

The State of the  
**National Vaccine Plan**

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**2013 Annual Report**



**U.S. Department of Health & Human Services**

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***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.<sup>1</sup> 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.<sup>2,3</sup>

The initial National Vaccine Plan was created in 1994<sup>4</sup> 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<sup>5</sup> 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.

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

<sup>2</sup> 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>

<sup>3</sup> 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)

<sup>4</sup> 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/](http://archive.hhs.gov/nvpo/vacc_plan/1994plan/)

<sup>5</sup> 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](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,<sup>6</sup> 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<sup>7</sup> 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,<sup>8</sup> which highlights the importance of

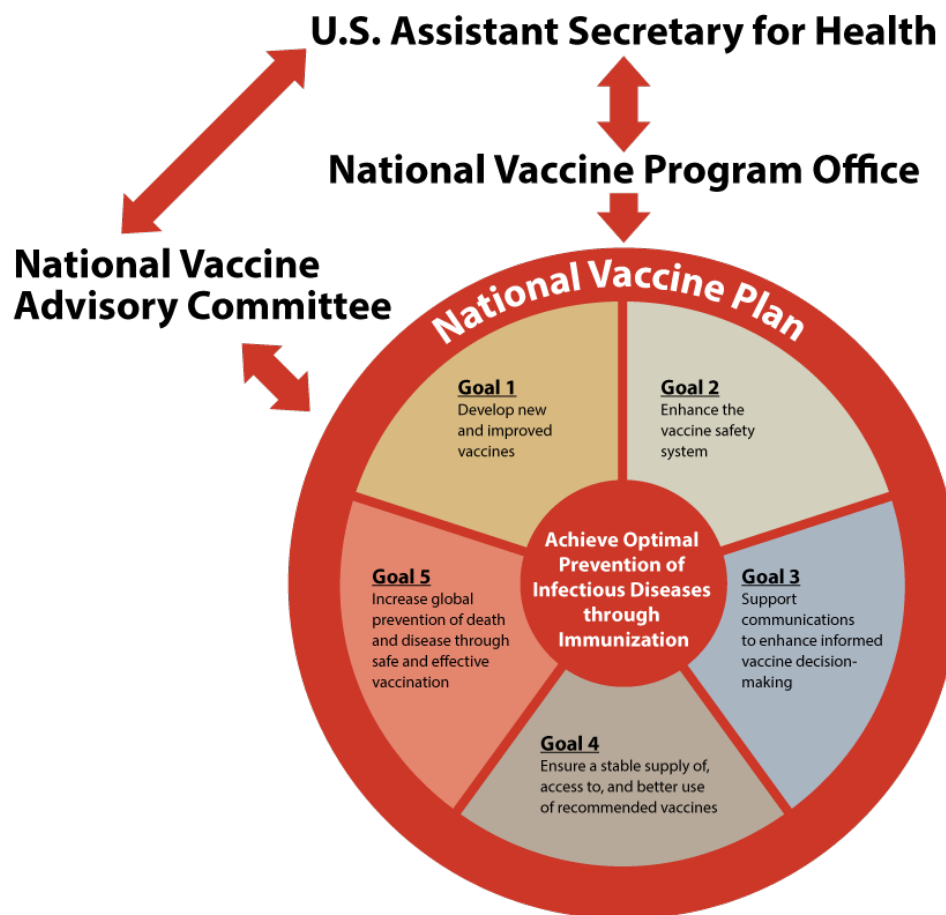
<sup>6</sup> Public Health Service Act, 42 U.S.C. § 300aa1. Retrieved from <http://www.hhs.gov/nvpo/about/legislation.pdf>

<sup>7</sup> Healthy People 2020. (2013). *Immunization and infectious diseases topic area*. Retrieved from <http://www.healthypeople.gov/2020/topicsobjectives2020/overview.aspx?topicId=23>

<sup>8</sup> 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,<sup>9</sup> the HHS Action Plan to Reduce Racial and Ethnic Disparities,<sup>10</sup> the National Health Security Strategy of the United States of America,<sup>11</sup> and a number of other strategic initiatives that promote a culture of prevention.

**Figure 1: Organizational Structure of the National Vaccine Plan**



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

<sup>10</sup> 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](http://minorityhealth.hhs.gov/npa/files/Plans/HHS/HHS_Plan_complete.pdf)

<sup>11</sup> 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  
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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.<sup>12</sup> 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,<sup>13</sup> 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.

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<sup>12</sup> 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>

<sup>13</sup> 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
<p><b>1. Develop new and improved vaccines.</b></p>	<ul style="list-style-type: none"> <li>• A new framework and open-source software for determining vaccine development priorities.</li> <li>• A new generation of influenza vaccines.</li> <li>• Advances in scientific understanding of diseases and vaccine responses, especially for pertussis, pneumococcal disease, dengue and hepatitis C.</li> <li>• New vaccine production techniques and technologies.</li> <li>• Licensure of the first cell- and recombinant-based influenza vaccines in the United States to improve response time and capacity for influenza pandemics.</li> </ul>	<ul style="list-style-type: none"> <li>• Research on currently licensed, safe, and effective vaccines that further informs their use.</li> <li>• Research contributing to the development of new vaccines and improvement of existing vaccines, particularly for diseases like human immunodeficiency virus (HIV) and influenza.</li> <li>• 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).</li> </ul>
<p><b>2. Enhance the vaccine safety system.</b></p>	<ul style="list-style-type: none"> <li>• Vaccines and Medications in Pregnancy Surveillance System established with HHS support, which helps monitor the safety of vaccines and medications administered during pregnancy.</li> <li>• The Food and Drug Administration’s Post-licensure Rapid Immunization Safety Monitoring covered &gt;100 million patients.</li> <li>• Continued support of the Centers for Disease Control and Prevention’s Vaccine Safety Datalink.</li> <li>• The Indian Health Service’s Influenza Awareness System, which helps monitor influenza vaccine safety, was created.</li> <li>• IOM reviews that focus on key vaccine safety concerns, including the safety of the childhood immunization schedule.</li> <li>• Advances in using electronic health data to monitor vaccine safety.</li> </ul>	<ul style="list-style-type: none"> <li>• Continued use of safety monitoring systems to monitor and assess vaccine safety, and identification of potential vaccine side effects or rare adverse reactions.</li> <li>• Continued identification and assessment of whether rare health outcomes have any association or link to vaccines or vaccination.</li> <li>• Continued development of more precise vaccine safety risk estimates and assessments.</li> <li>• Extension of efforts to monitor, assess, and identify vaccine safety issues in specific populations (e.g., pregnant women).</li> <li>• Continued investment in laboratory and other research methods that can foster vaccine safety assessments.</li> </ul>

Goal	Key accomplishments	The coming years
<p><b>3. Support communications to enhance informed vaccine decision-making.</b></p>	<ul style="list-style-type: none"> <li>• Research on adults’ knowledge, attitudes and beliefs with respect to recommended adult immunizations.</li> <li>• Establishment of Vaccines.gov website in English and Spanish.</li> <li>• Research and efforts to foster human papillomavirus (HPV) vaccination among adolescents, including the National Institutes of Health’s Go Healthy Girls web-based intervention.</li> <li>• Materials developed by the Food and Drug Administration for consumers and health care providers, including “Vaccines for Children: A Guide for Parents and Caregivers.”</li> <li>• The National Vaccine Program Office’s support of communication materials to promote adult immunization.</li> <li>• Collaboration with the new Adult Immunization Task Force, and National Adult and Influenza Immunization Summit.</li> </ul>	<ul style="list-style-type: none"> <li>• 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.</li> <li>• Continued publicity of the Vaccines.gov website so it becomes a widely used resource and tool for vaccine decision-making.</li> <li>• 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.</li> </ul>

Goal	Key accomplishments	The coming years
<p><b>4. Ensure a stable supply of, access to, and better use of recommended vaccines in the United States.</b></p>	<ul style="list-style-type: none"> <li>• 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.</li> <li>• 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.</li> <li>• Partnerships with nongovernment organizations to make influenza vaccination more financially accessible.</li> <li>• Accurate tracking of vaccine preventable diseases and disease rates, including supporting specialized systems (e.g., those for pertussis tracking).</li> <li>• New mapping tool to track influenza vaccination claims rates by Medicare beneficiaries.</li> <li>• Identification of health care system and provider barriers and facilitators of immunization.</li> <li>• Expansion of access to vaccines via partnerships with pharmacists and other immunization providers.</li> <li>• Broadening of access to vaccines without cost-sharing through the Affordable Care Act.</li> <li>• Working to foster use of health information technology for vaccine and immunization tracking.</li> </ul>	<ul style="list-style-type: none"> <li>• 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.</li> <li>• 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.</li> <li>• Identification and encouragement of expansion and adoption of “best practices” in childhood, adolescent, and adult immunization.</li> <li>• 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.</li> <li>• 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.</li> </ul>

Goal	Key accomplishments	The coming years
<p><b>5. Increase global prevention of death and disease through safe and effective vaccination.</b></p>	<ul style="list-style-type: none"> <li>• A strengthened commitment to global polio eradication.</li> <li>• 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.</li> <li>• Development and use of new vaccines tailored for global populations, such as MenAfriVac.</li> <li>• Greater and more widespread use of influenza vaccines, and development of influenza manufacturing capacity.</li> <li>• 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.</li> <li>• 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.</li> </ul>	<ul style="list-style-type: none"> <li>• Eradication of polio and successful implementation of the polio endgame strategy (i.e., a worldwide transition from oral polio vaccines to inactivated polio vaccines).</li> <li>• Continued efforts to use MenAfriVac to prevent meningitis in Africa and other regions of the world.</li> <li>• Continued efforts to expand global access to pneumococcal conjugate, rotavirus, influenza, HPV, hepatitis and other new and underutilized life-saving vaccines.</li> <li>• Collaborations that foster public and health care provider understanding of vaccines and immunization globally, including vaccine benefits and risks.</li> <li>• Continued collaboration between HHS and international organizations to expand pandemic influenza vaccine manufacturing capacity in developing countries.</li> </ul>



## Success through Collaboration: The National Vaccine Plan

By Bruce Gellin, MD, MPH  
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“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 <sup>^</sup>	HHS-AHRQ <sup>^</sup>	HHS-ASPR (BARDA) <sup>^</sup>	HHS-CDC <sup>^</sup>	HHS-CMS <sup>^</sup>	HHS-FDA <sup>^</sup>	HHS-HRSA <sup>^</sup>	HHS-IHS <sup>^</sup>	HHS-NIH <sup>^</sup>	HHS-NVPO <sup>^</sup>	HHS-ONC <sup>^</sup>	DHS <sup>^</sup>	DoD <sup>^</sup>	DoJ <sup>^</sup>	Dept. of State <sup>^</sup>	USAID <sup>^</sup>	VA <sup>^</sup>	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	
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

<sup>^</sup>=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.<sup>14</sup> 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

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<sup>14</sup> 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.

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.<sup>15</sup> 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.

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

## 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.<sup>16</sup> This work was funded by both FDA and NIH.

<sup>15</sup> 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>

<sup>16</sup> Warfel, J. M., Beren, J., & Merkel, T. J. (2012). Airborne transmission of *Bordetella 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.<sup>17</sup> 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>

<sup>17</sup> 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.<sup>18</sup> 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.<sup>19</sup> 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.<sup>20</sup> 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.<sup>21</sup> 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

<sup>18</sup> 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>

<sup>19</sup> 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>

<sup>20</sup> 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>

<sup>21</sup> 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.<sup>22</sup>

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>. [\(exit link disclaimer\)](#)

<sup>22</sup> 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](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

National Institute of Allergy and Infectious Diseases, NIH

U.S. Department of Health and Human Services

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 21<sup>st</sup> century.

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

By Marie-Paule Kieny, MD  
Assistant Director-General, Health Systems and Innovation  
World Health Organization

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” compartments (“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  
President, Global Health Program  
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.<sup>23</sup> 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,

<sup>23</sup> 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.<sup>24</sup>

### **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

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<sup>24</sup> 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.<sup>25</sup> 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.

The IOM report on the safety of the childhood immunization schedule,<sup>26</sup> 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

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

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/m6230a3.htm?s\\_cid=mm6230a3\\_w](http://www.cdc.gov/mmwr/preview/mmwrhtml/m6230a3.htm?s_cid=mm6230a3_w)

<sup>25</sup> 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 managed care organizations across the United States. *JAMA Pediatrics*, 167(3), 274–281. Retrieved from <http://www.ncbi.nlm.nih.gov/pubmed/23338829>

<sup>26</sup> 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.<sup>27</sup>

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.

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<sup>27</sup> 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.<sup>28</sup>

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.

<sup>28</sup> 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

By Marie C. McCormick, MD, ScD

Sumner and Esther Feldberg Professor of Maternal and Child Health, Department of Social and Behavioral Sciences, Harvard School of Public Health

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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.<sup>29</sup> 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.<sup>30</sup> 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,<sup>31</sup> 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.<sup>32</sup>

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

<sup>29</sup> 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>

<sup>30</sup> 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>

<sup>31</sup> 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>

<sup>32</sup> 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.<sup>33</sup>

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.

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<sup>33</sup> 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.<sup>34</sup> 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

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<sup>34</sup> 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.<sup>35</sup> 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.

<sup>35</sup> 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.<sup>36</sup>

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.<sup>37</sup> 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.<sup>38</sup>

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.<sup>39</sup>

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

<sup>36</sup> Indian Health Service. (2012). *Ramona's story* [Video]. Retrieved from <http://www.ihs.gov/forpatients/healthtopics/WhoopingCough/>

<sup>37</sup> U.S. Food and Drug Administration. (2013). *Vaccines for children – A guide for parents and caregivers*. Retrieved from <http://www.fda.gov/BiologicsBloodVaccines/ResourcesforYou/Consumers/ucm345587.htm>

<sup>38</sup> U.S. Food and Drug Administration. (2013). *The evolution, and revolution, of influenza vaccines*. Retrieved from <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm336267.htm>

<sup>39</sup> 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.

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.<sup>40</sup> The NAIIS meets annually, meeting for the first

**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>

<sup>40</sup> 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.<sup>41</sup> 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

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<sup>41</sup>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](http://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](http://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](http://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

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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.

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.

**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>

## 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.<sup>42</sup> 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.

<sup>42</sup> 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.<sup>43</sup> 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.<sup>44</sup> 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,

<sup>43</sup> 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/>

<sup>44</sup> 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

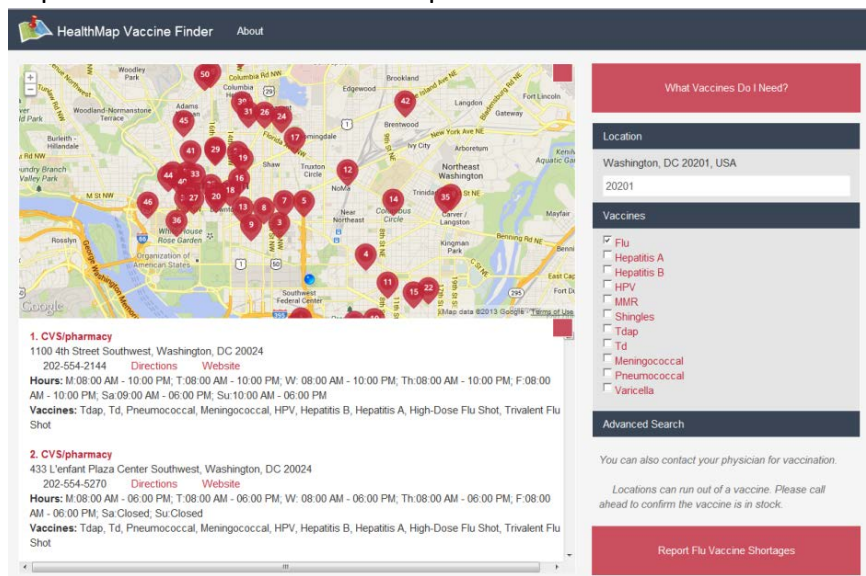
It is important to get an influenza vaccine every year. While awareness of seasonal influenza vaccination is high, there is low awareness that adults need more than a yearly influenza vaccination. Starting in January 2013, finding locations offering adult vaccines became easier through the HealthMap Vaccine Finder ([vaccine.healthmap.org](http://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., Piliushvili, 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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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**

David Blythe, MD, MPH, Maryland Department of Health and Mental Hygiene

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.<sup>45</sup> 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.<sup>46</sup> 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.

<sup>45</sup> 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/>

<sup>46</sup> 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.<sup>47</sup> 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

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<sup>47</sup> 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

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Vaccines are at the very top of public health's greatest success stories, averting millions of deaths annually.<sup>48</sup> 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<sup>49</sup> and hepatitis B,<sup>50</sup> 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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<sup>48</sup> World Health Organization. (2013). *Immunization coverage fact sheet*. Retrieved from <http://www.who.int/mediacentre/factsheets/fs378/en/index.html> (exit link disclaimer)

<sup>49</sup> World Health Organization. (2010). *Human papillomavirus (HPV)*. Retrieved from <http://www.who.int/immunization/topics/hpv/en/> (exit link disclaimer)

<sup>50</sup> 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,<sup>51</sup> 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

<sup>51</sup> 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](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	<p>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.</p>	<p>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 publicly through the NIH RePORT database by querying "Vaccine Related" <a href="http://report.nih.gov/categorical_spending.aspx">http://report.nih.gov/categorical_spending.aspx</a></p>	<p>Ongoing through the end of 2015</p>
ASPR	<p>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.</p>	<p>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.</p>	<p>Ongoing through 2015</p>

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 <a href="http://www.fda.gov/BiologicsBloodVaccines/ScienceResearch/ucm234680.htm">http://www.fda.gov/BiologicsBloodVaccines/ScienceResearch/ucm234680.htm</a> and <a href="http://www.fda.gov/BiologicsBloodVaccines/ScienceResearch/default.htm">http://www.fda.gov/BiologicsBloodVaccines/ScienceResearch/default.htm</a> , 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 recompleted 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. <a href="#">See NIH press release.</a>	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 <a href="http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Post-MarketActivities/ucm276981.htm">http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Post-MarketActivities/ucm276981.htm</a> , <a href="http://www.fda.gov/BiologicsBloodVaccines/ScienceResearch/ucm234680.htm">http://www.fda.gov/BiologicsBloodVaccines/ScienceResearch/ucm234680.htm</a> , and <a href="http://www.fda.gov/BiologicsBloodVaccines/ScienceResearch/default.htm">http://www.fda.gov/BiologicsBloodVaccines/ScienceResearch/default.htm</a> , 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 restructuring 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.	<p>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.</p> <p>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.</p>	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.	<i>No update</i>	

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
HRSA	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.	<p>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.</p> <p>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.</p>	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	13. 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	<p>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.</p>	<p>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</p>	<p>Ongoing through 2015</p>

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 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.<sup>52</sup>) 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

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<sup>52</sup> 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<sup>53</sup>:

- 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.<sup>54</sup> The nation experienced a marked increase in measles cases during this time, resulting in tens of thousands of cases of

<sup>53</sup> Public Health Service Act, 42 U.S.C. § 300aa1. Retrieved from <http://www.hhs.gov/nvpo/about/legislation.pdf>

<sup>54</sup> 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*.<sup>55</sup> 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.<sup>56</sup>

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

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<sup>55</sup> 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>

<sup>56</sup> 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,<sup>57</sup> 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

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<sup>57</sup> 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.<sup>58</sup> 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.<sup>59</sup> 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.

<sup>58</sup> 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>

<sup>59</sup> 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.<sup>60</sup> 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

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<sup>60</sup> 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](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.<sup>61</sup>

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.<sup>62</sup> 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.<sup>63</sup> 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

<sup>61</sup> 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](http://www.hhs.gov/nvpo/nvac/nvac_vswp.pdf)

<sup>62</sup> 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](http://www.hhs.gov/nvpo/nvac/reports/vsrawg_report_january_2012.pdf)

<sup>63</sup> 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,<sup>64</sup>

- 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.<sup>65</sup>

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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<sup>64</sup> 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)

<sup>65</sup> 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](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](http://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.