

A REPORT OF THE CSIS
GLOBAL HEALTH POLICY CENTER

Global Health Policy in the Second Obama Term

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Rebecca Katz

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February 2013



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YEARS

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OUR FUTURE

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Center for Strategic and International Studies
1800 K Street, NW, Washington, DC 20006
Tel: (202) 887-0200
Fax: (202) 775-3199
Web: www.csis.org



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INTRODUCTION

As the contributors to *Global Health Policy in the Second Obama Term* attest, U.S. leadership in global health advances core U.S. interests. It fulfills shared humanitarian values by saving and enhancing lives. It strengthens health security against common and emerging threats. And it promotes stability and prosperity in far-flung communities in the developing world who strive for better health and better lives for their families.¹ For all these reasons, supporting global health should remain a U.S. government and budget priority—and as the second Obama administration and incoming Congress commence their work, we hope these essays will offer pragmatic, informed guidelines for seizing the opportunities ahead.

The volume analyzes seven important dimensions of a complex, widening U.S. global health agenda: HIV/AIDS; malaria; polio eradication; women's health; health security; health diplomacy; and multilateral partners.² Each chapter strives to catalog and interpret the past four years' developments in their respective focal area, charting the measurable health impacts for which the United States can claim at least partial credit, and highlighting persistent problems and challenges. The essays conclude with concrete recommendations on how the United States can achieve the best results in the next four years in promoting the improvement of health, especially among the world's most vulnerable citizens.

As a whole, the volume brings to light three factors that have profoundly influenced the scope of U.S. global health engagement in recent years, and which must be at the forefront of the Obama administration's and incoming Congress's discussions of the future of U.S. global health policy: the remarkable bipartisan support for U.S. leadership on global health; the surprising conceptual and operational gains achieved even in the face of considerable austerity; and the essential ingredient to success: sustained, high-level U.S. leadership.

1. Matt Fisher and Alisha Kramer of CSIS were indefatigable in expertly and selflessly managing the overall production of this volume. Vinca Lafleur of West Wing Writers provided invaluable editorial assistance. Many friends and colleagues gave generously of their time and expertise to produce very impressive quality in a few short months. Alison Bours and Jim Dunton provided essential help by producing and copyediting this volume. Our greatest gratitude extends to my fellow authors for their prodigious efforts: Katherine Bliss; David Bowen; Nellie Bristol; Julie Fischer; Janet Fleischman; Amanda Glassman; Hannah Kaye; Rebecca Katz; Phil Nieburg; Sharon Stash; Todd Summers; and Judyth Twigg. Ultimately, as authors they are solely responsible for the opinions expressed. We are also grateful to the many experts outside government who participated extensively in the working groups that were mobilized by the authors: these individuals contributed enormously to creating a broad, majority consensus that informs the analyses. We are no less thankful to the officials from U.S. government departments and agencies and international organizations who kindly and patiently agreed to provide a sounding board on complex technical and programmatic issues. Their expertise and guidance were invaluable. They hold no responsibility for the final analysis and recommendations.

2. The World Health Organization (WHO); the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund); the GAVI Alliance; UNAIDS; and the World Bank Group.

Let me elaborate on these in turn.

First, in spite of ongoing debates over debt, deficits, taxes, and spending, and a highly polarized U.S. political environment, a broad American consensus has held these past four years that U.S. investments in global health genuinely advance U.S. national interests. In preserving investments in global health, the White House has successfully reached out to an enduring coalition of bipartisan supporters in Congress, as well as diverse leaders in the business, faith, foundation, scientific, development, and public health communities.

This remarkable and heartening achievement reflects sustained commitments by the Clinton, Bush, and Obama administrations to cultivate active dialogues with Republican and Democratic congressional leaders and forge strong partnerships with recipient governments, civil organizations, and international organizations. It was reinforced by credible evidence that U.S. investments are yielding concrete health impacts that enhance and save lives.

Paradoxically, however, this broad American consensus remains inherently vulnerable. As a decade of war winds down, calls are growing for the United States to look inward and make domestic challenges the overriding priority. Threats of sequestration and renewed recession persist, even as sweeping changes in Congress have thinned memories of why members once stood so dramatically in support of the steep expansion of U.S. commitments in global health. In such a climate, debates over the wisdom and affordability of U.S. overseas commitments are inevitable.

What does this suggest for U.S. global health policy going forward? If U.S. engagement is to be maintained, a first order of business for the administration and Congress is to shore up the American base consensus. That will require actively making the case that these investments are indeed affordable, that they do advance core U.S. humanitarian interests, that they are a “best buy” in the use of scarce resources, and that better health in the developing world will advance stability and prosperity and improve the United States’ standing in the world.

A second promising legacy of recent years is that major gains are indeed possible—conceptually as well as operationally—in a period of protracted budgetary stress, scarcity, and uncertainty. Recession is painful but does not necessarily stop progress. In fact, the pressures created by austerity can spark new ideas, motivate reform, and contribute to higher efficiencies. As one expert trenchantly noted, “Recessions are market adjustments that can help squeeze the silliness out of institutions and make them better.”

Recession certainly did not prevent considerable policy generation in the first Obama term. Most importantly, a doctrine of achieving sustainability has taken root, spelling out more clearly how orderly, negotiated transitions that better structure partnerships and expectations with national governments and multilateral institutions can enable partner countries to assume more political and financial ownership of their health sectors. The doctrine has also explicitly raised the expectation that multilateral institutions like the Global Fund, the GAVI Alliance, and others will be more active partners in building shared responsibility. It has directly contributed to a number of detailed compacts between the United States and partner governments describing their respective obligations to advance a successful transition. It has defined how the United States can and should decrease its role as a direct service provider and become predominantly a source of essential technical expertise.

The Obama administration's Global Health Initiative (GHI), unveiled with fanfare in the spring of 2009, suffered from poor follow-through but nonetheless laid down the essential principles of sustainability and country ownership, along with calls for greater integration across U.S. agencies and the elevation of gender as a guide to investments. The Presidential Directive on Development, issued in 2011, brought forward for the first time a broad, coherent framework that was very consistent with GHI.

In its first term, the Obama administration also issued other important policy guidance documents, often twinned with the launch of pilots and initiatives to test what was possible. In retrospect, the administration's policy thinking and action was especially energetic and creative on gender, HIV prevention (especially through the Blueprint for an AIDS-Free Generation), malaria, maternal mortality, polio eradication, and ending preventable childhood deaths. Implementing these innovations is now a key challenge for the second Obama term.

Major operational advances also became possible, both bilaterally and multilaterally, as rising demands for accountability drove efficiencies in the "science of delivery," improvement in the measurement of health impacts, and better implementation. The United States achieved major costs savings and efficiencies in its HIV/AIDS and malaria programs through a careful analysis of how dollars were invested, as compared with disease burdens and local capacities, and through more aggressive efforts to shape markets and thereby significantly reduce input costs. That effort, backed by new modeling exercises, resulted in a systematic rebalancing of investments that made it possible, with a fixed resource base, to expand the number of persons living with HIV on U.S.-assisted antiretroviral treatment from 4 million in 2011 to 5.1 million at the end of 2012, and to give policymakers confidence that 6 million could be reached by the end of 2013.

A similar phenomenon was seen with respect to both the Global Polio Eradication Initiative and malaria efforts; in each case, diagnostics and the delivery of key services were improved through a determined effort to get more reliable, cost-effective results.

As detailed in the chapter on multilateral institutions, the recession pushed the leadership and governing boards of the GAVI Alliance, the Global Fund, WHO, and UNAIDS to confront serious funding shortfalls; deficiencies in management, forecasting, and oversight; and the imperative to update goals and practices. As the aggregate resource base available for global health programs flattened and began to drop, competition across these international institutions intensified, as did the instability of budgets. But in recent years, systematic reform efforts have reaffirmed these institutions' value and helped renew their performance, governance, and reputations.

In 2011, following a period of uncertainty, the GAVI Alliance emerged in a much stronger, better-managed state, with a new executive director and board chair and a far clearer alignment around its core mandate and means to improve the quality of its immunization programs. The Global Fund, after a near crash in late 2011, underwent a wholesale revamping in 2012. As 2013 unfolds, a new executive director has taken the helm; and while the Fund is still fragile, its prospects for recovery are good—pending a successful replenishment and proof that the new funding model can work effectively. Both UNAIDS and WHO have pursued internal management and budgetary reforms and sharpened the definition of their core goals.

A similar argument can be made about partner countries. The abrupt stall in donor funds has ushered in a candid and focused discussion of partner countries' accountability and commitments to advancing the health of their citizens, reflecting a healthier, more mature, balanced, and long-range outlook.

These gains against the odds underscore the imperative of the United States staying the course—politically, financially, and operationally—to realize the full benefits of the policy innovations, cost savings, and institutional reforms under way. These promising processes are not yet complete, nor do they hold all the answers: additional resources are still needed. But they have set a path for the next few years around which to organize U.S. priorities.

The third lesson that surfaces across this volume is that sustained, high-level U.S. leadership—by the president, and no less important, by the secretary of state—is indispensable. It is essential to preserve the broad bipartisan consensus in support of global health, and to ensure long-term budgetary stability amid fiscal and political adversity.

It also provides the necessary diplomatic heft and political influence to drive forward complex, delicate transition agreements with partner governments and to encourage true country-ownership and commitment, while preserving trust and confidence in U.S. technical support. Ensuring that these processes are orderly, well planned, and well executed, and that neither vulnerable people nor the United States' reputation are put at risk, will demand building health into every exchange with that country's leadership.

Continuous high-level U.S. engagement is also needed to ensure that key multilateral partners improve their performance, align their efforts more closely with U.S. priorities, and undergo successful replenishments. This includes consolidating reforms at the Global Fund; moving the World Bank Group toward a more strategic approach to health; sharpening the World Health Organization's focus on its core missions; and making fuller use of the GAVI Alliance to maximize the cost-effective benefits of vaccines, especially in eliminating preventable childhood deaths and disability.

High-level U.S. diplomacy will be integral in persuading emerging powers such as China, Korea, Indonesia, India, and Brazil to adopt a more active and meaningful role in global health as emerging bilateral donors, as well as in support of the Global Fund, WHO, the GAVI Alliance, and other multilateral institutions.

It also will be a key factor in determining the endgame of the global polio eradication campaign, and whether it is possible to reach unvaccinated populations in Afghanistan, Pakistan, and Nigeria. That endgame rests to a significant degree on managing the clash between public health and global security interests. U.S. drones will continue to be deployed in Afghanistan and Pakistan, and reportedly in West Africa as well, over the coming years, at the same time that complex polio eradication efforts continue.

High-level leadership remains integral to strengthening health security worldwide. The threat posed by emerging pandemics is inherently difficult to forecast, yet the need to prepare systematically in building global partnerships is a constant. Through both civilian and military agencies, the United States is well positioned to strengthen the network of key partners' laboratories and public health institutes and expand the training of skilled personnel. At present, U.S. investments in these areas fall far short of what a long-term strategic approach really requires—a deficit that can only be overcome by leadership from the White House and the secretary of state's office.

Finally, high-level U.S. leadership is essential if the Obama administration is to remedy two chronic internal problems: the lack of a coherent, unitary vision for its global health policies; and persistent interagency conflicts stemming from the fact that no one of sufficient authority is routinely in charge.

As noted earlier, the first Obama term produced numerous creative new policies and initiatives; yet as the second term begins, there is considerable confusion surrounding their implementation. The United States claims to give priority simultaneously to an AIDS-Free Generation, maternal health, child survival, polio eradication, and malaria control.

Meanwhile, the Global Health Initiative, meant to provide an organizing framework for U.S. global health policies and programs, has collapsed without replacement.

Open tensions flared between the U.S. Agency for International Development (USAID) versus the Office of the Global AIDS Coordinator (OGAC) and the Centers for Disease Control and Prevention (CDC) during the first Obama term. The situation was exacerbated by the Quadrennial Diplomacy and Development Review (QDDR), commissioned by then– Secretary of State Hillary Clinton, which failed to clearly resolve the administration’s heated internal debate over the future leadership of U.S. foreign aid and whether or not USAID should become the premier U.S. development agency, with increased institutional autonomy and greater authority to oversee U.S. global health programs now under the control of OGAC in the Department of State.

A compounding factor was the absence of a clearly designated senior authority, above the level of the USAID administrator, the global AIDS coordinator, and the head of CDC, charged with day-to-day oversight of global health programs and integrating them into a broader development strategy. Uncertainty and weak accountability created incentives for USAID, OGAC, and CDC to prioritize preservation of their bureaucratic turf and budgets. Opportunities were missed to integrate and leverage fully the complementary assets of USAID, the State Department, and CDC. The internecine squabbles confused partner governments and international organizations and weakened the ability of U.S. ambassadors in key partner countries to achieve a coherent, unified U.S. program.

What is needed early in the second Obama administration is an updated vision that sets priorities and goals, lays down a clear division of responsibilities, and takes account of the full range of evolving U.S. commitments, as well as the widening global health agenda. It should give prominent consideration to the role of emerging powers, the trajectory of noncommunicable chronic diseases, and what development targets should replace the Millennium Development Goals, post-2015. What is also needed is clear action to put a stop to interagency dysfunction. The solution is not to re-litigate the debate over the future of U.S. foreign assistance. Rather, the solution is to designate someone at a very senior level to be in charge: e.g., a deputy secretary of state or an equivalent rank at the White House.

Across the chapters that follow, my coauthors and I have endeavored to be realistic and forward leaning; analytical and accessible; critical and fair. We encourage you to share this volume with colleagues and friends, and we welcome your feedback and comments.³

3. I can be contacted by e-mail at smorrison@csis.org.

1

U.S. PRIORITIES FOR GLOBAL HEALTH DIPLOMACY

By Katherine E. Bliss, Judyth Twigg, and J. Stephen Morrison¹

Synopsis

The practice of U.S. health diplomacy is increasingly concentrated in the domain of the secretary of state, drawing crucially on a broad range of implementing agencies. Secretary Clinton drove an unusually muscular health diplomacy during the first Obama term, emphasizing rationalizing the interagency process, elevating gender as a guiding lens, leveraging greater country ownership, committing to multilateral organizations, and focusing on results. Particular attention has been paid to building an AIDS-free generation, eliminating preventable child deaths, and launching innovative public-private partnerships.

The administration now faces questions over how—with a new secretary, fiscal challenges, and an expanding agenda—to sustain and consolidate its diplomatic outreach for global health. The strategic rationale for global health must be revised and updated. The emergence of middle-income countries as influential shapers of global health policy creates both opportunities and challenges. It is unclear whether and how the next secretary of state will pick up where Secretary Clinton left off.

Institutionalizing the expansionary use of the secretary of state's power to advance global health will be possible only through the success of the newly created Office of Global Health Diplomacy. In the current financial crisis, a robust diplomatic strategy to shore up the commitment of traditional G-8 allies is critical. The United States also needs a clearly defined diplomatic strategy toward emerging powers, leveraging both routine bilateral dialogues and the G-20.

We wish to acknowledge the many individuals who generously contributed their time and essential insights to this study. The findings and recommendations contained in this chapter are ultimately the sole responsibility of the authors. They also reflect a majority consensus of the working group members we assembled to guide this effort. We did not ask them as individuals to agree to each and every dimension of the resulting analysis, but rather to join into a process of creating a broad consensus. We would like to specifically acknowledge the following working group participants: Ed Burger, David Fidler, Julie Fischer, Yanzhong Huang, Rebecca Katz, Judith Kaufmann, John Lange, and David Shinn. We also reached out to a second tier of important experts serving in the Department of State, Department of Health and Human Services, the National Institutes of Health, and the National Intelligence Council, to provide strictly technical input; they bear no responsibility for the analysis that followed.

1. Katherine E. Bliss is a senior associate with the CSIS Global Health Policy Center. Judyth Twigg is a professor at Virginia Commonwealth University, the director of the CSIS Eurasia Health Project, and a senior associate with the CSIS Russia and Eurasia Program. J. Stephen Morrison is a senior vice president at CSIS and director of the Global Health Policy Center.

High-level State Department leadership and committed engagement across a range of departments and agencies remain essential for sustaining the global health successes that the United States has achieved. With a renewed focus on institutional capabilities, innovative multilateral approaches, and the articulation of strategic relationships on global health with emerging powers, there is ample reason to be optimistic this legacy of success will be carried forward into the next administration.

Introduction

By traditional standards, any consideration of health diplomacy should begin where the authority and leadership of U.S. diplomacy rests, namely in the domain of the secretary of state. It is that person and office, more than any other, that have the power and legitimacy to translate international health and development goals into high-level, focused diplomatic action. In the past decade, as the United States has invested billions in HIV/AIDS and other infectious diseases, the linkage between U.S. foreign policy and global health has become far more overt and profound, and the concept of health diplomacy has itself widened to encompass an ever-greater range of health-related issues. The most familiar include responses to infectious diseases (particularly HIV/AIDS, malaria, and tuberculosis, as well as emerging health threats like pandemic flu) and other risks to maternal health and child survival. Health diplomacy has expanded to encompass climate change and non-communicable diseases (NCDs, which have soared to account now for two-thirds of all mortality worldwide).² Practitioners increasingly contemplate questions such as sustainable financing of health services in low- and middle-income countries; future health targets after the Millennium Development Goals run their course in 2015; and how the United States can and should systematically engage emerging powers, which may still require foreign assistance even as they rise into new roles as donors with political muscle, financial clout, market influence, and technical expertise.

Although this essay focuses on where its practice is concentrated, at the Department of State, U.S. health diplomacy draws upon the expertise of many implementing agencies.³ Some are under the State Department's roof, most notably the Office of the Global AIDS Coordinator (OGAC), United States Agency for International Development (USAID), and Bureau of Oceans and International Environmental and Scientific Affairs (OES). Others are situated in the Department of Health and Human Services (HHS). The HHS Office of Global Affairs, whose director was elevated to assistant secretary rank in December 2012, traditionally has the lead responsibility for important multilateral relationships, most notably the World Health Organization (WHO).

Even as the Department of State has asserted greater authority over global health matters, the HHS Office of Global Affairs has remained vitally important. HHS houses the U.S. Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), the Health Resources and Services Administration (HRSA), and the National Institutes of Health

2. Richard Horton, "GBD 2010: Understanding disease, injury, and risk," *Lancet* 380, issue 9859 (December 15, 2012): 2053–54; also, Rafael Lozano et al., "Global and regional mortality from 235 causes of death for 20 age groups in 1990 and 2010: A systematic analysis for the Global Burden of Disease Study 2010," *Lancet* 380, issue 9859 (December 15, 2012): 2095–2128.

3. See Jennifer Kates and Joshua Michaud, "Raising the Profile of Diplomacy in the U.S. Global Health Response: A Backgrounder on Global Health Diplomacy," Kaiser Family Foundation, September 2012, <http://www.kff.org/globalhealth/upload/8360.pdf>.

(NIH). Health also figures in the work of the Peace Corps and the U.S. Department of Agriculture (USDA); and the departments of Defense and Homeland Security play special roles when it comes to biodefense and the intersection of health and security. As all of these players carry out their respective operational missions, each shapes bilateral relations with individual partner countries and multilateral ties through a range of international agencies and organizations.

The Obama administration in its first term had unusually muscular health diplomacy, driven by Hillary Clinton—an empowered and focused secretary of state who elevated global health as a priority tool in earning goodwill through enhancing and saving lives. An ambitious set of guiding principles and objectives emerged, along with important new initiatives, all intended to strengthen U.S. health diplomacy. In December 2012, Secretary Clinton announced that the global AIDS coordinator will now also lead a newly established Office of Health Diplomacy, further affirmation of the Department of State’s leadership in global health diplomacy.

Despite these promising developments, the results were mixed, and several uncertainties remain.

Most centrally, the Obama administration in its second term will face questions over how it will sustain and consolidate its diplomatic outreach for global health, with a new secretary, fiscal challenges, and an expanding agenda. How best to guarantee continued leadership by the secretary of state, backed by the White House, that stays abreast of a quickly evolving global health agenda? Will U.S. diplomacy be used effectively to structure orderly transitions that achieve higher “shared responsibility” by country partners—emerging priority global health goals that require sustained political will and influence? And through what vision and mechanisms can the United States best strengthen diplomatic coordination across multiple agencies, leverage their special assets, and institutionalize within them health priorities and expertise?

Policy Developments under the First Obama Administration

The recent ascent of global health as a U.S. foreign policy issue began during the second administration of President Bill Clinton, through new policy approaches to emerging infectious diseases within international environmental and scientific programs and the late elevation of HIV/AIDS in U.S. Africa policy. The foreign policy focus on global health intensified under President George W. Bush, who announced the President’s Emergency Plan for AIDS Relief (PEPFAR) in his January 28, 2003, State of the Union address, followed by the President’s Malaria Initiative (PMI) in 2005. Secretary of State Colin Powell oversaw U.S. support for the creation of the Global Fund in 2002, delivered a major speech on global health as a U.S. foreign policy priority on World AIDS Day in 2002, and established the Office of the Global AIDS Coordinator within the State Department following PEPFAR’s passage in 2003. By the end of the second Bush term in 2008, global health issues—principally HIV/AIDS but also malaria, tuberculosis, neglected tropical diseases, and pandemic influenza preparedness—had achieved unprecedented visibility and the commitment of administration officials at the highest levels, most notably the office of the president.

While global health had relatively modest visibility during President Obama’s first term in office, the White House issued the announcement of the Global Health Initiative (GHI) in April 2009; President Obama gave a major address on World AIDS Day in December 2011 and hosted a high-level reception during the International AIDS Conference (“AIDS 2012”) held in Washington, D.C., in July 2012.

No less important, President Obama provided ample space and encouragement for other senior personalities in his administration to continue and amplify the United States' ambitious global health agenda. During the Obama administration's first term, U.S. officials actively engaged their foreign country counterparts on a wide spectrum of global health issues, from HIV/AIDS to polio eradication, water and sanitation, and non-communicable diseases. In this same period, Secretary of State Hillary Clinton emerged as a dominant driver of policy and programs: she used the diplomatic power of the secretary of state's office, aggressively and strategically, to advance U.S. global health goals as part of a "smart power" agenda. In so doing, Secretary Clinton further refined the role of global health, moving it from its already important place within the U.S. foreign policy agenda closer to the core of the Department of State's mandate.

Five guiding principles received the greatest attention:

Rationalizing the interagency process. Just a few months after taking office, President Obama announced the Global Health Initiative as a vehicle for tackling fragmentation in the U.S. global health architecture. The GHI was to coordinate health programs across the State Department's Office of the Global AIDS Coordinator, the Centers for Disease Control and Prevention, and various programs led by the U.S. Agency for International Development (such as the President's Malaria Initiative, Feed the Future, and Neglected Tropical Disease Initiative) around shared goals. GHI outlined core principles, including improved monitoring and evaluation, sustainability through strengthening of country health systems, country ownership, strategic integration, and gender equality. It also set specific targets around HIV/AIDS, maternal and child health, family planning, nutrition, malaria, tuberculosis, and neglected tropical diseases. At the U.S. mission level, GHI was designed to be an integrated framework through which country teams would work coherently and comprehensively, across agencies, to implement health plans established by 42 partner countries.

GHI was integral to the 2010 Quadrennial Diplomacy and Development Review (QDDR). Under Secretary Clinton's direction, the QDDR was the first-ever effort to look across diplomacy and development efforts to devise "whole-of-government" strategies to unify multiple agencies under designated "chiefs of mission," carefully coordinating not just USAID, State, and CDC, but also the departments of Defense, Labor, Justice, and others, as appropriate, in pursuit of shared missions.⁴ This ambitious plan sought to remold the outlook of USAID and other implementing agencies behind a commitment to programmatic achievement over and above any individual agency's claim to credit. Although the QDDR's relevance for global health has recently been downplayed, it was an expansive and optimistic attempt to wrestle a diverse set of institutional players into the service of priority U.S. goals.

Elevating gender as a guiding lens. While maternal and child health have long been U.S. health and development priorities, the White House explicitly elevated women, girls, and gender equality as a core principle, and a required element of focus country strategies and implementation plans. While Clinton has repeatedly acknowledged that the Millennium Development Goal target of cutting maternal mortality by three-quarters by 2015 is probably unattainable, she has stressed vigorously the importance of new initiatives and approaches to promote the health and empowerment of women and girls. (The chapter on women's global health provides substantial additional detail.)

4. J. Stephen Morrison and Lisa Carty, "Reflections on Secretary Clinton's Launch of the QDDR," *CSIS Commentary*, December 16, 2010, <http://csis.org/publication/reflections-secretary-clintons-launch-qddr>.

Leveraging greater country ownership. Clinton has consistently trumpeted the imperative for countries that are ready to take the lead in defining their own priorities and designing their own programs to meet distinct needs—with full participation not just by country government officials and experts, but by users of health services as well. The United States’ job is to help key thinkers and implementers in these countries develop the capacity to manage, oversee, coordinate, and operate health programs over the long haul. Central to this conceptualization of U.S. partnership is devising mutually agreed transition compacts through which partner countries assume greater responsibility financially, a common-sense approach now that development assistance accounts for only 13 percent of the capital flowing into developing countries, and the majority of the world’s 10 fastest-growing economies are in Africa.⁵

Success requires sustained, high-level political will by partner countries: the tools of traditional diplomacy must be harnessed to enhance the scope and impact of other countries’ engagement to ensure that country resources are allocated both adequately and effectively and that health needs across populations are appropriately addressed. Success also requires acknowledging that country-defined priorities will occasionally lie in areas where the United States has neither funding possibilities nor interests.

Elevating multilateral organizations. In the midst of the Global Fund’s financial and managerial crisis in 2011, Secretary Clinton stood by the organization and intervened strategically to help put it on the right track. She helped keep donors from abandoning ship and set the course for instituting multiple reforms and appointing new leadership. She committed to enhanced U.S. coordination between U.S. bilateral programs and the Fund and similarly supported the role of the Global Alliance for Vaccines and Immunization (GAVI) in increasing access to new and under-used vaccines in poor countries. (The U.S. approach to the Fund, the GAVI Alliance, UNAIDS, WHO, and the World Bank are treated in greater detail in the chapter on multilateral partners.)

Focusing on results. A “results focus” on the cost-effective delivery of services and proof of health impacts has become a conspicuous part of the U.S. global health lexicon. Starting with efforts to overhaul the Foreign Assistance Framework under Secretary Condoleezza Rice, the Department of State has been increasingly engaged in the process of defining objectives, establishing indicators, and measuring outcomes of overseas health programs, among others. Over the past four years, Secretary Clinton has explicitly argued for the need to make tough calls, identify programs that don’t work, and phase out nonperformers. USAID’s procurement reform followed: a multiyear effort to achieve much higher accountability by implementers of U.S. programs.

Three substantive objectives received considerable emphasis:

Building an AIDS-free generation. Working with an interagency team under the leadership of Global AIDS Coordinator Ambassador Eric Goosby, Secretary Clinton has reframed and redefined the U.S. HIV/AIDS strategy. In a November 2011 speech at the National Institutes of Health marking the end of three decades battling HIV/AIDS, she renewed the push for an “AIDS-free generation,” a world where no child is born with the virus, adolescents and adults are at dramatically decreased risk of contracting it, and those already infected have universal access to treatment.⁶ Insisting that both strategy and tactics must be science-based, she has focused on three

5. Clinton, “A World in Transition,” June 1, 2012; and Hillary Rodham Clinton, “Keynote at the Fourth High-Level Forum on Aid Effectiveness,” November 30, 2011, <http://www.state.gov/secretary/rm/2011/11/177892.htm>.

6. “Clinton calls for evidence-based efforts to defeat AIDS,” *Global Health Matters*, NIH, November/December 2011, <http://www.fic.nih.gov/News/GlobalHealthMatters/nov-dec-2011/Documents/ghmnov-dec2011.pdf>.

key biomedical interventions of proven prevention/treatment effectiveness: ending mother-to-child transmission, expanding voluntary medical male circumcision, and scaling up treatment of those living with HIV/AIDS. These interventions form the cornerstone of a 54-page “blueprint” released in advance of World AIDS Day 2012. (The HIV/AIDS chapter treats these issues in greater detail.)

Eliminating preventable child deaths. At the June 2012 Child Survival Call to Action Conference held at Georgetown University, Secretary Clinton urged more than 700 leaders and experts from 80 countries to eliminate the gap in child mortality between rich and poor countries and to bring about dramatic reductions in the numbers of children worldwide who die before their fifth birthdays. Her remarks focused on investing in girls’ education, improving access to voluntary family planning, and most of all, targeting the 24 countries where 80 percent of all child mortality occurs, along with the illnesses and conditions that claim the most lives: pneumonia, diarrhea, malaria, and neonatal complications. (The malaria chapter treats these issues in greater detail.)

Launching innovative public-private partnerships. Building on initiatives launched during the Bush administration’s second term, nontechnical agencies contained in the Department of State increased the visibility of global health partnerships during the first Obama administration. A guiding presumption was that by working with NGOs, international organizations, philanthropic foundations, and the private sector, the United States can achieve foreign policy goals more effectively than it can alone.

“Saving Mothers, Giving Life” is a five-year effort to strengthen health systems specifically for the first 24 hours around labor, delivery, and the immediate postpartum period, piloting in Uganda and Zambia.⁷ “Together for Girls” facilitates data collection on sexual violence against children, starting in Kenya, Tanzania, and Zimbabwe. The Global Alliance for Clean Cook Stoves has set a goal of converting 100 million households from reliance on burning wood for household cooking and heating to the use of improved stoves by 2020, toward the dual ends of health improvement and reduction of climate change. “Pink Ribbon, Red Ribbon,” launched in September 2011, builds on existing PEP-FAR platforms for HIV/AIDS services to expand cervical and breast cancer prevention, screening, and treatment for women in sub-Saharan Africa and Latin America. And the relatively new U.S. Water Partnership unites dozens of public, private, and university partners to improve water security around the world.

Ongoing Challenges

Revising and updating the strategic rationale for global health. The elevation of global health within U.S. foreign policy has run parallel with a broader expansion of international efforts to integrate health and foreign policy initiatives over the past decade. For example, the 2007 Oslo Declaration affirmed the commitment of the seven signatory countries (Brazil, France, Indonesia, Norway, Senegal, South Africa, and Thailand) to integrate their health and foreign policy efforts.

From the U.S. standpoint, the strategic rationale for global health has shifted. The perceived threat of emerging infectious diseases has receded, and the “smart power” lens has lost much of its allure: there is a predominant emphasis today on shared responsibility and orderly transitions and far less on winning hearts and minds. At the same time, there are increased competitive pressures to invest scarce dollars in agriculture, nutrition, energy, and climate change mitigation, and to integrate

7. Janet Fleischman, “Clinton Launches Ambitious Maternal Health Project,” June 1, 2012, <http://www.globalpost.com/dispatches/globalpost-blogs/global-pulse/clinton-launches-ambitious-maternal-health-project>.

health investments with these other worthy development goals. A host of new challenges have also emerged, including discussions on what framework will replace the MDGs after 2015, whether “universal health coverage” or some similar singular concept can capture a multitude of health interests, climate change, the economic impact of non-communicable diseases, WHO reform, and other epidemiological and demographic challenges such as population aging, tobacco use, and the peak of HIV/AIDS mortality. The U.S. lacks a coherent health strategy that acknowledges and responds to these shifts, outlines priorities, and delineates the corresponding roles and responsibilities of various government agencies and partners.

Relating to emerging powers. The emergence of middle-income countries as activist members of the global health community creates opportunities and challenges for U.S. foreign policy during the next administration. Within their borders, many emerging powers face considerable economic inequality, heavy disease burdens, and the need for technical expertise and knowledge of best practices. To varying degrees, these emerging powers, many of them former recipients of U.S. overseas assistance, are also emerging donors who look outward to leverage their political acumen, financial clout, market influence, and technical expertise. It is not yet clear what diplomatic strategy the United States can and should pursue in engaging these states on common global health interests, beyond a general progression beyond the donor-recipient paradigm to one of partnership.

The governments of Brazil and China have accelerated the articulation of overseas health programs, typically framed in terms of horizontal or South-South cooperation. India, through both government programs and its private sector, is developing outreach on global health with neighboring countries. But in contrast to the United States’ broad agreement with the Europeans, Japanese, and Canadians on approaches to global health, U.S. health and foreign policy approaches are not always in line with South-South cooperation efforts. Brazil frames its health outreach as part of a larger human rights agenda, also using the strengthening of relationships on health with other southern countries to gain influence in multilateral settings and offset what some Brazilian officials view as the power and privilege of the northern countries. China’s health outreach, which began in the 1960s as an integral aspect of a revolutionary agenda, is now focused on establishing relationships with other developing countries. Trade relations are paramount for China as it cultivates favor in support of its political, economic, and natural resource agendas, sometimes at odds with U.S. commercial and other interests. India has begun to cultivate economic relationships with African countries in addition to its traditional relations with others in its immediate neighborhood (including Afghanistan). Mexico and South Korea are actively building new programs that may present opportunities for joint initiatives.

Achieving long-term leadership and institutional capacity. The legacy of the first Obama term creates two conspicuous challenges: how to raise the expectations and incentives for the next secretary of state to pick up where Secretary Clinton leaves off, sustaining the integration of global health into the overall U.S. foreign policy agenda; and how, in service of this goal, to strengthen the institutional framework for global health—within the Department of State and elsewhere—so that its prioritization is not unduly dependent on the secretary’s inclinations and preferences.

The legacy is mixed and uncertain in achieving interagency unity. Secretary Clinton’s success required a strong coordinating element within the State Department as the political hub for global health work. Clinton’s chief of staff has overseen a strong, reasonably integrated set of key officials that included the global AIDS coordinator (and PEPFAR Country Coordinators), the ambassador-at-large for global women’s issues (within the Office of the Secretary of State), the director of policy and planning (and codirector of the QDDR), the GHI executive director, and the USAID admin-

istrator (together with a strong field of USAID Bureau for Global Health deputies). There has also been an expansion of the network of HHS-associated health attachés and other agency officials working overseas, requiring close alignment with the secretary of health and human services, the HHS assistant secretary of global affairs, the director of the CDC, and the FDA commissioner (and CDC and FDA international staff).

Virtually across the board, the implementing agencies have achieved significantly greater muscularity over the last four years, with more successful technical engagement and bilateral ministry-to-ministry capacity building through the CDC and the recent release of the first-ever HHS and CDC global health strategies, and significant steps forward by the FDA in knitting the regulatory regime into a more coherent global entity.

Nonetheless, with a small number of exceptions, strategic coordination has faltered in key respects. First and foremost, the GHI executive director never gained sufficient budgetary or political authority, or staff capacity, to fulfill its mandate. The initial \$63 billion, six-year GHI funding pledge was scaled back almost immediately, and in any event it never represented significant new money. Despite its legislative mandate to strengthen interagency cooperation on HIV/AIDS, OGAC was also unsuccessful, especially with respect to USAID. Neither OGAC nor GHI enjoyed sufficient leverage; each often lacked high-level backing from the White House and secretary of state as each struggled to reduce interagency clashes. Consequently, tensions between USAID, State/OGAC, and the CDC intensified rather than waned, and the entire GHI initiative got tangled between competing White House and State Department visions for USAID and foreign aid reform.

Under the 2010 QDDR plan, GHI leadership was to shift to USAID by 2012, conditioned on “readiness” measured by achievement of a vaguely defined set of benchmarks: for example, level of interagency coordination, use of empirical evidence to guide policy, and engagement with local governments for program planning. By early summer of 2012, Secretary Clinton had determined not only that these conditions had not been met, but that the Office of the GHI would be shut down. In mid-December, the administration announced that the global AIDS coordinator would become also the head of a newly established Office of Global Health Diplomacy; its charge is to strengthen the authority and technical expertise of U.S. ambassadors to key partner countries. It remains to be seen if the new dual post—OGAC/GHD, actually two separate positions currently filled by the same person—has enough clout to achieve greater integration across agencies.

Sustaining the secretary’s many new partnerships. With the Department of State’s backing, a number of public-private partnerships were launched during the first Obama term, but the effort remains in a nascent stage. To varying degrees, each requires careful and intensive oversight, including coordination of far-flung business, multilateral, and nongovernmental interests. It is unclear whether there will be effective management within the State Department to carry these initiatives successfully into the future, absent an explicit mechanism for their support.

Policy Recommendations

1. Institutionalize the secretary of state's leadership role with respect to global health.

Although much of the recent U.S. effort on global health diplomacy has depended on Secretary Clinton's own commitments and interest in spotlighting global health as a foreign policy issue, there is a solid argument for institutionalizing the expansionary use of the secretary of state's power to advance global health goals. The president, Congress, and advocacy groups are well positioned to shape expectations that global health should be a permanent and priority part of the secretary's portfolio. The next secretary of state, and all those to follow, should share Hillary Clinton's expertise, interest, and passion for global health not just as a humanitarian endeavor, but as an organic component of U.S. diplomacy and of U.S. national security.

This will only be possible with a commitment to the success of the newly created GHD post: ensuring that its mission, roles, and responsibilities are clear, that it is adequately staffed, that all global health functions in the State Department fall under its purview, and that it truly has the means to enhance the capacity of ambassadors in key partner states through expanded ambassadors' briefing and training, greater technical expertise, and ambassadors' enhanced ability to summon high-level Washington political will and influence in negotiations with partner governments over shared responsibility and transition planning.

Finally, priority must be given to maximizing effective coordination across agencies and achieving true unity of programs under a "whole of government" approach to shared goals. Critically, as the leads on all diplomatic matters -- including health diplomacy -- ambassadors must gain more capacity to incentivize and reward field staff for productive contributions to interagency processes, including real impact on career paths in home agencies, and greater budgetary authority to shift funds nimbly to respond to emerging priorities. This will require routine high-level oversight—realistically not by the secretary but by a designated deputy secretary—and support directly from the White House and National Security Staff to strengthen the recognition and staffing necessary to implement this mandate. It may even require a new career path through the GHD framework, including experts with both technical and diplomatic skills, to replace the hodgepodge of hiring and reporting mechanisms that currently hinder unity of command and career development in such an important area.

2. Devise a robust G-8 diplomatic strategy.

The most logical and appropriate focal point for an aggressive G-8 strategy is the Global Fund, as its new funding model is piloted, its new leadership team settles into place, and the next three-year replenishment approaches in 2013. The Global Fund in a delicate process of rebuilding remains a priority not just for the United States, but for France, the United Kingdom, and Japan as well.

Over the past two decades, the G8 countries have been reliable partners in advancing the global health agenda, but in the current financial crisis, shoring up the commitment and resolve of traditional G8 allies is critical. Japan has traditionally been one of the foremost providers of overseas development assistance, but health has constituted a relatively small share of that portfolio. Japan is justifiably proud of its own domestic health record and has, through the Japan International Cooperation Agency (JICA) and its foreign ministry, engaged on global health issues through public-private partnerships, most notably the Sumitomo Chemical Company's support for Roll Back Malaria. The European countries, facing their own fiscal crises, are changing strategies on

global health. Canada is maneuvering to become a more influential global health player. The United States should work through G8 and existing bilateral channels to help focus the energies of traditional global health partners, identifying opportunities for partnering strategically—and with the private sector—where appropriate.

3. Define a U.S. diplomatic strategy toward emerging powers.

There is currently no U.S. strategy toward emerging powers and global health. Developing one will require setting clear priorities; defining target outcomes; designating lead offices within the State Department and elsewhere; and thinking through how such a strategy leverages both the routine U.S. bilateral dialogues with Brazil, China, India, South Africa, South Korea, and other powers, and the G-20 and other established forums for engaging emerging powers.

While the rise of so many middle-income countries as global health players presents challenges for the United States, it also provides opportunities for U.S. global health diplomacy. Beyond working with G8 partners to support global health initiatives, the United States should more strategically engage with countries such as China, Brazil, India, and South Africa to contribute to such multilateral organizations as the Global Fund and to collaborate trilaterally to further global health projects in third countries. This will allow the United States to better appreciate the topics that motivate emerging powers to engage in overseas outreach. It could also create opportunities for U.S. diplomats to better articulate strategies within traditional bilateral dialogues for discussion regarding key global health issues, including: intellectual property rights (a key issue given the growing global non-communicable disease threat and problems of access caused by high drug prices) and the implementation of the International Health Regulations; prequalification by WHO to produce high-quality, low-cost medications, vaccines, and medical products for poor consumers; reaching consensus on a framework to succeed the Millennium Development Goals after 2015; and cooperation across national regulatory agencies to improve the safety of internationally traded food and drugs. More effective harnessing of established multilateral forums is also essential. The BRICS health ministers, for example, meet regularly to identify areas of shared priority. The U.S. should leverage its relationships with the G-20, the Association of Southeast Asian Nations (ASEAN), the Organization of American States (OAS), the African Union (AU), and others to lay out systematically a diplomatic agenda to advance its global health interests.

Conclusion

High-level State Department leadership, combined with able and committed leadership across a range of departments and agencies, remains an essential element to the success and impact that the United States has achieved in the past decade in the area of global health. It has become evident in this period just how complex and difficult it can be to ensure coherence within the U.S. government, behind strategic goals; just how quickly evolving the global health agenda is, going beyond relatively simple clinical and technical fixes to encompass political, economic, cultural, financial, and social challenges, and in competition with other worthy development goals; and just how different and demanding the overall foreign assistance environment has become, several years into an era of austerity. During the past four years, U.S. diplomatic outreach to advance global health has benefited from the vision, dedication, and skill of a broad range of actors. There is ample reason to be optimistic this legacy will be carried forward into the second Obama term.

2

U.S. PRIORITIES FOR HIV/AIDS

By Sharon Stash¹

Synopsis

The United States, through its leadership and investments in the President's Emergency Plan for AIDS Relief (PEPFAR) and the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund), has helped partner countries achieve impressive gains in their fight against HIV/AIDS over the past decade.

Despite a difficult economic environment during its first term, the Obama administration systematically built on the George W. Bush administration's achievements, spurring greater political and financial commitments from donors, the private sector, and affected countries. In December 2011, the administration set ambitious new goals for the fight against HIV/AIDS; and in November 2012, the Office of the Global AIDS Coordinator (OGAC) outlined an approach—or Blueprint—for PEPFAR and partner countries to create an "AIDS-free generation." The Blueprint calls for focused, up-front investments in a few evidence-based, high-impact prevention interventions, with the aim of enabling national HIV/AIDS programs to prevent many new infections and reduce the future need for treatment.

Yet, implementing the Blueprint will prove challenging. Critical unanswered questions remain regarding how much the approach will cost and who will pay for it. The current climate of budget austerity could constrain financial commitments to PEPFAR and the Global Fund. Partner countries have already begun to shoulder greater shares of HIV/AIDS program costs, but will countries own the goals of an AIDS-free generation or will competing health and development priorities prevail?

In the coming years, national HIV/AIDS programs will be increasingly country-led and -financed, but U.S. leadership, technical, and financial support will remain no less essential. The administration can take a few steps to sustain progress made in reversing the HIV/AIDS pandem-

The findings and recommendations contained in this chapter are ultimately the sole responsibility of the author, who chaired several meetings of the CSIS working group on HIV/AIDS over the course of the fall of 2012. Special thanks are in order to the working group members: Chris Beyrer, Sally Canfield, Lisa Carty, Chris Collins, Jennifer Cooke, Gina Dallabetta, Janet Fleischman, Carolyn Hart, Alisha Kramer, Peter Lamptey, Steve Morison, Phillip Nieburg, Jirair Ratevosian, Cheryl Parker Rose, Todd Summers, and Jason Taylor Wright. The chapter's findings and recommendations reflect the majority consensus of that group: members did not need to agree, unanimously, to each and every dimension of the resulting analysis. Rather, they identified with a broad consensus that emerged through the group's deliberations. We are also grateful to a second tier of important experts serving in relevant U.S. government departments and agencies who kindly provided vital technical input. These individuals and their respective institutions bear no responsibility for the CSIS chapter on HIV/AIDS that the working group produced.

1. Sharon Stash is the deputy director and a senior fellow with the CSIS Global Health Policy Center.

HIV/AIDS Pandemic in 2011

HIV/AIDS remains a serious global threat.

- In 2011, there were approximately 2.5 million new HIV infections worldwide.
- In 2011, there were 1.7 million AIDS-related deaths.

Progress is being made.

- Between 2001 and 2011, the rate of new HIV infections was reduced by more than 50 percent among adults (age 15 to 49 years) in 25 countries.
- In 2011, 8 million people (54 percent of eligible people) worldwide received treatment with effective antiretroviral drugs.
- The number of people dying from AIDS-related causes in sub-Saharan Africa declined by 32 percent, from 1.8 million to 1.2 million, between 2005 and 2011.

Major challenges persist.

- In 2011, 6.8 million people remain eligible and waiting for treatment.
- In 2011, only 30% of treatment-eligible pregnant women living with HIV were receiving ART.

Source: UNAIDS, “UNAIDS World AIDS Day Report 2012,” December 2012, http://www.unaids.org/en/resources/campaigns/20121120_globalreport2012/globalreport/.

ic: provide high-level leadership and vision; prioritize shared responsibility and orderly transitions with partner countries; improve operational leadership within and between U.S. agencies; preserve a strong congressional role; and sustain current funding levels to partner countries and for research to advance the goals of an AIDS-free generation.

Introduction

The President’s Emergency Plan for AIDS Relief (PEPFAR), launched in 2003 by President George W. Bush, is the largest and most successful U.S. global health initiative in history, with an estimated cumulative expenditure of \$44.3 billion—\$6.4 billion in 2012 alone.² This includes a substantial U.S. contribution to the Global Fund to Fight AIDS, Tuberculosis and Malaria (Global Fund), a public-private partnership established in 2002 with strong U.S. backing, and which has become the largest financing mechanism of programs to fight three of the world’s deadliest pandemics.³

U.S. investments through PEPFAR and the Global Fund, coupled with technical and logistical support from numerous government and contracted agencies, have helped countries achieve impressive gains in their fight against HIV/AIDS. PEPFAR supports 5.1 million people with lifesav-

2. This is the sum of actual expenditures from 2004 to 2011 and expected expenditures for 2012. Tiaji Salaam Blyther, “The President’s Emergency Plan for AIDS Relief (PEPFAR): Funding Issues after a Decade of Implementation, FY 2004–FY 2013,” Congressional Research Service, October 10, 2012, <http://fpc.state.gov/documents/organization/200065.pdf>.

3. In the period 2011 to 2013, the United States pledged contribution to the Global Fund has amounted to \$4 billion, representing a 40 percent rise over earlier investments.

ing treatment for HIV, and is on track to reach the goal President Obama set on World AIDS Day 2011 of reaching 6 million people by the end of 2013.⁴ The Global Fund, which receives about one-third of its support from the U.S. government, currently extends treatment to 4.2 million people.⁵

Over the past four years, high-level U.S. leadership, in particular from Secretary of State Hillary Rodham Clinton and Ambassador Eric Goosby, the U.S. Global AIDS Coordinator, has helped spur commitments from other donor nations, private foundations, the private sector, and most importantly, affected countries. This has helped accelerate the dialogue between the United States and partner governments over increasing national governments' shares of HIV/AIDS program costs. Secretary Clinton has also called for PEPFAR to be integral to an ambitious, comprehensive effort to meet the health needs of women and girls.

PEPFAR has benefitted from exceptional bipartisan support. For more than a decade, a core group of activist members of Congress, both Republicans and Democrats, have provided strong leadership, drafting and winning passage of two detailed congressional authorizations for PEPFAR, monitoring results, visiting programs abroad, and taking personal pride in the program's achievements.

The State Department's Office of the Global AIDS Coordinator (OGAC), legislatively mandated to fulfill a central coordination role, and equipped with its own dedicated budget, has been integral to PEPFAR's performance. In late 2012, Secretary of State Clinton announced that Global AIDS Coordinator Goosby is now also to head the State Department's newly established Office of Global Health Diplomacy, tasked with strengthening the authority and influence of U.S. ambassadors serving in key partner countries.

In addition, recent scientific discoveries have reinvigorated the field of HIV prevention.⁶ Based on these promising results, the Obama administration set ambitious new goals for the fight against HIV/AIDS, outlined in the Secretary of State's *Blueprint for an AIDS-free Generation*, released November 29, 2012.⁷

Yet, sustaining the past decade's complex and costly achievements will be a challenge. The current climate of budget austerity will strain U.S. financial commitments to PEPFAR, the Global Fund, and other U.S. global health efforts. Already, U.S. appropriations for global HIV/AIDS programs have leveled off. Caution, realism, and a constructive long-term view will be watchwords during the Obama administration's second term.

There is much at stake: the real possibility of significantly reduced U.S. spending over the next four years could retard progress, have great ethical implications, and contribute to a resurgence of HIV infections. In its second term, the Obama administration will need to provide a smart, forward-looking vision to sustain U.S. gains against HIV/AIDS—one that acknowledges current U.S. economic realities and builds toward sustainable, country-led national HIV/AIDS programs.

4. Barack Obama, "Remarks by the President on World AIDS Day," December 2011, <http://www.whitehouse.gov/photos-and-video/video/2011/12/01/president-obama-world-aids-day#transcript>.

5. The Global Fund, "Global Fund Support Extends Antiretroviral Treatment to 4.2 Million People," news release, November 2011, http://www.theglobalfund.org/en/mediacenter/newsreleases/2012-11-29_Global_Fund_support_extends_antiretroviral_treatment_to_4,2_million_people/.

6. Nancy Padian et al., "HIV Prevention Transformed: The New Prevention Research Agenda," *Lancet*, 378, issue 9787 (July 16, 2011): 269–78.

7. U.S. Department of State, "PEPFAR Blueprint: Creating an AIDS-free Generation," November 2012, 33, <http://www.pepfar.gov/documents/organization/201386.pdf>.

Policy Developments under the First Obama Administration

Despite a difficult economic environment, the Obama administration systematically built on the George W. Bush administration's achievements, successfully making the case to the American people that U.S. leadership in the fight against HIV/AIDS is strategic and grounded in shared humanitarian values. Addressing HIV and other global health challenges is now seen as an important "soft power" tool that generates goodwill toward the United States abroad even as it saves and enhances lives, stabilizes communities, and contributes to productivity. Perhaps most important, the American public has strongly supported current levels of U.S. spending on HIV/AIDS in developing countries.⁸

Reducing costs. A heavy focus on reducing commodity and service delivery costs has contributed to significant management efficiencies and savings, making it possible to achieve considerably "more with less." PEPFAR's efforts to implement pooled procurement of lower-cost, generic antiretroviral drugs led to especially big payoffs: the annual cost of treatment per person dropped from nearly \$1,100 to \$335. In fiscal year 2010, roughly 97 percent of all antiretroviral drugs purchased by PEPFAR were generic formulations, up from about 15 percent in 2005.⁹

Ensuring a supportive U.S. domestic policy environment. In 2010, the administration launched a National HIV/AIDS Strategy to address the domestic epidemic, enacted major health reforms, and lifted an HIV travel and immigration ban, permitting the return of the International AIDS Conference to the United States in 2012.¹⁰ These steps have enhanced U.S. credibility globally.

Translating science into action. OGAC has done an impressive job of translating recent scientific advances into programmatic action, leading to the U.S. announcement in November 2011 that it would seek to achieve an AIDS-free generation. A landmark study found that in 2011 viral suppression achieved in patients receiving early and effective treatment with antiretroviral drugs dramatically reduced their risk of transmitting HIV to their sexual partners. Several studies demonstrated that male circumcision reduces HIV acquisition among heterosexual men and that wide-scale implementation of voluntary male circumcision programs is feasible and affordable. Far more effective approaches have been set in place to prevent mother-to-child transmission (PMTCT) and that address the needs of both mothers and babies. Recent success in South Africa and other countries suggests that perinatal HIV transmission and HIV-related deaths among infants can be reduced to low levels.

8. As in previous surveys dating back to 2002, few (16 percent) Americans in 2012 say the United States is currently spending too much on preventing and treating HIV in developing countries; over a third (37 percent) say the United States is spending the right amount in this area; while a slightly smaller share (32 percent) say we are spending too little. Washington Post/Kaiser Family Foundation, "What's new in public opinion on HIV/AIDS? Highlights from the Washington Post/Kaiser Family Foundation Survey of Americans on HIV/AIDS," July 2012, <http://www.kff.org/kaiserpolls/upload/8334-F.pdf>.

9. U.S. Department of State, "PEPFAR Blueprint: Creating an AIDS-free Generation," 41, November 2012, <http://www.pepfar.gov/documents/organization/201386.pdf>.

10. See Katherine Bliss, *The International AIDS Conference Returns to the United States: Lessons from the Past and Opportunities for July 2012* (Washington, D.C.: CSIS, March 2012), https://csis.org/files/publication/120327_Bliss_InterAIDSConference_Web.pdf.

OGAC has taken up these new scientific opportunities, through research to design more effective programs, timely guidance documents, and cost analyses and modeling exercises to inform its choice of priority programs.

Increasing the shared responsibility of partner countries. In line with the last PEPFAR reauthorization (2008–2013), U.S. programs have shifted from an emergency response to an approach that can sustain programs over time. This reorientation reflected a broader shift of opinion and norms in favor of country-led development.¹¹ The drive for increased country ownership has led OGAC to develop detailed partnership frameworks and implementation plans that lay out the respective commitments over time of the United States and partner governments, as well as other multilateral and bilateral donors.

Addressing social disparities that drive HIV epidemics. Under the first Obama administration, a special focus on women and girls and key high-risk populations was developed across OGAC's major policies and programs. (For more detail, see the chapter on women's global health.)

In reauthorizing PEPFAR, Congress recognized that an effective response to global HIV/AIDS requires addressing gender inequalities; creating an AIDS-free generation will require a similar focus. PEPFAR acknowledges that persistent disparities in HIV infection (women and girls account for 60 percent of those living with HIV in Africa) are rooted in “systematic disadvantages,” such as coerced sex and early marriage, that are linked to unintended pregnancy, HIV, and sexual violence.¹² Under the Obama administration, PEPFAR elevated its focus on women and girls, building on the gender strategies developed under the Bush administration and the supportive language in the 2008 reauthorization. Over the last five years, PEPFAR focused in particular on gender-based violence and HIV in over 28 countries, and in 2010 launched a gender-based violence response initiative in Tanzania, Mozambique, and Democratic Republic of Congo, totaling \$48 million. The initiative tried different approaches for working with communities and health facilities to prevent gender-based violence and to support its survivors.

To address the reproductive health needs of HIV-positive women, PEPFAR has strengthened its guidance on promoting linkages between HIV and family planning programs. Family planning not only improves HIV/AIDS outcomes for women, it reduces mother-to-child transmission. However, PMTCT programs have been less successful in linking HIV-positive pregnant women to treatment for themselves. UNAIDS estimates that, in low- and middle-income countries, only 30 percent of treatment-eligible pregnant women living with HIV were receiving antiretroviral therapy in 2011.¹³ As part of the Global Health Initiative, PEPFAR program implementation is to

11. As exemplified in the Paris Declaration on Aid Effectiveness (<http://www.oecd.org/dac/aideffectiveness/43911948.pdf>) and embraced by multilateral organizations including the Global Fund and UNAIDS, aid recipients are expected to forge their own national development strategies with their parliaments and electorates, and set clear goals and monitor progress toward them. On their part, donors are expected to support national strategies and work with countries and other development partners to streamline efforts.

12. U.S. Department of State, “PEPFAR Blueprint: Creating an AIDS-free Generation,” 33, November 2012, <http://www.pepfar.gov/documents/organization/201386.pdf>.

13. UNAIDS, “UNAIDS World AIDS Day Report 2012, December 2012, 35, http://www.unaids.org/en/media/unaids/contentassets/documents/epidemiology/2012/gr2012/JC2434_WorldAIDSday_results_en.pdf.

be guided by the 2011 Supplemental Guidance on Women, Girls, and Gender Equality, designed to address gender-related inequalities that impact the health of women and girls.¹⁴

OGAC has also emphasized the importance of addressing “key populations,” including gay and bisexual men, injecting drug users, and sex workers. Even in African countries where HIV is most commonly transmitted through heterosexual relationships, key populations suffer disproportionately high rates of HIV infection and poor access to treatment and care. PEPFAR reauthorization legislation called for PEPFAR to engage with countries to address epidemics occurring among these marginalized groups. PEPFAR subsequently developed technical guidance documents for implementers on how to reduce the transmission of HIV among men who have sex with men and people who inject drugs.

In July 2012, the secretary of state announced a three-part program to reach key populations, including a \$15 million investment in implementation research to identify specific interventions that are most effective for each key population; a \$20 million challenge fund to support country-led plans to expand services for key populations; and \$2 million investment to bolster the efforts of civil society groups to reach key populations. In December 2012, Ambassador Goosby emphasized his commitment to use U.S. diplomatic pressure to confront discriminatory laws and policies.

Achieving an AIDS-free generation. PEPFAR’s new *Blueprint for Creating an AIDS-free Generation* details the strategies that can maximize the impact of HIV prevention and treatment programs. Three core HIV prevention interventions include PMTCT; antiretroviral treatment (ART) for people living with HIV;¹⁵ and voluntary medical male circumcision (VMMC) for HIV prevention. HIV testing and counseling, condoms promotion, and other prevention activities targeted to key high-risk populations augment these interventions. The Blueprint employs statistical models to demonstrate that, even under varying country scenarios, it is possible to achieve dramatic reductions in new HIV infections through targeted investments in this combination prevention program.

Ongoing Challenges

Implementing the Blueprint’s recommendations. OGAC asserts that, when tailored to local epidemiologic and social contexts, combination prevention will reduce rates of HIV transmission. Yet many scientists and implementers are concerned that a disproportionate focus on biomedical interventions ignores the behavioral, social, and structural factors that drive HIV infections, that put women and girls and key populations at greater risk, and that prevent many from accessing treatment and prevention services. Others question the financial feasibility of the new approach, especially the heavy emphasis on broad and early access to HIV treatment.

As it strives to achieve an AIDS-free generation, the second Obama administration will face the challenge of balancing investments in the three core biomedical interventions while continuing to support condoms, HIV testing and counseling, and other effective prevention interventions. Where epidemics are occurring among higher-risk populations, countries will have to target effective HIV prevention programs to those groups that are most at risk of HIV infection

14. U.S. Global Health Initiative, “Global Health Initiative Supplemental Guidance on Women, Girls, and Gender Equality Principle, n.d., <http://www.ghi.gov/resources/guidance/161891.htm>.

15. Antiretroviral treatment (ART) reduces the amount of virus circulating in the body, thereby reducing the chance that an HIV-positive person transmits the virus to others.

based on the best available scientific evidence and to create and maintain a supportive environment for people to access programs.¹⁶ Programs to reduce gender-based violence will require improved measurement.

The next phase of implementation will also bring new programmatic challenges to the forefront. For example, better treatment and prevention outcomes are obtained when antiretroviral therapy is started early, when an individual's CD4 levels are high,¹⁷ and when that treatment is sustained without interruption. The success of programs depends not only on getting people into treatment early but also on having them adhere successfully to drug regimens. For countries that choose it, the Blueprint also supports a new approach to preventing mother-to-child transmission that places all HIV-positive pregnant women on treatment for life, without interruption (Option B+). Yet, expanding new prevention technologies, such as Option B+ and medical male circumcision, can be costly: their introduction will require high-level advocacy to persuade partner-country governments and providers that they are highly impactful and should be priorities.

Lastly, the Blueprint leaves unanswered the critical question of how much its implementation will cost and how that will be financed. As a December 2012 *Lancet* editorial explains, "Although there are proposed plans to achieve greater value for money in the report [PEPFAR Blueprint], something important is missing—how much the ambitious goal will cost in general and where the global resources or financial investments will come from. This question is imperative to ask and answer at this time of financial austerity."¹⁸ Will partner countries own the ambitious goals of an AIDS-free generation or will competing priorities prevail? In the majority of PEPFAR-supported countries, the annual cost of maintaining a person on treatment is several-fold higher than national health expenditures per capita. There is even more reason for concern in countries where HIV epidemics are concentrated in marginalized populations, and where restrictive laws and social prejudice already severely limit prevention and treatment options for men who have sex with men; sex workers; and people who inject drugs.

Achieving a coherent and unified effort. OGAC's ability to lead has been hindered from the outset by chronic interagency tensions and the absence of consistent high-level political backing of OGAC's leadership role from the secretary of state and the White House. The Global Health Initiative (GHI), announced by the White House in 2009, had the expressed goal of achieving greater integration across agencies—yet GHI ultimately languished in the absence of an adequate mandate, authority, or budgetary power to coax agencies into higher levels of cooperation.

Chronic interagency tensions often marred PEPFAR's strategic planning processes and injected confusion into dialogues with—and programming in—partner countries. In countries receiving large amounts of PEPFAR funding, this made it difficult for U.S. ambassadors, who lead PEPFAR efforts abroad, to bring sensible unity to country operating plans and coordinate with governments and other development partners.

16. Janet Fleischman, *Gender-based Violence and HIV: Emerging Lessons from the PEPFAR Initiative in Tanzania* (Washington, D.C.: CSIS, July 2012), https://csis.org/files/publication/120709_Fleischman_GenderBasedViolence_Web.pdf; Richard H. Needle and Lin Zhao, *HIV Prevention among Injection Drug Users: Strengthening U.S. Support for Core Interventions* (Washington, D.C.: CSIS, April 2010), http://csis.org/files/publication/100408_Needle_HIVPrevention_web.pdf; and Phillip Nieburg and Lisa Carty, *Injection Drug Use in Ukraine: The Challenges of Providing HIV Prevention and Care* (Washington, D.C.: CSIS, March 2012), http://csis.org/files/publication/120314_Nieburg_InjectionDrugUkraine_web.pdf.

17. Medical professionals refer to the CD4 count to decide when to begin treatment during HIV infection. Higher CD4 counts mean stronger immune systems.

18. Editorial, "The beginning of the end of AIDS?" *Lancet* 380, issue 9858 (December 8, 2012): 1967.

Over the past five years, OGAC took on the complex job of trying to reach scientific consensus on the most effective approaches to HIV prevention. The struggles that ensued ultimately highlighted differences between government agencies in their technical orientations: for example between the CDC's focus on biomedical interventions and USAID's focus on changing health behaviors. OGAC seemed often to concentrate on building its own internal technical capacity rather than on fully leveraging the resources and talents of the agencies it is called upon to lead.

There is hope that the December 2012 decision to have the AIDS coordinator also head the newly established Office of Global Health Diplomacy will strengthen OGAC's authority and capacities and contribute to better interagency cooperation. Whether that will prove true remains to be seen.

Setting congressional priorities. Two consecutive five-year congressional authorization acts have been highly valuable tools in creating congressional-executive consensus and laying out broad goals. The Blueprint for an AIDS-free generation lays out a future course for PEPFAR and, in so doing, provides a partial map for U.S. leadership. But with the 2008 five-year congressional authorization of PEPFAR authorization set to expire in September 2013, most informed observers agree that reauthorization for 2013–2018 is neither feasible nor advisable given the polarization in Congress. In the absence of a reauthorization bill, Congress and the administration will need to rely on other measures to define priorities: for example, language in appropriations bills; administration policy statements; and narrow authorizing legislation focused on specific issues.

Supporting basic and applied research. Moreover, as PEPFAR moves from basic science to implementation, U.S. health and development agencies will need to work with both medical and community-based staff to improve their skills in enlisting people to take full advantage of newer biomedical prevention options. Implementation research will be important in better understanding how to promote and deliver health services, so that new technologies are optimally adopted and used, and to improve retention and compliance among persons receiving antiretroviral treatment.

Relatively few studies to date definitively measure the impact of various prevention interventions on reducing rates of new HIV infections—information that is essential for understanding the relative merits of different approaches and for targeting the use of limited resources. The real-world impact of the combination prevention approach remains unknown; community-based studies are still in planning phases.¹⁹ The Blueprint's models are useful for guiding high-level policy discussion. However, these models generate estimates—not facts—and need to be validated through expanded scientific studies in actual community settings. As a starting point, PEPFAR should disclose the models' methodology and assumptions so that other scientists, not affiliated with PEPFAR, can test and replicate results.

Since the best-known prevention interventions are still only partially protective against HIV infection, research on new and even more-effective prevention technologies and their impact on HIV transmission, for example HIV vaccines and microbicides, is needed to stop the virus' spread.

19. In 2009, the National Institutes of Health (NIH) launched a research initiative called the Methods of Prevention Package Program (MP3) to fund combination HIV-prevention studies. The purpose of these studies is to devise optimal HIV-prevention packages for specific populations and to design evaluation strategies to examine their acceptability, safety, and efficacy.

Analyses have shown that even a partially efficacious HIV vaccine could cost-effectively reduce the number of new infections.²⁰ New research findings suggest that the HIV virus is transmitted much more efficiently among men who have sex with men, and new health technologies could help reduce the spread of HIV in this vulnerable group in particular.²¹

Most of OGAC's cost studies have focused on treatment services, with some notable exceptions; it will be useful for OGAC to place higher emphasis on understanding the costs of prevention interventions and other supportive services. In the next few years, PEPFAR will need to further estimate the costs of pursuing an AIDS-free generation in countries experiencing different epidemics, ranging from countries where HIV/AIDS remains a major cause of illness and death to those where it is less frequent.

Managing transitions effectively. Over the next five years, the U.S. government and partner countries face a rising imperative to negotiate complex, multiyear partnership frameworks. As called for in the 2008 reauthorization legislation, partner countries and PEPFAR are developing partnership frameworks and implementation plans to increase country ownership and reduce reliance on U.S. financing.

Successful partnership frameworks will also concentrate U.S. assets in priority areas, and address systematic weaknesses that inhibit the success of health programs, such as shortages of skilled personnel, weak procurement and supply chain management, inadequate health information systems, and overwhelmed (and sometime corrupt) financial systems.

Managing transitions effectively also requires much closer alignment of U.S. bilateral efforts with the Global Fund, including intensified coordination of funding flows and technical assistance. PEPFAR's programs and policies have already become increasingly interlinked with the Global Fund; partnership frameworks and country operational plans now clearly specify the relative expected contributions of the United States, the Global Fund, and other major donors. OGAC has pushed for greater coordination with the Global Fund at both the Geneva and country levels, placing one senior staff person full-time in Geneva and another 18 people in field offices, all tasked with improving coordination and collaboration.

Navigating U.S. domestic politics. U.S. domestic restrictions on the use of federal funding for providing clean needles and syringes to injection drug users have shaped U.S. policies overseas. In 2010, PEPFAR's proactive guidance on "Comprehensive HIV Prevention for People Who Inject Drugs" was overridden by a congressional amendment prohibiting use of PEPFAR funds to provide clean needles and syringes.

Similarly, U.S. domestic debates about abortion have led to legislative and policy restrictions on U.S. funding for voluntary family planning services, even though by law U.S. foreign assistance cannot under any circumstances pay for abortion as a method of family planning. PEPFAR policy is to provide family planning counseling and referrals, train health care providers, and strengthen logistical support. USAID is also the single largest bilateral procurer of condoms. Yet the admin-

20. International AIDS Vaccine Initiative, "AIDS Vaccines: Exploring the Potential Cost/Benefit." Policy Brief, May 2012. <http://www.iavi.org/Information-Center/Publications/Documents/Costs%20Impact%20Brief.pdf>

21. Patrick S. Sullivan et al., "Successes and challenges of HIV prevention in men who have sex with men," *Lancet* 380, issue 9839 (July 28, 2012): 388–99.

istration continues to proceed cautiously on the integration of HIV/AIDS programs with family planning efforts, due to resistance from some elected officials who erroneously equate family planning with abortion. Despite PEPFAR's commitment to improving synergies between HIV/AIDS programs and voluntary family planning to reduce mother-to-child transmission of HIV and improve the health of HIV-positive women,²² official policy is that no PEPFAR funds can be used to purchase family planning commodities (except condoms).

Policy Recommendations

1. Provide high-level leadership and vision.

Early in 2013, the president and the secretary of state should communicate through major speeches, overseas travel, and expanded engagement with Congress, constituencies, and media that HIV/AIDS will be a policy and budgetary priority for the administration's second term.

In devising its strategy, the administration will need to take a full and realistic account of the United States' protracted struggle to reduce deficits, renew economic growth, and find a new balance between taxes and spending. But even under tough budgetary conditions, U.S. leadership can be assured for the future through a strategy that reminds Americans of the core humanitarian values that drive U.S. investments in HIV/AIDS and that have helped achieve the successes of the past decade.

The strategy should build systematically on important scientific gains; strategize the most efficient and effective use of existing resources; encourage higher resource and political commitments from partner governments; identify innovative financing mechanisms; strengthen the focus on women, girls, and gender equality; and leverage investments to achieve broader development goals.

2. Prioritize shared responsibility and orderly transitions.

To advance PEPFAR transitions with key partner countries, the Obama administration will need to exercise higher levels of political will and influence—intensifying its efforts to forge negotiated partnership frameworks and implementation plans with key countries. These will be essential to guide an orderly process of change, anticipate mid-term financial commitments, and strengthen partner governments' health and management capacities in key areas. Sustaining congressional support will likely depend on proof that countries are paying for a greater share of their epidemics and transitioning to lesser levels of U.S. technical and financial support, while recognizing that some countries have greater resources than others to contribute to their AIDS response. There is likely to be increasing pressure from Congress for PEPFAR to set clear milestones and report on progress.

3. Improve operational leadership.

The White House and secretary of state should reaffirm OGAC's mandate to ensure effective interagency cooperation on HIV/AIDS programs, and should do everything possible to facilitate Ambassador Goosby's success in his new dual role as head of OGAC and head of the State Depart-

22. PEPFAR, "Integration and Coordination: Women's Health," http://www.pepfar.gov/press/strategy_briefs/138409.htm.

ment's Office of Global Health Diplomacy. In the latter role, he is charged with strengthening the authority, expertise, and influence of U.S. ambassadors in countries where U.S. global health interests are greatest, and where considerable U.S. political will and influence will be needed to achieve orderly transitions. Improved operational leadership also calls for continued high-level focus on better aligning U.S. policies, programs, and planning with those of the Global Fund.

4. Preserve a strong congressional role.

The administration should maintain a close, regular bipartisan dialogue with Congress—encouraging members and staff to visit program sites overseas. It should also seek out opportunities beyond Washington, D.C., in key congressional districts to address U.S. global health priorities, preferably in collaboration with congressional members. Congress should expand OGAC's annual administration reporting requirements to monitor progress toward achieving the goals of shared responsibility and increased ownership by assisted countries. Congress should also continue to prioritize support for HIV/AIDS research.

5. Maintain funding.

The administration needs to make a convincing case to Congress and the American people to sustain PEPFAR's current funding levels and to sustain U.S. investments in basic and applied research. The Blueprint predicts that through focused, up-front investment in the core prevention interventions, it is possible now to prevent many new cases of HIV, thereby reducing the demand for treatment in the future, with its associated human and financial costs. Although some of the largest gains may have already been achieved, PEPFAR's experience has shown that smarter use of available funds can deliver greater health impacts and save more lives. At this juncture, it will be useful for OGAC to develop a communications plan to educate Congress about PEPFAR's successes and the potential now to significantly reduce the spread of HIV/AIDS.

In addition, the United States should make another substantial pledge to the Global Fund in 2014, while leveraging increased commitments from other donors.

Conclusion

A decade of sustained high-level U.S. leadership has contributed to substantial achievements in the global fight against HIV/AIDS, especially in HIV treatment, in partnership with governments, multilateral institutions, the faith community, and other vital civic organizations. Americans continue to support and take pride in these gains, at the same time that these investments have earned the United States substantial goodwill overseas, especially among the individuals whose lives have been enhanced and in many instances saved. Recent scientific and programmatic developments now make possible new HIV prevention approaches that can reduce the numbers of new infections. In the coming years, resources will be tighter, partner countries will shoulder greater shares of costs, but U.S. leadership will remain no less essential.

3

U.S. PRIORITIES FOR MALARIA

By David Bowen and Hannah Kaye¹

Synopsis

Increased funding and political support for efforts to control malaria have resulted in dramatic declines in related morbidity and mortality. These gains are fragile, however, and could be reversed if success slows momentum.

The U.S. government has played an enhanced leadership role in this effort since 2005, when President George W. Bush created the President's Malaria Initiative and enhanced contributions to the Global Fund. The Obama administration has increased support for both of these programs. Alongside the government, U.S.-based entities, including private companies, nonprofit organizations, and philanthropic institutions, have provided critical funding, innovation, and expertise.

Financial and programmatic continuity are required for ongoing progress, along with new efforts to maximize use of existing interventions and develop necessary new tools. Bed nets used for malaria prevention last only three years and must be replaced. Rapid, inexpensive diagnostic tests must be used more consistently to confirm suspected malaria cases and avoid overuse of antimalarial drugs. Lack of regulatory and enforcement capacity must be addressed to reduce availability of counterfeit and substandard medicines. Emerging drug and insecticide resistance (and the current lack of second-line options) threaten future progress, and strategies and technical expertise for tracking, containing, and responding to resistance are essential.

To reflect current realities and complexities, strategies and success metrics will have to emphasize solidifying progress rather than the rapid case decreases measured a decade ago. Programmatic improvements including enhanced surveillance capacity; greater availability, accessibility, and affordability of medicines and diagnostics; and increased attention to border areas and highly vulnerable populations are needed alongside innovative, sustained funding and new partnerships. Malaria investments will also have to balance existing needs with the urgency of developing tools for the future.

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1. David Bowen is the CEO of Malaria No More. Hannah Kaye is director of policy and advocacy at Malaria No More.

Introduction

Malaria, an infectious mosquito-borne disease, has afflicted humanity since before the dawn of history. Infected people initially experience fever, chills, and flu-like illness; without treatment, their symptoms can intensify to anemia, organ failure, cerebral edema, and death. In 2010 there were an estimated 219 million cases of malaria per year and 660,000 fatalities; 91 percent of these fatalities were in sub-Saharan Africa.² The disease remains one of the biggest killers of children under five.³

Beyond the health challenge and devastating loss of life, malaria poses a serious obstacle to stability and economic growth.⁴ Africa is estimated to lose at least \$12 billion⁵ per year due to the direct costs of malaria, but indirectly loses much more: Malaria is a leading cause of school absence,⁶ and a 2005 survey found that nearly three-quarters of companies in Africa reported that malaria was negatively affecting their business.⁷ Even though simple, effective tools exist to prevent and treat the disease, it absorbs 40 percent of health-system capacity.⁸ A group of African military leaders recently concluded that malaria is the number-one concern for their troops, many of whom are involved in peacekeeping.⁹ Malaria's impact is thus severe for societies and human security as a whole.

Over the past decade, governments, the private sector, nonprofit organizations, faith-based organizations, and other entities have significantly increased efforts on malaria control, using a suite of interventions that include long-lasting insecticide-treated nets (LLINs), indoor residual spraying (IRS), intermittent preventive treatment for pregnant women (IPTp), and artemisinin combination therapies (ACTs).¹⁰ These efforts have shown that progress can be swift and cost-effective: after significant scale-up of programs funded in large part by the United States and other international donors, estimated malaria deaths dropped from 755,000 annually in 2000 to 660,000 in

2. World Health Organization, *World Malaria Report 2012* (Geneva: World Health Organization, 2012), 59, http://www.who.int/malaria/publications/world_malaria_report_2012/wmr2012_full_report.pdf.

3. UNICEF, *Committing to Child Survival: A Promise Renewed* (Geneva: UNICEF, September 2012), 15, http://www.unicef.org/videoaudio/PDFs/APR_Progress_Report_2012_final.pdf.

4. One example of this finding is from the *World Malaria Report 2012*, xiii, which notes that “Malaria is strongly associated with poverty. Estimated malaria mortality rates are highest in countries with a lower GNI per capita.”

5. Roll Back Malaria Partnership, *The Global Malaria Action Plan* (Geneva: World Health Organization, 2008), 27, <http://www.rbm.who.int/gmap/gmap.pdf>.

6. Jeffrey Sachs and Pia Malaney, “The Economic and Social Burden of Malaria,” *Nature* 415 (2002): 680–85, 683.

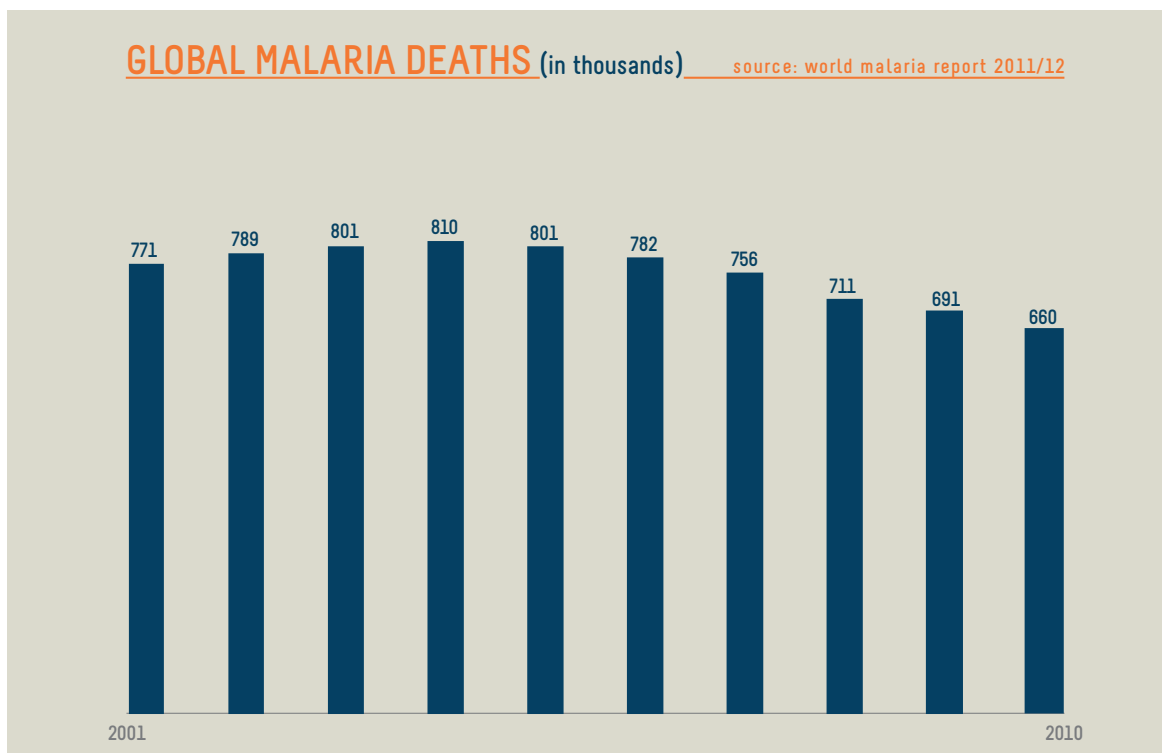
7. Roll Back Malaria Partnership, *Business Investing in Malaria Control: Economic Returns and a Healthy Workforce for Africa* (Geneva: World Health Organization, May 2011), 11, <http://www.rbm.who.int/ProgressImpactSeries/docs/report6-en.pdf>.

8. President's Malaria Initiative, “The President's Malaria Initiative: Sixth Annual Report to Congress: Executive Summary,” USAID, April 2012, 3, http://www.pmi.gov/resources/reports/pmi_annual_exec-sum12.pdf.

9. Donna Miles, “New Malaria Task Force Will Address Top Africa Killer,” U.S. Department of Defense, June 13, 2012, <http://www.defense.gov/news/newsarticle.aspx?id=116721>.

10. An ACT is a medication in which a compound derived from the Chinese wormwood, *Artemisia annua*, is combined with a drug from a different class, such as lumefantrine or mefloquine.

2010¹¹ (see Figure 1). The WHO estimates that, without these investments, if the malaria incidence and mortality rates estimated for 2000 had remained unchanged over the decade, 274 million more cases and 1.1 million more deaths would have occurred between 2001 and 2010.¹²



Today, 36 of the 99 remaining endemic countries are moving from controlled low-endemic malaria to elimination, though only four of these countries are in Africa.¹³ Investing in malaria is bringing benefits far beyond health improvements. A 2011 study found that companies achieved a 28 percent return¹⁴ when investing in malaria prevention programs for their employees, with a 94 percent reduction in malaria-related work absence.¹⁵ An increasing range of companies, particularly in the oil and gas production, mining, and consumer goods sectors, are recognizing the need to invest in malaria control, not only as a humanitarian priority but as a business decision, and are making significant contributions to the fight.

Yet, these gains are still fragile. Status quo program implementation, lack of research and development, emerging drug and insecticide resistance, and reduced resources could all contribute to a dramatic reversal in the progress that has been achieved so far, with devastating consequences. A renewed commitment to malaria could support even more progress toward elimination and, ultimately, eradication. The growing list of countries advancing through pre-elimination and elimination stages demonstrates that this achievement is possible, despite the challenges.

11. World Health Organization, *World Malaria Report 2011*.

12. World Health Organization, *World Malaria Report 2012*, ix.

13. Global Health Group and Malaria Atlas Project, *Atlas of Malaria-Eliminating Countries, 2011* (San Francisco, CA: Global Health Group, October 2011), 5, <http://www.malariaeliminationgroup.org/sites/default/files/atlas/global/Global-Atlas-2011.pdf>; and Malaria Elimination Group, “Elimination Resources,” <http://www.malariaeliminationgroup.org/resources>.

14. Roll Back Malaria Partnership, *Business Investing in Malaria Control: Economic Returns and a Healthy Workforce for Africa*, 9.

15. *Ibid.*

Policy Developments under the First Obama Administration

The United States has long viewed malaria control as in the national interest. Indeed, the Centers for Disease Control and Prevention (CDC) was originally established to fight malaria in the United States.¹⁶

In 2005, recognizing the strategic value of global reductions in malaria, President George W. Bush launched the President's Malaria Initiative (PMI), an interagency effort housed at USAID, co-implemented with CDC, and carried out in partnership with DOD, NIH, and other agencies, through which the U.S. government substantially increased its focus on malaria control.

With bipartisan congressional support, PMI has grown from \$30 million and 15 countries in FY 2006 to a peak of \$650 million in FY 2012¹⁷ and 19 countries.¹⁸ The Obama administration has set ambitious targets for future success. PMI has now been directed to “achieve Africa-wide impact by halving the burden of malaria in 70 percent of at-risk populations in sub-Saharan Africa.”¹⁹

An independent, external evaluation of PMI's first five years concluded that PMI “quickly reoriented a problematic U.S. government malaria program, took it to a large scale quickly, efficiently, and effectively complemented the larger global malaria program, and contributed to the reduction in child mortality.”²⁰

The Obama administration has also supported the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM). In 2012, the GFATM funded an estimated 40 percent of global malaria programs worldwide,²¹ with the U.S. government providing nearly 25 percent of its funding and actively engaging in programmatic and governance reforms. Funding levels for the GFATM have risen since FY 2007, reaching \$1.3 billion in FY 2012—a significant increase in a climate of fiscal austerity.

All these initiatives are part of the overarching Global Health Initiative, begun by the Obama administration in 2009 as an effort to coordinate sometimes-disparate global health programs to maximize their impact around a theme of improving maternal and child health. Although the administrative structure of the Global Health Initiative has changed since its inception, it remains a conceptual framework for the administration's global health efforts.

Ongoing Challenges

The successes in combating malaria these past 10 years have resulted in a profoundly changed landscape—one that holds great promise, but also peril. Just as the results of successful antimalarial efforts are quickly apparent, so are the costs of backsliding. Successful efforts to control malaria

16. Centers for Disease Control and Prevention, “CDC's Origins and Malaria,” February 8, 2010, http://www.cdc.gov/malaria/about/history/history_cdc.html.

17. U.S. Congress, *Conference Report 112-331* to accompany H.R. 2055 (P.L. 112-74), December 2011, 1330.

18. President's Malaria Initiative, “The President's Malaria Initiative: Sixth Annual Report to Congress: Executive Summary,” 3.

19. *Ibid.*, 3.

20. *Ibid.*, 4.

21. World Health Organization, *World Malaria Report 2012*, 15.

give rise to an increasing population of people in formerly malaria-endemic areas who have little exposure to the disease, and thus have little or no malaria resistance. If malaria returns to these areas, these malaria-naïve populations are at extreme risk for illness and death.

When countries deprioritize malaria control after a period of success, the disease's rebound can be swift and severe. For example, WHO cut funding and staff from its malaria control program in Swaziland after the country had all but eliminated malaria in the late 1950s, and epidemics soon followed.²² India, Sri Lanka, and Zanzibar also experienced surges in malaria after donor funding was withdrawn.²³

A Changed Landscape, New Challenges. In many ways, today's most pressing anti-malaria challenges are the by-products of success.

For example, only 3 percent of African households owned insecticide-treated bed nets in 2000; but thanks to mass distribution campaigns, nearly 53 percent do so today.²⁴ These nets do not provide permanent protection, since the insecticide loses potency within three to four years, and nets themselves can get worn out, ripped, or torn sooner. As a consequence, millions of LLINs must be replaced, now or very soon.

Programs must now grapple with how to replace worn-out nets without incurring the unnecessary cost of replacing nets that still function.²⁵ Particularly as countries achieve national progress, donors and affected countries alike will need to focus on improvements in subnational pockets/regions not performing as well as the nation as a whole. Addressing these areas of persistent challenge may involve additional attention to issues such as cross-border transmission, vulnerable populations, delivery bottlenecks, and lack of health workers.

The effectiveness of malaria drugs and insecticides is also under pressure as resistance emerges to the relatively few approved products for treatment. All of the ACTs recommended by WHO rely on the same key ingredient, artemisinin, and only one class of insecticide, pyrethroids, is approved for use in LLINs.²⁶ Four classes of insecticides are approved for indoor residual spraying, but pyrethroids are the safest, most effective, and least expensive,²⁷ and thus used in the majority of IRS programs,²⁸ including those in the highest-burden areas.²⁹

In recent years, several worrying forms of resistance have emerged, which could cripple programmatic effectiveness, drive up costs, and reverse global progress: resistance of the malaria

22. Justin M. Cohen et al., "Malaria resurgence: a systematic review and assessment of its causes," *Malaria Journal* 11 (April 2012): 1–17, 8.

23. *Ibid.*, 3.

24. World Health Organization, *World Malaria Report 2012*, x.

25. Paul Wilson and Ya'ir Aizenman, "Value for Money in Malaria Programming: Issues and Opportunities," Working Paper 291, Center for Global Development, April 2012, 4, http://www.cgdev.org/files/1426120_file_Wilson_Aizenman_ValueforMoney_FINAL.pdf.

26. *Ibid.*, 41.

27. World Health Organization, *Global Plan for Insecticide Resistance Management in Malaria Vectors* (Geneva: World Health Organization, 2012), 13, http://apps.who.int/iris/bitstream/10665/44846/1/9789241564472_eng.pdf.

28. World Health Organization, *World Malaria Report 2012*, 29.

29. Wilson and Aizenman, "Value for Money in Malaria Programming," 42. Also note an interesting example: KwaZulu-Natal switched from DDT to deltamethrin for IRS in 1996, causing malaria rates to rise fourfold over four years; when studies showed local resistance, the program switched back and experienced a 91 percent drop in malaria cases, 41–42 citing 94, 5, 96.

parasites to artemisinin has been found in limited areas within four countries in Southeast Asia so far;³⁰ and resistance of the malaria vector (mosquitoes) to the insecticides approved for public health programs has been identified in 64 countries with ongoing malaria transmission.³¹

While progress is being made against *Plasmodium falciparum*, one species of the malaria-causing parasite, attention is also needed on *Plasmodium vivax*, another species associated with high morbidity and which, unlike *P. falciparum*, has a dormant stage in the human liver that can shelter it from antimalarial drugs, and can cause recurring bouts of disease in infected individuals.³²

Quality and Surveillance. One factor contributing to drug and insecticide resistance is a lack of surveillance and enforcement capacity to ensure that cases are tracked and reported. The WHO has banned artemisinin monotherapies (i.e., those that lack the additional active elements found in combination treatments) since 2007, because these drugs have limited efficacy and build resistance to artemisinin,³³ but as late as November 2012, 16 countries were still allowing use of these products, and 28 pharmaceutical companies were manufacturing them.³⁴ Low-quality or counterfeit drugs also reach markets, and few affected countries have adequate capacity to regulate, monitor, and enforce quality standards.

In addition to ensuring the quality of antimalarial commodities, in-country programs also face the challenge of adequate training and monitoring for those prescribing and using drugs. Many practitioners and patients still treat malaria preemptively, based on the appearance of symptoms before diagnosis. In 2010, the WHO recommended that all suspected malaria cases be confirmed prior to treatment. Though the proportion of suspected malaria cases receiving a diagnostic in the public sector increased in much of Africa from 20 percent in 2005 to 47 percent in 2011 and globally from 68 percent to 77 percent, many fevers are still treated preemptively and diagnostic testing appears to be less available in the private sector than in the public sector.³⁵ This can lead to overuse of malaria drugs, as well as improper treatment for patients with non-malaria fever cases such as pneumonia.³⁶ Better use of diagnostics could also have cost implications, as the need for malaria treatment would be dramatically reduced if all suspected cases were tested and only confirmed cases treated with antimalarial drugs.³⁷

Finally, the need to develop and integrate new tools has taken on new urgency. The interventions developed to combat malaria are effective and low-cost, but all treatments eventually lose effectiveness as diseases and vectors adapt to them. Enhancing diagnostic capacity, in addition to meeting the urgent need for the development of new drugs, will be essential to progress, by ensuring that the potency of antimalarial drugs is not squandered through misuse.

30. Global Health Group and Malaria Atlas Project, *Atlas of Malaria-Eliminating Countries, 2011*, 9, noting citations 22 and 23.

31. World Health Organization, *Global Plan for Insecticide Resistance Management in Malaria Vectors*, 13.

32. World Health Organization, *World Malaria Report 2012*, 8 and 9.

33. Rachel Nugent et al., *The Race Against Drug Resistance: A Report of the Center for Global Development's Drug Resistance Working Group* (Washington, D.C.: Center for Global Development, 2010), 17 and 25, http://www.cgdev.org/files/1424207_file_CGD_DRWG_FINAL.pdf. It is worth noting, however, that artesunate monotherapy (parenteral) is required for treatment of severe malaria.

34. World Health Organization, *World Malaria Report 2012*, xii.

35. World Health Organization, *World Malaria Report 2012*, xi–xii.

36. UNICEF, *Committing to Child Survival: A Promise Renewed*, 17.

37. World Health Organization, *World Malaria Report 2012*, 36.

An effective malaria vaccine would be a key addition to the set of interventions used to combat malaria, but it has proven an elusive goal. After decades of unrealized hopes, a partnership consisting of GlaxoSmithKline, PATH (with funding from the Bill & Melinda Gates Foundation), and 11 African research centers is now testing the RTS,S vaccine candidate in a large-scale clinical trial. Results published in 2011 showed a 50 percent reduction in malaria cases over one year among toddlers enrolled in the trial. Later results for a younger cohort in the same trial, however, showed that the vaccine was somewhat less efficacious, reducing the number of cases by approximately one-third for this group. Further trial results, expected in 2014, will be essential in determining whether RTS,S can make a major contribution to malaria control.

Policy Recommendations

1. Improve the use of rapid diagnostics for case management.

Diagnosis of malaria has historically been complicated and slow, and with a high prevalence of the disease, presumptive treatment was standard. As malaria rates fall, however, and patients' fevers are less likely to be caused by malaria, it is important to treat only confirmed malaria cases so that patients receive appropriate treatment and antimalarials are not overused.

Now, researchers have developed cheap, easy-to-use, rapid diagnostic tests (RDTs) that detect true malaria cases. In 2005, fewer than 200,000 RDTs were in use, but by 2011, that number had skyrocketed to more than 50 million.³⁸ Continuing to improve use of RDTs remains essential, particularly in areas that have significantly reduced their malaria burden and where rates of over-treatment are consequently likely to be high. More diagnostics are needed at the community health worker level in particular, along with training and policies to ensure they are used properly.

Beyond expanding access to diagnostics, the PMI should improve support for efficient, strategic case management to ensure that patients presenting with fevers not caused by malaria receive appropriate treatment. It is estimated that current malaria surveillance systems detect only around 10 percent of the estimated global number of cases.³⁹ Enhanced surveillance is thus a critical component of case management, and PMI should work with other donors and partners to develop consistent standards for identifying malaria cases to improve completeness and consistency of reporting that can be used to better design and carry out programs.⁴⁰

2. Innovate finance to stretch available resources.

In an era of fiscal constraints, creative approaches to financing take on special importance. New sources of funds, such as service fees on airline tickets or financial transactions, are beyond the scope of this paper, but the high risk of resurgence over the next few years has spurred an urgent need to do more with less. New approaches to financing, both at the global and national levels, are needed to help address funding gaps in the short- and medium-term that threaten the gains of recent years. As its major funder, the United States should work closely with the World Bank to help formulate new mechanisms, such as a "malaria bond" or performance-based forgivable loans. The United States should also support efforts to catalyze country-generated financing, and work with the World Bank, private sector, and affected countries to incentivize affected countries

38. World Health Organization, *World Malaria Report 2012*, 37.

39. *Ibid.*, v and 51.

40. *Ibid.*, 51.

to consolidate and expand upon hard-won progress against malaria. Such mechanisms could have the additional benefit of providing smoother and more predictable funding flows that are important for adequate program planning.

3. Adapt to reflect the changing malaria-control landscape.

The landscape of malaria control has changed markedly in a decade, with widespread deployment of malaria interventions, new tools, and a changed profile of the epidemic. These changes require similar adjustments in the ways the United States fights the disease.

One aspect of this adjustment is the need for new measures of success. Measuring success on more than just reducing the number of cases will help ensure that funding rewards countries that are excelling not only at initial control but in maintaining their gains. When the global scale-up in malaria control began, the burden was so high that programs necessarily focused on case reduction. Where countries are at high risk of disease resurgence or where the risk of spreading resistance is elevated, funding decisions should also take into account measures such as maintenance of low case burden to ensure that gains are consolidated. The U.S. government, acting through its representative on the GFATM Board, should ensure that GFATM properly takes into account these measures as the Fund implements a sweeping reform of its grant structure. In addition, funding allocations for countries should also consider risks of cross-border transmission, or special risks in subnational regions. Finally, new research should focus on the best ways to combat *P. vivax*, as this species assumes greater importance in the epidemic.

4. Invest in future success.

To improve outcomes and avoid resistance, new tools, methods, and combinations of interventions must be developed and brought to scale. Federal agencies conducting malaria research should ensure that their research portfolios take into account the changing landscape of the malaria epidemic, particularly the acute need for better strategies and tools to contain drug and insecticide resistance. It will also be important to urge coordination and cooperation across sectors; for example, research sharing with the agricultural sector could enhance efforts to develop new insecticides without excessive additional cost.

5. Strengthen safeguards against substandard products.

PMI continues to prioritize efforts within its programs to ensure that substandard or counterfeit drugs do not enter the malaria commodity supply chain. Despite reductions in the number of manufacturers marketing monotherapies, substandard and counterfeit drugs continue to put patients at risk and increase the risk of resistance. The Obama administration should make it a priority to raise these issues in bilateral diplomatic talks with the manufacturing country of the origin's government. The United States can also enhance its work with the international global health, development, and diplomatic community to strengthen partner countries' drug regulatory and enforcement regimes through governance programs. To assist in this effort, the administration should provide adequate support to improve the capacity of the Food and Drug Administration and other agencies to provide technical assistance to aid such efforts. Just as important is renewed effort to ensure that malaria-endemic countries no longer permit the sale of monotherapies. Ultimately, the continued allowance of such sales should be taken into account in determining funding allocations.

While drug quality has rightly attracted significant attention from policymakers, the need to ensure the quality of LLINs should not be overlooked. PMI should continue to stress best value (i.e., a measure that properly takes into account cost per year of effective protection) in addition to up-front cost, in its procurement decisions, and work with the GFATM to see that these quality criteria are broadly adopted.

Conclusion

U.S. leadership—political, financial, and technical—has made possible a decade of dramatic progress against malaria, and enabled opportunities for economic growth, stability, and education that had previously been limited by the ravages of this devastating disease. All government partners in the PMI initiative have contributed unique strengths in program support, research, and capacity development that have been leveraged for even higher impact by the decision to invest the U.S. global malaria coordinator with the clear authority to lead the U.S. malaria effort.

With creative approaches to ensuring drug quality, proper use of diagnostics, and sustained financial and political commitment from governments, communities, and industry alike, the United States can ensure this success continues—and usher in the day when malaria no longer threatens or obstructs human health and development around the world.

For Additional Information:

- World Malaria Report 2012: http://www.who.int/malaria/publications/world_malaria_report_2012/wmr2012_full_report.pdf
- Roll Back Malaria: www.rbm.who.int
- President's Malaria Initiative: www.pmi.gov
- Malaria No More: www.malarianomore.org

4

U.S. PRIORITIES FOR GLOBAL POLIO ERADICATION

By Nellie Bristol and Phillip Nieburg¹

Synopsis

The U.S. government is a major contributor to the Global Polio Eradication Initiative (GPEI), a World Health Organization-led program that has reduced the incidence of paralytic polio to its lowest level ever. While the initiative continues to encounter serious challenges, new strategies and personnel additions in the last several years have had a substantial positive impact, including the elimination of polio from India as of January 2011.

Efforts at global polio eradication have enjoyed broad bipartisan congressional support since the program's inception in 1988, including more than \$2 billion in appropriations. In fiscal year 2012 alone, U.S. funding for polio eradication increased by nearly \$19 million. Recent U.S. policy developments and achievements in polio eradication have included: activation of the Centers for Disease Control and Prevention's (CDC) Emergency Operations Center to better coordinate resources and to support rapid response to outbreaks; increases in polio staff in the field; and continued technical and financial support to the Global Polio Laboratory Network.

The GPEI is finalizing a six-year strategy to end transmission of the polio virus; transition to inactivated polio vaccine; better integrate activities with national health services; and generate sufficient resources to fund the initiative's final push. It also is beginning to catalog new tools and resources developed by the initiative that could be transferred to other health activities in a process known as "legacy planning."

To support polio eradication to its conclusion, the administration and Congress should continue to provide U.S. support including high-level political and diplomatic leadership. They also

We wish to acknowledge the many individuals who generously contributed their time and essential insights to this study, particularly the members of the CSIS Polio Eradication Working Group: Jon Andrus, Pan American Health Organization; Melissa Covelli, Bill & Melinda Gates Foundation; Neal Halsey, Johns Hopkins Bloomberg School of Public Health; Alan Hinman, Task Force for Global Health; Judith Kaufmann, Independent Consultant; Apoorva Mallya, Bill & Melinda Gates Foundation; Carol Pandak, Rotary International; and Robert Steinglass, John Snow, Inc. The findings and recommendations contained in this chapter are ultimately the sole responsibility of the authors. They also reflect a majority consensus of the working group members we assembled to guide this effort. We did not ask them as individuals to agree to each and every dimension of the resulting analysis, but rather to join into a process of creating a broad consensus. We also reached out to a second tier of important experts serving in relevant government departments and agencies to provide strictly technical input; they bear no responsibility for the analysis that followed.

1. Nellie Bristol is a research fellow with the CSIS Global Health Policy Center, and Phillip Nieburg is a senior associate with the CSIS Global Health Policy Center.

should prioritize completion of polio eradication and related activities separately from implementation of the legacy strategy currently being discussed. In addition, whenever possible, the CDC and USAID should deliver a cohesive U.S. government message on polio-eradication efforts, while the CDC should continue to contribute to regular status reports on initiative milestones.

Introduction

By the late 1980s, several regions of the world including the Americas and Europe were on their way to banishing paralytic polio from their borders, offering freedom from the crippling disease to millions of children. To provide that protection permanently everywhere, the World Health Assembly (WHA) in 1988 passed a resolution calling for the global eradication of polio by the year 2000. The move led to the formation of the Global Polio Eradication Initiative (GPEI), a coalition of international organizations, national governments, private-sector foundations, donor governments, corporate partners, and nongovernmental organizations. GPEI is spearheaded by the World Health Organization (WHO), the U.S. Centers for Disease Control and Prevention (CDC), Rotary International, and the United Nations Children's Fund (UNICEF). Since 2007, the Bill & Melinda Gates Foundation has been a major donor and policy-setting partner.

Shortly after the WHA resolution was passed, global polio incidence began falling sharply. Since 1988, the annual number of cases has plummeted from an estimated 350,000 to just 222 in 2012—the lowest number ever reported—representing a drop of more than 99 percent.

But this achievement has been hard fought, and completion of eradication is not yet assured. While the number of paralytic polio cases continued to fall fairly steadily through the 1990s, progress stalled through much of the early 2000s, with the number of cases settling at between 1,000 and 2,000 per year for most of the decade. The initiative has met with technical and operational difficulties and other challenges, including funding shortages, political instability, corruption, anti-Western sentiment, and parental refusal of the vaccine. It also struggled to gain access to migrant and other marginalized populations—especially in parts of India, Nigeria, Afghanistan, and Pakistan, which by 2010 were the only countries where polio transmission had never been interrupted. In January 2011, the initiative received a much-needed boost in morale when a long, concerted political and financial commitment by the Indian government resulted in the country's reporting its last case of polio, an achievement many had believed impossible given India's vast population and uneven health services. The accomplishment convinced many doubters that the technological capacity existed to eradicate polio worldwide.²

But polio campaigns in the three remaining endemic countries, Nigeria, Afghanistan, and Pakistan, continued to struggle, with the number of cases climbing in each country in 2011 compared to the previous year. In October 2011, the GPEI's Independent Monitoring Board (IMB), a panel of eight global health experts established in December 2010 at the request of the World Health Assembly, issued a review that was critical of the initiative, identifying program weaknesses and lack of innovation. In response, the GPEI increased the transparency of its deliberations, modified its governance structure, and refocused its efforts in endemic countries. Along with

2. For more information, see Teresita C. Schaffer, *Polio Eradication in India: Getting to the Verge of Victory—and Beyond* (Washington, D.C.: CSIS, January 2012), http://csis.org/files/publication/120117_Schaffer_PolioIndia_Web.pdf.

additional recommendations for program improvement, the IMB in its November 2012 report praised the GPEI for its previous response. “We have seen leadership reflect, learn, change its emphasis, and increase its urgency,” the panel said.³

While the GPEI modified its operations, world health leaders called for greater concentration on polio eradication from other quarters. In May 2012, the World Health Assembly passed a resolution calling polio eradication a “programmatically emergency for global public health,” in order to mobilize new attention and resources for the initiative. “Polio eradication is at a tipping point between success and failure,” said Dr. Margaret Chan, director-general of the World Health Organization. “We are in emergency mode to tip it towards success—working faster and better, focusing on the areas where children are most vulnerable.”⁴

The GPEI has operated under a global Emergency Action Plan through 2012 and into 2013. Each of the remaining three endemic countries also has developed its own national emergency plan with the specific goals of increasing polio vaccination rates and interrupting poliovirus transmission. Although there were more cases of paralytic polio in 2012 in Nigeria than in the previous year, and cases in more districts there compared to 2011, overall global rates have fallen to an all-time low and the virus is now being reported from the fewest geographic areas ever recorded. Nonetheless, the IMB warned in November: “History shows how cruel polio can be—that it resurges more easily than it is contained. There is a significant risk of having more polio cases in 2013 than in 2012, and in more countries. The Programme must receive a level of priority to not just mitigate this risk, but to achieve another year of major progress towards stopping transmission.”⁵

To continue the push toward complete eradication, the GPEI in the first quarter of 2013 finalized and began to implement a six-year “Polio Eradication and Endgame Strategic Plan” that runs through 2018. The \$5.5 billion, four-part strategy calls for⁶:

- Halting transmission of wild poliovirus⁷;
- Improving routine immunization systems and transitioning to inactivated poliovirus vaccine (IPV) in place of the currently used oral polio vaccine (OPV);
- Formal certification of eradication and containment of polioviruses in facility-based settings; and
- Initiating a “legacy” planning process.⁸

3. Independent Monitoring Board of the Global Polio Eradication Initiative, “Polio’s Last Stand?” November 2012, http://www.polioeradication.org/Portals/0/Document/Aboutus/Governance/IMB/7IMBMeeting/7IMB_Report_EN.pdf.

4. Global Polio Eradication Initiative (GPEI), “Polio Eradication Shifts into Emergency Mode,” May 24, 2012, <http://www.polioeradication.org/tabid/461/iid/219/Default.aspx>.

5. Independent Monitoring Board of the Global Polio Eradication Initiative, “Polio’s Last Stand?”

6. This description is based on the most recent draft seen by working group members: Global Polio Eradication Initiative, “Polio Eradication and Endgame Strategic Plan (2013-2018): Working Draft: 23 January, 2013,” http://www.polioeradication.org/Portals/0/Document/Resources/StrategyWork/EndGameStratPlan_20130123_ENG.pdf

7. “Wild poliovirus” refers to those polioviruses that routinely circulate in nature, as opposed to the rare disease-causing polioviruses that have evolved from weakened polio strains included in the oral polio vaccine (OPV).

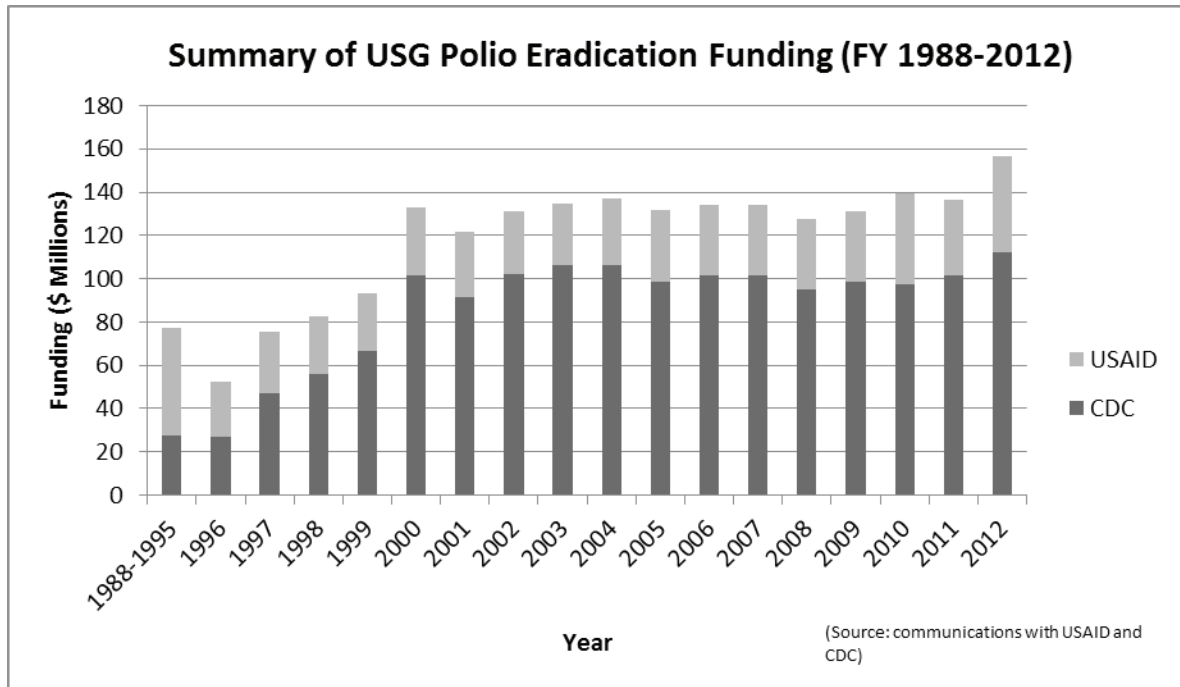
8. The legacy-planning strategy calls for a 17-month effort to catalog methods and innovations developed through polio eradication activities and determining whether and how they could be incorporated into other national health services. These assets include surveillance and diagnostic capacities, a trained workforce, social-mobilization networks, communications strategies, proven partnerships, and methods

The U.S. Government's Roles. Beginning with the U.S. Agency for International Development (USAID) and CDC's support of polio elimination in the Americas in the 1980s, the U.S. government has played a critical, multifaceted role in global polio eradication, providing political, diplomatic, and intellectual leadership, along with technical and operational resources. Between 1988 and 1994, USAID provided the Pan American Health Organization (PAHO) with \$50 million, which supported regional advisers and staff training as well as operational costs for polio surveillance and laboratories. CDC experts served as policy advisers, provided specialized reference laboratory support, and offered training and technical expertise to help develop capacity for polio diagnosis and surveillance activities.

Shortly after the WHA global polio eradication resolution was passed, Congress began appropriating funds to support the global program, spurred by effective advocacy by Rotary International. The initiative has enjoyed broad bipartisan congressional support ever since, including more than \$2 billion in appropriations, making the United States the single largest supporter of the GPEI. The bulk of these funds has been allocated to CDC, while \$600 million has been administered by USAID. More than \$155 million in U.S. funds were used for polio eradication activities in FY 2012, a nearly \$19 million increase over the previous year's level.

As the primary U.S. government entities involved in polio eradication activities, CDC and USAID make valuable and complementary contributions to eradication, both by providing tools for eradication activities and by developing program assessments that have improved the GPEI's effectiveness. In addition to substantial resources and technical expertise, the U.S. government has provided high-level advocacy for the initiative, including at the United Nations and at the G-8.

for providing services to difficult-to-reach populations. Maintaining these capacities beyond the lifetime of the GPEI will require substantial new resources and partnerships above those currently envisioned for eradication.



Policy Developments under the First Obama Administration

In December 2011, CDC director Thomas Frieden activated CDC’s Emergency Operations Center (EOC) to provide better coordination of CDC and other polio resources and to support rapid response to polio outbreaks. Usually reserved for acute emergency response, EOC activation raised the profile of polio eradication at CDC. To further support its engagement, CDC increased its polio staff in the field and at its Atlanta headquarters. In addition, the United States is funding more than 50 percent of polio staff costs at WHO’s Geneva headquarters and from 10 to 90 percent of polio staff costs in WHO regional and country offices.

In other operational support, the United States continues to provide primary technical and financial backing to the 146 laboratories in the Global Polio Laboratory Network, including resources for WHO regional management staffing. In recent years, the polio laboratory network has participated in surveillance of and response to other diseases, including pandemic influenza and severe acute respiratory syndrome (SARS). The United States also supports the active polio surveillance systems of more than 25 countries, including the use of civil society groups for community-based surveillance in migrant and mobile populations.

Further, through networks of NGOs and in partnership with UNICEF, USAID contributed to using social-mobilization activities to significantly reduce polio vaccine refusal rates in Uttar Pradesh, “one of the last strongholds of polio virus in India.”⁹

In recent examples of diplomatic leadership, USAID administrator Rajiv Shah engaged senior staff from the ministries of health of India, Pakistan, Afghanistan, and Tajikistan at the June 2012

9. Elaine Murphy, *Social Mobilization: Lessons from the CORE Group Polio Project in Angola, Ethiopia, and India* (Washington, D.C.: USAID, 2012), <http://www.coregroup.org/our-technical-work/initiatives/polio/272-social-mobilization-lessons-from-the-core-group-polio-project-in-angola-ethiopia-and-india>.

Child Survival Call to Action in Washington, DC to encourage cross-border cooperation in facilitating polio vaccination. Later in the year, Department of Health and Human Services Secretary Kathleen Sebelius and CDC director Frieden participated in an event during the UN General Assembly in September that highlighted the need for continued resources for and ongoing attention to polio eradication. The event also featured the presidents of Nigeria, Afghanistan, and Pakistan, the prime ministers of Australia and Canada, and Gates Foundation cochair Bill Gates.

Ongoing Challenges

Four primary hurdles remain to complete eradication of polio: adapting to local circumstances; transitioning to inactivated polio vaccine (IPV); better integrating activities with national health services; and generating sufficient resources to fund the initiative's final push. Progress also is dependent on successful negotiation of the political and security situations in endemic countries as was made clear by recent lethal attacks on health workers in Pakistan and Nigeria, which slowed immunization efforts there.

First, GPEI believes that the prospects of success are more positive than ever before and that it is well positioned to interrupt transmission by its current milestone of the end of 2014. That said, interruption of transmission by any particular calendar date cannot be guaranteed and various challenges could prove more difficult to overcome. For example, halting transmission of poliovirus in the remaining endemic countries will require ongoing program adaptations that include better systems for managing eradication programs within those countries and better integration of eradication activities with the needs and wishes of local communities.

Second, completing eradication requires successfully carrying out the same polio vaccine transition already made in many developed countries, including the United States. OPV, used broadly for polio immunization, including by the GPEI, is inexpensive and can be administered orally by minimally trained vaccinators, making it well suited for mass campaigns. But because OPV is made from polioviruses that have been weakened but are still alive, it can itself in rare cases cause paralytic polio in recipients or their close contacts. It also can revert to a form that can pass from person to person, causing localized outbreaks in populations with low polio immunity. With the GPEI on the verge of stopping transmission of all wild poliovirus, a transition is planned from OPV to the use of inactivated vaccine, which is made from killed poliovirus particles and therefore carries no risk of vaccine-related paralytic polio. Current IPV is significantly more expensive than OPV, however, and must be administered via injection, requiring the more complex vaccination process used for other injectable routine vaccinations such as measles and rubella. For example, health workers must be trained to give injections safely, and needles and syringes must be purchased and properly disposed of after use. The GPEI is pursuing development of more affordable versions of IPV and the financial means to incorporate them into the program, as well as working with the GAVI Alliance, UNICEF, WHO, and other organizations to facilitate routine IPV vaccination globally.

Third, the GPEI must determine how its existing capacities can best be adapted to enhance the effectiveness of national immunization programs that provide the bulk of childhood immunizations in developing countries for diseases other than polio (e.g., tetanus, diphtheria, whooping cough, and measles). In some places, the initiative has evolved to rely on its own freestanding mass polio vaccination campaigns that often are not linked to national routine immunization programs. However, because the ultimate success of the GPEI will depend on the ability of national programs

to take on the responsibility for routinely providing IPV, successfully making linkages to local immunization services is now essential.

Finally, and perhaps most significantly, new resources and funding partners are needed to help meet the \$5.5 billion 2013–2018 budget the GPEI estimates it will need to halt transmission in remaining areas and start the transition to IPV.

Policy Recommendations

1. Maintain U.S. leadership and support.

Polio eradication is unlikely to succeed without a continued U.S. commitment of funding, staff, and laboratory resources. In addition, high-level U.S. political and diplomatic leadership remains essential to the GPEI in order to encourage the ongoing focus and participation of other donors and polio-affected countries.

2. Put the eradication endgame strategy first.

Prioritize the global polio eradication endgame, namely development and implementation of effective strategies, recommendations for program improvements, and budgets for enhanced population immunity and surveillance, virus containment, vaccine transitions, and completion and certification of eradication. This will require keeping eradication and related activities separate from implementation of the legacy strategy currently being discussed. U.S. contributions to carrying out GPEI legacy activities beyond eradication should be considered and made independently of decisions surrounding ongoing eradication activities.

3. Pursue a U.S. government approach on polio eradication that systematically leverages the comparative advantages of individual U.S. institutions.

Whenever possible, CDC and USAID should deliver a cohesive U.S. government message on polio eradication that leverages both the broader development perspectives of the U.S. Agency for International Development and the disease-prevention orientation of the Centers for Disease Control and Prevention. Both perspectives are critical at this point, as the GPEI must find new ways to overcome challenges in the remaining endemic areas, successfully make the transition to IPV, and build closer links with national routine immunization programs, many of which require significant strengthening. U.S. government activities also should include diplomatic engagement with countries at particular risk for polio infections.

4. Support the recommendations of the Independent Monitoring Board.

The United States should strongly support the IMB's independent efforts to identify problems and obstacles faced by and within the GPEI, including by encouraging the board's continuation beyond the expiration of its current term at the end of 2012. The United States also should urge the GPEI to respond quickly to problems identified by the IMB—in particular, by experimenting with innovative solutions to political obstacles, such as working through NGOs and other civil entities.

5. Continue to produce and disseminate independent U.S. assessments.

High-quality external assessments provide the GPEI with crucial insight and information to improve its operations. CDC should continue contributing to regular status reports that present data on progress on GPEI milestones, surveillance and immunity, performance indicators, and that in-

clude UNICEF data on characteristics of children missed in campaigns. It also should continue to work with WHO regional offices in assessing the risk of polio introduction and spread in countries that currently are polio free. USAID should continue its vital efforts to identify program weaknesses and potential solutions.

Conclusion

Although the polio eradication effort suffered several agonizing setbacks at year's end—the vaccinator killings in Pakistan and the spread of paralytic polio from Nigeria to a boy in Niger—the IMB judges positively the GPEI's overall performance for 2012. Nonetheless, the board urges maximum continued effort to capitalize on the initiative's momentum. "It is 2013 that matters the most. Stopping transmission is urgent—progress must be seen in weeks and months, not months and years," IMB Chair Liam Donaldson wrote in a January 18 letter to WHO director-general Chan.¹⁰ "The world is on the brink of eradicating polio," Donaldson added. "This goal absolutely must be seen through to completion."

While conditions remain difficult in many endemic areas and the poliovirus is a tough and resilient adversary, the right combination of local, national, and global political commitment and technical, managerial, and operational innovation could achieve the worldwide eradication of a dreaded disease. Continued U.S. funding, technical support, and political and diplomatic advocacy through the initiative's conclusion would promote humanitarian values and could help secure a major global health achievement.

For Additional Information:

- The Global Polio Eradication Initiative: <http://www.polioeradication.org/>
- Polio This Week—polio case count: <http://www.polioeradication.org/Dataandmonitoring/Poliothisweek.aspx>
- The Independent Monitoring Board of the Global Polio Eradication Initiative: <http://www.polioeradication.org/Aboutus/Governance/IndependentMonitoringBoard.aspx>
- U.S. Centers for Disease Control and Prevention polio eradication link: <http://www.cdc.gov/polio/updates/>
- U.S. Agency for International Development polio eradication link: http://www1.usaid.gov/our_work/global_health/mch/ch/techareas/polio_brief.html

10. Sir Liam Donaldson, Chair, Independent Monitoring Board of the Global Polio Eradication Initiative, Letter to World Health Organization Director-General Margaret Chan, January 18, 2013 <http://www.polioeradication.org/Aboutus/Governance/IndependentMonitoringBoard/Reports.aspx>.

5

U.S. PRIORITIES FOR WOMEN'S GLOBAL HEALTH

Janet Fleischman¹

Synopsis

Over the past decade, U.S. policymakers have increasingly recognized that advancing women's global health and gender equality is among the most pressing challenges of the twenty-first century. A growing body of evidence demonstrates that investments focusing primarily on women and girls—maternal health services, voluntary family planning, access to HIV services, education for girls, economic empowerment of women, preventing and responding to gender-based violence—not only are critical to improving health outcomes, but also produce substantial positive returns in poverty reduction, development, and economic growth.

Despite the often-polarized atmosphere in Washington, a number of bipartisan successes have been achieved in support of women's health. This has been the case under both Democratic and Republican administrations: the George W. Bush administration created the President's Emergency Plan for AIDS Relief (PEPFAR) and developed gender strategies to reach women and girls; the Obama administration elevated women's health and gender equality as a key foreign policy goal and accelerated policy development in this area.

Yet significant challenges remain. Administration and congressional leaders will have to navigate around political obstacles, notably the politically polarizing discussion around abortion, which is often erroneously conflated with family planning, and build support for the resources necessary for women's health and gender programs at a time of severe budget constraints. Despite

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1. Janet Fleischman is a senior associate with the CSIS Global Health Policy Center.

these challenges, focusing on the health of women and girls heightens the impact, life-saving potential, and cost-effectiveness of U.S. investments.

The Obama administration has created an enabling policy and strategy environment for women's global health and gender equality. To achieve successful outcomes, the administration and Congress should consider four priority policy recommendations:

1. Sustain high-level U.S. leadership on women's health and gender equality.
2. Implement for results; translate U.S. policies to program implementation.
3. Monitor and evaluate progress in addressing women's health and gender equality.
4. Build partnerships to leverage existing funds for sustainability.

Introduction

Over the past decade, U.S. policymakers have increasingly recognized that advancing women's global health and gender equality is among the most pressing challenges of the 21st century. A growing body of evidence demonstrates that investments focusing primarily on women and girls—maternal health services, voluntary family planning, access to HIV services, education for girls, economic empowerment of women, preventing and responding to gender-based violence (GBV)—not only are critical to improving health outcomes, but also produce substantial positive returns in poverty reduction, development, and economic growth. That is why, even in a difficult budgetary environment, as Secretary of State Hillary Clinton has often said, “Investing in women and girls is not only the right thing to do—it's the smart thing to do.”

“Everything I have done and everything I have learned in my work over the years has convinced me that improving the rights and the status of women is not simply a matter of human dignity, although it certainly is. It is also essential to our shared prosperity and security.... It's the right thing to do, and it is also the smart thing to do.”

—Secretary of State Hillary Clinton, July 19, 2012

The advent of a second Obama administration and a new Congress presents a pivotal opportunity to develop a comprehensive approach to women's health as a smart and strategic way to advance U.S. interests in saving lives, promoting healthy families and communities, and protecting the rights of women and girls. Progress in women's health also requires advancing gender equality, which means going beyond viewing women and girls simply as beneficiaries of health services. A multisectoral approach is required—one that engages women and girls as decisionmakers and agents of change and that ensures linkages between health and other sectors.

Despite the often-polarized atmosphere in Washington, a number of bipartisan successes have been achieved in support of women's health. This has been the case under both Democratic and Republican administrations: the George W. Bush administration created the President's Emergency Plan for AIDS Relief (PEPFAR) and developed gender strategies to reach women and girls with HIV/AIDS prevention, care, and treatment services; the Obama administration elevated women's health and gender equality as a key foreign policy goal and accelerated policy development in this area.

Yet progress on prioritizing women's health and gender equality is persistently vulnerable, at home and abroad. In the United States, high-level leadership and bipartisan support are necessary to keep up momentum on policy and program implementation. The exit of Secretary Clinton will

test the degree to which recent advances are embedded into the U.S. government's institutional machinery or if the energy and commitment she has brought to these issues leave with her. In addition, host country governments will have to demonstrate high-level commitment to advancing women's health and gender equality in their own countries, working with civil society organizations and other development partners.

Even with recent advances, significant challenges remain. Administration and congressional leaders will have to navigate around political obstacles, notably the politically polarizing discussion around abortion,² which is often erroneously conflated with family planning, and build support for the resources necessary for women's health and gender programs at a time of severe budget constraints. Despite these challenges, focusing on the health of women and girls heightens the impact, life-saving potential, and cost-effectiveness of U.S. investments, underscoring that these programs should be carried forward as a cornerstone of U.S. global health.

The transition to a second Obama administration and a new Congress is a unique opportunity to build on past U.S. investments to lead to real progress for women's health globally—during the next four years and over the next decade. Although current U.S. government funding streams often result in vertical programming, operationalizing a more integrated model of service delivery could advance progress in reducing maternal mortality, increasing access to voluntary family planning, reducing HIV infection in young women, and preventing and responding to gender-based violence. However, this approach will require high-level and committed leadership from both the White House and congressional leaders from both parties.

This report outlines key policy developments on women's global health and gender equality under the first Obama administration, describes lessons learned and outstanding challenges particularly focused on women's health issues, and makes priority policy recommendations that are concrete and actionable for the new Obama administration and Congress.

Healthy Women, Healthy Societies: Key findings supporting emphasis on women and girls as timely and necessary

Health and development gains: According to the World Bank's 2012 Development Report, "[G]ender equality is a core development objective in its own right. But greater gender equality is also smart economics, enhancing productivity and improving other development outcomes, including prospects for the next generation and for the quality of societal policies and institutions." The report then presents compelling data about the importance of gender equality in several areas, noting that if barriers that discriminate against women working in certain sectors and occupations were eliminated, labor productivity would be increased by some 25 percent in some countries. In addition, improvements in women's health and education have positive impacts on these and other outcomes for their children, including better child health and survival, higher immunization rates, and better nutrition, as well as educational attainment.

2. The Helms amendment states that no foreign-assistance funds may be used to pay for abortion as a method of family planning or to motivate or coerce any person to practice abortions. See USAID, "Family Planning Guiding Principles and U.S. Legislative and Policy Requirements," http://transition.usaid.gov/our_work/global_health/pop/policy.html.

Violence against women and children: Data from the Violence Against Children Surveys, supported through the Together for Girls partnership, show the strong ties between the experience of violence as a child and the negative long-term consequences that carry into adulthood. In the participating countries, an estimated 30 percent of girls and 10 percent of boys have had an unwanted sexual experience before the age of 18. Data also confirm a growing body of evidence that the experience of violence, especially sexual violence, places a child at higher risk for multiple negative consequences that emerge throughout the life cycle. For example, girls who experience abuse as children are up to twice as likely to be HIV positive, and boys also are more likely to practice high-risk behaviors and are at high risk to become perpetrators as adults. Both are likely to do poorly at school, suffer depression and other illnesses, and find themselves caught in a cycle of violence. The data have mobilized policymakers in Swaziland, Tanzania, Zimbabwe, and Kenya to develop and implement national action plans in response.

Family planning reduces maternal and child deaths, and is highly cost-effective: Numerous studies demonstrate that investments in voluntary family planning can significantly improve maternal, infant, and child health and avert millions of unintended pregnancies and abortions. Increased contraceptive use has cut maternal deaths by 40 percent in the past 20 years; meeting the unmet need for family planning, estimated to be 222 million women, could reduce maternal deaths by a further 30 percent. In addition, voluntary family planning increases child survival by widening birth spacing to at least two years, which could reduce infant deaths by 10 percent and reduce deaths of 1- to 4-year-old children by more than 20 percent.³ The government of the United Kingdom and the Bill & Melinda Gates Foundation, cohosts of the London Family Planning Summit in July 2012, wrote that: “Access to safe, effective methods of contraception is considered one of the most cost-effective investments a country can make in its future. Studies show that every US \$1 invested in family planning services yields up to \$6 in savings on health, housing, water, and other public services.”⁴

HIV/AIDS disproportionate impact on women and girls: The goal of reaching an AIDS-free generation cannot be achieved without targeting women and girls. PEPFAR’s own data put this in stark relief: In low- and middle-income countries, HIV is the leading cause of death and disease in women of reproductive age. In sub-Saharan Africa, 60 percent of those living with HIV are female, and young women between the ages of 15 and 24 are infected at rates on average three times higher than their male peers. According to PEPFAR, “This disparity arises from systematic disadvantages faced by adolescent girls and young women’s increasing early exposure to HIV at a time of particular biological and often social vulnerability. Many girls are forced into sexual activity and marriage at very young ages and are extraordinarily vulnerable to unintended pregnancy, HIV, sexual violence and exploitation.”⁵

3. John Cleland et al., “Contraception and Health,” *The Lancet* 380, issue 9837 (July 14, 2012): 149–156.

4. Bill & Melinda Gates Foundation and Department for International Development (DFID), “Landmark Summit Puts Women at the Heart of Global Health Agenda: Global leaders unite to provide 120 million women in the world’s poorest countries with access to contraceptives by 2020,” July 22, 2012, <http://www.londonfamilyplanningsummit.co.uk/1530%20FINAL%20press%20release.pdf>.

5. U.S. Department of State, “PEPFAR Blueprint: Creating an AIDS-free Generation,” November 2012, p. 33, <http://www.pepfar.gov/documents/organization/201386.pdf>.

Policy Developments under the First Obama Administration

The first Obama administration embraced gender equality and the advancement of women and girls as a key global health and foreign policy objective. The decision to elevate these issues and tie them to U.S. diplomatic and development policy sent an important signal about the administration's commitment and instigated a series of policy changes that began in January 2009 and continued through the first term.

The administration's efforts involved three central strategies: the appointment of leadership and personnel in U.S. government agencies with responsibility for women's global health and gender equality, especially at the State Department, where Secretary of State Hillary Clinton was a highly visible champion; the development of policies and operational guidance to steer U.S. government agencies' efforts and program implementation; and participation in public-private partnerships to build sustainability and leverage U.S. foreign assistance investments.

In terms of leadership and personnel, President Obama appointed the first ambassador-at-large for global women's issues, Melanne Verwee, who heads an elevated State Department office on Global Women's Issues to ensure that gender issues and the advancement of women's and girls rights are fully integrated into the formulation and conduct of foreign policy. At the White House, the National Security Council added staff to focus on human rights and gender, and gender-based violence.

USAID administrator Rajiv Shah and USAID deputy administrator Donald Steinberg advocated for the agency's work on gender equality and women's empowerment, and USAID's work in this area was strengthened with the appointment of a senior coordinator for gender equality and women's empowerment and a USAID senior gender adviser. At PEPFAR, Ambassador Eric Goosby led the implementation of the PEPFAR gender strategies, especially through initiatives such as the PEPFAR Gender-based Violence Response initiative;⁶ while the PEPFAR interagency Gender Technical Working Group supported countries in expanding and improving gender-sensitive programming.

“The very words ‘family planning’ light up the limbic centers of American politics. From a distance, it seems like a culture war showdown. Close up, in places such as Bweremana [in the Democratic Republic of Congo], family planning is undeniably pro-life. When births are spaced more than 24 months apart, both mothers and children are dramatically more likely to survive. Family planning results not only in fewer births, but in fewer at-risk births, including those early and late in a woman’s fertility.” —Michael Gerson, August 29, 2011

Developing policies and operational guidance was an area of particular focus. Though these policies took many months, and sometimes years, to complete, and some have not yet been fully

6. The PEPFAR GBV Response initiative is a three-year, centrally funded project in three countries—Tanzania, the Democratic Republic of Congo, and Mozambique—totaling \$48 million. The initiative aims to use PEPFAR platforms to provide comprehensive services for survivors of GBV, and to strengthen community-based responses and referral networks. See Janet Fleischman, *Gender-based Violence and HIV: Emerging Lessons from the PEPFAR Initiative in Tanzania* (Washington, D.C.: CSIS, July 2012), http://csis.org/files/publication/120709_Fleischman_GenderBasedViolence_Web.pdf.

implemented, they were designed to embed gender-related outcomes, procedures, and policies into each agency's structure and way of operating.

Some of the most notable policies and guidance documents include:

- *The Global Health Initiative (GHI)*, the Obama administration's main framework for an integrated approach to global health, which included seven core principles, the first of which focused on women, girls, and gender equality. This led to the issuance of "Supplemental Guidance on Women, Girls and Gender Equality," prepared by an interagency working group on women and girls and designed to guide the development of GHI country strategies.
- *USAID's revised Gender Equality and Female Empowerment Policy*, its first update in nearly 30 years. The revised policy articulates three overarching outcomes: reducing gender disparities in access to and control over resources and opportunities; reducing gender-based violence and mitigating its harmful effects; and increasing the rights of women and girls by influencing decisionmaking in households, communities, and societies.
- *The State Department's first Secretarial Policy Guidance on Promoting Gender Equality to Achieve Our National Security and Foreign Policy Objectives*, which provides the department with guidance on how to promote gender equality in U.S. foreign policy, focusing across all areas to reduce disparities and proactively promote gender equality to foster economic growth, peace, and security.
- *President Obama's executive order directing the implementation of the first National Action Plan on Women, Peace, and Security*, which focused on women's participation in peace negotiations and reconstruction, protection of women and children from abuse in conflict areas, and the needs of women and girls in disaster and crisis response.
- *President Obama's executive order directing the first-ever U.S. Strategy to Prevent and Respond to Gender-Based Violence Globally*, including Department of State and USAID implementation plans, provides federal agencies with concrete goals and actions to be implemented and monitored over a three-year time frame, after which the agencies will evaluate progress and chart a course forward.

The Obama administration also participated in new public-private partnerships in the health arena to promote sustainability and country ownership around women's and girls' health issues.

Examples include:

- *Together for Girls (TfG)*, a public-private partnership that seeks to end sexual violence against girls and violence against children more broadly. TfG includes the U.S. government, five UN agencies, led by UNICEF, and various private-sector partners. Bringing together issues of gender-based violence, HIV, and child protection, TfG promotes country-driven efforts for change.
- *The Alliance for Reproductive, Maternal and Newborn Health*, a five-year global public-private partnership announced by the governments of the United States, the United Kingdom, Australia, and the Bill & Melinda Gates Foundation. The aim is to contribute to the goal of reducing the unmet need for family planning⁷ by 100 million women, expand skilled birth attendants

7. The unmet need for family planning refers to the number of women of reproductive age who are married or in a union, who are sexually active but are not using any method of contraception, and report

and facility-based deliveries, and increase the numbers of women and newborns receiving postnatal care.

- *The Pink Ribbon Red Ribbon Initiative*, designed to build off PEPFAR platforms to expand cervical and breast cancer prevention, screening, and treatment for women in developing countries in sub-Saharan Africa and Latin America. The link with PEPFAR is critical, since HIV-infected women are four to five times more susceptible to cervical cancer. Led by the George W. Bush Institute, the U.S. State Department, Susan G. Komen for the Cure, and UNAIDS, the initiative was launched in September 2011, and includes several corporate partners.
- *Saving Mothers Giving Life*, an initiative designed to reduce maternal mortality in selected districts of Zambia and Uganda by up to 50 percent. This program is supported by the U.S. government, the government of Norway, Merck for Mothers, the American College of Obstetrics and Gynecology, and Every Mother Counts, as well as the governments of Zambia and Uganda.

Ongoing Challenges

The Obama administration has made important progress in advancing the status of women and girls and making gender equality a cornerstone of U.S. foreign policy. Lessons learned along the way should help guide the second Obama administration and congressional leaders in addressing outstanding challenges, the most pressing of which are summarized below.

Ensuring high-level leadership. Over the past four years, the engagement of high-level administration officials, beginning with Secretary of State Clinton and President Obama himself, has been fundamental to the administration's ability to move the policy agenda forward in support of women's global health and gender equality outcomes, but continued engagement will be required to advance implementation. Given that some of the most active champions in the first Obama administration may soon move on, the administration should consider candidates' commitment to these issues as key vacancies arise. Strong, committed leadership is indispensable to outline clear principles, initiate policy change, and ensure program implementation and accountability.

“We’re not talking about abortion. We’re not talking about population control. What I’m talking about is giving women the power to save their lives, to save their children’s lives and to give their families the best possible future.” —Melinda Gates, April 2012

Strong leadership is also needed to drive and coordinate multisectoral program integration in support of women's health and gender equality outcomes in partner countries. At the country level, the leadership of U.S. ambassadors is a critical component to achieving success, both by engaging with partner governments on the importance that the U.S. attaches to these issues and by ensuring that U.S. government country teams prioritize implementation. Cultivating this leadership and strong U.S. government country teams focused on and trained in women's health and gender equality should be supported and recognized by the administration.

not wanting any more children, or wanting to delay the birth of their next child. See World Health Organization, “Unmet Need for Family Planning,” http://www.who.int/reproductivehealth/topics/family_planning/unmet_need_fp/en/index.html.

Leveraging the PEPFAR platform. In establishing and reauthorizing PEPFAR, Congress recognized that an effective response to global HIV/AIDS requires a focus on women, girls, and gender inequalities, and PEPFAR has enhanced its work to promote greater gender-related programming. In particular, PEPFAR has expanded its work on and investments in GBV prevention. Yet challenges remain in getting PEPFAR country programs to support the research and programmatic investment to go beyond a biomedical approach to a more holistic approach that addresses the social drivers of the epidemic that put women and girls at greater risk of infection, and keep those living with HIV from accessing necessary health and support services.

Many women access HIV services through programs to prevent mother-to-child transmission (PMTCT), and this opportunity can also be used to connect women with prevention, care, and treatment services for themselves. As more women living with HIV access antiretroviral (ARV) treatment, the PEPFAR platform has become an important entry point for providing more comprehensive and integrated health services for women and girls, such as voluntary family planning, maternal and child health services, and cervical cancer screening. PEPFAR has recognized the value of making these services bidirectional and could expand on this front, so that HIV services are offered at maternal health or family planning clinics where women may be more likely to seek information and services.

Despite improvements in PEPFAR's gender-related work, HIV-family planning integration remains a particular challenge for the U.S. government. Administration officials and PEPFAR leaders have acted cautiously in this area, faced with stiff resistance from some politicians who oppose family planning or who mistakenly equate family planning with abortion.⁸ As a result, PEPFAR currently states that its funds cannot be used to purchase family planning commodities other than condoms, although PEPFAR supports linkages between HIV/AIDS and voluntary family planning programs.⁹ The strategic integration of HIV and voluntary family planning—and determining how the voluntary family planning needs of HIV-positive women can be met in the context of their HIV care and treatment, if these services are not otherwise accessible—is a question that the administration should revisit, given the potential for significant benefit to women, men, children, and their communities.

Shifting to program implementation. The first Obama administration focused on building and strengthening the policy foundations for women's global health and gender equality programs. However, implementation of these policies will require a new level of sustained efforts, including human and financial resources.

With supportive strategies and policies generally in place, the challenge now is to operationalize them at the country level. This step will require the development of indicators and targets to measure performance and progress, training staff in the field and at headquarters, sharing best practices, and providing resources to support scale-up of programs.

Expanding access to voluntary family planning and maternal health services. Expanding access to voluntary family planning and maternal health services is a key global priority. The impact of

8. U.S. foreign assistance prohibits U.S. funds to pay for abortion as a method of family planning.

9. PEPFAR funds can be used to support family planning counseling and referrals in HIV programs, as well as HIV counseling and testing in antenatal, maternal child health, and family planning sites. See: PEPFAR, "FY 2013 Country Operational Plan Appendices," p. 59, <http://www.pepfar.gov/documents/organization/198960.pdf>.

such services is clear: They have been shown to save and improve women's lives, allow families to space their children at intervals proven to be the safest for the woman and the family, reduce infant mortality, promote economic development, and avert millions of abortions. Data from the Demographic and Health Survey (DHS) have shown that nearly 40 percent of women in sub-Saharan Africa want to space their children by two years or more, and some 222 million women have an unmet need for family planning. Voluntary family planning and maternal health services are fully consistent with U.S. law, best health practices, and broader U.S. foreign policy and security goals.

The first Obama administration's budget requests for bilateral and multilateral family planning programs increased steadily during the first three years of the administration, reaching a high of \$769 million requested for FY 2012. The current funding level of \$610 million (under the continuing resolution) is an increase of more than 30 percent over the spending level of 2009. These resources have helped millions more women access the services they need, but remain inadequate to meet the existing unmet need. National governments will also have to contribute leadership and resources.

The ongoing challenge for the Obama administration is how to de-politicize these issues in the United States and to focus on the importance of access to voluntary family planning services for women and men around the world. Given the likelihood of tight budgets in the years ahead, this will involve sustaining U.S. global leadership in family planning, leveraging developing country resources and pushing for policy and legal reforms, and actively participating in global initiatives such as Family Planning 2020.¹⁰

“These women aren’t dying because the global health community doesn’t know how to prevent their deaths. They are dying because the world has not stepped up and helped.”

—Representative Kay Granger, June 2010

Communicating more effectively. Clear communication will be essential in working with the new Congress to ensure implementation and coordination of gender-related policies and programs. Yet, the first Obama administration was not always effective or consistent in communicating the health and development benefits of addressing women's global health and gender issues, whether domestically, bilaterally, or in interagency discussions.

For example, the Global Health Initiative's promise to improve coordination across U.S. agencies to achieve health outcomes was never fulfilled as hoped; and, in the wake of interagency tensions in Washington, the administration was unable to convey the importance of GHI's key principles to Congress, including and especially the emphasis on women, girls, and gender equality. That said, the GHI process did successfully shift the way the U.S. government works on these issues in some countries, and the progress it sparked toward a coordinated approach on women, girls, and gender equality should be preserved and strengthened in the years ahead. These issues should be a focal point for the new Office of Global Health Diplomacy, which will be headed by Ambassador Goosby.

10. Family Planning 2020 is an initiative that seeks to ensure compliance with the commitments made at the London Family Planning Summit in July 2012 by both developing and developed countries, to remove the policy, financing, and delivery barriers that prevent women from accessing contraceptive information, services, and supplies.

Policy Recommendations

Over the past four years, the Obama administration has built a strong foundation and created an enabling policy and strategy environment for women's global health and gender equality. The experience of the first Obama administration has shown that policy development on its own is not enough; the next step is to ensure that those policies are supported by political commitment and financial resources aimed at accelerating program implementation. To achieve successful outcomes, U.S. government agencies will have to translate the recent gender policies and guidance into effective programs, provide appropriate resources and gender-related training and staffing, and be accountable for success. The U.S. government should use this opportunity to build on past U.S. investments in critical areas such as maternal health, voluntary family planning, HIV/AIDS, and gender-based violence, and work toward sustainability by strengthening partnerships and supporting countries with a demonstrated commitment to address these issues.

To succeed, the administration and Congress should consider four priority policy recommendations:

1. Sustain high-level U.S. leadership on women's health and gender equality.

The president should direct each U.S. implementing agency to embed the new policies and strategies on women's global health and gender equality into their programs, and require reports on progress to hold them accountable for results. This will require obtaining funding allocations adequate to achieve success, and necessary leadership to ensure that candidates for relevant high-level positions are committed to these issues.

The president and congressional leaders should work assiduously to expand bipartisan support for women's global health and gender equality and to cultivate new champions. The president should take the lead in the United States in prioritizing voluntary family planning for women and men around the world, initiating a high-level dialogue to develop a clear agenda to increase access and enlisting key stakeholders—including faith-based organizations and the private sector, as well as family-planning advocates.

The State Department should expand its efforts to enlist other donor governments to the cause of prioritizing programs to serve women and girls and the expansion of gender equality. This should be a key function of the new Office of Global Health Diplomacy.

2. Implement for results; translate U.S. policies to program implementation.

The administration should hold its development and health personnel working at the country level accountable for implementing existing interagency guidance on women's health and gender equality, and reflecting that guidance in program planning, country strategies, budgeting, and training. Country teams that are successfully implementing this guidance should be recognized to further motivate progress.

The State Department's global AIDS coordinator should build on its guidance relating to integration of HIV with voluntary family planning by developing indicators to measure integration, working proactively with health service providers to identify unmet need for family planning among HIV-positive women, and developing specific strategies in response. PEPFAR-supported PMTCT and treatment programs should include access to voluntary family planning education and commodities (beyond condoms); commodities not otherwise available for HIV-positive clients should be provided.

Congress should maintain strong U.S. funding for voluntary family planning and maternal health in both bilateral and multilateral programs, including for improving access to a full range of family planning methods.

U.S. government agencies and implementing partners should integrate gender-based violence prevention and response services (emergency care, PEP, emergency contraception, community mobilization and support, and linkages with legal services) in health and development programs, and build on new evidence to enhance program implementation and impact.

3. Monitor and evaluate progress in addressing women's health and gender equality.

The administration should actively monitor and evaluate progress of U.S. government global health and development programs promoting women's health and gender equality by conducting a series of impact evaluations over the next five years to measure improvements in these areas.

U.S. government implementing agencies should publish the funding and other resources being directed at maternal health, gender-based violence, women and HIV, and gender equality programs. This information should be included on the foreign-assistance funding "dashboard" (foreignassistance.gov) in an easy-to-understand format.

U.S.-funded global health programs should be required to collect gender-related data, including sex and age disaggregated data, as well as work in other ways to capture evidence on what works in women's health and gender equality, and use it to guide programing and improve outcomes.

4. Build partnerships to leverage existing funds for sustainability.

Countries with demonstrated commitments to women's health and gender equality should be prioritized for funding. This could be measured through USAID gender assessments, as part of the Country Development Cooperation Strategies (CDCS), and used to determine eligibility for participation in Partnership for Growth programs.

The new ambassador for global health diplomacy should develop a coordinated approach to engage national governments, civil society (including faith-based organizations), private sector, foundations, and other development partners to catalyze an integrated, national strategy on women's global health and gender equality. Priority should be given to countries in different geographic regions with the greatest needs. The added value of these coordinated efforts should be monitored and evaluated.

The administration should develop clear lines of communication with the Congress to increase support for women's health and gender equality programs and resources, especially new leadership and staff on relevant authorizing and appropriation committees.

The administration should engage with multilateral organizations and development partners including UN agencies such as UN Women, UNAIDS, UNFPA, and UNICEF, as well as the Global Fund to Fight AIDS, Tuberculosis and Malaria, the World Bank Group and other donor governments to define concrete joint actions to advance progress and to ensure that their programs focus on women's health outcomes.



APPENDIX

TIMELINE OF KEY DEVELOPMENTS ON WOMEN'S GLOBAL HEALTH ISSUES UNDER THE OBAMA ADMINISTRATION

- January 2009—President Obama repealed the Mexico City Policy (“Global Gag Rule”) that prohibited U.S. funds from going to any international organization that uses its own funds to provide any service relating to abortion, including counseling, referral, or advocacy. The policy was first imposed by President Ronald Reagan in 1984; rescinded by President Bill Clinton in 1993; and then reinstated by President George W. Bush in 2001.
- March 2009—President Obama signed an executive order creating the White House Council on Women and Girls “to ensure that each of the agencies in which they’re charged takes into account the needs of women and girls in the policies they draft, the programs they create, the legislation they support.”
- April 2009—President Obama appointed Melanne Verveer as first ambassador-at-large for global women’s issues to head an elevated office at State Department on Global Women’s Issues.
- May 2009—President Obama announced the Global Health Initiative (GHI), with a particular focus on preventing new HIV infections, reducing maternal mortality, and averting unintended pregnancies. The first of seven core principles is focused on women, girls, and gender equality.
- July 2009—President Obama announced Feed the Future (FtF) as the U.S. global hunger and food-security initiative, which included a focus on gender integration and promoted women’s leadership in agriculture, land ownership, and access to financial services and new technology.
- April 2010—GHI issued Supplemental Guidance on Women, Girls and Gender Equality Principle, outlining ten key elements of implementation for use by GHI country teams in developing their GHI strategies.
- May 2010—PEPFAR launches Gender-based Violence Initiative, a three-country project to scale up prevention and response efforts against gender-based violence.
- May 2010—PEPFAR launches the Gender Challenge Fund, which makes additional resources available to PEPFAR country programs, using central funds to match funds from country budgets, and totaling \$28 million.
- December 2010—Secretary Clinton released the Quadrennial Diplomacy and Development Review (QDDR), a review of U.S. diplomatic and development policies, which included an increased focus on women and girls in U.S. foreign policy and assistance.
- May 2011—The Millennium Challenge Corporation (MCC) released its gender policy, which requires that gender analyses be included in the design and implementation of programs funded by MCC.

- September 2011—Secretary Clinton and President George W. Bush launch the Pink Ribbon Red Ribbon Initiative, a public-private partnership to expand cervical and breast cancer screening and treatment for women in developing countries of sub-Saharan Africa and Latin America.
- October 2011—U.S. Department of Health and Human Services issued its Global Health Strategy, which identified a key priority to be focusing on the health of women, newborns, and children through programs for nutrition, reproductive, maternal and child health, and safe water.
- December 2011—President Obama issued an executive order directing the implementation of the first National Action Plan on Women, Peace, and Security, which focused on women’s participation in peace negotiations and reconstruction, protection of women and children from abuse in conflict areas, and the needs of women and girls in disaster and crisis response.
- March 2012—USAID administrator Rajiv Shah launched USAID’s new Gender Equality and Female Empowerment Policy, which aimed to reduce gender disparities in access to resources, opportunities, and services; reduce gender-based violence and mitigate its harmful effects; and increase the capability of women and girls to realize their rights, determine their life outcomes, and influence decisionmaking in households, communities, and societies.
- March 2012—Secretary Clinton issued the State Department’s first Secretarial Policy Guidance on Promoting Gender Equality to Achieve Our National Security and Foreign Policy Objectives, providing guidance on promoting gender equality to foster economic growth, peace, and security.
- June 2012—Secretary Clinton announced Saving Mothers, Giving Life, a public-private partnership to help reduce maternal mortality during the 24 hours around labor and delivery.
- July 2012—USAID administrator Rajiv Shah participated in the London Summit on Family Planning, cosponsored by DFID and the Bill & Melinda Gates Foundation with the goal of providing 120 million of the world’s poorest women access to life-saving contraceptives, information, and services by 2020.
- August 2012—The Department of State and USAID released the first U.S. Strategy to Prevent and Respond to Gender-Based Violence Globally, accompanied by an executive order from President Obama directing all relevant agencies to implement the strategy.
- October 2012—USAID launches its policy on ending child marriage and meeting the needs of married children.
- November 2012—USAID launches its policy on youth in development, which also focuses on girls.

6

U.S. PRIORITIES FOR MULTILATERAL PARTNERS

INTRODUCTION

This chapter focuses on five multilateral institutions of central importance to any discussion of U.S. policy approaches to global health: the World Health Organization (WHO); the Global Fund to Fight AIDS, Tuberculosis and Malaria; the GAVI Alliance; UNAIDS; and the World Bank Group. In each case, the authors define how the organization specifically aligns with key U.S. interests; summarize the major policy developments seen during the first Obama administration, followed by the outstanding challenges that remain today; and outline select policy priorities for the second Obama term and the incoming Congress.¹ Three propositions emerge across the five brief analyses.

First, despite weaknesses in their governance and performance, these institutions advance U.S. interests.

Across a widening agenda of health priorities, these institutions provide access, vital data, technical expertise, legitimacy, and perspective that cannot be attained simply through unilateral U.S. action. They have a proven record of generating consensus, legal frameworks, and timely guidance on present and emerging U.S. policy priorities. They are getting better at measuring and demonstrating their outcomes.

Moreover, in an era of scarce resources, these multilateral institutions have arguably become even more important to U.S. goals in global health. In part, that is because they can mobilize greater burden sharing by other donors; in addition, they can spur partner national governments to take better ownership of their health agenda and invest more political and financial capital in creating effective health services and fiscally sustainable health systems.

Second, for each of these organizations there are important ready opportunities for the United States to partner operationally in advancing key common policy priorities.

For example, the United States has moved the President's Emergency Plan for AIDS Relief (PEPFAR) closer to the Global Fund as an essential step in enlarging global access to antiretroviral treatment. It has done the same with WHO on building order, predictability, and health safety across the world. It relies deeply upon UNAIDS for reliable trend data on the global AIDS pandemic, strategic thinking on investments, and approaches to marginalized populations and regressive regimes. The U.S. linkage with the GAVI Alliance is fundamental to reducing preventable childhood deaths; and its partnership with the World Bank in developing countries helps promote effective self-financing of health.

1. The priority multilateral institutions could well include UNICEF, the UN Development Program, and others; however, space and time demand selectivity.

Indeed, the strategic synergy between the United States and its key multilateral partners—the deepening alignment of policies and programs—has become an ever-more-visible requisite to achieving U.S. policy goals.

Third, while each of these institutions has room to improve its management and operational performance, steady progress requires effective engagement by competent, working-level U.S. managers and diplomats, as well as sustained attention at high U.S. political and diplomatic levels.

To varying degrees, each of the multilaterals under consideration operates in a state of fluid stress. In the face of declining resources, they increasingly compete for funding, and are subject to heightened scrutiny, including demands to reaffirm their comparative value and provide concrete outcomes. To regenerate, reform, be fiscally sound, and perform effectively, each institution's leaders must ultimately be responsible for guaranteeing continued progress. Durable progress also requires that the United States have an ongoing dialogue with these multilateral leaders based on candor, good faith, and respect; and that the United States provide hands-on managerial and technical support, based on long-term shared goals. The newly formed Office of Global Health Diplomacy has the potential to strengthen the United States' relations across these institutions.

Multiyear replenishments and periodic internal reviews provide the focal moments for these dialogues; those tests will be in full motion in 2013 and 2014.

THE WORLD HEALTH ORGANIZATION (WHO)

By Nellie Bristol²

Key Assets that Align with U.S. Interests

The World Health Organization (WHO) is a critical health security partner for the United States. The principal global authority for setting norms and standards for public health in areas such as medical-product quality and disease control, WHO enables worldwide disease surveillance and response, facilitates international negotiations on sensitive health and related trade topics, and is a key U.S. partner in the global effort to eradicate polio.

In recent years, WHO has faced serious budgetary woes. Its director-general Margaret Chan, elected in 2012 with strong U.S. backing to a second five-year term, has at the same time sought to advance management reforms to address chronic problems. These problems include, most importantly, weak financial controls, accountability, and monitoring of service delivery, especially in highly autonomous regional offices; rigid UN personnel policies; limited authority and budgetary clout of the Geneva headquarters, including the office of the director-general; and difficulty in prioritizing goals and programs. Chan's reforms are unfolding in the midst of intensified competition on an increasingly crowded global health stage that now includes multiple large organizations such as the Global Fund to Fight AIDS, Tuberculosis and Malaria and the GAVI Alliance.

Despite increased competition, fiscal constraints, and complex management and governance challenges, WHO possesses critical assets that make it essential to the advancement of public health globally—an important component of U.S. security. Based on its broad political legitimacy and reputation as a neutral, fair space for setting common norms, standards, and guidelines, WHO has a proven ability to convene expert technical and policy panels to address sensitive, complex issues of common interest. It is welcomed virtually everywhere in the world, allowing it to facilitate disease surveillance and response in places where groups with a specific national identity may be seen as suspect.

To maximize WHO's value as a global partner, the United States, in concert with like-minded governments and through close engagement with the director-general, should continue to advance internal reforms essential to making the organization stronger and more effective.

2. Nellie Bristol is a fellow with the CSIS Global Health Policy Center.

Policy Developments under the First Obama Administration

The United States' annual assessed contributions stayed steady at \$109 million in 2010 and 2011,³ a level equaling 22 percent of the organization's regular budget.⁴ U.S.-assessed contributions to WHO totaled \$107 million in fiscal year 2009 and \$101 million in fiscal year 2008.⁵ Additional voluntary funding from the United States totaled \$424 million for the 2008–2009 period⁶ and \$438 million for 2010–2011.⁷ U.S. voluntary contributions helped support WHO activities in areas such as tuberculosis control and pandemic influenza preparedness.⁸

WHO officials and other observers credit the Obama administration with significantly improved diplomatic interactions with WHO and other member states compared to the previous administration. The change helped encourage member states to support reforms and fostered important diplomatic gains especially with respect to sharing virus specimens and resolving related intellectual-property disputes. A framework arranging the sharing of pandemic flu virus samples needed for vaccine production serves as one example. In April 2011, the WHO Open-Ended Working Group of Member States on Pandemic Influenza Preparedness agreed on the document after five years of negotiation.⁹ The framework responds to the concerns of the governments of Indonesia and of other developing countries that have been reluctant to share virus samples with WHO, since resulting vaccine manufacturing is carried out largely by developed countries and sold at prices unaffordable in the developing world. The framework outlines a Benefit Sharing System that will provide and build capacity for pandemic surveillance for all countries and provide more equitable access to antiviral medicines and vaccines against H5N1 and other potentially pandemic influenza viruses.

WHO-U.S. dialogues also have advanced on health security priorities. In September 2011, WHO and the U.S. Department of Health and Human Services signed a memorandum of understanding to increase cooperation on disaster and pandemic preparedness as well as disease surveillance, reporting, and response. The agreement encourages coordination between the United States and WHO in enhancing the existing global alert and response network; supporting the implementation of the International Health Regulations (for more detail, see the chapter on global health

3. World Health Organization, "Status of Collection of Assessed Contributions, Including Member States in Arrears in the Payment of Their Contributions to an Extent That Would Justify Invoking Article 7 of the Constitution," April 5, 2012, http://www.who.int/about/resources_planning/A65_30-en.pdf.

4. World Health Organization, "Scale of Assessments 2010–2011," February 16, 2010, http://www.who.int/about/resources_planning/scale_of_assesment_2010-2011_a63_31-en.pdf.

5. Marjorie Ann Browne, "United Nations System Funding: Congressional Issues," Congressional Research Service, January 14, 2011, <http://www.fas.org/sgp/crs/row/RL33611.pdf>.

6. World Health Organization, "Voluntary Contributions by Fund and by Donor for the Financial Period 2008–2009," April 29, 2010, http://apps.who.int/gb/ebwha/pdf_files/WHA63/A63_ID4-en.pdf.

7. World Health Organization, "Voluntary Contributions by Fund and by Donor for the Financial Period 2010–2011," April 5, 2012, http://apps.who.int/gb/ebwha/pdf_files/WHA65/A65_29Add1-en.pdf.

8. Office of Management and Budget, "Annual Report on United States Contributions to the United Nations," June 6, 2011, http://www.whitehouse.gov/sites/default/files/omb/assets/legislative_reports/us_contributions_to_the_un_06062011.pdf.

9. World Health Organization, "Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and Other Benefits: Report by the Open-Ended Working Group of Member States on Pandemic Influenza Preparedness," May 5, 2011, http://apps.who.int/gb/ebwha/pdf_files/WHA64/A64_8-en.pdf.

security); strengthening global, regional, and national public health systems; and enhancing global health leadership and cooperation.¹⁰

WHO also is taking a role in addressing the critical problem of production and distribution of substandard and fraudulent medicines, an issue increasingly important to the United States as more products and ingredients originate overseas. In recent action, WHO cosponsored in November 2012 the first meeting of the Member State Mechanism on Substandard/Spurious/Falsely-Labelled/Falsified/Counterfeit Medical Products with the goal of developing strategies for promoting national regulatory capacity to ensure the quality of medical products.¹¹

Improving research and development (R&D) that meets the specific health needs of developing countries is another WHO priority. At the May 2013 World Health Assembly, member states will consider adopting a resolution to establish a Global Health R&D Observatory housed at WHO, intended to monitor and analyze relevant information, identify gaps and opportunities, and define health R&D priorities in consultation with member states.

On broader issues, WHO is taking center stage in devising indicators for the control of non-communicable diseases (NCDs), including cancer, cardiovascular disease, diabetes, and chronic respiratory disease. Currently, the organization is developing an updated action plan for a strategy for controlling and preventing NCDs that would cover 2013–2020, with a global goal of reducing premature mortality from NCDs by 25 percent by 2025.¹²

WHO also is leading discussions on universal health coverage, an overarching concept that would foster equitable access to health services while ensuring against catastrophic health-related financial losses. Universal health coverage is intended to serve as an umbrella approach that encompasses infectious diseases, maternal and child health, and NCDs. The goal is to facilitate self-reliant, sustainable, country-level mechanisms for health financing involving a mix of public and private resources.

Ongoing Challenges

Excessive financial earmarks. There is a serious imbalance between annual assessed contributions to WHO and those earmarked for specific projects. This stems to a significant degree from a lack of confidence in WHO's financial controls, accountability, and performance, especially in its regional offices. This budgetary imbalance, however, hinders the director-general's ability to fund administrative core costs in Geneva, preserve technical expertise, and use her budgetary sway both to encourage reforms and to pursue priority global health objectives.

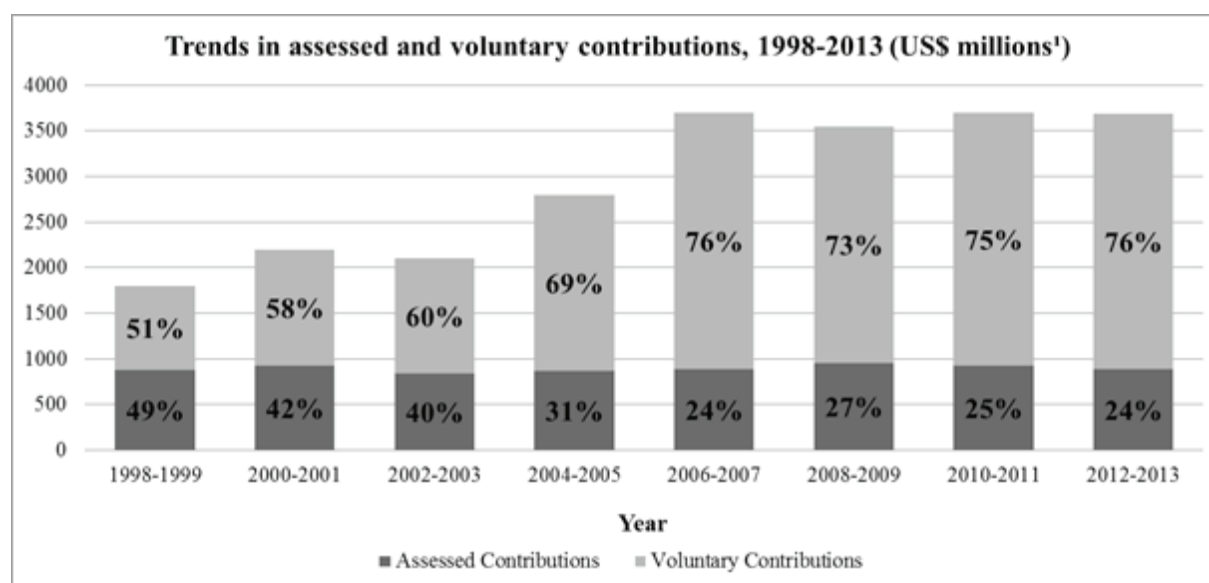
10. U.S. Department of Health and Human Services, "Memorandum of Understanding Between the Government of the United States of America and the World Health Organization Regarding Cooperation on Global Health Security Initiatives," September 19, 2011, <http://www.globalhealth.gov/global-health-topics/health-diplomacy/agreements-and-regulations/20110922-mem.html>.

11. World Health Organization, "New Global Mechanism to Combat Substandard/Spurious/Falsely-labelled/Falsified/Counterfeit Medical Products," November 21, 2012, http://www.who.int/medicines/news/TRA-SE_EMP.pdf.

12. World Health Organization, "Zero Draft: Global Action Plan for the Prevention and Control of Noncommunicable Diseases, 2013–2020," October 10, 2012, http://www.who.int/nmh/events/2012/ncd_zero_draft_action_plan_2013-2020.pdf.

Currently, about 75 percent of WHO’s funding comes in the form of voluntary contributions while the remainder results from annual assessments (see Figure 1). Donors specify a large portion of voluntary funding for certain projects, diseases, or regions. The trend has turned WHO into a “donor-driven” organization with fragmented programs.¹³ “Most voluntary funding is for short-term projects,” explained WHO director-general Chan. “The management of a large amount of earmarked and specified voluntary income increases overhead costs...and reduces efficiency. Programmes and offices compete for funds and become territorial in protecting their interests, which works against policy coherence.”¹⁴

Figure 1: Trends in Assessed and Voluntary Contributions, 1998–2013



¹ Data *exclude* in-kind contributions. Assessed contributions and voluntary contributions are projected for 2012–2013.

Source: World Health Organization, http://apps.who.int/gb/ebwha/pdf_files/EBSS/EBSS2_ID2-en.pdf.

Shrinking resources. Even as it confronts restrictions on how it can use its funds, WHO is downsizing its budget expectations. The organization had an approved budget for 2010–2011 of \$4.54 billion, but because of the global economic downturn, was able to collect only \$3.84 billion of the

13. Committee on the U.S. Commitment to Global Health, *The U.S. Commitment to Global Health: Recommendations for the Public and Private Sectors* (Washington, D.C.: National Academies Press, May 2009), <http://www.iom.edu/Reports/2009/The-US-Commitment-to-Global-Health-Recommendations-for-the-Public-and-Private-Sectors.aspx>.

14. World Health Organization, “Director-General Addresses Reforms in WHO Financing” (remarks by Dr. Margaret Chan, director-general of the World Health Organization, at the Programme, Budget and Administrative Committee of the Executive Board, Second Extraordinary Meeting, Geneva, Switzerland, December 6, 2012), http://www.who.int/dg/speeches/2012/reforms_20121206/en/index.html.

total.¹⁵ WHO officials originally hoped for a budget of \$4.8 billion for 2012–2013, but member states approved a budget of \$3.96 billion.¹⁶ The reductions have resulted in staff layoffs, focused primarily at the organization’s Geneva headquarters and in the African region. Between the end of 2010 and August 2012, WHO reduced staff by 937 people with either long-term or temporary contracts. Nearly 500 staff members were eliminated at headquarters, while an additional 300 losses occurred in the Africa region.¹⁷ The reductions and other management problems have raised questions about WHO’s continued technical expertise.¹⁸

Cumbersome governance. WHO has a challenging management structure distributed across six geographic regions and subject to the direction of its 194 member states with divergent health needs, available resources, and political philosophies. WHO often is criticized for taking on too many activities to do them all effectively, but member states have had a difficult time agreeing on a select set of core priorities. In addition, accountability and transparency have been longstanding problems in the WHO regional offices. The ambitious and much-needed organizational reform initiated by Director-General Chan is at an early phase,¹⁹ and the next few years will test what level of concrete progress is achievable. If even partially successful, the reform effort will help focus WHO’s mission upon core priorities, better connect financing with that mission, enhance transparency and accountability, and create a far more effective secretariat.

A key goal of reform is narrowing WHO’s mission to focus on its strengths. In 2012, the organization developed criteria to determine its priorities. They include current health problems, including burden of disease at the global, regional, or country levels; the needs of individual countries for WHO support; and WHO’s comparative advantage, including capacity to gather and analyze data in response to current and emerging health issues. WHO also will focus on five technical categories: communicable diseases; noncommunicable diseases; promoting health through the life course, which considers the long-term health implications of biological and social experiences; strengthening health systems; and preparedness, surveillance, and response.²⁰

Outmoded personnel rules. WHO is also hampered by outdated and cumbersome UN personnel rules that limit the secretariat’s ability to employ the most-qualified people. Rules governing pensions, employment, and reemployment privileges need to be modernized to strengthen incentives for flexibility and nimbleness versus permanence and rigidity.

15. Author communication with Elilarasu Renganathan, director of planning, resource coordination, and performance monitoring, World Health Organization, January 3, 2013.

16. Stephanie Nebehay and Barbara Lewis, “WHO Slashes Budget, Jobs in New Era of Austerity,” Reuters, May 19, 2011, <http://www.reuters.com/article/2011/05/19/us-who-idUSTRE74I51320110519>; also, author communication with Elilarasu Renganathan, January 3, 2013.

17. World Health Organization, “Human Resources: Annual Report,” November 30, 2012, http://apps.who.int/gb/ebwha/pdf_files/EB132/B132_38-en.pdf.

18. Oxfam International, “Long-Term Future of World Health Organization at Risk from Financial Crisis,” press release, May 18, 2012, <http://www.oxfam.org/en/pressroom/pressrelease/2012-05-18/long-term-future-world-health-organization-risk-financial-crisis>; also, Jack C. Chow, “Is the WHO Becoming Irrelevant: Why the World’s Premier Public Health Organization Must Change or Die,” *Foreign Policy*, December 8, 2010.

19. World Health Organization, “Implementation of WHO Reform, 2012,” January 8, 2012, http://www.who.int/about/who_reform/managerial/B132_5Add8-en.pdf.

20. World Health Organization, “WHO Reform: Report by the Director-General,” March 22, 2012 http://apps.who.int/gb/ebwha/pdf_files/WHA65/A65_40-en.pdf.

Advocacy challenges. Other challenges faced by WHO fall in the category of advocacy. For example, while universal health coverage provides the opportunity to encourage self-financing of country health systems, it may prove a hard sell to American audiences that view it as a vehicle for greater government involvement in providing and funding health services. Some universal health-coverage proposals call for mandatory participation of individuals in arrangements to pool health financing, another requirement that has attracted opposition in the United States. In addition, a focus on NCDs has turned attention to salt, sugar, and fat levels in commercial foods. While the movement has prompted some companies to reduce the amounts of those substances in their products, global goals on NCDs could call for further concessions from multinational food and beverage corporations and their suppliers, some of which are headquartered in the United States.

Palestinians and the WHO. The Palestinians in recent years have renewed efforts to seek membership in WHO. Since U.S. law calls for a funding halt to any UN agency that allows membership by the Palestine Liberation Organization, admittance would trigger a major disruption to WHO funding and to the U.S. partnership with the organization. The situation requires careful monitoring to avoid threatening the U.S. relationship with WHO and compromising global health security.²¹

Post 2015-MDG process. The United Nations has begun a process to formulate the future of the Millennium Development Goals (MDGs) after the current 15 year phase concludes in 2015. While the current goals include several related specifically to health, including reducing child mortality, improving maternal health and combating AIDS, malaria and other diseases, the next round could involve more general, overarching themes. While the creation of broad objectives would expand health concerns covered by the MDGs to emerging issues like noncommunicable disease and financial risk protection, a lack of specific targets and measurements could weaken accountability for health outcomes.

WHO and the private sector. WHO struggles with how to engage with the private sector in a way that avoids potential conflicts of interest. WHO is developing guidelines to govern interactions with both NGOs and private commercial enterprises. The U.S. is encouraging adoption of policies that allow the organization to receive input with sufficient transparency to ward against undue influence on WHO policy. Clearer guidelines should allow WHO to be more inclusive and better leverage the private sector's unique assets.

Lastly, WHO may have a difficult time keeping attention on preparedness: attention to global pandemic preparation often wanes in the absence of major threats, even though preparedness is essential to mitigating the effects of worldwide disease outbreaks.

21. For more information see J. Stephen Morrison and Haim Malka, *U.S. Global Health Policy in Palestinian Hands?* Center for Strategic and International Studies, March 2012, http://csis.org/files/publication/120307_Morrison_GlobalHealthPalestinian_Web.pdf.

Policy Recommendations

In response to these challenges, the administration and Congress should consider the following policy options:

1. Maintain U.S. focus on critical priorities.

The United States should maintain focus through WHO on critical global priorities, including health security (disease surveillance and response, bioterrorism containment, and pandemic preparedness); norms and standards; and successful conclusion of global polio eradication.

2. Support WHO reform by providing incrementally greater flexibility for core secretariat needs and disease categories.

While ensuring that specific U.S. priorities continue to receive targeted support through WHO, the United States should at the same time be more flexible in its funding, rely less on earmarking, and encourage other donors to respond similarly. To that end, the United States should provide the director-general with increased budgetary clout and discretionary power by providing more flexible voluntary funds, tied to concrete proof that reform efforts are strengthening accountability and performance. That step will more effectively encourage better WHO personnel practices, greater management and financing flexibility, and improved long-term planning. It will provide incentives for reform, support comprehensive approaches to health, and attract and hold top talent. Directing a larger proportion of U.S. voluntary funds to broad categories such as infectious diseases or NCDs as opposed to allotments to specific diseases would provide WHO more leeway to target funding to areas with the greatest needs.

3. Continue to provide ample U.S. technical expertise to extend WHO's capacity.

Traditionally, the United States has provided skilled personnel in areas of disease detection and control, health sciences, and operational leadership. As globalization continues, additional expertise is needed in areas such as advancing international regulatory structures to assure the quality of imported health-related products.

4. Actively contribute to debates over universal health coverage, the prevention and control of noncommunicable diseases, and global health research and development.

The United States can offer significant expertise in a variety of arrangements to pool health-services financing, in both the public and private sector. In addition, the United States has struggled with the treatment and control of chronic diseases for several decades and can provide important guidance as well as learn new approaches from other countries. Finally, as a major funder in R&D that benefits the developing world, the U.S. can lead in the establishment of health R&D norms and priorities and encourage member states to increase R&D commitments.

THE GLOBAL FUND

By Todd Summers²²

Key Assets that Align with U.S. Interests

The Global Fund to Fight AIDS, Tuberculosis and Malaria was established in 2002 to raise and disburse funds needed to address three of the world's deadliest epidemic diseases. Over the past twelve years, it has helped finance over 150 developing countries to mount prevention and treatment programs, contributing to millions of lives saved. By the end of 2012, the Global Fund had supported 4.2 million people on antiretroviral (ARV) drugs, treated 9.7 million cases of TB, and distributed 310 million insecticide-treated bed nets to protect against malaria.²³ It has recently adopted an ambitious five-year strategy and started its implementation by revamping its funding mechanism.

The U.S. government, under President George W. Bush, provided strong support; administration officials helped design and stand up the new entity, and the United States was one of its first major donors. Today, the United States remains the Global Fund's single largest donor, providing over \$7.2 billion of the Fund's total contributions of \$24.4 billion. Because U.S. law limits its contribution to no more than one-third of the total, it has also helped drive up funding from other donors. The U.S. government is also actively engaged in the Global Fund's governance, currently represented on its board by Ambassador Eric Goosby and his alternate Assistant Secretary of Health Nils Daulaire. It has led recent efforts to improve Global Fund operations and management, with the State Department's John Monahan serving as vice chair of the board's Finance and Operational Performance Committee, and Julia Martin serving on the board's Strategy, Investment and Impact Committee..

Together with U.S. bilateral programs, Global Fund disbursements account for a significant majority of donor assistance on all three diseases. For malaria, Global Fund support accounts for about half of all donor financing; for tuberculosis, about 80 percent of donor support flows through the Global Fund; and for HIV, it represents about one-quarter of donor funding. In sum, the Global Fund is a critical partner in all three diseases, as well as broader efforts to strengthen underlying health systems in developing countries and to address other urgent needs such as maternal and child health.

Going into 2013, the Global Fund faces an uncertain future: a new three-year replenishment cycle has begun, where donors will be asked to pledge support from 2014–2016; Dr. Mark Dybul, an American physician and former head of the President's Emergency Plan for AIDS Relief (PEPFAR) program under President George W. Bush, will start as the new executive director in January 2013; and an ambitious new funding model will be piloted, demanding greatly expanded technical and political engagement with recipient countries.

22. Todd Summers is a senior adviser with the CSIS Global Health Policy Center.

23. Global Fund, "The Global Fund's 2012 End-Year Results at a Glance," http://www.theglobalfund.org/en/mediacenter/videos/Video_The_Global_Fund_2012_End-Year_Results_at_a_Glance/.

Policy Developments under the First Obama Administration

The Obama administration, led by the Office of the Global AIDS Coordinator at the State Department, has made a concerted effort to strengthen programmatic ties with the Global Fund as well as to push for essential reforms in its management, governance, and overall approach to financing country-led programs on the three diseases. Critical ties have been established with high-need countries, especially those in sub-Saharan Africa that carry the greatest shares of disease burden. Guidance for applications to PEPFAR now requires coordination with Global Fund-supported programs, making clear that their success is part of the PEPFAR mandate. Senior U.S. representation in Geneva has also helped, bringing day-to-day engagement between the United States and the Global Fund's secretariat.

Funding levels have also increased, with the United States making its first three-year pledge of \$4 billion during the last replenishment cycle (2012–2014), although a tightened fiscal environment has made fulfillment of that pledge more challenging. However, the Global Fund has garnered important congressional support and has narrowly escaped the major reductions experienced by other foreign aid programs.

Ongoing Challenges

A major challenge in 2013 and beyond is turning reform commitments into action: getting the new leadership team in place, and implementing the Global Fund's reform overhaul in a timely, effective, and sustained fashion. Major governance and leadership reforms have been initiated, with a new executive director taking the reins and the search for a new inspector general under way. An ambitious new strategy and funding mechanism approved by the board now await concrete next steps in bringing them into force. These changes address some of the most pressing concerns raised by the United States and other donors, which had become increasingly unhappy with how the secretariat was being managed and how grant funds were being utilized. Moreover, the funding environment is forbidding. U.S. support remains strong, but mustering the political energy to increase funding as the Global Fund initiates its next three-year funding drive will be tremendously challenging. Other major donors, including France, Japan, and the European Commission, also face dwindling budgets, although advocates are working hard to maintain or increase their support as well as explore innovative financing mechanisms that could attract new sources of revenue.

One way to stretch funding is to get better value for money from grants, especially in the costs of goods and services purchased with Global Fund support. The board has already approved a focused "market-shaping strategy," charting a path to harness the Global Fund's immense purchasing power to drive down prices, improve quality, and ensure adequate supplies. For insecticide-treated bed nets used to protect against the mosquitoes that bring malaria, for example, one recent analysis estimated a potential savings of over \$600 million dollars through an improved purchasing approach.²⁴ Most of this benefit would come to the Global Fund since it dominates the bed net market. Unfortunately, work to implement the market-shaping strategy has been slow.

24. Kanika Bahl and Pooja Shaw, *Expanding Access to LLINs: A Global Market Dynamics Approach* (Washington, D.C.: Results for Development Institute, 2012), http://www.resultsfordevelopment.org/sites/resultsfordevelopment.org/files/resources/R4D_LLIN%20report_24Apr_Final.pdf.

Beyond funding levels, major challenges continue to threaten to reduce the impact of Global Fund grants. Many countries hit hardest by the three diseases also face considerable problems designing and implementing grant-supported programs because of limitations in health infrastructure and human resources, as well as limited political support for tackling stigmatized diseases and investing domestic resources into health. This makes long-term sustainability of these programs an urgent challenge to the Fund and its supporters. Countries that can do more to finance their own response often don't, letting the Global Fund and other outside donors carry the load. Even for countries that will continue to require substantial external funding, real political leadership is often lacking.

This makes it particularly difficult to overcome the broader social and political challenges that limit access to prevention and treatment services for a variety of marginalized groups that are disproportionately at risk. The Global Fund operates in environments where human rights violations, discrimination, and gender inequity are real threats to the very people it's trying to help. While the Global Fund's 2012–2016 strategy identifies promoting and protecting human rights as one of its five core objectives, engaging successfully on what are often highly political issues is going to be difficult and will require the Global Fund to develop its own capacity for political engagement as well as to utilize better the influence of its donors and partners.

Policy Recommendations

To address these challenges the administration and Congress should consider the following policy options:

1. Maintain strong U.S. leadership and support.

The Global Fund needs continued high-level support from the administration, both at the Geneva level to help incoming Executive Director Mark Dybul succeed, and at the country level, where Global Fund-supported and U.S. bilateral programs must work synergistically to achieve maximum public health impact. The Global Fund's recently approved new funding model offers tremendous opportunity to refocus Global Fund grants to harmonize better with U.S. bilateral funding, but a major culture change is also required to seize this opportunity and overcome years of risk aversion, inflexibility, and insularity. It will also require work by PEPFAR, UNAIDS, the World Health Organization, and others like the Roll Back Malaria and Stop TB Partnerships to help countries develop better national disease strategies around which funders can organize.

2. Promote a whole-of-government approach.

Despite the apparent demise of the U.S. Global Health Initiative, its call for cross-agency coordination and coherence should remain an important goal of the U.S. approach to health, including the United States' relationship with the Global Fund. For grants to succeed, help is needed not only from the United States but also from an array of multilateral and technical partners—including the U.N. Joint Program on AIDS (UNAIDS), the World Health Organization, and the World Bank—all of whom are supported and influenced by the United States. In addition, important bilateral trade and military relationships can help—or hinder—success in Global Fund and bilateral health programs and so require a “whole-of-government” approach.

3. Focus on the most urgent cases.

While the Global Fund has committed to remaining a global institution, working in over 130 developing countries, most of the burden of AIDS, TB, and malaria rests in about 20 countries. The United States needs to work assiduously with the Global Fund and other partners to get those countries' efforts in high gear, which includes: developing optimized national plans that identify the core prevention and treatment interventions needed to achieve maximum health impact; harnessing the domestic political, financial, and policy supports needed to implement those strategies; complementing those resources, as needed, with external support from the Global Fund and others; and ensuring real-time monitoring to course correct as needed to keep up with these three dynamic epidemics.

4. Implement the market shaping strategy.

The United States should push and support the Global Fund to extract maximum value for money for its grants by implementing rapidly the board-approved market dynamics strategy. It should also work to better leverage the capacity of UNITAID, another multilateral organization established by France and others to help address market failures in HIV, TB, and malaria that lead to higher prices or reduced availability of key medicines, diagnostics, and other health commodities. Up until now, UNITAID has provided a lot of funding directly to the Global Fund, and helped with the supply and price of a number of key commodities like pediatric antiretroviral treatments for AIDS, but there's been inadequate attention from the Global Fund to maintain and optimize what should be a symbiotic relationship.

5. Keep Global Fund contributions at or above current levels.

The Global Fund is a smart investment, leveraging U.S. donations by 2:1. It also offers a significant opportunity to transition some countries from heavy reliance on bilateral support to a higher percentage of Global Fund financing (coupled with increased domestic contributions). The United States should work hard to expand its funding to the Global Fund, and push other donor countries to also do better.

THE GAVI ALLIANCE

By Amanda Glassman²⁵

Key Assets that Align with U.S. Interests

Though vaccines are among the most cost-effective interventions to improve health, low-income countries have historically benefited the least.²⁶ To remedy this situation, the public-private GAVI Alliance was created in 2000 with active support from the governments of Norway and the United States, the Bill & Melinda Gates Foundation, and other organizations, with a mission to “save children’s lives and protect people’s health by increasing access to immunization in the world’s poorest countries.”²⁷ GAVI defines “poorest countries” as countries with an average income of less than US\$1,500 per capita. In these countries, GAVI provides financial support for new and underused vaccines, immunization services, vaccine introduction, civil society organizations, and activities to strengthen related health systems. Its mission and track record of effective spending align closely with the growing U.S. interest in enhancing child survival.²⁸

The total resources available to GAVI from 2011–2015 are \$7.6 billion,²⁹ and annual spending has risen from \$350 million in 2008 to \$1.1 billion in 2012. U.S. contributions and pledges to GAVI between 2000 and 2014 total almost \$1.1 billion (see Figure 1). The United States currently funds 11.2 percent of GAVI’s annual budget.³⁰

25. Amanda Glassman is the director of global health policy and a senior fellow at the Center for Global Development.

26. GAVI Alliance, “Cost-effective,” <http://www.gavialliance.org/about/value/cost-effective/>; and Centers for Disease Control and Prevention, “CDC Global Vaccines and Immunization,” <http://www.cdc.gov/globalhealth/immunization/>.

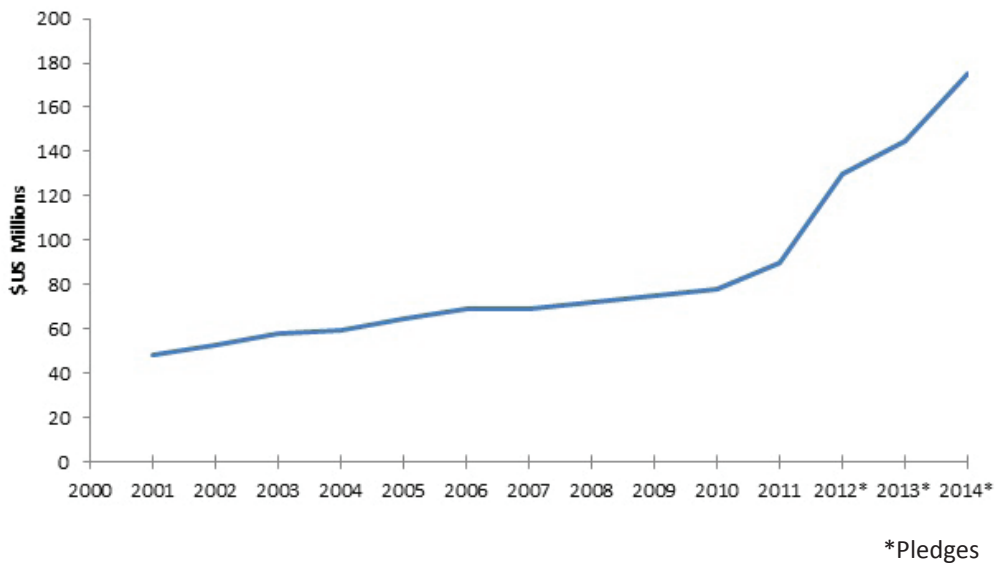
27. GAVI Alliance, “Cost-effective.”

28. USAID, “Every Child Deserves a 5th Birthday: Vision,” <http://5thbirthday.usaid.gov/pages/Vision.aspx>.

29. Ann Danaiya Usher, “GAVI funding meeting exceeds expectations,” *Lancet* 337, issue 9784 (June 25, 2011): 2165–66.

30. GAVI Alliance, “United States of America: Proceeds to GAVI from donor contributions & pledges (2011–2015) as of 5 September 2012,” <http://www.gavialliance.org/funding/donor-profiles/united-states/>; and GAVI Alliance, “Annual donor contributions to GAVI 2000–2031 as of 5 September 2012,” <http://www.gavialliance.org/library/gavi-documents/funding/annual-donor-contributions-to-gavi-2000-31-as-of-5-september-2012/>.

Figure 1. Actual and Pledged U.S. Contributions 2000–2014, as of September 2012³¹



The United States represents Canada, Australia, Japan, and Korea on the GAVI Alliance board. The board is responsible for strategic direction and policymaking, oversees the operation of the Alliance, and monitors program implementation. During the second Obama administration, the board will oversee an important external evaluation of the Alliance’s activities. It will also weigh measures to improve the quality of data, strengthen the incentives of partner governments to use vaccines more effectively, and better assess whether to adopt new cost-effective vaccines.

Policy Developments under the First Obama Administration

In recent years, following a difficult period of leadership change and funding uncertainty, GAVI has undergone a promising renewal.³² During the GAVI Alliance’s first pledging conference in June 2011, the United States pledged \$450 million over three years (fiscal years 2012–2014) subject to congressional approval.³³ This represented a substantial increase over the previous year U.S. \$90 million annual contribution. Overall, the replenishment was quite successful, with \$4.3 billion pledged over five years. Meanwhile, a strong new chief executive officer, U.S. citizen Seth Berkley, and a new board chair, Norway’s Dagfinn Høybråten, have generated a renewed sense of purpose and commitment among Alliance members.

31. GAVI Alliance, “Annual donor contributions to GAVI 2000–2031 as of 5 September 2012.”

32. Lisa Carty, Amanda Glassman, Stephen Morrison, and Margaret Reeves, “GAVI’s Future: Steps to Build Strategic Leadership, Financial Sustainability, and Better Partnerships” (Washington, D.C.: CSIS, June 2011), http://csis.org/files/publication/110609_Carty_GAVI_0.pdf.

33. GAVI Alliance, “Donors commit vaccine funding to achieve historic milestone,” June 13, 2011, <http://www.gavialliance.org/library/news/press-releases/2011/donors-commit-vaccine-funding-to-achieve-historic-milestone-in-global-health/>.

Due to U.S. Department of the Treasury and congressional objections,³⁴ the United States has not provided funding support to the GAVI Alliance's longer-term funding sources, the International Finance Facility for Immunization (IFFIm) and the Pneumococcal Vaccine Advanced Market Commitment (AMC).³⁵ These multiyear funding sources enable the Alliance to make longer-term commitments to countries and to vaccine manufacturers that can lead to reduced vaccine prices and quicker scale-up in country.

On the programmatic side, pneumococcal and rotavirus vaccines have been introduced in many GAVI-eligible countries, and although progress to date is slower than expected,³⁶ the pace is expected to increase and GAVI estimates that the introduction of the vaccine against pneumococcal disease in eligible countries could prevent approximately 500,000 premature deaths by 2015 and up to 1.5 million premature deaths by 2020, while the vaccine against rotavirus would prevent 2.4 million child deaths by 2030.³⁷

The vaccine portfolio has recently been expanded to include vaccines against the human papilloma virus (HPV) and measles/rubella. The board has also agreed to future investments in vaccines against Japanese encephalitis and typhoid, when appropriate vaccines become available and have been reviewed by the World Health Organization (WHO). GAVI is also considering investments in additional vaccines, including inactivated poliovirus vaccine. An expert group supported by the GAVI secretariat—tasked with developing the next vaccine investment strategy³⁸—will consider these proposed investments.

The 2002–2010 GAVI-initiated partnership with China to combat vaccine-preventable hepatitis B³⁹ was a notable achievement, increasing HepB3 coverage to more than 85 percent and timely birth dose vaccination coverage to more than 75 percent. In recent years, GAVI has expanded its efforts in Afghanistan, the Democratic Republic of Congo, and Somalia. The Democratic People's Republic of Korea has just launched the introduction of the five-antigens-in-one pentavalent vaccine, as has Myanmar. The pentavalent vaccine is a single vaccine that protects against diphtheria, pertussis, tetanus, hepatitis B, and *Haemophilus influenzae* type B, the bacterial microorganism that causes several serious childhood illnesses like meningitis and pneumonia.

GAVI has commissioned external evaluations to be conducted in five countries over 2013–2016, with the aim of generating real-time quantitative analysis of the relevance, effectiveness, impact, efficiency, and sustainability of GAVI support.

34. Benjamin Leo, *Can Donors Be Flexible within Restrictive Budget Systems? Options for Innovative-Financing Mechanisms*, Working Paper 226 (Washington, D.C.: Center for Global Development, October 2010), http://www.cgdev.org/files/1424497_file_Leo_Budget_Systems_Paper_FINAL.pdf.

35. IFFIm, *The International Finance Facility for Immunisation: Annual Report of the Trustees; Annual Financial Statements: Year Ended 31 December 2010*, <http://www.iffim.org/finance/trustees-reports-and-financial-statements/>; and GAVI Alliance, *Progress Report 2011* (Geneva: GAVI Alliance, 2011), <http://www.gavialliance.org/results/gavi-progress-reports/>.

36. Rotavirus vaccines have been rolled out in 9 countries since 2011, and to date, 18 countries have begun the introduction of pneumococcal vaccines. GAVI Alliance, "Vaccine goal indicators," <http://www.gavialliance.org/results/goal-level-indicators/vaccine-goal-indicators/>.

37. GAVI Alliance, "Factsheet: Advance Market Commitment," 2012; GAVI Alliance, "Factsheet: Rotavirus disease," 2012.

38. The board will consider this strategy at the end of 2013.

39. GAVI Alliance, "China's dramatic fall in hepatitis B infections," December 1, 2010, <http://www.gavi-alliance.org/library/news/roi/2010/china-s-dramatic-fall-in-hepatitis-b-infections/>.

Ongoing Challenges

Poor-quality data: GAVI and its partners face chronic data problems that significantly impede GAVI's ability to track coverage, progress, and health impacts. Currently, GAVI relies on country data and WHO-UNICEF estimates of vaccination coverage, which are mainly derived from routine administrative data, and are frequently uneven, inconsistent, and of poor quality.⁴⁰

Poor-quality data means that neither recipient countries nor the Alliance have a reliable understanding of the effects of their programs or the degree to which children are truly protected from vaccine-preventable diseases. Although GAVI is actively working with partners to improve data, much more needs to be particularly if cash-based support is conditioned on improvements in coverage. GAVI is considering mandating that partner countries fund household surveys of vaccination coverage and timeliness, where needed.

Limited incentives for effective coverage: GAVI has provided limited incentives to partner countries to improve effective and equitable coverage of basic vaccines. GAVI offers support for new vaccine introduction conditional on a threshold level of DTP-3 coverage as reported to WHO/UNICEF; its discontinued Immunization Support Strengthening (ISS) program previously awarded cash for each additional child vaccinated beyond the baseline. However, GAVI funding was not directly tied to independently measured improvements in the coverage or equity of the vaccines actually financed by the Alliance. The GAVI board recently approved the consolidation of its cash-based support into one window that would have a performance-based element, tying funding directly to improvements in the coverage of DTP-3 and measles. However, the new system continues to rely on highly problematic data, and lacks an equity focus.

Few sources of long-term funding: Long-term, predictable funding will help GAVI scale up its programs, improve its demand forecasts, and increase UNICEF's leverage with producers to reduce prices. However, only a small share of the Alliance's funding is long-term; the rest is available on only the recently instituted three-year replenishment cycle.

Limited economic analyses for vaccine selection: GAVI needs a more rigorous, consistent, and country-specific approach to selecting vaccines that will take systematic account of the large pipeline of new vaccines, the higher relative prices of new vaccines compared to existing alternatives, the limited budgetary capacity of GAVI-eligible countries, and GAVI's country co-financing requirements. As GAVI begins its next vaccine investment strategy to guide future investment decisions, GAVI needs to accelerate this effort, make it a strategic priority, and put in place economic evaluation processes that reliably demonstrate the cost-effectiveness, affordability, and feasibility of new vaccines proposed for specific countries.

Dilemmas associated with graduation: There is a risk that countries that graduate from GAVI support will face challenges sustaining higher-cost, recently introduced vaccines. At present there

40. As the World Health Organization acknowledged in 2009, "In no instance do we have complete, consistent, multiple measures for an entire country/vaccine time series. In some instances, we have complete administrative data validated by periodic or occasional consistent survey findings. In others, data are available from a single source—usually administrative data—and appear internally consistent over time and across vaccines. In several countries, administrative data and survey results are inconsistent; in others, the administrative time series is incomplete, internally inconsistent or both." See Anthony Burton et al., "WHO and UNICEF estimates of national infant immunization coverage: methods and processes," *Bulletin of the World Health Organization* 87 (June 2009): 535–41.

is no explicit strategy to address this risk, although the GAVI secretariat is developing options for consideration by the GAVI board. GAVI's board has set a country-eligibility threshold that progressively graduates countries that obtain an average gross domestic product of more than \$1,500 per capita. In 2000, 72 countries were eligible for GAVI assistance; currently 57 are eligible. By 2020, under GAVI's current policy and considering International Monetary Fund (IMF) growth projections, only 42 countries, representing half of the currently eligible population of children under 5 years old, will qualify for new GAVI support.⁴¹

Policy Recommendations

1. Commit to the replenishment, subject to continued progress.

The Obama administration, in concert with bipartisan leadership in Congress, should make a robust long-term commitment during the 2014 GAVI replenishment. It should explicitly tie the work of the GAVI Alliance to the continued U.S. policy priority of ending childhood preventable diseases. Increased and longer-term support should be connected to GAVI's progress in improving the quality of data, incentives for partner governments, and assessment of new vaccines.

2. Improve data quality.

Through its GAVI board participation, continued work with WHO and UNICEF, and expanded assignment of CDC technical experts, the United States should champion the improvement of the quality of data that GAVI relies upon to track the delivery of vaccines and health impacts. In those countries where both GAVI and the United States have substantial health programs, there should be a concerted effort to draw upon U.S. technical expertise to improve the measurement of GAVI's coverage and impact.

3. Use cash-based assistance to focus on effective coverage.

The Secretariat and the GAVI board should focus on how its cash-based resources to countries, and the provision of technical assistance by partners, can more effectively improve the coverage and equity of immunization in the next two years. The new performance-based scheme should work alongside efforts to improve data quality in order to get the incentives right for higher coverage, while equity improvements should also be rewarded.

4. Use more rigorous economic evaluation methods to select new vaccines.

As a member of the GAVI Alliance, the United States should actively engage in developing the new vaccine investment strategy and designate an expert to participate in deliberations aimed at developing and deploying a standardized and rigorous approach to economic evaluation and affordability of new vaccines. This approach will deepen GAVI's understanding of the relative priority and affordability of each type of vaccine in each of the GAVI-eligible countries; it will also inform price negotiations with industry in order to obtain a fair price that reflects the value of a vaccine in a particular country setting.

41. Amanda Glassman et al., *Global Health and the New Bottom Billion: What Do Shifts in Global Poverty and the Global Disease Burden Mean for GAVI and the Global Fund*, Working Paper 270 (Washington, D.C.: Center for Global Development, October 2011), http://www.cgdev.org/files/1425581_file_Glassman_Duran_Sumner_MIC_global_health_FINAL.pdf.

5. Assess alternatives for graduating countries.

The United States should support the Alliance's efforts to work with WHO to assess lower-middle-income countries' preparedness and political will to take on greater shares of financing their national immunization programs, considering country budget cycles and governance conditions. The new Office of Global Health Diplomacy should establish an interagency task force with a mandate to deliver analyses, conduct systematic outreach, and develop policy options that can raise the political will of GAVI countries to pay for vaccines. That should be part of a larger effort to examine how this problem emerges and can be addressed across a range of multilateral institutions. The results of the task force can provide input to the GAVI board on alternative scenarios and options for the future.

UNAIDS

By J. Stephen Morrison and Alisha Kramer⁴²

Key Assets that Align with U.S. Interests

UNAIDS was launched in 1996 with a mandate to strengthen the United Nations' response to the HIV/AIDS epidemic, calling upon diverse skill sets and expertise within the UN family. UNAIDS is a partnership of 11 cosponsors.⁴³ The United States is the largest donor to UNAIDS, providing \$45 million of UNAIDS' annual budget of \$230 million.⁴⁴ The United States also plays a pivotal role on the UNAIDS' Program Coordinating Board⁴⁵ that sets the organization's overall strategic direction and monitors program implementation and impact.

UNAIDS aligns strongly with U.S. interests in combating HIV/AIDS. UNAIDS generates timely quality data on the global HIV/AIDS epidemic; tracks epidemiological, programmatic, and policy trends; provides leadership on human rights, most-at-risk populations (MARPs), pediatric AIDS, and reducing stigma and discrimination; builds outreach to civil society organizations; prioritizes effective HIV prevention and pushes national investments toward proven, high-impact programs; and engages in high-level dialogue with heads of state of impacted countries to secure higher political and financial leadership.

Policy Developments under the First Obama Administration

Increased Collaboration. Over the last four years, UNAIDS has worked with its partners to increase the effectiveness of its collaborations. Joint planning by the U.S. Office of the Global AIDS Coordinator and UNAIDS, for example, resulted in the *Global Plan towards the Elimination of New HIV Infections among Children by 2015 and Keeping their Mothers Alive*.⁴⁶ The *Global Plan* was launched by Michel Sidibé, executive director of UNAIDS, and Eric Goosby, U.S. global AIDS coordinator, among others, at the 2011 UN High Level Meeting on AIDS. In response to the Glob-

42. J. Stephen Morrison is senior vice president and director of the Global Health Policy Center at CSIS. Alisha Kramer is program coordinator and research assistant with the Global Health Policy Center.

43. The cosponsors include the Office of the United Nations High Commissioner for Refugees (UNHCR), United Nations Children's Fund (UNICEF), World Food Programme (WFP), United Nations Development Programme (UNDP), United Nations Population Fund (UNFPA), United Nations Office on Drugs and Crime (UNODC), UN Women, International Labour Organization (ILO), United Nations Educational, Scientific and Cultural Organization (UNESCO), World Health Organization (WHO), and World Bank.

44. UNAIDS, "Total contributions 2011," http://www.unaids.org/en/media/unaids/contentassets/documents/document/2012/2011-donor-total-contributions_en.pdf.

45. UNAIDS Program Coordinating Board includes representatives of 22 governments, the UNAIDS cosponsors, and give representatives of non-governmental organizations.

46. UNAIDS, *Countdown to Zero: Believe It, Do It: Global Plan towards the Elimination of New HIV Infections among Children by 2015 and Keeping their Mothers Alive* (Geneva: UNAIDS, 2011), http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/20110609_JC2137_Global-Plan-elimination-HIV-Children_en.pdf.

al Plan's call to action, the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) pledged an additional \$75 million toward preventing mother-to-child transmission of HIV.⁴⁷

World leaders at the UN High Level Meeting also set clear, measurable global AIDS targets for 2015, which were adopted in the "Political Declaration on HIV/AIDS: Intensifying our Efforts to eliminate HIV/AIDS."⁴⁸ The Declaration calls on countries to focus more intensely on populations at higher risk for HIV infection—sex workers, men who have sex with men, and people who inject drugs—and to base national strategies on epidemiological and national contexts.⁴⁹ HIV prevention in these key populations⁵⁰ continues to be a top priority for UNAIDS.

A joint effort with the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) and PEPFAR is under way to work with highly impacted countries to pilot the new investment case approach, and Secretary of State Hillary Clinton recently commended the African Union's "Shared Responsibility Roadmap" that sets a course for greater national ownership and investment.

UNAIDS, in a June 2011 *Lancet* article⁵¹ provided a framework to guide investments in prevention activities that are cost effective and produce maximum impact. This framework has helped inform PEPFAR strategies and guidance documents. A subsequent UNAIDS document issued in 2012 provides guidance on how to implement the investment framework.

More Rigorous Evaluation and Reform. In December 2007, UNAIDS commissioned its second external review.⁵² That effort resulted in a new budgeting, accountability, and results framework, which aims to better demonstrate how finances are tied to goals and concrete outcomes. The first full reporting, based on that framework, will become available in June 2013. Sidibé also launched an internal restructuring in 2011, which reduced UNAIDS aggregate staffing as of 2012 by 100 (from 930 to 830); redeployed a number of staff from its Geneva headquarters to field posts (achieving a 30/70 split between Geneva and country offices); and increased the concentration of personnel deployed to high impact countries with the greatest disease burden and need, where UNAIDS can make the greatest difference.

Greater Engagement with Africa. Sidibé launched a major initiative with the African Union to achieve greater political, financial, and personnel commitments to national HIV/AIDS efforts. In July 2012, African heads of state and government adopted the *Roadmap on Shared Responsibility and Global Solidarity*, which calls on African governments and development partners to "fill...

47. UNAIDS, "World leaders launch plan to eliminate new HIV infections among children by 2015," press release, June 9, 2011, <http://www.unaids.org/en/resources/presscentre/pressreleaseandstatementarchive/2011/june/20110609prglobalplanchildren/>.

48. UN General Assembly, "Political Declaration on HIV and AIDS: Intensifying Our Efforts to Eliminate HIV, and AIDS," June 10, 2011, http://www.unaids.org/en/media/unaids/contentassets/documents/document/2011/06/20110610_un_a-res-65-277_en.pdf.

49. UNAIDS, "Bold new AIDS targets set by world leaders for 2015," press release, June 10, 2011, <http://www.unaids.org/en/resources/presscentre/pressreleaseandstatementarchive/2011/june/20110610psdeclaration/>.

50. UNAIDS defines key populations as those "disproportionately impacted by HIV when compared with the general population. While this may vary according to local epidemic dynamics, principally this describes gay men and other men who have sex with men, women and men who inject drugs, sex workers and transgender people."

51. Bernhard Schwartländer et al., "Towards an Improved Investment Approach for an Effective Response to HIV/AIDS," *The Lancet* 377, issue 9782 (June 11, 2011): 2031–2041.

52. UNAIDS, "Second Independent Evaluation of UNAIDS," <http://www.unaids.org/en/ourwork/managementandgovernance/dxdmanagementandgovernance/secondindependentevaluationofunaids/>.

funding gaps together, investing their ‘fair share’ based on ability and prior commitments.”⁵³ Secretary of State Hillary Clinton commended the *Roadmap*.

In recent years, some African countries have introduced policies that criminalize and severely punish homosexuality. These regressive human rights policies threaten HIV/AIDS response efforts. Sidibé has made it a priority to use UNAIDS’ good offices systematically to address these egregious policies.

Ongoing Challenges

UNAIDS faces a range of challenges:

Coordination. UNAIDS-GFATM coordination has in the past been problematic—protracted tension and uneven cooperation—but the level of trust and confidence between the two organizations has increased, and UNAIDS is more actively participating in GFATM joint technical committees and reviews. The challenge ahead is to keep a priority focus upon further strengthening concrete alignment of plans, programs, and policies with the Global Fund. More progress is still warranted. UNAIDS has been far less effective coordinating its work with WHO and the other UNAIDS cosponsoring agencies. That has proven to be problematic, and progress in this area will require a concerted effort.

Staffing. UNAIDS also needs to justify its large staff count, demonstrate that it is delivering consistent quality in its personnel where they are needed most and in achieving concrete impact. Though UNAIDS trimmed its staff, it still employs 830 people, a sizeable number, and there is continued uncertainty about what the optimal size is for UNAIDS, given its mandate. The quality of technical assistance in country remains inconsistent, and donor concern over appropriate and balanced distribution of personnel remains. A tough budget climate will require UNAIDS to continue to find efficiencies both in size and distribution of its staff.

Post-2015 Role. The evolving Millennium Development Goal (MDG) landscape requires that UNAIDS clearly explain its future role. As the HIV-prevention agenda continues to evolve rapidly based on new science, UNAIDS will need to better help countries and international service providers stay ahead of these changes with optimized and focused national strategies. The MDGs established in 2000 will reach their target completion date in 2015. MDG 6 set out targets to combat HIV/AIDS, malaria, and other diseases. By 2015, MDG 6 calls for the halt and reversal of the spread of HIV/AIDS and to have achieved universal access to HIV/AIDS treatment by 2010. UNAIDS rallied around these two targets and campaigned to reach them by devising strategy documents, reporting on progress, and advocating on behalf of human rights and increased resources. The Post-2015 MDG agenda is unlikely to include a specific goal related to HIV/AIDS.

Confronting Governments. UNAIDS is inherently constrained in what political leverage it can bring against regressive national human rights policies. UNAIDS has been outspoken against policies that inhibit the human rights of sex workers, men who have sex with men, and injection drug users. However UNAIDS must walk a tight line to address policies that threaten human rights and an individual’s ability to access health services, while maintaining cordial and cooperative rela-

53. UNAIDS, “African Union adopts new roadmap to accelerate progress in HIV, TB and malaria responses,” press release, July 16, 2012, <http://www.unaids.org/en/resources/presscentre/pressreleaseandstatementarchive/2012/july/20120716aprausummit/>.

tionships with country governments. Given this reality, UNAIDS' voice and influence, to be really effective, have to be closely harnessed to the efforts of other like-minded governments and multi-lateral institutions, including most importantly the United States.

Policy Recommendations

To address these challenges, the Obama administration and Congress should adopt the following priority policy options:

1. Maintain funding, contingent on continued reform.

The United States should sustain its current funding levels to UNAIDS, but make it contingent upon continued efforts to more clearly define the UNAIDS mission, guarantee high quality of its technical expertise, and achieve greater efficiencies in staffing. The quantity, quality, and distribution of staff must remain a priority area of reform and should be the subject of an independent expert review.

2. Focus on national strategies.

The United States should press UNAIDS to help and as needed push countries to develop and maintain optimized national HIV/AIDS strategies. UNAIDS' role as a global advocate remains important, but it should resist the temptation to launch new public campaigns and instead focus more on the basics: getting more people treated and reducing the number of new infections.

3. High-level leadership and collaboration.

The United States should give high priority to collaborating with UNAIDS leadership to build country ownership in Africa and address regressive human rights policies against sex workers, men who have sex with men, and injection drug users. UNAIDS should continue to work with country leaders to eliminate pediatric AIDS and develop clear investment cases to help guide national governments and donor programs.

THE WORLD BANK GROUP

By J. Stephen Morrison and Nellie Bristol⁵⁴

Key Assets that Align with U.S. Interests

As low- and middle-income countries and the international community begin to focus on more comprehensive health service delivery and self-sustaining financing, the World Bank Group has special strengths to offer in both the public and private sectors. It has the knowledge and the capital to foster strong health systems and the expertise and cross-sectoral connections in finance and health to aid in developing innovative ways to provide financial risk protection for health services. In order to assume this pivotal role, the Bank needs to systematically bolster its health portfolio and take a more strategic approach. It currently gives relatively modest priority to its health programs, a situation stemming from leadership priorities and competition from other sectors including agriculture, energy and mining, transportation, education, climate change, labor, and social protection. In addition, during the past decade ample, far more concessionary bilateral and multilateral health resources have become available from other sources, including the President's Emergency Plan for AIDS Relief (PEPFAR), the Global Fund to Fight AIDS, Tuberculosis and Malaria, and the GAVI Alliance. But these circumstances are shifting in the face of flat or declining global health resources. In addition, there is an ever-louder call for creating sustainable, country-owned health systems that move away from disease-specific approaches to address a broad disease burden, including, increasingly, noncommunicable conditions such as heart disease, diabetes, and cancer. Such a change would rest upon co-financing that allows individuals and families access to services without the risk of financial catastrophe.

With its new president, Dr. Jim Yong Kim, a well-known and highly respected innovator in global health appointed in July 2012, the Bank is positioned to step up its health presence. Kim quickly initiated a promising reorientation of the Bank's mission, including a focus on better addressing extreme poverty and improving implementation programs—the “science of delivery”—that could have important health dimensions. As the Bank's mission and future priorities are actively debated in the coming months through the 17th replenishment of the International Development Association, there is a timely opening for the United States and other like-minded governments to steer the Bank's approach to health in directions that help achieve U.S. global priorities.

Since its creation in 1944, the World Bank has taken a leadership role, intellectually, analytically, and financially, in advancing strategies to alleviate poverty and achieve economic development. To that end, it provides concessionary loans and grants to developing countries through three mechanisms: the International Bank for Reconstruction and Development (IBRD), the International Development Association (IDA), and the International Finance Corporation (IFC), the latter focusing solely on the private sector in developing countries.

The IBRD, which raises most of its funds via financial markets, has 188 member countries and provides loans and advice to middle-income and “credit worthy” low- income countries.⁵⁵ IDA

54. J. Stephen Morrison is a senior vice president at CSIS and director of the CSIS Global Health Policy Center. Nellie Bristol is a research fellow with the CSIS Global Health Policy Center.

55. World Bank, “International Bank for Reconstruction and Development,” <http://web.worldbank.org/WBSITE/EXTERNAL/EXTABOUTUS/EXTIBRD/0,,menuPK:3046081~pagePK:64168427~piPK:64168435~theSitePK:3046012,00.html>.

distributes grants and concessional loans—with zero or low interest paid over 25–40 years—to the 81 poorest countries, 39 of which are in Africa.⁵⁶ These funds provide support for health, part of a broader category of funding for health, nutrition, and population (HNP). For fiscal years 2009–2012, IDA committed \$4.2 billion to health, about 7 percent of its total resources. IBRD lending for health during the period amounted to \$8.3 billion, roughly 6.7 percent of IBRD resources.⁵⁷

Nearly 65 percent of IDA funding comes from the governments of its 172 member countries. Every three years, donors meet to replenish IDA resources and review its policy framework. The 16th and most recent replenishment, finalized in 2010, resulted in pledges totaling \$49.3 billion dedicated to projects approved during the three-year period ending June 30, 2014. The United States is the largest and most influential World Bank shareholder; its \$4.1 billion pledge to IDA 16 accounted for 16 percent of the total. Negotiations on the 17th replenishment will unfold and be concluded over the course of 2013.

The International Finance Corporation (IFC) has expanded its investments in health since 2007. IFC committed almost \$2 billion to health projects in 2007–2012, up from \$474 million in 2001–2006. In sub-Saharan Africa, IFC commitments grew from \$12 million in 2001–2006 to \$300 million in 2007–2012.⁵⁸ The increase followed an analysis that showed that approximately 50% of health services in the region were provided by the private sector.

Unlike most other development multilateral institutions, the World Bank Group reaches across a broad spectrum of both low- and middle-income countries. Its multisectoral approach to development and poverty alleviation encompasses finance, health, education, transport, and agriculture, among others, which gives the Bank a unique bully pulpit and a special capacity to integrate planning. With its wide-ranging access to heads of state, finance ministers, and other cabinet officers, along with the private sector and increasingly civil-society groups, it can shape countries' choices, encouraging low- and middle-income countries to give health a visibly higher priority, and to make significant, long-term commitments to creating effective health systems. It is able to draw on its expertise in health financing, pensions, taxation, public/private insurance schemes, supply chains, and data management to track investments against the delivery of health services and actual health impacts.

The Bank can point to considerable expertise gained through partnerships in such countries as Mexico, Thailand, Brazil, Turkey, and more recently Rwanda and Burundi, which focused on sustainable health financing, effective and affordable delivery of core health services, and building the systems for ensuring accountability and impacts.

56. World Bank, "International Development Association: The World Bank's Fund for the Poorest," <http://www.worldbank.org/ida/what-is-ida/fund-for-the-poorest.pdf>.

57. Author communication with Melanie Mayhew, Communications Officer, World Bank, January 24, 2013.

58. Author communication with Melanie Mayhew, Communications Officer, World Bank, February 2, 2013.

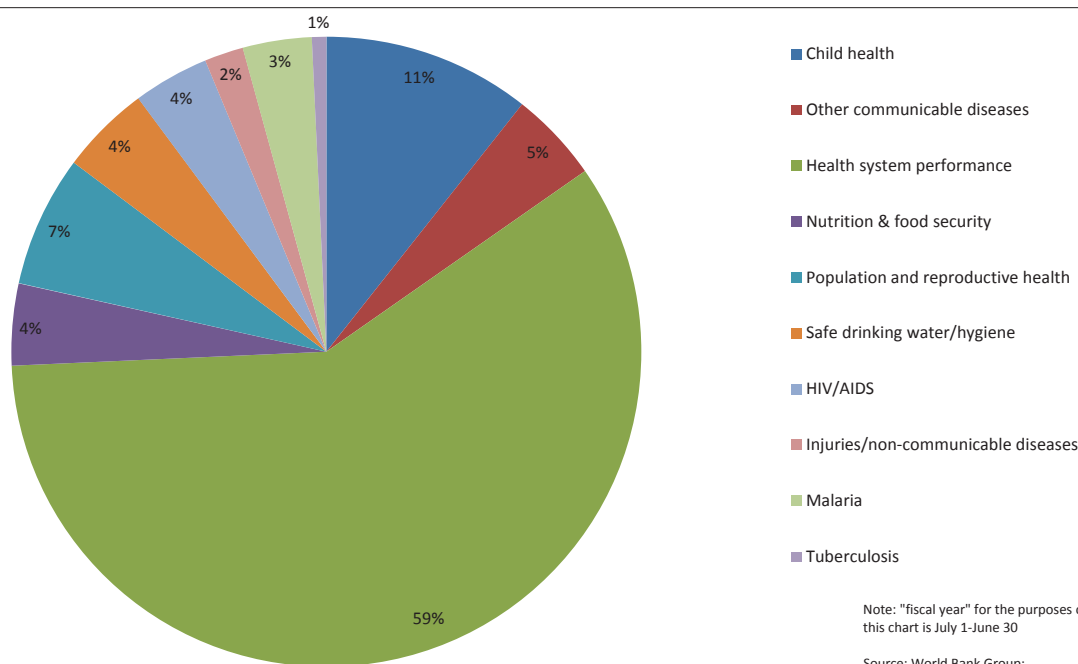
Policy Developments under the First Obama Administration

As the first Obama term unfolded, the Bank was in the early stages of implementing its 10-year health program, “Healthy Development: The World Bank Strategy for Health, Nutrition and Population Results,” launched in 2007.⁵⁹ The strategy focuses on preventing poverty as a result of illness and supporting country efforts to develop well-organized, sustainable health systems. It acknowledges the change in the global health architecture in the first decade of the 2000s, noting the proliferation of multilateral organizations, initiatives, and foundations that began financing health programs during the period.

Much of the funding from outside the Bank, it notes, prioritizes specific diseases such as malaria, tuberculosis, and HIV/AIDS, with less focus on broader categories such as health systems and maternal and child health. The Bank stakes out a comparative advantage in strengthening health systems along with health financing and economics and supporting government leadership. While emphasizing system strengthening, the strategy also notes the need for measured outcomes.

Bank commitments over 2009–2012 reflect the strategy’s emphasis on systems, with nearly 60 percent of lending devoted to health through the IDA and IBRD focused on “health system performance” (see chart). In line with the three health-specific Millennium Development Goals (MDGs), the Bank has prioritized access to providing reproductive health services; scaling up support for early childhood nutrition; and preventing HIV/AIDS and other communicable diseases.⁶⁰

World Bank Funding Commitments for Health, Nutrition and Population (FY09-FY12)



59. World Bank, “Healthy Development: the World Bank Strategy for Health, Nutrition, and Population Results,” April 24, 2007, <http://siteresources.worldbank.org/HEALTHNUTRITIONANDPOPULATION/Resources/281627-1154048816360/HNPStrategyFINALApril302007.pdf>.

60. Author communication with Melanie Mayhew, Communications Officer, World Bank, January 11, 2013.

One central facet of the health development strategy is results-based financing (RBF), a strategy to improve the quality, reliability, and reach of health services in the poorest countries by linking finance to concrete proof of results. RBF focuses on paying for health outcomes (e.g., increasing the percentage of women receiving antenatal care and delivering their children by a trained health worker) as opposed to financing simply inputs or processes, such as salaries, training, or medicines.

In addition, the Bank has committed in recent years to collaborate more closely with the UNAIDS Joint Program (where it is a cosponsoring organization), the Global Fund (where the Bank is the financial trustee), the Office of the U.S. Global AIDS Coordinator, and the President's Malaria Initiative, with a special focus on accelerating progress on HIV/AIDS, tuberculosis, and malaria (MDG 6) in high-burden countries. In late 2012, Bank President Kim and USAID Administrator Rajiv Shah agreed to launch a pilot in four priority countries to intensify their health collaborations.

Since 2007, the World Bank has been the co-administrator, along with the World Health Organization, of the International Health Partnership (IHP+), which aims to unify donors, developing countries, and international agencies behind a single national health plan. IHP+ has helped generate in 20 countries a compact or similar partnership agreement to coordinate health aid.

In his first few months as head of the Bank in the second half of 2012, Kim began charting a course for the future. He indicated that the Bank should prioritize addressing extreme poverty, with a special emphasis on economic growth that generates new jobs: a “shared prosperity” that will benefit both private capital and the poor. He also identified climate change and fragile states as high priorities, and said that across all development sectors, the Bank should concentrate on the “science of delivery”—achieving better value for dollars invested by focusing assiduously on implementation.⁶¹

Despite concerns in some corners that Kim might deemphasize health to avoid the appearance of favoring an area in which he has so much experience, he has signaled his desire to reenergize the Bank's efforts to implement its Health, Nutrition, and Population strategy. At the July 2012 International AIDS Conference in Washington, D.C., he made a forceful case for greater global engagement in fighting the epidemic, and committed the World Bank to playing a leading role primarily through its systems-development work: “successful countries have tackled AIDS as a systems problem.... Building systems is what the World Bank does best.”⁶²

Across multiple areas, including health, Kim has begun to translate his strong interest in the science of delivery into pilot models in major “hubs.” In late 2012, he swiftly concluded an agreement with then-incoming President Xi to partner in putting together on a six-month crash basis plans for managing the influx of an estimated 350 million persons into China's coastal urban

61. World Bank Group president Jim Yong Kim, “Remarks as Prepared for Delivery: World Bank Group President Jim Yong Kim at the Annual Meeting Plenary Session,” Tokyo, Japan, October 11, 2012, <http://www.worldbank.org/en/news/2012/10/12/remarks-world-bank-group-president-jim-yong-kim-annual-meeting-plenary-session>. See also World Bank Group President Jim Yong Kim, “Make climate change a priority,” *Washington Post*, January 24, 2013, http://www.washingtonpost.com/opinions/make-climate-change-a-priority/2013/01/24/6c5c2b66-65b1-11e2-9e1b-07db1d2ccd5b_story.html.

62. World Bank Group, “World Bank Group President Jim Yong Kim Remarks at the Opening Plenary of the International AIDS Conference,” July 22, 2012, <http://www.worldbank.org/en/news/2012/07/22/world-bank-group-president-jim-yong-kim-remarks-at-the-opening-plenary-international-aids-conference-2012>.

centers in the next 10–15 years. The multisectoral approach will address food security, education, infrastructure, and health. Similar pilots, each with a varying focus based on the country's priorities, are expected to be launched in South Africa, Brazil, and one to two other hubs in the coming year.

Ongoing Challenges

The Bank faces several obstacles to taking on a more strategic, robust approach to health in low- and middle-income countries.

First, over the past decade, developing countries have had comparatively weak incentives to utilize their borrowing capacity with the Bank when the Global Fund, the GAVI Alliance, the U.S. bilateral HIV/AIDS and malaria programs, along with other donor funding facilities, have offered ample concessionary grants, including in support of strengthening health systems. Increasingly, however, as resources from these funders have flattened or declined, that mix of incentives and disincentives has begun to shift.

Second, health competes against other of the Bank's sectoral priorities, including agriculture, education, climate change, transportation, labor, and social protection. Demand on these other priorities has grown in the midst of the protracted global recession. If Bank President Kim is to do more on health, he will almost certainly need to do less in one or more of these sectors, and to carefully rally his senior management and the executive directors on his governing board behind any such a strategy. Moreover, he will need to do that as new leadership is transitioning into place charged with directing the Bank's health, nutrition, and population programs.

Third, the Bank's policy and programmatic alignment and coordination with the Global Fund, the GAVI Alliance, UNAIDS, and U.S. bilateral HIV/AIDS and malaria efforts remains at an early point. Much more aggressive action in this area is warranted, if the efficiencies of integration are to be realized, and if there is to be clearer specialization across these institutions.

Fourth, many countries are projected to graduate in the next decade out of low-income status, as they attain annual incomes of \$1,500 per capita. As this transition unfolds, the pool of IDA-eligible countries will steadily diminish, at the same time that the pool of lower-middle-income countries—countries with considerable impoverished populations and high disease burdens but which are *not IDA-eligible*—expands.

Finally, at a macro level, the Bank is constrained in the depth of its expert pool and its budgetary flexibility.⁶³ Internal reforms could dominate the Bank's agenda in 2013.⁶⁴

63. Through a "diagnostic" organized through the 1818 Society, former Bank officials concluded that the Bank is "under-performing" and saddled with a "very cumbersome inefficient internal structure." The report highlights weak Bank human resource strategies that have resulted in depleting its core of experts and left the Bank "excessively decentralized to the point that the budget is a serious and growing constraint." "The World Bank's competitive advantage as a provider of integrated financial and advisory services is falling behind, largely because of internal failures," it concludes. Danny Leipziger et al., "The Key Challenges Facing the World Bank President: An Independent Diagnostic," The 1818 Society World Bank Group Alumni, April 16, 2012, http://siteresources.worldbank.org/1818SOCIETY/Resources/World_Bank_Diagnostic_Exercise.pdf.

64. Udani Samarasekera, "Jim Kim Takes the Helm at the World Bank," *Lancet*, July 7, 2012, vol. 380, 15–17.

Policy Recommendations

1. Urge the World Bank Group to strengthen and expand its global health focus.

In 2013 discussions over the IDA 17th replenishment, and during this promising period of reappraisal under Kim's new leadership, the Obama administration should press the World Bank to use its influence more strategically in the area of health for coordinating lending and grants programs for both the public and private sectors. The administration should make clear its strong preference that the Bank lead more aggressively in public administration and accountability systems for health financing and improving health data collection and supply chains, tied to the "science of delivery." The Bank can provide expertise on public/private options for pension and health insurance schemes; taxation and other measures to reduce tobacco consumption; and how to lower the long-term burden of noncommunicable diseases (NCDs).

2. Encourage the World Bank to update its health strategy for public- and private-sector development.

The administration should press the Bank to measure progress on its HNP strategy, and to formulate an updated version that reflects clear goals and spells out how investments in health are to fit with broader efforts to alleviate extreme poverty, generate economic growth and new jobs, stabilize fragile states, and strengthen the "science of delivery" to derive higher value for every dollar invested. Furthermore, the administration should press the Bank and its private-sector development arm, the International Finance Corporation (IFC), to aggressively support an expanded portfolio of investments in the private health sector that brings improved health benefits to the impoverished majority through greater access to affordable loans and other financial services.

3. Better integrate U.S. policies and programs with the World Bank.

Where feasible, the administration should shape its health diplomacy to support the World Bank's pilot "hubs" in China, South Africa, Brazil, and elsewhere, and give priority to better aligning the work of U.S. bilateral programs, the Global Fund, the GAVI Alliance, the World Bank, and other UN agencies involved in health, including UNAIDS. The newly established Office of Global Health Diplomacy at the State Department should formulate a strategy in 2013, in concert with the Department of the Treasury and the White House, that spells out the concrete steps the United States will pursue, in league with like-minded governments, to strengthen the Bank's health engagement in the coming four years.

4. Better align with other funding and technical partners.

The Global Fund, the GAVI Alliance, and U.S. bilateral health programs have had to invest significant resources to address deficient health systems. Over the long term, this responsibility is better undertaken by the World Bank, which has a clear comparative advantage in this area and the technical and financial resources to be successful. The Bank should also increase its efforts to build more sustainable health-financing mechanisms—social-insurance schemes, special taxes, innovative financing arrangements—in developing countries, decreasing dependence on outside donors to cover long-term commitments such as for AIDS treatment and replacement of bed nets.

7

U.S. PRIORITIES FOR GLOBAL HEALTH SECURITY

By Julie Fischer and Rebecca Katz¹

Synopsis

Accelerated globalization, urbanization, and changing human behaviors continually create opportunities for the emergence and resurgence of diseases that threaten public health. Faced with the effects of diseases from HIV/AIDS to H5N1 influenza, decisionmakers began to call for new global strategies to detect and respond to emerging infections and to characterize public health risks as security concerns.

The Obama administration developed national strategies aimed at helping partner countries develop the capacities to detect and respond to disease threats. President Obama supported many global health security goals by engaging public health expertise in international forums for cooperative threat reduction, and realigning the resources of U.S. security agencies to support implementation of the revised International Health Regulations (IHR).

U.S. government leaders have relied on personal relationships to bypass challenges to inter-agency and intersectoral cooperation. Most of the 194 countries that agreed to implement IHR still need assistance in building core capacities to detect, assess, report, and respond to public health emergencies, straining the resources of international partners such as the World Health Organization (WHO). Questions of how best to support international and national partners are complicated by tensions between U.S. global health development and security actors.

To meet its global health security objectives, the U.S. government will have to find a way to strengthen its policies, programs, and partners. The U.S. government should:

1. Develop a cohesive, whole-of-government global health security strategy that clearly designates agency roles and responsibilities.
2. Strengthen the capacities of WHO and other international institutions to promote global health security.
3. Develop a shared technical framework to align U.S. global health development and security programs at the operational level.

We wish to thank the many individuals who generously contributed their time and essential insights to this study. The findings and recommendations contained in this chapter are ultimately the sole responsibility of the authors. We appreciate the efforts of the important experts serving in relevant government departments and agencies who took time to provide strictly technical input; they bear no responsibility for the analysis that followed.

1. Dr. Julie Fischer is a lead research scientist in the Department of Health Policy at George Washington University, and Dr. Rebecca Katz is an associate professor in the Department of Health Policy at George Washington University.

Introduction

Accelerated globalization, urbanization, and changing human behaviors continually create opportunities for the emergence and resurgence of diseases that threaten public health. For example, changing land use and agricultural practices can allow diseases of animal origin to spread into human populations. Inadequate treatment and urban crowding permit old scourges such as tuberculosis to reemerge in drug-resistant forms. Increasingly commonplace trade and travel increase the odds that any emerging or reemerging diseases will spread rapidly. Emerging infectious disease events have occurred more frequently in recent decades, and the location, timing, and public health significance of such events still cannot be predicted reliably.²

By the end of the twentieth century, the catastrophic impact of HIV/AIDS had spurred U.S. and international decisionmakers to call for new global strategies to detect and respond to emerging infections, and to characterize public health risks as security concerns.³ The Bush administration's 2002 National Security Strategy defined the HIV/AIDS epidemic in poor countries as a U.S. security priority.⁴ In authorizing the President's Emergency Plan for AIDS Relief (PEPFAR), the largest global health initiative ever focused on a single disease, Congress defined the HIV/AIDS burden as a threat to economic productivity, social cohesion, and international security.⁵ The rapid scaling up of PEPFAR programs put new demands on U.S. health and development agencies, and formally included the U.S. Departments of State and Defense as key partners in overseas health engagements.

At the same time, a series of high-profile emerging infections demanded policy responses. In October 2001, anthrax spores mailed to congressional offices and media outlets infected 22 people, killing five.⁶ The Bush administration and Congress responded with the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, increasing resources to strengthen public health capacities for biodefense at the federal, state, and local levels and demanding more stringent laboratory biosecurity.⁷

2. David M. Morens, Gregory K. Folkers, and Anthony S. Fauci, "The challenge of emerging and re-emerging infectious diseases," *Nature* 430 (2004): 242–49.

3. In 1995, the World Health Assembly tasked the World Health Organization (WHO) with strengthening global capacities to detect and respond to emerging infectious diseases, and a directive issued by U.S. president Bill Clinton assigned U.S. agencies specific roles in enhancing global capacities to detect and respond to "worldwide disease outbreaks that have the potential to adversely affect the United States." See World Health Assembly, *Communicable disease prevention and control: new, emerging and re-emerging infectious diseases—WHA Resolution 48.13* (Geneva: World Health Assembly, May 12, 1995); and White House, *Presidential Decision Directive NSTC-7* (Washington, D.C.: White House, June 12, 1996), <http://www.afhsc.mil/viewDocument?file=pdd-nstc-7.pdf>.

4. White House, *The National Security Strategy of the United States of America* (Washington, D.C.: White House, September 17, 2002), 23, <http://www.state.gov/documents/organization/63562.pdf>.

5. U.S. Congress, *The United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003*, Public Law 108-25 (2003), <http://www.gpo.gov/fdsys/pkg/PLAW-108publ25/pdf/PLAW-108publ25.pdf>.

6. U.S. Department of Justice, *Amerithrax Investigation Summary* (Washington, D.C.: U.S. Department of Justice, 2010), 1–5, <http://www.justice.gov/amerithrax/docs/amx-investigative-summary.pdf>.

7. Senator Bill Frist, "Public Health and National Security: The Critical Role of Increased Federal Support," *Health Affairs* 21, no. 6 (November 2002): 117–30.

Severe acute respiratory syndrome (SARS) spread from China to two dozen countries in early 2003, causing about 800 deaths and billions of dollars in lost trade and travel.⁸ In response to SARS and the emergence of highly pathogenic H5N1 avian influenza or “bird flu” in East and Southeast Asia, the Bush administration developed an all-hazards U.S. policy framework that encompassed pandemic preparedness as well as deliberate biological attacks.⁹ The Bush administration recognized the need to support these domestic policies by enhancing disease detection and response capabilities abroad, asserting U.S. leadership in negotiations to transform international public health cooperation.

In 2005, 194 participating countries—referred to as States Parties—adopted the revised International Health Regulations [IHR (2005)], agreeing to develop and maintain the core capacities required to detect, assess, report, and respond to any potential “public health emergency of international concern,” regardless of source.¹⁰ Under Article 44 of IHR (2005), they agreed to share technical, logistical, and financial assistance to help other countries develop the public health surveillance, preparedness, and laboratory capabilities required to report and respond to outbreaks before they spread across borders. President Bush accepted IHR (2005) obligations through a 2006 Executive Agreement, tasking the Department of Health and Human Services (HHS) with leading U.S. implementation.

In 2005, President Bush also announced that the United States would launch the International Partnership on Avian and Pandemic Influenza (IPAPI), a ministerial-level forum for strengthening influenza surveillance and response capacities cooperatively.¹¹ Although IPAPI ultimately mobilized hundreds of millions of dollars in bilateral and multilateral commitments, the Bush administration left an unfinished agenda in global pandemic preparedness. By the end of 2006, the government of Indonesia, which accounted for about one-third of all reported human H5N1 avian influenza cases, announced that it would cease sharing its specimens until WHO guaranteed equitable access to any benefits (such as vaccines) realized from global influenza surveillance. Indonesia’s claims of “viral sovereignty” drew condemnation from global health leaders, but resonated with other emerging economies.¹² The U.S. government assumed a leadership role in negotiations to resume sample sharing under WHO’s Open-Ended Working Group of Member States on Pandemic Influenza Preparedness, but terms remained unresolved at the end of the Bush administration.¹³

8. Asian Development Bank, “Assessing the impact and cost of SARS in developing Asia” in *Asian Development Outlook 2003* (Manila: Asian Development Bank, 2003); and World Health Organization, *Summary of probable SARS cases with onset of illness from 1 November 2002 to 31 July 2003* (Geneva: World Health Organization, April 21, 2004), http://www.who.int/csr/sars/country/table2004_04_21/en/.

9. White House, *Biodefense for the 21st Century: NSPD 33/HSPD 10* (Washington, D.C.: White House, 2004); White House, *National Strategy for Pandemic Influenza* (Washington, D.C.: White House, 2005), <http://www.flu.gov/planning-preparedness/federal/pandemic-influenza.pdf>.

10. World Health Organization, *International Health Regulations (2005)*, 2nd ed. (Geneva: World Health Organization, 2008), http://whqlibdoc.who.int/publications/2008/9789241580410_eng.pdf.

11. Avian Influenza Action Group, *Avian and Pandemic Influenza: The Global Response* (Washington, D.C.: U.S. State Department, 2008), <http://www.state.gov/documents/organization/111559.pdf>.

12. Stefan Elbe, “Haggling over viruses: the downside risks of securitizing infectious disease,” *Health Policy and Planning* 25, no. 6 (2010): 476–85.

13. John E. Lange, “Negotiating Issues Related to Pandemic Influenza Preparedness: The Sharing of Influenza Viruses and Access to Vaccines and Other Benefits,” in *Negotiating and navigating global health: case studies in global health diplomacy*, ed. Ellen Rosskam and Ilona Kickbusch (Singapore: World Scientific, 2012), 129–60.

Policy Developments under the First Obama Administration

President Barack Obama quickly signaled that his administration would build on these global health security priorities. The 2009 National Strategy for Countering Biological Threats (Presidential Policy Directive-2), the first substantive strategy released by the Obama administration's National Security Staff, addresses naturally, accidentally, and deliberately released biological threats. The strategy calls for the United States to enhance global health security by helping partner countries and regions develop sustainable capabilities to detect and report human and animal diseases, and to promote international dialogue on biological threats through IHR (2005) and other processes.¹⁴ While primarily domestic in focus, the 2009 National Health Security Strategy also stressed the revised IHR as a platform for coordinating with international partners to “obtain and share information needed for situational awareness and response to a health incident... [and to] provide technical assistance to other countries and agencies to help them strengthen their core public health capacities and capabilities.”

Moving the Influenza Agenda. In early 2009, the emergence of novel H1N1 influenza A in neighboring Mexico and its quick spread to the United States tested an Obama administration still in transition. Mexico and the United States both reported cases transparently to WHO in the first real test of the IHR (2005) mechanism. Although fewer people died of H1N1 than feared, the pandemic highlighted gaps in technical capacities worldwide, as well as in policy coordination at the local, state, federal, and international levels.

This experience helped inform the Obama administration's leadership in the ongoing technical and intergovernmental meetings over sharing of influenza specimens. WHO Member States finally agreed on the Pandemic Influenza Preparedness (PIP) framework in 2011, although its complex mandates have yet to be fully implemented.¹⁵

The Obama administration also sought to reinforce the trust built with its nearest neighbors. In 2012, through the North American Leaders' Summit, the United States, Canada, and Mexico revised the North American Plan for Animal and Pandemic Influenza (NAPAPI) to enhance trilateral cooperation in preparedness and response.¹⁶

H5N1 influenza soon lay at the center of new controversies. In late 2011, scientists in The Netherlands and the United States independently announced findings on genetic mutations that increase transmissibility of H5N1 viruses between laboratory animals, the results of projects funded by the U.S. National Institutes of Health (NIH) to improve understanding of pandemic threats. The findings raised concerns about the public health consequences should the altered H5N1 viruses be accidentally or deliberately released, or the published methods misused—weighed against the consequences of not expanding current knowledge. Debate focused on how best to communicate the results to the international scientific community, and how (or whether) to pro-

14. White House, *Presidential Policy Directive 2* (Washington, D.C.: White House, November 2009), http://www.whitehouse.gov/sites/default/files/National_Strategy_for_Countering_BioThreats.pdf.

15. World Health Organization, *Pandemic influenza preparedness framework for the sharing of influenza viruses and access to vaccines and other benefits* (Geneva: World Health Organization, 2011), http://www.who.int/influenza/resources/pip_framework/en/index.html.

16. White House, *North American Plan for Animal and Pandemic Influenza* (Washington, D.C.: North American Leaders Summit, April 2012), <http://www.phe.gov/Preparedness/international/Documents/na-papi.pdf>.

ceed with similar future research. WHO and the U.S. government hosted technical consultations, while influenza researchers adopted a voluntary moratorium on such “gain-of-function” research. In 2012, U.S. and international stakeholders began mapping a way forward, including the U.S. government’s domestic “Policy for Oversight of Life Sciences Dual Use Research of Concern” and proposed policy framework on funding H5N1 “gain-of-function” research, but many questions about next steps remain unresolved.¹⁷

Engaging the Security Community in Support of Global Health. During his first term, President Obama supported many of his global health security strategies by encouraging engagement of public health expertise in forums dedicated to deliberately released biological threats, and realigning the resources of U.S. security agencies and programs to support implementation of IHR (2005).

For example, the Obama administration used the intersessional process of the Biological and Toxin Weapons Convention (BWC) to cultivate new health and security partnerships.¹⁸ Senior technical officials from the Obama administration articulated a strong U.S. commitment to helping other countries develop capacities to detect and respond to disease events, regardless of origin, through programs spearheaded by traditional health actors like the U.S. Centers for Disease Control and Prevention (CDC) as well as by the Departments of Defense and State.¹⁹

With reinvigorated U.S. leadership, the BWC work program has engaged technical experts from the life sciences and public health communities, allowing discussions of cooperative capacity building across sectors within as well as between governments. In the words of Assistant Secretary of State Thomas Countryman, “The meetings were no longer just for diplomats; we had participants from all parts of the world and had the interaction of the disarmament, scientific, law enforcement, academic and private sector communities. These meetings stimulated significant activity at the national level and increased the knowledge base around the world in best practices in biosafety and biosecurity, disease surveillance, in science education.”²⁰

The Obama administration also sought support for global health security objectives through the Global Partnership Against the Spread of Weapons and Materials of Mass Destruction, a collaborative forum for 24 countries to strengthen cooperative threat reduction.²¹ The United States chaired the Global Partnership in 2012, using the opportunity to encourage partners to support capacity-building for disease detection and response as an avenue to meet the mutual objectives of

17. Anthony S. Fauci, “Research on Highly Pathogenic H5N1 Influenza Virus: The Way Forward,” *mBio* Vol. 3 No. 5 (2012), <http://mbio.asm.org/content/3/5/e00359-12.full.html>.

18. The BWC intersessional process work program includes an annual Experts Meeting, in which technical delegations develop concepts and proposals on specific topics, followed by the formal meeting of States Parties. The 2009 work program focused on building disease surveillance capacity.

19. “United States Government Efforts to Support Global Capacity for Disease Surveillance and Response” (paper presented at the Meeting of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Biological and Toxin Weapons and on their Destruction, Geneva, Switzerland, August 21, 2009).

20. Thomas Countryman, “Ten Years After the Anthrax Attacks” (remarks at the Center for Biosecurity, University of Pittsburgh Medical Center, Pittsburgh, Pennsylvania, October 4, 2011), <http://www.state.gov/t/isn/rls/rm/175121.htm>.

21. U.S. Department of State, Bureau of International Security and Nonproliferation, “Highlighting the Work of the Global Partnership in Countering Biological Threats,” press release, December 26, 2012, <http://www.state.gov/t/isn/gp2012/rls/prs/202409.htm>.

the Global Partnership and IHR (2005). The Obama administration also explored opportunities to strengthen global biosecurity and biosafety through its leadership of the Biosecurity Working Group.

To support such objectives, the Obama administration dramatically expanded the obligations and activities of the Departments of State and Defense (DOD) under the aegis of global health security. In 2009, DOD announced that the Nunn-Lugar Cooperative Threat Reduction (CTR) program would both expand biological security initiatives beyond the former Soviet Union and enlarge the scope of these programs to include strengthening capacities for detection of naturally occurring biological threats in addition to enhancing laboratory biosecurity. The DOD Defense Threat Reduction Agency's Cooperative Biological Engagement Program has subsequently invested in global health security partnerships in sub-Saharan Africa and in Asia. The State Department's Biosecurity Engagement Program has expanded even more broadly, also including the Middle East, North Africa, and Latin America.

The Obama administration also continued to strengthen DOD's existing programs that enhance capacities for global disease detection and response, including the overseas laboratories that conduct research cooperatively with partner nations, the Armed Forces Health Surveillance Center's Global Emerging Infections Surveillance and Response System (GEIS) Division, and other technical assistance to help partner militaries build their capacities to diagnose, treat, and prevent communicable diseases.²²

Engaging Health Actors to Support Security Priorities. The Obama administration's 2010 National Security Strategy committed to building disease surveillance and response capabilities at home and abroad, in order to detect, prevent, and contain outbreaks before they affect U.S. interests.²³ In 2010, Secretary of State Hillary Clinton described the objectives for U.S. global health engagement in terms of development, diplomacy, and the need to “invest in global health to protect our nation's security. To cite one example, the threat posed by the spread of disease in our interconnected world in which thousands of people every day step on a plane in one continent and step off in another. We need a comprehensive, effective global system for tracking health data, monitoring threats, and coordinating responses.”²⁴

In 2011, an interagency working group under the National Security Staff developed the “Guidance and Principles for U.S. Government Departments and Agencies to Strengthen IHR Core Capacities Internationally.” President Obama indirectly referenced this strategy in his address to the UN General Assembly in September 2011, stating that “(t)o stop disease that spreads across borders, we must strengthen our system of public health.... And we must come together to prevent, and detect, and fight every kind of biological danger—whether it's a pandemic like H1N1, or a terrorist threat, or a treatable disease.”²⁵

22. James B. Peake, J. Stephen Morrison, Michèle M. Ledgerwood, and Seth E. Gannon, *The Defense Department's Enduring Contributions to Global Health: The Future of the U.S. Army and Navy Overseas Medical Research Laboratories* (Washington, D.C.: CSIS, June 2011), http://csis.org/files/publication/110615_Peake_DoDOverseasLabs_Web_0.pdf.

23. White House, *National Security Strategy* (Washington, D.C.: White House, May 2010), http://www.whitehouse.gov/sites/default/files/rss_viewer/national_security_strategy.pdf.

24. Hillary Rodham Clinton, “The Global Health Initiative: The Next Phase of American Leadership in Health around the World,” (remarks at the Paul H. Nitze School of Advanced International Studies, Washington, D.C., August 16, 2010), <http://www.state.gov/secretary/rm/2010/08/146002.htm>.

25. Barack Obama, “Address to the United Nations General Assembly” (remarks at the United Nations, New York, New York, September 21, 2011), <http://www.whitehouse.gov/the-press-office/2011/09/21/remarks-president-obama-address-united-nations-general-assembly>.

The Obama administration followed this speech by urging other nations to join the United States in “pursuing a common vision where disease no longer threatens the security and prosperity of nations.”²⁶ A 2011 Memorandum of Understanding with WHO affirmed “that WHO and the U.S. Government seek to establish guiding principles and a framework for collaboration on common goals in the area of global health security and in line with the principles set forth in the International Health Regulations.”²⁷

These priorities have also been increasingly reflected in the policies and programs of key health and development agencies. HHS, which represents the United States in global health security actions undertaken with WHO, published its first Global Health Strategy in 2011. This included specific strategies “to protect and promote the health and well-being of Americans through global health action,” including working with other agencies and global partners “to enhance health security and prevent the introduction, transmission and spread of infectious diseases and other health threats within and across borders.”²⁸ The Division of International Health Security in the office of the HHS Assistant Secretary for Preparedness and Response provides technical guidance and foreign assistance, particularly in IHR implementation, while the Office of Global Affairs coordinates HHS diplomatic and interagency policy and strategy in global health security.

The Obama administration reorganized CDC’s global health functions under the new Center for Global Health, which published its own five-year global health strategy in 2012. Within CDC’s Center for Global Health, the Global Disease Detection and Emergency Response Division (GDD) plays a significant role in implementing this strategy through the seven regional centers it operates with partner countries, support for field epidemiology training programs, and technical assistance in public health surveillance, outbreak response, training, and research. In 2009, WHO designated GDD a Collaborating Center for Implementation of IHR National Surveillance and Response Capacity, recognizing GDD as a technical resource to support partner nation capacity-building.²⁹

USAID’s global health programs generally assist partner countries in strengthening health systems and services. The USAID Emerging Pandemic Threats program launched in 2009 focuses specifically on strengthening capacities for disease detection at the human-animal health interface, aiming to detect emerging infectious diseases in geographic “hotspots” before they cross into human populations.

26. Office of the Press Secretary, “Fact Sheet: Global Health Security,” White House, September 22, 2011, <http://www.whitehouse.gov/the-press-office/2011/09/22/fact-sheet-global-health-security>.

27. U.S. Department of Health and Human Services, *Memorandum of Understanding between the Government of the United States of America and the World Health Organization Regarding Cooperation on Global Health Security Initiatives* (Washington, D.C.: Department of Health and Human Services, September 19, 2011), <http://www.globalhealth.gov/global-health-topics/health-diplomacy/agreements-and-regulations/20110922-mem.html>.

28. U.S. Department of Health and Human Services, *The Global Health Strategy of the U.S. Department of Health and Human Services* (Washington, D.C.: Department of Health and Human Services, 2011), <http://www.globalhealth.gov/Strategy.pdf>.

29. Rebecca Miller and Scott F. Dowell, *Investing in a Safer United States: What Is Global Health Security and Why Does It Matter?* (Washington, D.C.: CSIS, August 2012), http://csis.org/files/publication/120816_Miller_InvestingSaferUS_Web.pdf.

Ongoing Challenges

Coordinating Global Health Security Programs. The leaders of U.S. health and security programs have tried to achieve an unprecedented level of interagency and intersectoral cooperation. Questions remain about how best to institutionalize the existing level of cooperation.

The financial resources and technical expertise for global health security capacity building are not equitably distributed across stakeholder agencies. Since 2009, the allocation of resources from the CTR programs at State and DOD (for example, \$300 million from the Cooperative Biological Engagement Program) has dramatically increased the resources available for U.S. global health security engagement. A significant portion of those funds has been channeled through technical agencies, such as CDC, that have existing expertise and relationships necessary to help partner nations strengthen their capacities to detect and respond to emerging infectious disease outbreaks in a timely, reliable, and safe way. However, these CTR funds are ultimately driven by security rather than health priorities, exacerbating tensions when experts at the operational level begin translating policies into actions and leaving gaps in resources to help partner countries address their IHR priorities beyond biological threats, such as capacities for surveillance and response at points of entry and to chemical, radiological/nuclear, and foodborne events.

Agency leaders have relied on strong personal relationships to circumvent many of these obstacles, but this is not a sustainable model for long-term interagency cooperation.

The current global health security policy framework represents an aggregation of related, but not always harmonized, security strategies. Key U.S. agencies have developed global health security strategies for individual countries or regions in isolation. Each prioritizes different factors in identifying promising countries or regional organizations for capacity-building partnerships.

The last presidential directive that assigned U.S. government agencies and programs specific roles in enhancing disease detection and response overseas appeared in the Clinton administration. The 2011 strategy for IHR implementation began to touch on this question, but did not address the more comprehensive needs (such as evaluating current legislative, regulatory, and policy mandates) for each agency to define and carry out its global health security roles. The current administration has relied heavily on the National Security Staff to manage a dynamic and small community in the short term, facilitated by the strong personal relationships among senior decisionmakers within key agencies, but the roles and relationships among agencies have not been clearly defined.

Working through International Institutions. IHR (2005) conferred new responsibilities and authorities on WHO to collect and evaluate reports of public health emergencies and to coordinate an evidence-informed international response to events when necessary. This responsibility placed new practical demands on WHO to develop mechanisms for real-time monitoring and management of confidential information. WHO coordinates a network of technical partners in more than 60 countries to support outbreak response, and has tested its capacities for evaluating reported events and sharing disseminating information electronically to IHR National Focal Points.³⁰

30. International Health Regulations Coordination Department, *Activity Report 2011* (Geneva: World Health Organization, 2012), 6–15, http://whqlibdoc.who.int/hq/2012/WHO_HSE_GCR_LYO_2012.3_eng.pdf.

However, the demands of providing national health authorities with the tools needed to assess and strengthen capacities to respond to any public health event, across sectors and from the local to the national levels, have strained WHO's institutional resources. IHR (2005) required all participating countries to report by June 2012 that they had fully implemented the required core capacities, thus meeting their obligations, or that they would require a two-year extension to carry out their national action plans. Of the 194 States Parties, 106 countries requested extensions, and another 49 submitted no information at all. Only 40 reported full compliance with IHR (2005). Merely evaluating what it will take for these countries to develop the required core capacities by June 2014—and maintain them indefinitely—is an enormous burden for a small staff at WHO Headquarters and for WHO's six regional offices.

In late 2012, the Obama administration began working directly with WHO and its six regional offices to facilitate meetings where member states could identify immediate gaps in IHR (2005) core capacities, the first step in highlighting these for technical and financial assistance. WHO will clearly need support to help nations develop short- and long-term plans for investing in IHR core capacities. At present, the U.S. government faces significant policy questions about how best to provide this support. Despite the memorandum of understanding between the U.S. government and the WHO director-general on global health security, how individual U.S. agencies interact with WHO regional offices and WHO-Geneva depends more on institutional ties than a comprehensive strategy for WHO engagement. The U.S. government and WHO both face questions about how best to strengthen partnerships with the World Organization for Animal Health (OIE), the UN Food and Agriculture Organization (FAO), and other international organizations to achieve the multisectoral cooperation so critical to addressing all hazards under IHR.

The Disconnect between Global Health Security and Global Health for Development. As the Obama administration attempted to bridge disease-focused assistance programs for HIV/AIDS, tuberculosis, malaria, neglected tropical diseases, and other conditions under the Global Health Initiative, global health security remained a separate focus for practical and political reasons. Although the National Security Staff and the Global Health Initiative leadership each created cross-cutting goals and priorities, their efforts at interagency coordination remain isolated within “clustered stovepipes” under each framework. On one hand, this insulates each community from political fallout at home and abroad (where partner countries may perceive either security or humanitarian actors more favorably). On the other, in a situation where all of the actors are approaching capacity building using the tools of public health on a systems level, the lack of shared technical terms and metrics means that many cross-cutting efforts with significant impact are simply not being captured.

For example, funds from the President's Emergency Plan for AIDS Relief (PEPFAR) used to reach goals in prevention, treatment, and care of people living with HIV can build cross-cutting capacities in laboratory and surveillance that also support IHR implementation. Because PEPFAR guidance and technical considerations exclude support for integrated disease surveillance not clearly linked to HIV and tuberculosis—just as security actors face challenges in supporting capacity-building not explicitly tied to specific biological threats—the mutual benefits of these outcomes for U.S. health and development and health and security priorities are difficult to measure on the ground. Opportunities to make the most of investments in other partner countries through similar dual-benefit investments are undoubtedly being lost. The disconnect between U.S. global health programs for development and security can undermine U.S. credibility with partners as well as program effectiveness.

Policy Recommendations

1. Strengthen the U.S. global health security policy framework.

The second Obama administration should focus on developing a cohesive, whole-of-government strategy for strengthening global public health surveillance and response capacities that aligns the equities and strategies of each U.S. department and agency and considers the needs of partner nations.

The lessons learned by coordinating through the National Security Staff during the Obama administration's first term should be captured in a new global health security policy that clearly designates lead agencies or programs in specific areas of global health security. The first step should be evaluating exactly what role each agency serves, and determining whether changes to legislative or regulatory frameworks are needed to support that role.

The current influx of security funds has enabled U.S. agencies to scale up efforts to support IHR (2005) implementation rapidly, seizing on an unprecedented opportunity to help partner nations fulfill their commitments to building capacities to respond to any potential public health emergency of international concern. A rational U.S. global health security policy should treat this short-term surge in security funds for public health tools as a strength, but anticipate a transition to the long-term engagement possible only through sustained relationships between technical partners—the kind of work in which organizations like CDC, USAID, and GEIS and the military overseas labs specialize. This requires a commitment from the administration and Congress to protect funding for programs that build global capacities for disease detection and response in a time of budget pressures, especially as Cooperative Threat Reduction programs face competing priorities. The same pressures should also drive a plan for building the capacities of regional organizations and middle-income governments with strong training, diagnostic, and response systems to assume greater roles as partners in global health security capacity-building. Determining where to concentrate finite U.S. resources could be more effectively informed by evidence: where could coordinated investments in disease detection and response capacities yield the greatest marginal benefits for human security, ultimately serving U.S., partner country, regional, and global interests?

2. Strengthen the international institutions that promote global health security.

The U.S. government needs to determine how best to support WHO and other organizations in implementation of the International Health Regulations, including how to engage the WHO regional offices and WHO Geneva headquarters. WHO will require additional technical personnel to help carry out these core functions, as well as financial support for programs and discussions among Member States. The next administration should develop a coherent approach to providing this support in the short and long terms.

3. Align U.S. efforts to engage in global health for development and security.

The United States needs to ensure that all actors providing partner countries and organizations with assistance to strengthen public health systems—whether public health, development, or security partners—operate with shared technical frames of reference at the program level. A human security approach, along with shared operational definitions based on principles of health systems strengthening and risk reduction, could go far in identifying standards for evaluating global health security interventions, reaching sustainability, and enhancing compatibility across sectors.

Experts in relevant agencies can begin this process where programmatic goals most clearly overlap. For example, respiratory diseases represent a risk to public health in terms of emerging infections and endemic disease burden. Both communities have prioritized strengthening health systems to detect and respond to such diseases (from point-of-care diagnostics to the abilities to analyze and use data for decisionmaking at the highest levels). The countries with which the United States has partnered most actively to strengthen health systems can offer case studies to identify mutually acceptable standards and metrics, leading to more sustainable programs, partnerships, and outcomes. In terms of low-hanging fruit, the United States could also fulfill its own IHR obligations to share best practices in building IHR core capacities with the other States Parties, an exercise that would require dialogue across U.S. sectors and agencies, with the WHO Collaborating Center for IHR Implementation within CDC as an obvious focus for translating U.S. experiences into technical assistance.



1800 K Street, NW | Washington, DC 20006
Tel: (202) 887-0200 | Fax: (202) 775-3199
E-mail: books@csis.org | Web: www.csis.org