

Policy Paper: At the Midpoint of the Decade of Vaccines



Recommendations for catalyzing US government leadership and maximizing impact in global immunization

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POLICY PAPER: AT THE MIDPOINT OF THE DECADE OF VACCINES

Recommendations for catalyzing US government leadership and maximizing
impact in global immunization

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SUMMARY

Every year, 1.5 million children die from diseases that could be prevented by existing vaccines.¹ At the beginning of this decade, world leaders and experts came together to outline a vision for a Decade of Vaccines—an era in which rapid scale-up of immunization programs could ensure a world where everyone lives free from vaccine preventable diseases. In 2012, the United States joined countries around the world, turning this vision into a bold plan to extend the full benefits of immunization to all people by 2020 called the Global Vaccine Action Plan (GVAP). Halfway through this decade, progress has been disappointing, and the world is off track to achieve most of the GVAP targets. The United States government (USG)—one of the largest contributors to global immunization efforts in terms of technical expertise and resources—has not yet articulated its strategy for meeting these globally agreed upon goals.

At the midpoint of the Decade of Vaccines the USG cannot wait any longer to declare a strategy for achieving GVAP targets. Pending revisions to several agency and government-wide strategies that relate to global immunization offer opportunities to align policies with the global goals to which the US has committed. Furthermore, as the world nears the eradication of polio—one of the most significant achievements in immunization—stakeholders, including the US must ensure that the momentum that has fueled the polio effort can be leveraged to advance other immunization and global health priorities. The USG should take advantage of this moment to design an approach for interagency coordination and develop mechanisms to translate its unparalleled technical leadership into political leadership. Without amplified leadership and better coordination from the United States and other partner countries, these important global goals will not be met, and millions will continue to suffer and die from vaccine-preventable diseases.

This paper—designed for use by US executive branch officials, members of Congress, advocates, and other stakeholders—presents an analysis of the USG's role in global immunization and offers recommendations to strengthen its efforts to achieve ambitious, but reachable, global immunization targets. Through discussions with government officials and technical experts, as well as the review of publically available US policies and strategies, PATH has identified gaps and challenges in current USG efforts around global immunization. We recommend four actions to address these challenges called out in Box 1.

Box 1. Key policy recommendations

1. The National Vaccine Program Office (NVPO) should update the National Vaccine Plan (NVP) to improve US impact and accountability through a shared strategy for US leadership in immunization, aligned with the targets included in the Global Vaccine Action Plan.
2. The Department of Health and Human Services (HHS) Office of Global Affairs (OGA) and the Assistant Secretary for Health (ASH) should strengthen coordination by establishing an interagency working group to coordinate activities, surface and address challenges, report progress, and liaise with external entities.
3. OGA should improve political leadership by placing immunization on the agenda at high-level global forums and bilateral discussions.
4. The White House and Congress should maintain and increase global immunization as national priority by ensuring robust funding and accountability for achieving global immunization goals.

CURRENT SITUATION

Vaccination is one of the most cost-effective, highest-impact public health interventions. It prevents an estimated 2 to 3 million deaths a year.¹

Still, 1.5 million children die every year from diseases that could be prevented by existing vaccines.¹ In addition, more than 3.5 million people die annually from HIV, tuberculosis, and malaria—diseases for which no vaccines are commercially available.²

Many deaths, particularly among poor and vulnerable populations, could be averted by increasing both access to and coverage of existing vaccines to target populations and developing new vaccines to prevent infections that cause the greatest number of deaths.

What are the global immunization goals and why do they matter?

In 2010, the world's leaders in health came together around a bold vision: **a world where everyone lives free from vaccine-preventable diseases**. This aspirational vision was intended to galvanize efforts to extend the benefits of immunization to all people, everywhere. It also included a call to unleash the vast future potential of vaccines by accelerating research and development (R&D) for promising vaccine candidates. The World Health Organization (WHO) subsequently published the GVAP,³ which created a roadmap for work during a “Decade of Vaccines,” and the plan was endorsed in May 2012 by the 194 member states of the WHO, including the United States.⁴ Developed through extensive global consultation, the plan includes global goals with milestone targets for 2015 and 2020 (Table 1). The US played a formative role in developing the GVAP, with the National Institute of Allergy and Infectious Diseases (NIAID) serving on the leadership council of the Decade of Vaccines Collaboration and multiple US agency leaders serving on a range of technical working groups.

The GVAP is an important framework for galvanizing leadership and encouraging targeted actions to meet global immunization goals. Every country has a role to play in reaching the goals.

Are we on track to meet the GVAP targets?

Despite strong commitment from the United States and countries around the globe, in 2014, the WHO Strategic Advisory Group of Experts on Immunization (SAGE) found that **the world was far off track in efforts to reach six of seven targets for 2015 that were identified in the GVAP** (Table 1).⁵ Based on annual data WHO releases from national-level monitoring and accountability databases, the 2014 SAGE assessment reported on progress against each GVAP target and made recommendations to address shortcomings. The SAGE report called on all countries, their technical partner agencies, and donors to respond to the recommendations with the greatest possible urgency to prevent needless deaths among unvaccinated children. In the absence of a clear responsible party to coordinate and articulate a USG response, no specific action was taken by any actor within the USG to specifically address the gaps noted in the SAGE assessment. Without a concerted effort by the USG, partner governments around the world, and the global community as a whole, we are likely to miss the 2020 targets as well.

1. Immunization Coverage. World Health Organization (WHO) website. Available at: <http://www.who.int/mediacentre/factsheets/fs378/en/>. Accessed August 26, 2015.

2. MDG 6: combat HIV/AIDS, malaria and other diseases. WHO website. Available at: http://www.who.int/topics/millennium_development_goals/diseases/en/. Accessed August 26, 2015.

3. WHO. *Global Vaccine Action Plan 2011-2020*. Geneva: WHO; 2013. Available at: http://www.who.int/immunization/global_vaccine_action_plan/GVAP_doc_2011_2020/en/.

4. WHO. *World Health Assembly Resolution. WHA65.17/A65/13.12*. Geneva: WHO; 2012. Available at: http://www.who.int/immunization/global_vaccine_action_plan/GVAP_World_Health_Assembly_Resolution.pdf.

5. WHO. *2014 Assessment Report on the Global Vaccine Action Plan: Strategic Advisory Group of Experts on Immunization*. Geneva: WHO; 2014. Available at: http://www.who.int/immunization/global_vaccine_action_plan/SAGE_DoV_GVAP_Assessment_report_2014_English.pdf?ua=1.

TABLE 1: GVAP goal-level indicators and targets.

Goal	Target by 2015	Target by 2020
Achieve a world free of poliomyelitis	<ul style="list-style-type: none"> Interrupt wild poliovirus transmission globally (by 2014) OFF TRACK 	<ul style="list-style-type: none"> Certification of poliomyelitis eradication (by 2018)
Meet global and regional elimination targets	<ul style="list-style-type: none"> Neonatal tetanus eliminated in all WHO regions OFF TRACK Measles eliminated in at least four WHO regions OFF TRACK Rubella/congenital rubella syndrome eliminated in at least two WHO regions OFF TRACK 	<ul style="list-style-type: none"> Measles and rubella eliminated in at least five WHO regions
Meet vaccination coverage targets in every region, country, and community	<ul style="list-style-type: none"> Reach 90% national coverage and 80% in every district or equivalent administrative unit with vaccines containing diphtheria-tetanus pertussis (DTP) OFF TRACK 	<ul style="list-style-type: none"> Reach 90% national coverage and 80% in every district or equivalent administrative unit with all vaccines in national programs, unless otherwise recommended
Develop and introduce new and improved vaccines and technologies	<ul style="list-style-type: none"> At least 90 low- and middle-income countries have introduced one or more new or underutilized vaccines 	<ul style="list-style-type: none"> All low- and middle-income countries have introduced one or more new or underutilized vaccines Licensure and launch of vaccine or vaccines against one or more major currently non-vaccine preventable diseases Licensure and launch of at least one platform delivery technology
Exceed the Millennium Development Goal 4 target for reducing child mortality	<ul style="list-style-type: none"> Reduce by two-thirds, between 1990 and 2015, the under-five mortality rate (Target 4.A) OFF TRACK 	<ul style="list-style-type: none"> Exceed the Millennium Development Goal 4 Target 4.A for reducing child mortality

ROLE OF THE US GOVERNMENT

What role does the United States play in global immunization?

The USG has a long history of involvement in global immunization and is one of the largest contributors to global immunization efforts in terms of funding and technical expertise. Its investments in global immunization reflect a deep commitment to protecting the health security of Americans at home and abroad; driving economic growth by enabling children and families to survive, thrive, and reach their full potential; and preventing needless deaths as a moral imperative.

The US dedicates global immunization resources to many areas, including:

- **R&D** of new and improved vaccines and related tools.
- **Financial support** for multilateral groups and initiatives, including the WHO, United Nations Children's Fund (UNICEF), and Gavi, the Vaccine Alliance.
- **Technical assistance to developing-country health ministries** to strengthen surveillance, cold chain and logistics, regulatory capacity-building, and health information systems.
- **Placing USG-funded technical staff** in key offices in UNICEF, WHO, and Gavi to provide leadership and technical assistance.

Advancing immunization worldwide is tightly woven into the mandate of a number of US technical agencies, including the Centers for Disease Control and Prevention (CDC), Department of Defense (DoD), US Food and Drug Administration (FDA), National Institutes of Health (NIH), office of the Assistant Secretary for Preparedness and Response, and United States Agency for International Development (USAID). It is also a priority for leadership entities such as the Office of Management



PATH/Cabe Blenczycki

A woman brings her children to receive MenAfriVac in Burkina Faso. A consortium of partners around the world, which included support from the US government, worked to develop and deliver an effective, affordable vaccine to prevent against a disease which previously caused epidemics of meningitis A that devastated countries in sub-Saharan Africa.

and Budget (OMB), NVPO (HHS), OGA (HHS), and the National Security Council (NSC). In addition, US agencies play leadership roles on global technical bodies. For example, the CDC is a key partner of the Global Polio Eradication Initiative (GPEI), a public-private partnership coordinating the effort to achieve a polio-free world.

Why does US leadership in immunization matter?

The United States has a great deal at stake in ensuring progress toward global immunization goals and much to contribute toward its success. Vaccines are among the most cost-effective tools for improving public health. In an era of mass travel, preventing disease overseas helps keep Americans safe at home and abroad. In addition, a healthier world is a more stable and prosperous world—one that fosters greater American security and economic well-being. For these reasons, the United States is the largest public funder of vaccine R&D⁶ and among the largest donors to global immunization programming. It also possesses unparalleled technical expertise in immunization, allowing US technical experts to inform and influence global vaccine-related policies and priorities. Yet the USG has not formulated a cohesive plan for how it will channel its expertise and investments in immunization to reach the quantifiable targets adopted globally. Without the dedicated support of the United States to propel progress, achieving the 2020 GVAP targets—which are already off track—will be even more difficult.

Although the United States has agreed to short-term global targets to move toward the vision of a “world free from vaccine-preventable diseases,” those targets have not been articulated in guiding plans and strategies of US agencies with global immunization mandates, and no US agency is formally charged with tracking overall inputs to achieving these global goals. By defining a shared national agenda, and tracking progress against it, stakeholders within the USG will be able to see a holistic picture of US contributions and lay a foundation for stronger, more ambitious US impact.

In addition to its financial and technical contributions, the USG carries tremendous authority and political power in global and bilateral public health priority-setting discussions. While ensuring that national efforts are owned by countries, appropriate use of the USG voice can maximize its catalytic investments.

6. G-FINDER public search tool. Policy Cures website. Available at: <https://gfinder.policycures.org/PublicSearchTool/>. Accessed September 11, 2015.

CURRENT OPPORTUNITIES

Now is the time for the USG to recommit itself to the targets of the GVAP and take action to accelerate its impact. 2015 is a pivotal year, marking not only the midpoint of the Decade of Vaccines but also the expiry of the Millennium Development Goals and the start of a new set of global goals that will shape health priorities over the next 15 years. Vaccines have the potential to play an outsized role in achieving targets for lives saved that are articulated in the Sustainable Development Goals, which may include indicators relevant to GVAP targets.

Pending updates and additions to US policies and strategies—including the National Vaccine Plan, CDC’s Global Immunization Strategic Framework, and USAID’s Immunization Blueprint for Action—provide an opportune moment for the US to leverage the collective expertise and resources of the USG to inform global policy and keep the GVAP targets at the forefront of the global public health agenda.

What policies are currently being updated or drafted?

Three US policies and strategies that influence America’s role in global immunization programs are currently being revised or developed, as highlighted in Table 2 and detailed below.

TABLE 2. Goals and status of selected key US government strategies and initiatives relevant to global immunization programs.

Strategy	Goals (as of August 2015)	Opportunity for incorporating global goals
U.S. National Vaccine Plan (2010 – 2020) <i>Note: The National Vaccine Plan has an accompanying Implementation Strategy (currently 2010 – 2015)</i>	<ol style="list-style-type: none"> 1. Develop new and improved vaccines. 2. Enhance understanding of the safety of vaccines and the safety of vaccination practices. 3. Support informed vaccine decision-making by the public, providers, and policymakers. 4. Ensure a stable supply of, access to, and better use of recommended vaccines in the United States. 5. Increase global prevention of death and disease through safe and effective vaccination. 	The National Vaccine Program Office is currently updating the Plan for 2016 – 2020 as part of a mid-course review.
CDC’s Global Immunization Strategic Framework (2011–2015)	<ol style="list-style-type: none"> 1. Control, eliminate, or eradicate targeted vaccine-preventable disability and death globally. 2. Strengthen capacity and enhance performance of health systems to sustainably deliver routine immunization services. 3. Strengthen health information and surveillance systems to enhance decision-making capacity for immunization programs. 4. Increase the appropriate development, introduction, and use of new and underused vaccines to prevent diseases of global and regional public health importance. 5. Promote synergies between vaccination and other public health interventions to strengthen health systems and help to decrease maternal and child mortality and morbidity. 6. Build and strengthen partnerships that maximize coordination and synergy in meeting immunization goals. 	CDC’s Global Immunization Division is currently developing a new framework for 2016 – 2020.
USAID Immunization Blueprint for Action	Under development.	USAID’s Bureau for Global Health is currently developing.

US NATIONAL VACCINE PLAN (2010–2020)⁷

The US NVP is the USG's leading roadmap for vaccines and immunization and articulates a strategy to enhance vaccination, domestically and globally. While the NVP is the roadmap, the National Vaccine Plan Implementation Strategy⁸ is the “how-to guide,” outlining high-priority federal agency activities to reach the NVP goals. Each year, the NVPO issues the State of the National Vaccine Plan⁹ (“State of the NVP”) to track and report on the progress of activities in the Implementation Plan.

The NVP includes both a goal focused on global immunization (Goal 5) and another on developing new and improved vaccines (Goal 1) (see Table 2). Within Goal 5, the NVP priorities are improving global surveillance and health information systems (priority I) and supporting global introduction of new and underutilized vaccines (priority J). These two priorities present only a partial view of the full breadth of USG activities in global immunization, leaving out critical priorities such as strengthening routine immunization systems and promoting equitable access to vaccines. Also, because the State of the NVP reports only against the high-priority activities described in the Implementation Strategy, there is no accountability for actions taken outside these two high-priority areas.

Both the NVP and Implementation Strategy were developed in advance of finalizing GVAP targets and, therefore, do not commit the USG to contributing to those targets. At first glance, some of the priority areas overlap with the goals and strategic objectives of the GVAP, such as new vaccine introduction. However, when reviewing the details of the Implementation Strategy, associated activities strongly emphasize introduction of and access to influenza vaccine and limit activities related to priority new and underutilized vaccines emphasized in the GVAP, such as pneumococcal, rotavirus, and meningococcal vaccines.

Although the NVP did call for development of indicators in the Implementation Strategy, they were not ultimately included. In fact, there are no measurable targets or indicators associated with any goals or priorities listed the NVP or Implementation Strategy. Any indicators that might be added in future iterations (beyond whether an activity was completed) or measurable targets would need to take into consideration the NVP as a whole, including the domestic components.

The NVP references coordination with other USG initiatives but does not address how coordination within the plan will take place. Improving coordination across the plan was a recommendation made by both the Institute of Medicine in its report *Priorities for the National Vaccine Plan*¹⁰ and the National Vaccine Advisory Committee (NVAC) in its recommendations for improving US impact in global immunization (see NVAC report).

The authors make clear that the NVP is designed to be a national plan, not a *federal government* plan, but there is no accountability mechanism for non-USG stakeholders. Even within the USG, although immunization-related strategies are intended to align with the NVP, federal agency staff—especially those working on global immunization—do not universally view the NVP as a foundational roadmap. Some are not even aware that the NVP includes global components. Others are aware but because they were not involved in the development of the strategy, or because their agency may not be named in the Implementation Strategy, they do not feel accountable to it.

Beginning in 2015, NVPO and NVAC—a group of experts who advise the Assistant Secretary for Health at HHS on issues related to immunization, especially the NVP—are charged with conducting a mid-course review of the plan. This review is expected to result in indicators, strategies, actions, and milestones that will guide subsequent annual evaluation through the overall ten-year horizon of the plan. Updating the NVP provides a tremendous opportunity to align the United States' guiding national policy with the larger global effort to improve immunization globally under the GVAP.

CDC'S GLOBAL IMMUNIZATION STRATEGIC FRAMEWORK (2011 – 2015)¹¹

One of the most visible USG agencies on global immunization, the CDC, has its own global immunization policy, the Global Immunization Strategic Framework, which describes the CDC's goals, objectives, measures of success, and strategies for effectively meeting global immunization challenges during the 2011 to 2015 timeframe and aligns with the NVP. The framework was finalized before the GVAP was endorsed, but the CDC targets are similar to the global targets, likely due to the fact that the CDC was heavily involved in shaping the global plan. Although the targets do not directly align, the

7. Department of Health and Human Services (HHS). *2010 National Vaccine Plan: Protecting the Nation's Health through Immunization*. Washington, DC: HHS; 2010. Available at: http://www.hhs.gov/nvpo/vacc_plan/.

8. HHS. *National Vaccine Plan Implementation*. Washington, DC: HHS; 2011. Available at: http://www.hhs.gov/nvpo/vacc_plan/2010-2015-Plan/implementationplan.pdf.

9. HHS. *The Annual Report of the State of the National Vaccine Plan – 2014*. Washington, DC: HHS; 2014. Available at: http://www.hhs.gov/nvpo/vacc_plan/annual-report-2014/nvp-2014.html.

10. Institute of Medicine (IOM). *Priorities for the National Vaccine Plan*. Washington, DC: IOM; 2008. Available at: <http://www.nap.edu/catalog/12796/priorities-for-the-national-vaccine-plan>.

11. HHS Centers for Disease Control and Prevention (CDC). *CDC Global Immunization Strategic Framework 2011-2015*. Atlanta: CDC; 2011. Available at: <http://www.cdc.gov/globalhealth/immunization/docs/gid-strat-framework.pdf>.

framework addresses every global GVAP focus area. Variations are minor, such as timelines that are more ambitious than the GVAP targets for polio eradication and certification and less ambitious for measles regional elimination goals.

In listing specific global measures of success in its framework, the CDC appropriately acknowledges that it is one of many contributors to achieving a global goal. However, there is no regular reporting against the CDC's contribution toward achieving the GVAP targets. The CDC does include activity-level reporting in its annual congressional budget justifications. Annual reporting against the targets is important for shaping the CDC's ongoing role and justifies future investments.

As the CDC's Global Immunization Division updates the framework for 2016 to 2020, it will not only need to revise its activities and measures of success to strive for the targets in the GVAP but also need to address the implications of a promising shift in the global immunization landscape: the eradication of polio. The infrastructure and personnel supported by polio resources is vast. In many instances, the systems and health workforce that have been delivering polio vaccines have served as the backbone of otherwise frail routine immunization systems.¹² The CDC is currently a key partner in the GPEI,¹³ which has targeted 2018 for certifying the world as polio free—a process that requires no wild polio virus cases for three years. Given existing levels of wild polio virus in Afghanistan and Pakistan, a revised target will likely be established.

A group of experts, chaired by the CDC, has come together to advise the GPEI regarding how the polio-funded surveillance systems, health workforce, and infrastructure should be managed. Donor countries, including the United States, will need to plan carefully to wind down intensive polio efforts without eliminating resources crucial to maintaining routine immunization systems and other public health infrastructure. The CDC has devised a country-by-country approach, working with national governments to shift system costs currently supported by polio assets to other domestically supported programs. However, it is clear that domestic resources will not be substantial enough to sustain programming.

The CDC will need to carefully articulate the process for transitioning polio programs to ensure that resources (including those from the United States) continue to be available to routine immunization programs and broader global goals can still be met. The risk is that with the eradication of polio, polio-specific funding, appropriated by Congress annually, will be eliminated to the detriment of routine immunization coverage.

At the same time, the CDC is one of the largest contributors to the Measles and Rubella Initiative, which aims to eliminate measles and rubella in five of the six WHO regions by 2020.¹⁴ The CDC will also need, at minimum, to put forward a plan to fill gaps in the measles and rubella effort that are currently being filled by polio resources.

USAID IMMUNIZATION BLUEPRINT FOR ACTION

Immunization is a top priority of USAID because it is a key means of achieving one of the agency's signature goals, ending preventable maternal and child deaths in a generation,¹⁵ as outlined in its 2014 report, *Acting on the Call*.¹⁶ Given the importance of immunization in achieving child mortality goals, USAID's Bureau for Global Health is currently developing an Immunization Blueprint for Action to serve as a more detailed guide for immunization-related activities to be supported by USAID leadership, USAID's headquarters-led programs, and USAID Missions in its 24 priority countries.

Although a draft strategy is not yet publically available, USAID issued a brief¹⁷ in 2014 outlining its headquarters-supported programming in routine immunization, which will likely serve as the foundation for this document. The activities described in the brief are very limited and do not reference USAID's role or contributions to the GVAP targets or leadership activities in global forums, such as serving on the board of Gavi. It is promising, however, that the blueprint calls on USAID leadership to play an enhanced role at the global level.

USAID should ensure its blueprint stipulates that USAID immunization activities feed into the NVP, defines which GVAP targets it aims to support, outlines the ways in which the agency will leverage its global leadership, and, importantly, includes metrics to track progress toward the global targets.

12. Objective 4: Legacy planning. Global Polio Eradication Initiative (GPEI). Available at: http://www.polioeradication.org/Portals/0/Document/Resources/StrategyWork/PEESP_CH8_EN_US.pdf. Accessed September 2, 2015.

13. GPEI website. Available at: <http://www.polioeradication.org>. Accessed September 11, 2015.

14. About the Initiative. Measles & Rubella Initiative website. Available at: <http://www.measlesrubellainitiative.org/learn/about-us/>. Accessed on August 26, 2015.

15. Department of State. (2015). *Department of State and U.S. Agency for International Development 2016 Budget [Fact sheet]*. Available at: <http://www.state.gov/r/pa/prs/ps/2015/02/236859.htm>.

16. United States Agency for International Development (USAID). *Acting on the Call*. Washington, DC: USAID; 2014. Available at: https://www.usaid.gov/sites/default/files/documents/1864/USAID_ActingOnTheCall_2014.pdf.

17. USAID. *Saving Children's Lives: USAID's Support for Immunization*. Washington, DC: USAID; 2015. Available at: https://www.usaid.gov/sites/default/files/documents/1864/MCHimmunizationFactSheet_0.pdf

What other initiatives influence US actions in global immunization?

In addition to the activities noted in Table 2, global immunization recommendations issued by NVAC and the Global Health Security Agenda (GHSa) influence US immunization programming and priorities.

NVAC REPORT: THE HHS NATIONAL VACCINE PROGRAM AND GLOBAL IMMUNIZATION

In 2013, the NVAC released a set of six recommendations¹⁸ for improving immunization worldwide. Although the recommendations are considered strongly, adoption into policy by HHS is not compulsory. To date, US policies or plans have not incorporated the NVAC recommendations, which are:

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 post-marketing surveillance.
4. Building global capacity for R&D related to immunization.
5. Strengthening the capacity for decision-making related to vaccines and vaccination.
6. Coordinating global immunization efforts within HHS.

Taking up these well thought-out recommendations would lead to improved global impact.



PATH/Will Boase

A woman reviews child health records in Uganda. Data is essential to ensuring all children are reached with immunizations.

18. National Vaccine Advisory Committee (NVAC). *The HHS National Vaccine Program and Global Immunization*. Washington, DC: HHS; 2013. Available at: <http://www.hhs.gov/nvpo/nvac/reports/nvac-global-report-supplement.pdf>.

GLOBAL HEALTH SECURITY AGENDA

In 2014, the United States and other countries, international organizations, and public and private stakeholders launched the GHSA to accelerate progress toward a world safe and secure from infectious disease threats and to promote global health security as an international priority. In 2015, Congress reinforced this political priority by appropriating funds to the CDC for implementation of related activities.

GHSA is an integrated approach to achieve sustainable improvements toward the International Health Regulations (IHRs).¹⁹ The IHRs were agreed to in 2005 by all WHO member states following the 2003 SARS epidemic, which proved that public health infrastructure was too weak to prevent pandemics.

The GHSA includes 11 Action Packages,²⁰ organized into categories of activities that prevent, detect, or respond to global health security threats. An Action Package on immunization²¹ is included under the category of prevention. The identified five-year goal for this group of activities is a functioning national vaccine delivery system—with nationwide reach, effective distribution, access for marginalized populations, adequate cold chain, and ongoing quality control—that can respond to new disease threats. The indicator for the immunization action package is 90 percent coverage with measles-containing vaccine—an important data point for the Measles and Rubella Initiative, as measles has not traditionally been tracked as a measure for broader immunization coverage. Because USG leadership in the GHSA is housed at the White House through the NSC, the USG has an influential and visible platform from which to exhibit greater leadership in immunization.



Photo courtesy of the Bill & Melinda Gates Foundation

Vaccines are prepared at a child health center in Beijing. Many partners are involved in the numerous steps required to get a vaccine from the lab where it is developed to the manufacturer and then to patients around the world. Global goals are important for catalyzing efforts to reach more patients with vaccines to protect against leading causes of illness and death.

19. About International Health Regulations. WHO website. Available at: <http://www.who.int/ihr/about/en/>. Accessed September 2, 2015.

20. Global Health Security Agenda: Action Packages. CDC website. Available at: <http://www.cdc.gov/globalhealth/security/actionpackages/>. Accessed September 2, 2015.

21. Global Health Security Agenda: GHSA Immunization Action Package (GHSA Action Package Prevent-4). CDC website. Available at: <http://www.cdc.gov/globalhealth/security/actionpackages/immunizationap.htm>. Accessed September 2, 2015.

DELIVERING ON THE PROMISE

What challenges does the US government face in maximizing the impact of its global immunization efforts?

An overarching conclusion based on our discussions and review of policies is that the USG is failing to achieve the full potential impact of its immunization investments because it has not reflected its commitment to the goals and targets outlined in the GVAP in policy and has not yet harnessed cross-agency expertise and leadership to inform global efforts.

- **The USG has no unifying strategy that articulates how it will achieve the targets of the GVAP.** Without this unifying vision, which addresses the full range of global priorities listed in the GVAP, USG activities related to global immunization remain fragmented across multiple agencies and are not poised to drive impact in the areas where progress is lagging.
- **There is no clear coordinating mechanism for agencies to share information and maximize impact.** Although many individual USG technical staff have worked to connect with counterparts at other US agencies, those interactions have largely been ad hoc and have tended to focus on narrow elements of work. For example, CDC's Global Immunization Division and USAID's immunization leads meet regularly, but those conversations focus predominantly on coordinating polio eradication and measles elimination efforts. Discussions of other topics do not occur in a systemic manner.
- **US technical expertise in immunization is not being fully leveraged to inform political positions in multilateral and bilateral public health forums.** The USG carries tremendous authority and political power in global public health priority-setting discussions—such as the World Health Assembly (WHA)—yet the extent to which it intends to use its political power to achieve results in global immunization is unclear. Without a mechanism to harvest information across relevant US agencies to develop a common US position, the USG is missing opportunities to see where its weight in these conversations can be used to correct or put pressure on specific problems and gaps arising in the effort to achieve GVAP targets.
- **In an era of constrained budgets and shifting global crises, there is a risk that immunization could decrease in priority in the minds of Congressional champions.** Political leaders within Congress and the administration have been generally supportive of US engagement in global immunization. However, it is unclear how prioritization of vaccination will fare as the visibility of key issues—such as polio and Ebola—waned. Because of the outsized impact of US investments globally, any reductions in US political prioritization could have devastating impacts on immunization programs globally and ultimately result in even greater delays in achieving global immunization targets.
- **Respect for country ownership has unnecessarily limited US government leadership on GVAP goals.** Underpinning the strategic objectives of the GVAP is the critical concept of country ownership. Donor governments have pointed to this principle as the reason for limited engagement on GVAP goals. Although it is vital that countries drive their own decision-making and plan for domestic financing of activities, donor governments have a key role to play in maintaining political momentum, funding research and programs, providing technical assistance, and building financial and program management capacity to ensure that immunization efforts achieve scale sustainably.

What can the US government do to overcome these challenges and deliver on the promise of the decade of vaccines?

Based on these findings, we have outlined four recommendations for strengthening US government contributions and leadership to reach global immunization targets. They are outlined below, with specific steps identified for key agencies.

• RECOMMENDATION 1:

Improve US agency impact through a shared strategy for US leadership in immunization, aligned with the targets included in the Global Vaccine Action Plan

NVPO, guided by the NVAC, should update the NVP to reflect a vision for US leadership in achieving GVAP targets and accountability metrics.

As noted previously, the NVP is the nation's leading strategy for immunization. It should present a shared vision for the US government, aligned under the goal of achieving the GVAP targets. To translate the US commitment to the GVAP goals into actionable steps for US immunization programs, the NVP should explicitly state, at minimum, internationally agreed-upon global immunization targets. Namely, the NVP's global immunization Goal 5 should align with GVAP targets for polio eradication, measles and rubella elimination, national and district-level coverage, and introduction of new and underutilized vaccines. Goal 1, relating to R&D, already aligns with the GVAP targets of licensure and launch of a vaccine (or vaccines) against one or more major currently non-vaccine preventable diseases, and should continue to do so.

Equally important, the NVP Implementation Plan must include, along with the targets outlined previously, concrete, measurable actions to be taken by US agencies. This includes actions relating to technical contributions, coordination between US agencies through an interagency working group (see Recommendation 2), and political leadership through annual responses to technical reports and participation in multilateral forums (see Recommendation 3).



PATH/Doune Porter

One of the greatest challenges in immunization is reaching the most remote populations, as demonstrated here by two health workers carrying vaccines on a motorbike to remote centers in Malawi.



PATH/Satvir Malhotra

A health worker prepares a vaccine for a child in Andhra Pradesh, India. Vaccines are an essential intervention that can help to ensure that all children, no matter where they are born, survive and lead healthy lives.

Finally, to ensure accountability, the State of the NVP should report annually on the activities of the USG toward achieving the GVAP targets and include discussion of where the global targets are off track and where opportunities exist for the USG to use its leadership, programming, and technical expertise to contribute to solutions.

CDC and USAID plans should include specific commitment to targets in the GVAP and jointly report annually on progress made toward achieving those outcomes.

To achieve the greatest impact, agency-specific strategies must also articulate which GVAP targets they aim to support, how the agency will leverage its leadership around the global targets, and metrics of impact. The CDC and USAID should report annually on progress toward the GVAP targets individually and through the NVP.

• **RECOMMENDATION 2:**

Strengthen interagency coordination

The **HHS OGA** and the **HHS ASH** should establish a global immunization interagency working group, supported by the NVPO.

The HHS secretary leads the US delegation to the WHA, representing US interests in issues such as health security, international guidelines and standards, emergency response, and public health capacity building. OGA supports the HHS secretary in this effort—coordinating US statements on topics of importance and conducting bilateral and multilateral discussions—and is well-positioned to oversee the convening of technical partners across agencies on an ongoing basis in order to ensure the perspectives and positions of the USG are fully realized in various global health forums, including the WHA. Because the ASH (staffed by NVPO) is responsible for tracking progress on the NVP—which should serve as the guiding document for interagency collaboration on global immunization activities—NVPO should provide support in ensuring the proper stakeholders are invited to participate, developing a map of agencies working on global immunization with points of contact to facilitate communication, and feeding outputs from NVP-related reports into materials from the interagency working group.

This global immunization interagency working group should meet regularly to:

- Advise agency leaders on opportunities for the United States to deepen engagement and improve its programming and response to global immunization challenges (see Recommendation 3).
- Surface and address challenges and barriers.
- Support the tracking of progress in a consistent and transparent manner and communicate USG activities and global health impacts to leadership and the public.
- Facilitate communication among USG agencies and with critical non-USG partners about pressing public health issues and departmental priorities, capabilities, and resources for immunization.

RECOMMENDATION 3:

Improve political leadership and policy decision-making

OGA, as a policy-setting office, requires robust connections to technical programs to use leadership to advance global public health. The USG should leverage the collective expertise of the global immunization interagency working group to provide increased political leadership and visibility for global immunization by developing policy positions, putting immunization on the agenda of global and regional forums, identifying areas where political pressure can be applied, and spurring other governments to take action.

*The **OGA and technical experts across agencies, including leaders from USAID, CDC, and NIAID**, should advocate for including immunization on the agenda at global and regional forums and ensure the participation of high-level US officials.*

As a top priority for the USG, US leaders should ensure the continued visibility of immunization and the need to achieve globally adopted immunization goals at global and regional health events, such as the WHA, and promote the attendance of senior US officials to reinforce this political prioritization with other nations. While OGA is the voice of the USG in multilateral meetings such as the WHA, other agencies have strong recognition and credibility in many global forum and should make use of their positioning to communicate the USG's priorities.



A young girl receives a vaccine in Peru. The US government has worked with partners around the world to support early scientific research and testing that has led to new vaccines to protect children against leading causes of death including diarrhea, pneumonia, and meningitis.

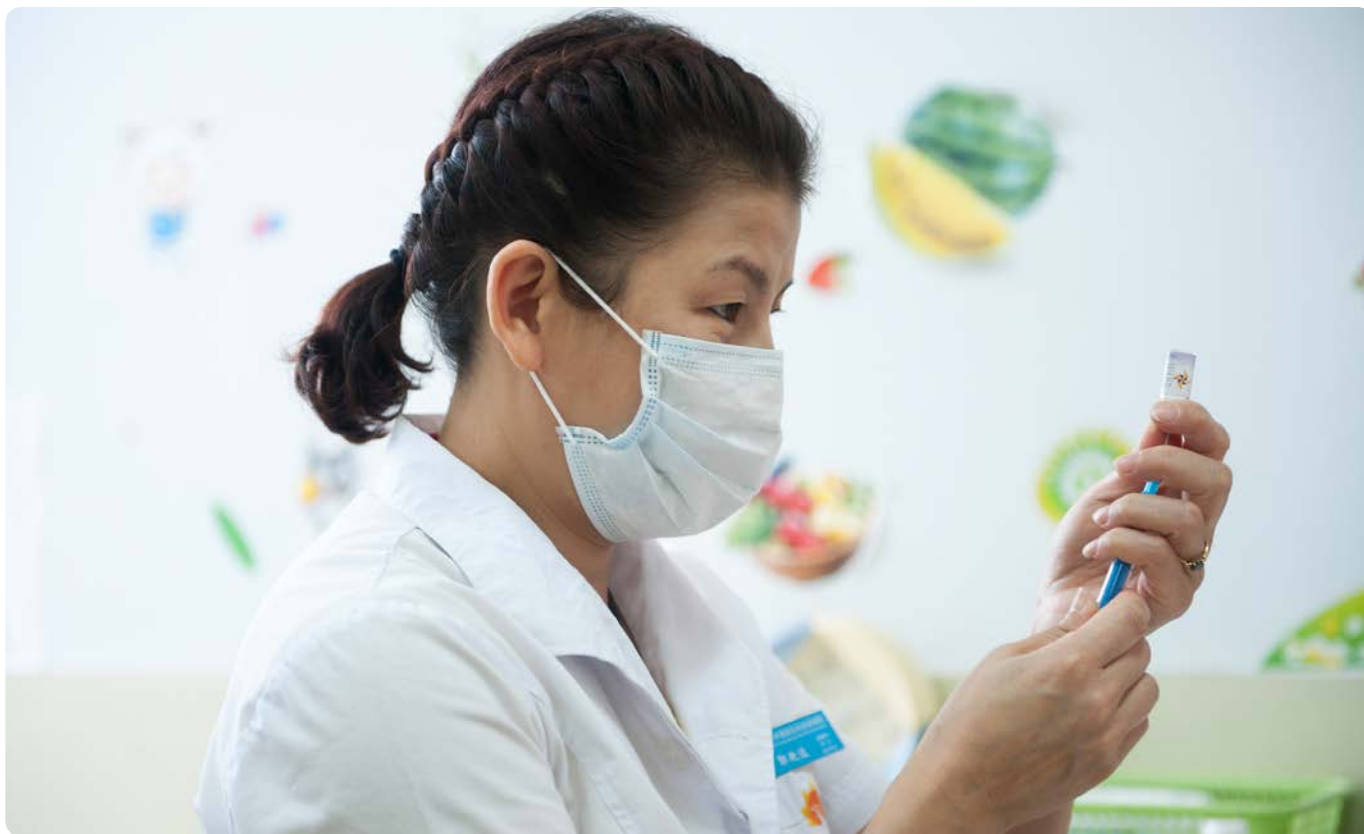


Photo courtesy of the Bill & Melinda Gates Foundation

A Chinese health worker prepares to deliver a vaccine. Health workers around the world play a vital role in delivering vaccines and educating patients about the importance of immunization. Technical assistance and training from governments like the US has helped strengthen the capacity of health workers in low-resource settings to deliver quality care.

*The **OGA**, with technical inputs from the interagency working group, should develop and share an annual response to the SAGE GVAP Assessment Report to be made available publicly and be presented via a statement at the WHA.*

Upon the release of the SAGE GVAP Assessment Report each year, OGA should convene the working group to evaluate which recommendations have bearing for US actions and commit to a series of actions the USG will take to respond. For example, the 2014 Assessment Report notes that increased urgency is needed for regions and countries to rapidly finalize their own vaccine action plans and establish bodies to guide and monitor implementation. Health attachés in US embassies, CDC offices, and USAID missions can arrange meetings with ministry of health officials to bring about a sense of urgency and offer technical assistance for the development and monitoring of plans. A summary of actions should be reported in the State of the NVP.

OGA and other technical leaders should ensure that the USG response is strongly presented in multilateral and bilateral settings, particularly at the WHA, where each year member nations are called upon to provide a statement on progress, challenges, and plans to improve immunization. To date, statements by the US and other member states have been weak and lack the specificity required to be actionable. The USG should provide a strong statement about the state of vaccination within the United States' own borders and its planned actions as a donor and technical partner, and use its position of leadership to set expectations for both developed and developing nations to do the same.

The USG should develop a plan for transitioning US-supported polio infrastructure and personnel to improve coverage and equitable reach of routine immunization programs.

The USG has made significant investments in reducing the burden of polio over the years. As the world nears polio eradication, the GPEI (chaired by the CDC) is leading discussions of how polio-funded assets (including funding, infrastructure, and personnel), which also provide the backbone of routine immunization programs in some countries, can be sustained after eradication. Although various USG entities—largely the CDC—have analyzed the

impact of the polio programs on broader immunization, the USG has not yet taken a position on how the resources should be transitioned or articulated a vision for evolving US and domestic-funded polio programming to support a broader set of critical immunization priorities.

RECOMMENDATION 4:

Sustain and grow administration and Congressional leadership on global immunization, including needed funding.

***OMB** should request robust resources for global immunization in the President's budget.*

Sustained multilateral financing for Gavi, UNICEF, and WHO as well as funding for CDC's Global Immunization Division and USAID's Maternal and Child Health Bureau is critical for pursuing global objectives. To ensure that the President's budget includes robust resources for global immunization, CDC, USAID, NIH, Gavi, civil society advocates, and others should educate OMB about the importance of the USG's broad role in global immunization. Funding should be provided to fill gaps, as identified by the interagency working group and include appropriate resources to sustain immunization programs that have been up until now supported by polio-specific funds.

*The **NSC** should lead a dialogue on the strategic importance of immunization—such as the importance of transitioning polio programming to broader immunization efforts—in achieving global health and development goals.*

As the primary forum for consideration of foreign policy matters among executive branch leadership, the NSC should play a more visible role in linking global immunization activities of the agencies with key executive branch priorities, such as ending preventable child and maternal deaths and ensuring global health security. In particular, the pending eradication of polio and the transition of associated assets presents a key moment to ensure that US flagship foreign policy initiatives—which inherently rely on success in global immunization programs—can reach their objectives. The NSC should, therefore, convene a dialogue with leaders from relevant agencies to consider how the transition of polio resources relates to strategic Administration priorities.

*Members of the **Senate Health, Education, Labor and Pensions, Senate Foreign Relations, House Energy and Commerce, and House Foreign Affairs Committees** should promote transparency and hold agencies accountable for achieving every one of the above recommendations.*

Congressional committees with oversight over the federal agencies play a vital role in ensuring impact. For each of the recommendations in this document, it is essential that committees of relevant jurisdiction take steps to encourage the responsible agency to act and to report on progress. Similarly, global health and development advocates and constituents can ensure appropriate members of Congress are aware of commitments made and prioritize actions regarding global immunization.

CONCLUSION

Although immunization programs around the world save millions of lives each year, the world is off track in realizing their full potential. It's time for the USG to recommit to the GVAP. The USG needs to prioritize the globally agreed upon targets with associated activities within the USG's own plan and provide political leadership to leverage the collective expertise of the USG to inform global policy and activities and ensure that progress in immunization remains at the forefront in the global agenda.

Implementing the recommendations in this report will help to strengthen USG leadership of global immunization efforts and achieve the goals agreed to by all nations, as outlined in the Global Vaccine Action Plan. As a result, millions more children around the world will survive vaccine-preventable childhood diseases and have the potential to live healthy, productive lives.

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