Global Health
Technologies Coalition

From idea to impact:
How the US government can improve
coordination of global health research
and development

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Acronyms

CDC   Centers for Disease Control and Prevention

DoD   Department of Defense

FDA   Food and Drug Administration

HHS   Department of Health and Human Services

NIAID   National Institute of Allergy and Infectious Diseases, NIH

NICHD   National Institute of Child Health and Human Development, NIH

NIH   National Institutes of Health

OSTP   Office of Science and Technology Policy, White House

PEPFAR President's Plan for Emergency AIDS Relief

R&D   research and development

USAID   US Agency for International Development

Background

The Global Health Technologies Coalition is a group of almost 30 nonprofit organizations working to increase awareness of the urgent need for technologies that save lives in the developing world.

Funded in part by the Bill & Melinda Gates Foundation and housed at PATH, the Coalition supports policies and funding that advance the goals of global health research and development (R&D) in many areas. The Coalition works to:

- Build and support an informed and influential constituency for global health technologies.
- Conduct policy analysis to inform, develop, and pursue a strategic advocacy agenda.
- Conduct outreach and pursue strategic alliances.
- Educate and inform policymakers.

Through policy analysis, strategic alliances, and outreach to US policymakers, the Coalition advocates for new vaccines, microbicides, drugs, devices, and diagnostics that will improve health in developing countries. Coalition members advocate for specific topics, including:

- Increased financing, coordination, and strategic investments by the US government in global health R&D.
- Streamlined regulatory processes to accelerate licensing of safe and effective global health technologies.
- Adoption of new market-based incentives to encourage private industry investments in global health R&D.

Project objectives

The Global Health Technologies Coalition commissioned an analysis to examine the current programmatic support and strategic thinking of key US agencies involved in global health research and product development. This analysis was conducted to inform strategic alignment of US-supported global health R&D programs by:

- Accounting for all global health R&D activities in related US agencies.
- Delineating the US government role in product development for global health and highlighting areas of collaboration.
- Recognizing areas for improvement in US support for global health product development and developing policy recommendations to address those issues.

Methodology

Research, development, and innovation for global health technologies take place across a variety of US government agencies. Interagency coordination is essential to ensuring US investment in a portfolio of research approaches, is efficient, and achieves the greatest possible impact. Each agency possesses unique expertise, and only true partnership and collaboration will help deliver the most effective programs possible.

In recent years, there have been a few key mechanisms established to increase and improve coordination of global health R&D programs within the US government. These efforts have been useful in clarifying various priorities at US agencies. However, more is needed to ensure gaps in product development are filled, overlap is minimized, and priority-setting is more transparent.

Scope

The scope of the project included data gathered on all US agencies that conduct work on global health and/or R&D. These agencies and programs include the Centers for Disease Control and Prevention (CDC), Department of Defense (DoD), Food and Drug Administration (FDA), National Institutes of Health (NIH), National Security Council, Office of Management and Budget, Office of Global Affairs at the Department of Health and Human Services (HHS), White House Office of Science and Technology Policy (OSTP), President's Emergency Plan for AIDS Relief (PEPFAR), President's Malaria Initiative, Department of State, US Agency for International Development (USAID), and other interagency initiatives and policies such as the Global Health Initiative, the Presidential Policy Directive: Global Development Policy, the Quadrennial Diplomacy and Development Review, and the US Strategy for Meeting the Millennium Development Goals.

Literature Review

A literature review was conducted of publicly available data and agency websites. All agencies in the scope of work were included in this review. This review focused on the structure of agencies' global health R&D programs, insight on how agencies work to guide those programs, possible duplications or gaps, and examples of collaboration.

The full literature review is included as Appendix A.

Agency Consultations

Interviews were conducted with 16 representatives from several of the agencies within the scope of the project and staff from the Global Health Technologies Coalition. These consultations were used to supplement the literature review and understand how agencies could better align global health R&D programming in order to speed new tools to patients that need them.

Below is a list of US government offices from which staff were interviewed:

- National Center for Emerging Zoonotic Infectious Diseases, CDC
- Military HIV Research Program, Walter Reed Army Institute for Research, DoD
- Office of Global Regulatory Operations Policy, FDA
- Office of Global Affairs, HHS
- Fogarty International Center, NIH
- National Institute of Allergy and Infectious Diseases, NIH
- National Institute of Child Health and Human Development, NIH
- Bureau of Global Health, USAID
- Center for Accelerating Innovation and Impact, USAID

The interview template that was used in the consultations is included as Appendix B.

Data Analysis

An analysis was conducted from the data gathered in the literature review and the findings from agency consultations. This analysis was used to determine several key themes and conclusions about US policy on global health R&D.

Policy Recommendations

Based on the analysis, several policy recommendations were developed for US government actions to improve global health R&D programs.

MCC Robert P. Gallagher

A scientist from the US Army Medical Research Unit in Kenya gives instructions to students as part of a two-week malaria microscopy training class in Tanzania.

Summary of the literature review

US agencies have developed programs, policies, and strategies that guide work on global health R&D. This literature review contains data collected from publicly available information and agency websites, and it accounts for global health R&D activities, delineates the US government role in global health R&D, and identifies some gaps and areas of collaboration.

The following is a brief overview of each agency's structure and policies.

Centers for Disease Control and Prevention

The CDC outlines its strengths and global health priorities in its agency-wide global health strategy,[1] which identifies R&D as a priority. CDC research includes evaluating existing interventions and programs as well as developing and assessing new tools, strategies, and interventions that can then be implemented and brought to scale or used to modify existing programs for greater impact.[2] The offices within CDC that include a focus on global health R&D are the Center for Emerging Zoonotic and Infectious Diseases[3] and the Center for Global Health.[4] The CDC is also involved in an international effort to eradicate polio through the Global Polio Eradication Initiative.[5]

1   The Centers for Disease Control and Prevention. *Global Health Strategy 2012–2015*. http://www.cdc.gov/globalhealth/strategy/pdf/CDC-Global-HealthStrategy.pdf

2   The Centers for Disease Control and Prevention. *Global Health Strategy 2012–2015*. http://www.cdc.gov/globalhealth/strategy/pdf/CDC-Global-HealthStrategy.pdf

3   The National Center for Emerging Zoonotic and Infectious Diseases. *Strategic Plan 2012–2017*. http://www.cdc.gov/ncezid/pdf/strategicplan_NCEZID.pdf

4   The Centers for Disease Control and Prevention. Global Health. http://www.cdc.gov/globalhealth/index.html

5   Global Polio Eradication Initiative. *Polio Eradication and Endgame 2013–2018*. http://www.polioeradication.org/Portals/0/Document/Resources/StrategyWork/PEESP_EN_US.pdf

Department of Defense

DoD has several offices that conduct global health R&D: The Defense Advanced Research Projects Agency,[6] Army Medical Research and Materiel Command,[7] Army Medical Research Institute of Infectious Diseases,[8] Walter Reed Army Institute for Research,[9] Military HIV Research Program,[10] Military Malaria Research Program,[11] Military Infectious Disease Program[12] and Navy Medical Research Centers.[13] The agency's efforts in global health R&D include advancing medical research in infectious diseases, innovating new tools and strategies for their control and prevention, tracking and responding to outbreaks around the world, and strengthening other countries' efforts to address diseases.[14]

Food and Drug Administration

The FDA conducts neglected disease product review and regulation through several offices including the Center for Biologic Evaluation and Review[15] and the Office of International Programs.[16] The Center for Drug Evaluation and Research[17] and the Center for Devices and Radiological Health[18] support FDA's global presence and health systems strengthening initiatives. The FDA also funds global health R&D through the Critical Path Initiative to close the gap between early-stage biomedical research and product development.[19] The FDA plays a role in global health issues by ensuring the safety and effectiveness of health products that prevent, diagnose, and treat diseases that affect millions of people worldwide.

Michael J. Ermarth

An FDA chemist prepares to test the melting point of a drug.

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6   Defense Advanced Research Projects Agency. *DARPA Strategic Plan 2009*. http://www.carlisle.army.mil/DIME/documents/StratPlan091.pdf

7   US Army Medical Research and Material Command. *Medical Countermeasures to Chemical and Biological Threats*. http://mrmc.amedd.army.mil/assets/docs/media/CDBPCommPlan.pdf

8   Army Medical Research Institute of Infectious Diseases. Mission of AMRIID. http://www.usamriid.army.mil/aboutpage.cfm

9   Walter Reed Army Institute for Research. Mission of WRAIR. http://wrair-www.army.mil/AboutWRAIR.aspx

10   US Military HIV Research Program. *Strategic Plan 2010*. http://www.hivresearch.org/media/pnc/2/media.392.pdf

11   Military Malaria Research Program. Mission. http://wrair-www.army.mil/ReAndDevelop_InfectDisRe_MalariaResearch.aspx

12   Military Infectious Diseases Research Program. MIDRP Historical Achievements. https://midrp.amedd.army.mil/info/HAchieve.jsp

13   Naval Medical Research Center. Overview. http://www.med.navy.mil/sites/nmrc/Pages/id_main.htm

14   US Global Health Policy. *The Department of Defense Global Health Policy, 2012*. http://kaiserfamilyfoundation.files.wordpress.com/2013/01/8358.pdf

15   Center for Biologics Evaluation and Review. *Strategic Plan for Regulatory Science and Research, 2012–2016*. http://www.fda.gov/downloads/Biologics-BloodVaccines/ScienceResearch/UCM303542.pdf

16   The Food and Drug Administration (FDA). The Office of International Programs. http://www.fda.gov/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/OfficeofInternationalPrograms/

17   The Food and Drug Administration (FDA). The Center for Drug Evaluation and Research. http://www.fda.gov/aboutfda/centersoffices/officeofmedicalproductsandtobacco/cder/default.htm

18   The Food and Drug Administration (FDA). The Center for Devices and Radiological Health. http://www.fda.gov/training/cdrhlearn/default.htm

19   The Critical Path Institute. http://c-path.org/about/

National Institutes of Health

NIH has several offices that address global health including the National Institute of Allergy and Infectious Diseases (NIAID),[20] Office of AIDS Research,[21] National Institute of Child Health and Human Development (NICHD) Office of Global Health,[22] National Center for Advancing Translational Sciences,[23] Office of Disease Prevention,[24] Fogarty International Center,[25] and Office of Technology Transfer.[26]

NIAID, NICHD, and the National Center for Advancing Translational Sciences all identify global health R&D as a priority on their websites. The mission of NIAID is to conduct and support basic and applied research to better understand, treat, and ultimately prevent infectious and immunologic and allergic diseases. The Office of Global Health at NICHD facilitates international research and coordinates the HIV/AIDS portfolio. The National Center for Advancing Translational Sciences was established to transform the translational science process so that new treatments and cures for disease can be delivered to patients faster.

An NIH scientist examines a specimen.

Office of Global Affairs, Department of Health and Human Services

HHS has a global health strategy that outlines the agency's priorities for R&D. One of its main objectives is to catalyze biomedical and public health research and innovation globally to promote the discovery, development, delivery, and evaluation of new interventions that improve health and well-being across national borders.[27] In addition, the National Vaccine Program in Global Immunizations is led by HHS and implemented through several agencies.[28]

20   The National Institute of Allergy and Infectious Diseases, The National Institutes of Health (NIH). http://www.niaid.nih.gov/about/whoweare/Pages/default.aspx

21   Office of AIDS Research, The National Institutes of Health (NIH). http://www.oar.nih.gov/about/mission.asp

22   The National Institutes of Child Health and Development, Office of Global Health, The National Institutes of Health (NIH). http://www.nichd.nih.gov/about/org/od/ogh/Pages/index.aspx

23   The National Center for Advancing Translational Science, The National Institutes of Health (NIH). http://www.ncats.nih.gov/about/about.html

24   Office of Disease Prevention, The National Institutes of Health (NIH). http://prevention.nih.gov/aboutus/strategic_plan/mission.aspx

25   The Fogarty International Center. The Framework Programs for Global Health. http://www.fic.nih.gov/programs/pages/framework-innovations.aspx

26   The Office of Technology Transfer. *FY 2011 Annual Report*. http://www.ott.nih.gov/sites/default/files/documents/pdfs/AR2011.pdf

27   The Department of Health and Human Services. *Global Health Strategy 2011*. http://www.globalhealth.gov/pdfs/Global%20Health%20Strategy.pdf

28   National Vaccine Program. Global Immunizations Presentation on Enhancing the Work of the NVP. http://www.hhs.gov/nvpo/nvac/meetings/pastmeetings/2013/enchancing_global_immunization_sept2013.pdf

White House Office of Science and Technology Policy

The White House focuses on technology and innovation through the work of the Office of Science and Technology Policy (OSTP). The mission of OSTP is threefold: 1) to provide the president and his senior staff with accurate, relevant, and timely scientific and technical advice on all matters of consequence; 2) to ensure the policies of the executive branch are informed by sound science; and 3) to ensure the scientific and technical work of the executive branch is properly coordinated so as to provide the greatest benefit to society.[29] The White House also guides its programs by several strategies including the *US Strategy for American Innovation*,[30] *Harnessing Innovation for Global Development*,[31] and *The America Competes Act*.[32]

The President's Emergency Plan for AIDS Relief, Department of State

PEPFAR has developed a *Blueprint for an AIDS Free Generation*,[33] a *5-year Strategy*[34] and a *Research Policy*[35] that identify R&D goals for the agency. The Scientific Advisory Board informs these goals, and PEPFAR collaborates with its implementing agencies to achieve them.[36] PEPFAR also identifies priorities of investment in research on new preventions (microbicides and vaccines) and new treatments for TB and HIV.

The President's Malaria Initiative

The President's Malaria Initiative is overseen by the US Global Malaria Coordinator and an interagency steering group made up of representatives from USAID, CDC, Department of State, DoD, National Security Council, and Office of Management and Budget.[37] The *US Malaria Strategy for 2009–2014* states that one of its general principles is to conduct operational research that helps overcome implementation bottlenecks, contributes to the scale-up of malaria control activities, and identifies the most cost-effective mix of currently recommended interventions under different malaria transmission settings.[38] However, the President's Malaria Initiative does not conduct R&D for new biomedical technologies to combat malaria.

The US Agency for International Development

USAID identifies R&D as a core principle of the agency. USAID collaborates with diverse partners to address critical barriers to the development, introduction, and scale-up of priority global health interventions. The agency has a *Global*

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29   The White House Office of Science and Technology Policy. http://www.whitehouse.gov/administration/eop/ostp/about

30   A Strategy for American Innovation. *Ensuring Our Economic Growth and Prosperity, 2011*. http://www.whitehouse.gov/sites/default/files/uploads/InnovationStrategy.pdf

31   White House. *Harnessing Innovation for Global Development: Fact Sheet. 2012*. http://www.whitehouse.gov/the-press-office/2012/02/08/fact-sheet-harnessing-innovation-global-development

32   *Prize Authority in The America COMPETES Act Reauthorization*. https://cio.gov/wp-content/uploads/downloads/2012/09/Prize_Authority_in_the_America_COMPETES_Reauthorization_Act.pdf

33   PEPFAR. *Blueprint: Creating an AIDS-free Generation*. 2012. (Pages 52–53). http://www.pepfar.gov/documents/organization/201386.pdf

34   PEPFAR. *Five-Year Strategy*. (Page 6). http://www.pepfar.gov/documents/organization/133035.pdf

35   Office of the US Global AIDS Coordinator. *Unsolicited Research Policy.* 2012. http://www.pepfar.gov/about/research/184923.htm

36   PEPFAR. *Scientific Advisory Board Charter*. 2010. http://www.pepfar.gov/documents/organization/154879.pdf

37   The President's Malaria Initiative. http://www.pmi.gov/about/index.html

38   *Lantos-Hyde US Government Malaria Strategy, 2009–2014*. http://www.pmi.gov/resources/reports/usg_strategy2009-2014.pdf

Health Strategic Framework,[39] a *Health-Related Research and Development Strategy*[40] and a *Strategy for the Development of Vaccines for HIV/AIDS, TB, Malaria and other diseases*.[41] These strategies outline specific R&D objectives. The offices within USAID that work on these issues include the Bureau for Global Health,[42] the Office of Science and Technology[43] and the Office of Innovation and Development Alliances.[44] USAID also has several science and technology ventures, including the Grand Challenges for Development Initiative.[45]

Other Agencies

The Office of Management and Budget has specific priorities for science and technology; however, there isn't a clear global health component. The National Security Council has a framework for national health security that is designed to achieve two goals: build community resilience and strengthen and sustain health emergency response systems.[46] The National Security Council was the lead in the recent *Global Health Security Strategy* released by the White House in early 2014. This is an interagency strategy and has a global health R&D component. The Department of State's Office of Global Health Diplomacy (GHD) coordinates with other agencies to implement global health policies. However, there is no clear R&D priority.[47]

USAID/Deliver

As part of its global health activities, USAID supports research to develop new contraceptive methods and improve upon existing methods.

39   USAID. *Global Health Strategic Framework, 2012–2016*. (Page 27). http://reliefweb.int/sites/reliefweb.int/files/resources/Full_Report_3837.pdf

40   USAID. *Health-Related Research Strategy, 2011–2015*. http://www.ghtcoalition.org/files/HRRStrategy_web.pdf

41   USAID. *Coordinated Strategy to Accelerate Development of Vaccines for Infectious Diseases*. 2009. (Page 10). http://pdf.usaid.gov/pdf_docs/PDACN525.pdf

42   USAID. Center for Accelerating Innovation and Impact. http://www.usaid.gov/what-we-do/global-health/cross-cutting-areas/innovation-and-impact

43   USAID. Office of Science and Technology. http://www.usaid.gov/who-we-are/organization/independent-offices/office-science-and-technology

44   USAID. Office of Innovation and Development Alliances. http://www.usaid.gov/who-we-are/organization/independent-offices/office-innovation-and-development-alliances

45   USAID. Grand Challenges for Development. http://www.usaid.gov/grandchallenges

46   US Department of Health and Human Services. *National Health Security Strategy*. 2009. http://www.phe.gov/preparedness/planning/authority/nhss/strategy/documents/nhss-final.pdf

47   US Department of State. Office of Global Health Diplomacy. http://www.state.gov/s/ghd/about/index.htm

In addition to the information collected on US agencies, other interagency initiatives were reviewed, including the Global Health Initiative, the Presidential Policy Directive: Global Development Policy, the Quadrennial Diplomacy and Development Review, and the US Strategy for Meeting the Millennium Development Goals. These initiatives provide examples of overarching direction in global health, R&D, and agency coordination.

Final Overview

USAID, NIH, and DoD have made the most information publicly available about their global health R&D programs through strategies and their websites. USAID focuses on funding research programs that encourage innovation and have a clear link to development. The agency has achieved key successes in global recommendations for the development and adoption of strategies to prevent maternal mortality, innovations in contraceptive methods, and new drug formulations for malaria. NIH funds research in several policy areas, including HIV/AIDS, TB, malaria, and neglected tropical diseases. DoD has research programs that focus on a wide range of diseases and appear to have the most comprehensive strategy toward global health R&D, funding research from start to finish. However, the agency conducts global health R&D only as it relates to its mandate to protect military personnel.

Most of the strategies reviewed are broad and do not identify a clear mechanism for implementation. There are very few documents that dictate how research funding should be allocated and what targets to pursue. Policies like the Presidential Policy Directive on Global Development Policy and the Quadrennial Diplomacy and Development Review cast the vision for the use of innovation to create efficiencies and foster participation in the area of global health R&D.

Few policies cover global health R&D prioritization specifically, and most that cover it do so in a disease or population-specific manner. For example, PEPFAR and the President's Malaria Initiative have clear vaccine development priorities for HIV/AIDS and malaria. The CDC focuses on research for HIV/AIDS, TB, malaria, vaccine preventable diseases, and childhood morbidity and mortality. USAID is one of the few agencies that—among its global health R&D programs—funds specific R&D platforms like development of contraceptive technologies. USAID's Health-Related Research and Development Strategy is one of the only publicly available guidance documents that provides specific expected results and identifies clear funding numbers for each research focus.

There are some examples of agency coordination in global health R&D including the National Vaccine Program in Global Immunizations[48] and the research efforts of the President's Malaria Initiative. In addition, the Global Health Initiative was created to be a model for agency coordination and has priorities for global health R&D. However, this interagency initiative doesn't appear to have achieved coordination or impacted other agencies' priorities in the area of global health R&D.

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48 National Vaccine Program. *Global Immunizations Presentation on Enhancing the Work of the NVP*. http://www.hhs.gov/nvpo/nvac/meetings/pastmeetings/2013/enchancing_global_immunization_sept2013.pdf

Key themes

Key themes were developed from the literature review and the agency consultations. It was determined from this analysis that global health R&D is a priority for the US government. However, there is no clear interagency strategy to guide programs. There are examples of coordination among US agencies and that coordination usually occurs in an informal capacity. There are obvious gaps in global health R&D that were recognized by the agencies and need to be addressed. Every agency recognized that funding is a barrier to the expansion of programs, and the strict limits on conference participation are an obstacle to collaboration and a hindrance to innovation. Finally, successful case studies of US global health R&D programs that have clear areas of coordination are provided. These themes provide a platform for policy recommendations to improve US global health R&D programs.

Global Health R&D is a priority for the US government, but there is no clear interagency strategy

Agencies' Mandates for Global Health R&D

All the agencies that were interviewed (CDC, DoD, FDA, HHS, NIH, and USAID) identified clear priorities for global health R&D. These priorities are set independently by agency and in very different ways.

The CDC sees itself as the lead in US global health R&D. The agency has developed a global health strategy that is currently being refined. It reviews global research proposals and decides whether it has a unique role to play, but there isn't a formalized process for priority-setting. Each division within offices at the CDC has its own set of rules for what research they will encourage. In addition, staff in the field gives feedback on priority areas. The CDC has large investments in certain regions and countries in East Africa, Southeast Asia, and more recently in parts of the Middle East.

DoD has a very specific mandate for global health R&D: defense and the protection of service members. The agency has a very formal process for R&D. There are a number of advisory boards that decide what diseases are risks to service members, which countermeasures are needed, and

CDC/ Dr. Scott Smith

A mother and her child stand outside a health clinic in rural Kenya.

then when to invest in R&D. DoD looks at both preclinical research and advanced development and works on everything from basic science to products almost ready for approval by the FDA.

The FDA has a global footprint, and the agency identified two reasons for a global focus. First, product developers seek FDA approval for products in order to achieve an internationally recognized endorsement. Other international regulatory agencies usually adopt products with FDA's approval. The agency sees itself as the international "gold standard." Second, the US has a strategic interest in regulating products around the world to maintain the safety of its citizens. The FDA has a catalytic role in regulatory systems strengthening and post-market surveillance. The Office of International Programs in particular focuses on building strong regulatory systems globally.

HHS is considered a domestic organization but because of the changing landscape of science, the agency has expanded its focus to work on global health engagement. The agency includes the work of the FDA, CDC, and NIH, which all conduct programs related to global health R&D. In order to reinforce those programs the agency created a global health strategy that demonstrates a global health mandate.

NIH has a clear mandate for research. The agency addresses global health technology needs by asking, "What are the scientific opportunities?" and "What are the public health service needs?" NIH then issues proposal requests accordingly. The agency has a complex process for identifying priorities that takes input from leadership, managers of scientific portfolios, and researchers. In addition, the agency receives direction from the White House, Congress, and the Secretary of HHS.

The leadership at NICHD recently conducted a visioning project that obtained feedback from external and internal policymakers to identify priorities for the next ten years. NICHD is particularly focused on maternal and child health and maximizing impact in the first 1,000 days of a child's life. NIAID works on infectious diseases, which have a global breadth. Therefore, NIAID has a global mandate to address those diseases. This center focuses on basic science research and not as much on late-stage or clinical trials. Although the Fogarty International Center does not have a specific mandate for biomedical R&D, it functions as a "convener" within NIH to bring together international programs.

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USAID is a development organization; therefore, its research has to be directly related to its mandate. The majority of the work on global health R&D is led by the Bureau for Global Health. This office has a long-standing commitment to robust global health R&D efforts. The technical teams at USAID have a lot of autonomy and are able to set priorities for each program. Technical teams take into consideration the perspective of staff working in field as well. In addition, USAID funds very little early-stage discovery because it does not fall under the agency's mandate and it believes that is the role of NIH.

This analysis did not include a consultation with the White House Office of Science and Technology Policy (OSTP). However, some agency representatives identified the White House as the government "convener" on overarching policy issues related to global health R&D. Part of OSTP's mission is to ensure the scientific and technical work of the executive branch is properly coordinated so as to provide the greatest benefit to society. The role of the OSTP is to bring agencies to the table when coordination needs to happen.

Challenges in the Division of Labor

Most agencies mentioned certain challenges that have arisen due to lack of understanding about priorities and divisions of labor. These issues have made it difficult for agencies to coordinate on global health R&D. Differing agency mandates result in varied priorities. For example, DoD conducts a wide range of global health R&D programs. Although the agency's mandate is specific to the health and well-being of US service members, other agencies often don't recognize areas where collaboration could occur with DoD programs.
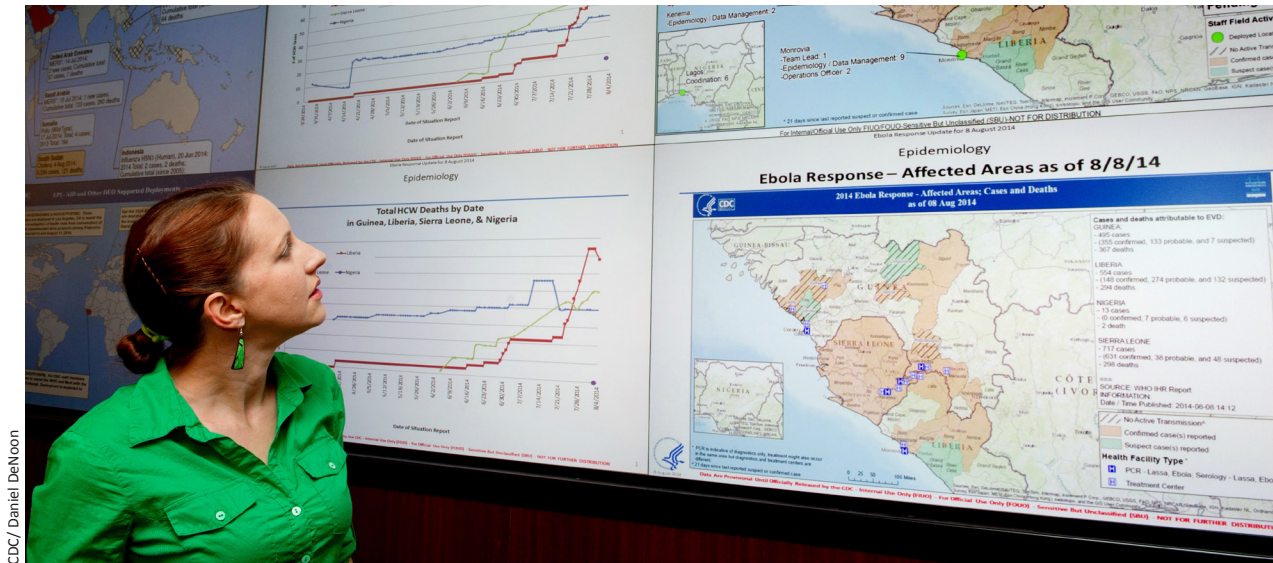
Each agency has a different set of expertise. Roles and responsibilities for global health R&D need to be more clearly defined in order to better identify gaps and overlap in programs. This also would enable a smoother transition for potential breakthrough technologies within the R&D process from one agency to the other or from one program to another within one agency. NIH focuses on early-stage research, but agencies noted that because of the structure of the agency there is no clear transition from early-stage research at NIH to later-stage research at other agencies, which results in a gap.

An assistant research officer at the Kenya Medical Research Institute/CDC facility prepares a sample to detect tuberculosis drug resistance.

Several agencies stressed the importance of an open dialogue early on in the development of global health R&D programs within agencies. Some agency representatives felt that other agencies were not engaging their expertise when needed. For example, agencies stressed that navigating the FDA regulatory system can be challenging. However, the FDA noted that with early and frequent collaboration the regulatory system is less burdensome. The CDC also noted that it would be beneficial to other agency's global health R&D programs to bring in their expertise early in the development of large-scale research and technology development programs.

A clear strategy for a government-wide approach to global health R&D could potentially address these challenges. However, there are other ways agencies could foster better collaboration. For example, early dialogue on priority-setting would help agencies identify gaps in programs, and regular information-sharing among staff of different agencies would provide more transparency in programs. Agencies need to recognize where expertise exists, what the divisions of labor are, and where collaboration could occur.

A CDC communications specialist sent to West Africa in response to the 2014 Ebola outbreak stands in front of a display of maps and graphs outlining epidemiologic trends exhibited by the outbreak.

Lack of an Interagency Strategy

Most agencies identified the need for an interagency strategy or guidance to align priorities and identify gaps and overlap in global health R&D. They continually stressed the need for a more integrated approach. There were a few agency representatives opposed to a government-wide approach because previous attempts to form an interagency strategy were cumbersome and slowed action on individual agency programs. Each agency sets its own priorities and funding of programs. Some agencies like DoD have a very formal process and other agencies like CDC have a less structured process. Many agencies stressed that there needs to be more transparency in programs. Multiple agencies mentioned the word siloed in describing global health R&D programs both within agencies and government-wide.

When agencies mentioned the need for coordination there was hesitation about how that coordination should occur. Several agencies stressed that top-down coordination can slow progress. Each agency has different priorities, so alignment is sometimes too difficult and coordinating in an informal capacity is easier and more efficient.

Most agencies expressed concern when asked to identify one agency that could lead a government-wide strategy for global health R&D. If one particular agency was chosen to lead, the others could potentially have to sacrifice their own priorities for the priorities of the lead agency. These contrasting sentiments from agencies make it difficult to coordinate at a high level. Most agencies want high-level coordination in theory, but cannot identify a particular agency that is equipped to lead the whole of government approach or a clear mechanism for where government-wide priorities could be set.

Other Interagency Strategies

Agencies did identify strategies that have attempted to achieve interagency coordination on global health R&D. Several agencies identified the Global Health Initiative as having an overarching strategy for innovation. However, it didn't achieve its intended goal because it had no clear mechanism for implementation and no new funding. *The Quadrennial Diplomacy and Development Review* was another interagency strategy that identified clear areas for improvement in US programs. It was a robust effort but a cumbersome process. Multiple agencies also mentioned the recently developed Global Health Security Agenda initiative as a possibility in providing a government-wide framework for coordination on global health R&D.

There are examples of coordination among US agencies in global health R&D, usually occurring in an informal capacity

Coordination within Agencies

Most agencies that were interviewed mentioned specific areas where coordination occurs within their respective agencies. Programs within agencies have regular interactions and share information. These interactions occur in an informal and formal capacity.

FDA's Center for Biologic Evaluation and Review and the Office of International Programs collaborate often. The Office of International Programs manages their programs by steering committees and the Center for Biologic Evaluation and Review has representatives on each committee. In addition, the diagnostics and drug divisions at the FDA naturally have to collaborate on reviews because of common technical targets. Representatives from CDC mentioned that the Center for Global Health and the National Center for Emerging Zoonotic Infectious Diseases interact frequently in an informal capacity. At NIH, coordination occurs at multiple levels, when there is a directive from NIH leadership or when there is program alignment. The Fogarty International Center at NIH is a clear example of formal coordination on global health R&D—it is the smallest center at NIH, however, the director works across all of NIH to collaborate. This center is often the main convener across global health at NIH. In addition, Fogarty holds an international representatives' meeting once a month and global health is included on the agenda.

Interagency Coordination

There are examples of interagency coordination in the literature review that were highlighted during the agency consultations. The vast majority of coordination between agencies occurs in an informal capacity.

Individual staff within agencies coordinate on a variety of global health R&D programs. These are a few examples highlighted during the agency consultations:

- Currently, the new National Center for Advancing Translational Sciences at NIH and FDA is working on creating a public internet database containing research on different drugs that may be able to be repurposed for new uses. The database would allow agencies to share best practices and provide more information to other agencies to improve programs.

- Agency representatives also mentioned that USAID, NIH, and DoD coordinate on jointly funded malaria vaccine research.

- It was identified that CDC and FDA coordinate on TB research. USAID funds TB research, however they do not currently fund TB vaccine research due to limited resources.

- Coordination on HIV research was mentioned frequently during the consultations and identified in the literature review. The Military Infectious Diseases Research Program works on HIV prevention. This DoD program focuses on the development of a global HIV-1 vaccine. Field sites have been established in Africa and Southeast Asia and management is shared by the Military Infectious Disease Program and NIAID.

- When the Global Health Initiative was established it included neglected diseases among its priorities. As a result, USAID and NIAID began to have informal discussions about how to address these research needs. In particular they were focused on mass drug administration. Both agencies mentioned coordination on R&D issues related to neglected diseases.

There were fewer instances where agencies identified a formal mechanism for coordination, like USAID's *Strategy for the Development of Vaccines for HIV/AIDS, TB, Malaria and other diseases* that lays out formal ways in which agencies should coordinate.

USAID's strategy lays out the following agency roles in the development of vaccines:

- NIH and DoD support basic research, preclinical testing in animal models, development of candidate vaccine products, and clinical testing of vaccines.
- CDC supports clinical trials, field preparedness, epidemiological research, surveillance; provides data on disease burden to establish baseline, monitor impact, and track specific changes in serotypes as necessary; supports economic studies on cost-effectiveness; and provides technical support for vaccine procurement, distribution, and delivery.
- USAID supports preclinical testing in animal models, development of candidate vaccine products, clinical testing of vaccines, operations and applied research to strengthen immunization programs and logistics, prepare for the introduction of new vaccines; and provides global expertise in demand forecasting, supply and procurement, and distribution and delivery to developing countries.[49]

USAID's *Health-Related Research and Development Strategy* highlights the following partners in addressing critical barriers to the development, introduction, and scale-up of priority global health interventions: the Department of State, Office of the US Global AIDS Coordinator, CDC, NIH, FDA, and DoD.

There are gaps in US global health R&D programs that need to be addressed

Agencies identified several areas where there are gaps in US programs for global health R&D. Agencies focused particularly on broader gaps in the research process instead of specific programs.

Implementation, Host Country Capacity, and Scalability

Several agencies mentioned a significant gap in the implementation of research. Representatives stressed that once there is an idea for a new technology, there is a challenge in then bringing it to a population and scaling it up. Agency representatives mentioned there needs to be more of a focus from US agencies on technology and research utilization. This was mentioned as a focus of USAID's work on global health R&D.

Many agencies identified the lack of host-country capacity as a major barrier in global health R&D. Once a product is developed, there is lack of infrastructure in other countries to absorb new products. In addition, there is very little investment in national global health R&D by host countries. Some agencies recommended US global health R&D programs should focus on building capacity in other countries. The Fogarty International Center's work was mentioned as an example in this area.

Several agencies stressed that US programs lack scale-up capabilities. Agencies identified scalability as difficult to measure and stated that there is a need for more early thinking about manufacturing, introduction, and scale-up of products. Agencies identified that this gap was due to a lack of resources.

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49 USAID. *Coordinated Strategy to Accelerate Development of Vaccines for Infectious Diseases.* 2009. (Page 10). http://pdf.usaid.gov/pdf_docs/PDACN525.pdf

Other Gaps in US Global Health R&D

Agencies also provided other examples of gaps in global health R&D that need particular focus. The following are specific areas where more work needs to be done:

- There are gaps in expanding platforms to other diseases beyond HIV, malaria, and TB. Some agencies suggested using the current product development partnership model to expand publicly funded platforms, such as clinical trial networks, to include neglected tropical diseases.

- There is a gap in translational stage research. There are barriers to bringing research from one phase to the next and it is usually a matter of financing.

- More attention needs to be paid to basic investigative disease surveillance.

- Earlier interventions in the progression of the diseases are needed to reverse or minimize the impact on populations.

Staff at the Jayapura Health Laboratory in Indonesia—which received support from USAID to renovate and upgrade its laboratory facilities—examines a patient.

It is also important to note that most agencies did not identify duplications in US global health R&D. A few noted that programs within their agencies were complementary and that overlap can help in filling gaps as long as there is coordination.

Funding is a barrier to the expansion of US global health R&D programs

Every agency that was consulted on this project identified funding as a barrier to the continuation or expansion of its global health R&D programs. Even when agencies have clear directives, without adequate funding, it is a challenge to expand or sometimes to sustain existing programs. It is difficult for agencies to discuss new areas of research when there currently isn't enough funding for existing global health R&D. Agencies mentioned the government shutdown and sequestration as being a particular challenge in carrying out their global health R&D programs. These types of budget disruptions have a ripple effect on programs. Agencies are faced with difficult tradeoffs in order to make budgets work and carry out mandates. Agencies try to be strategic in how funding is used and leverage partnerships but are not able to count on consistent funding, and this is an issue in global health R&D government-wide.

Strict limitations on conference participation by agency representatives is hindering innovation and collaboration

Several agencies identified a lack of funding for conferences and scientific meetings in particular as a serious hindrance in agency collaboration. These gatherings can be a place where information is exchanged in a constructive way. They also provide a forum for coordination between different agency programs. It is a place where representatives from different agencies can learn from each other and build partnerships. Agencies noted that these limitations impact younger scientists in particular. They are generating a disproportionate number of ideas and often attend conferences.
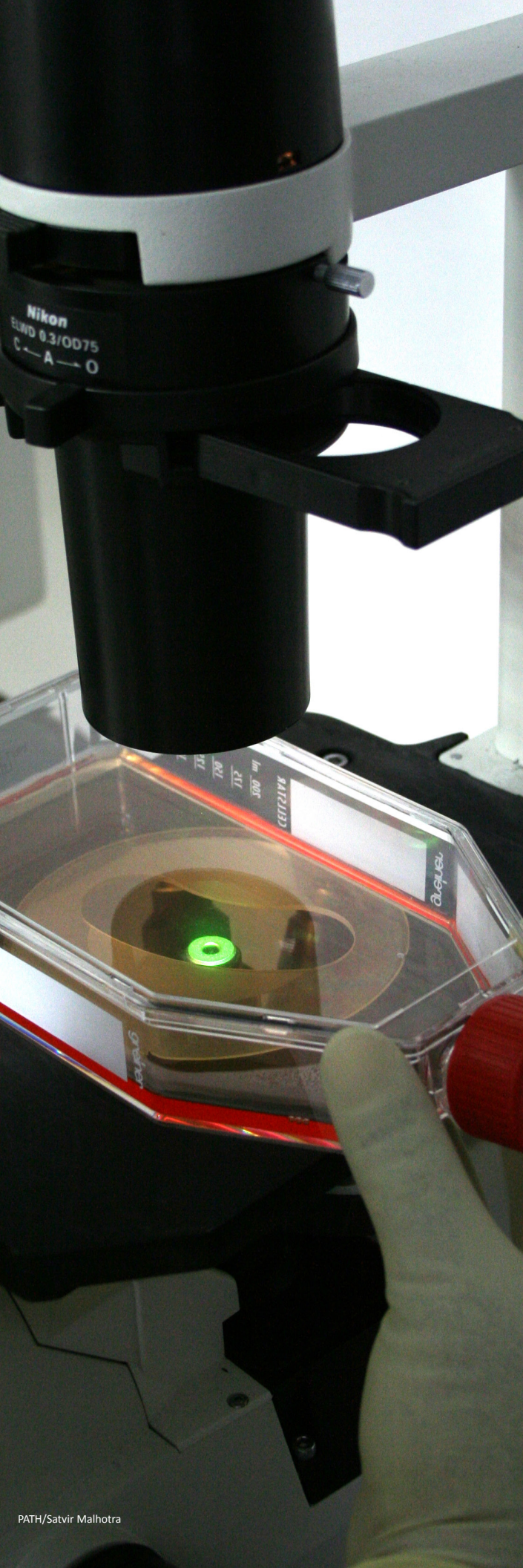
Successful case studies of US global health R&D programs

Agencies provided the following examples of success in collaboration in US global health R&D.

Chlorhexidine for Neonatal Sepsis

The research and development of chlorhexidine for neonatal sepsis is an example of coordination and collaboration on multiple levels. Chlorhexidine is an intervention to reduce the development and transmission of infections in mothers and newborns. USAID, along with NIH and the Bill & Melinda Gates Foundation, funded the first completed study of neonatal and umbilical cord care with chlorhexidine for over 15,000 infants in Nepal.[50] The Ministry of Health in Nepal was swayed by the incredibly promising results (24% reduction in neonatal mortality) and approved a USAID-funded pilot of chlorhexidine in four districts throughout the country. USAID country missions, ministries of health, and the local private sector all collaborated to implement this product.

USAID is now helping fund the national scale-up through a Saving Lives at Birth award. The project is also manufactured locally, through Lomus Pharmaceuticals. To support the implementation, USAID and the UN Commodity Commission created and funded a working group to support the introduction activities in 15 countries. As a result of this collaboration experts say this lifesaving intervention has the potential to reach large populations and avert an estimated 500,000 neonatal deaths per year.[51]

MenAfriVac

The development of MenAfriVac is an outstanding example of US agency collaboration and FDA leadership in global health R&D. Meningococcal meningitis is a disease that particularly impacts sub-Saharan Africa. Scientists from the FDA's Office of Vaccine Research and Center for

50   USAID. *Navel Glazers*. 2012. http://www.usaid.gov/news-information/frontlines/child-survival-ethiopia-edition/navel-glazers

51   USAID. *Navel Glazers*. 2012. http://www.usaid.gov/news-information/frontlines/child-survival-ethiopia-edition/navel-glazers

Biologic Evaluation and Review made a critical contribution in developing the technology needed to manufacture a vaccine against this terrible disease and at an affordable cost for countries in Africa. With critical investments from NIH and the Bill & Melinda Gates Foundation, and a unique FDA technology, the vaccine was developed. In 2009, MenAfriVac was licensed. In 2010, the World Health Organization prequalified the vaccine for global immunization programs and by the end of 2011, an estimated 55 million people had been vaccinated at a cost of only 40 cents per dose.[52] This is an example of both intra- and interagency collaboration that has saved lives around the world.

USAID collaborated with other US government agencies and partners to develop and introduce chlorhexidine for use in preventing neonatal sepsis.

Evidence Summits

USAID initiated a series of Evidence Summits, through support of the Global Health Initiative, bringing together academics and development practitioners to review the evidence on some of the world's most difficult development challenges. The Global Health Initiative identifies seven core principles emphasizing the importance of evidence-based best practices to inform country-owned and sustainable outcomes. These summits, led by USAID, brought together multiple agencies to collaborate and encourage innovation.

These summits included:

- Protecting Children Outside of Family Care
- Enhancing Provision and the Use of Maternal Health Services through Financial Incentives
- Community and Formal Health System Support for Enhanced Community Health Worker Performance
- Population-Level Behavior Change to Enhance Child Survival

The ultimate goal was to improve health policies, programs, and research in low- and middle-income countries. These summits included representatives from several US agencies working on global health R&D and provided an important avenue for information-sharing and interagency coordination.

Microbicides

Since 2000, USAID, NIH, CDC, and FDA have collaborated to develop and implement the *US Government Strategic Plan for Microbicides*. These agencies are committed to supporting the development of safe, effective, acceptable, and affordable microbicide products that are suitable for use in developing-country public sector programs.[53]

The Center for the AIDS Program of Research in South Africa 004 trial was recently completed in Durban, South Africa. The use of 1 percent tenofovir gel by 889 women at high risk of HIV infection proved to be 39 percent effective in reducing a woman's risk of HIV infection. The successful outcome of this new tool has encouraged continued collaboration among US agencies.[54] USAID continues to work with PEPFAR, multilateral agencies, and partner countries to ensure the full impact of this advancement can be offered to vulnerable women and girls worldwide, especially in low-resource settings.[55]

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52 FDA Assists in the Success Against Epidemic Meningitis in Africa. FDA Voice. 2012. http://blogs.fda.gov/fdavoice/index.php/tag/menafrivac/

53 USAID. HIV/AIDS: Microbicides. 2013. http://www.usaid.gov/news-information/fact-sheets/hivaids-microbicides

54 USAID. HIV/AIDS: Microbicides. 2013. http://www.usaid.gov/news-information/fact-sheets/hivaids-microbicides

55 USAID. HIV/AIDS: Microbicides. 2013. http://www.usaid.gov/news-information/fact-sheets/hivaids-microbicides

The FDA worked in conjunction with NIH and other partners to develop MenAfriVac—a low cost vaccine to prevent meningococcal meningitis.

Cryptococcus

Cryptococcal meningitis cases occur in people living with HIV/AIDS, and the majority of cases are found in sub-Saharan Africa. The CDC is working with other US agencies to implement targeted cryptococcal screening programs in areas with the highest disease burden. Many of the countries in these areas do not always have the resources to reliably detect Cryptococcus as the underlying cause of meningitis, so these US agencies are also helping countries build their laboratory capacity. CDC and PEPFAR are working collaboratively on the new cryptococcal antigen dipstick test that will hopefully work on urine, and possibly a finger-prick of blood, so that people in remote areas of the world will be able to use the test even if there are no advanced laboratories nearby.[56]

US agencies are working to equip half of all HIV clinics in Africa and Asia to perform Cryptococcus testing and treatment, which could save 50,000 to 100,000 lives every year. Early identification of cryptococcal-infected patients in resource-limited settings may lead to more timely treatment, reduced mortality due to cryptococcal meningitis, and overall improved quality of life.[57]

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56   Centers for Disease Control and Prevention. Preventing Deaths Due to Cryptococcus with Targeted Screening. 2014. http://www.cdc.gov/fungal/diseases/cryptococcosis-neoformans/screening.html

57   Centers for Disease Control and Prevention. Preventing Deaths Due to Cryptococcus with Targeted Screening. 2014. http://www.cdc.gov/fungal/diseases/cryptococcosis-neoformans/screening.html

Policy recommendations

Develop an interagency strategy on global health R&D with clear divisions of labor for agencies and a funding mechanism for enforcement.

The US government needs a strategy for global health R&D. This strategy needs to include a mandate for coordination and identify the staff capacity to carry out the mandate. Most importantly, this strategy needs to have a funding allocation included. Past attempts at developing strategies have failed because there was no new funding for implementation and no clear lead agency with divisions of labor identified. This strategy should also be developed in collaboration with all agencies working on global health R&D.

There were many differing opinions among agencies about who should lead an interagency strategy. Although there was no obvious conclusion, there are clear characteristics that a lead agency must have to effectively implement a US strategy on global health R&D. The agency's mandate must include robust priorities for global health R&D and the agency must be capable of bringing other agencies together to align priorities.

Convene an annual meeting of agencies conducting global health R&D programs.

Agencies continually recognized the need to gather and share information and best practices. An annual meeting would provide an avenue to encourage innovation among agencies. This should be led by the White House Office of Science and Technology Policy and integrated into the interagency strategy on global health R&D. This meeting will bring together representatives from each agency working on global health R&D to leverage resources for the greatest impact.

Create a clear map of US agencies' involvement in global health R&D.

Agencies identified several gaps in US global health R&D. These gaps could be more clearly identified if there were a publicly available mechanism to show what each agency is doing in the area of global health R&D and where it could expand its work. This is already being done to an

extent through the development of several different mechanisms. The NIH Research Portfolio Online Reporting Tools (RePORTER) is an initiative led by NIH to account for all US health research funded by NIH. There is opportunity and potential to expand this tool to include other agencies. The G-FINDER is a new effort, which may improve tracking systems. The goal of the G-FINDER survey is to help target investments into neglected disease product R&D. This survey will track global investments in order to provide funders more information. The Global R&D Observatory, recently approved by the World Health Organization, is intended to track all global health R&D efforts. Agencies should be encouraged to buy into the RePORTER programs, and the US should be participating in the Global R&D Observatory. These mechanisms could help identify gaps in programs and areas where coordination could occur. This will also promote much needed transparency in global health research programs.

Provide more funding for programs with existing mandates in global health R&D.

Each agency that was interviewed identified a clear mandate to address global health and/or R&D. These agencies also identified funding as a clear barrier to the continuation or expansion of global health R&D programs. Programs are driven by funding and when there is a clear funding mechanism, those programs are made a priority. When agencies are mandated to address issues related to global health R&D those mandates should be tied to adequate funding. In addition, agencies need stable funding streams with less budget insecurity. Gaps will continue to exist among US global health R&D programs unless agencies have adequate stable funding allocations.

Restore funding for agency representatives to participate in scientific meetings/conferences.

Several agencies identified a lack of funding for conferences/scientific meetings as a serious hindrance in agency collaboration. These conferences provide a forum for coordination within different agency programs. Funding should be restored for these types of gatherings that promote transparency, foster innovation, and encourage partnerships.

Areas for Further Analysis

This comprehensive analysis covered a wide range of agencies involved in global health R&D. However, there are still areas where more information could be gathered.

It would be beneficial to interview representatives from PEPFAR, OSTP at the White House, the CDC's Office of Global Health, and USAID's Office of Science and Technology or the Office of Development Alliances. These offices are merging into the US Global Development Lab. PEPFAR has an interesting model for coordination with the Scientific Advisory Board, which serves in an advisory capacity concerning scientific, implementation, and policy issues related to the global response to HIV/AIDS, and which has representatives from each agency. A consultation with PEPFAR may provide insight into more agency coordination. OSTP was highlighted by a few agencies as a convener of other agencies on global health R&D and it would be helpful to get the office's perspective on how to bring agencies together to create an interagency strategy on global health R&D. This analysis did not include a consultation with the CDC's Office of Global Health. The CDC has a significant role in US global health R&D, and it is clear that more information could be gathered on the agency. Although several interviews were conducted with USAID, the US Global Development Lab was not represented. It could be beneficial to have their insight on that particular office's involvement with global health R&D.

Conclusions

This analysis accounted for global health R&D activities within US agencies; delineated the US government role in product development for global health; highlighted areas of collaboration; recognized areas for improvement in US support for and alignment of global health research; and developed policy recommendations to address those issues.

US agencies have made global health R&D a priority and continue to fund programs. However, challenges in the division of labor and the lack of a clear interagency strategy have made it difficult to coordinate US efforts. There are a few examples of formal coordination among agencies, but the majority of coordination happens on an informal level. There are a few successful examples of interagency coordination like the development of MenAfriVac and microbicides. There are gaps in US global health R&D including implementation of research, host country capacity, and scalability. Funding is a significant barrier to the continuation and expansion of current global health R&D programs.

Based on the analysis, there are several policy recommendations to improve US global health R&D programs. An interagency strategy should be developed with a funding allocation and clear divisions of labor. Agencies should meet annually to share best practices and discover new areas for coordination. A clear map of all US agencies' work on global health R&D should be developed, and finally, more funding should be provided for programs with existing mandates in global health R&D.

With the creation of an interagency strategy, gaps in R&D could be filled and programs made more efficient. Interagency coordination will foster innovation, improve global health product development, and speed up new health technologies to those who need them around the world.

APPENDICES

The appendices include the full literature review, the interview template for agency consultations, and a list of references.

Appendix A: Literature Review

Literature Review of US Global Health R&D Programs
February 2014

Prepared by:
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Gilchrist & Company
Advocacy, Policy and Communications

Introduction

This research includes a review of each US agency/program that works on global health research and development (R&D): The Centers for Disease Control and Prevention (CDC), Department of Defense (DoD), Food and Drug Administration (FDA), National Institutes of Health (NIH), National Security Council, Office of Global Affairs at the Department of Health and Human Services (HHS), Office of Management and Budget, White House Office of Science and Technology Policy (OSTP), President' Emergency Plan for AIDS Relief (PEPFAR), President's Malaria Initiative (PMI), State Department, US Agency for International Development (USAID), and other inter-agency initiatives such as the Global Health Initiative, the Presidential Policy Directive on Global Development, the Quadrennial Diplomacy and Development Review (QDDR), and the US Strategy for Meeting the Millennium Development Goals. This information was compiled through a review of publicly available data and agency websites.

The Centers for Disease Control and Prevention

The CDC outlines its strengths and global health priorities in the agency's global health strategy, which identifies R&D as a priority. The offices within CDC that focus on global health R&D are the Center for Emerging Zoonotic and Infectious Diseases and the Center for Global Health. The CDC is also involved in an international effort to eradicate polio through the Global Polio Eradication Initiative (GPEI).

The CDC outlines its strengths and global health priorities in the agency's global health strategy.

One of CDC's strengths in R&D is translating research into public health policy and practice. CDC conducts and supports research to influence public health policy and practice in addressing global health challenges. This research includes evaluating existing interventions and programs as well as developing and assessing new tools, strategies, and interventions that can then be implemented and brought to scale, or used to modify existing programs for greater impact.[58]

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[58]   The Centers for Disease Control and Prevention. *Global Health Strategy, 2012–2015*. http://www.cdc.gov/globalhealth/strategy/pdf/CDC-GlobalHealth-Strategy.pdf

CDC objectives related to global health R&D:

- Prevent new HIV infections and serve the needs of HIV positive individuals globally:

  ◊ The CDC will achieve this objective by conducting research to determine the most efficacious and cost-effective interventions and regimens for HIV prevention, care, and treatment.

- Reduce TB mortality and morbidity:

  ◊ The CDC will achieve this objective by supporting the implementation of evidence-based TB activities through technical guidance, training, and piloting new tools and approaches in designated countries.

- Reduce malaria morbidity and mortality:

  ◊ The CDC will achieve this objective by improving prevention and control of malaria through the development and testing of innovative methods and tools.

- Reduce child morbidity and mortality:

  ◊ The CDC will achieve this objective by conducting research to better define the etiology of disease among infants and children and assess the effectiveness of prevention strategies that might reduce childhood morbidity and mortality.

- Control, eliminate, or eradicate vaccine-preventable diseases:

  ◊ The CDC will achieve this objective by increasing the appropriate development, introduction, and use of new and underused vaccines, such as pneumococcal and rotavirus vaccines, to prevent diseases of global and regional public health importance.[59]

CDC's strategic priorities to improve research capacity:

- Identify new and strengthen existing public health interventions and validate the effectiveness of interventions and tools.

- Assist countries to develop expertise and capacity to conduct research (operational, applied, and laboratory) activities.

- Develop and disseminate guidelines to translate research into national initiatives for implementation to improve health activities.

- Develop, evaluate, and deploy innovative technologies to support epidemiologic and laboratory public health programs and global health security initiatives, with a particular focus on field and low-resource settings.

- Collaborate with host countries and US government partners to strengthen the capacity of local institutional review boards.[60]

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59   The Centers for Disease Control and Prevention. *Global Health Strategy 2012–2015.* http://www.cdc.gov/globalhealth/strategy/pdf/CDC-GlobalHealth-Strategy.pdf

60   The Centers for Disease Control and Prevention. *Global Health Strategy 2012–2015.* http://www.cdc.gov/globalhealth/strategy/pdf/CDC-GlobalHealth-Strategy.pdf

The Center for Global Health

The CDC's Center for Global Health coordinates and manages the agency's resources and expertise to address global challenges such as HIV/AIDS, malaria, emergency and refugee health, non-communicable diseases, injuries, and more.[61]

Center for Emerging Zoonotic and Infectious Diseases

The goal of this division of CDC is to prevent infections, protect people, and save lives; and its mission is to reduce illness and death associated with emerging and zoonotic infectious diseases and to protect against the unintentional or intentional spread of infectious diseases.[62]

The strategic plan for 2012–2017 is divided into four overall objectives. The following are the two objectives related to global health R&D:

1. Strengthen fundamentals—to ensure a solid foundation of laboratory, surveillance, and epidemiologic investigation necessary for public health action to continue by improving the center's core laboratory capacity and accelerate development and application of novel diagnostic methods.[63]

2. Implement interventions—the strategic direction for addressing the first part of the center's mission is "to reduce illness and death" associated with infectious diseases by using established and innovative methods and tools to better prevent and control zoonotic and vector-borne diseases domestically and globally.[64]

The CDC is involved in an international effort to eradicate polio through the GPEI.

The GPEI's spearheading partners (World Health Organization, Rotary International, CDC, and UNICEF) and the Bill & Melinda Gates Foundation are responsible for providing overall technical direction and strategic planning for the management and coordination of the GPEI, including the development of strategic plans for the GPEI and the delivery of accompanying budgets.[65]

GPEI's Research and Policy Development

An intensified research agenda has underpinned many of the approaches outlined in the plan and will be critical in its implementation. The core elements of the research work are designed to accelerate eradication of the remaining wild poliovirus transmission and to ensure the necessary strategies and products are in place to manage the long-term poliovirus risks associated with the polio endgame.[66]

The Department of Defense

The Department of Defense has several offices that are focused on global health R&D: the Defense Advanced Research Projects Agency, Army Medical Research and Materiel Command, Army Medical Research Institute of Infectious Diseases, Walter Reed Army Institute for Research, Military HIV Research Program, Military Malaria Research Program, Military Infectious Disease Program, and Navy Medical Research Centers.

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61   Centers for Disease Control and Prevention. Global Health. http://www.cdc.gov/globalhealth/index.html

62   National Center for Emerging Zoonotic and Infectious Diseases. *Strategic Plan 2012–2017*. (Page 1) http://www.cdc.gov/ncezid/pdf/strategicplan_NCE-ZID.pdf

63   National Center for Emerging Zoonotic and Infectious Diseases. *Strategic Plan 2012–2017*. (Page 3) http://www.cdc.gov/ncezid/pdf/strategicplan_NCE-ZID.pdf

64   National Center for Emerging Zoonotic and Infectious Diseases. *Strategic Plan 2012–2017*. (Page 3) http://www.cdc.gov/ncezid/pdf/strategicplan_NCE-ZID.pdf

65   Global Polio Eradication Initiative. *Polio Eradication and Endgame 2013–2018*. (Page 89) http://www.polioeradication.org/Portals/0/Document/Resources/StrategyWork/PEESP_EN_US.pdf

66   Global Polio Eradication Initiative. *Polio Eradication and Endgame 2013–2018*. (Page 95) http://www.polioeradication.org/Portals/0/Document/Resources/StrategyWork/PEESP_EN_US.pdf

Defense Advanced Research Projects Agency

The Defense Advanced Research Projects Agency's mission is to prevent technological surprise for the United States and to create technological surprise for its adversaries. Stealth is one example of how the agency created technological surprise.[67] Although this office is involved in R&D there is no clear global health priority.

The agency's Defense Sciences Office programs bridge the gap from fundamental science to applications by identifying and pursuing the most promising ideas within the science and engineering research communities and transforming these ideas into new defense capabilities.[68]

Army Medical Research and Materiel Command

The US Army Medical Research and Materiel Command's mission is to provide medical knowledge and materiel life-cycle management to protect, treat, and optimize warfighter health and performance across the full spectrum of operations. It provides R&D in a variety of areas, including chemical and biological defense. Medical chemical and biological research supports the mission of the Chemical and Biological Defense Program to provide chemical and biological defense capabilities in support of national military strategies.[69]

Army Medical Research Institute of Infectious Diseases

The mission of the Army Medical Research Institute of Infectious Diseases is to protect the warfighter from biological threats and to be prepared to investigate disease outbreaks or threats to public health. The office's core competencies include:

- Conducting research on biological agents
- Maintaining safety, security, and surety standards
- Testing and evaluation of medical countermeasures
- Rapid identification of biological agents
- Training and educating the force[70]

Walter Reed Army Institute for Research

The Walter Reed Army Institute for Research's mission is to conduct biomedical research that is responsive to DoD and US Army requirements and delivers life-saving products including knowledge, technology, and medical material that sustain the combat effectiveness of the warfighter.

Since its inception, the challenge has been disease prevention based on evaluation, control, and treatment of naturally occurring infectious diseases.

The Center for Infectious Disease Research is comprised of the following research branches:

- Bacterial Diseases
- Entomology
- Military HIV Research Program
- Military Malaria Research Program
- Preventive Medicine Viral Diseases[71]

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67   Defense Advanced Research Projects Agency. *Strategic Plan*. 2009. (Page 1) http://www.carlisle.army.mil/DIME/documents/StratPlan091.pdf

68   Defense Advanced Research Projects Agency, Defense Sciences Program. Focus Areas. http://www.darpa.mil/Our_Work/DSO/Focus_Areas/Biology.aspx

69   US Military HIV Research Program. *Strategic Plan*. 2010. http://www.hivresearch.org/media/pnc/2/media.392.pdf

70   Army Medical Research Institute of Infectious Diseases. Mission. http://www.usamriid.army.mil/aboutpage.cfm

71   Walter Reed Army Institute for Research. Mission. http://wrair-www.army.mil/AboutWRAIR.aspx

Military HIV Research Program

The Military HIV Research Program's mission is achieved through the careful coordination of established services, platforms, and activities; its exceptional breadth reflects four crosscutting domains of activity:

1. Research activities encompass basic, preclinical, and all stages of clinical research, with a primary focus on HIV vaccine development (e.g. host/viral genetic diversity, analysis of innate and adaptive immune responses, pathogenesis, and vaccine candidate and adjuvant development). These activities also encompass a focus on understanding the epidemic in human populations through HIV prevention, diagnostics, and treatment research.

2. Research platforms and services include critical processes, infrastructure, and support activities that underpin productive vaccine research and development, such as regulatory compliance, specimen management and distribution, biostatistical analysis of trial data, data warehousing, and IT capacity and resources.

3. Clinical and public health services span programs, such as PEPFAR and force health protection, focused on the prevention, diagnosis, treatment, and monitoring of HIV and related infections in human populations.

4. Capacity-building focuses on expanding capabilities and resources at international sites, and enriching the potential for innovation through the recruitment and training of basic and clinical scientists and critical support staff.[72]

Research priorities:

1. Maintain the capacity to conduct HIV vaccine evaluation in human trials in Africa and Asia.

2. Seek opportunities to integrate HIV therapeutics research with studies of the management of HIV co-infections inclusive of, but not limited to, malaria, tuberculosis (TB), and typical HIV-related opportunistic infections.

3. Commit itself to the development of the highest impact translational and discovery science programs to support its vaccine development efforts.[73]

Military Malaria Research Program

The Military Malaria Research Program's mission is to discover and develop new products to eliminate mortality and reduce morbidity in military personnel and in vulnerable populations for the benefit of global public health.

Research priorities:

- Malaria drugs near FDA approval and investment in malaria prevention
- Evaluating new tools for malaria diagnostics
- Surveillance with new technologies that aim to help achieve Millennium Development Goals[74]

72   US Military HIV Research Program. *Strategic Plan*. 2010. (Page 5). http://www.hivresearch.org/media/pnc/2/media.392.pdf

73   US Military HIV Research Program. *Strategic Plan*. 2010. (Page 11). http://www.hivresearch.org/media/pnc/2/media.392.pdf

74   Military Malaria Research Program. Mission. http://wrair-www.army.mil/ReAndDevelop_InfectDisRe_MalariaResearch.aspx

Military Infectious Disease Program

The mission of the Military Infectious Diseases Research Program (MIDRP) is to protect the US military against naturally occurring infectious diseases via the development of the FDA-approved vaccines, drugs, and diagnostic assays and Environmental Protection Agency (EPA)-approved vector control protection systems (to prevent transmission of infections by insects, ticks, etc.) It is also important to note that NIAID is a major partner of MIDRP and through HIV vaccine development activities.[75]

Current projects:

Diarrhea Prevention

Diarrhea afflicts up to 50% of troops deployed to high-risk areas. Currently, no guaranteed protective measures exist, and the global problem of antimicrobial resistance may limit treatment options. Candidate vaccines for three major causes of diarrhea (E. coli, Campylobacter and Shigella) are being developed and evaluated by the MIDRP.

Rickettsial Disease

Scrub typhus is caused by a bite from an infected mite or chigger and can cause severe fever with a long convalescence or death. The disease is prevalent in Asia, Australia, and many Pacific Islands. Outbreaks occurred in US marines training at Camp Fuji Japan in 2000 and then again in 2001.

Wound Infection Research

MIDRP's Wound Infection Program is primarily focused on development of preventive and treatment measures to control wound infections and sepsis and nosocomial transmission of bacteria following blast wound injuries and burns.

Malaria Drugs and Vaccines

Malaria has historically caused more casualties than enemy fire in deployments to tropical regions. Impact on soldiers ranges from loss of 14 man-days to death and can affect more than 80% of an unprotected force. The MIDRP is developing new vaccines and drugs to prevent infection and accelerate recovery from severe and multidrug-resistant malaria infections.

Leishmaniasis

Hundreds of military personnel stationed in Iraq have been diagnosed with cutaneous leishmaniasis, a disease transmitted to humans through the bite of infected sandflies. The most common forms are cutaneous leishmaniasis, which causes skin lesions, and visceral leishmaniasis, which affects the internal organs of the body. The MIDRP is developing diagnostic and treatment devices as well as personal protective measures.

HIV Prevention

Military personnel can become infected with HIV via blood transfusions, accidental blood exposure while providing humanitarian assistance, or sexual exposure. HIV impacts troop strength of US and allied forces, and the political and economic stability of developing nations. Research focuses on the development of a global HIV-1 vaccine. Field sites have been established in Africa and Southeast Asia. Management is shared by the MIDRP and the National Institutes of Health.

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75 Military Infectious Diseases Research Program. Historical Achievements. https://midrp.amedd.army.mil/info/HAchieve.jsp

Flavivirus Vaccines

Dengue fever is a painful disease caused by a flavivirus transmitted by a bite from an infected mosquito. Dengue is a leading cause of hospital admission in units operating in the tropics. There is currently no vaccine or drug to prevent the disease. The MIDRP manages a program for pathogenesis studies, diagnostics, and vaccine development to protect against the four types of dengue virus.

Lethal Viruses Countermeasures

Hemorrhagic fever with renal syndrome (HFRS) and other Hantavirus diseases are transmitted by contact with rodents. Endemic throughout Asia and Europe, HFRS requires evacuation and long-term extensive care, and has caused thousands of occurrences of troop morbidity and mortality. The MIDRP is pursuing DNA vaccines to prevent HFRS and other lethal viruses.

Vector Control

Seventy percent of soldiers experience problems related to biting insects. The current military repellent is a greasy compound that dissolves plastic, is removed by abrasion or wetting, and is not popular with soldiers. The MIDRP is developing a new standard military insect repellent that is effective and acceptable to the user. Other efforts focus on the identification and control of the insect vectors of dengue and malaria and a sandfly vector control system.

Diagnostic

There is an urgent demand for field-worthy methods to rapidly diagnose infectious diseases. Timely and accurate diagnosis will permit appropriate medical treatments and other protective measures.[76]

Navy Medical Research Centers

The Infectious Diseases Directorate consists of four research departments: Malaria, Enteric Diseases, Viral and Rickettsial Diseases, and Wound Infections. Within these departments, over 100 scientists and technicians conduct research with an annual budget exceeding $10 million per year.[77]

The primary objective of the Navy Malaria Program is to develop a vaccine that kills the parasite during its first few days of development in the liver, before it breaks out into the blood. If this approach is successful, it will prevent the clinical manifestation of malaria, which occurs only in conjunction with blood stage infection and not with the liver stage.[78]

The Navy Medical Research Centers has developed a strategic plan with the following goals:

- Deployment readiness
- Agile forces
- Effective force health protection
- People
- Quality of care
- Patient and family-centered care
- Performance-based budget
- Research and development

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76 Military Infection Disease Research Program. Current Projects. https://midrp.amedd.army.mil/info/PGAreas.jsp

77 Naval Medical Research Center. Overview. http://www.med.navy.mil/sites/nmrc/Pages/id_main.htm

78 Navy Medical Research Center. Malaria Research Department. http://www.med.navy.mil/sites/nmrc/Pages/id_m.htm

It will conduct relevant research, development, testing, evaluation, and clinical investigations, which protect and improve the health of those in our care. The agency will achieve this by:

1. Producing required research products that preserve, protect, treat, rehabilitate, or enhance the performance of Navy and Marine Corps personnel and health care services.

2. Engaging in partnerships to enhance efficiencies and raise Navy Medicine visibility in the research and academic communities.

3. Achieving and maintaining a national and international reputation as a high-quality, high-performance biomedical research enterprise.[79]

The Food and Drug Administration

The FDA works on neglected disease product review and regulation through several offices including the Center for Biologic Evaluation and Review, the Office of International Programs, the Center for Drug Evaluation and Research, and the Center for Devices, and Radiological Health. The FDA also works on global health R&D through the *Critical Path Initiative* to close the gap between early-stage biomedical research and product development.[80]

Center for Biologic Evaluation and Review

The center's mission is to protect and enhance the public health through the regulation of biological and related products including blood, vaccines, allergenics, tissues, and cellular and gene therapies. Its international activities can be categorized in the following functional areas: regulatory harmonization, regulatory capacity-building, information-sharing, international standards setting, and collaborative research.[81]

The Center for Biologic Evaluation and Review has six strategic goals related to R&D:

1. Increase the nation's preparedness to address threats as a result of terrorism, pandemic influenza, and emerging infectious diseases

2. Improve global public health through international collaboration including research and information-sharing

3. Enhance the ability of advances in science and technology to facilitate development of safe and effective biological products

4. Ensure the safety of biological products

5. Advance regulatory science and research

6. Manage for organizational excellence and accountability[82]

The Center for Biologic Evaluation and Review's vision for regulatory science and research will be proactive, anticipating regulatory and public health issues while being responsive to emerging public health and regulatory issues. Therefore, our research will be collaborative, of highest quality and relevance, and integral to the center's regulatory mission and public health portfolio. The research program will provide the center with appropriate scientific expertise, tools, and data to support science-based decision-making and policy development.[83]

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79 *Navy Medicine Strategic Plan*. (Page 27) http://www.med.navy.mil/bumed/Documents/SP%20Draft%20120ver2a.pdf

80 The Critical Path Institute. http://c-path.org/about/

81 The Food and Drug Administration. About CBER. http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm123340.htm

82 Center for Biologics Evaluation and Review. *Strategic Plan for Regulatory Science and Research, 2012–2016*. http://www.fda.gov/downloads/Biologics-BloodVaccines/ScienceResearch/UCM303542.pdf

83 Center for Biologics Evaluation and Review. *Strategic Plan for Regulatory Science and Research, 2012–2016*. (Page 8) http://www.fda.gov/downloads/BiologicsBloodVaccines/ScienceResearch/UCM303542.pdf

The Office of International Programs

To improve its international engagement efforts at the FDA, the agency established the Office of International Programs to coordinate and oversee the many individual efforts that were initiated over time. These efforts aimed to better ensure the safety of products bought and used in the United States, but they also offer a unique opportunity for the FDA to engage in important global health initiatives.[84]

The Office of International Programs' mission is to lead, manage, and coordinate all of FDA's international activities, with the following goals:

- Effect an affirmative public health agenda in the international area.
- Enhance and maximize FDA›s communications and interactions globally, to assure they reflect the agency›s policies and best scientific, legal, and policy thinking.
- Assure that FDA international communications and interaction are consistent with the HHS public health objectives.
- Leverage resources with counterpart agencies to meet our public health missions.[85]

The FDA has guidance specifically for R&D related to rare and neglected diseases. Its objectives are to:

1. Increase biomedical and regulatory scientific development for rare diseases.
2. Increase collaboration of rare disease stakeholders both within and outside FDA.
3. Conduct a thorough review of the development and regulatory history of orphan drug products to help identify effective development approaches.[86]

The Critical Path Initiative

The FDA also plays a vital role in global health issues by ensuring the safety and effectiveness of health products that prevent, diagnose, and treat diseases that affect millions of people worldwide. Recognizing a decline in the number of new innovative medical products submitted for approval, the FDA established the Critical Path Initiative in 2004 to close the gap between early-stage biomedical research and product development. The Critical Path Initiative is now the Critical Path Institute, a nonprofit, public-private partnership.[87]

From 2013 to 2014 a report by the Institute of Medicine was conducted, which found several challenges that the FDA faces in promoting a regulatory structure:

- Adherence to international standards
- Controlling food supply chains
- Regulatory infrastructure and support
- Sufficient laws

84 Global Health Technologies Coalition, *Improving Health at Home and Abroad: How the US Food and Drug Administration can maximize its Global Impacts*, September 2013. http://ghtcoalition.org/files/September2013FDApolicybrief_final.pdf

85 FDA. Office of International Programs. http://www.fda.gov/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/OfficeofInternationalPrograms/ucm236579.htm

86 FDA. *Report to Congress: Improving the Prevention, Diagnosis and Treatment of Rare and Neglected Diseases*. (Page 6) http://www.fda.gov/downloads/ScienceResearch/SpecialTopics/CriticalPathInitiative/UCM265525.pdf

87 The Critical Path Institute. http://c-path.org/about/

- Trained workforce
- Fragmentation of their regulatory infrastructure
- Disease and product surveillance
- Interagency communication
- Political will[88]

The National Institutes of Health

NIH has several offices that focus on global health R&D: National Institute of Allergy and Infectious Diseases (NIAID), Office of AIDS Research, National Institute of Child Health and Human Development (NICHD), National Center for Advancing Translational Sciences, Office of Disease Prevention, Fogarty International Center, and Office of Technology Transfer.

National Institute of Allergy and Infectious Diseases

The mission of NIAID is to conduct and support basic and applied research to better understand, treat, and ultimately prevent infectious, immunologic, and allergic diseases.[89]

The strategic management of such a complex research mission has two core components: 1) maintaining a breadth and depth of knowledge in all areas of infectious and immune-related diseases, and 2) developing flexible domestic and international capacity to efficiently undertake research required in response to newly emerging threats wherever they occur.[90]

Priority areas:

- Infectious diseases (non-AIDS) including emerging and re-emerging diseases and biodefense:
    ◊ Continue to build a solid base of diverse research expertise to quickly address the emergence and re-emergence of new and existing infectious diseases around the globe.
    ◊ Support the participation of international investigators in the conduct of infectious diseases research in order to enhance our understanding of these diseases in their natural environments.
    ◊ Continue to support existing partnerships and develop new collaborations with institutions and organizations involved in global research. Partnerships and collaborations enable NIAID to leverage its resources for international research.
- HIV/AIDS:
    ◊ Establish, enhance, and build on the in-country research capacity of low- and middle- income countries. The aim is for these nations to develop sustainable research programs focused on developing biomedical strategies to prevent transmission of HIV and to treat HIV disease and its associated co-infections and co-morbidities.
    ◊ Assist in developing vaccines, other prevention strategies, and therapeutic interventions that reflect local population/regional determinants, processes, and cultural and contextual issues and that will be widely affordable, accessible, and practical in those settings.
- Allergy, immunology, and immune- mediated diseases[91]

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88 Institute of Medicine. *The Science Board Subcommittee Report on Ensuring Safe Foods and Medical Products through Stronger Regulatory Systems Abroad.*

89 National Institutes of Health (NIH). The National Institute of Allergy and Infectious Diseases (NIAID). http://www.niaid.nih.gov/about/whoweare/Pages/default.aspx

90 National Institutes of Health (NIH). The National Institute of Allergy and Infectious Diseases (NIAID). http://www.niaid.nih.gov/about/whoweare/Pages/default.aspx

91 National Institute for Allergy and Infectious Diseases. *Strategic Plan.* 2013. (Page 2) http://www.niaid.nih.gov/about/whoWeAre/planningPriorities/Documents/NIAIDStrategicPlan2013.pdf

NIAID Malaria Research

The guiding principles of the NIAID *Strategic Plan for Malaria Research: Efforts to Accelerate Control and Eradication of Malaria Through Biomedical Research* are:

- To define and implement a structured set of R&D activities that will support and sustain momentum toward global malaria control and eventually eradication.
- To develop, expand, and support the human, intellectual, and social capital and networks, both nationally and internationally, that in turn can support and sustain the long-term commitment for efficient and effective R&D activities to achieve global elimination and eradication of malaria.

NIAID commits to the pursuit of the following goals:

1. Increase fundamental understanding of the complex interactions among malaria parasites, the mosquito vectors responsible for their transmission, and the human host.
2. Strengthen the ability to identify, develop, validate, and evaluate new tools and strategies for treatment, prevention, and control of malaria.
3. Enhance both national and international research and research training infrastructure to meet malaria research needs, particularly for community-based and -supported clinical trials in malaria- endemic countries.
4. Advance research to develop tools to support and sustain global efforts to control, eliminate, and eventually eradicate malaria.[92]

NIAID TB Research

NIAID's role in research for TB:

- Improve health
- Translate knowledge into tools and products
- Develop foundation of knowledge through biomedical research[93]

Improvements in TB control and patient care:

- Develop point-of-care diagnostics
- Transform the field of therapeutics
- Develop a safe and effective vaccine[94]

Office of AIDS Research

The Office of AIDS Research coordinates the scientific, budgetary, legislative, and policy elements of the NIH AIDS research program. Through its annual comprehensive trans-NIH planning, budgeting, and portfolio assessment processes, the Office of AIDS Research sets scientific priorities, enhances collaboration, and ensures that research dollars are invested in the highest priority areas of scientific opportunity that will lead to new tools in the global fight against AIDS.[95]

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92 National Institute for Allergy and Infectious Diseases. *Strategic Plan for Malaria Research*. 2008. (Page 4) http://www.niaid.nih.gov/topics/malaria/documents/strategicplan.pdf

93 National Institute for Allergy and Infectious Diseases. *TB Research Program: Priorities, Funding and Collaborations in Global TB Research*. (Page 2) http://www.bc.lung.ca/association_and_services/documents/Sizemore.pdf

94 National Institute for Allergy and Infectious Diseases. *TB Research Program: Priorities, Funding and Collaborations in Global TB Research*. (Page 5) http://www.bc.lung.ca/association_and_services/documents/Sizemore.pdf

95 National Institutes of Health (NIH). Office of AIDS Research. http://www.oar.nih.gov/about/mission.asp

Office of AIDS Research priorities:

- Plan, coordinate, and evaluate the large, complex, and multifaceted NIH AIDS research portfolio, which encompasses research projects supported by nearly every NIH IC. The major scientific areas of emphasis in the NIH AIDS research portfolio are: Natural History and Epidemiology; Etiology and Pathogenesis; Therapeutics; Vaccines; Behavioral and Social Science; Microbicides; Racial and Ethnic Minorities; Women and Girls; and Research in International Settings. Cross-cutting areas include Training, Capacity-building, and Infrastructure; and Information Dissemination.

- Develop an annual trans-NIH strategic plan for all HIV/AIDS research activities that guides the development of the AIDS research budget.

- Formulate the annual trans-NIH AIDS research budget. Review and approve IC initiatives to ensure that funds are provided for projects and initiatives with the highest scientific priority, eliminating duplication, and assuring cross-Institute collaboration.

- Develop an annual Presidential By-Pass budget for AIDS research based solely on scientific opportunity.

- Identify emerging scientific opportunities and public health challenges that require focused attention; manage and facilitate multi-Institute and trans-Institute activities to address those needs; foster research by designating funds and supplements to jump-start or pilot program areas; sponsor reviews or evaluations of research program areas; and convene scientific workshops.

- Ensure that the NIH AIDS research portfolio is aligned with the highest priority AIDS research objectives, as articulated in the Plan, by conducting annual portfolio analyses.

- Convene the Office of AIDS Research Advisory Council, and its associated working groups, including those that develop federal guidelines for treatment and prevention of HIV and its associated co-infections in adults, adolescents and children.

- Facilitate international AIDS research and training.[96]

NICHD Office of Global Health

The OGH facilitates international research and coordinates the HIV/AIDS portfolio at the NICHD. OGH seeks to improve overall health worldwide by providing leadership, coordination and support for NICHD's global heath mission and activities.[97]

Some of the global R&D activities that the OGH coordinates and directs include the following:

- Facilitating new and enhanced research opportunities and fostering partnerships to support NICHD's global health research initiatives

- Providing consultation and assistance to NICHD staff in planning for and addressing issues related to international research and training projects

- Serving on the NIH International Representatives' Committee

- Advocating for the role of evidence-based research in the design and implementation of global health programs[98]

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96 National Institutes of Health (NIH). Office of AIDS Research. http://www.oar.nih.gov/about/mission.asp

97 National Institutes of Health (NIH). National Institutes of Child Health and Development, Office of Global Health. http://www.nichd.nih.gov/about/org/od/ogh/Pages/index.aspx

98 National Institutes of Health (NIH). National Institutes of Child Health and Development, Office of Global Health. http://www.nichd.nih.gov/about/org/od/ogh/Pages/index.aspx

National Center for Advancing Translational Sciences

The National Center for Advancing Translational Sciences is the newest of 27 institutes and centers (ICs) at NIH. This center was established in December 2011 to transform the translational science process so that new treatments and cures for disease can be delivered to patients faster.[99]

The Therapeutics for Rare and Neglected Diseases (TRND) program in the center's Division of Pre-Clinical Innovation aims to encourage and speed the development of new drugs for rare and neglected diseases. TRND stimulates drug discovery and development research collaborations among NIH and academic scientists, nonprofit organizations, and pharmaceutical and biotechnology companies working on rare and neglected illnesses.[100]

TRND is an opportunity to collaborate; hence, it is not a grant mechanism. A collaboration agreement (e.g., NIH Collaborative Research and Development Agreement, Memorandum of Understanding) will be established between TRND and successful applicants, NIH intramural funds will be used to support the costs of the project.[101]

Office of Disease and Prevention

The mission of the ODP is to improve the public health by increasing the scope, quality, dissemination and impact of prevention research supported by the NIH. The ODP will fulfill this mission by providing leadership for the development, coordination and implementation of prevention research in collaboration with NIH Institutes and Centers and other partners.[102] Although this office focuses on disease and prevention research there is no clear global health priority on its website.[103]

Fogarty International Center

Framework Programs for Global Health Innovation (FRAME Innovation) will provide support to institutions in the United States and in low- and middle-income countries to build capacity within their institutions to develop broadly interdisciplinary, postdoctoral (or post-terminal degree) research training programs in global health directed toward encouraging innovation in health-related products, processes and policies. The program emphasizes hands-on, problem-solving, and collaborative approaches and allows US and low- and middle-income country trainees to be trained together.[104]

Office of Technology Transfer

The mission of OTT is to improve public health through the management of NIH and FDA inventions and in doing so serve a leading role in public sector biomedical technology transfer policy and practice.

OTT serves as a bridge that connects the inventive discoveries made in the NIH and FDA intramural research programs to commercial partners that develop these technologies into products and services to benefit public health. Without this bridge, the public would not benefit from the full potential of these biomedical discoveries. In carrying out its mission and purpose, OTT applies its policies and practices to the management of NIH's and FDA's inventions, including: the

99 National Institutes of Health (NIH). National Center for Advancing Translational Science. http://www.ncats.nih.gov/about/about.html

100 National Institutes of Health (NIH). National Center for Advancing Translational Science. http://www.ncats.nih.gov/about/about.html

101 National Institutes of Health (NIH). National Center for Advancing Translational Science. http://www.ncats.nih.gov/about/about.html

102 National Institutes of Health (NIH). Office of Disease Prevention. http://prevention.nih.gov/aboutus/strategic_plan/mission.aspx

103 National Institutes of Health (NIH). Office of Disease Prevention. http://prevention.nih.gov/aboutus/strategic_plan/mission.aspx

104 National Institutes of Health (NIH). The Fogarty International Center. The Framework Programs for Global Health. http://www.fic.nih.gov/programs/pages/framework-innovations.aspx

appropriate use of the patent system; marketing NIH and FDA technologies to identify appropriate commercial partners; negotiating licenses to ensure the timely development of technologies; and monitoring the progress of the development of the technology to ensure commercialization milestones are reached and royalties are paid.[105]

The National Security Council

The National Security Council has a framework for national health security that is designed to achieve two goals: build community resilience and strengthen and sustain health emergency response systems.[106]

Strategic objectives:

1. Foster informed, empowered individuals and communities

2. Develop and maintain the workforce needed for national health security

3. Ensure situational awareness

4. Foster integrated, scalable health care delivery systems

5. Ensure timely and effective communications

6. Promote an effective countermeasures enterprise

7. Ensure prevention or mitigation of environmental and other emerging threats to health

8. Incorporate post-incident health recovery into planning and response

9. Work with cross-border and global partners to enhance national, continental, and global health security

10. Ensure that all systems that support national health security are based upon the best available science, evaluation, and quality improvement methods.[107]

In order to achieve national health security, the United States must have a plan for disease mitigation and containment. The framework identifies the following priority to ensure disease mitigation and containment:

Research, development, and procurement of medical countermeasures - Set research, development, and procurement priorities for medical countermeasures; develop and test medical countermeasures; submit marketing applications for medical countermeasures to the FDA for review and approval; create and maintain a stockpile of medical countermeasures.[108]

The Office of Global Affairs at the Department of Health and Human Services

HHS has a global health strategy that outlines the agency's priorities. HHS' approach to global health includes:

• Implementation and evaluation of research, policies, programs, and practices that improve health, health services, and health equity

• Emphasis on transnational health issues, determinants, and solutions

• Promotion of interdisciplinary collaboration within and beyond the health sciences[109]

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105 National Institutes of Health (NIH). Office of Technology Transfer. *FY 2011 Annual Report.* http://www.ott.nih.gov/sites/default/files/documents/pdfs/AR2011.pdf

106 US Department of Health and Human Services. *National Health Security Strategy*. 2009. http://www.phe.gov/preparedness/planning/authority/nhss/strategy/documents/nhss-final.pdf

107 Department of Health and Human Services. *National Health Security Strategy*. 2009. http://www.phe.gov/preparedness/planning/authority/nhss/strategy/documents/nhss-final.pdf

108 Department of Health and Human Services. *National Health Security Strategy*. 2009. http://www.phe.gov/preparedness/planning/authority/nhss/strategy/documents/nhss-final.pdf

109 Department of Health and Human Services. *Global Health Strategy*. 2011. http://www.globalhealth.gov/pdfs/Global%20Health%20Strategy.pdf

One of the agency's main objectives is to catalyze biomedical and public health research and innovation globally to promote the discovery, development, delivery, and evaluation of new interventions that improve health and wellbeing across national borders.

Key priorities:

- Address research priorities that are linked to scientific opportunity, public health needs, and the evolving burden of disease
- Support the rapid translation of research results into new or improved preventive, diagnostic, and treatment products and processes, and incorporation into health policies and practice, in diverse global settings, including resource-poor environments
- Encourage research that identifies causative pathways of the spread of infectious disease and other health threats[110]

The National Vaccine Program in Global Immunizations

The National Vaccine Program is led by HHS and implemented through several agencies. In 2013, HHS did a review of the agency's National Vaccine Program. The review resulted in several key findings:

1. Tackling time-limited opportunities to complete polio eradication and to advance measles mortality reduction and regional measles/rubella elimination goals
2. Strengthening global immunization systems
3. Enhancing Global Capacity for Vaccine Safety Monitoring and Post- Marketing Surveillance
4. Building global immunization R&D capacity
5. Strengthening capacity for vaccine decision-making
6. Coordination of HHS Global Immunization Efforts[111]

The Office of Management and Budget

The Office of Management and Budget has specific priorities for science and technology. However, there isn't a clear global health component. The following are the science and technology priorities for its 2015 Budget:

R&D for informed policy-making and management

Agencies, especially those with primary missions other than R&D, should give priority to R&D that strengthens the scientific basis for decision-making in their mission areas, including but not limited to health, safety, and environmental impacts. This includes efforts to enhance the accessibility and usefulness of data and tools for decision support, as well as research in the social and behavioral sciences to support evidence-based policy and effective policy implementation.

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110 Department of Health and Human Services. *Global Health Strategy*. 2011. (Page 34) http://www.globalhealth.gov/pdfs/Global%20Health%20Strategy. pdf

111 National Vaccine Program. *Global Immunizations Presentation on Enhancing the Work of the NVP*. http://www.hhs.gov/nvpo/nvac/meetings/pastmeetings/2013/enchancing_global_immunization_sept2013.pdf

R&D for National-Security Missions

National and Homeland Security and Intelligence mission agencies should invest in science and technology to meet the threats of the future and develop innovative new security capabilities. In order to provide cutting-edge capabilities to meet current and future mission requirements, national security agencies need to support a balanced portfolio of basic and applied research and advanced technology development.

Innovation in Biology and Neuroscience

Agencies should give priority to R&D investments that have the potential to foster biological innovations in health, national security, energy, and agriculture.[112]

The White House Office of Science and Technology Policy

The White House focuses on technology and innovation through the Office of Science and Technology Policy (OSTP). The White House also has several strategies that guide R&D, including the *US Strategy for American Innovation, Harnessing Innovation for Global Development*, and *The America Competes Act*.

The mission of OSTP is threefold; first, to provide the president and his senior staff with accurate, relevant, and timely scientific and technical advice on all matters of consequence; second, to ensure that the policies of the Executive Branch are informed by sound science; and third, to ensure that the scientific and technical work of the Executive Branch is properly coordinated so as to provide the greatest benefit to society.[113]

Strategic goals and objectives:

- Ensure that Federal investments in science and technology are making the greatest possible contribution to economic prosperity, public health, environmental quality, and national security

- Energize and nurture the processes by which government programs in science and technology are resourced, evaluated, and coordinated

- Sustain the core professional and scientific relationships with government officials, academics, and industry representatives that are required to understand the depth and breadth of the Nation's scientific and technical enterprise, evaluate scientific advances, and identify potential policy proposals

- Generate a core workforce of world-class expertise capable of providing policy-relevant advice, analysis, and judgment for the president and his senior staff regarding the scientific and technical aspects of the major policies, plans, and programs of the Federal government[114]

In 2009, OSTP, the National Economic Council, and the Council of Economic Advisers put together the *US Strategy for American Innovation*.

The following are the priorities for innovation:

- Strengthen and broaden American leadership in fundamental research - America's universities, federal labs, and industrial laboratories must continue to do the research that will lead to breakthrough products and new companies.

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112 *Science and Technology Priorities for the FY 2015 Budget.* http://www.dtic.mil/dtic/pdf/st_priorities.pdf

113 The White House Office of Science and Technology Policy. http://www.whitehouse.gov/administration/eop/ostp/about

114 The White House Office of Science and Technology Policy. http://www.whitehouse.gov/administration/eop/ostp/about

- Enact the largest R&D increase in our nation's history - With $18 3 billion in research funding, the Recovery Act was part of the largest annual increase in research and development in America's history The President's FY 2012 Budget provides additional support for science and basic research, delivering on the president's commitment to double funding for three key basic research agencies—the National Science Foundation, the Department of Energy's Office of Science, and the National Institute of Standards and Technology laboratories.

- Set national goal to invest three percent of GDP in R&D - The President has set a goal for America to invest more than three percent of our GDP in public and private research and development.

- Support research for next-generation information and communications technology - The Obama Administration is dedicated to keeping the US on the cutting edge of IT developments. In addition to the Administration's support for wireless innovation, the Networking and Information Technology Research and Development (NITRD) Program funds research in areas such as high-speed networks, next-generation supercomputers, cyber-physical systems, software engineering, and information management.

- Enable innovation in medical technologies and medical care - The FDA is working to accelerate the development of medical device technologies. In June 2009, the FDA launched a "Transparency Initiative" which will improve the market's understanding of the approval process and encourage innovation.[115]

In 2012, the White House released a fact sheet on *Harnessing Innovation for Global Development*. This fact sheet includes the following priorities:

- Engaging University Students and Faculty
- Making the greatest use of scientific breakthroughs
- Leveraging technology to accelerate research and scale innovations[116]

The America Competes Act

The America Competes Act is monitored by the OSTP and is a good example of agency coordination around advancing innovation.

This law provides agencies with authority to conduct prize competitions in order to spur innovation, solve tough problems, and advance their core mission, as called for in the president's Strategy for American Innovation and the 2010 Office of Management and Budget *Guidance on the Use of Challenges and Prizes to Promote Open Government* (OMB Memorandum M-10-11 of March 8, 2010).

- Permits any agency head to "carry out a program to award prizes competitively to stimulate innovation that has the potential to advance the mission of the respective."

- Authorizes agencies to use both Federal appropriated funds and funds provided by the private sector in order to design prizes, administer prizes, and offer monetary awards for prize competitions.[117]

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115 Harnessing Innovation for Global Development: Fact Sheet. 2012. http://www.whitehouse.gov/the-press-office/2012/02/08/fact-sheet-harnessing-innovation-global-development

116 Harnessing Innovation for Global Development: Fact Sheet. 2012. http://www.whitehouse.gov/the-press-office/2012/02/08/fact-sheet-harnessing-innovation-global-development

117 *Prize Authority in The America COMPETES Act Reauthorization*. https://cio.gov/wp-content/uploads/downloads/2012/09/Prize_Authority_in_the_America_COMPETES_Reauthorization_Act.pdf

The President's Emergency Plan For AIDS Relief (PEPFAR) at the Department of State

PEPFAR has R&D goals built into the agency's structure. The Scientific Advisory Board informs these goals, and PEPFAR collaborates with its implementing agencies to achieve them. PEPFAR also identifies priorities of investment in research on new preventions (microbicides and vaccines) and new treatments for TB and HIV.

PEPFAR's 2012 *Blue Print for Creating an AIDS-free Generation* identifies roadmaps for saving lives, smart investments, shared responsibility and driving results with science. Its goals include evidence-based interventions, promoting sustainability, efficiency and effectiveness, creating an AIDS-free generation, and science-guided efforts.

In order to implement the goal of science-guided efforts, PEPFAR will do the following in the area of R&D:

1. Leverage greatest impact by investing in continued implementation science through agency-specific mechanisms, rigorous evaluations of new PEPFAR programs and promotion of innovative methods of delivery.

2. Support implementation research:

   a. On decentralization strategies to help reach and retain more people in care (and put people more in charge of their care), such as community-based testing and treatment strategies.

   b. On interventions that can help address gaps in the continuum of care—plugging the holes in the leaky cascade— including ways to increase testing, improve linkage to care for people testing positive, and reduce attrition by helping people remain in care.

   c. Test interventions, including innovative technologies and other strategies to reduce the burden on patients, the cost of the package of care and the requirements of the health system to deliver.

3. Evaluate the impact of optimized combination prevention.

4. Support innovative research to develop new technologies for prevention (e.g., microbicides, vaccines) and care (e.g., new treatments or treatment regimens).

   a. Work with NIH and others to move forward the scientific agenda to develop new technologies including the search for a cure.

5. Develop evidence-based approaches to reaching people early enough in their disease progression to help maintain a strong immune system, stave off opportunistic infections, particularly TB, and reduce new HIV infections.

6. Support the deployment of suitable technology for measurement of viral load, both through tiered laboratory networks and 'point-of-care' tests as they become available. This technology is particularly important in helping people on ART and their care providers monitor how their treatment is working and assist them in achieving an "undetectable" level or virus in their bodies.

7. Assist countries in adopting breakthrough new technologies with proven impact, such as new molecular-based TB tests that have dramatically reduced time of diagnosis and treatment for people living with TB and HIV.[118]

PEPFAR's Five-Year Strategy includes the following goals:

1. Transition from an emergency response to promotion of sustainable country programs.

2. Strengthen partner government capacity to lead the response to this epidemic and other health demands.

3. Expand prevention, care, and treatment in both concentrated and generalized epidemics.

4. Integrate and coordinate HIV/AIDS programs with broader global health and development programs to maximize impact on health systems.

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118 PEPFAR. *Blueprint: Creating an AIDS-free Generation*. 2012. (Page 52–53) http://www.pepfar.gov/documents/organization/201386.pdf

5. Invest in innovation and operations research to evaluate impact, improve service delivery and maximize outcomes.[119]

PEPFAR's Research Policy states the following: "As part of its mandate to coordinate the US government (USG) response to the global HIV epidemic, the Office of the US Global AIDS Coordinator oversees a portfolio of rigorous scientific and program evaluations. These studies are carried out through PEPFAR implementing agencies, notably CDC, NIH, and USAID, in-country USG teams, and partner country institutions. The Office of the US Global AIDS Coordinator has put in place mechanisms and a coordination structure to ensure that all PEPFAR research is rigorous, addresses priority questions, and is carried out by implementing agencies with transparency and in conformity with USG procurement regulations."[120]

PEPFAR's Scientific Advisory Board serves in an advisory capacity concerning scientific, implementation, and policy issues related to the global response to HIV/AIDS. The board consists of 25 to 30 members, serving for one-year terms, appointed and reporting to the Office of the US Global AIDS Coordinator. The Board meets on a semi-annual basis.[121]

Duties:

a. Advise on priority global evaluation and research issues to guide the PEPFAR agenda.

b. Review the quality and relevance of the scientific and technical evidence being used or proposed as the basis for PEFAR policies.

c. Advise on broad scientific matter in technology, social and economic issues relevant to PEFAR.

d. Advise on emergency and short-notice scientific issues of immediate concern to PEPFAR.[122]

The President's Malaria Initiative

PMI is an initiative overseen by the US Global Malaria Coordinator and an Interagency Steering Group made up of representatives of USAID, CDC/HHS, the Department of State, the Department of Defense, the National Security Council, and the Office of Management and Budget.[123]

The *US Malaria Strategy for 2009–2014* states that one of its general principles is to conduct operational research that helps overcome implementation bottlenecks, contributes to the scale-up of malaria control activities, and identifies the most cost-effective mix of currently recommended interventions under different malaria transmission settings.[124]

It is expected that existing NIH, CDC, and Department of Defense efforts to develop and test new malaria prevention and control tools, such as new antimalarial drugs, insecticides, and malaria vaccines, as well as to train qualified malariologists, entomologists, and malaria researchers will be continued under those agencies' intra- and extramural research programs.[125]

119 PEPFAR. *Five-Year Strategy*. (Page 6) http://www.pepfar.gov/documents/organization/133035.pdf

120 Office of the US Global AIDS Coordinator. *Unsolicited Research Policy*. 2012. http://www.pepfar.gov/about/research/184923.htm

121 PEPFAR. *Scientific Advisory Board Charter*. 2010. http://www.pepfar.gov/documents/organization/154879.pdf

122 PEPFAR. *Scientific Advisory Board Charter*. 2010. http://www.pepfar.gov/documents/organization/154879.pdf

123 The President's Malaria Initiative. http://www.pmi.gov/about/index.html

124 *Lantos-Hyde US Government Malaria Strategy, 2009–2014*. http://www.pmi.gov/resources/reports/usg_strategy2009-2014.pdf

125 *Lantos-Hyde US Government Malaria Strategy, 2009–2014*. (Page 15) http://www.pmi.gov/resources/reports/usg_strategy2009-2014.pdf

The Department of State

The Office of Global Health Diplomacy (GHD) coordinates with other agencies to implement global health policies. However, there is no clear R&D priority.

The office of Global Health Diplomacy identifies the following objectives:

- Strengthening Sustainable Health Programs: GHD encourages sustainability of health programs by supporting partner countries as they strive to meet the health care needs of their citizens through effective leadership of their health care systems.

- Promoting Shared Responsibility: GHD uses diplomatic outreach across the family of nations to build shared global responsibility for sustained, ongoing improvements to health systems and health care delivery.

- Supporting Our Embassies: GHD supports our ambassadors and embassies on the ground, where our investments in health are translated into lives saved. Within the State Department, we champion global health training for diplomats, equipping them to elevate health in diplomatic discourse with partner countries.[126]

The Global Partnership Initiative

In 2009, Secretary of State Hillary Rodham Clinton launched the Global Partnership Initiative, promoting a new generation of public-private partnerships to strengthen foreign policy, maximize foreign aid impact, and enhance collaboration to solve problems. This collective action has inspired innovating new approaches to diplomacy and development.

Global Partnership Initiative serves three key roles:

1. Convener: Bringing people together across industries, sectors, and regions to work on shared issues

2. Catalyst: Kick-starting new solutions through collective action and innovation

3. Collaborator: Working closely to plan, implement, and realize best practices[127]

Four flagship initiatives:

1. Global Alliance for Clean Cookstoves

2. Partners for a New Beginning

3. International Diaspora Engagement Alliance

4. Accelerating Market-Driven Partnerships[128]

The Global Partnership Initiative is a good example of collaboration between agencies. However, there is no clear global health R&D priority.

The US Agency for International Development (USAID)

USAID identifies R&D as a core principle of the agency. USAID collaborates with diverse partners to address critical barriers to the development, introduction, and scale-up of priority global health interventions. The agency has a *Global Health Strategic Framework*, a *Health-Related Research and Development Strategy* and a *Strategy for the Development of*

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126 US Department of State. About the Office of Global Health Diplomacy. http://www.state.gov/s/ghd/about/index.htm

127 US Department of State's Global Partnerships Initiative. Key Partnership Achievements. http://www.state.gov/s/partnerships/achievements/202394.htm

128 US Department of State's Global Partnerships Initiative. Key Partnership Achievements. http://www.state.gov/s/partnerships/achievements/202394.htm

Vaccines for HIV/AIDS, TB, Malaria and other diseases. These strategies outline specific R&D objectives. The offices within USAID that work on these issues include the Bureau for Global Health, the Office of Science and Technology and the Office of Innovation and Development Alliances. USAID also has several science and technology ventures, including the *Grand Challenges for Development Initiative*.

USAID identifies several operational principles in its policy framework including:

- Promote gender equality and female empowerment
- Apply science, technology, and innovation strategically
- Apply selectivity and focus
- Measure and evaluate impact
- Build in sustainability from the start
- Apply integrated approaches to development
- Leverage "solution holders" and partner strategically[129]

USAID's *Global Health Strategic Framework* includes accelerating the development and application of innovation, science, and technology as one of its core principles.

Recognizing the power of equitably applied science, technology, and innovation to solve human problems, over the next five years, USAID's global health program will invest in a new wave of technologies, tools, and service delivery approaches that can save lives. USAID will focus its investments in medical technologies on low-cost technologies appropriate for use in low resource settings. It will also work with other key international actors to support global research into innovations, such as new contraceptive technologies and microbicide gels that would allow women to protect themselves from HIV infection.

The potential of eHealth and its mobile version, mHealth, will specifically be explored as a means of improving further the effectiveness and efficiency of health development efforts. To accelerate product development and the introduction of new technologies in the field, USAID will establish a center of excellence that brings together industry experts and academic fellows to inform Agency thinking, to invest seed capital in promising ideas wherever they are found, and to bring promising ideas to scale.[130]

Health-Related Research and Development Strategy

In 2006, USAID outlined for Congress its 5-year health research strategy. From 2006 to 2010, USAID-funded research led to key successes, including global recommendations for newborn survival and child health, the development and adoption of strategies to prevent maternal mortality, innovations in contraceptive methods, and new drug formulations for malaria.

In order to achieve health impact, USAID collaborates with diverse partners to address critical barriers to the development, introduction, and scale-up of priority global health interventions. These partners include the US State

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129 USAID. *Policy Framework, 2011–2015*. http://www.usaid.gov/sites/default/files/documents/1870/USAID%20Policy%20Framework%202011-2015.PDF

130 USAID. *Global Health Strategic Framework, 2012–2016*. (Page 27) http://reliefweb.int/sites/reliefweb.int/files/resources/Full_Report_3837.pdf

Department, Office of the US Global AIDS Coordinator, CDC, the National Institutes of Health (NIH), the Department of Defense, multilateral health organizations, other donor agencies, foundations, host country governments, academia, nongovernmental organizations, and the private sector.[131]

This strategy outlines the agency's priorities according to policy area, including rationale and expected results from 2010-2015. The strategy also identifies both obligated funds for 2011 and expected funds for 2012 for each policy area.

Maternal and Newborn Health

- Develop and introduce new and improved evidence-based interventions for care during pregnancy and at birth.
- Strengthen and standardize high-quality obstetric care for the prevention, management, and treatment of fistula.
- Design, evaluate, and introduce evidence-based interventions to reduce newborn morbidity and mortality from birth asphyxia.
- Develop, test, and introduce community-based health interventions to treat and prevent newborn infections.
- Develop scalable, cost-effective approaches for integrating maternal and neonatal health services.
- Assess evidence-based approaches to improve the access and utilization of quality maternal, neonatal, and child health interventions.
- Develop standardized criteria and effective tools for measuring maternal and perinatal mortality and morbidity.

Child Health

- Support implementation research to inform the uptake of integrated Community Case Management.
- Develop and test cost-effective approaches to decrease the incidence of acute lower respiratory infections due to household air pollution.
- Evaluate interventions to increase the use of efficacious diarrhea treatments.
- Develop and test scalable approaches to improve drinking water quality, access, use of sanitation, and hygiene behaviors.

Nutrition

- Strengthen and expand the evidence base on integrated multisectoral approaches to improve nutrition outcomes, including stunting and maternal and child anemia.
- Support implementation research for improved diet diversity and quality.
- Develop, refine, and expand use of state-of-the-art measurement tools for nutrition programs and policies.

Family Planning and Reproductive Health

- Refine, develop, and introduce new contraceptive methods.
- Improve and expand the use of family planning methods in developing countries.
- Develop and introduce effective, scalable service delivery models to increase the healthy timing and spacing of pregnancies.

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131 USAID. *Health-Related Research Strategy, 2011–2015.* http://www.ghtcoalition.org/files/HRRStrategy_web.pdf

HIV/AIDS

- Develop and introduce microbicides for women to reduce their risk of HIV infection.
- Accelerate the development and clinical testing of novel HIV vaccine candidates.
- Strengthen the evidence base to improve HIV/AIDS prevention, care, and treatment programs.

Malaria

- Develop safe and effective vaccines to reduce morbidity and mortality due to Plasmodium falciparum. Develop effective and affordable medicines for the treatment and prevention of malaria.
- Improve malaria control program implementation and impact.

TB

- Develop diagnostic tools to more effectively detect TB in individuals with and without HIV.
- Develop shorter TB regimens that are effective against all forms of TB, can be used with antiretroviral therapy, are suitable for children, affordable, and easily managed in resource-limited settings.
- Conduct operations research for improving TB program performance and management of TB-HIV.

Pandemic Influenza and Other Emerging Threats

- Develop and introduce surveillance models to increase pathogen detection.
- Develop and test methods to improve the understanding of risk, including how human behavior contributes to the risk of disease emergence.

Health Systems Strengthening

- Strengthen and improve health systems performance and contribute to more sustainable programmatic outcomes.
- Advance methodologies to measure health systems strengthening and performance.
- Strengthen evidence-based practices for the uptake and use of proven approaches to improve health systems performance at the country level.[132]

USAID has created a *Strategy for the Development of Vaccines for HIV/AIDS, TB, Malaria and other diseases*. The priorities include:

- Initiatives to create economic incentives for the research, development, and manufacturing of vaccines for HIV/AIDS, tuberculosis, malaria, and other infectious diseases
- An expansion of public-private partnerships and the leveraging of resources from other countries and the private sector
- Efforts to maximize United States capabilities to support clinical trials of vaccines in developing countries and to address the challenges of delivering vaccines in developing countries to minimize delays in access once vaccines are available.[133]

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132 USAID. *Health-Related Research Strategy, 2011–2015.* http://www.ghtcoalition.org/files/HRRStrategy_web.pdf

133 *Coordinated Strategy to Accelerate Development of Vaccines for Infectious Disease.* 2009. http://pdf.usaid.gov/pdf_docs/PDACN525.pdf

The following is each US agency's role in the development of vaccines:

- National Institutes of Health supports basic research, preclinical testing in animal models, development of candidate vaccine products, and clinical testing of vaccines

- Department of Defense supports basic research, preclinical testing in animal models, development of candidate vaccine products, and clinical testing of vaccines

- CDC supports clinical trials, field preparedness, epidemiological research, surveillance; provides data on disease burden to establish baseline, monitor impact, and track specific changes in serotypes as necessary; supports economic studies on cost effectiveness; provides technical support for vaccine procurement, distribution and delivery

- The US Agency for International Development supports preclinical testing in animal models, development of candidate vaccine products, clinical testing of vaccines, operations and applied research to strengthen immunization programs and logistics, prepare for the introduction of new vaccines; and provides global expertise in demand forecasting, supply and procurement, and distribution and delivery to developing countries[134]

The Bureau for Global Health "…supports field health programs, advances research and innovation in selected areas relevant to overall Agency health objectives, and transfers new technologies to the field through its own staff's work, coordination with other donors, and a portfolio of grants."[135]

Within the Bureau for Global Health, the Center for Accelerating Innovation and Impact "promotes and reinforces innovative, business-minded approaches and solutions to accelerate impact against some of the world's most important health challenges, convening industry experts and academic thought leaders to inform the office's thinking. The Bureau will invest seed capital in the most promising ideas and cut the time it takes to transform discoveries in the lab to impact on the ground. The Center focuses on three areas: identifying state of the art practices, catalyzing innovation and partnerships and scaling for impact."[136]

The Office of Science and Technology's goal is to use the transformative power of science and technology to deliver more effective, cost-efficient results by:

- Improving understanding of development problems and solutions through better data and analytics

- Creating better solutions through revolutionary, high-payoff research that bridges the gap between fundamental discoveries and development

- Expanding the impact of solutions and solvers in development by incubating new technologies and approaches, and catalyzing global action to meet the greatest challenges of our time.[137]

The Office of Innovation and Development Alliances (IDEA) was created in 2011 to lead the Agency's efforts on reimagining ways to catalyze development, crowd source new ideas, build high-impact innovative partnerships with traditional and non-traditional stakeholders to achieve greater aid effectiveness and lasting change. These principles reflect the reform agenda embodied in the Administration's Global Development Policy, the Quadrennial Diplomacy and Development Review, and USAID Forward. This office focuses on four systematic approaches:

- Development Innovation Ventures: Supports promising projects to improve development through a 3 stage funding mechanism.

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134 *Coordinated Strategy to Accelerate Development of Vaccines for Infectious Diseases.* 2009. (Page 10) http://pdf.usaid.gov/pdf_docs/PDACN525.pdf

135 USAID. Bureau for Global Health. http://www.usaid.gov/who-we-are/organization/bureaus/bureau-global-health

136 USAID. Center for Accelerating Innovation and Impact. http://www.usaid.gov/what-we-do/global-health/cross-cutting-areas/innovation-and-impact

137 USAID. Office of Science and Technology. http://www.usaid.gov/who-we-are/organization/independent-offices/office-science-and-technology

- Global Partnerships: Advances private sector partnerships to produce cost-effective scalable programs.
- Local Sustainability: Works with 50 missions and Washington DC to strengthen civil society and private sector capacity to improve aid effectiveness.
- Mobil Solutions: Leverages the power and reach of mobile technology to accelerate USAID's development goals.[138]

Other USAID Science and Technology Ventures

The Future Can't Wait: On November 4, 2011, USAID hosted the first-ever "Symposium on the Future of Development Challenges." Along with partners at the Department of State, the Woodrow Wilson International Center for Scholars, and the National Defense University, the symposium brought together development theorists and practitioners, economists and demographers, scientists and futurists to explore and discuss emerging development trends that will shape USAID's collective policies and programs long into the future.[139]

Grand Challenges Development: Under the Grand Challenges for Development initiative, USAID will focus on defining problems, identifying constraints, and providing evidence-based analysis. Addressing these challenges will require the creation and support of self-perpetuating systems, rather than one-off inventions or interventions.[140]

One of the Grand Challenges is Saving Lives at Birth. USAID, the Government of Norway, the Bill & Melinda Gates Foundation, Grand Challenges Canada, The World Bank, and the UK Department for International Development (DfID) call for groundbreaking prevention and treatment approaches for pregnant women and newborns in poor, low-resource communities around the 48 hours of delivery through: 1) Science and technology advances that prevent, detect or treat maternal and newborn problems at the time of birth; 2) New approaches to delivering high-quality care at the time of birth; and 3) Empowering and engaging pregnant women and their families.[141]

International Research in Science: USAID supports a range of programs and activities, including:

- Empowering scientists and engineers in developing countries
- Working to use S&T as platforms on which to build, strengthen, and renew bilateral relationships with other countries and scientists.
- Enhancing and catalyzing USAID partnerships with federal science agencies
- Connecting universities in developing countries with digital scientific resources[142]

LAUNCH: USAID, NASA, the Department of State, and NIKE joined together to form LAUNCH in an effort to identify, showcase and support innovative approaches to global sustainability challenges in both developing and developed countries. LAUNCH searches for visionaries, whose world-class ideas, technologies or programs show great promise for making tangible impacts on some of the biggest challenges in international development.[143]

USAID's website mentions R&D for the following global health policy priorities: Family Planning, HIV/AIDS, Malaria and TB.

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138 USAID. Office of Innovation and Development Alliances. http://www.usaid.gov/who-we-are/organization/independent-offices/office-innovation-and-development-alliances

139 USAID. *The Future Can't Wait*. http://www.usaid.gov/documents/15396/future-cant-wait

140 USAID. Grand Challenges for Development. http://www.usaid.gov/grandchallenges

141 USAID. Grand Challenges for Development. http://www.usaid.gov/grandchallenges

142 USAID. International Research and Science Programs. http://www.usaid.gov/what-we-do/science-technolog-and-innovation/international-research-science-programs

143 USAID. Launch. 2013. http://www.usaid.gov/what-we-do/science-technolog-and-innovation/launch

Family Planning: In its objectives for family planning, USAID identifies "advancing research and innovation" as a means to achieve its objective of supporting voluntary family planning and reproductive health programs.[144]

HIV/AIDS: USAID supports research on the development of products to prevent HIV infection and transmission, including vaccines and microbicides. USAID-funded research has led to the development of a microbicide proven to be effective in preventing the sexual transmission of HIV to women. USAID also conducts research in such areas as HIV prevention among youth, PMTCT, and treatment of pediatric HIV infections.[145]

Malaria: USAID also invests in the discovery and development of new antimalarial drugs and malaria vaccines. USAID's malaria programs support international programs such as the Abuja Summit, the Millennium Development Goals and the Global Malaria Action Plan.[146]

TB: USAID has developed a Path to TB Innovation, which includes increasing the pipeline for new drugs, diagnostics and vaccine candidates.[147]

The Presidential Policy Directive: Global Development Policy

The President's approach to global development addresses the new strategic context faced by the US through the following three pillars:

- A policy focused on sustainable development outcomes that place a premium on broad-based economic growth, democratic governance, game-changing innovations, and sustainable systems for meeting basic human needs.
- A new operational model that positions the US to be a more effective partner and to leverage our leadership.
- A modern architecture that elevates development and harnesses development capabilities spread across government in support of common objectives.[148]

Invest in game-changing innovations with the potential to solve long-standing development challenges. Leveraging the power of R&D, the United States will:

- Increase our investments and engagement in development-focused innovation by seeking and scaling up potential game-changing development technologies such as vaccines for neglected diseases, weather-resistant seed varieties, and clean energy technologies.
- Increase public funding - while securing more private funding - for development-focused research, including by:
  - ◊ Capitalizing new models for innovation and bringing sustainable models to scale
  - ◊ Using our leadership, bilaterally and multilaterally, to foster, highlight, and reward innovation
  - ◊ Increasing developing countries' creation and utilization of science and technology and removing impediments to innovation faced by the private sector.[149]

This policy will be implemented through the president's current global initiatives, Feed the Future, the Global Health Initiative, and the Global Climate Initiative.[150]

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144 USAID. Family Planning. 2014. http://www.usaid.gov/what-we-do/global-health/family-planning

145 USAID. Our HIV/AIDS Work. 2012. http://www.usaid.gov/sites/default/files/documents/1864/hiv_fastfacts_0.pdf

146 USAID. Fighting Malaria. 2014. http://www.usaid.gov/what-we-do/global-health/malaria

147 USAID. The Path to TB Innovation. http://www.usaid.gov/sites/default/files/documents/1864/tbtimeline.pdf

148 Fact Sheet: US Global Development Policy, Presidential Policy Directive 4. http://www.fas.org/irp/offdocs/ppd/global-dev.pdf

149 Fact Sheet: US Global Development Policy, Presidential Policy Directive 4. http://www.fas.org/irp/offdocs/ppd/global-dev.pdf

150 Fact Sheet: US Global Development Policy, Presidential Policy Directive 4. http://www.fas.org/irp/offdocs/ppd/global-dev.pdf

The Quadrennial Diplomacy and Development Review

The QDDR resulted in several policy changes within the global development work of US agencies.

Guiding Policy Principles:

- Restore and Sustain American Leadership
- Build a new architecture of cooperation
- Elevate development and integrate the power of development and diplomacy
- Mobilize civil society and business to address common problems
- Prevent violent conflict and reduce the growing costs of conflict
- Integrate gender into our diplomacy and development work
- Facilitate innovative, flexible, and tailored responses in an age of uncertainty

The following are priorities related to global health R&D:

Practice High Impact Development

Incubate innovation and develop best practices by creating a Development Lab at USAID and establishing an Innovation Fellowship that will bring 20 to 25 leading development thinkers to work there.

Rebuilding USAID as the preeminent global development agency

Continue implementing the USAID Forward agenda, which includes establishing a Bureau of Policy, Planning, and Learning; strengthening USAID's budget management capacity; incorporating science and technology in our development efforts; and reforming procurement systems.

Building a 21st Century Workforce

Foster innovation by seeking revisions to the Foreign Service Examination so that it can better identify innovative thinkers and entrepreneurial leaders. We will also reward innovation in leadership posts, expand training for critical skills, and launch a Development Studies Program.

USAID FORWARD: Partnership. Innovation. Results.

USAID has embarked on an ambitious reform agenda, USAID Forward, announced by Administrator Shah in August 2010, to change the way the Agency does business. This expansive effort gives the Agency an opportunity to transform itself, unleashing its full potential to achieve high-impact development, while making the best use of limited resources.

USAID FORWARD Reforms:

1. Procurement: To provide grants to more and varied local partners, USAID is streamlining its procurement processes, increasing the use of small businesses and using host country systems where feasible.
2. Talent Management: To fully utilize the enormous talent that lies within the broader USAID family, USAID is seeking to attract and retain best-in-class employees who reflect global diversity and who share one common trait: the ability to be innovative problem-solvers.
3. Rebuilding Policy Capacity: To make smart, informed decisions, USAID has created a new Bureau of Policy, Planning and Learning (PPL) that will serve as the intellectual nerve center for the agency, devising cutting-edge, creative and evidence-based development policies.

4. Strengthening Monitoring and Evaluation, and Fulfilling Commitments to Transparency: To ensure we are accountable for results and improving our practices based on new knowledge, USAID is introducing a state-of-the-art monitoring and evaluation process, linked to program design, resource allocation, and strategy development. Moreover, USAID is fulfilling commitments to publicly share information about what we spend and what we achieve.

5. Rebuilding Budget Management: To direct resources toward effective pro- grams and key priorities, USAID has created an Office of Budget and Resource Management.

6. Science and Technology: To deliver transformational development breakthroughs, USAID is upgrading its internal science and technology capabilities, supporting the expansion of technical expertise, and improving access to analytical tools such as geospatial analysis.

7. Innovation: To seek out new, effective development approaches, USAID is creating opportunities to connect staff to leading innovators in the private sector and academia.[151]

The Global Health Initiative

Principles:

- Focus on women, girls and gender equality

- Encourage country ownership and invest in country-led plans

- Build sustainability through the strengthening of health systems

- Strengthen and leverage key multilateral organizations, global health partnerships, and private sector engagement

- Increase impact through strategic coordination and integration

- Improve metrics, monitoring, and evaluation

- Promote research and innovation to identify what works[152]

Commitment to Innovation:

Science, Research, and Innovation Are Critical Drivers of Transformational Development and Progress in Global Health

The success of President Obama's Global Health Initiative (GHI) rests largely on innovative approaches to achieve integration, synergy, and strategic alignment of high-impact research results with country-owned, sustainable, and effective health delivery systems.

Why Research and Innovation Are Essential

Achievement of the GHI goals requires innovative translation of investments in health research into real and measurable population- level health outcomes. GHI encourages innovation along the scientific continuum, reflected in the full range of US government-funded research, from discovery, to new interventions, to implementation of health programs.

US Approach to Promoting Research and Innovation

GHI country teams leverage US government-supported activities to facilitate the development of country-led research and research capacity building, including provision of technical assistance to countries on strategy, study design, human-subject protections, study implementation, and data collection/interpretation. Two common country challenges

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151 *Leading Through Civilian Power, The Quadrennial Diplomacy and Development Review*. 2010. http://www.state.gov/documents/organization/153108.pdf

152 Global Health Initiative. *Saving Lives and Promoting Security*. 2012. http://www.state.gov/documents/organization/191821.pdf

are a) the gap between advances made in evidence-based interventions and services, and the effective application/ implementation of these interventions; and b) the knowledge base for how to best adapt and effectively scale up these interventions.

Achieving GHI Goals for Research and Innovation

Traditional research identifies game-changing breakthroughs in information and interventions, while implementation science informs how to efficiently and effectively scale up novel health services to populations in a sustainable manner. GHI-supported research and program investments concurrently seek to improve the evidence base and application of key knowledge and practices through operational research and implementation science. Special attention is given to strengthening the integral connections between research activities, their effective application in programs, and the achievement of health goals.

Collaboration

GHI provides an opportunity to link the scientific and the development communities to innovatively accelerate the strategic health goals of partner countries. GHI teams are also translating advances in technology, such as mobile telephones and the Internet, into health benefits through implementation science. GHI is committed to leveraging the full US government science community, universities, and the new community of solvers to achieve global health gains.

Enhancing Evidence

GHI commits to both advancing the utilization and application of existing knowledge and to advancing the evidence base for host country GHI strategic health goals. Collectively, research and monitoring and evaluation informs innovation and contributes to the GHI learning agenda. GHI headquarters supports learning across GHI countries by advancing (or advocating for) the active, rapid dissemination of high-quality research findings and evidence-based priority interventions and programs among GHI countries.[153]

The US Strategy for Meeting the Millennium Development Goals

The US strategy for meeting the Millennium Development Goals was established in 2010. The strategy is based on the following objectives:

- Leverage innovation
- Invest in sustainability
- Track development outcomes, not just dollars
- Enhance the principle and the practice of mutual accountability

Fostering innovation to meet the Millennium Development Goals will require the following:

- Fund applied research by supporting local, national, and global research networks working on key problems related to the Millennium Development Goals.
- Expand access to existing technologies and practices though partnerships among governments; international organizations; the private sector; philanthropic and other civil society organizations; and research, technical, and social networks.
- Build learning partnerships that facilitate the transfer of knowledge and skills to developing countries and nurture a local capacity for innovation in those countries.

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153 Global Health Initiative. *Promoting Research and Innovation*. http://www.ghi.gov/principles/docs/innovation.pdf

- Stimulate innovation in partner countries through prizes, competitions, technical support, specialized funds, and tapping diaspora networks for capital and know-how.
- Expand global access to knowledge by harnessing modern information technology to narrow the "digital divide" and give developing-country innovators access to the knowledge they need to address development challenges.[154]

Conclusions

USAID, NIH, and DoD have made the most information publicly available about their global health R&D programs through strategies and their websites. USAID focuses on funding programs that encourage innovation and have a clear link to development. The agency has achieved key successes in global recommendations for newborn survival and child health, the development and adoption of strategies to prevent maternal mortality, innovations in contraceptive methods, and new drug formulations for malaria. NIH funds research in several policy areas, including HIV/AIDS, TB, malaria, and neglected tropical diseases. DoD has research programs that focus on a wide range of diseases and appear to have the most comprehensive strategy toward global health R&D, funding research from start to finish. However, the agency conducts global health R&D only as it relates to its mandate to protect military personnel.

Most of the strategies reviewed are broad and do not identify a clear mechanism for implementation. There are very few documents that dictate how research funding should be allocated and what targets to pursue. Policies like the Presidential Policy Directive on Global Development and the QDDR cast the vision for the use of innovation to create efficiencies and foster participation in the area of global health R&D.

Few policies cover global health R&D prioritization specifically, and most that cover it do so in a disease or population-specific manner. For example, PEPFAR and PMI have clear vaccine development priorities for HIV/AIDS and Malaria. CDC focuses on research for HIV/AIDS, TB, malaria, vaccine preventable diseases and childhood morbidity and mortality. Even fewer agencies like USAID, focus on specific platforms like development of contraceptive technologies. USAID's Health-Related Research and Development Strategy is one of the only publicly available guidance documents that provides specific expected results and identifies clear funding numbers for each policy focus.

There are some examples of agency coordination in global health R&D: the National Vaccine Program and the research efforts of PMI. In addition, the Global Health Initiative was created to be a model for agency coordination and has priorities for global health R&D. However, this interagency initiative doesn't appear to have achieved coordination or impacted other agencies' priorities in the area of global health R&D.

It can be concluded from this review that more coordination is needed to ensure gaps in product development are filled, overlap is minimized, and priority setting is more transparent. A mechanism is needed to set interagency priorities for global health R&D and to ensure that coordination among the various agencies fills gaps and leverages resources for the greatest impact.

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154 *Celebrate, Innovate and Sustain, Toward 2015 and Beyond: The US Strategy for Meeting the Millennium Development Goals, 2010.* (Page 9) http://usun.state.gov/documents/organization/147679.pdf

Appendix B: Interview Template

General Questions:

1. What is the agency's/program's global health research and development (R&D) strategy or approach?

2. Describe the agency's/program's specific global health R&D programs?

3. What (if any) is the agency's/program's long-term strategy for global health R&D?

4. Do you think there are any gaps in global health R&D within your agency/program or other US agencies/programs?

5. Do you think there are any duplications in global health R&D within your agency/program or other US agencies/programs?

6. What areas does the agency/program coordinate with other agencies in global health R&D?

7. Are there any barriers to continuing or expanding your agency's global health R&D?

8. Do you consider there to be a 'hub' or center of global health research policy decision-making? Where do you think that could sit?

9. Are there other people we should reach out to within US agencies that would be helpful in this research?

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