaccine, BioThrax (Anthrax Vaccine Adsorbed), for postexposure prophylaxis. At present,

The Role of Vaccines in the Fight against Antimicrobial Resistance

While antimicrobial drugs have greatly reduced illness and death from infections caused by microbes (such as bacteria), after many years of widespread use of antimicrobial drugs, many microbes have evolved and adapted to the drugs designed to kill them, making the drugs less effective or not effective at all.

When infections are prevented, they do not require the use of antimicrobial drugs. Therefore, by preventing infections, vaccines could be a useful part of the approach to address the growing problem of antimicrobial resistance. Several vaccines protect us against bacteria, such as the pneumococcal vaccine, which prevents pneumococcal disease by creating protection against the bacteria *Streptococcus pneumoniae*.

References:

U.S. Centers for Disease Control and Prevention. (2013). *About antimicrobial resistance: A brief overview*. Retrieved from http://www.cdc.gov/drugresistance/about.html

[17] U.S. National Institutes of Health. (2012). *NIH-funded study to test pneumococcal vaccine in older adults*. Retrieved from http://www.nih.gov/news/health/oct2012/niaid-15.htm

BioThrax is licensed only for general use prophylaxis in persons 18 through 65 years of age who are at high risk for exposure. It is projected that these studies will be completed in 2014. ASPR/BARDA is also funding the development of three "next generation" recombinant protective antigen-based anthrax vaccines, all three of which received NIH/NIAID support at various stages of development, and one "third generation" anthrax vaccine based on adenovirus-vectored expression of protective antigen. The adenovirus-vectored vaccine offers advantages such as nasal route of administration and potential protection with a single dose. Additional vaccine candidates are under development and will be evaluated in clinical studies during 2014–2016. NIH/NIAID-funded researchers are also evaluating novel vaccine technologies to accelerate immune response and facilitate vaccine delivery to enhance post-event responses.

- While we have safe and effective vaccines for the prevention of hepatitis A and hepatitis B, about 3.2 million people in the United States are chronically infected with hepatitis C, a type of hepatitis for which there is currently no vaccine. Hepatitis C causes liver disease that can lead to serious health problems including liver damage, cirrhosis, and liver cancer. In 2012–2013, NIH/NIAID supported a clinical trial to test a hepatitis C vaccine candidate for efficacy and safety, representing a potential step toward the development of a much-needed vaccine.
- Adenovirus, in most cases, causes cold-like symptoms, but it can also lead to pneumonia and other serious outcomes. A vaccine against adenovirus was used in U.S. military recruit trainees until 1996 when the manufacturer of the vaccine stopped production. Without the availability of this vaccine, respiratory illness in military recruits increased significantly. DoD worked with FDA and a vaccine manufacturer to develop a new vaccine, which was licensed in March 2011. Data show that the new vaccine is highly effective and has led to a large reduction in respiratory illness due to adenovirus in U.S. troops, who are at higher risk for adenovirus infection because of close living conditions, and whose training can be significantly disrupted by this disease.

New Vaccine Production Techniques and Vaccine Technologies

Research to produce new and improved vaccines also includes advances in vaccine production techniques and vaccine technology. Some of the many recent advances, highlighted here, illustrate how this research can affect the availability of vaccines and the impact they have in preventing serious infectious diseases:

- Improvements in influenza vaccine production techniques are also strengthening pandemic preparedness and response. For example, two of the six new influenza vaccines previously mentioned, Flucelvax and Flublok, are manufactured using new production techniques. Although these manufacturing processes have been used to produce other vaccines, they are new for influenza vaccines. Flucelvax is the first seasonal influenza vaccine licensed in the United States that is produced using cultured

animal cells.[18] Flublok is the first seasonal influenza vaccine made using recombinant DNA technology and does not require the influenza virus for its production, but rather uses an insect virus expression system in its manufacturing process.[19] Both technologies offer the potential for a faster start-up of the vaccine manufacturing process in the event of an influenza pandemic, and serve to increase the domestic capacity for influenza vaccine production available for both seasonal and pandemic response.

- In 2013, FDA approved the first adjuvanted vaccine for the prevention of H5N1 influenza.[20] The vaccine Influenza A (H5N1) Virus Monovalent Vaccine, Adjuvanted, is for use in people 18 years of age and older who are at increased risk of exposure to the H5N1 influenza virus. It contains the adjuvant AS03, an oil-in-water emulsion. The adjuvant makes it possible to use a small amount of influenza protein per dose of vaccine to elicit the desired immune response in an individual to prevent influenza disease. Reducing the amount of influenza protein per dose helps to increase the total number of doses of a safe and effective vaccine available for the public during a pandemic. Development of this vaccine was supported by ASPR/BARDA. HHS has purchased the vaccine from the manufacturer, ID Biomedical Corporation of Quebec, Quebec City, Canada (a subsidiary of GlaxoSmithKline Biologicals), for inclusion within the U.S. pandemic vaccine stockpile for distribution by public health officials if needed.
- In 2012, NIH-funded researchers showed that a new silk-based stabilizer can keep vaccines stable up to 113 degrees Fahrenheit and antibiotics stable up to 140 degrees Fahrenheit.[21] This finding could eliminate the need to keep some vaccines and antibiotics refrigerated, thus reducing the complexity of the "cold chain," which involves ensuring that vaccines stay at the right temperature during transport. This would save money, and the simplified logistics of vaccine distribution could increase vaccine accessibility to populations in developing countries around the world.
- NIH/NIAID, through the Vaccine and Treatment Evaluation Units and in partnership with vaccine developer and manufacturer Sanofi Pasteur and medical technology company Becton Dickinson and Company, contributed to the development of a new way to deliver influenza vaccine – intradermal injection (through the top layer of skin) rather than intramuscular injection (through an injection into the muscle). This method requires less antigen – the active ingredient in vaccines – and in the case of influenza vaccines, also could be helpful in the event of a vaccine shortage. By using less antigen in each vaccination, more vaccine can be produced from a given or limited supply of antigen. Fluzone Intradermal, an influenza vaccine that is delivered through

[18] U.S. Food and Drug Administration. (2012). *FDA approves first seasonal influenza vaccine manufactured using cell culture technology*. Retrieved from http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm328982.htm

[19] U.S. Food and Drug Administration. (2013). *FDA approves new seasonal influenza vaccine made using novel technology*. Retrieved from http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm335891.htm

[20] U.S. Food and Drug Administration. (2013). *FDA approves first adjuvanted vaccine for prevention of H5N1 avian influenza*. Retrieved from http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm376444.htm

[21] U.S. National Institute of Biomedical Imaging and Bioengineering. (2012). *Vaccine and antibiotics stabilized so refrigeration is not needed – NIH study*. Retrieved from http://www.nibib.nih.gov/news-events/newsroom/vaccine-and-antibiotics-stabilized-so-refrigeration-not-needed-%E2%80%93-nih-study

intradermal injection, was licensed by FDA in 2011. It is safe and provides a similar level of protection against influenza as traditional intramuscular injection of the vaccine.

- In 2012, FDA convened its Vaccines and Related Biological Products Advisory Committee to examine the role of emerging technologies for detecting adventitious agents in assessing whether novel human tumor-derived cell-line substrates are suitable for vaccine production. The scientific experts who constituted the committee recognized that human-tumor derived cell lines could be an important addition to the repertoire of cell substrates for the manufacture of viral vaccines, and safety concerns of the potential applications of the new technologies have been adequately addressed by FDA. The use of these cell lines is important to advance the development of various vaccines, such as those for the prevention of HIV and influenza, including pandemic influenza.

SMART Vaccines

As technological opportunities emerge and patterns of disease change over time, it can be difficult for policy makers to decide how best to invest in new vaccine development and introduce new vaccines into routine and campaign immunization programs. In 2012 the IOM, with support from NVPO, began developing a decision-support tool for prioritizing vaccine targets for development and use. In a novel approach for IOM, its Committee on Identifying and Prioritizing New Preventive Vaccines for Development developed software, called Strategic Multi-Attribute Ranking Tool for Vaccines, or SMART Vaccines.[22]

The SMART Vaccines software makes it possible for decision-makers to develop and test hypotheses and assumptions, weigh competing values, and explore alternative scenarios and vaccine attributes to assist in setting priorities for vaccine targets for development and introduction. Users can take into account multiple factors, including health, economic, demographic, scientific, and policy considerations, and to assess their relative rank among a range of factors. The tool allows the flexibility of factoring in values such as aiming to eradicate or eliminate a disease. Users are also able to generate information on cost-effectiveness, premature deaths averted, and gains in worker productivity, among other topics of importance to vaccine development and introduction. Using this model, SMART Vaccines has the potential not only to guide discussions regarding vaccine goals, but also to provide a common platform for determining priority areas of national and global interests.

After a period of testing and refinement, SMART Vaccines 1.0 was made available in September 2013 for public use. In the next phase of development, launched in December 2013, a targeted group of users will be guided through SMART Vaccines, using realistic and specific scenarios and vaccine candidates, which will help guide further development of the tool. The IOM committee that guided development of the software wrote, "We hope to inspire a community of users who will improve, enhance, and potentially manage the capabilities of this product." The SMART Vaccines software is now available to the public for download and use online through the National Academy of Sciences website at http://www.nap.edu/smartvaccines. (exit link disclaimer)

[22] National Research Council. (2013). *Ranking vaccines: A prioritization software tool: Phase II: Prototype of a decision-support system.* Washington, DC: The National Academies Press. Retrieved from http://www.nap.edu/catalog.php?record_id=13531 (exit link disclaimer)

Vaccine Research and Development: Doing Better than Nature

By Anthony S. Fauci, MD
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A key challenge for vaccinologists is developing vaccines against microbes for which the immune response to natural infection does not adequately control or eliminate the pathogen in question. For many pathogens for which effective vaccines have been developed—including smallpox, measles, and polio—the human immune system can generate a response that clears the infection and confers lifelong protection against reinfection. This natural proof-of-concept has led to a fundamental tenet of vaccinology: To develop an effective vaccine, one should mimic natural infection, without causing disease. However, when natural immunity does not adequately protect against a pathogen, vaccines must be designed to induce "unnatural immunity"—that is, an effective immune response that natural infection either does not elicit, or does so poorly.

Two well-recognized examples of infections for which natural immunity falls short are HIV and influenza.

Broadly neutralizing antibodies are made by approximately 20 percent of HIV-infected individuals, and only after two or more years of infection. It is believed that components of the HIV envelope that must be targeted for viral neutralization are not presented to the immune system during natural infection in a manner that rapidly induces a protective response. The challenge for vaccinologists is to present those components of the viral envelope to the immune system in a form that is recognizable and that will elicit a robust response, much better than the response to natural infection.

Similarly, with influenza, despite repeated exposures over one's lifetime to both influenza infections and vaccines, most people are not protected against all emerging influenza strains. Current vaccines target components on the head of the influenza hemagglutinin spike protein that are readily accessible to the immune system but that constantly evolve and escape from previously induced immune responses. Recently, scientists have identified conserved components on the stem of the hemagglutinin spike that are capable of inducing broadly protective responses, but are shielded from the immune system during natural infection and in response to classic influenza vaccines by other confounding molecules. The challenge now is to present this conserved stem region of the hemagglutinin to the immune system in a way that is structurally unencumbered and that will induce a broadly protective immune response, here again, a response that is even better than the response to natural infection.

Thus, with the scientific tools available today, we now can develop vaccines that improve on natural immunity, bringing vaccinology squarely into the 21st century.

New Business Models for Vaccines Targeting Diseases in Low-income Countries

By Marie-Paule Kieny, MD
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There is no doubt that vaccination is among the most effective public health interventions—being accountable for the eradication, elimination, or control of many pathogenic agents that represented in the past major scourges for mankind—and that vaccines are also among the most cost-effective tools available to reduce global disease burden.

Yet vaccines are "special." They currently nearly exclusively target healthy persons, and among those, mainly infants and children. There is therefore an expectation that they should be 100 percent safe—which no intervention ever is. Vaccination is also a global public good. Indeed, vaccination of an individual also protects to a certain degree the family and friends of that person, and vaccination of many protects the community, through what is referred to as "herd immunity." Therefore, it is important to research and develop new vaccines, to improve the effectiveness and safety of those that are already available, to study how best to reach all populations in need, and to advocate for universal vaccination. This last point is critical to avoid the development of "free-rider" comportments ("why vaccinate my child and take any risk of side effects, if all children in the neighborhood are immunized?"), which could compromise today's impressive gains.

The U.S. 2010 National Vaccine Plan has very ambitious objectives in terms of fostering vaccine research and development. It intends to develop evidence-based processes to prioritize investment, to advance the science of vaccines and of human immunology, to develop new production and administration methods, as well as to establish new evaluation criteria. All these are valuable goals, and they will benefit children and other populations in the United States, and also in other countries. They also hold promise for protecting children where the toll of infectious diseases is the largest: in developing countries.

But the development of vaccines needed in low-income countries also needs new thinking in terms of research and development. Indeed, traditional market approaches fail to deliver technologies for diseases that affect predominantly developing countries. This is the purpose of the Global Strategy and Plan of Action for Public Health, Innovation and Intellectual Property, endorsed by the World Health Assembly in 2009, as well as of intense international negotiations around recommendations of the Consultative Expert Working Group on Research and Development: Financing and Coordination. New models are thus being elaborated, and demonstration projects are being proposed to address the above challenge, with active participation of the United States in this endeavor within WHO's processes. Moving along the path of the great success of the MenAfriVac meningitis A vaccine (developed for Africa by a consortium of willing partners, and used today in more than 100 million people), these novel approaches have potential to expand the benefits of vaccination to eliminate or control many

infectious diseases that affect developing countries, such as HIV/Acquired Immunodeficiency Syndrome (AIDS), malaria, tuberculosis (TB), and schistosomiasis, to name only a few.

Overcoming the Complexity of Vaccine Development for Global Health

By Trevor Mundel, MD, PhD
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Bill and Melinda Gates Foundation

Worldwide, immunization coverage has never been higher, and vaccines are saving more lives than ever. Yet every 20 seconds a child still dies from a disease that could be prevented by a vaccine.

Overwhelmingly, the burden of infectious diseases continues to fall on poor countries, in part because the technology hurdles associated with producing vaccines for developing countries are much higher than in wealthy countries.

Not only must vaccines for the developing world be safe and effective, but they must also be affordable, and possess other attributes essential for low-infrastructure settings, including single-dose efficacy, thermostability, ease of administration, prolonged shelf life, and low-volume packaging.

Often, innovations in these areas occur incrementally. The new ROTAVAC rotavirus vaccine, which recently concluded successful Phase III clinical trials in India, is expected to have enormous life-saving potential—preventing up to 100,000 child deaths a year from the predominant strain of rotavirus. Scientists are now working on a second-generation rotavirus vaccine with enhanced thermostability and greater ease of administration.

Building on the success of a three-in-one vaccine for diphtheria, whooping cough, and tetanus, a five-in-one vaccine added protection against two other deadly diseases, hepatitis B and *Haemophilus influenzae* type b (Hib) (which causes meningitis and pneumonia).

A six-in-one vaccine, which also immunizes against polio, is available in some markets. And researchers have now set their sights on an eight-in-one vaccine that would add protection against pneumococcal disease and rotavirus.

Innovative partnerships with vaccine manufacturers are also critical in getting lifesaving vaccines to children in developing countries. A nearly two-thirds drop in the cost of the five-in-one vaccine, for example, has led to an 18-fold increase in the number of children reached.

Research breakthroughs, such as high-throughput DNA sequencing technologies and advances in structural biology, also have the potential to help scientists accelerate the development of effective prevention and treatment measures for global health.

The biopharmaceutical company Atreca is working on a platform to identify the antibodies produced in humans during immune responses, which can be useful in creating new vaccines, drugs, and diagnostics to tackle infectious diseases like tuberculosis, HIV, and malaria. And

advances producing human antibodies in mice (known as transgenic platforms) hold promise for accelerating vaccine development by informing the design of vaccines for humans.

Other areas of promise include enabling technologies that decrease production costs of vaccines and other biopharmaceutical products, and computer simulations that help increase mammalian cell culture-based production.

With more of the right investments, we have the potential within a generation to create a more equitable world where all people have the opportunity to build a healthy and productive life.

Goal 2: Enhance the Vaccine Safety System

In this section:

- Vaccine Safety Signals and Adverse Reactions
- Research on the Administration and Use of Different Childhood Rotavirus Vaccines for Ensuring Safety and Effectiveness
- Feature: Examining the Safety of the Childhood Immunization Schedule
- Feature: Using Electronic Health Data to Monitor Vaccine Safety
- Commentary: *Advances in the Science, Surveillance, and Safety of Vaccines*, by Dr. Margaret Hamburg
- Commentary: *The Vaccine Safety Data System*, by Dr. Marie McCormick
- Commentary: *Vaccine Safety: Evidence and Belief,* by Dr. Harvey Fineberg

Background

The development, production, and use of safe and effective vaccines are the cornerstone of any immunization program. As vaccines are recommended for use among large populations, ensuring the safety of vaccines is absolutely critical. Vaccines undergo rigorous testing to determine safety and effectiveness in support of their licensure. Vaccines continue to be monitored closely after they are licensed and in use. In recognition of the continuing need to strengthen our ability to detect and address potential adverse events associated with vaccines, there are aspects of our vaccine safety system addressed within each of the five goals of the National Vaccine Plan.

The vaccines that are part of today's infant, childhood, adolescent, and adult immunization schedules are very safe, and severe adverse events related to vaccines and immunization are rare. To ensure that remains the case, several agencies within HHS continue to enhance safety monitoring systems, conduct research related to vaccine safety, and develop new strategies to detect adverse events quickly. The overall goal of this work is to determine whether immunizations are causing adverse events, and if so, to minimize their occurrence. Examples of recent achievements, provided below, demonstrate HHS's commitment to ensuring the safety of vaccines. In addition to the efforts outlined in this section, NVPO works on an ongoing basis to foster communication and collaboration across HHS agencies and with partners in the DoD and VA to improve our overall vaccine efforts and our response to safety-related issues.

Recent Accomplishments and Progress

Vaccine Safety Signals and Adverse Reactions

Minimizing the occurrence of adverse events from immunization and the early detection of vaccine safety signals is crucial to the success of the U.S. vaccine safety system. A number of systems and initiatives are in place to enhance rapid detection. Several components of this system—such as the Vaccine Safety Datalink (VSD), a collaborative effort between the Centers for Disease Control and Prevention (CDC) and nine managed care organizations; the Vaccine Adverse Event Report System (VAERS) managed by FDA and CDC; and the VA's web-based Adverse Drug Event Reporting System—have a long-established place in vaccine safety surveillance. Some new and important components have been added in the past few years and are providing valuable new information on vaccine safety:

- The Vaccines and Medications in Pregnancy Surveillance System (VAMPSS), which has received financial support from HHS, was created in 2010 through a collaborative effort between nonfederal partners. VAMPSS monitors the safety of vaccines and medications administered during pregnancy. VAMPSS activities are informed by an advisory committee that includes representatives from CDC and NIH.
- FDA's Post-Licensure Rapid Immunization Safety Monitoring (PRISM), a component of the agency's broader product safety Sentinel Initiative, was initiated in 2009 to monitor the safety of the H1N1 pandemic influenza vaccine by linking four health care data systems to immunization registries. PRISM was integrated into FDA's Mini-Sentinel

program in 2010 to strengthen ongoing federal vaccine safety monitoring that in 2013 covered more than 100 million patients.

- The Indian Health Service (IHS) Influenza Awareness System was created in 2009 and monitors potential adverse events associated with influenza vaccines. This system encompasses approximately 1.2 million American Indian/Alaska Native people who receive care from IHS-funded facilities.

An example of how these systems complement each other can be found in a study led by NVPO and published in March 2013.[23] In an effort to get a better estimate of the occurrence of a rare adverse event, Guillain-Barré syndrome (GBS), following influenza vaccination, the study examined the association between the 2009 pandemic H1N1 influenza vaccine and GBS. The study was conducted using data from CDC's Emerging Infections Program, Centers for Medicare and Medicaid Services (CMS) Medicare claims data, the VSD, PRISM, the DoD, and the VA. Data from these U.S.-supported adverse event monitoring systems were collected and analyzed to show that a very small increase in risk of GBS could be attributed to the vaccine, amounting to 1.6 excess cases of GBS per million people vaccinated. Despite this very small increase in risk, the benefits of immunization against pandemic influenza greatly outweigh the risks. For instance, officials estimate that in 2009, the pandemic H1N1 vaccine prevented between 700,000 and 1.5 million cases of influenza, kept 4,000 to 10,000 people from hospitalization due to influenza-related symptoms, and prevented 200 to 500 deaths.

Guillain-Barré Syndrome (GBS) is a rare neurological disorder in which attacks by the body's own immune system cause nerve damage, often leading to weakness and even paralysis. In the United States, GBS affects about 80 to 160 people a week, regardless of vaccination. A number of illnesses have been found to trigger GBS and, rarely, some vaccines have been found to cause GBS. Two-thirds of the individuals who develop GBS do so a few days or weeks after being sick with diarrhea or a respiratory infection, such as influenza, the bacterium Campylobacter jejuni, or Epstein Barr virus.

Reference:
MedlinePlus. (2013). *Guillain-Barre syndrome*. Retrieved from http://www.nlm.nih.gov/medlineplus/ency/article/000684.htm

In another example of complementary vaccine safety monitoring systems, in 2013, two vaccine safety systems, VSD and PRISM, were used by CDC and FDA to study whether intussusception, a type of bowel blockage most common among children under 2 years, was associated with rotavirus vaccines (RotaTeq and Rotarix). These safety assessments were undertaken to better quantify the potential risk of intussusception among U.S. children. In 1999, a different rotavirus vaccine, RotaShield, was voluntarily withdrawn from the U.S. market by the manufacturer because of an association with intussusception. Prior to FDA licensing of RotaTeq and Rotarix, the risk of intussusception was assessed in large clinical trials of more than 60,000 children for each vaccine. No increased risk for intussusception was observed for either vaccine. However,

[23] Salmon, D. A., Proschan, M., Forshee, R., Gargiullo, P., Bleser, W., Burwen, D. R., Cunningham, F., ... H1N1 GBS Meta-Analysis Working Group. (2013). Association between Guillain-Barré syndrome and influenza A (H1N1) 2009 monovalent inactivated vaccines in the USA: a meta-analysis. *Lancet, 381*(9876), 1461-1468. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/23498095

several post-licensure studies conducted in other countries subsequently suggested potential increased risk of intussusception after both Rotarix® and RotaTeq®. Using VSD data, CDC was able to determine the association of monovalent rotavirus vaccine with intussusception that was approximately 1 extra case of intussusception for every 20,000 children fully vaccinated, and provided the Advisory Committee on Immunization Practices (ACIP) with this new information. VSD data did not uncover an increased risk of intussusception following RotaTeq. FDA Mini-Sentinel researchers observed 1 to 1.5 additional cases of intussusception per 100,000 first doses of RotaTeq. The data from the Mini-Sentinel PRISM study regarding the risk of intussusception following the use of Rotarix were inconclusive. FDA approved required revisions to the Prescribing Information and Patient Information for RotaTeq as a result of the new safety data from this Mini-Sentinel PRISM study and publicly communicated that the benefits of RotaTeq and Rotarix vaccination continue to outweigh the risks associated with vaccination, including the risk of intussusception. FDA also provided the ACIP with its study results. These findings were considered by ACIP, which concluded that the benefits of either rotavirus vaccine continue to outweigh the risks associated with vaccination, including the small excess risk of intussusception. More information on FDA's findings, VSD, and PRISM can be found below.

Research on the Administration and Use of Different Childhood Rotavirus Vaccines for Ensuring Safety and Effectiveness

Physicians and other immunization providers who switch between vaccines made by different companies or administer sequential vaccinations using different delivery methods may raise concerns regarding both effectiveness and safety. An example can be found in the prevention of rotavirus, for which there are two licensed vaccines in the United States—Rotarix and RotaTeq—that have different dosing schedules. To understand the clinical implications of this practice, NIH/NIAID is conducting a study with these two different rotavirus vaccines to assess safety and effectiveness when the vaccines are interchanged during sequential vaccinations. Additionally, in August 2011, NIH published the results of a study conducted during the 2005–2006 and 2006–2007 influenza seasons that showed children under the age of 3 receive the same protection against influenza from two doses of seasonal influenza vaccine regardless of whether they receive two different vaccines during the two-dose series, providing reassurance for parents that their children will still be protected using two different influenza vaccines.[24]

Examining the Safety of the Childhood Immunization Schedule

Through the use of recommended childhood vaccines, the rates of most vaccine preventable diseases in children are at historic lows. However, it is important to continuously monitor the safety of vaccines for possible side effects or very rare adverse effects to fully protect the health of children. HHS is committed to ensuring the safety of vaccines, when administered according to the childhood immunization schedule. In early 2013, two key findings were

[24] U.S. National Institute of Allergy and Infectious Diseases (NIAID). (2011). *Any prime-boost mix of injected or spray flu vaccine shields toddlers.* Retrieved from http://www.niaid.nih.gov/news/newsreleases/2011/Pages/fluMixMatch.aspx

released reinforcing the safety of the childhood schedule. The results of the investigations, one conducted by the IOM at the request of NVPO and the other by CDC, reaffirmed the overall safety of childhood vaccines, and the safety of the timing of the recommended childhood immunization schedule.

The results of the IOM and CDC studies directly address parents' concerns regarding the childhood immunization schedule. Parental vaccine-related safety concerns include children receiving too many vaccines before their second birthday, the administration of many vaccines in one doctor visit, and the possibility of a link between vaccines and learning disabilities. Some parents of young children report refusing or delaying vaccines, believing that delaying vaccine doses is safer than following the recommended immunization schedule. In a study conducted using the VSD and published in March 2013, the health care utilization patterns of under-vaccinated children aged 2 to 24 months were examined.[25] The study found that under-vaccination in children is a growing trend, with the percentage of children in the study population that spent any time under-vaccinated increasing from 41.8 percent in 2004 to 54.4 percent in 2008. The study also found that under-vaccinated children had fewer outpatient visits but higher inpatient admission rates than fully vaccinated children. The patterns in health care usage found through this study shed light on a complicated public health challenge and will shape future research on the safety of alternative immunization schedules.

An **under-vaccinated** individual has not received all recommended vaccines according to immunization schedules recommended by ACIP and CDC.

The IOM report on the safety of the childhood immunization schedule,[26] commissioned by NVPO and informed by the VSD study mentioned above, emphasized the importance of the childhood immunization schedule and the utility of the VSD and other systems to continue to monitor its safety. The report also encouraged the continued use of the United States' vaccine safety monitoring systems to identify adverse events following immunization. In another study, CDC, working in collaboration with public health consultants Abt Associates, found no evidence of an association between following the recommended vaccination schedule during the first

Rates of routine vaccine coverage among kindergartners have remained near the Healthy People 2020 goal of 95 percent for the past two school years. **However, during the 2012–2013 school year, over 91,000 exemptions were reported among kindergartners.** In many states, parents can request that their child be exempt from some or all routine vaccines on the basis of medical, religious, or philosophical grounds. Exemptions often cluster geographically.

If the number of unvaccinated children reaches a certain threshold in a school or community, outbreaks of vaccine preventable disease could occur.

Reference:
Seither, R., Shaw, L., Knighton, C. L., Greby, S. M., & Stokley, S. Vaccination coverage among children in kindergarten -- United States, 2012–2013 School Year. *Morbidity and Mortality Weekly Report, 62*(30), 607–612. Retrieved from http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6230a3.htm?s_cid=mm6230a3_w

[25] Glanz, J. M., Newcomer, S. R., Narwaney, K. J., Hambidge, S. J., Daley, M. F., Wagner, N. M., McClure, D. L., ... Weintraub, E. S.(2013). A population-based cohort study of undervaccination in 8 managedcare organizations across the United States. *JAMA Pediatrics, 167*(3), 274–281. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/23338829

[26] National Research Council. (2013). *The childhood immunization schedule and safety: Stakeholder concerns, scientific evidence, and future studies*. Washington, DC: The National Academies Press. Retrieved from http://www.iom.edu/Reports/2013/The-Childhood-Immunization-Schedule-and-Safety.aspx (exit link disclaimer)

two years of life and the risk of developing an autism spectrum disorder.[27]

It is important to highlight that serious adverse events following immunization are very rare. In most cases, vaccines do not cause health problems, or cause only mild reactions such as fever or soreness. To ensure safety, HHS and other partners have developed a robust, multicomponent vaccine safety monitoring system to detect and evaluate rare serious adverse events. HHS will continue working with its partners to support and improve these systems to better understand and continue ensuring the safety of vaccines that are used in the United States.

Using Electronic Health Data to Monitor Vaccine Safety

Over the past decade, electronic health data has become increasingly available. The use of electronic health records (EHRs) has enabled CDC to develop one of the nation's flagship vaccine safety monitoring systems. Since 1990, the CDC's VSD has been the backbone of post-marketing U.S. vaccine safety research. It has allowed CDC to quickly assess the safety of vaccines received by children, adolescents, and adults in an innovative way through active surveillance of electronic health data, identifying adverse events after vaccination and assessing risks and risk factors in near real-time. VSD provides scientific expertise and has been the primary source for population-based evaluations of vaccine safety in the United States. Results from VSD studies answer urgent questions about vaccine safety and help guide interventions and risk management strategies.

The VSD network currently has approximately 3 percent of the U.S. population under active surveillance (approximately 9 million people) and has an annual birth cohort of approximately 90,000. Since VSD was established, it has accrued, and has access to, approximately 2 billion patient records and over 137 million vaccination records. VSD investigators publish in the medical and scientific literature, with many studies contributing to the evidence used in IOM reviews of vaccine safety and ACIP policy recommendations. VSD data are presented at public meetings of federal advisory committees and are published in the peer-reviewed literature, providing transparency of the monitoring and research processes.

VSD studies have been instrumental in development of U.S. vaccine policy. In the last couple of years, VSD studies have found that influenza and pneumococcal conjugate vaccines were associated with febrile seizures in young children, leading to communications and policy changes; that a rotavirus vaccine was associated with a 1 in 20,000 chance of intussusception; and that no significant adverse health outcomes have been associated with the human papillomavirus (HPV) vaccine. VSD identified the significant diversity among children in use of vaccination schedules other than the schedule recommended by ACIP and CDC, aiding the IOM in understanding the complexity of their charge to assess the safety of the recommended childhood schedule; the IOM recommended VSD be used for future studies of the immunization schedule and health.

[27] DeStefano, F., Price, C. S., & Weintraub, E. S. (2013). Increasing exposure to antibody-stimulating proteins and polysaccharides in vaccines is not associated with risk of autism. *The Journal of Pediatrics, 163*(2), 561–567. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/23545349

HHS has further expanded its capabilities to study vaccine safety using electronic health data with the Mini-Sentinel pilot project. Mini-Sentinel is being sponsored by FDA to create a large population-based active surveillance system that will help monitor the safety of FDA-regulated medical products using pre-existing electronic health care data from multiple sources. Collaborating institutions provide access to data as well as scientific and organizational expertise.

The PRISM program is the part of Mini-Sentinel that focuses specifically on vaccines. The association between intussusception and RotaTeq and Rotarix vaccination was recently evaluated in Mini-Sentinel's PRISM program. Intussusception is a serious and potentially life-threatening condition that occurs when the intestine gets blocked. One portion of the intestine telescopes into a nearby portion, causing an intestinal obstruction. The results of this important study, summarized below, were released in June 2013.[28]

More than 1.2 million RotaTeq vaccinations (507,000 first doses) and 103,000 Rotarix vaccinations (53,000 first doses) were evaluated among infants 5 through 36 weeks of age. From 2004 through 2011, potential cases of intussusception were identified from the inpatient or emergency department settings, and vaccine exposures were identified through electronic procedure and diagnosis codes. Medical records were reviewed to confirm intussusception and vaccination status.

The risk of intussusception was assessed in the periods 1–7 days and 1–21 days after vaccination. The study identified an increased risk of intussusception within 21 days following the first dose of RotaTeq, with the majority of cases occurring in the first seven days. No increased risk was identified after the second or third doses. Based on these results, approximately 1 to 1.5 additional cases of intussusception would occur per 100,000 vaccinated U.S. infants within 21 days following the first dose of RotaTeq.

As a result of the new safety data from this Mini-Sentinel PRISM study, FDA required and approved revisions to the Prescribing Information and Patient Information for RotaTeq and issued a safety communication to the public explaining the findings. The data from the Mini-Sentinel PRISM study regarding the risk of intussusception following the use of Rotarix were inconclusive because of the relatively small number of infants under surveillance who received Rotarix. However, the Rotarix Prescribing Information includes information on an estimated risk of approximately 1 to 3 additional cases of intussusception hospitalizations per 100,000 vaccinated infants in the United States within seven days following the first dose of Rotarix, based on data from a post-marketing active surveillance study conducted in Mexico. The vast majority of babies who get rotavirus vaccine do not experience any adverse events following immunization, and the benefits of RotaTeq and Rotarix vaccination continue to outweigh the risks associated with vaccination, including the risk of intussusception.

[28] U.S. Food and Drug Administration. (2013). *FDA releases final study results of a Mini-Sentinel postlicensure observational study of rotavirus vaccines and intussusception.* Retrieved from http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ucm356758.htm

FDA's PRISM program is establishing a national system for active vaccine safety surveillance within Mini-Sentinel, a system that includes data from more than 100 million patients in the United States. PRISM addresses key gaps in existing vaccine safety monitoring capabilities in the United States by assembling a nationally representative surveillance population with very large size and statistical power, and by capturing data from sources outside traditional health care systems.

Advances in the Science, Surveillance, and Safety of Vaccines

By Margaret Hamburg, MD
Commissioner of Food and Drugs, FDA
U.S. Department of Health and Human Services

Vaccines play a critical role in protecting people of all ages from serious and sometimes deadly diseases. Because vaccines play such an important role in public health, vaccine safety is one of our highest priorities at FDA. FDA begins its evaluation of vaccine safety before a vaccine is even studied in human clinical trials and continues the evaluation as long as a vaccine is on the market. Once clinical trials begin, and throughout the clinical trial process, physicians and other scientists at FDA's Center for Biologics Evaluation and Research (CBER) carefully assess the emerging safety information as well as information on effectiveness. FDA may license a vaccine only after clinical studies demonstrate that it is safe and effective. After licensure, physicians and other experts at FDA/CBER continue to evaluate safety information from any post market clinical trials and from routine use of the vaccine.

FDA has many tools to continually evaluate the safety of vaccines. One of the ways we monitor for safety is through the VAERS, which is jointly managed by FDA and CDC. Anyone can report adverse events following vaccinations, and we encourage reporting because it helps us better understand and identify potential emerging safety issues. FDA also combines data mining of adverse event reports with clinical review of individual cases to detect new safety issues, which are known as "safety signals." Such issues may trigger additional evaluation. FDA calls this a "life-cycle" approach to vaccine safety because monitoring continues as long as the vaccine remains on the market.

To further enhance the evaluation of vaccine safety signals, FDA now utilizes the PRISM system, which is the vaccine safety component of the FDA's Mini-Sentinel program. PRISM is the largest vaccine safety surveillance system in the United States, with active observation of a representative subset of the general population. Because PRISM has access to historical information for over 100 million people, FDA is able to identify and analyze rare health outcomes that have previously been challenging to assess.

With PRISM, we have greatly advanced vaccine safety surveillance. For example, beginning in 2010, several epidemiological studies conducted outside the United States suggested that intussusception, a potentially life-threatening intestinal condition, might be linked to use of U.S. licensed rotavirus vaccines. Such information led FDA to initiate the largest study of this issue in PRISM to quantify the potential risk of intussusception after administration of rotavirus vaccine among U.S. children. Less than three years later, the PRISM system reported conclusions from an analysis of more than 1.2 million RotaTeq (rotavirus vaccine, live, oral, pentavalent) vaccinations among infants 5 through 36 weeks of age. The study identified an increased risk of intussusception 21 days following the first dose of RotaTeq, with the majority of cases occurring in the first 7 days. As a result, FDA required a safety labeling change in the Prescribing Information and Patient Information for RotaTeq. The label now describes

important signs and symptoms of intussusception as well as the risk attributed to vaccine use. Safety data had previously indicated a risk of intussusception with use of another U.S. licensed rotavirus vaccine, Rotarix, leading to a similar labeling change. It is important to note that the risk of intussusception is small, and the benefits of these rotavirus vaccines continue to outweigh the risks.

FDA devotes considerable scientific expertise to monitoring and evaluating reports of potential adverse events following vaccination. Now, the PRISM system can significantly decrease the time between safety signal identification and evaluation. PRISM has also increased the precision of risk estimates, which better inform FDA in actions it may take to protect and promote the health of the American public.

The Vaccine Safety Data System

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The response to the pandemic of influenza due to H1N1 with a rapidly developed vaccine presented a substantial challenge for monitoring its safety. This challenge required a major, rapid expansion of surveillance strategies. Under the aegis of an interagency coordinating committee, surveillance techniques and analyses developed by CDC and FDA were extended to data from DoD and VA, and IHS, and a new network was developed to link vaccine registries with medical records obtained from insurance firms.[29] The success of this endeavor to provide timely oversight, and eventually, reassurance about the safety of the vaccine rested on the almost two decades of development and methodological investment in monitoring vaccine safety.

After the investigations that lead to the licensing of a vaccine, the mainstay of post-marketing surveillance is the mandated reporting of adverse events following vaccines, a reporting system jointly overseen by CDC and FDA was created, VAERS.[30] Because it is a passive reporting system, VAERS incurs a number of limitations including variable clinical information, potential underreporting and overreporting, vague descriptions of adverse events, uncertainty about the generalizability of the information, lack of data on concomitant exposures and supportive tests, and, perhaps most importantly, major limitations in assessing the causal relationship between vaccine exposure and the adverse event. To address these deficiencies, CDC began to explore the use of large linked databases consisting of computerized medical records with information on both vaccines and health events. This experience led to a partnership between CDC and several health maintenance organizations (HMOs) to create a mechanism for examining adverse medical events following vaccine administration, the VSD,[31] for both descriptive epidemiological studies of vaccine administration and assessments of causal links between vaccines and a variety of adverse outcomes. Further work led to the development of analytic techniques for surveillance of adverse events rapidly.[32]

The experience with the H1N1 surveillance highlighted both the potential of the new surveillance techniques as well as some of the challenges of expanding coverage that point to

[29] Salmon, D. A., Akhtar, A., Mergler, M. J., Vannice, K. S., Izurieta, H., Ball, R., ... H1N1 Working Group of Federal Immunization Safety Task Force. (2011). Immunization-safety monitoring systems for the 2009 H1N1 monovalent influenza vaccination program. *Pediatrics, 127*(Suppl 1), S78–86. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/21502251

[30] Chen, R. T., Rastogi, S. C., Mullen, J. R., Hayes, S. W., Cochi, S. L., Donlon, J. A., & Wassilak, S. G. (1994). The Vaccine Adverse Events Reporting System (VAERS). *Vaccine, 12*(6), 542–550. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/8036829

[31] Chen, R. T., Glasser, J. W., Rhodes, P. H., Davis, R. L., Barlow, W. E., Thompson, R. S., ... Hadler, S. C. (1997). Vaccine Safety Datalink project: A new tool for improving vaccine safety monitoring in the United States. The Vaccine Safety Datalink Team. *Pediatrics, 99*(6), 765–773. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/9164767

[32] Yih, W. K., Kulldorff, M., Fireman, B. H., Shui, I. M., Lewis, E. M., Klein, N. P., ... Lieu, T.A. (2011). *Pediatrics, 127*(Suppl 1), S54–64. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/21502252

the future. First, the rapid implementation of analytic capacity in systems with EHRs (both medical records and registries) points to the potential for broader surveillance with the expansion of EHRs more generally. In particular, broadening the reach of the systems will permit better understanding of the risk of adverse events in smaller, potentially vulnerable populations. This approach is being developed in a pilot project, the FDA Mini-Sentinel.[33]

However, as the H1N1 experience revealed, including populations that have not previously been covered requires additional methodological work to be assured of the validity of the diagnoses for adverse events related to vaccines rather than reflections of other, coexisting morbidity. Second, the diagnostic coding system is currently less than optimal for examining vaccine safety on some groups, especially pregnant women, and additional strategies may be needed for this important subgroup, such as that developed for H1N1. Moreover, timeliness remains an issue. Although the vast majority of potential adverse reactions to the H1N1 vaccine were rapidly eliminated, assessing the causal connection in the remaining few was not completed until three years after the roll-out of the vaccine. Improved timeliness of assessment may occur with some of the methodological work needed to refine the precision of detecting adverse events related to vaccines. However, improved timeliness and accuracy of establishing vaccine-related adverse events will also require laboratory methods to validate the epidemiologic findings, and new characterizations at the genetic or immunologic levels of the risk for adverse events, as outlined in the National Vaccine Plan.

[33] Mini-Sentinel. (2011). *Mini-Sentinel*. Retrieved from http://www.mini-sentinel.org/ (exit link disclaimer)

Vaccine Safety: Evidence and Belief

By Harvey V. Fineberg, MD, PhD
President, Institute of Medicine

Over the past 35 years, the Institute of Medicine has conducted more than 60 studies related to vaccine safety. Two years ago, a committee of experts reviewed possible adverse effects of eight vaccines, assessing the possible relation to immunization of 158 specific health problems.[34] Some vaccines were found to cause anaphylaxis in rare instances. The committee found evidence sufficient to favor rejection of a causal association in five instances, including measles, mumps, and rubella vaccine (MMR) and autism, and inactivated influenza vaccine and asthma. While few health problems are clearly associated with vaccines and some putative associations can be rejected based on evidence, in the majority of cases evidence was inadequate to accept or to reject a causal relationship.

Physicians and public health champions, mindful of the devastating consequences of vaccine preventable illness and the profound role of vaccines in saving lives and increasing life expectancy, stress the few demonstrated associations of adverse events and vaccines and the enormous value of vaccines for health. And yet, some individuals and groups in the United States reject immunization for themselves and their children. Some are convinced of an association because the timing of an adverse event's presentation followed soon after immunization, such as the first symptoms of autism appearing a few weeks or months after immunization and a febrile reaction—and no amount of epidemiological evidence will dislodge this conviction. Others may be suspicious of science, resist all medical interventions on the basis of religious belief, or simply believe that avoiding vaccines is the safer course for their child, especially when the evidence is inconclusive on most possible side effects.

Identifying potential adverse events in connection with vaccines depends in the first instance on surveillance and reporting. Surveillance tools that have been developed and deployed over the years include VAERS jointly administered by CDC and FDA, the VSD that connects electronic data systems at selected health maintenance organizations with CDC, and the PRISM system at FDA. Although these systems each have their limitations, they can help trigger attention to possible side effects and aid in their assessment.

Confidence in vaccine safety requires more than surveillance and reporting in real time. In light of the paucity of strong conclusions about possible vaccine side effects, continued and selective investment in epidemiologic and other investigations into the risks of immunization will be necessary. A scientific research design is generally intended to test whether an effect is present, or more precisely, whether the evidence for an association is sufficient to reject the assumption of no causal association. However, insufficient evidence for a causal connection is not the same as evidence for the absence of any association. About the best one can do is to

[34] National Research Council. (2012). *Adverse effects of vaccines: Evidence and causality.* Washington, DC: The National Academies Press. Retrieved from http://www.iom.edu/Reports/2011/Adverse-Effects-of-Vaccines-Evidence-and-Causality.aspx (exit link disclaimer)

estimate, based on the evidence, the probability that the frequency of an adverse event is less than a specified, low level. This may be enough for the physician who weighs the public health and personal health benefit against a very low risk, but not enough to satisfy a wary parent.

Continued, candid, and open communication is also an essential ingredient to a successful vaccine safety regime. This means more than the experts explaining the benefits and risks to parents and families. It means listening carefully to the anxieties and doubts, staying true to the strength of evidence without exaggeration or misrepresentation, and reporting fully and fairly on scientifically sound investigations into possible adverse events.

Goal 3: Support Communications to Enhance Informed Vaccine Decision-Making

In this section:

- Research on and Development of Communication Strategies
- Vaccine Communications to the Public and Key Intermediaries
- Vaccine Communications to Policy Makers
- Feature: Understanding Adult Vaccine Decision-making: Insights from Recent Research
- Feature: Vaccines.gov
- Commentary: *Understanding Parental Decision-making about Vaccines: A Neglected Research Area,* by Seth Mnookin
- Commentary: *Communications and Vaccines,* by Dr. K. Viswanath

Background

Developing communication that effectively informs vaccine decision-making, promotes public support for vaccines, and increases compliance with immunization recommendations is a complex process. Developing effective communication is also profoundly important in reaching immunization coverage goals and protecting the health of people in the United States. Goal 3 focuses on developing communications and disseminating materials and messages that provide accurate, timely, transparent, and audience-appropriate information about vaccines and vaccination.

Through its work in communications in this area, HHS and its partners have set out to reinforce the importance of vaccines and help people make decisions about immunization for themselves and their families across the United States—and the world. A few examples of these communication efforts can be found in this section. In order to facilitate collaboration and coordination among agencies, NVPO works to ensure that vaccine communicators are connected and sharing information, aligning communications efforts across HHS.

Recent Accomplishments and Progress

Research On and Development of Communication Strategies

Research can help us better understand the nature of vaccine decision-making and the factors that support such decisions. An example of this research is work being undertaken by NIH to examine strategies to provide information about the health benefits of the HPV vaccine and to address misinformation that sometimes surrounds the HPV vaccine. NIH-supported investigators developed a web-based intervention, *Go Healthy Girls*. The intervention is being tested in New Mexico, which is home to many families of Hispanic and Native American descent and represents a multiethnic population. The goal of the project is to test two websites—one for parents and another for adolescent girls—that provide accurate information about the vaccine in order to reduce uncertainty and support informed decision-making about HPV vaccination. If the project is successful, it may be launched in other locations.

Vaccine Communications to the Public and Key Intermediaries

Over the past two years, several HHS agencies have made noteworthy progress in creating communication and educational materials to inform the public of the importance of vaccines. For example, in 2012, the IHS partnered with CDC to develop culturally appropriate flyers and posters for intermediaries to use to educate American Indian/Alaska Native communities on the importance of the influenza vaccine.[35] In preparation for the 2013–2014 influenza season, CMS developed educational materials in English and Spanish for use by key

Key intermediaries are those in a position to present important health information to the public. Health care personnel such as doctors and nurses are key intermediaries, along with important community members, such as religious leaders.

[35] Centers for Disease Control and Prevention. (2013). *Seasonal influenza (flu): Print materials: American Indian and Alaska Natives*. Retrieved from http://www.cdc.gov/flu/freeresources/print-native.htm

intermediaries and the general public to promote the influenza vaccine and offer tips for preventing influenza infections. In 2012, IHS also created "Ramona's Story," a digital story of an American Indian grandmother who contracted pertussis and passed it along to her infant granddaughter, communicating the importance of immunization for the whole family.[36]

FDA developed communication materials for consumers and health care providers on a variety of topics, of which a few are highlighted here. The agency issued a safety communication on FDA-required and FDA-approved revisions to the Prescribing Information and Patient Information for RotaTeq (rotavirus vaccine) explaining the findings of the new safety data from the Mini-Sentinel PRISM study described in Goal 2. FDA also released "Vaccines for Children: A Guide for Parents and Caregivers," which provides an overview of vaccines routinely given to infants and children, discusses how vaccines work, provides specific information about each vaccine, and answers common questions.[37] Additionally, FDA provided an update for the public on influenza vaccines titled "The Evolution and Revolution of Flu Vaccines," which describes the manufacturing process for influenza vaccines and the development and FDA-approval of vaccines that utilize new technologies.[38]

In 2013, NVPO supported the creation of communication materials to promote adult immunization to the public and key intermediaries. In partnership with JBS International, NVPO gave small grants to 30 community organizations, health clinics, local health departments, and others. The grantees used their funds to promote immunization to adolescents and adults through education, communication, and outreach. One project, called "Give It a Shot! Adults Need Them Too!" in Watertown, New York, included a comprehensive social marketing campaign to increase community demand for pneumococcal, shingles, and tetanus-diphtheria-pertussis (Tdap) vaccinations. The project relied on key intermediaries, such as food pantries, public libraries, and faith-based organizations, to get the message out to the community.

Vaccine Communications to Policy Makers

Good decision-making on vaccine policy requires the communication of accurate and timely information to vaccine policy makers. To meet this need, groups of federal and nonfederal experts inform vaccine policy in a variety of ways. For example, NIH/NIAID publishes *The Jordan Report: Accelerated Development of Vaccines*, which provides a snapshot of vaccine research and development and offers expert articles on topics related to vaccine development. The most recent issue of *The Jordan Report* was published in 2012.[39]

NVAC, established in 1987, is an advisory group created to provide expert guidance to policy makers on all vaccine and immunization issues. Supported at HHS by NVPO, NVAC has also provided a guiding vision for the National Vaccine Plan and meets three times a year. Since the

[36] Indian Health Service. (2012). *Ramona's story* [Video]. Retrieved from http://www.ihs.gov/forpatients/healthtopics/WhoopingCough/
[37] U.S. Food and Drug Administration. (2013). *Vaccines for children – A guide for parents and coregivers*. Retrieved from http://www.fda.gov/BiologicsBloodVaccines/ResourcesforYou/Consumers/ucm345587.htm
[38] U.S. Food and Drug Administration. (2013). *The evolution, and revolution, of influenza vaccines*. Retrieved from http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm336267.htm
[39] U.S. National Institute of Allergy and Infectious Diseases. (2012). *The Jordan report: Accelerated development of vaccines 2012*. (NIH Publication No. 11-7778). Washington, D.C. Retrieved from http://www.niaid.nih.gov/topics/vaccines/pages/Jordan2012.aspx

launch of the 2010 National Vaccine Plan, NVAC has made significant contributions to inform vaccine policy decision-making, authoring reports and making recommendations on vaccine safety, health care personnel immunization, and adult immunization, among other topics. One example of NVAC's role in vaccine policy communication can be found in their recent report on the Section 317 Immunization Program. Their report highlighted the attributes of this important program, made a strong recommendation for continued support by the U.S. government, and called for innovative solutions from health officials that would improve vaccine coverage rates through the Section 317 Immunization Program. The report not only provides guidance to HHS policy leadership on the importance and continued support of the Section 317 Immunization Program at the national level, it has also shed light on the important work being done by state health departments to support the U.S. immunization infrastructure. An overview of the recent accomplishments and historical contributions of NVAC is included in this report.

The ACIP is a federal advisory committee consisting of medical and public health experts who develop recommendations on how to best use vaccines to control diseases in the United States. The ACIP, supported at HHS by CDC, provides essential guidance to parents, health care providers, the Director of CDC, HHS, and other agencies and departments within the U.S. government on the use of vaccines. The ACIP reviews all relevant medical and epidemiologic data on FDA-approved vaccines and regularly reviews its recommendations based on the best available data.

Recent ACIP Recommendations:

- Influenza vaccines (2013–2014 season)
- Updated recommendations for use of VariZIG (to prevent varicella)
- PCV13 and PPSV23 for ages 6–18 years with immunocompromising conditions
- MMR and CRS
- Meningococcal disease
- Tdap and pregnancy
- Infant meningococcal vaccination
- PCV13 and PPSV23 for adults with immunocompromising conditions
- Influenza vaccines (2012–2013 season)
- Tdap for adults age 65 and older
- PCV13 for adults age 50 and older
- New framework (GRADE) for development of evidence-based recommendations
- VariZIG for postexposure prophylaxis of varicella

Reference:
U.S. Centers for Disease Control and Prevention. (2013). *Vaccine recommendations of the ACIP*. Retrieved from http://www.cdc.gov/vaccines/hcp/acip-recs/recs-by-date.html

Finally, the Adult Immunization Task Force (AITF), which grew from a prior focus on influenza vaccination and began its work in 2012, is the federal component of the National Adult and Influenza Immunization Summit (NAIIS), a collaboration between a broad range of immunization stakeholders including representatives from government, professional organizations, the public health community, and representatives from the public and private sector to work toward a strong domestic adult and influenza immunization program. The adult immunization focus of the NAIIS and the AITF was established in 2011 in response to NVAC recommendations on adult immunization.[40] The NAIIS meets annually, meeting for the first

[40] National Vaccine Advisory Committee. (2011). A pathway to leadership for adult immunization: Recommendations of the National Vaccine Advisory Committee. *Public Health Reports, 127*(Suppl 1), 1–42. Retrieved from http://www.publichealthreports.org/issueopen.cfm?articleID=2762 (exit link disclaimer)

time in 2012, and again in 2013. The NAIIS collaboratively seeks to improve adult immunization at all levels through activities that support the fostering of easy vaccine access, addressing health disparities, and facilitating patient and provider education. The AITF leverages the strengths of the U.S. government to enhance adult immunization through improved coordination and collaboration throughout HHS and in conjunction with other federal partners.

Understanding Adult Vaccine Decision-making: Insights from Recent Research

Rates of routine adult immunization remain low overall and below Healthy People 2020 targets, causing concern in the public health community.[41] In March 2013, CDC conducted focus groups with adults to better understand their knowledge, attitudes, and beliefs on adult immunization, including adults' reasons for not protecting themselves from vaccine preventable diseases through immunization. CDC is using this information to refine communications strategies as part of a larger effort to increase adult immunization rates in the future.

During the focus groups, CDC found that many adults have low awareness and knowledge about adult vaccines besides influenza. Adults do believe that being vaccinated is important, especially for certain people, such as older adults, people with chronic conditions, and people whose jobs or hobbies expose them to many people and/or sick people. However, adults without chronic conditions are not concerned about getting vaccinated because they do not think they are at high risk for getting a vaccine preventable disease. Focus group participants also said there were barriers to adults getting recommended vaccinations. Commonly reported barriers included a lack of awareness about vaccine preventable diseases and available vaccines, questions about vaccine effectiveness and safety, concerns about side effects, and cost. Adults trust their doctors to provide information about vaccines and turn to them with questions about vaccination and vaccine safety. Most are likely to get a vaccine if recommended by their doctor.

CDC found that raising awareness about adult vaccination is necessary, but that awareness alone will not be enough to increase vaccination rates. Adults need to be encouraged to ask if they need vaccines each time they see a health care provider. Communication to adults on vaccine preventable diseases and vaccines should be focused on the value and benefits of vaccination and presented in plain language. Adults need materials and information to help them understand the benefits and risks of immunization to make informed decisions. Health care providers need resources to assist them in routinely assessing vaccination status and making recommendations as well as providing resources to help them handle patient questions and concerns.

Based on these findings, CDC is working with health care professionals, consumer groups, and other partners to develop a comprehensive communication program that addresses the needs

[41] Williams, W. W., Lu, P. J., Greby, S., Bridges, C. B., Ahmed, F., Liang, J. L., Pilishvili, T., & Hales, C. (2013). Noninfluenza vaccination coverage among adults – United States, 2011. *Morbidity and Mortality Weekly Report, 62*(04), 66–72. Retrieved from http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6204a2.htm

uncovered during these focus group discussions. By addressing these needs, the program aims to make adult vaccination a higher priority among health care providers, increase demand for adult vaccines, and contribute to the national effort to increase adult vaccination rates.

Vaccines.gov

In 2011, NVPO launched vaccines.gov, a cross-government website that brings together the best in federal resources on vaccine and immunizations. It provides easy-to-understand health information specifically designed for the general public. Vaccines.gov is the result of unprecedented collaboration among federal health and communications experts to offer accurate online content about vaccines and immunization. It includes content and expertise from CDC, FDA, NIH, the Health Resources and Services Administration (HRSA), and other federal agencies.

The site includes information about vaccine safety and effectiveness, immunization recommendations, the diseases that vaccines prevent, important information for getting vaccinated, and tips on travel health. It also provides information on local and state vaccine requirements for school and daycare entry. The site was developed with significant public input and as such, is designed to be user-friendly. It provides a one-stop resource for information about diseases that vaccines prevent, and connects the public with resources that will allow parents, patients, and others to make informed decisions for their health. All of this information is also available in Spanish at espanol.vaccines.gov, the first federal website to offer a comprehensive resource for vaccine and immunization information in Spanish.

Vaccines.gov was awarded the 2011 WebAward for Outstanding Achievement in Web Development in the Government Standard of Excellence category in September 2011 by the Web Marketing Association. Vaccines.gov has also been a popular source of immunization information for consumers, with over 375,000 visitors coming to the site in 2012.

Understanding Parental Decision-making about Vaccines: A Neglected Research Area

By Seth Mnookin
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Author, *The Panic Virus*

In February 1998, Andrew Wakefield published what was eventually shown to be a fraudulent paper speculating on a possible link between the measles component of the MMR vaccine and autism spectrum disorders. On the day the paper was released, Wakefield stood at a lectern at London's Royal Free Hospital and told the assembled news media, "I cannot support the continued use of [the measles, mumps, and rubella] vaccines given together." The response of the majority of the medical and scientific communities at the time ranged from mild concern to shrugging indifference: Wakefield's research was so obviously shoddy, his conclusions so demonstrably unsupported by the evidence, who could possibly take him seriously? Lots of people, it turned out—and in the coming years, MMR uptake dropped to as low as 54 percent in some areas of the UK.

The following summer, CDC and the American Academy of Pediatrics released statements explaining why they were recommending that the mercury-based preservative thimerosal be removed from most pediatric vaccines. The language used in those statements—there was "no evidence of harm"; the move would "make safe vaccines even safer"—was meant to reassure the public. They did the opposite, sparking a parent-led movement whose members remain convinced to this day that mercury is a leading cause of autism—despite the fact that thimerosal has been absent from standard pediatric vaccines for more than a decade.

Medical interventions do not take place in a vacuum—they occur in particular societal frameworks at specific moments in history. Without scientific advances these interventions would not be possible, but without effective communications strategies, they will never reach their full potential. Perhaps nothing illustrates this better than the ways in which the two events described above—events that occurred across an ocean from each other, well over a decade ago—continue to influence public sentiment about vaccine efficacy and safety even today. In the late 1990s, it was difficult to find reliable, evidence-based information about vaccines that could be easily understood by the layperson. When misinformation began to spread, there was no way to contain it and no plans in place as to how best to combat it.

Today, that is no longer the case. This welcome new reality is illustrated by the projects and programs that have emerged out of Goal 3 of the 2010 National Vaccine Plan, including the development of vaccines.gov as an easy-to-navigate web portal for reliable, straightforward information about vaccines.

But producing reliable content is only one part of the challenge. Even more important are the ongoing efforts to understand *how* and *why* people make the decisions they do. We would not, after all, rely on guesswork when making decisions about vaccines, so why should we depend on informed speculation when coming up with effective communications strategies? Ongoing, sophisticated research programs that examine people's attitudes and beliefs about vaccination, as well as the factors that influence these sentiments, will determine whether we'll be successful in inoculating ourselves against the misinformation and propaganda campaigns of the future.

Communications and Vaccines

By K. Viswanath, PhD
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We are in exciting times for science and technology. Developments in biological sciences and information and communication technologies (ICT) offer tremendous potential for advancing our understanding of disease causation, prevention, discovery, development, and delivery of treatments. The communications revolution has changed radically the way we learn, play, work, entertain ourselves, and relate to each other. It is in the way we learn and relate to each other that is germane to our discussion on vaccines. To understand the importance of the communications revolution to vaccines, we must understand its four key features as noted elsewhere in our writings.

First, the sheer amount of information that is being generated, good and bad, accurate and inaccurate, trivial and important, is overwhelming, unlike anything we have seen in history, and it can be accessed from a variety of platforms and devices.

Second, because of these multiple platforms virtually ANYONE with access to the Internet and a few technical skills can generate information and offer opinions or critiques. The consequence is that traditional command and control over dissemination of scientific information is increasingly contested by grassroots participation of interested stakeholders. That is the good news. On the other hand, it is also true that scientific facts become malleable in the hands of those who have a stake in working against them, and the platforms allow them to disseminate their opinions widely.

Third, the networked environment has brought about a marvelous ability to connect people and places. Yet the same environment, especially in social media, where people tend not to be exposed to other viewpoints, has become an echo chamber for misrepresentation of science and repetition of canards.

Last, the benefits of the ICT revolution are accruing unequally across socioeconomic, racial, and ethnic groups, a phenomenon characterized as communication inequalities. While informed decision-making is noble, important, and necessary, not all groups benefit because of lack of access to information, the complexity of the information, or the lack of capacity to act on it.

Where does this leave us? The National Vaccine Plan boldly lays out goals for the country to address such critical topics as developing new and improved vaccines, enhancing the vaccine safety system, and using communications to enhance informed decision-making, among others. The recommendations are timely if not urgent. We can draw on the social sciences to understand the individual and social contextual determinants that influence perceptions of vaccine safety, affect confidence and acceptance, and affect vaccination behaviors. Based on

this understanding, drawing upon health communication sciences and social marketing principles, we should be able to address misperceptions, reinforce trust in science, and improve access to reliable information and facilitate action. Specifically, we need more work in three areas: (1) What are the individual, population, and contextual determinants that engender, influence, reinforce, and change attitudes and perceptions towards vaccines, and how do they, in turn, influence actual behaviors? (2) How do we construct messages that promote confidence in vaccines and their acceptance among different audience groups and for different types of vaccines across the lifespan—childhood, adolescence and youth and adults? (3) What role do new ICTs (e.g., social media) play in disseminating information about vaccines? What kind of evidence-based interventions do we need to deliver the information effectively across population groups of different socioeconomic, racial, ethnic, and geographic backgrounds and promote informed decision making? In short, we need a solid evidence base to inform our vaccine policies and programs, and there is an urgent imperative to develop one.

The ICT revolution provides an incredible opportunity to interact with people about vaccines and make them partners in advancing the benefits from one of the most powerful tools in the public health arsenal. It is said that vaccines are one of the greatest public health success stories of the 20th century. We should take advantage of developments of the 21st century to ensure that the story continues and thrives.

Goal 4: Ensure a Stable Supply of, Access to, and Better Use of Recommended Vaccines in the United States

In this section:

- Vaccine Supply, Delivery, and Access
- Vaccine Financing
- Disease Surveillance and Vaccine Coverage Measurement
- Health Information Technology for Immunization
- Health Care Provider Education and Support
- Feature: Improving Vaccine Tracking through the Use of New Technologies
- Feature: HealthMap Vaccine Finder: Helping Adults Find the Vaccines They Need
- Commentary: *Lack of Progress in HPV Vaccination: A Crisis of Missed Opportunities for Cancer Prevention,* by Dr. Anne Schuchat
- Commentary: *Integrating Pharmacies into a Public Health Approach to Vaccination,* by Dr. Joshua Sharfstein, Dr. David Blythe, and Dr. Laura Herrera
- Commentary: *Is the National Vaccine Plan's Vision for Immunization Infrastructure a Brave New World for Immunization?*, by Dr. LJ Tan

Background

Healthy People 2020 data show that in 2011 the majority of childhood and toddler vaccination coverage rates met or exceeded their Healthy People 2020 targets. Substantial disparities exist among racial and ethnic groups in adult and adolescent vaccination levels for many vaccines. And, for many vaccines targeted to adolescents and adults such as the HPV vaccine, current coverage levels are falling short of targets.

HPV is a common sexually transmitted virus that usually causes no symptoms, but in some cases can lead to serious health problems, including cancer. Approximately 79 million persons in the United States are infected with HPV. In spite of the availability of a safe and effective vaccine for HPV, vaccination coverage among adolescent girls is behind that of other recommended vaccines for adolescents, and did not increase from 2011 to 2012. For every year that HPV vaccine coverage stays at its current level, approximately 4,400 additional adolescent girls will go on to needlessly develop cervical cancer later on in life.

Reference:
U.S. Centers for Disease Control and Prevention. (2013). *HPV vaccine: Safe, effective, and grossly underutilized.* Retrieved from http://www.cdc.gov/media/releases/2013/p0725-HPV-vaccine.html

Goal 4 focuses on addressing barriers to reaching goals for vaccine coverage. The intent of Goal 4 is clear: Make sure people of all ages in the United States have access to a readily available supply of recommended vaccines, and develop effective strategies to increase their use. To achieve this, the implementation of the National Vaccine Plan focuses on several areas, including ensuring a consistent and adequate supply of vaccines, ensuring adequate delivery of vaccines to patients by health care providers, reducing financial barriers to vaccination, educating health care providers in vaccination counseling, and conducting surveillance of vaccine coverage, vaccine effectiveness, and the occurrence of vaccine preventable diseases as well as diseases that may one day be prevented by vaccines that are not yet available. One of the primary responsibilities of NVPO is fostering collaboration across HHS agencies as a way to efficiently and effectively achieve these goals.

Recent Accomplishments and Progress

Vaccine Supply, Delivery, and Access

Ensuring that vaccines are available when they are needed is an essential part of the U.S. immunization program for both routine immunizations and public health emergencies. To better prepare the country's vaccine manufacturers for the possibility of an influenza pandemic, HHS (through ASPR/BARDA) awarded three-year contracts to five U.S.-licensed influenza vaccine manufacturers to produce master vaccine seed stocks for influenza viruses with pandemic potential so that vaccine can be produced rapidly before a pandemic occurs. This effort can shorten the time needed to produce a supply of pandemic vaccine, meaning that more people can be vaccinated and protected before and during a pandemic.

ASPR/BARDA also invested heavily in U.S. vaccine manufacturing infrastructure to expand domestic pandemic influenza vaccine manufacturing capacity. By partnering with vaccine developer and manufacturer Sanofi Pasteur and biotechnology developer MedImmune to retrofit existing vaccine manufacturing facilities, an additional 10 to 15 percent manufacturing

capacity was realized by 2013. Additionally, at the end of 2011, pharmaceutical company Novartis opened a new state-of-the-art cell-based influenza vaccine manufacturing facility in Holly Springs, North Carolina. It was built through a public-private partnership between ASPR/BARDA and Novartis, with extensive technical assistance from FDA. The facility substantially increases U.S.-based manufacturing capacity. It is designed to handle fast, high-volume cell-culture influenza vaccine and adjuvant production, which, once fully operational, can aid in speedier start-up of the vaccine manufacturing process in the event of an influenza pandemic. The facility will increase domestic manufacturing capacity another 25 percent for seasonal and pandemic influenza vaccines, as well as vaccines for other emerging infectious diseases in a public health emergency.

Recent FDA approval of additional seasonal influenza vaccines provides more diversity in the vaccine supply. The United States is now supplied by seven vaccine manufacturers who produce 15 safe and effective licensed influenza vaccines made by various manufacturing processes, including novel technologies, such as cell culture and recombinant protein expression. These technologies have the potential for a faster start-up of the vaccine manufacturing process in the event of a pandemic. A diverse vaccine supply fosters a more stable vaccine supply by reducing dependence on any individual vaccine manufacturer. FDA's expertise in the areas of research, vaccine manufacturing, and regulatory science has facilitated the availability of additional safe and effective influenza vaccines for the United States.

Many people are more likely to get a routinely recommended vaccination when access to that vaccine is very easy. In the case of influenza and other adult vaccines, for instance, pharmacists and other community-based immunizers are often uniquely positioned to promote and provide convenient access to vaccines. In 2012, NVPO and CDC worked with pharmacists and other vaccine providers to increase vaccine administration in nontraditional settings through a variety of strategies, such as

1. Raising awareness and knowledge.
2. Recommending and offering vaccines.
3. Stocking vaccines.
4. Linking with immunization registries.
5. Increasing collaboration with other local partners.

By working with pharmacists and other providers in this way, NVPO and CDC created momentum among pharmacists to re-envision themselves as vaccine providers in the "immunization neighborhood." This underscores the importance of strengthening immunization information systems (IIS) and EHRs to ensure that up-to-date immunization status is available to all health care providers at all times, regardless of where patients may receive a vaccine.

Vaccine Financing

For some Americans, cost has been a barrier to getting vaccinated. The Vaccines for Children program (VFC) provides free vaccines to eligible low-income children, and other limited funds

are available for adults in selected circumstances, but the Affordable Care Act of 2010 seeks to remedy this situation in a more comprehensive way. The Affordable Care Act expands access to health insurance and requires that recommended clinical preventive services be provided with no cost sharing in most health insurance plans. This means that millions more Americans will be able to receive recommended vaccines without paying out of pocket for them. The HHS Office of Health Reform, in collaboration with many other agencies and offices within HHS, is currently implementing this law and working hard to communicate the many coming changes with the public, health insurers, and health care providers. Big steps forward in 2013 included the launch of the new HealthCare.gov website in June, which provides individuals, families, and small businesses the information they need on the benefits of the program and how to access affordable health insurance.

Although all individuals over 6 months of age are recommended to get vaccinated every year to prevent influenza, some do not because of financial and other barriers. Walgreens partnered with HHS, nonfederal, and community partners from 2010 to 2013 in an innovative initiative. Each year, Walgreens donated up to 350,000 vouchers for free influenza vaccines. During the 2012–2013 influenza season, 182,000 vouchers were redeemed by those without health insurance who otherwise might not have been able to receive an influenza vaccine.

Disease Surveillance and Vaccine Coverage Measurement

Accurately tracking vaccine preventable disease rates is an important component of making informed vaccine policy and program decisions. CDC operates the National Notifiable Disease Surveillance System (NNDSS), which is a principal source of U.S. national surveillance data for these pathogens. These data are analyzed and results are routinely shared with local, state, national, and international public health partners. For example, NNDSS surveillance showed that in 2011 the United States had the highest number of measles cases since elimination of measles in the country was declared in 2000. NNDSS data also showed the majority of cases were imported from countries without adequate measles control or linked to unvaccinated or under-vaccinated individuals.

Ensuring high rates of childhood immunization not only protects the health of children, it can also indirectly prevent vaccine preventable diseases and their consequences in the community more broadly. **By protecting children from communicable disease, transmission of disease to older individuals can be prevented.** For example, after seven years of routine use of seven-valent pneumococcal vaccine in children, overall rates of pneumococcal disease in all age groups has decreased, but the specific types of pneumococcal infection covered by the vaccine have decreased especially dramatically. Additionally, in the years after the routine recommendation for rotavirus vaccine in infants, rates of gastroenteritis (viral intestinal infections) decreased among adults and children over the age of 5.

References:

Pilishvili, T., Lexau, C., Farley, M. M., Hadler, J., Harrison, L. H., Bennett, N. M., ...Active Bacterial Core Surveillance/Emerging Infections Program Network. (2010). Sustained reductions in invasive pneumococcal disease in the era of conjugate vaccine. *The Journal of Infectious Diseases, 201*(1), 32–41. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/19947881

Gastañaduy, P. A., Curns, A. T., Parashar, U. D., & Lopman, B. A. (2013). Gastroenteritis hospitalizations in older children and adults in the United States before and after implementation of infant rotavirus vaccination. *JAMA, 310*(8), 851–853. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/23982372

For certain diseases, data is received from specialized surveillance systems to address specific surveillance requirements to monitor the number of cases and to evaluate program and policy impact. For instance, as the incidence of pertussis has risen in recent years, CDC launched the Enhanced Pertussis Surveillance network to better monitor this public health issue. CDC has partnered with six states to conduct rigorous surveillance of pertussis. As another example, CDC monitors the impact of rotavirus vaccine in the United States through the National Respiratory and Enteric Viruses Surveillance System and the New Vaccine Surveillance Network. Using this surveillance data, CDC has demonstrated that rotavirus vaccines are highly effective in preventing severe rotavirus disease and that vaccine effectiveness does not wane over time in U.S. children.

The number of cases of **pertussis** in the United States has been rising since the early 1990s. In 2012, more than 48,000 cases of pertussis were reported—the highest number of cases reported since 1955. This has caused concern in the public health community, and experts are working to find solutions.

Reference:
U.S. Centers for Disease Control and Prevention. (2013). *Pertussis (whooping cough): Outbreaks – questions and answers*. Retrieved from http://www.cdc.gov/pertussis/outbreaks/faqs.html

In the absence of formal surveillance systems, CDC uses several methods to monitor herpes zoster (more commonly known as "shingles") disease patterns, vaccine uptake, and vaccine effectiveness. This monitoring includes administrative data available from VSD and Medicare and from commercial vendors, as well as data collected from a variety of special projects conducted in collaboration with partners. To complement information on vaccine program implementation, CDC also uses physician surveys to monitor knowledge, attitudes, and practices regarding herpes zoster vaccination. Using these approaches, CDC found that rates of shingles are increasing for reasons that remain unknown and as such, are now the focus of additional studies. In a post-licensure observational evaluation, CDC and collaborators confirmed the effectiveness of the herpes zoster vaccine found in the initial clinical trial and provided vaccine effectiveness estimates against severe outcomes of herpes zoster including hospitalizations and herpes zoster ophthalmicus. Finally, CDC found that vaccine uptake has been relatively low, and has identified important physician barriers to vaccine uptake, such as the cost of the vaccine, prolonged vaccine shortages after the vaccine was licensed, and the requirement of freezer storage for the vaccine.

In order to make informed decisions on vaccine policy and program issues, it is also important to ascertain the percentage of the population receiving vaccines through the monitoring of vaccine coverage. In an effort to better monitor coverage of adult vaccines, IHS's Tribal and Urban Indian immunization programs have begun to collect and report on this data. While data on the immunization status of American Indian and Alaska Native children and adolescents have been collected for many years, IHS collected data for its first Adult Immunization Report at the end of 2012. This new initiative provides IHS with information on vaccination rates for routine adult vaccines. As adult immunization rates nationwide are below Healthy People 2020 goals, this new data collection initiative will provide the information necessary to focus

immunization resources where they are most needed, and demonstrates the promise of EHRs in tracking and increasing vaccination coverage.

NVPO partnered with CMS and their data analytics partners at Acumen on a vaccination coverage and disparities mapping project. Based on CMS Medicare claims data, a publically available mapping tool was developed that tracks influenza vaccine coverage for Medicare Fee for Service beneficiaries over the age of 65.[42] This includes two-thirds of the U.S. population in this age group. This undertaking allows the monitoring of more than 30 million Medicare beneficiaries and also allows the tracking of vaccine coverage for current influenza seasons in real time. Additionally, coverage and disparities rates can be visualized down to the zip code level allowing communities access to their local data. These data provide public health and community-based leaders the ability to recognize areas where this population is under-immunized and where health disparities in influenza vaccination may exist. This is an important first step toward understanding the reasons for under-immunization and to evaluate the effectiveness of interventions.

Health Information Technology for Immunization

IIS and EHRs make health information more accessible to health care providers and the public by putting a patient's health history into electronic format, and can lead to better immunization recordkeeping. However, these separate electronic systems need to have interoperable information exchange capabilities. Ideally, the information collected in one system should be compatible with other systems, so that the information can be shared as needed. To promote this interoperability, the Office of the National Coordinator for Health Information Technology (ONC) collaborated with CDC and the National Institute of Standards and Technology in 2012 to develop new guidance for enhancing information exchange between EHRs and IIS. This guidance will facilitate the exchange of immunization records between different systems, making immunization records more accessible to individuals and their health care providers and reducing missed opportunities for vaccination.

CMS establishes the measures on which eligible health care providers and hospitals must report to achieve

In the United States, 83 percent of children under 6 years of age have immunization records that are included in **immunization information systems** (IIS), less than the Healthy People 2020 target of 95 percent. While the rate of children participating in IIS needs attention, the rates of adolescent and adult participation in IIS are far lower— only 53 percent of adolescents and 24 percent of adults have immunization records in an IIS.

IIS are an important tool that can be used by individuals and health care professionals to track whether or not someone has received all of the vaccinations recommended for them. By having an immunization record available electronically in an IIS, an individual or their health care provider can find out their immunization status when and where they need to. This can help ensure that no one misses any needed vaccines, and prevents vaccinations that may not be needed.

[42] U.S. Department of Health and Human Services: National Vaccine Program Office. (2013). *Live-tracking influenza vaccinations of Medicare beneficiaries: How is your community doing?* Retrieved from http://www.hhs.gov/nvpo/flu-vaccination-map

"meaningful use" of EHRs.[43] CMS works with ONC to set the data transport and vocabulary standards by which data must be exchanged to achieve national goals. The goal of Stage 1 of meaningful use of EHRs is to capture and share data before moving on to advancing clinical processes and improving outcomes in later stages. Both eligible providers and eligible hospitals have the option to choose from a menu of objectives, including reporting immunization information to the appropriate public health agency.

Eligible providers and hospitals report to CMS on their success in meeting these meaningful use objectives. From data available for 2011 through May 2013, CMS observed that 30 to 35 percent of eligible providers have chosen to submit immunization data to registries. For eligible hospitals, 40 to 50 percent have submitted data to immunization registries. Reporting to immunization registries becomes required in Stage 2 beginning in 2014, which will lead to more providers and hospitals submitting immunization data to public health agencies.

Another way that information technology can improve immunization levels is through interventions, such as reminder-recall systems. IHS is using this technology to improve adult vaccine coverage by including provider reminders for age-based adult vaccine recommendations in the IHS EHR system. When eligible patients visit an IHS facility, the health care provider is prompted to remind the patient to get vaccinated, which ultimately results in increased immunization levels.

Health Care Provider Education and Support

A key approach to increasing immunization coverage is strengthening vaccination communication and education activities with health care providers. For example, IHS has proactively communicated to health care providers within IHS on issues of immunization through outreach and web-based trainings. In January 2013, IHS held a web-based training for health care providers on immunization recommendations for all ages, the importance of adult immunization, and evidence-based strategies to increase immunization coverage. CDC has also developed a variety of tools and resources for providers to use to educate adult patients about vaccines, such as their vaccine "prescription pad" for recommended adult vaccines, which they released in 2012.[44] CMS conducted outreach to providers in 2012 directing them to useful immunization materials and tools on their website, including materials for patient education in several languages, such as posters and fact sheets. All of these activities helped promote the importance of immunization to providers and provided tools that the providers could use in communicating with their patients regarding the benefits of staying up-to-date on immunizations.

Improving Vaccine Tracking through the Use of New Technologies

Accurately tracking vaccines through the processes of production, ordering, distribution, and administration is important for a variety of reasons, such as vaccine safety monitoring,

[43] U.S. Centers for Medicare and Medicaid Services. (2013). *EHR Incentive programs.* Retrieved from http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/index.html?redirect=/EHRIncentivePrograms/

[44] U.S. Centers for Disease Control and Prevention. (2013). *Vaccines for adult patients: Resources for educating adult patients about vaccines.* Retrieved from http://www.cdc.gov/vaccines/hcp/patient-ed/adults/

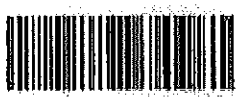
maintaining a sufficient supply of vaccine, and higher efficiency in locations where vaccines are administered. Two recent advances that are helping to improve vaccine tracking are progress toward the use of 2D barcodes in all parts of the vaccine manufacturing and delivery process, and the launch and expansion of CDC's Vaccine Tracking System (VTrckS).

2D Barcodes

When giving a vaccine, health care providers need to keep track of vaccine product identification, vaccine lot number, and vaccine expiration date. However, this information is currently either handwritten or typed into an EHR system or IIS, and is frequently missing or incorrect. Using 2D barcodes on vaccines could allow for rapid, accurate, and automatic recording of these data by all vaccine providers, saving time and money.

Using a handheld scanner to retrieve information from a 2D barcode on a vaccine vial or syringe, health care providers would be able to quickly and automatically add a vaccination to a patient's EHR or their record in an IIS. 2D barcodes contain more information than linear barcodes while taking up less space. Linear barcodes on vaccine containers provide only vaccine product identification information. If used for vaccines, 2D barcodes could include the vaccine product identification information, lot number, and expiration date.

In September 2011, CDC initiated a pilot project designed to assess the ability of 2D barcoding technology to improve the completeness of immunization record keeping as well as the availability and accuracy of immunization information. The project tested the use of 2D barcodes on selected vaccines and also evaluated and documented the impact of 2D barcoding on manufacturers, immunizers, and reporting systems. The findings will be used to foster the use of 2D barcoding in all parts of the vaccine manufacturing and delivery process. The pilot project involved 10 CDC immunization program grantees, more than 200 immunizers (public, private, and commercial), and two vaccine manufacturers.



Linear Barcode
Vaccine Product Identification Only

2D Barcode
Vaccine Product Identification, Lot Number and Expiration Date

VTrckS

VTrckS is an information technology system developed by CDC that can be used to manage the entire publicly funded vaccine supply chain throughout all parts of the immunization system from purchasing to distribution. This system was launched in December 2010 and is used by state, local, and territorial health departments to monitor the purchasing, ordering, and distribution of publicly funded vaccines by health care providers in their jurisdiction who administer vaccines as part of the VFC and other publicly funded vaccination programs.

VTrckS allows vaccine providers to order vaccine directly online. The system then evaluates their orders against guidelines set by CDC and state, local, and territorial health departments, in order to ensure that orders are appropriate. This can help improve the efficiency and accountability of health care providers that administer publicly funded vaccines.

As of May 2013, all state, local, and territorial health departments around the country are using VTrckS to better manage the purchasing, ordering, and distribution of publicly funded vaccines in their jurisdiction.

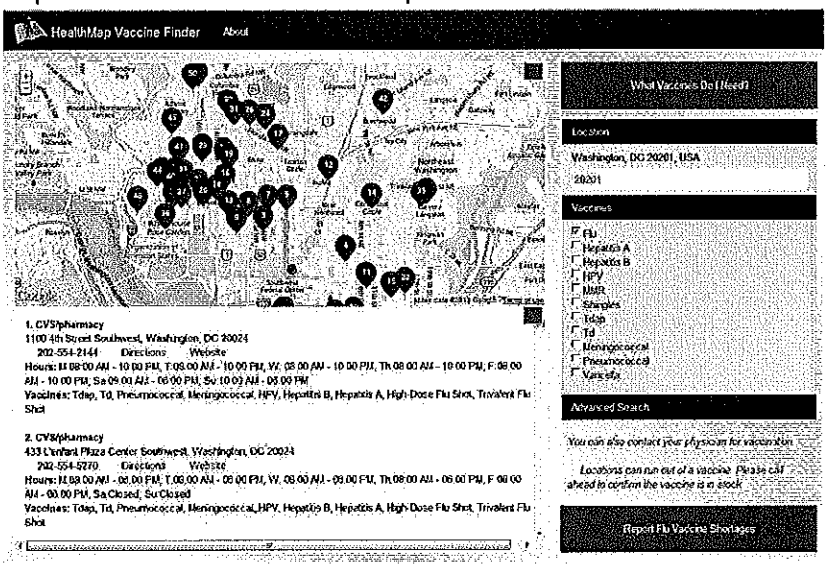
HealthMap Vaccine Finder: Helping Adults Find the Vaccines They Need

It is important to get an influenza vaccine every year. While awareness of seasonal influenza vaccination is high, there is low awareness that adults need more than a yearly influenza vaccination. Starting in January 2013, finding locations offering adult vaccines became easier through the HealthMap Vaccine Finder (vaccine.healthmap.org), which is a free online service to help users locate nearby vaccine providers (including pharmacies and health clinics) by entering an address or zip code. The Vaccine Finder launched in August 2012 and initially provided only information about where to get influenza vaccines. It subsequently expanded in January 2013 to include all routine adult vaccines.

Adults need more than just an influenza vaccine. Although several vaccines are recommended for routine use in adults, **coverage rates of most adult vaccines are very low and did not increase significantly from 2010 to 2011.** Many adults have not received one or more vaccines recommended for them. These low coverage rates indicate that most adults are not receiving the vaccines they need for preventing the health consequences of vaccine preventable diseases.

Reference:
Williams, W. W., Lu, P. J., Greby, S., Bridges, C. B., Ahmed, F., Liang, J. L., Pilishvili, T., & Hales, C. (2013). Noninfluenza vaccination coverage among adults – United States, 2011. *Morbidity and Mortality Weekly Report, 62*(04), 66–72. Retrieved from http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6204a2.htm

The HealthMap Vaccine Finder helps users find locations that provide eleven routine adult vaccines: hepatitis A, hepatitis B, HPV, influenza, MMR, varicella (chickenpox), Td (tetanus-diphtheria), Tdap, meningococcal, pneumococcal, and herpes zoster (shingles). The Vaccine Finder lists more than 47,000 locations across the country that offer vaccinations, and almost 600,000 consumers have used the tool as of September 2013. The HealthMap Vaccine Finder makes locating vaccines easier



and more convenient, and will help to increase national coverage of routine adult vaccines, which are below Healthy People 2020 targets. HHS is supporting this initiative as a part of its efforts to build a better system of prevention for adults.

Lack of Progress in HPV Vaccination: A Crisis of Missed for Cancer Prevention

By Anne Schuchat, MD, RADM
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Director, National Center for Immunization and Respiratory Diseases, CDC
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National goals should focus efforts on reducing the gap between today's reality and a desired future. Nowhere in the U.S. immunization program is the gap between current performance and the impact achievable with existing tools greater than for HPV immunization of teens. The National Vaccine Plan report on Goal 4 could highlight various successes: sustained high coverage of early childhood immunization; impressive local, state, and federal responses to resurgent pertussis; maintenance of measles elimination despite numerous importations of the virus; or improving health care worker influenza vaccination. Instead, this commentary shines a harsh spotlight on where we are failing.

Our nation's deplorable performance with HPV vaccination is at first difficult to comprehend. HPV vaccines are highly effective and safe, their supply is ample, and financing secure through the VFC and private insurance, reinforced by the ACIP's recommendation for routine use and by provisions of the 2010 Affordable Care Act. HPV infections are common and the consequences of persistent infection are severe. Despite a strong rationale and enabling environment, the 2012 National Immunization Survey - Teen found that only 53.8 percent of girls 13–17 years of age had initiated the series and only 33.4 percent had received three doses. There was no improvement in HPV coverage in girls from 2011 to 2012. Modeling suggests that about 50,000 girls who are under 12 today will develop cervical cancer during their lifetimes if we do not raise coverage to the target of 80 percent for the three-dose series. Each year we remain at current levels, another 4,400 of these girls will develop cervical cancer. Raising coverage will prevent additional cancers in both women and men.

What accounts for our nation's failure? Adolescents are in the doctors' offices. We have achieved high coverage with other routinely recommended vaccines (e.g., Tdap and meningococcal conjugate), and if every time a teenaged girl received another vaccine she also received HPV, first dose coverage would exceed 90 percent. Access is not our problem. Clinicians are.

Clinician recommendation is the leading influence on a family's decision to vaccinate. Recent qualitative research found clinicians are giving weak or no recommendation for HPV vaccination of teenaged patients. The CDC's National Immunization Survey - Teen for 2012 found that parents who did not intend to vaccinate their daughters described lack of a provider recommendation as the most common factor influencing their plans. The disparity between HPV and other teen vaccination reflects clear missed opportunities. The last time our country faced a national crisis of missed opportunities was 1989–90 when measles resurgence killed over 100 children and caused illness in 55,000. Clinicians reduced missed opportunities and

raised coverage among preschool-aged children, and by 2000 the United States had eliminated indigenous measles. Pediatric caregivers recognized they had the responsibility and means to prevent measles and its associated complications. We need clinicians caring for teenagers to realize that future cervical and other HPV-associated cancers are their responsibility, too. A generation of young people is depending on them.

Integrating Pharmacies into a Public Health Approach to Vaccination

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Laura Herrera, MD, MPH, Maryland Department of Health and Mental Hygiene
Joshua M. Sharfstein, MD, Secretary, Maryland Department of Health and Mental Hygiene

Pharmacists providing vaccinations can be an important way to reduce barriers and increase access to vaccinations. For nearly 10 years, Maryland pharmacists have had the authority to administer some vaccinations—in particular, influenza vaccinations and pneumococcal and shingles vaccinations to adults. In response to the 2009 H1N1 pandemic, the authority was expanded so that Maryland pharmacists could administer influenza vaccination to anyone 9 years old and older.

This option has substantially expanded access to vaccination. Our overall influenza vaccination coverage rates are increasing, and, per national data from CDC, around one in five of all vaccinated adults in the United States now get their vaccination at a pharmacy. Pharmacies are the most common place to get influenza vaccination outside of doctors' offices and other medical facilities.

At the same time, it is critical for information to be accessible in multiple medical settings, and for primary care clinicians to have information about the vaccination status of their patients.

Recognizing the important role that pharmacists can play in providing vaccines safely and conveniently, and mindful of adolescent and adult vaccination rates below the Healthy People 2020 goals, in 2013, the Maryland legislature passed and Governor Martin O'Malley signed legislation expanding the ability of pharmacists to vaccinate. The measure allows pharmacists who have been trained and certified to vaccinate, to administer all CDC recommended vaccinations to adolescents with a prescription and to adults without a prescription but in accordance with a protocol. It also requires pharmacists to notify an individual's primary care provider of the vaccination.

In 2009, there were about 500 Maryland pharmacists trained and certified to provide vaccinations. Today, there are over 3,000 pharmacists from all across the state trained and certified to provide vaccinations. We expect that number to increase even more throughout the coming years, as the new law went into effect this October.

Recognizing the importance of primary care, one other feature of the new Maryland law is that pharmacists administering vaccinations are required to notify primary clinicians and report those vaccinations to ImmuNet, the Maryland immunization registry. ImmuNet has the capacity to receive those records directly electronically from pharmacy information systems. Currently, four large pharmacy chains representing 379 sites throughout the state—and thousands of immunizations annually—are reporting directly electronically from their existing pharmacy information systems into ImmuNet.

Primary care clinicians can then obtain information directly from pharmacies as well as through the registry.

This reporting should ultimately lead to better coordination of care and vaccination services, fewer duplicate vaccinations, and better provision of recommended vaccines.

Is the National Vaccine Plan's Vision for Immunization Infrastructure a Brave New World for Immunization?

By L. J. Tan, MS, PhD
Chief Strategy Officer, Immunization Action Coalition
Co-Chair, National Adult Immunization Summit and National Influenza Vaccine Summit

Since the National Vaccine Plan was published, NVPO, in implementing the Plan, has wisely encouraged and welcomed collaboration with external partners. The NAIIS serves as a wonderful example of the trusted collaboration that can result from external partnerships. Indeed, NAIIS is part of a responsive framework that now exists to not only connect the efforts of the agencies within the federal government, but also to connect the federal government with multiple external partners, through which activities to improve immunization objectives can be identified and accomplished.

Through Goal 4 of the National Vaccine Plan, which is focused on the nation's immunization infrastructure, the country has significantly improved its ability to monitor immunization coverage and vaccine effectiveness, as well as survey for vaccine preventable diseases. Recognizing the diversity of the adult population and adult vaccination providers, NVAC has updated its Standards for Adult Immunization Practice to emphasize the responsibility of ALL providers of adult care to assess for, strongly recommend and provide appropriate vaccines, or refer the adult to a provider who immunizes. Our ability to detect and respond to outbreaks has been tested with pertussis and measles, and Hib disease outbreaks, and the system has responded admirably. However, as pointed out in the recent NVAC report on the 317 program, the immunization infrastructure is fragile as a result of a lack of resources and from funding cuts, and we must commit resources and continue collaboratively to maintain this delicate system.

Priorities for Implementation of Goal 4:

1. Use evidence-based science to enhance vaccine preventable disease surveillance, to measure vaccine coverage, and to measure vaccine effectiveness.
2. Eliminate financial barriers for providers and consumers to facilitate access to routinely recommended vaccines.
3. Create an adequate and stable supply of routinely recommended vaccines and vaccines for public health preparedness.
4. Increase and improve the use of interoperable health information technology and EHRs.

The implementation of the Affordable Care Act will play an important role in the elimination of financial barriers to immunizations for patients. Indeed, no-cost access to recommended vaccines will be much improved, especially for privately insured persons and those covered under expanded Medicaid. The NAIIS and others have worked to increase awareness among providers and the public about the impact of the Affordable Care Act, but continued education is necessary. Challenges remain, including persistent confusion about vaccine coverage within the Affordable Care Act. Additionally, the need to improve access points to vaccines for a large number of newly eligible persons will stress the infrastructure. Vigilance is necessary to ensure

the adequacy of payment to all providers of immunization services, especially as the Affordable Care Act improves access.

As we improve the immunization infrastructure, an adequate vaccine supply is necessary. More significantly, we need to be able to determine the status of vaccine supply at any given time. As the National Vaccine Plan is implemented, we must continue to respect the importance of our vaccine manufacturers, and to support continued research and development into new vaccines. NVPO's collaboration with the IOM to prioritize vaccines for research and development is an excellent starting point.

Integration of IIS into EHRs is necessary to improve assessment, administration, and documentation of immunizations. Perhaps more importantly, this key component of our infrastructure will allow us to measure the outcomes from our immunization efforts. As immunizations, particularly for adults, are provided at multiple access points, the ability to record immunizations received into an integrated system is critical. If meaningful use is successfully implemented, health systems, providers, patients, and public health will be able to harness the data from IIS and EHRs to improve immunization activities.

In conclusion, the remarkable health and cost benefits that we have achieved in immunization can only be advanced if the nation values the immunization infrastructure that is its foundation. As a country we need to commit the resources (financial and otherwise) necessary to advance the bold vision of Goal 4 of the NVP and the progress it promises. In addition, it is *imperative* that the existing critical, but often invisible, immunization infrastructure not collapse as a result of lack of funding or political will. Should this happen, the public will lose the hard fought gains in immunizations that we have accomplished.

Goal 5: Increase Global Prevention of Death and Disease through Safe and Effective Vaccination

In this section:

- Commitment to Global Immunization and Polio Eradication
- Global Collaboration to Improve Health Systems in Africa
- Vaccine Development for Global Populations
- Global Introduction of New and Under-utilized Vaccines (NUVI)
- Feature: Expanding Global Access to Influenza Vaccines
- Feature: MenAfriVac: Saving Lives in Africa through Global Collaboration
- Commentary: *Fulfilling the Potential of Vaccines to Protect Health and Save Lives around the World*, by Dr. Nils Daulaire
- Commentary: *Global Health Diplomacy and Immunization*, by Ambassador Eric Goosby
- Commentary: *The Road Ahead*, by Dr. Seth Berkley

Background

Global commitment to immunization programs has achieved unparalleled success in improving health. Immunizations now save the lives of approximately 2.5 million children around the world per year. However, vaccine preventable diseases still account for a quarter of deaths in children under 5 years of age worldwide. It is estimated that 22.4 million children around the world go without the full benefits of vaccination. HHS recognizes that the health of those in the United States and the health of people around the world are closely linked. An outbreak of an infectious disease in another country can impact the health of people in the United States, just as a scientific discovery made in another country can lead to better treatment for diseases globally.

In 2010, in a demonstration of global commitment to immunization, partners from all over the world came together to begin the Decade of Vaccines, which spans from 2010 to 2020. This international effort aims to extend the benefits of immunization to all individuals and communities. The Decade of Vaccines Collaboration's Global Vaccine Action Plan provides a guiding vision toward achieving this goal. HHS is dedicated to this endeavor, with leadership from NIH and CDC involved in the leadership council and steering committee of the Global Vaccine Action Plan. This dedication is reflected not only in Goal 5 of the National Vaccine Plan, but also in the 2011 HHS Global Health Strategy's objective to reduce infectious disease worldwide, with vaccine development, use, and evaluation as a key priority.[45] Additionally, NVAC's recent report and recommendations on global immunization will inform how HHS can best continue to contribute to global immunization efforts, consistent with the Global Health Strategy, Goal 5 of the National Vaccine Plan, and the Global Vaccine Action Plan.

Below, examples of recent advances and successes made by HHS and its partners to increase global prevention of death and disease through safe and effective vaccination are described. NVPO helps to coordinate HHS work related to global immunization and facilitates collaboration among HHS agencies that work on global immunization issues.

Recent Accomplishments and Progress

Commitment to Global Immunization and Polio Eradication

CDC's Global Immunization Division provides important support for polio eradication, measles elimination, rubella reduction, integrated vaccine preventable disease surveillance, and strengthening immunization systems, which has contributed greatly to global immunization initiatives. In 2011, the Global Immunization Division developed the Global Immunization Strategic Framework.[46] The purpose of the Framework is to articulate CDC's current goals, objectives, and strategies for effectively meeting global immunization challenges during 2011–2015, with the end goal of preventing disease and death, and protecting the health of all Americans and global citizens through the use of vaccines.

[45] U.S. Department of Health and Human Services. (2011). *The global health strategy of the U.S. Department of Health and Human Services*. Retrieved from http://www.globalhealth.gov/global-programs-and-initiatives/global-health-strategy/

[46] U.S. Centers for Disease Control and Prevention. (2011). *Global immunization strategic framework 2011–2015*. Retrieved from http://www.cdc.gov/globalhealth/gid/framework/

CDC has been fighting to reduce the incidence of polio in all parts of the world since the 1950s, and global collaboration to eradicate polio through the Global Polio Eradication Initiative (GPEI) is the latest development in CDC's polio efforts. Launched in 1988, GPEI has been the largest public health initiative in history, spearheaded by national governments, CDC, Rotary International, WHO, the United Nations Children's Fund (UNICEF), and the Bill & Melinda Gates Foundation. In December 2011, Dr. Thomas Frieden, Director of CDC, activated CDC's Emergency Operations Center to provide additional support for the push to eradicate polio. CDC prepared quarterly risk assessments measuring progress toward meeting goals outlined in the GPEI 2010-2012 strategic plan, and continues to provide essential leadership to the efforts to achieve important milestones on the path to polio eradication.

USAID has also been a leader in polio eradication efforts, supporting the implementation of the polio endgame strategy by providing support to surveillance and laboratory capacity in 23 countries. At the global level, USAID supports work to accredit the 148 laboratories in the polio laboratory network. At the regional level, USAID supports WHO to convene country and regional activities including certification commissions, regional advisory groups, cross-border meetings, and support training and technical meetings. At the country level, USAID provides funding support for the full-time surveillance officers who conduct polio surveillance and community mobilization efforts aimed at increasing demand and acceptance of immunization. All of these activities have been a focus of USAID for many years, and are currently ongoing as partners around the world work together to eradicate polio once and for all.

CDC is a leader in the WHO coordinated global laboratory networks that provide data for vaccine preventable disease surveillance and evaluation of vaccine effectiveness and implementation studies, helping to advance the fight against polio and other vaccine preventable diseases. Recent efforts include working with WHO to ensure accreditation of polio, measles, and rubella laboratories in key endemic and outbreak-affected countries. CDC has also increased global lab capacity to support vaccine preventable disease surveillance through transfer of CDC-developed polio, measles, and rubella virus genetic detection and characterization technologies. CDC conducts training in diagnostics and proficiency testing for global rotavirus network laboratories and monitored circulating rotavirus strains to detect emerging strains that may escape vaccine protection.

Global Collaboration to Improve Health Systems in Africa

One of the objectives of Goal 5 is to build and strengthen multilateral and bilateral partnerships and other collaborative efforts to support global immunization. A prime example of this type of collaboration is the support USAID and CDC are providing the African Field Epidemiology Network (AFENET), a nonprofit organization and networking alliance dedicated to helping Ministries of Health in Africa build strong, effective, sustainable programs and capacity to improve public health systems in African countries. This collaborative effort used the Field Epidemiology and Laboratory Training Program (FELTP) of AFENET to strengthen field epidemiology and public health laboratory capacity toward addressing public health priority

problems in sub-Saharan Africa. In 2012, a USAID-funded cohort of 11 master's-level students began immunization-related projects addressing formative and operational research questions to inform country-specific health service delivery.

Vaccine Development for Global Populations

Diseases caused by pneumococcus bacteria kill about one million children under age 5 each year. In 2010, FDA began a two-year collaboration with PATH, a nonprofit organization dedicated to global health, to advance the development of a vaccine to protect children against pneumococcal disease. As a part of this collaboration, FDA scientists successfully adapted an FDA-method of conjugation (conjugation is a specific vaccine development technique) that they had previously developed for a vaccine to prevent meningitis in Africa, to the preparation of a different type of pneumococcal vaccine. Following this accomplishment, beginning in May 2012, FDA scientists trained staff from China's Chengdu Institute of Biological Products for five weeks in FDA laboratories to perform this adapted conjugation technique and transferred the technology to them at no cost for their work in advancing the development of cost-effective vaccine candidates for use in other parts of the world.

Ixiario, a vaccine to prevent Japanese encephalitis (JE) produced by Novartis, received FDA approval in May 2013 for use in children as young as 2 months of age. JE is a mosquito-borne virus that is the most common vaccine preventable cause of encephalitis in Asia. Another JE vaccine is no longer being produced, and all doses of that vaccine expired in May 2011. JE vaccine is recommended for travelers who plan to spend a month or longer in endemic areas during the JE virus transmission season. This would include U.S. military personnel and their dependents deployed to Asia.

Global Implementation of New and Under-utilized Vaccines (NUVI)

Goal 5 emphasizes the importance of supporting NUVI to prevent diseases of public health importance around the world. One new vaccine that shows exceptional promise is ROTAVAC, a rotavirus vaccine that was manufactured and tested in India, where rotavirus claims the lives of approximately 100,000 children each year. The development of this vaccine resulted from a public and private collaboration involving NIH/NIAID, CDC, the India Ministry of Science and Technology, Department of Biotechnology, Bharat Biotech, Stanford University School of Medicine, the Bill & Melinda Gates Foundation, the Research Council of Norway, the United Kingdom Department for International Development, and PATH. In May 2013, results from a Phase III clinical trial of the vaccine were announced: the trial found ROTAVAC to be safe and effective.[47] Bharat Biotech plans to file for registration of the vaccine in India, and if licensed for use in that country, it would provide a less costly alternative to already existing rotavirus vaccines.

Immunization is a central component of USAID's strategy to end preventable child and maternal deaths. USAID supports countries' access to vaccines through its financial, strategic

[47] Fauci, A. S. (2013). *Statement: Results of the ROTAVAC rotavirus vaccine study in India*. Retrieved from http://www.niaid.nih.gov/news/newsreleases/2013/Pages/ROTAVAC.aspx

and technical contributions to GAVI. GAVI's mission is to save the lives of children and protect health by increasing access to immunization in low-income countries. In 2011, USAID made a three-year, $450 million funding pledge to GAVI bringing USAID's GAVI contributions to over $1 billion. Additionally, in 2012 alone, USAID's technical contributions included support of 11 GAVI applications, 14 new vaccine introductions, 10 new vaccine launches, nine post-vaccine-introduction evaluations and one WHO Expanded Programme on Immunization vaccine coverage evaluation. Given the rapid increase in the number of vaccine introductions in the next few years, USAID anticipates the need to continue technical support to countries in collaboration with other partners in the field.

CDC's National Center for Immunization and Respiratory Diseases (NCIRD) (particularly the Divisions of Bacterial and Viral Diseases) works closely with GAVI, as part of the Accelerated Vaccine Initiative, to support introduction of pneumococcal conjugate vaccine and rotavirus vaccines in low- and middle-income countries. Over the last year, a total of 26 GAVI countries introduced pneumococcal conjugate vaccine. To date, 47 countries around the world have introduced rotavirus vaccines through their national immunization programs, including 15 GAVI-eligible countries. CDC provided assistance to WHO and GAVI in supporting these introductions. CDC supported many countries to assess the impact of vaccine preventable diseases prior to vaccine introduction and is assisting countries in evaluating the impact of the vaccines, conducting surveillance and case-control studies, and monitoring adverse events such as intussusception (for rotavirus).

Expanding Global Access to Influenza Vaccines

Though influenza vaccines have been used routinely in the United States for many decades, they are not commonly available in the developing world. In 2006 WHO initiated a Global Action Plan for Influenza Vaccines (GAP) to increase the availability and use of seasonal and pandemic influenza vaccines worldwide. ASPR/BARDA has made significant contributions to this effort, providing support to develop in-country influenza vaccine manufacturing and to develop biomanufacturing training courses that have trained more than 250 scientists from around the world, with the goal of increasing vaccine manufacturing capacity in developing nations. The GAP was revised and updated in 2011 and continues to support developing country manufacturers in the development of new influenza vaccines based on lessons learned from the 2009 H1N1 pandemic. The GAP encourages vaccine uptake through policy changes and targeted communications to complement the "push" mechanisms of direct assistance to manufacturers.

Since 2006, ASPR/BARDA has provided grants in excess of $60 million to help WHO strengthen the capacity of developing countries to manufacture influenza vaccine. The grants were used to improve pandemic influenza vaccine manufacturing infrastructure in developing countries, provide training on influenza vaccine manufacturing, and assist developing countries with the development and distribution of technologies for pandemic influenza vaccines.

In support of GAP, the Office of Global Affairs (OGA) cohosts a series of workshops with WHO. These workshops represent an important partnership effort with WHO, designed to support and inform the implementation of the GAP for the creation of regionally based and sustainable vaccine production capacity in developing countries through capacity building and technology transfer. The workshops are attended by staff from governments, international donor organizations, academic institutions, vaccine manufacturers, and other key stakeholders. Staff from CDC, FDA, NVPO, and ASPR/BARDA participate in the workshops to share their experience, knowledge, and expertise with country participants. Topics include technology transfer, regulatory capacity building, global workforce development, health and economic impact of influenza, business modeling for sustainability, and communications on influenza vaccines.

Since 2010, OGA has held seven workshops, five of them in the last two years. Over 110 participants from more than 30 countries have attended each of these workshops. Each workshop generates a new group of technical experts who come into the fold of new partners: regulators, epidemiologists, researchers, policy makers, communication experts, financial ministries, and many others. Many topical initiatives have emerged from these workshops:

- FDA's continuing work with manufacturers in developing countries to strengthen their regulatory capacity.
- CDC leveraging its international surveillance collaborations and research portfolio to transform disease burden data into communications and cost-effectiveness data that will help Ministries of Health and international partners to make decisions about introduction and expansion of influenza vaccination.
- WHO maintaining workforce training initiatives and public-private partnerships with universities and academic centers for the grantee vaccine manufacturers.
- WHO facilitating Influenza Vaccine Communication Plan workshops to directly develop country-level risk-communications and vaccine uptake messaging strategies.

Of particular note is the fact that the OGA-WHO workshops provide a forum to facilitate and generate new partnerships. The African Vaccine Manufacturing Initiative (AVMI) is a notable new partnership formed through the workshop series in 2011. AVMI brought together 12 vaccine manufacturers in Africa, for Africa. This major initiative was formally announced by the President of Benin at the Africa Union meeting in January 2013.

MenAfriVac: Saving Lives in Africa through Global Collaboration

For far too long, meningococcal meningitis has been a punishing disease, especially in sub-Saharan Africa where its tragic toll can be measured in very significant human, social, and economic losses. It kills 10 percent of people it infects within two days after they start showing symptoms. Although an antimicrobial drug saves large numbers of infected individuals, about 10 percent die from the infection and about 10 to 20 percent of survivors develop mental retardation, hearing loss, or seizures.

After the largest meningitis epidemic in African history swept across sub-Saharan Africa in 1996–97 and killed 25,000 people, African ministers of health turned to WHO for help. In response to this, the Meningitis Vaccine Project (MVP) was created. This partnership between WHO, PATH, HHS, USAID, the Bill & Melinda Gates Foundation, the Michael & Susan Dell Foundation, GAVI, UNICEF, and others led to the development of MenAfriVac. MenAfriVac is now saving lives in African countries where meningitis epidemics have ravaged populations for a century.

MVP's goal was to develop, test, and license a new type of cost-effective vaccine against group A meningococcus bacteria, which could protect people *before* an epidemic began. The new vaccine used conjugation technology, where a chain of sugars connects to a protein that the immune system responds to very well. When MVP hit a hurdle during the development stage, FDA/CBER's scientists provided an alternative conjugation technology that was more efficient and less costly. Through a technology transfer agreement, FDA provided the technology to MVP via PATH, with help from NIH. Scientists at FDA/CBER also developed reagents for evaluating the vaccine's performance and safety and developed methods to monitor the manufacturing process. MVP had partnered with the Serum Institute of India Limited, a developing-country vaccine manufacturer, to make the new conjugated vaccine. Scientists from the Serum Institute spent time at FDA to learn the conjugation method to manufacture the vaccine.

USAID supported the business case for vaccine development, including the socioeconomic impact of meningitis outbreaks in endemic countries. Once a candidate vaccine was developed, CDC and FDA provided extensive laboratory testing services for the necessary clinical studies.

In December 2009, the new vaccine, MenAfriVac, was licensed by India, and by June 2010, WHO had prequalified the vaccine. USAID, through GAVI, purchased vaccine and supported higher programmatic costs associated with campaigns after a licensed and WHO prequalified vaccine was available. MenAfriVac is the first vaccine developed specifically for African populations and is affordable to low- and middle-income countries at less than 50 cents a dose (compared to more than $80 for one dose of other meningitis vaccines). It also is the first meningitis vaccine that can be used on infants and is expected to create immunity that lasts at least ten years.

Early in December 2010, MVP began a vaccination campaign with MenAfriVac aimed at protecting millions of people in West Africa from meningococcal disease. On December 3, 2012, PATH announced that the 100 millionth person had received the vaccine. It is anticipated that by the end of 2013, 150 million people will have been vaccinated with MenAfriVac. The success of MenAfriVac demonstrates what can be accomplished when governments, organizations, and industry work together.

Fulfilling the Potential of Vaccines to Protect Health and Save Lives around the World

By Nils Daulaire, MD, MPH
Assistant Secretary for Global Affairs
U.S. Department of Health and Human Services

Vaccines are at the very top of public health's greatest success stories, averting millions of deaths annually.[48] But precisely because of immunization's enormous impact, we must do more to increase the use of existing vaccines and accelerate the discovery and development of new ones. No parent should have to experience their child dying from a vaccine preventable disease, yet every year 1.5 million children who have not been adequately immunized die before reaching their fifth birthday. And in today's world, vaccines are no longer just to save the lives of children. With continued discovery of new vaccines against viruses proven to cause cancer, such as the HPV[49] and hepatitis B,[50] we have the capability to prevent nearly 874,000 adult deaths each year.

Preventing infectious diseases, both within the United States and around the world, is a key objective of the HHS Global Health Strategy. As our National Vaccine Plan acknowledges, access to safe and effective vaccines is one of the most powerful tools we have to stop the spread of disease. Developing and disseminating vaccines cannot be done by one agency or country alone. As the MenAfriVac story demonstrates, successes come from collaboration with other U.S. departments and agencies, nongovernmental organizations, international organizations, and the governments of other countries. Through multilateral capacity building efforts, low- and middle-income countries are now beginning to build seasonal influenza vaccine manufacturing capacity to support pandemic preparedness by producing vaccines for their own countries and regions with less reliance on the United States and other developed countries. This expanded and diversified capacity makes all of us safer and more secure.

Ensuring access also requires putting an end to disproven and unfounded claims about the safety and purpose of vaccinations. Although scientifically debunked, the oft-echoed belief that certain childhood vaccinations lead to autism has resulted in hundreds of thousands of children around the world being denied lifesaving immunizations, even in wealthy communities. We have also seen unfounded rumors derail global immunization efforts and lead to unnecessary illness and death. In Nigeria, a mass boycott followed false stories that the polio vaccine was a Western ploy to spread HIV and sterilize Muslim girls. This immunization boycott led to a rash of new polio infections in the country, and to the further spread of the polio virus to a dozen other countries as far away as Indonesia.

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[48] World Health Organization. (2013). *Immunization coveroge fact sheet*. Retrieved from http://www.who.int/mediacentre/factsheets/fs378/en/index.html (exit link disclaimer)
[49] World Health Organization. (2010). *Human papillomavirus (HPV)*. Retrieved from http://www.who.int/immunization/topics/hpv/en/ (exit link disclaimer)
[50] World Health Organization. (2013). *Hepatitis B fact sheet*. Retrieved from http://www.who.int/mediacentre/factsheets/fs204/en/ (exit link disclaimer)

The medical truth is proven and straightforward: vaccines are safe, effective, and save hundreds of thousands of lives every day. Yet, while we celebrate the successes of vaccines, we must also acknowledge the work left to be done. The world still suffers from many potentially preventable diseases for which no effective vaccine yet exists, including HIV, TB, malaria, and hepatitis C. Continued research is crucial to developing new vaccines for these and other diseases that kill and disable. In the meantime we need to work towards universal access for existing vaccines so that every person in the world receives the full benefit of the greatest contribution that science has made to public health.

Global Health Diplomacy and Immunization

Ambassador Eric P. Goosby, MD
Special Representative for Global Health Diplomacy and U.S. Global AIDS Coordinator
U.S. Department of State

Goal 5 of the National Vaccine Plan protects the health of the American public and addresses human suffering globally by reducing the burdens of morbidity and mortality, of vaccine preventable illnesses.

The Office of Global Health Diplomacy was established within the U.S. Department of State to add the skills and abilities of the diplomat to the pursuit of U.S. global health priorities. Diplomatic expertise complements the considerable technical, systems strengthening, and development capabilities applied by personnel of federal agencies like HHS and USAID.

Successfully implementing the global elements of the National Vaccine Plan is contingent on productive engagement with multilateral institutions like WHO, and partner governments around the world who we support and depend upon to successfully scale surveillance of vaccine preventable illnesses and sustainable immunization programs. Many milestones can already be celebrated, but we must use every tool at our disposal – including the soft power of diplomacy – to have finite resources stretch as effectively as possible.

I am delighted to salute the considerable progress already underway in implementing the 2010 National Vaccine Plan here at home and around the world. Internationally, we have helped low- and middle-income countries increase their capacity for vaccine production, made great strides in polio eradication, and have launched important public-private partnerships like MenAfriVac, and the Pink Ribbon Red Ribbon Alliance to address meningitis and HPV, respectively.

In the coming year we will look for expanded opportunities to have our ambassadors and diplomats around the world contribute to even stronger and more productive bilateral and multilateral relations associated with our global health priorities. This will help to speed the day when we all celebrate the broadest possible coverage of protective vaccines.

The Road Ahead

By Seth Berkley, MD
Chief Executive Officer, The GAVI Alliance

The last decade has seen remarkable progress in global immunization, huge strides that have and are continuing to transform the health, lives, and futures of millions of families around the world. Global immunization rates have risen from 73 percent in 2000 to 83 percent, with the largest increases coming from low-income countries, and the total number of unimmunized children has fallen from 32.9 million to 22.6 million over the same period. But while such advances are to be applauded, it would be a mistake to confuse progress with a job done.

In terms of the scale of what needs to be done, the reality is that we have only just begun, and considerable challenges still lie ahead. For, while increases in immunization coverage are cause for celebration, they merely represent the number of children in receipt of their third dose of diphtheria-pertussis-tetanus (DPT) vaccines, the current gauge for routine immunization. Yet when you factor in the number of children that are fully immunized with the range of WHO-recommended vaccines, a very different picture starts to emerge. WHO recommends that every child receives 11 antigens—Bacillus Calmette-Guérin vaccine, DPT, measles, polio, hepatitis B, Hib, pneumococcal, rotavirus, and rubella—but currently only 5 percent of children are fully immunized in this way.

Organizations like my own, the GAVI Alliance, are making some headway by moving beyond the DPT model and introducing more effective vaccines like the 5-in-1 pentavalent vaccine, which combines DPT with hepatitis B and Hib. And besides providing the world's poorest children with better access to a broader range of vaccines, we are also finding ways to shorten the time it takes for new vaccines to reach them. Recently introduced vaccines, such as pneumococcal and rotavirus vaccines, protect against the two diseases that kill more children in developing countries than any others. We are also expanding beyond children. Cervical cancer now rivals childbirth as a cause of death in young women. This year developing countries began exploring the addition of HPV to their vaccination program for girls 9–11 years old.

But if we are to ever see every child on this planet fully immunized, then we need to do more. Through global collaborations we can secure adequate resources for immunization, develop supportive health systems and infrastructure, and work with countries to train health workers, all of which will help maximize the benefits of vaccines around the world for years to come. Indeed, this is the goal of the Decade of Vaccines Collaboration. Through the development of the Global Vaccine Action Plan, the Decade of Vaccines aims to find new and effective ways to stimulate the discovery, development, and delivery of lifesaving vaccines. Through global collaborations, we now have the opportunity to extend, by 2020 and beyond, the full benefits of immunization to all people, regardless of where they are born, who they are, or where they live, thus saving lives, reducing morbidity, and allowing children around the world to grow to their full potential.

Conclusion and Future Direction of the National Vaccine Plan

This report represents a collaboration between HHS agencies and other federal partners to describe progress they have made in all parts of the national immunization system, and the ongoing work of NVPO to coordinate this progress. The wide variety of stakeholders, projects, and programs represented in this document demonstrates that no single agency or organization can do all the work needed to maintain and improve the U.S. immunization program. Through this work, HHS, USAID, DoD, VA, and other federal and nonfederal partners are collectively moving immunization forward in the United States, and contributing to major advances in global immunization.

As we enter 2014, leaders at HHS are analyzing the immunization landscape to identify priority areas to address in the near future. A clear priority for HHS is the implementation of the Affordable Care Act and communicating effectively about elements of the law that will directly affect the public, such as expansion of access to health insurance and the coverage of recommended clinical preventive services, including immunizations, with no cost sharing. This work has already begun and will be ongoing throughout the next few years as the law is fully implemented. To address low adult immunization rates, HHS is developing a strategic plan for adult immunization that will guide ongoing work. HHS and its partners are also focused on improving coverage rates of HPV vaccine in adolescent girls and boys. Other important priorities include improving bidirectional exchange between EHRs and IIS for better documentation and innovation in vaccine development. Future reports will provide updates on these key issues, as well as advances in all other elements of the national immunization program.

When developed in 2010, the National Vaccine Plan had a 10-year vision. Given the dynamic nature of the field, the ASH asked NVAC to conduct a midcourse review. This midcourse review, done in conjunction with HHS and its federal partners and facilitated by NVPO, will result in recommendations for adjustments to implementation that would be beneficial to the public and global vaccine community. The review also will lead to future advances and achievements that will benefit the overall U.S. vaccine and immunization enterprise, and these improvements will be covered in future State of the National Vaccine Plan annual reports.

Along with the work described in this report, HHS agencies and offices have been working to carry out the strategic action steps that were laid out in the National Vaccine Plan Implementation, 2010–2015. Updates on this progress are summarized in Table 3. An overview of the historical contributions and recent achievements of NVAC is also presented, and NVAC Chair Dr. Walter Orenstein has provided a commentary on NVAC's recent report and recommendations on global immunization. Additionally, an overview of progress that has been made toward the achievement of Healthy People 2020 immunization and infectious disease objectives has been provided by the HHS Office of Disease Prevention and Health

Promotion, the CDC National Center for Health Statistics, and the CDC National Center for Immunization and Respiratory Diseases.

Appendices

Table 3: Progress on the Implementation of the National Vaccine Plan

The action steps listed below constitute the National Vaccine Plan Implementation, 2010–2015,[51] and were chosen to ensure a robust immunization program for the United States. These action steps were or are currently being carried out by HHS and its federal partners, the VA and the DoD. Updates on the progress toward achieving these action steps are listed in the table.

Goal 1: Develop New and Improved Vaccines

Priority A: Develop a catalogue of priority vaccine targets of domestic and global health importance.

Lead agency	Action step	Progress report	Status
NVPO	A1. NVPO will support the development of a framework to prioritize preventive vaccines and convene a workshop to obtain input from key partners on this framework through a contract with the IOM.	Framework has been developed by the IOM. A stakeholder meeting was held in November 2012 to obtain stakeholder input on the tool.	Completed
NVPO	A2. NVPO will support the development of a methodology for identifying priority vaccine targets for domestic and global health priorities through a contract with the IOM.	IOM developed a software tool called SMART Vaccines that helps inform prioritization of needed vaccines. The software was made available to the public for download and use on September 30, 2013.	Completed
NVPO	A3. NVPO will support the production of a catalogue of priority vaccine targets of domestic and international importance through a contract with the IOM.	An effort to evaluate the SMART Vaccines software with potential stakeholder users began October 2013. Following this step, the process to create a catalogue of priority vaccine targets will begin.	Projected completion date: Early 2015

[51] U.S. Department of Health and Human Services. (2011). *National vaccine plan implementation: Protecting the nation's health through immunization.* Retrieved from http://www.hhs.gov/nvpo/vacc_plan/2010%20Plan/nationalvaccineplan.pdf

Priority B: Strengthen the science base for the development and licensure of new vaccines

Lead agency	Action step	Progress report	Status
NIH	B1. NIH will fund a broad range of basic and clinical research studies on topics including mechanisms of host-pathogen interaction, host immune response, new vaccine targets, and vaccines against bacterial, viral, and parasitic microbes. Information about these projects will be included on publicly available websites, such as NIH RePORT (Research Portfolio Online Reporting Tools) and ClinicalTrials.gov, as well as in scientific publications.	Per NIH's RePORT, NIH spent ~ $1.69 billion on vaccine-related research in fiscal year (FY) 2012 (last itemized reporting year available as of 7/1/2013). The budget figure includes extramural and intramural projects. Each NIH Institute/Center's contribution to vaccine related research can be accessed publically through the NIH RePORT database by querying "Vaccine Related" http://report.nih.gov/categorical_spending.aspx	Ongoing through the end of 2015
ASPR	B2. ASPR/BARDA will support the advanced development of next-generation cell-based and recombinant influenza vaccines with the goal of making more influenza vaccine available faster during influenza pandemics.	In November of 2012, the FDA approved Flucelvax, a cell-based influenza vaccine. The vaccine was developed through a public-private partnership between ASPR/BARDA and Novartis. Additionally, in 2009, ASPR entered into a public-private partnership with Novartis to build the first facility in the United States capable of manufacturing cell-based influenza vaccine. In 2012, ASPR expanded that partnership and established a Center for Innovation in Advanced Development and Manufacturing at this facility, with a future goal of manufacturing this new cell-based influenza vaccine at this new facility. This will allow a substantial increase in the capacity to produce pandemic influenza vaccine within the United States. In January 2013, the FDA approved FluBlok, the first trivalent influenza vaccine made using an insect virus (baculovirus) expression system and recombinant DNA technology.	Ongoing through 2015

Lead agency	Action step	Progress report	Status
ASPR	B3. ASPR/BARDA will coordinate and support efforts to optimize production and testing of influenza vaccines with the goal of decreasing the time needed to make vaccine available in an influenza pandemic.	The Influenza Vaccine Manufacturing Initiative is an interagency program with participation from ASPR/BARDA, CDC, FDA, and NIH. As a result of efforts to optimize production, high-yielding production strains have moved into clinical testing with H7N9, and additional candidates are being developed for evaluation. Work to develop more rapid, improved testing, has identified several new potency methods that are being evaluated by government and manufacturer laboratories. The International Federation of Pharmaceutical Manufacturing Associations and WHO have agreed to harmonize efforts to evaluate and perform comparative studies of alternative potency assays beginning in 2014. A newly developed rapid sterility system that reduces the time for sterility testing from 14 days to 5 days is being beta tested by several manufacturers.	Ongoing through 2015
FDA	B4. FDA will develop and implement a research agenda that focuses on expanding the development of applied research with the goal of enhancing the safety and effectiveness of vaccines and facilitate product development.	For information on relevant FDA research, see http://www.fda.gov/BiologicsBloodVaccines/ScienceResearch/ucm234680.htm and http://www.fda.gov/BiologicsBloodVaccines/ScienceResearch/default.htm, which are links to scientific publications and select summaries on current FDA research relevant to enhancing the safety and effectiveness of vaccines and facilitating product development.	Ongoing through 2015
ASPR	B5. ASPR/BARDA will fund cooperative agreements with U.S.-based universities to support Advanced Biomanufacturing Training Programs for scientists from manufacturers in developing countries.	As of May 2013, over 250 scientists from developing countries have attended this training, with additional courses planned for summer 2013. In 2013, the courses were expanded, in collaboration with the FDA and WHO, to include participants from National Regulatory Authorities in developing countries.	Ongoing through 2015
ASPR	B6. ASPR/BARDA will fund development of clinical trial and laboratory infrastructure in developing countries for the evaluation of candidate influenza vaccines in preclinical research.	To date, eight ASPR/BARDA-funded vaccine manufacturers in developing countries have conducted clinical trials with their own influenza vaccine. Seven of these manufacturers have now licensed influenza vaccines, and one vaccine has achieved WHO prequalification status.	Ongoing through 2015

Lead agency	Action step	Progress report	Status
NIH	B7. NIH will fund product development research on 15 vaccines for infectious diseases and related conditions.	The NIH/NIAID Partnership program stimulates collaborative efforts and multidisciplinary approaches to rapidly advance promising infectious disease vaccine candidates and platform technologies through the product development pathway. This program has uniquely fostered many new research collaborations between experts from different disciplines of academia and industry. In FY 2013, NIH/NIAID supported multiple projects through the Partnerships for Development of Vaccine Technologies initiative, which focuses on preclinical development of candidate technologies (including adjuvants) that would improve vaccine effectiveness and/or simplify vaccine delivery to patient populations during a natural outbreak of an infectious disease or following the intentional release of an infectious agent.	Projected completion date: End of 2015
NIH	B8. NIH will evaluate five new formulations/technologies with potential to improve vaccine immunogenicity, safety, delivery, and/or dosing.	NIH supports research on new and improved vaccine formulations/technologies, including products that may be easier to store, ship, and deliver in resource-limited settings and during public health emergencies. Examples include a needle-free device for delivering tetravalent dengue vaccine, adjuvanted anthrax vaccine, and silk protein for vaccine stabilization.	Projected completion date: End of 2015
NIH	B9. NIH will fund preclinical services for investigators to develop and evaluate five candidate vaccines.	NIH/NIAID provides vaccine development services for use in the investigation, control, prevention, and treatment of a wide range of infectious agents. These services support the following products: vaccines, vaccine components including adjuvants, vaccine delivery systems, other biologics, and challenge material. Vaccine testing services include assay development for nonclinical and clinical samples; nonclinical immunogenicity and efficacy studies; clinical and nonclinical sample testing; and safety and toxicity testing. Vaccine manufacturing services include feasibility, gap analysis, and product development plan support; process development; product release assay development including potency assays; pilot and cGMP manufacture; audits; and regulatory activities and documentation.	Projected completion date: End of 2015

Lead agency	Action step	Progress report	Status
NIH	B10. NIH will fund multifunctional clinical research sites to expand the range of studies conducted among diverse populations in the United States and international settings.	NIH/NIAID recompeted the Vaccine and Treatment Evaluation Units. Awards were made in late FY 2013. The sites will carry out clinical studies and trials spanning a wide spectrum of infectious diseases and will have the ability to conduct studies in international populations, including in resource-poor settings. Studies may include healthy volunteers from birth to mature adults, pregnant women, and subjects with diseases that are endemic to the specific location. See NIH press release.	Projected completion date: End of 2015

Goal 2: Enhance the Vaccine Safety System

Priority B: Strengthen the science base for the development and licensure of new vaccines.

Lead agency	Action step	Progress report	Status
FDA	B11. FDA will develop and implement a research agenda focusing on enhancement of vaccine safety evaluation; including laboratory research, bioinformatics for exchanging information, overseeing the safety of vaccine products, and new epidemiological methods.	For information on relevant FDA research, see http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Post-MarketActivities/ucm276981.htm, http://www.fda.gov/BiologicsBloodVaccines/ScienceResearch/ucm234680.htm, and http://www.fda.gov/BiologicsBloodVaccines/ScienceResearch/default.htm, which are links to scientific publications and select summaries on current relevant FDA research.	Ongoing through 2015
NIH	B12. NIH will fund preclinical and clinical research related to the development of safe and effective vaccines, including studies among healthy adults as well as specific populations such as infants and children, the elderly, and people with weakened immune systems.	NIH/NIAID supports preclinical and clinical vaccine research, including studies among special populations. Examples include Pertussis Vaccine in Healthy Pregnant Women, Safety and Immunogenicity of Sequential Rotavirus Vaccine Schedules, Staged Phase I/II Hepatitis C Prophylactic Vaccine, A Phase IIb, Open-Label, Dose-Ranging Study of 13-Valent Pneumococcal Conjugate Vaccine in Adults 55 through 74 Years of Age Previously Vaccinated with 23-Valent Pneumococcal Polysaccharide Vaccine, and H7N9 Vaccine Clinical Trials.	Projected completion date: End of 2015

Priority C: Enhance timely detection and verification of vaccine safety signals and develop a vaccine safety scientific agenda.

Lead agency	Action step	Progress report	Status
NVPO	C1. NVPO will fund a literature review of vaccine safety to inform development of a vaccine safety scientific agenda.	Via an Interagency Agreement with AHRQ, RAND Corporation is performing the vaccine safety literature review. A draft of the report has been released and the final is planned to be available January 2014.	Projected completion date: January 2014
Federal Immunization Safety Task Force (ISTF): CDC, FDA, VA, IHS, and DoD	C2. The ISTF will increase the number of infants, children, adolescents, and adults enrolled in active surveillance systems for adverse events following immunizations [e.g., VA, IHS, DoD] in the United States to 90 million.	As of November 2012, 107 million individuals were enrolled.	Completed
FDA	C3. FDA will contract with private health care data systems to access claims-based information for vaccine safety surveillance in the PRISM program under FDA's Mini-Sentinel initiative. This will allow FDA to assess whether vaccine exposure might be associated with health outcomes of interest.	Under the PRISM program of FDA's Mini-Sentinel Initiative, the first protocol-based safety assessment of over 1 million doses of rotavirus vaccines is complete, and the results were publicly posted in June 2013. These results led to the first safety labeling change stemming from a Mini-Sentinel protocol-based safety assessment.	Completed
FDA and CMS	C4. FDA and CMS will monitor the safety of seasonal influenza vaccines in Medicare beneficiaries using Medicare databases.	In the 2012/13 season, actively monitored for GBS with no observable signal to date among over 16.1 million influenza vaccinations in the Medicare System. Actively working to expand methodologies to conduct surveillance for other adverse events such as anaphylaxis.	Ongoing through 2015
ISTF	C5. The ISTF will use the information from the NVPO-funded literature review of vaccine safety and develop a vaccine safety	ISTF is awaiting the literature review, which has been delayed; the expected delivery of the review was May 2013. A draft report has been released and a final report is expected during	Projected completion date: First quarter of

Lead agency	Action step	Progress report	Status
	scientific agenda.	January 2014.	2014
ISTF	C6. The ISTF will increase the number of infants, children, adolescents, and adults enrolled in active surveillance systems for adverse events following immunizations [e.g., VA, IHS, DoD] in the United States to 100 million.	As of February 2013, 111.5 million individuals were enrolled.	Completed
CDC	C7. CDC will redesign the online electronic reporting form for VAERS to include new fields that capture additional demographic information and implement web-based features to expedite complete and accurate online reporting.	A redesigned VAERS form is currently undergoing usability testing.	Projected completion date: End of 2013
FDA and CDC	C8. FDA and CDC will enhance reporting by improving the ability to submit reports to VAERS electronically, to facilitate efficient, complete, and accurate reporting of adverse events following immunization.	A redesigned VAERS form is currently undergoing usability testing.	Projected completion date: End of 2015
CDC	C9. CDC will conduct research and development for technologies to facilitate reporting to VAERS from handheld devices such as application software and to incorporate technologies into EHRs to facilitate VAERS reporting, such as provider prompts.	Under a Phase I Small Business Innovation Research grant, a feasibility project has developed a prototype app. CDC has supported an ongoing study to implement provider prompts for possible vaccine safety concerns in EHRs.	Projected completion date: End of 2015

Lead agency	Action step	Progress report	Status
FDA	C10. FDA will take steps toward providing patients, providers, and manufacturers with a single reporting portal for adverse events by recommending VAERS data structure modifications to allow compatibility with adverse event reporting systems used for other medical products.	Consumer and health care providers can report vaccine adverse events to VAERS online on the VAERS website. While this reporting is still a separate portal from that used for other regulated medical products, FDA and CDC are working to align vaccine adverse event data elements with those used for drugs and other products. The eVAERS initiative, a joint FDA and CDC project, is restructuring the VAERS database to allow it to accept electronic adverse event reports from vaccine manufacturers, in the same way that FDA currently accepts electronic reports for drugs and other products.	Projected completion date: End of 2015
CDC	C11. CDC will ensure that health plans with the capacity to rapidly and regularly provide complete medical records and chart review data for immunization participate in vaccine safety surveillance through the VSD.	CDC announced and work has begun under a new IDIQ contract with health plans. In competing this new contract, CDC invited any health plan with the capacity to provide this level of health data to apply; the IDIQ includes all successful applicants.	Projected completion date: End of 2015
CDC	C12. CDC will support VSD contractors in rapid assessments of all vaccine safety signals of significance.	VSD conducted rapid cycle analysis for influenza vaccine safety (2012–2013) and will implement active monitoring for adverse events for influenza vaccine for the 2013–2014 season. Through the VSD Indefinite Deliverable Indefinite Quantity contract, the VSD detected a signal of increased risk of intussusception following RV1 vaccine through continuous monitoring. In FY 2014, rapid cycle analysis will be conducted for HPV vaccine administered to males.	Projected completion date: End of 2015
FDA and CDC	C13. FDA and CDC will receive manufacturer reports of vaccine adverse events electronically in accordance with International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) E2B(R3) standards.	The eVAERS initiative, a joint FDA and CDC project, is re-tructuring the VAERS database to allow it to accept electronic adverse event reports from vaccine manufacturers in compliance with the ICH E2B (R3) standards for electronic adverse event reporting. The ICH E2B (R3) standards are international standards for the format and content of electronic adverse event submissions from manufacturers. The agencies have made significant progress in defining the technical requirements and structure for eVAERS. Pilot testing with	Projected completion date: End of 2015

Lead agency	Action step	Progress report	Status
		manufacturers is anticipated to be late 2013/early 2014.	

Goal 3: Support communications to enhance informed vaccine decision-making

Priority D: Increase awareness of vaccines, vaccine preventable diseases, and the benefits/risks of immunization among the public, providers, and other stakeholders.

Lead agency	Action step	Progress report	Status
FDA	D1. FDA will enhance communication to stakeholders by utilizing social media (including Twitter) to distribute FDA-specific news and content about vaccines (e.g., new approvals, safety issues, etc.).	During Calendar Year 2013, FDA developed vaccine-related content for consumers, health care providers and regulated industry on an array of topics including but not limited to safety information on rotavirus vaccine; global vaccine safety surveillance; research on influenza vaccine development; research findings on residual formaldehyde in infant vaccines; a guide for parents on childhood vaccines, etc. FDA/CBER averaged 3–4 vaccine-specific postings per month during this time period.	Ongoing through 2015
NVPO	D2. NVPO will launch a comprehensive government website on vaccines and immunization.	Vaccines.gov was launched in March 2011	Completed
ONC	D3. ONC will promote consumer engagement projects to allow parents access to vaccination history data from IIS, including clinical decision support tools.	ONC has begun a project with the Minnesota Health Information Exchange to make technical changes in the HP IIS, which is used by multiple public health agencies across the country. This project will develop the technical capacity for this system to enable consumer engagement. Additionally the Interagency Agreement with NVPO to develop communication materials around consumer engagement and provider funding to two additional states to pay for technical changes is moving forward.	Ongoing through 2015
NVPO	D4. NVPO will launch a Spanish language comprehensive government website on vaccines and immunization.	The Spanish translation of vaccines.gov launched in February of 2012.	Completed
FDA	D5. FDA will use specified metrics to evaluate use of Twitter as a means to communicate with stakeholders.	Metrics have been identified, and tracking has begun.	Projected completion date: End of 2013

Lead agency	Action step	Progress report	Status
CDC	D6. CDC will assess the accessibility and usability of Vaccine Information Statements (VIS) for different target audiences. CDC will use this information to revise VIS as needed.	All updated VISs are being produced in a simplified and standardized format, and these changes underwent ad hoc testing associated with Education, Information and Partnership Branch training courses. The VIS website was updated and includes all VISs in html format, which will be easily accessible with smart phones. VIS pages will now be syndicated, so VISs will be automatically updated for people who link to them. All VISs have also been made assessable in rtf format, at the request of some providers, to be compatible with their electronic systems. Barcodes are added to all updated VISs to facilitate recording of VIS name and edition date.	Projected completion date: End of 2015

Goal 4: Ensure a stable supply of, access to, and better use of recommended vaccines in the United States

Priority E: Use evidence-based science to enhance vaccine preventable diseases surveillance, measurements of vaccine coverage, and measurement of vaccine effectiveness.

Lead agency	Action step	Progress report	Status
CDC	E1. CDC will increase the number of virus specimens received and characterized annually from global National Influenza Centers for use in determining vaccine strain selection (Target: 11,000 virus specimens characterized).	11,358 virus specimens were characterized in FY 2013	Completed
CDC	E2. CDC will continue to monitor the number of indigenous cases of paralytic polio, rubella, congenital rubella syndrome (CRS), measles, Hib, diphtheria, tetanus, mumps, pertussis (in persons <7 years), and varicella (in persons <18 years) to evaluate the impact of vaccine policy and programs.	CDC continues to support the NNDSS, which is the source of U.S. national surveillance data for these pathogens. For certain pathogens, data is received from specialized surveillance systems to address specific surveillance requirements to monitor the number of cases and to evaluate program/policy impact. These data are analyzed and results are routinely shared with local, state, national, and international public health partners.	Ongoing through 2015

Lead agency	Action step	Progress report	Status
CDC	E3. Within one year of a disease becoming newly vaccine preventable CDC will implement a plan for documenting and reporting vaccine impact.	Critical investments were made to enhance the influenza vaccine effectiveness surveillance network so that more providers and patients are enrolled, allowing for rapid and more comprehensive VE data gathering. Evaluations of vaccine effectiveness continue for pneumococcal conjugate vaccine (PCV13, recommended for young children in 2010) and meningococcal conjugate vaccine for adolescents; published a study showing the impact of PCV7 vaccination of infants in reducing pneumonia in all age groups. Published studies of diphtheria-tetanus-pertussis vaccine (DTaP) effectiveness in 5–10 year old children, showing waning immunity within 5 years after the 5th DTaP dose, and they completed a study showing waning immunity within 2 years after a Tdap booster dose in adolescents. CDC has published data showing that rotavirus vaccines are highly effective in preventing severe rotavirus disease and that vaccine effectiveness does not wane over time in U.S. children. CDC monitors the impact of rotavirus vaccine in the United States through the National Respiratory and Enteric Viruses Surveillance System and the New Vaccine Surveillance Network.	Ongoing through 2015
CMS	E4. CMS will track and publicly report the percentage of nursing home residents that are assessed and appropriately given influenza vaccine.	*No update*	

Lead agency	Action step	Progress report	Status
CDC	E5. CDC will increase the number of public health laboratories monitoring influenza virus resistance to antiviral agents to 15.	18 public health laboratories are monitoring influenza virus resistance to antiviral agents.	Completed
CDC	E6. CDC will increase the percentage of Pandemic Influenza Collaborative Agreement grantees (CoAg) (state, local, territorial, and tribal project areas) that meet the standard for surveillance and laboratory capability criteria.	42.5 percent of CoAg grantees met the standard for surveillance and laboratory capability criteria for 2012.	Completed

Priority F: Eliminate financial barriers for providers and consumers to facilitate access to routinely recommended vaccines.

Lead agency	Action step	Progress report	Status
NVPO	F1. NVPO will provide an annual update to NVAC on progress toward strengthening and improving the vaccine financing system in the United States to facilitate access to routinely recommended vaccines.	NVPO has provided or coordinated updates to NVAC on issues related to the U.S. vaccine financing system multiple times per year since 2009. NVPO has ensured that NVAC has continually been kept abreast of information regarding the Affordable Care Act and its impact on vaccine access and payment. Presentations have been given on this topic in September 2010, June 2011, February 2013, June 2013, and September 2013. In September 2009 and September 2012, NVPO gave updates on the implementation of NVAC recommendations for vaccine financing. In September of 2011, NVAC heard information on vaccine financing coordination. In February 2010, June 2010, and June 2011, NVAC was given vaccine financing updates.	Ongoing through 2015
HR5A	F2. HRSA will measure the percentage of children seen at HRSA-funded health centers who receive all-age appropriate routinely recommended vaccines by their third birthday.	Relevant HRSA programs measure the percentage of children who receive recommended vaccines. In addition, HRSA continues dialogue with stakeholders toward aligning childhood immunizations to increase immunization rates and reduce preventable infectious diseases.	Ongoing through 2015
CDC	F3. CDC will support 28 immunization grantees to develop plans and 14 immunization grantees to implement plans to enable billing for vaccine services provided by public health clinics.	Of the original 14 grantees, 11 are implementing third party billing. Currently, 38 of 64 immunization grantees have received funds for planning or are implementing plans for billing, or both. The National Association of County and City Health Officials developed a national toolkit on third-party billing.	Completed
CDC	F4. CDC will provide guidance to immunization grantees to not use Section 317 vaccines for routine vaccination of fully insured patients. Section 317 is a discretionary federal program distributed to the states to provide money for vaccine	Immunization grantees received guidance on the use of Section 317 vaccines for routine vaccination of fully insured patients in July 2012. Beginning October 1, 2012 all grantees indicated compliance with the policy in their vaccine-purchasing plans.	Completed

Lead agency	Action step	Progress report	Status
	purchase and to develop vaccine infrastructure.		

Priority G: Create an adequate and stable supply of routinely recommended vaccines and vaccines for public health preparedness.

Lead agency	Action step	Progress report	Status
CDC	G1. CDC will continue to track the status of vaccine supplied in the United States and maintain a strategic national stockpile of vaccines that are available to state and local health departments during public health emergencies and when local supplies are depleted or unavailable.	All FY 2013 pediatric stockpile purchases have been submitted.	Ongoing through 2015
ASPR	G2. ASPR/BARDA will continue to support, through public-private partnerships, the development of domestic influenza vaccine manufacturing capacity to address seasonal and pandemic influenza vaccine needs.	Through ASPR/BARDA, HHS awarded three-year contracts to five U.S.-licensed influenza vaccine manufacturers to produce master vaccine seed stocks, clinical investigational lots, and prepandemic vaccine stockpiles for viruses with pandemic potential before a pandemic occurs. The contracts also allow HHS to purchase live-attenuated and cell-based vaccines in addition to conventional egg-based vaccine in a pandemic.	Ongoing through 2015
FDA	G3. FDA will convene/cosponsor three scientific meetings to facilitate the development of an effective vaccine against a number of preventable infectious diseases for which there is not a vaccine currently available.	In 2012, FDA convened or cosponsored three scientific meetings. January 2012: FDA, in partnership with NIH, CDC and NVPO convened a public workshop to identify and discuss key issues related to the development and evaluation of human cytomegalovirus vaccines. June 2012: FDA cosponsored the Universal Influenza Vaccines Meeting with NIH/NIAID. September 19, 2012: FDA's Vaccines and Related Biological Products Advisory Committee met to examine the role of emerging technologies for detecting adventitious agents in assessing whether novel human tumor-derived cell-line substrates are suitable for vaccine production.	Completed

Priority H: Increase and improve the use of interoperable health information technology and EHRs.

Lead agency	Action step	Progress report	Status
ONC	H1. ONC will certify national standards for EHRs to ensure that eligible professionals and hospitals may be assured that the systems they adopt are capable of performing the required functions.	2014 certification criteria were completed in December 2013 and included a new implementation guide that better facilitates interoperability.	Ongoing through 2015
ONC	H2. ONC will collect information on barriers to implementing meaningful use requirements for immunization through the CRM (Sales Force) tool. The CRM (Sales Force) is a milestone management tool that tracks the progress of Regional Extension Centers (RECs) towards meeting their goals of enrolling providers and getting providers to achieve meaningful use.	Barriers such as testing during year two and year three of Stage 1 Meaningful Use and transport issues have been identified. Frequently Asked Questions (FAQ) and other resources to address these issues have been developed and will be placed on HealthIT.gov.	Ongoing through 2015
ONC	H3. ONC will perform surveys of select providers enrolled to receive services from RECs to determine issues/barriers with IIS and compatibility with EHRs.	Barriers such as testing during year two and year three of Stage 1 Meaningful Use and transport issues have been identified. FAQs and other resources to address these issues have been developed and will be placed on HealthIT.gov.	Ongoing through 2015
ONC	H4. ONC will register 100,000 primary care providers to receive services from RECs and ensure that 60 percent of those have adopted the use of EHRs.	Well over 100,000 primary care providers have registered with RECs as of 12/31/2012.	Completed

Goal 5: Increase global prevention of death and disease through safe and effective vaccination.

Priority I: Improve global surveillance for vaccine preventable diseases and strengthen global health information systems to monitor vaccine coverage, effectiveness, and safety.

Lead agency	Action step	Progress report	Status
CDC	I1. CDC will continue to serve as a global reference lab for polio, measles, and rubella.	CDC provided basic and advanced diagnostic support, including genomic sequencing, to polio-endemic and outbreak-affected countries, to identify virus reservoirs and sources of outbreaks. Molecular methods for confirming measles and rubella infections were introduced in all 6 WHO Regions in the Regional Reference Labs (some national). A system for QA/QC is actively being pursued to standardize and validate the methods. Domestic Reference Centers (4) were established and perform CDC-developed molecular methods for rRT-PCR, sequencing, and genotyping.	Ongoing through 2015
CDC	I2. CDC will provide surveillance and laboratory capacity to monitor progress in reaching global polio eradication, guide programmatic response, and implement the polio eradication end-game strategy.	CDC has contributed significantly to the more than 99 percent decline in global polio cases from more than 350,000 cases reported annually in 1988 to 223 cases reported in 2012, a decline of nearly two-thirds from the 650 cases in 2011. India, one of the four remaining endemic countries (Nigeria, Afghanistan, and Pakistan) in 2010, has not had a case of polio transmission since January 2011. CDC and the GPEI partners are aligned behind a joint strategy, which is articulated in the Polio Eradication and Endgame Strategic Plan (2013–2018). The Plan has four major pillars: (1) poliovirus detection and interruption; (2) routine immunization strengthening and OPV (oral polio vaccine) withdrawal; (3) containment and certification; and (4) legacy planning. CDC has continued to work with WHO to ensure accreditation of polio, measles, and rubella laboratories in key endemic and outbreak-affected countries and increased global lab capacity to support sensitive VPD surveillance by transfer of CDC-developed polio, measles, and rubella virus detection and characterization technologies.	Ongoing through 2015

Lead agency	Action step	Progress report	Status
CDC	I3. CDC will provide a descriptive report of progress on immunization activities in the FETP.	Working with ministries of health and other partners, FETP residents conduct investigations and share scientific data to improve health outcomes. Recently, CDC trained FETP residents in Ethiopia, Uganda, and Sudan to recognize the signs and symptoms of polio as a mechanism to strengthen the surveillance capabilities in those countries (as the FETP residents conduct field investigations).	Ongoing through 2015

Priority J: Support global introduction and availability of new and under-utilized vaccines to prevent diseases of public health importance.

Lead agency	Action step	Progress report	Status
CDC	J1. CDC will continue to provide surveillance, laboratory, and vaccine program implementation capacity to support national decision-making on new vaccine introduction, and to enable introduction of new vaccines including pneumococcal vaccine, rotavirus vaccine, meningococcal vaccine, and HPV vaccine in GAVI eligible countries.	CDC's Division of Bacterial Diseases is providing support for accelerating introduction of pneumococcal conjugate vaccines, as part of GAVI's Accelerated Vaccine Initiative-Technical Assistance Consortium and works closely with other strategic countries in various regions. As part of this CDC supports PCV effectiveness studies in South Africa, Kenya, Brazil, and Uruguay and initiated a study with Bangladesh and Pakistan. CDC has supported evaluation of the impact of meningococcal conjugate vaccines surveillance in Burkina Faso, Niger, Mali, Nigeria, and Ghana, and plans to initiate similar studies in 6 additional countries in the meningitis African belt. As the global reference laboratory for the WHO invasive Bacterial Surveillance network, CDC provides assistance to all WHO regions to strengthen laboratory and epidemiologic capacity for bacterial disease surveillance, in order to provide countries with evidence to help them introduce bacterial vaccines (pneumococcal, Hib, meningococcal conjugate vaccines) or evaluate their impact post introduction to sustain the immunizations program long term. Over 50 countries are currently part of the surveillance network, mainly located in the African region. For HPV, CDC has a qualitative study in Kenya regarding communication issues for HPV vaccine introduction as well as ongoing consultations by CDC HPV laboratory with the Pan American Health Organization (PAHO) and Argentina's Ministry of Health regarding laboratory preparations for HPV prevalence monitoring in the Americas. CDC participates in several key international meetings, including a WHO Regional Consultation on Cervical Cancer Prevention and Control; a WHO Scoping Meeting on development of second generation HPV vaccines; a PAHO TAG meeting during which CDC presented data on alternative HPV vaccination schedules; and the President's Cancer Panel on Challenges of Global HPV Vaccination Introduction. To date, 47 countries around the world have introduced rotavirus vaccines	Ongoing through 2015

Lead agency	Action step	Progress report	Status
		through their national immunization programs, including 15 GAVI-eligible countries. CDC provided assistance to WHO and GAVI Alliance in supporting these introductions.	
ASPR	J2. ASPR/BARDA will provide financial and technical support for the WHO GAP, including capacity building for vaccine production at developing country manufacturers, royalty-free adjuvant production, specialized training in advanced biomanufacturing skills, and clinical/laboratory infrastructure building.	To date, thirteen manufacturers in twelve developing countries have received technical and financial support from ASPR/BARDA to establish influenza vaccine manufacturing capacity. Seven manufacturers have licensed influenza vaccines for use in their own country, increasing the manufacturing capacity for pandemic vaccines to over 280 million doses to date.	Ongoing through 2015

Lead agency	Action step	Progress report	Status
FDA	J3. FDA will develop and implement a research agenda to facilitate the development of vaccines against tropical and neglected diseases.	FDA is working to develop an assay to identify the serotype of the infecting dengue virus in subjects whose illness meets the diagnostic criteria for dengue, during clinical trials of dengue vaccines in endemic areas. FDA has demonstrated that a monoclonal antibody that recognizes all four serotypes of NS1 (a glycoprotein secreted from dengue-infected cells) is able to bind to the infected cells and give a positive result in the ELISA. Further, FDA research has shown that two monoclonal antibodies, one against dengue serotype 2 and one against dengue serotype 1, do recognize the respective NS1 proteins in a specific manner.	Ongoing through 2015
FDA	J4. FDA will participate in international collaborative studies to establish and maintain international reference materials and standards for biologics.	Efforts in this area for various vaccines are underway. For example, pneumococcal reference standard sera was developed by the FDA in 2011 for ELISA assay for use by the global scientific community. Another example is the Salmonella Typhi Vi antiserum, which was selected by NIBSC in the UK for testing with nine participating laboratories worldwide to establish an anti-Vi polysaccharide IgG (human) as a WHO International Standard Preparation for quantitative analysis of antibody directed against Salmonella Typhi. It is made available to WHO through the FDA. The FDA is also is a member of the Working Group on Quality, Safety and Efficacy of Typhoid Vi Capsular Polysaccharide Conjugate Vaccine, chosen as the major author of the nonclinical section and major contributor to the manufacturing and quality control section. A major outcome of the meeting of that working group was a first draft of WHO guidelines on these conjugate vaccines. The working group efforts are ongoing. The draft has been released for public comment and an advanced draft is expected to be submitted to the Expert Committee on Biological Standardization of WHO in June. FDA is also a part of the U.S. Pharmacopeial Convention Working Group on Glycoconjugates Vaccines. In October 2012, the group completed a final draft of the U.S. Pharmacopeial Convention chapter outlining recommendations for the manufacture of polysaccharide and glycoconjugate vaccines for human use.	Ongoing through 2015

Lead agency	Action step	Progress report	Status
FDA	J5. FDA will build regulatory capacity in developing countries, which may include training, participation in WHO assessments, and other international activities.	FDA has participated in approximately 18 WHO-sponsored meetings to strengthen regulatory capacity building and provide advice to developing countries' National Regulatory Authorities on vaccine development and evaluation.	Ongoing through 2015
ASPR	J6. ASPR/BARDA will provide technical support in vaccine manufacturing, including training on vaccine production, analytical evaluation, laboratory techniques, and clinical evaluation, to developing country manufacturers for the WHO GAP. This training may take place on-site in developing countries and at established educational institutions in the United States.	As of May 2013, over 250 scientists have attended ASPR/BARDA-supported biomanufacturing training courses, with additional courses planned for Summer 2013. In 2013, the courses were expanded, in collaboration with FDA and WHO, to include participants from National Regulatory Authorities in developing countries.	Projected completion date: End of 2015
OGA	J7. OGA will provide policy and diplomatic support for the WHO GAP by co-organizing and facilitating workshops to bring together supporting infrastructures in influenza vaccine development in developing countries, including ministers of health, ministers of finance, vaccine manufacturers, nongovernmental organizations, regulatory authorities, and policy makers.	OGA has cohosted 7 workshops with WHO since 2010. The most recent workshop was in June 2013 in Atlanta, Georgia, and was titled Workshop on Enhancing Communication around Influenza Vaccination. The workshop welcomed 93 participants from 31 countries. The outputs from the breakout sessions and discussions directly informed a framework to strengthen national and regional communication systems around vaccination.	Projected completion date: End of 2015
OGA	J8. OGA will facilitate development of new partnerships across HHS, across the U.S. government, and with other international partners not previously engaged for support of the WHO Action Plan to Increase Pandemic Influenza Vaccines.	Through workshops cosponsored with WHO (see Action Step J7) OGA facilitated the development of new partnerships that support Pandemic Influenza Vaccines. The AVMI is a notable new partnership formed through the workshop series in 2011. AVMI brings together 12 vaccine manufacturers in Africa, for Africa. This major initiative was formally announced by the President of Benin at the Africa Union meeting in January 2013.	Projected completion date: End of 2015

The National Vaccine Advisory Committee (NVAC): Historical Contributions and Recent Accomplishments

NVAC was established in 1987 and held its first meeting in 1988. Its purpose is to advise and make recommendations to the ASH, who serves as the Director of the National Vaccine Program, on matters related to the goals of the National Vaccine Program. As the external federal advisory committee that oversees the National Vaccine Program, NVAC also monitors and provides feedback on the updating and implementation of the National Vaccine Plan. The Director of NVPO acts as a liaison between the ASH and NVAC, coordinating and facilitating communication and collaboration between the ASH, NVPO, HHS, and NVAC. In this way, the Director of NVPO and NVPO staff ensure that the ASH's priorities for vaccines and immunization are communicated to NVAC, that the recommendations of the committee on the implementation of the National Vaccine Program's responsibilities and the National Vaccine Plan are communicated to the ASH for his or her consideration.

NVAC brings together nonfederal subject matter experts from all areas of the field of immunization, including scientists, public health officials, and industry leaders. Its membership is composed of 15 representatives from public and private organizations, including vaccine manufacturers, insurance providers, physicians, state and local health agencies, and nonprofit organizations and the public. To ensure that all members are truly qualified to serve on NVAC, the legislation establishing the committee requires all nominees to be evaluated by the IOM before they can be appointed. In addition, to ensure optimal coordination of the National Vaccine Program, representatives from governmental agencies that contribute to the National Vaccine Program serve as ex-officio members on NVAC. Chairs of other vaccine and immunization-related federal advisory committees also serve as members in an ex-officio capacity on NVAC (e.g., CDC's ACIP, FDA's VRBPAC, and HRSA's Advisory Commission on Childhood Vaccines [ACCV]). (NVAC's membership roster can be found on the NVPO website.[52]) NVAC meets in person three times a year in Washington, DC, to hear and comment on timely information relating to the issues in vaccines and immunization that need attention.

NVAC does its work mainly through working groups, which meet regularly outside of the three annual in-person NVAC meetings. NVAC working groups are developed to explore specific vaccine-related issues in depth, bring their findings back to NVAC for discussion, and develop recommendations for the full committee to consider. If recommendations are accepted by the full committee, they are submitted to the ASH for his or her consideration to guide HHS's work on these topics. Both NVAC members and nonmember experts participate on these working groups. Working group recommendations lay out possible solutions for HHS and its partners that will remove barriers to achieving national goals for immunization, as identified by Healthy People 2020 and the National Vaccine Plan. Currently, NVAC has three active working groups

[52] U.S. Department of Health and Human Services: National Vaccine Program Office. (2013). *NVAC membership/roster.* Retrieved from http://www.hhs.gov/nvpo/nvac/roster/index.html

considering available evidence and developing recommendations on HPV vaccination coverage, maternal immunization, and vaccine hesitancy/confidence and its impact on childhood immunization coverage, which were identified as important areas by the ASH, and align with Healthy People 2020 goals for immunization and infectious disease.

By bringing together stakeholders that represent all areas of immunization, NVAC is capable of providing advice and insights into the full range of vaccine- and immunization-related activities in the United States. Through continuous monitoring and feedback into the immunization system, NVAC ensures that the work of HHS, the U.S. government, and its many stakeholders is being directed appropriately to achieve the goals of the National Vaccine Program as outlined in the Public Health Service Act[53]:

- Vaccine research.
- Vaccine development.
- Safety and efficacy testing of vaccines.
- Licensing of vaccine manufacturers and vaccines.
- Production and procurement of vaccines.
- Distribution and use of vaccines.
- Evaluating the need for, the effectiveness of, and adverse effects of vaccines and immunization activities.
- Coordinating governmental and nongovernmental activities.
- Funding of federal agencies.

Historical Contributions and Recent Accomplishments of NVAC

During its 25 years of leadership, NVAC has addressed concerns in all parts of the immunization system. Through its review of issues in vaccine research and development, vaccine safety, vaccine communications, and vaccine delivery, and most recently, through HHS's contributions to global immunization efforts, NVAC has provided key recommendations and made major contributions to strengthening the national immunization system.

Immunization Across the Lifespan

Traditionally, immunization has been associated with the prevention of serious childhood infections. NVAC has worked to both strengthen the childhood immunization system and identify program needs to foster the development and use of vaccines across all stages of life. This is important given that vaccine preventable diseases can infect and harm people during childhood, adolescence, and adulthood, and can also infect and harm pregnant women.

Childhood immunization

Opportunities to improve our childhood immunization program moved into the spotlight during the measles epidemic in the United States in 1989–1991.[54] The nation experienced a marked increase in measles cases during this time, resulting in tens of thousands of cases of

[53] Public Health Service Act, 42 U.S.C. § 300aa1. Retrieved from http://www.hhs.gov/nvpo/about/legislation.pdf

[54] U.S. Centers for Disease Control and Prevention. (1991). Current trends measles -- United States, 1990. *Morbidity and Mortality Weekly Report, 40*(22), 369-372. Retrieved from http://www.cdc.gov/mmwr/preview/mmwrhtml/00001999.htm

measles and more than one hundred deaths. Almost half of all cases occurred in unvaccinated pre-school children, mostly minorities. The principal cause for the epidemic was the failure to provide measles vaccine on schedule to young children.

In an effort to analyze the situation and provide solutions, NVAC released their 1991 report, *The Measles Epidemic: The Problems, Barriers, and Recommendations.*[55] NVAC noted in their report that there were barriers in the health care system to obtaining immunization, most notably inadequate access to care and inadequate public awareness of the importance of immunization. This report contributed to the strengthening of our immunization system and played an important role in major reform of immunization financing for childhood vaccines. Through an act of Congress, the federally funded VFC was created. This program provides vaccines at no cost to some of the neediest children (e.g., those eligible for Medicaid, those without insurance, and American Indians/Alaska Natives) who might not otherwise be vaccinated because of inability to pay. The VFC provides vaccines for children to both private and public providers so children can be vaccinated in their medical homes by their primary doctor. VFC also covers provision of free vaccines in federally qualified health centers for children with insurance but whose insurance does not cover immunizations.

NVAC has made many other contributions to the childhood immunization system. For example, in 1992, NVAC provided guidance on the establishment of Standards for Pediatric Immunization Practices, which were created to provide national guidelines on best practices for immunization providers in all areas of the health care system. By changing the practices that contributed to the low immunization rates leading to the 1989–1991 measles epidemic, and establishing new policies that promote on-time immunization for children according to the recommended schedule, the Standards help to keep coverage rates high and prevent outbreaks of vaccine preventable diseases. The Standards were revised and updated under NVAC's supervision in 2003.[56]

With the use of recommended childhood vaccines, the rates of vaccine preventable diseases in children are at historically low levels. Although vaccines, like any drug or medical treatment, have their risks, research has shown childhood immunization and the childhood vaccine schedule to be very safe. However, a small subset of parents in the United States is refraining from vaccinating their children, or choosing to follow alternative vaccination schedules. To better understand this phenomenon and create strategies to prevent the small number of children who have not been fully vaccinated from growing, an NVAC working group is examining the issue of vaccine confidence among parents of children aged 0–6 years.

This working group is currently reviewing the available evidence and literature concerning how confidence in vaccines and in our immunization program and services impacts the optimal use

[55] National Vaccine Advisory Committee. (1991). The measles epidemic: The problems, barriers, and recommendations. *JAMA, 266*(11), 1547–1552. Retrieved from http://www.ncbi.nlm.nih.gov/pubmed/1880887

[56] National Vaccine Advisory Committee. (2003). Standards for Child and Adolescent Immunization Practices. *Pediatrics, 112*, 958–963. Retrieved from http://archive.hhs.gov/nvpo/nvac/documents/StandardsCAImm.pdf

of recommended childhood vaccines in the United States. After considering the available information on this topic, the working group will issue recommendations to the ASH on how to best measure confidence in our vaccines and vaccination recommendations as well as our immunization programs, and types of interventions that may be needed to ensure that parental confidence does not become an impediment to optimal use of vaccines to prevent serious childhood infections and their consequences.

Adolescent and adult immunization

Through the VFC program, routine immunization is provided to eligible children through age 18. However, rates of routine immunization for both adolescents and adults have continued to fall below Healthy People 2020 goals. Low coverage stems from a variety of issues. For example, adolescents and adults have fewer preventive care visits with health care providers than infants and young children, resulting in fewer opportunities to vaccinate. Additionally, providers often neglect to vaccinate adolescents and adults at sick visits, resulting in many missed opportunities. Overall, much work is needed to change the culture of adolescent and adult immunization in order to increase coverage.

NVAC has done a great deal of work to provide guidance on how to address this issue, both for adolescents and adults, throughout the past 25 years.

Adolescent immunization

Since 1998, NVAC has drawn attention to the issue of low adolescent vaccination rates through resolutions, recommendations, and oversight. Following a resolution on adolescent vaccine coverage in 1998, NVAC included adolescents in the Standards for Immunization Practice in 2003. In 2008, the NVAC working group on adolescent immunization released recommendations on how to increase routine adolescent immunization coverage, with their major recommendations focusing on strategies to reduce the number of missed opportunities to immunize adolescents,[57] including

- Promoting and strengthening the delivery of vaccines in the medical home during both preventive and nonpreventive care visits.
- Exploring the possibility of vaccinating adolescents outside of the medical home, in locations such as schools, pharmacies, retail locations, hospitals, etc., and promoting the implementation of vaccination services in those locations.
- Promoting the use of IIS (i.e., immunization registries) for adolescents.
- Improving surveillance of adolescent vaccine coverage and adverse events following immunization.

Uptake of the HPV vaccine has been low among adolescents and has leveled off in recent years. The working group on HPV vaccination is conducting a review of the current state of HPV immunization to understand the root causes for the observed relatively low vaccine uptake of HPV vaccine (both initiation and series completion), and to identify existing best

[57] National Vaccine Advisory Committee. (2008). *Adolescent vaccination: Recommendations from the National Vaccine Advisory Committee Adolescent Working Group.* Retrieved from http://www.hhs.gov/nvpo/nvac/adolescentvaccinationrecommend.pdf

practices, all with a goal of providing recommendations on how to increase use of this vaccine in young adolescents.

Adult immunization

NVAC has been working on issues relating to adult immunization since its inception. In 1990, NVAC oversaw the creation of the first Standards for Adult Immunization, which provide national guidelines on best practices for adult immunization providers.[58] NVAC still serves in this capacity and oversaw a revision to the Adult Standards in 2013.

Although leaders in the field of vaccines have known of the importance of adult immunization for many years, the problem remains: Large numbers of adults remain unvaccinated and in danger of complications or death from preventable diseases. About 42,000 adults die each year from complications attributed to vaccine preventable diseases.[59] Despite the high toll vaccine preventable diseases take on the health of adults, routine immunization rates among adults remain unacceptably low. In 2009, the ASH asked NVAC to develop recommendations for establishing a comprehensive and sustainable national adult immunization program to better address this problem.

In 2011, NVAC released recommendations on how to move toward the removal of barriers to adult immunization. These recommendations included

- Improving leadership on adult immunization at HHS.
- Allocating appropriate resources for adult immunization.
- Creating a national strategic plan for adult immunization.

NVAC's recommendations had a large impact on the work of HHS and its partners. Following the release of NVAC's recommendations, the AITF was formed within HHS to better coordinate adult immunization work across agencies and offices. The AITF forms the federal component of the NAIIS, a partnership of more than 140 organizational stakeholders in adult and influenza vaccine research, production, distribution, administration, and advocacy, committed to achieving the Healthy People 2020 goals for adult and influenza vaccination. Both the AITF and the NAIIS are working continuously to identify and carry out solutions to barriers to adult immunization. Additionally, there are plans for the development of a comprehensive adult immunization strategic plan, and a final document should be completed within two years.

Identifying "special" populations

Other recent NVAC efforts have focused on increasing immunization in two groups that can experience a unique impact from vaccine preventable diseases: health care personnel and pregnant women.

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[58] U.S. Centers for Disease Control and Prevention. (1990). Health objectives for the nation public health burden of vaccine-preventable diseases among adults: Standards for adult immunization practice. *Morbidity and Mortality Weekly Report, 39*(41), 725–729. Retrieved from http://www.cdc.gov/mmwr/preview/mmwrhtml/00001803.htm

[59] Healthy People 2020. (2013). *Immunization and infectious diseases topic area*. Retrieved from http://www.healthypeople.gov/2020/topicsobjectives2020/overview.aspx?topicId=23

Health care personnel both gain and give significant health benefits from receiving an annual influenza vaccination. Through their immunization against influenza, they both protect themselves from contracting influenza despite high exposure to sick individuals, and prevent passing on influenza to vulnerable patients. NVAC made a series of recommendations in 2012 that aimed to address gaps in health care personnel influenza immunization.[60] In summary, NVAC recommended that

- Health care personnel employers establish a comprehensive influenza infection prevention program, including educating health care personnel on the benefits of influenza vaccination both to them and their patients.
- Health care personnel employers integrate influenza vaccination programs into their existing infection prevention programs.
- The ASH encourage CDC and CMS to continue efforts to standardize the methodology used to measure health care personnel influenza vaccination rates across settings.
- Health care personnel employers strongly consider employer requirement policies for influenza vaccination of health care personnel in facilities that have implemented the above strategies yet continue to fail to reach target vaccination coverage goals.

Work by HHS and its partners to address these issues is ongoing and includes the creation of a comprehensive toolkit for long-term care health care facilities looking to establish a wide-ranging immunization program for health care personnel.

NVAC only recently began to examine the issue of maternal immunization—immunizing pregnant women for its impacts on both the mother and the vulnerable newborn. When certain vaccines are given to pregnant women, the vaccine can prevent serious illness in both the mother and the baby following birth. In addition, influenza vaccine protects the developing fetus, reducing the incidence of low birth weight and prematurity. Currently, two vaccines are recommended for pregnant women: the seasonal influenza vaccine and Tdap. Because pertussis is most severe in infants in the first months of life before they can be protected through vaccination themselves, the best way to prevent pertussis in these young infants is through transfer of immunity from the pregnant mother through a Tdap booster vaccination during pregnancy. In 2012, the Maternal Immunization Working Group was formed to examine the existing best practices related to maternal immunization, and to provide recommendations that will contribute to the formation of a maternal immunization platform for seasonal influenza vaccine, Tdap, and other vaccines in development such as respiratory syncytial virus and Group B strep.

Vaccine Safety

Vaccine safety is an important element of any immunization program, and NVAC has made vaccine safety a consistent priority since its founding 25 years ago, issuing reports, resolutions, and recommendations. Most recently, NVAC reviewed the U.S. vaccine safety system in the

[60] National Vaccine Advisory Committee. (2012). *Recommendations on strategies to achieve the Healthy People 2020 annual influenza coverage goal for health care personnel.* Retrieved from http://www.hhs.gov/nvpo/nvac/influenza_subgroup_final_report.pdf

context of achieving the key elements of vaccine safety as outlined in Goal 2 of the National Vaccine Plan. In 2012, NVAC released a report on the U.S. vaccine safety system, which provided guidance on the infrastructure needs for a federal vaccine safety system for the 21st century.[61]

During the H1N1 pandemic of 2009–2010, NVAC served as a vital resource for HHS and the public on the safety of the H1N1 pandemic vaccine. In July and August 2009, NVAC made recommendations on monitoring the safety of the H1N1 pandemic vaccine. These recommendations dealt with safety monitoring and safety communications. Following these recommendations, NVAC provided independent oversight of safety monitoring of the H1N1 pandemic vaccine. Starting in December 2009, the NVAC H1N1 Vaccine Safety Risk Assessment Working Group began to issue monthly reports assessing the safety profile of the 2009 H1N1 pandemic vaccine. These reports led to a final report, which the Working Group presented to the full committee in February 2012.[62] The efforts made by the Working Group ensured both that vaccine safety signals were closely monitored throughout the pandemic, and that this information was communicated to stakeholders and the public in a rapid and ongoing manner.

Vaccine Financing

The creation of the VFC program ensured that all eligible children would have access to recommended vaccines, regardless of their parent's or guardian's financial means. However, the VFC does not necessarily guarantee vaccine access to every child or adolescent. For this reason, NVAC examined the financing of routinely recommended vaccines for children and adolescents in the United States, identified financial barriers to the effective delivery of vaccines to these populations, and explored policy options to address these barriers in a 2008 report.[63] NVAC made many recommendations to address these financial barriers, including

- Expanding the VFC program to cover underinsured children (i.e., children with insurance but whose insurance does not cover immunization) at state and local public health department clinics. At the time underinsured children could only receive VFC vaccine if they went to a Federally Qualified Health Center.
- Funding and improving vaccine administration reimbursement for VFC-eligible children and adolescents.
- Recommending strategies for federal and state government agencies that would enhance vaccine access for VFC-eligible children and adolescents.

A few years later, NVAC turned its attention to the Section 317 Immunization Program. Section 317, administered by CDC, provides resources to ensure an immunization infrastructure that

[61] National Vaccine Advisory Committee. (2011). *White paper on the United States vaccine safety system.* Retrieved from http://www.hhs.gov/nvpo/nvac/nvac_vswp.pdf

[62] National Vaccine Advisory Committee. (2012). *H1N1 vaccine safety risk assessment working group report.* Retrieved from http://www.hhs.gov/nvpo/nvac/reports/vsrawg_report_january_2012.pdf

[63] Lindley, M. C., Orenstein, W. A., Shen, A. K., Rodewald, L. E., Birkhead, G. S., & NVAC Vaccine Financing Working Group. (2009). *Assuring vaccination of children and adolescents without financial barriers: Recommendations from the National Vaccine Advisory Committee (NVAC).* Retrieved from http://www.hhs.gov/nvpo/nvac/nvacfwgreport.pdf

can support high vaccination coverage levels and ensure low incidence of vaccine preventable diseases. NVAC's recommendations, published in 2013,[64]

- Confirmed the importance of maintaining the Section 317 Immunization Program.
- Requested that Section 317 be assessed by CDC in regards to the appropriateness of its size and scope, and that CDC present these findings to NVAC for deliberation and discussion.
- Called for innovative and efficient solutions from federal, state, tribal, and local public health officials that would help move vaccine coverage rates toward Healthy People 2020 goals through efficient means.

In 2013, NVAC has also paid close attention to the implementation of the Affordable Care Act, which has important implications for vaccine access and financing for the United States. Many of the concerns raised in the 2008 NVAC report on financing should be resolved through the full implementation of the Affordable Care Act. Through updates at NVAC meetings from experts, NVAC has continuously considered the impact that the Affordable Care Act will actually have on overcoming vaccine financing problems.

Enhancing the Impact and Effectiveness of NVAC

Since its founding, NVAC has made a significant impact on vaccine and immunization policy and practice. However, in an effort to ensure that HHS benefitted more fully from NVAC's unique input, RAND Corporation was commissioned to assess NVAC's impact and effectiveness. The results of this evaluation were released in 2009.[65]

The evaluation identified several areas in which adjustments would lead to greater effectiveness of NVAC. Notably, the evaluation found that by creating specific and actionable recommendations that align with HHS priorities, NVAC could multiply its impact by increasing the likelihood that its recommendations will be carried out.

Additionally, the evaluation found that by working more closely with the ASH, who directs the National Vaccine Program, and by being more strategic in the dissemination of their recommendations, NVAC could have more success in having its recommendations communicated to those that need to take action (e.g., HHS operating divisions, state and local health departments, nonprofit organizations, etc.).

Another important issue identified by the evaluation was in the area of monitoring and tracking the implementation of NVAC recommendations. By doing this, NVAC can measure its impact on an ongoing basis, and foster accountability among those that are carrying out its recommendations.

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[64] National Vaccine Advisory Committee. (2013). Protecting the public's health: Critical functions of the Section 317 Immunization Program – A report of the National Vaccine Advisory Committee. *Public Health Reports, 128*, 78–95. Retrieved from http://www.publichealthreports.org/issueopen.cfm?articleID=2949 (exit link disclaimer)

[65] Ringel, J. S., Adelson, M., Harris, K. M., Khodyakov, D., & Lurie, N. (2009). *Improving the impact and effectiveness of the National Vaccine Advisory Committee.* Washington, DC: RAND Corporation. Retrieved from http://www.rand.org/pubs/technical_reports/TR752.html (exit link disclaimer)

In the years following the release of this report, NVAC has taken great strides to improve the way it functions to achieve maximum impact. A close relationship has developed between the ASH and NVAC, and work has aligned with HHS priority areas more and more over time. Additionally, NVAC recommendations have become more specific and actionable, and efforts are being made to better follow through on the implementation and tracking of recommendations.

Conclusion: Looking Forward

The landscape of health care is shifting with the implementation of the Affordable Care Act, as millions of adults of all ages are gaining access to preventive clinical health services with no cost-sharing, including immunizations. NVAC continues to monitor the Affordable Care Act's impact on immunization access, along with other emerging areas of importance such as HPV vaccination coverage, pertussis outbreaks and maternal immunization, and parental vaccine delay and refusal.

NVAC work on adult immunization continues to come to fruition through efforts being made by HHS and other partners. These initiatives to create a strong adult immunization system in the United States will help to support the increased demand for immunization that may be brought about by the Affordable Care Act. While this new adult immunization system takes shape, NVAC will play a pivotal role in monitoring its creation.

For the last 25 years, NVAC has played a significant role in enhancing the nation's immunization efforts. As NVAC persistently improves the approach of its work and focuses its attention on issues of national importance, its impact and effectiveness continues to grow. Using this new formula for success, NVAC will maintain their progress in guiding the nation toward reaching its goals for immunization set out in the National Vaccine Plan and Healthy People 2020.

Commentary on the National Vaccine Advisory Committee: Historical Contributions and Recent Accomplishments

By Walter A. Orenstein, MD
Chairperson, National Vaccine Advisory Committee

The major focus of NVAC over the past 25 years has been on enhancing the use of licensed and recommended vaccines. The measles white paper issued by NVAC in 1991 was a major turning point that provided what would ultimately be the foundation for the current immunization system for children. In addition, NVAC developed standards of practice for providers of childhood and adult vaccines and issued guidance on how to overcome financial barriers to receipt of childhood vaccines. While NVAC will continue to contribute in these areas, other areas that will come into focus for this committee include ensuring progress is made on prevention of vaccine preventable diseases globally and incentivizing development of new vaccines and vaccine technologies that are considered high priority.

Improving delivery of currently recommended vaccines in countries throughout the world as well as development and incorporation of new vaccines into developing country immunization programs is critical to decrease the substantial infectious disease burdens in these countries. Improving global immunization is vital from a humanitarian perspective and will play a role in our own domestic health security. Recent outbreaks linked to measles importations from other countries vividly illustrate the risks the United States faces for importation of viruses into the country from other countries resulting in outbreaks. In 2013, 159 cases of measles have been reported so far (as of August 24). Of these, 157 (99 percent) were associated with importations (two cases had an unknown source but presumably were import related since indigenous transmission of measles has been eliminated in the United States). Import-associated cases were linked to 42 importations by 23 returning U.S. residents and 19 visitors to the United States from 18 countries. These are sobering numbers that increasingly cannot be ignored, as this represents the highest number of cases in 15 years. Five of the six WHO Regions have set targets for eliminating measles in their regions within the next few years, and polio eradication, too, presents an important, urgent calling. Failure to meet the polio eradication goal in the next few years creates the risk of a major global polio resurgence.

NVAC has developed a comprehensive report on global immunizations that outlines the current role of the U.S. government as well as future direction, goals, and recommendations. The NVAC report focuses on six key areas:

1. Tackling time-limited opportunities to complete polio eradication and to advance measles mortality reduction and regional measles/rubella elimination goals.
2. Strengthening global immunization systems.
3. Enhancing global capacity for vaccine safety monitoring and postmarketing surveillance.
4. Building global immunization R&D capacity.
5. Strengthening capacity for vaccine decision-making.

6. Coordination of HHS global immunization efforts.

Moreover, the report calls for a coordinated effort by multiple HHS departments to deliver an annual report to Congress on progress in these areas. The United States directly benefits from strong, effective global immunization systems by reducing the risk of disease importations, strengthening global surveillance for infectious diseases, and contributing to overall global economic growth and stability through supporting immunization innovation, facilitating developing country markets, and taking steps to ensure a healthier world.

Advancements in the development of new vaccines and vaccine technologies could ultimately lead to the prevention of even more infectious disease burdens. NVAC will soon look at what government efforts are needed to facilitate the development of vaccines, which are considered high priority. Though vaccine and vaccine technology developments primarily happen in the private sector, there are important ways the government can and should be incentivizing the development of new vaccines (e.g., HIV, malaria) as well as new vaccine technologies and delivery methods (e.g., microneedle patches) that have the potential to increase immunogenicity, ease delivery, reduce wastage, expand temperature ranges and reduce the overall burden on the vaccine delivery systems in the United States and abroad.

These two areas, global immunizations and vaccine science innovation, are vital areas for NVAC to give close attention and unwavering support in coming few years. At the same time, NVAC will continue to work to ensure optimal use is made of existing vaccines within the United States to reduce the disease burden that could be prevented by vaccines.

Healthy People 2020: Status of Immunization and Infectious Disease Goals

For more than three decades, Healthy People has provided science-based, 10-year national health promotion and disease prevention goals and objectives for improving the health of all Americans. Launched in December 2010 by the Office of Disease Prevention and Health Promotion within HHS, Healthy People 2020 establishes benchmarks, sets targets, and monitors progress over time in order to

1. Encourage collaborations across communities and sectors.
2. Empower individuals toward making informed health decisions.
3. Measure the impact of prevention activities.

The objectives in the Immunization and Infectious Diseases Topic Area focus on increasing immunization rates for people of all ages, which will reduce the incidence of vaccine preventable infectious diseases. The National Vaccine Plan was developed with Healthy People 2020 immunization objectives in mind. The plan reinforces the work of HHS and its partners to achieve the Healthy People 2020 vaccination coverage goals.

Vaccines are among the most cost-effective clinical preventive services and are a core component of any preventive services package. Childhood immunization programs provide a very high return on investment. For example, each birth cohort vaccinated with the routine immunization schedule (this includes DTaP, Td, Hib, polio, MMR, hepatitis B, and varicella vaccines) saves 33,000 lives, prevents 14 million cases of disease, reduces direct health care costs by $9.9 billion, and saves $33.4 billion in indirect costs. Despite the progress made to date, approximately 42,000 adults and 300 children in the United States die each year from vaccine preventable diseases. Communities with pockets of unvaccinated and under vaccinated populations are at increased risk for outbreaks of vaccine preventable diseases.

Healthy People 2020 data show that in 2011 the majority of childhood and toddler vaccination coverage rates are at or are higher than their Healthy People 2020 targets. Our challenge is to maintain these high coverage rates. In addition, more work needs to be done to improve adolescent and adult vaccination coverage rates. The National Vaccine Plan provides a roadmap on how to protect all Americans from vaccine preventable diseases.

Healthy People 2020 Immunization and Infectious Diseases Objective Status

Information provided by the HHS Office of Disease Prevention and Health Promotion, the CDC National Center for Health Statistics, and the CDC National Center for Immunization and Respiratory Disease

Table 4: Vaccine Preventable Diseases

Vaccine-preventable diseases	Target met	Improving	Little or no change	Getting worse	Baseline only	Developmental	Informational
IID-1.1 CRS in children	X						
IID-1.2 Hib in children	X						
IID-1.3 HepB in children					X		
IID-1.4 Measles				X			
IID-1.5 Mumps	X						
IID-1.6 Pertussis in children		X					
IID-1.7 Pertussis in adolescents		X					
IID-1.8 Polio	X						
IID-1.9 Rubella	X						
IID-1.10 Varicella (chicken pox)		X					
IID-2 Group B strep in newborns		X					
IID-3 Meningococcal disease	X						

Vaccine-preventable diseases	Target met	Improving	Little or no change	Getting worse	Baseline only	Developmental	Informational
IID-4.1 Pneumococcal infections in children		X					
IID-4.2 Pneumococcal infections in older adults		X					
IID-4.3 Antibiotic-resistant pneumococcal infections in children		X					
IID-4.4 Antibiotic-resistant pneumococcal infections in older adults		X					

Table 5: Antibiotic Use

Antibiotic	Target met	Improving	Little or no change	Getting worse	Baseline only	Developmental	Informational
IID-5 Antibiotics for ear infections in children					X		
IID-6 Antibiotics for common cold					X		

Table 6: Vaccine coverage in children 19-35 months

Vaccine	Target met	Improving	Little or no change	Getting worse	Baseline only	Developmental	Informational
IID-7.1 DTaP vaccine			X				
IID-7.2 Hib vaccine		X					
IID-7.3 HepB vaccine	X						
IID-7.4 MMR vaccine	X						
IID-7.5 Polio vaccine	X						
IID-7.6 Varicella (chicken pox) vaccine	X						
IID-7.7 Pneumococcal conjugate vaccine		X					
IID-7.8 HepA vaccine		X					
IID-7.9 HepB vaccine, birth dose		X					
IID-7.10 Rotavirus vaccine		X					
IID-8 LHI Complete vaccination		X					
IID-9 Vaccination, zero doses							X

Table 7: Vaccine coverage in kindergartners

Vaccine	Target met	Improving	Little or no change	Getting worse	Baseline only	Developmental	Informational
IID-10.1 DTaP vaccine	X						
IID-10.2 MMR vaccine			X				
IID-10.3 Polio vaccine	X						
IID-10.4 HepB vaccine	X						
IID-10.5 Varicella (chicken pox) vaccine		X					

Table 8: Vaccine coverage in adolescents

Vaccine	Target met	Improving	Little or no change	Getting worse	Baseline only	Developmental	Informational
IID-11.1 Tdap booster	X						
IID-11.2 Varicella (chicken pox) vaccine		X					
IID-11.3 Meningococcal vaccine		X					
IID-11.4 HPV vaccine in girls		X					

Table 9: Flu vaccine coverage

Vaccine	Target met	Improving	Little or no change	Getting worse	Baseline only	Developmental	Informational
IID-12.1 Flu vaccine, children					X		
IID-12.2 Flu vaccine, adults					X		
IID-12.3 Flu vaccine, healthcare personnel					X		
IID-12.4 Flu vaccine, pregnant women						X	

Table 10: Vaccine coverage in adults

Vaccine	Target met	Improving	Little or no change	Getting worse	Baseline only	Developmental	Informational
IID-13.1 Pneumococcal disease vaccine: older adults					X		
IID-13.2 Pneumococcal disease vaccine: high-risk adults					X		
IID-13.3 Pneumococcal disease vaccine: institutionalized adults					X		
IID-14 Zoster (shingles) vaccine					X		
IID-15.1 HepB vaccine: dialysis patients						X	
IID-15.2 HepB vaccine: MSM						X	
IID-15.3 HepB vaccine: health care personnel					X		
IID-15.4 HepB vaccine: injection drug users						X	

Table 11: Immunization Information Systems

Vaccine	Target met	Improving	Little or no change	Getting worse	Baseline only	Developmental	Informational
IID-16 Knowledge on vaccine safety						X	
IID-17.1 Measured vaccine coverage levels: public providers	X						
IID-17.2 Measured vaccine coverage levels: private providers		X					
IID-18 Children with records in immunization information systems		X					
IID-19 States with kindergarten vaccination coverage data		X					
IID-20 States with adolescent vaccination coverage data					X		
IID-21 States with rabies surveillance data			X				
IID-22 States with labs monitoring flu resistance to antiviral agents	X						

Table 12: Viral Hepatitis

Hepatitis	Target met	Improving	Little or no change	Getting worse	Baseline only	Developmental	Informational
IID-23 HepA					X		
IID-24 Chronic perinatal HepB					X		
IID-25.1 HepB, adults					X		
IID-25.2 HepB, injection drug users					X		
IID-25.3 HepB, MSM					X		
IID-26 HepC					X		
IID-27 Aware of HepC infection					X		
IID-28 Tested for HepB in minority communities					X		

Table 13: Tuberculosis

Tuberculosis	Target met	Improving	Little or no change	Getting worse	Baseline only	Developmental	Informational
IID-29 TB cases		X					
IID-30 TB treatment		X					
IID-31 TB treatment, persons with latent TB			X				
IID-32 TB test confirmation timeliness					X		

Web Guide

Stakeholder Websites

Administration for Children and Families (ACF) - http://www.acf.hhs.gov
Agency for Healthcare Research and Quality (AHRQ) - http://www.ahrq.gov
Assistant Secretary for Health (ASH) - http://www.hhs.gov/ash
Assistant Secretary for Preparedness and Response (ASPR) - http://www.phe.gov/about/aspr
Bill and Melinda Gates Foundation - http://www.gatesfoundation.org (exit link disclaimer)
Biomedical Advanced Research and Development Authority (BARDA) - http://www.phe.gov/about/barda
Center for Biologics Evaluation and Research (CBER) - http://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cber
Centers for Disease Control and Prevention (CDC) - http://www.cdc.gov
Centers for Medicare and Medicaid Services (CMS) - http://www.cms.gov
Decade of Vaccines Collaboration - http://www.dovcollaboration.org (exit link disclaimer)
Food and Drug Administration (FDA) - http://www.fda.gov
(The) GAVI Alliance (GAVI) - http://www.gavialliance.org (exit link disclaimer)
Health Resources and Services Administration (HRSA) - http://www.hrsa.gov
Healthy People Initiative - http://www.healthypeople.gov
Indian Health Service (IHS) - http://www.ihs.gov
Institute of Medicine (IOM) - http://www.iom.edu (exit link disclaimer)
Immunization Action Coalition - http://www.immunize.org (exit link disclaimer)
National Center for Immunization and Respiratory Diseases (NCIRD) - http://www.cdc.gov/ncird
National Institute of Allergy and Infectious Diseases (NIAID) - http://www.niaid.nih.gov
National Institutes of Health (NIH) - http://www.nih.gov
National Vaccine Program Office (NVPO) - http://www.hhs.gov/nvpo
NIH Research Portfolio Online Reporting Tools (RePORT) - report.nih.gov
Office of Global Affairs (OGA) - http://www.globalhealth.gov
Office of Global Health Diplomacy - http://www.state.gov/s/ghd
Office of the National Coordinator for Health Information Technology (ONC) - http://www.healthit.gov
United Nations Children's Fund (UNICEF) - http://www.unicef.org (exit link disclaimer)
U.S. Agency for International Development (USAID) - http://www.usaid.gov
U.S. Department of Defense (DoD) - http://www.defense.gov
U.S. Department of Health and Human Services (HHS) - http://www.hhs.gov
U.S. Department of Homeland Security (DHS) - http://www.dhs.gov
U.S. Department of Justice (DoJ) - http://www.justice.gov
U.S. Department of State - http://www.state.gov
U.S. Department of Veterans Affairs - http://www.va.gov
World Health Organization (WHO) - http://www.who.int (exit link disclaimer)

Information and Resources for the Public

http://www.vaccines.gov and espanol.vaccines.gov
Vaccines.gov, available in English and Spanish, is the federal gateway to information on vaccines and immunization for infants, children, teenagers, adults, and seniors. Vaccines.gov provides resources from federal agencies for the general public and their communities about vaccines across the lifespan.

http://www.flu.gov
Flu.gov provides one-stop access to U.S. government seasonal, H1N1 (swine), H5N1 (bird), H3N2, and pandemic flu information for the general public, health professionals, policy makers, and community leaders.

http://www.cdc.gov/vaccines
This website includes vaccine and immunization information from CDC. Individuals can also contact CDC with questions about vaccines and immunizations at 1-800-CDC-INFO (1-800-232-4636).

http://www.fda.gov/BiologicsBloodVaccines.default.htm
This website provides information about how the FDA evaluates the safety and effectiveness of vaccines before they are licensed (approved) for use in the United States, monitors safety and quality after licensure, and uses available tools to report adverse events following vaccination. The website also includes information on FDA-approved labeling for vaccines.

http://www.niaid.nih.gov/topics/vaccines
This website provides information about NIAID's role in vaccine research and highlights particular research projects.

http://www.vaccineinformation.org (exit link disclaimer)
The Immunization Action Coalition provides a wide variety of educational resources for health professionals and the public on vaccines and the diseases they prevent.

http://vaccine.healthmap.org (exit link disclaimer)
The HealthMap Vaccine Finder is a free, online service where users can search for locations that offer vaccines, including pharmacies, health clinics, and health departments.

http://vaers.hhs.gov
VAERS is a national vaccine safety surveillance program that collects information about adverse events that occur after the administration of vaccines. Individuals can report a reaction following vaccination to VAERS online, by fax, or by mail. More information on how to report adverse events following vaccination can be found on the VAERS website.

http://www.hrsa.gov/vaccinecompensation
The Vaccine Injury Compensation Program provides a way to resolve vaccine injury claims and compensate those found injured as a result of vaccines. This site provides information about how to file a claim, a review of adverse events related to vaccines, and answers to frequently asked questions.

http://www.healthit.gov/patients-families
Learn about how health information technology, such as electronic health records, can improve health care for you, your family, and your community.

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U. S. Court of Federal Claims

717 Madison Place, NW
Washington, DC 20439
202-357-6400

Brian H. Corcoran

Brian H. Corcoran was appointed as a Special Master of the United States Court of Federal Claims on January 13, 2014. He graduated cum laude, with high honors in his major, from Dartmouth College in 1988. He received his J.D. in 1991 from the University of Virginia School of Law.

Mr. Corcoran is a seasoned trial attorney with experience in a wide variety of legal matters, including intellectual property, general commercial disputes, tax matters, and pro bono civil rights and employment discrimination actions. Until 2008, he was employed in the private sector, rising to the level of partner in the Washington, D.C. office of Katten Muchin Rosenman LLP. From 2008 to 2014, Mr. Corcoran worked for the Department of Justice, Tax Division, as a trial attorney, where he obtained numerous permanent injunctions against fraudulent tax preparers and the promoters of illegal tax schemes across the United States.

Mr. Corcoran is admitted to the bars of New York and the District of Columbia, as well as numerous federal district courts.

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Herzog, Andrea (HRSA)

From: Jean Public <jeanpublic1@yahoo.com>
Sent: Tuesday, February 18, 2014 12:03 PM
To: Herzog, Andrea (HRSA); americanvoices@mail.house.gov; president@whitehouse.gov
Subject: Fw:pulic comment on federarl register drug pushers for kids to be vaccinated too many times

this agency is nothing but a drug pusher to make alot o fmoney vaccinating kids. they inflate the few who die from vaccines because most of them have other health issues so it is not really a flu death. they allow flu vaccine mfrs to produce poisonous vaccines that are not adequately monitored for safety. its been yearrs that the public has asked where are the eggs coming from since we just had a million recalled because they are fullof salmonella. the chickens where are those healthy chickens? raised in the horror that is chicken raising in america today? and what dogs are you takign cells from to make flu vaccine? why should dogs suffer for a vaccine that is only 50% effective? you never match up the flu issues with the vaccines. YET BIG PHARMA ROLLS MERRILY ON FAKING THE US PUBLIC WITH THE EFFICACY OF THIS DRUG. YOU ARE ALL DRUG PUSHERS. I AM SORRY I CANT GET TO WASHINGTON TO TELL YOU. BUT THIS COMEMNT IS FOR THE PUBLIC RECORD FOR THE MEETNIG. PLEASE RECEIPT. JEAN PUBLIC

On Tuesday, February 18, 2014 6:05 AM, jean public <jeanpublic1@gmail.com> wrote:

[Federal Register Volume 79, Number 32 (Tuesday, February 18, 2014)]
[Notices]
[Pages 9235-9236]
From the Federal Register Online via the Government Printing Office [www.gpo.gov]
[FR Doc No: 2014-03441]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Commission on Childhood Vaccines; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act

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(Public Law 92-463), notice is hereby given of the following meeting:
Name: Advisory Commission on Childhood Vaccines (ACCV).
Date and Time: March 6, 2014, 1:00 p.m. to 4:15 p.m. EDT; March 7, 2014, 9:00 a.m. to 12:00 p.m. EDT.
Place: Parklawn Building (and via audio conference call and Adobe Connect), Conference Room 10-65, 5600 Fishers Lane, Rockville, MD 20857.
The ACCV will meet on Thursday, March 6, 2014, 1:00 p.m. to 4:15 p.m. EDT and Friday, March 7, 2014, 9:00 a.m. to 12:00 p.m. EDT. The public can join the meeting by:
1. (In Person) Persons interested in attending the meeting [in person] are encouraged to submit a written notification to: Annie Herzog, DVIC, Healthcare Systems Bureau (HSB), Health Resources and Services Administration (HRSA), Room 11C-26, 5600 Fishers Lane, Rockville, Maryland 20857 or email: aherzog@hrsa.gov. Since this

meeting is held in a federal government building, attendees will need to go through a security check to enter the building and participate in the meeting. This written notification is encouraged so that a list of attendees can be provided to expedite entry through security. Persons may attend in person without providing written notification, but their entry into the building may be delayed due to security checks and the requirement to be escorted to the meeting by a federal government employee. To request an escort to the meeting after entering the building, call Mario Lombre at (301) 443-3196. The meeting will be held at the Parklawn Building, Conference Room 10-65, 5600 Fishers Lane, Rockville, MD 20857.

2. (Audio Portion) Calling the conference phone number, 877-917-4913, and providing the following information:

Leaders Name: Dr. Vito Caserta
Password: ACCV

3. (Visual Portion) Connecting to the ACCV Adobe Connect Pro Meeting using the following URL: https://hrsa.connectsolutions.com/accv/ (copy and paste the link into your browser if it does not work directly, and enter as a guest). Participants should call and connect 15 minutes prior to the meeting in order for logistics to be set up. If you have never attended an Adobe Connect meeting, please test your connection using the following URL: https://hrsa.connectsolutions.com/common/help/en/support/meeting_test.htm and get a quick overview by following URL: http://www.adobe.com/go/connectpro_overview. Call (301) 443-6634 or send an email to aherzog@hrsa.gov if you are having trouble connecting to the meeting site.

Agenda: The agenda items for the March meeting will include, but are not limited to: (1) Updates from the Division of Vaccine Injury Compensation (DVIC), Department of Justice, National Vaccine Program Office, Immunization Safety Office (Centers for Disease Control and Prevention), National Institute of Allergy and Infectious Diseases (National Institutes of Health) and Center for Biologics, and Evaluation and Research (Food and Drug Administration); (2) Report from the ACCV Process Workgroup; (3) Review of Vaccine Information Statements; and (4) Presentation on Pneumococcal Polysaccharide (Pneumovax 23) Vaccine Safety Review. A draft agenda and additional meeting materials will be posted on the ACCV Web site (http://www.hrsa.gov/vaccinecompensation/accv.htm) prior to the meeting. Agenda items are subject to change as priorities dictate.

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

FOR FURTHER INFORMATION CONTACT: Anyone requiring information regarding the ACCV should contact Annie Herzog, DVIC, HSB, HRSA, Room 11C-26, 5600 Fishers Lane, Rockville, MD 20857; telephone (301) 443-6634 or

email: aherzog@hrsa.gov.

Dated: February 11, 2014.
Jackie Painter,
Deputy Director, Division of Policy and Information Coordination.
[FR Doc. 2014-03441 Filed 2-14-14; 8:45 am]
BILLING CODE 4165-15-P