

The Global Immunization Working Group

of the National Vaccine Advisory Committee

Update on Working Group Progress
NVAC Meeting
6 February 2013

GIWG Co-Chairs
Phil LaRussa, MD
Amy Pisani, MS



Charge

Purpose:

- To review US government global vaccination efforts to ensure that HHS is on track to fulfill responsibilities and meet the goals and objectives outlined in Goal 5 of the National Vaccine Plan and the HHS Global Health Strategy
 - Increase global prevention of death and disease through safe and effective vaccination

Charge:

- To review the role of HHS in global vaccination, the effects of global vaccination on global populations, the effects of global vaccination on US populations
- To recommend how HHS can best continue to contribute, consistent with its newly established Global Health Strategy and Goal 5 of the National Vaccine Plan
- To recommend how to best communicate this information to decision makers and the general public to ensure continued sufficient resources for the global vaccination effort

Adopted:

- NVAC adopted this resolution at the February 2012 meeting
- The Global Immunization Working Group was formed in April 2012 to address charge

Membership

NVAC Members

Walt Orenstein- NVAC chair
Phil LaRussa – GIWG co-chair
Amy Pisani – GIWG co-chair
Charles Mouton
Thomas Stenvig
Clem Lewin
Seth Hetherington
Jim Mason

Federal Ex Officio Members

Steve Cochi – CDC
Theresa Fin – FDA
Cyril Gay – USDA/ARS
Marion Gruber - FDA
Rick Hill – USDA/APHIS
Jeff Kelman- CMS
Philip Krause - FDA
Iris Mabry-Hernandez- AHRQ
Richard Martinello- VA
Justin Mills- HRSA
Barbara Mulach- NIH
Jane Seward- CDC
Angela Shen - USAID
Diana Parzik- DoD
Holly Wong - OGA

Liaison Representatives

Alan Hinman – Task Force for Global Health
Steve Landry – Bill and Melinda Gates Foundation
Nina Schwalbe- GAVI Alliance
Andrea Gay – United Nations Foundation
Bonnie Maldonado – American Academy of Pediatrics
*Peter Strebel – WHO, Dept. of Immunization, Vaccines, and
Biologicals*
Armin Fidler – World Bank, Health, Policy, and Strategy
Maritel Costales – UNICEF, Immunization Team
*Akira Homma – Developing Countries Vaccine
Manufacturers Network*
*Mahima Datla – Developing Countries Vaccine
Manufacturers Network*

NVPO

Mark Grabowsky – Designated Federal Official
Jennifer Gordon
Claire Slesinski

Special Assistants

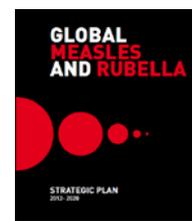
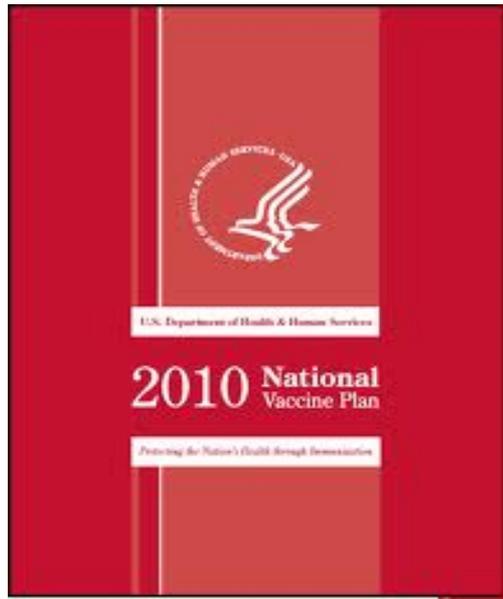
Katy Seib – Special Assistant to the NVAC chair

Updates Since Last NVAC Meeting

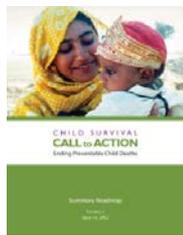
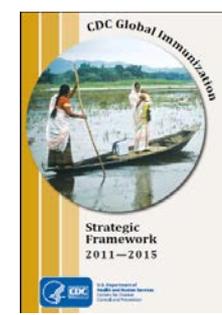
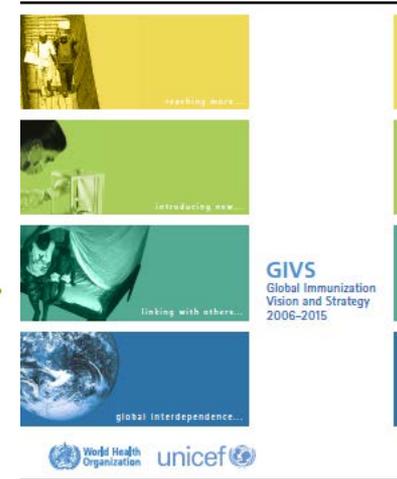
Since the September NVAC, the WG has:

- Identified key areas of focus for recommendations and the report.
- Continued drafting recommendations, grouped by key areas of focus, and worked to refine them.
- Draft report is in progress, and working group members have been asked to comment on the outline of the report.

GIWG Recommendations will strengthen HHS contributions towards national and international goals and objectives



DECADE of VACCINES COLLABORATION



Areas of Focus

Focus 1: Tackling time-limited opportunities to complete polio eradication and to advance measles mortality reduction and regional measles/rubella elimination goals

Focus 2: Strengthening Global Immunization Systems

Focus 3: Introduction of new and underutilized vaccines

Focus 4: Building global immunization research and development capacity

Focus 5: Implementation of the Global Immunization Working Group's recommendations

Focus 1: Tackling time-limited opportunities to complete polio eradication and to advance measles mortality reduction and regional measles/rubella elimination goals

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- 1.1 The Assistant Secretary for Health (ASH) should communicate to key audiences (including Capitol Hill and the general public) the urgency of completing global goals for polio eradication and advancing global measles mortality reduction goals and regional goals for measles/rubella elimination. The ASH should engage these key audiences via briefings, receptions, and other educational activities.
 - 1.1.1 The ASH should emphasize that polio eradication efforts and measles mortality reduction and regional elimination efforts should complement and strengthen routine immunization systems.
 - 1.1.2 The ASH should emphasize that failure to complete polio eradication goals or to advance goals for measles mortality reduction and regional goals for measles/rubella elimination may threaten the health of US populations due to importations of these diseases from endemic areas.
 - 1.1.3 The ASH should emphasize that political and public support is fundamental to achieving polio eradication and advancing global goals for measles mortality reduction and regional goals for measles/rubella elimination. Achieving these goals would equal a monumental public health and humanitarian accomplishment for the entire global community and if done appropriately, will potentially strengthen support for routine immunization goals.

Focus 1: Tackling time-limited opportunities to complete polio eradication and to advance measles mortality reduction and regional measles/rubella elimination goals

1.2 The ASH should strongly encourage the HHS Secretary to seek additional funding to ensure achieving the unique time-limited opportunities to complete global goals for polio eradication and to support measles mortality reduction and regional goals for measles/rubella elimination. The ASH should advocate to the HHS Secretary that completion of these goals will yield significant economic and public health returns on investments and shed new light on the value of vaccines and immunization. Conversely, failure to reduce and/or eliminate these threats will require substantial ongoing financial and public health resources.

Focus 1: Tackling time-limited opportunities to complete polio eradication and to advance measles mortality reduction and regional measles/rubella elimination goals

- 1.3 The ASH should encourage the Centers for Disease Control and Prevention (CDC) to continue to enhance the public health impact of its Stop Transmission of Polio (STOP) Program by increasing the number and length of training opportunities. STOP Team assignments should focus on building broad subject matter expertise that can be applied to polio and measles efforts, as well as to strengthen routine immunization systems and disease surveillance.
- 1.4 The ASH should work with the CDC to create opportunities to bring together stakeholders and leadership from the Global Polio Eradication Initiative (GPEI) and the Measles Rubella Initiative (MRI) to discuss 1) lessons learned and best practices and 2) consider opportunities for joint programming that lead to program efficiencies and improve the delivery of vaccines using routine systems. As a leading partner in both these initiatives, CDC should work to capture and review these findings so as to inform current programming, the introduction of new vaccines, and other global public health efforts.

Focus 2: Strengthening Global Immunization Systems

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- 2.1 The ASH should support on-going policy revisions to facilitate long-term assignment of HHS professional staff to international multilateral organizations, on bilateral assignments to support country Ministries of Health, public-private global health partnerships, and other US federal agencies/departments.

- 2.2 The ASH should work with CDC and USAID to increase core support to the CDC's Field Epidemiology and Laboratory Training Program (FELTP) as a key tool to transferring epidemiologic and laboratory capacities for strengthening programs. This support should specifically be used to incorporate immunization topics into FELTP training.

Focus 2: Strengthening Global Immunization Systems

2.3 The ASH should work with the Office of Global Affairs and CDC to assist national governments, development agencies (including USAID), multilateral organizations (including WHO and UNICEF), and civil society in encouraging the use of immunization contacts (both through routine systems as well as campaign activities) as a platform for delivering additional health services and vice versa. Evaluations of these efforts should include the types of interventions, the cost benefits of combining new interventions with global immunization efforts, and the effect these strategies have on building community demand for health services overall.

Focus 2: Strengthening Global Immunization Systems

2.4 The ASH should endorse HHS coordination with other USG agencies to support efforts that provide routine overseas administration and documentation of vaccinations for all US-bound refugees with vaccines that have been identified for pre-departure administration.

Focus 2: Strengthening Global Immunization Systems

- 2.5 The ASH should advocate for HHS efforts that support USAID, GAVI, and multilateral organizations such as WHO and UNICEF in the development of “best practices” and technologies to support countries in their efforts to more accurately track immunization coverage at the national and sub-national levels and improve data quality.
- 2.6 The ASH should support the work of HHS within the international community to define standards for measuring the impact of routine delivery strategies such as the Reaching Every District (RED) strategy. These metrics can be used for the evaluation of how well these strategies perform in fully vaccinating children with routine immunizations.

Focus 2: Strengthening Global Immunization Systems

2.7 The ASH should work with other HHS offices to develop sustainable support for quality global vaccine preventable disease (VPD) surveillance systems, including the existing global and regional VPD laboratory surveillance networks. This support* ideally should include technical and financial resources needed to support early warning/outbreak surveillance; laboratory diagnostics; emergency communication systems to detect and respond to outbreaks of vaccine-preventable diseases (VPDs); surveillance requirements for the eradication of targeted VPDs, including case-based polio, measles and rubella surveillance; and laboratory networks to support the introduction and monitor the impact of new and underutilized vaccines against diseases such as influenza*, rotavirus, pneumococcal, meningococcal and other invasive bacterial diseases, and HPV.

Focus 2: Strengthening Global Immunization Systems

- 2.8 The ASH should support efforts to strengthen national regulatory authorities in other countries through collaborations with the FDA. The ASH should also support on-going FDA efforts with other National Regulatory Authorities and the WHO to continue seeking opportunities to inform, shape, and communicate global regulatory standards and requirements for the development and manufacturing of safe and effective vaccines. In doing so, HHS will continue to strengthen international programs including building and strengthening global regulatory capacity and quality systems.
- 2.9 The ASH should identify mechanisms to encourage ongoing collaborations and technical support between HHS agencies involved in post-licensure vaccine safety and related global agencies and partners to 1) to enhance capacities to build vaccine safety surveillance systems to monitor the safety of vaccines as they are broadly administered; 2) to assess and respond to vaccine safety concerns or signals, effectively communicate vaccine risks; and 3) to support the political will to respond to vaccine safety concerns with evidence based decisions.

Focus 3: Introduction of new and underutilized vaccines

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- 3.1 The ASH should continue to support the development of an evidence base to support informed country-level decisions regarding the development, introduction, and monitoring of new vaccines based on evaluation of disease incidence and prevalence, financial sustainability, safety, cost-benefits, and programmatic considerations.
- 3.2 The ASH should work with HHS offices and non-HHS partners to increase investments in national evidence-based decision making by National Immunization Technical Advisory Groups (NITAGs) (similar to the US Advisory Committee on Immunization Practices). Support should include technical assistance and provisions to develop and train these national immunization technical advisory bodies.
- 3.3 The ASH should encourage HHS leadership to identify ways to coordinate with and support efforts towards developing sustainable country-owned vaccine financing and procurement mechanisms to maintain adequate global supplies of safe, high quality vaccines, including new vaccines.

Focus 4: Building global immunization research and development capacity

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4.1 The ASH should support efforts that increase global health research capacity through partnerships between health research institutions in the U.S. and abroad. These partnerships create opportunities to train the next generation of U.S. and foreign scientists to better address current and future global health needs, including the development and evaluation of new vaccines, new vaccine delivery systems or immunization schedules, and new technologies that facilitate global immunization efforts.

Focus 4: Building global immunization research and development capacity

4.2 The ASH should support the FDA in their efforts to develop training modules and workshops for vaccine manufacturers in developing countries on best practices and approaches for clinical trials research and GMP guidelines.

Working group to discuss further

4.3 The ASH should encourage NIH and FDA to work closely with the WHO, end-users (including national immunization program managers, Ministries of Health, NITAGs), and vaccine manufacturers to support WHO in their efforts to define vaccine target product profiles. The ASH should support NIH and FDA ongoing efforts to communicate strategies for minimizing barriers to the progression of products through the clinical trial phases, ensuring candidate vaccines advance more quickly through the development pipeline.

**Focus 5: Implementation of the Global Immunization
Working Group's recommendations**

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5.1 As the director of the National Vaccine Program, the ASH should work with the HHS Secretary, the HHS Office of Global Affairs, and HHS Operating Divisions to define a process to strengthen coordination of HHS-led global immunization efforts. Enhanced coordination would ensure alignment of priorities, minimize duplication in global immunization efforts, support tracking progress in a consistent and transparent manner, and facilitate discussing and addressing challenges and barriers on an ongoing basis.

5.1.1 As part of these efforts, HHS should consider convening an HHS cross-departmental working group to create an HHS Global Immunizations Implementation Plan that includes: measurable outcomes defined by the HHS agencies, how the agencies will track progress towards these outcomes, and potential barriers to achieving the NVAC recommendations and other objectives described in Goal 5 of the National Vaccine Plan.

5.1.2 An HHS cross-departmental working group should also determine a mechanism to enhance HHS coordination with USG agencies (e.g., USAID, DoD) and other critical non-USG partners (e.g., GAVI Alliance, UNICEF, WHO, the Bill and Melinda Gates Foundation, and others) for improved information sharing and decision-making on USG global immunization activities.

5.1.3 This HHS cross-departmental working group should also collaborate with USG agencies to understand how the whole of USG global immunization efforts are supporting implementation of the Decade of Vaccines Global Vaccine Action Plan, and identify areas where enhanced collaboration can increase the impact of US efforts.

Next Steps

- Finalize recommendations (Feb. 2013 NVAC meeting)
- Draft report (currently in progress)
- Finalize report in May
- NVAC consideration and vote on draft report and recommendations (June 2013 NVAC meeting)

Questions and Discussion



EXTRA

Proposed Influenza- specific recommendations

Support Influenza vaccine introduction and expansion globally and pandemic preparedness

- The ASH should work with USG-partners (BARDA, FDA, CDC) and WHO to continue to promote the manufacture and licensing of influenza vaccines in key countries to enhance country and regional pandemic preparedness.
- The ASH should work with CDC to maintain and increase support for countries to develop policies for influenza vaccine programs and expand coverage according to WHO Strategic Advisory Group Experts target populations.
- The ASH should work with CDC and non-USG partners to maintain and increase support for evaluation of influenza vaccines and vaccine strategies in different settings.