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Global Health Working Group  
White Paper on Fostering  
Global Health Innovation

**GROUP 7**

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# Global Health Working Group

## White Paper on Fostering Global Health Innovation

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### Introduction: An Opportunity to Foster Global Health Innovation

The recent outbreak of Ebola hemorrhagic fever in West Africa was tragic for thousands of people and terrifying for millions. The outbreak of this highly infectious diseases also reminded policy makers, global health professionals and scientists<sup>1</sup> about the challenges facing health systems across the world, and the global risks created when these systems are weak or nonexistent.

The recent outbreak of Ebola hemorrhagic fever in West Africa was tragic for thousands of people and terrifying for millions. The outbreak of this highly infectious disease also reminded policy makers, global health professionals and scientists about the challenges facing health systems across the world, and the global risks created when these systems are weak or nonexistent.<sup>2</sup>

While many problems arose in the global response to Ebola, key stakeholders collaborated in successful ways to rapidly develop a new vaccine.<sup>3</sup> This exceptional instance – the innovation of a critically needed new product for global health – highlights an endless global health challenge. How can global health research and development (R&D), the scientific discovery and development of new products to fight neglected diseases, be promoted in the absence of news-making crises?

At Ise-Shima G7 Summit in Japan in May 2016, the G7 governments can review prior successes in global health innovation and put in place new mechanisms to sustain and leverage the impact of recent investments in global health. The Ise-Shima Summit provides an excellent opportunity to build on lessons learned in recent years about successful approaches to fostering global health innovation by making bold commitments of new financial, technical and human resources.<sup>4</sup>

This policy brief argues that increasing the G7's investments in global health innovation is a sound – and necessary – investment that will yield dividends in terms of economic, diplomatic and humanitarian progress. Based on interviews with key leaders in global health, this policy brief concludes that the most significant impediments to global health innovation are:

- *Insufficient funding* invested in research and development of new vaccines, diagnostics and medicines needed for those diseases that disproportionately affect developing countries;
- The *regulatory complexities and systemic redundancies* in licensing new global health products, especially in countries that lack a strong national regulatory framework; and,
- Profound *inefficiencies in global information sharing* and collaboration on innovation processes for global health products.

In response to these challenges, we propose that the G7 countries take three actions to foster global health innovation:

- *Increase government and philanthropic funding* to support global health innovation processes;
- Advance efforts to *streamline and harmonize national regulatory practices* for new global health products; and,
- Follow through with *support for more effective information/knowledge-sharing systems* in order to promote collaboration in global health innovation.

Despite the medical advances of the past century, the world is still struggling with how to assure that scientific discovery and technological progress benefit all people. In short, how do we assure the fair distribution of investment in the development of new health products, both among and within countries? The three proposals presented in this policy brief will lead to improvements in global health innovation, and thus to progress in global health. Ultimately, the investments in global health innovation proposed here will benefit people, and will strengthen health systems and economies, around the world.

## **The Need for Technological Innovation in Global Health**

Global health is the “study, research, and practice that places a priority on improving health and achieving equity in health for all people worldwide.”<sup>5</sup> Global health practice emphasizes interdisciplinary and transnational approaches to understanding the determinants of health, prominent health issues and the implementation of proposed solutions at all levels. Many global health programs focus on infectious diseases, which disproportionately affect people living in developing countries. Increasingly, however, global health programs are addressing heart disease, diabetes, cancers, and other non-communicable and lifestyle diseases that affect all countries.

This policy brief focuses primarily on policies to foster innovation of products to address infectious diseases, because they continue to present major obstacles to economic growth, health security and human development in poor countries. By extension, infectious diseases also have a major impact on global development. However, infectious diseases are increasingly rare in industrialized countries. The infectious diseases that cause a majority of associated death and disability are endemic only in poor countries. (In this paper, the term “endemic diseases” is used to refer to HIV/AIDS, tuberculosis, malaria and the 17 neglected tropical diseases (NTDs) that disproportionately affect people in poor countries.)

The health burden of endemic infectious diseases is immense. Over 25 million people are living with HIV, more than 2 billion people are infected with tuberculosis, and over 500 million people die each year of malaria.<sup>6</sup> Infectious diseases are the leading cause of death in children worldwide.<sup>7</sup> And non-fatal endemic diseases cause considerable disability. The effects of these diseases extend across generations, limiting the ability of individuals, their communities and their nations to thrive.

Despite the global toll of infectious diseases, many of the “tools” (vaccines, diagnostics and medicines) needed to prevent, treat and control them have not been discovered. A few examples of the need for technological innovation for endemic diseases: there is neither a vaccine for HIV

nor a cure for AIDS; there is no medicine to treat Dengue fever, chikungunya disease or dracunculiasis; and there are no clinical diagnostic tests available for Buruli Ulcer and Chagas disease, while the diagnostic methods use for tuberculosis are notoriously unreliable. Table 1 shows which of the top 20 endemic diseases have a vaccine, diagnostic, and treatment, and which diseases do not have these technologies or have only suboptimal options. (Additional information is available in Appendix A.)

In addition to the 20 endemic diseases listed, the world regularly experiences sudden emergent infectious diseases such as Ebola, SARS, avian influenza, and MERS. These outbreaks generate fear around the world, as they threaten not only individuals but also national and economic security, and because existing tools often do not work to fight these new diseases.

Another critical global problem related to infectious diseases is that the effectiveness of existing tools, particularly medicines, is increasingly threatened by the evolution of resistance among the infectious agents. Anti-microbial resistance (AMR) exacerbates the spread of both endemic and emerging infectious diseases by undercutting existing prevention and treatment options.

Widespread resistance to antibiotics among disease-causing organisms is rolling back previously achieved health gains, while no major new antibiotics have been developed in the last 30 years.<sup>8</sup> Resistance problems are occurring with various endemic diseases. For example, after a decade of decreases, malaria deaths increased among African children under age five beginning in the 1970s due to spreading chloroquine resistance in the malaria parasite.<sup>9</sup> Similarly, new strains of multi-drug resistant tuberculosis, streptococci and other diseases are increasingly ubiquitous.

All of these problems – missing tools, tools for emerging new diseases, and new tools to replace those becoming obsolete – urgently require global health innovation. Strengthening global investments in R&D for global health innovation is vitally important.

**Table 1: The Need for Innovations for Endemic Diseases: Current Portfolio and Gaps in Key Global Health Tools (Vaccines, Diagnostics, and Medicines)**

Disease	Vaccine	Diagnostic	Therapeutic
HIV/AIDS	NO	Yes	Yes
Tuberculosis	NO	SUBOPTIMAL	Yes
Malaria	SUBOPTIMAL	Yes	SUBOPTIMAL
Buruli Ulcer	NO	NO	SUBOPTIMAL
Chagas Disease	NO	NO	SUBOPTIMAL
Dengue and Chikungunya	SUBOPTIMAL	Yes	NO
Dracunculiasis	NO	SUBOPTIMAL	Worm extraction
Echinococcosis	NO	NO	Surgery
Endemic treponematoses	NO	NO	Yes
Foodborne trematodiasis	NO	NO	Yes
Human African trypanosomiasis	NO	SUBOPTIMAL	SUBOPTIMAL
Leishmaniasis	NO	Yes	SUBOPTIMAL
Leprosy (Hansen's disease)	NO	NO	Yes
Lymphatic filariasis	NO	SUBOPTIMAL	SUBOPTIMAL
Onchocerciasis	NO	SUBOPTIMAL	Yes
Rabies	Yes	NO	NO
Schistosomiasis	NO	SUBOPTIMAL	Yes
Soil-transmitted helminthiasis	NO	SUBOPTIMAL	Yes
Taeniasis/Cysticercosis	NO	NO	SUBOPTIMAL
Trachoma	NO	NO	Yes

## **Barriers to Global Health Innovation**

Significant hurdles exist in improving global health, particularly around the development of new vaccines, drugs, and diagnostics. Yet there is little consensus about how to accelerate investment in global health innovation, especially for products that will primarily benefit people in poorer countries.

Major stakeholders in global health innovation include governments, donors, multilaterals, industry, and non-government organizations. In 2013, more than three quarters of all funding for R&D for global health was provided by seven institutions, including five governments and two philanthropies. In preparing this policy brief, we interviewed representatives in the seven funding institutions. (Details on the methodology and results are in Appendix B.) Key stakeholders from these institutions were asked to identify the major bottlenecks that impede global health R&D for vaccines, diagnostics, and medicines needed to control and eradicate endemic infectious diseases.

The respondents noted that considerable progress has been made in the fight against infectious diseases, thanks in part to economic development, improved health systems and targeted control programs, along with increased access to effective vaccines, diagnostics, and medicines. All of these factors have contributed to reducing the global burden of infectious diseases. But in many areas the rate of decline of infectious diseases has plateaued or fallen short—especially in countries with weak health systems. The respondents were then asked to identify the key obstacles, as well as the most promising strategies, to fostering global health innovation that could address the persistent challenges of endemic infectious diseases. Their responses pinpointed three areas: funding, regulation, and knowledge management.

## **Strategies for Accelerating Innovation for Global Health**

### **I. Substantially Increase Funding for Global Health Innovation**

#### *The Problem*

Major, and systemic, funding gaps exist for financing the processes that lead to the introduction of a novel, licensed product for an endemic disease. Further, the sources of funding for global health innovation are different from other areas.

Funding for global health R&D has already increased significantly over the past decade, and the investments are beginning to pay off, leading to new innovations and subsequent formulations. Over the past half century, governments and philanthropic foundations have been the primary funders of research and development of new products targeting infectious diseases of the developing world. Their investment totaled US\$3.2 billion in 2013.<sup>10</sup> The pipeline of new products is steadily increasing. For example, by 2011 the Drugs for Neglected Diseases initiative (DNDi), which was founded in 2003, enabled the development of two antimalarials, a new treatment for visceral leishmaniasis, and pediatric formulations for Chagas disease treatment, among others.

The pharmaceutical industry, on the other hand, spent an aggregate US\$400 million on global health research and development in 2013. For-profit companies in the biomedical industry are the primary developers of new vaccines, diagnostics and medicines for developed markets, and they have the infrastructure, professional expertise and other resources needed to bring new products from discovery to market. Yet for-profit companies typically invest only in areas where they see

potential for profitable financial return. Market incentives are minimal to encourage for-profit companies to invest in developing new products for endemic infectious diseases that primarily affect poor people in poor countries. The potential returns on investment are viewed as low because of the limited market power of the people who need the products.

These arguments, however, are now being challenged. Recent studies at the national and global levels demonstrate that investment in global health innovation has both economic and social benefits. According to a 2013 report in *The Lancet*, funds invested in global health R&D generate a benefit between 9 and 20 times the cost in the global economy.<sup>11</sup> Likewise, GHPD investments have a significant benefit at the national level. In the U.S.A., for example, approximately 64 cents of every government dollar on global health R&D is invested domestically.<sup>12</sup> In the European Union, 66 cents of every Euro invested in global health R&D is spent within the E.U.<sup>13</sup> Research!America, an advocacy and education alliance made up of over 350 institutions, has examined the issue in depth, and prepared a top-ten list of reasons to invest in global health R&D (see panel).<sup>14</sup>

Public and private donors have often stepped in to fill gaps left by pharmaceutical companies in funding for global health innovation. However, government and other non-industry funding is often directed to basic science, discovery and early product development phases; funding later stage clinical trials, for example, is far less common. Increasingly, donors are partnering with the biomedical industry to shepherd important scientific research into usable products efficiently. Product-development and public-private partnerships (PDPs and PPPs) are mechanisms frequently used to incentivize these collaborations.

Public and private philanthropic funding is subject to politics, local particularities, and changing priorities. Fear and mounting panic often drive a surge of funding for emerging infectious diseases. With the 2014-2015 outbreak of Ebola in West Africa, governments and charities pledged nearly US\$8 billion for control programs and R&D. But once an outbreak recedes, funding invariably does as well. Meanwhile, endemic infectious diseases like malaria and tuberculosis do not generate a similar response. They infect large numbers of people, but they have little money to pay for life-saving products, and because they are not perceived as an imminent threat to wealthier nations, they attract less funding. Finally, although governments may have significant resources, priority-setting and decision-making processes can be spread across several different agencies, with independent mandates and funding processes.

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*10 Reasons to Invest in Global Health R&D*

Global Health R&D:

1. Saves lives
2. Creates jobs and opportunity for [donor country citizens]
3. Helps countries maintain competitive edge in the global economy
4. Benefits citizens and soldiers when they are abroad
5. Supports research universities and fulfills students' interest
6. Intersects with domestic R&D to drive cutting-edge medical discovery
7. Contributes to economic development and export markets
8. Investments save money in the long term
9. Is supported by a majority of Americans – and likely the citizens in other G7 countries
10. And finally, global diseases do not recognize national borders

Adapted from: *Research!America's Top 10 Reasons to Invest in Global Health R&D*<sup>13</sup>

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### *Proposed Solution*

More funding is needed for all stages of innovative global health R&D in order to secure critically needed vaccines, diagnostics, medicines and other tools. We propose that the G7 should double their investments in global health innovation over the next five years to ensure a robust pipeline of new products that will radically improve the health of the people who need them. This applies to ongoing initiatives as well as the need to explore the establishment of a funding mechanism to support the development of vaccines for emerging infections and epidemics for which there is no market incentive such as Ebola, Marburg and Lassa infections.

We propose, in particular, that Japan initiate this doubling with a pledge to double its investment in innovative global health R&D, beginning with a replenishment of the Global Health Innovative Technology (GHIT) Fund. This Japanese model is demonstrating that pairing front-loaded investments with incentives for partnerships among research institutions and the pharmaceutical industry is highly effective in accelerating global health innovation. Within three years since its conception, GHIT has invested in more than 40 potential products, facilitating the use of Japanese technology in the process. Further, the government funding invested through GHIT is leveraged one-to-one with contributions from philanthropic and corporate partners.<sup>15</sup> With this strong foundation, GHIT's partners are poised to generate major contributions to global health innovation, particularly as industry partners are engaged early in the process. Doubling Japan's financial commitment would also push Japan into the top ten public funders of global health research and product development (for more detail see Figure 2 in Appendix A).

## **II. Streamline Regulatory Review Processes Globally**

### *The Problem*

Regulatory policies are critically important – they exist to ensure the safety of consumer products. However, in most instances, each country requires the data for each new vaccine, diagnostic or medicine to be reviewed and approved by its national regulatory agency (NRA). In some instances, the NRA may require additional clinical trials to be conducted locally. The many requirements, some of which are redundant, and the pervasive lack of adequate resources at the NRAs in developing countries, contribute to notoriously slow review and approval process timelines.

Should individual countries actually have to act independently in these processes, especially if they lack the capacity to do so efficiently? This brief argues that supranational policies or practices could be used to expedite approvals for new vaccines, diagnostics and medicines for priority endemic diseases.<sup>16</sup> Already, international law allows regulatory review processes to be expedited in cases of “public health emergency of international concern”. For Ebola, WHO served as a convening body which negotiated expedited regulatory processes for new tools. A vaccine and other products were moved into clinical trials in a matter of months rather than years.<sup>17</sup> When, inevitably, there is another outbreak in the future, critical tools will be available which did not exist this time around.

Yet as these approvals jumped ahead in the queue, other products for endemic diseases continue to languish for years.<sup>18</sup> WHO's “pre-qualification program” for essential medicines aims to obviate some of the obstacles. The program, which generates “unified standards of quality,

safety and efficacy/performance” for use in product assessment, offers one proven model for avoiding redundancies in regulation.<sup>19</sup> Other models include the *Pan American Network for Drug Regulatory Harmonization* and the unified registration procedures of the European Union. These examples indicate that it is possible to engage nations in harmonizing and streamlining regulatory mechanisms in order to expedite reviews and approvals of new vaccines, diagnostics and medicines for priority diseases. Policy options to consider would include the use of surrogate endpoints (e.g., biomarkers) for licensure, priority and/or expedited licensing mechanisms for diseases with low market potential and the facilitation of mutual recognition of licensure among countries, based on common technical guidelines.

Regulatory processes can be difficult to change. Achieving reform through legislation necessitates the engagement, and ultimately the agreement, of high-level decision makers. And if the intent is to create supranational policies and structures, lawmakers may have concerns about national autonomy, maintaining standards and protecting citizens.

### *Proposed Solution*

In the short-term, G7 countries should empower WHO or other convening bodies to establish an expedited path of review for new products for infectious diseases or to combat antimicrobial resistance. Over the longer term, the G7 should convene stakeholders to design a process to streamline national regulatory processes, as well as to invest in building capacity within the NRAs.

## **III. Create Efficient Mechanisms for Collaboration and Knowledge-Sharing**

### *The Problem*

When a highly infectious disease outbreak like Ebola occurs, leaders and policy makers frequently commit resources to creating new tools. Time and again, however, as the various actors rush to implement a flurry of activities, some efforts are needlessly duplicated while large gaps exist. Developing mechanisms for working collectively emerge more gradually.<sup>20</sup> Intense global collaboration is required to minimize the damage and control further spread.<sup>21</sup> As was evident during the Ebola outbreak, however, sharing information and knowledge can be an endeavor fraught with difficulties.

Further, the urgency and the resulting political commitment is often lacking when addressing endemic diseases and AMR. And in many instances, the collaborations that do emerge are bilateral, not global. The lack of an efficient global “ecosystem” for sharing and coordinating activities significantly hampers the ability of funders to pursue innovations in global health product development. Prior initiatives aimed at coordinating work across multiple funders and organizations have been perceived as adding work without bringing the desired benefits of efficiency and effectiveness. Even the creation of coordination mechanisms faces duplication, as new funding mechanisms, frameworks and collaboration platforms are developed. While the major global health innovation funders also agree that better collaboration and knowledge sharing could speed support for innovations, many stakeholders are skeptical of ceding authority, proprietary information or priority-setting to a third party.

The challenges of incentivizing and facilitating information-sharing among global health innovators was acknowledged by the G7 during its 2015 meeting in Schloss Elmau, Germany. However, concrete steps to improve the situation have not been forthcoming.

### *Proposed solution*

Japan can lead the G7 to build on the foundation laid in Germany. The Ise-Shima Summit offers an opportunity to follow up by clarifying a process and concrete milestones for the rapid development and deployment of functional global platforms to allow information-sharing, knowledge dissemination and creation of collaborative efforts across national and regional lines and among public, philanthropic and for-profit sectors. A G7 commitment to develop and announce a plan to realize this solution by the 2017 G7 Summit is achievable.

## **The Way Forward: Implementation Considerations**

The world's arsenal of tools – vaccines, diagnostics and medicines, among others – against infectious diseases remains insufficient, particularly when considering endemic diseases in poor countries. Effective vaccines and medicines are not yet available for prevalent killers. Powerful existing diagnostic technologies are often unsuitable for widespread use in the developing world. And for many existing medicines, the formulations and costs present insurmountable problems in patient access and adherence. Further, the development of AMR threatens the many gains that have already been made.

Global health innovation is therefore necessary to sustaining and expanding efforts to control and eradicate infectious diseases with heavy global burdens. Yet while developing countries experience a disproportionate burden of infectious disease, the majority of funding remains in high-income countries, and among for-profit companies. This results in a lack of urgency, poorly aligned incentives, and ineffective market structures.

The 2016 Ise-Shima G7 Summit offers nations a critical opportunity to develop and promote new mechanisms to incentivize global health innovation and to increase global public accountability. The Summit is a chance to create blueprints for increasing innovation in the discovery, development, and regulatory approval of essential new vaccines, diagnostics, and medicines.

The following steps are therefore recommended for consideration by Japan and its colleagues at the G7 Summit:

1. **Double the current global funding for global health innovation.** We recommend setting a global goal of reaching US\$6.4 billion per year for global health R&D within ten years. This level of funding would enable a sea change in GHPD, in particular by making later stage clinical trials possible. Japan, for instance, could lead by doubling its support to initiatives such as the GHIT Fund.
2. **Convene a process to harmonize and streamline regulatory pathways.** Allowing endemic and emerging infectious diseases, as well as instances of emerging anti-microbial resistance, to be eligible for accelerated and/or coordinated review will reduce duplication and time to market for new products. Further, additional resource capacity for regulatory review must be developed in endemic country governments. Japan can support high-level meetings to champion harmonization of policies.
3. **Initiate a process to follow through on establishment of knowledge-sharing platforms for global health innovation.** The G7 countries have already made commitments in this area; now, with Japan as the organizer, next steps need to be elaborated to support platforms to share information on global health R&D strategies in order to identify

duplication, encourage collaboration and limit gaps. A commitment to announce a plan to realize this solution by the 2017 G7 Summit is achievable.

A significant increase in funding, a more streamlined process for product approval, and a global platform for collaboration would, together, lead to more innovation. Establishing and advancing a robust pipeline for, and portfolio of, new products we need to control, eliminate, and eradicate infectious diseases. These diseases continue to pose significant risks to human security and health; they also menace the global economy.

At this Summit, the G7 countries have an unprecedented opportunity to radically transform the environment for global health innovation; Japan, which is known for its support of health innovations and global health policy, can offer critical leadership by championing these recommendations.

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# **Appendix A: Backgrounder on the Global Landscape for Developing New Vaccines, Diagnostics and Medicines for Infectious Diseases**

## **Introduction**

Today, diseases like malaria, HIV and tuberculosis are the leading cause of death in children worldwide<sup>22</sup>. Infectious diseases are a persistent threat to global economic growth, health, security, and human development in many of the world's poorest countries. Each year the major diseases kill almost nine million people, many of them children under five. They also cause enormous burdens of life-long disability that disproportionately impact those who are poor<sup>23</sup>. Stepping up research and investments into Global Health Product Development (GHPD) that can effectively treat infectious diseases and prevent them from spreading could have an enormous impact on fulfilling global commitments to lift people out of poverty and build a better world for future generations.

Considerable progress has been made in controlling and even eradicating some infectious diseases in some nations. However, progress has stalled in many areas. Getting the right treatments to those who need them most remains a challenge. Further, new tools are needed to sustain and expand control efforts. Many infectious diseases are still under-researched and poorly understood, and the innovations to address them are of limited commercial interest. This paper focuses on the state of research and development of new vaccines, diagnostics, and medicines to combat infectious disease.

## **An Innovation Gap**

Despite the widespread need for many new vaccines, diagnostics and medicines for infectious diseases, innovator companies and manufacturers see few incentives to invest in developing and producing the products. Among the twenty endemic infectious diseases shown in Table 1, only one has an effective vaccine available. Most diagnostics that do exist cannot be properly used in developing countries. Available medicines for infectious disease have safety and efficacy limitations. Other than HIV/AIDS medicines and dengue vaccines, most of the needed tools for these diseases could not yield enough of a market return to make them an appealing investment<sup>24</sup>.

**Table 1: Current Repertoire of Vaccine, Diagnostics, and Drugs for Endemic Diseases**

	Vaccine	Diagnostic	
HIV/AIDS	No	Yes	Yes –treatment but not cure
Tuberculosis	No	No – low tech, rapid dx needed	Yes – treatment and long timeline to cure
Malaria	Yes – limited protection	Yes	Yes – one dose cure needed
Buruli Ulcer	No	No – clinical symptoms	Yes – 80% cure rate but oral treatment sought
Chagas Disease	No	No	Yes – better drugs needed
Dengue and Chikungunya	Yes (Dengue)	Yes	No
Dracunculiasis	No	Yes – with limitations	No – cure is through worm extraction
Echinococcosis	No	No	Yes – in addition to surgery
Endemic treponematoses	No	No – clinical symptoms	Yes
Foodborne trematodiasis	No	No	Yes
Human African trypanosomiasis	No	Yes – with limitations	Yes – better drugs needed
Leishmaniasis	No	Yes	Yes – oral drugs with few side effects needed
Leprosy	No	No – clinical symptoms	Yes -
Lymphatic filariasis	No	Yes – with limitations	Yes – better drugs needed
Oncocerciasis	No	Yes – with limitations	Yes – treatment but not cure
Rabies	Yes – post bite	No	No
Schistosomiasis	No	Yes – with limitations	Yes
Soil-transmitted helminthiasis	No	Yes – with limitations	Yes – treatment not cure
Taeniasis/Cysticercosis	No	No	Yes – drugs needed for neuro stage
Trachoma	No	No	Yes

The need for innovation in GHPD efforts goes beyond just expediting the development of new drugs. We need to be improving upon the products already on the market. Many of the available treatments for infectious diseases were developed decades ago and their effectiveness is diminishing due to anti-microbial resistance (AMR)<sup>26</sup>. This is not a hypothetical threat. From the 1970s through the 1990s, malaria deaths in Africa, and globally in children under 5, rose sharply due to resistance to the affordable drug chloroquine<sup>27</sup>. The compounding effect of increasing AMR and a slowdown of new antibiotics discovery have created new challenges for treating infectious diseases.

To counter the lack of a commercial incentive, governments and foundations are increasingly partnering with industry to convert important scientific research into needed products. This investment has grown dramatically to US \$3.2 billion in 2013<sup>28</sup>, and the pipeline of products has increased substantially over the past two decades. But that level has plateaued and this pipeline needs to grow if we are to address the demand. New innovation is vital to control, eliminate and eradicate infectious diseases that primarily affect those who are poor.

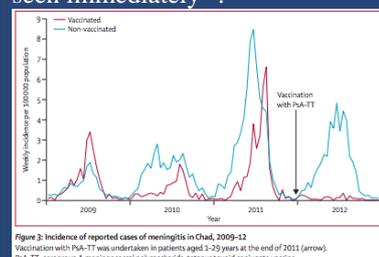
## GHPD: An Overview of the Product Development Landscape

There is no one entity in the public or philanthropic sectors that manages the innovation pipeline for infectious diseases. The coordination of activities and the sharing of knowledge are largely bilateral

### Case Study Box:

#### MenAfriVac Success

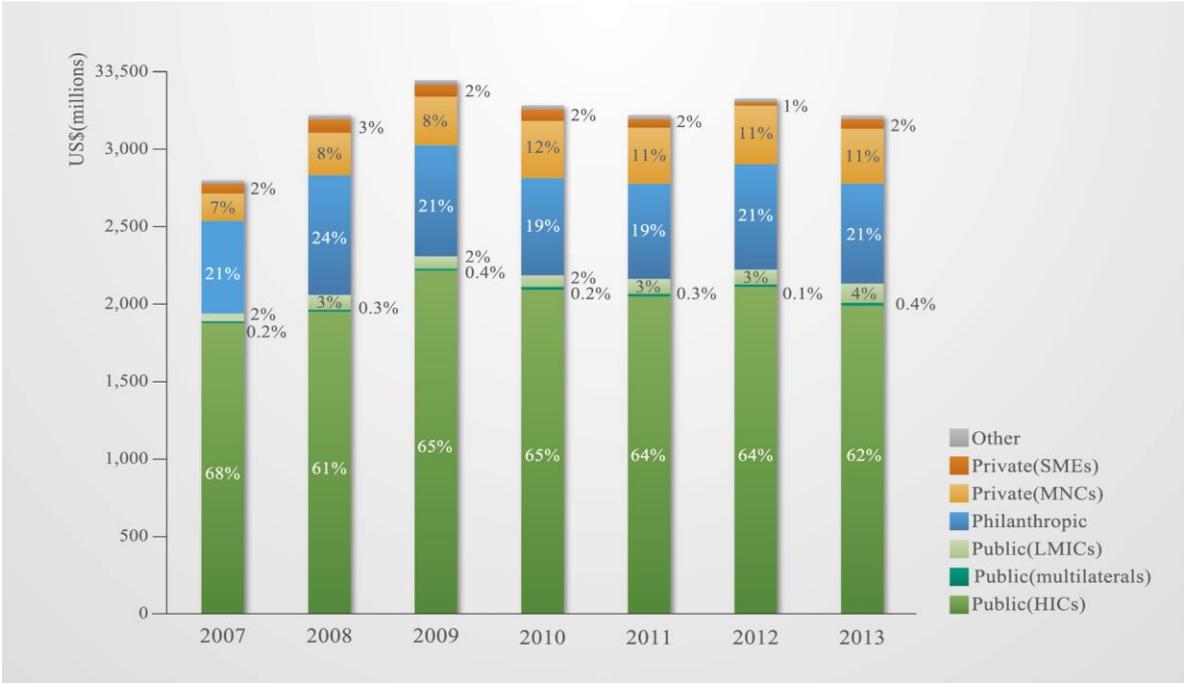
Sub-Saharan Africa is known for its consistent outbreaks of meningitis within thirteen countries composing “the Meningitis belt.” MenAfriVac was developed through a public private partnership and introduced in the affected countries in 2010. A dramatic decrease in cases was seen immediately<sup>25</sup>.



rather than global, and agreements are non-binding. Early stage innovation can be driven by an individual funder or a partnership of organizations, investors, and countries. Below is an outline of the various sectors and entities that are investing in and developing new GHPD.

Today, Over 80% of the GHPD efforts are funded by governments and foundations<sup>29</sup> (Figure 1), with the vast majority of funding from the world’s high-income countries (HICs). In 2013, the United States government was the largest funder of global health R&D – investing more than ten times The European Commission, the second top funder (Figure 2).

**Figure 1. Total R&D funding by sector 2013**



**National Governments**

National governments primarily finance global health R&D in three different ways: 1) through investigator initiated research led by the government (24% of total funding), 2) through investigator initiated grants to research institutions and companies (59% of total funding), and 3) by granting money to Product Development Partnerships (PDPs) and other intermediaries (17% of total funding). The bulk of government funding is often directed to the early development phases of pharmaceuticals, with less money being devoted to later-stage clinical trials

**Figure 2. Top Public R&D Funders 2013**

Country	US\$(millions)							2013 % of total	2007-2013 trend
	2007	2008	2009	2010	2011	2012	2013		
United states of America	1,381	1,402	1,617	1,540	1,507	1,605	1,432	67	
European Commission	132	143	130	101	117	104	123	5.8	
United Kingdom	99	101	141	155	125	88	120	5.6	
France	17	32	53	44	67	59	92	4.3	
India		38	25	39	43	43	50	2.4	
Germany	13	4.1	38	41	35	61	49	2.3	
Australia	25	34	31	34	43	54	28	1.3	
Netherlands	37	30	32	20	27	17	26	1.2	
Canada	22	26	19	11	11	20	22	1.0	
Brazil	27	29	38	13	14	25	20	0.9	
Switzerland	8.0	5.1	9.1	16	16	18	18	0.9	
South Africa	4.1	5.3	7.5	8.1	7.3	5.9	13	0.8	
Subtotal of top 12*	1,826	1,909	2,182	2,041	2,048	2,113	1,994	94	
Total public funding	1,946	2,061	2,323	2,194	2,163	2,232	2,128	100	

In the U.S. and other HICs, global health R&D spending are spread across multiple agencies, which can lead to cumbersome and inefficient processes. Advocacy groups have called for a “whole-of-government approach for global health R&D” to reduce silos, and increase transparency and information-sharing across agencies. When this issue is expanded to multinational global health efforts, it quickly becomes apparent how exceedingly difficult it is to align toward a single objective.

In addition to providing financial support, governments can also create policy initiatives, such as the Orphan Drug Legislation (ODL) and the Priority Review Voucher (PRV), which both have enabled the development of products for rare diseases and could foster greater GHPD.

## Philanthropy

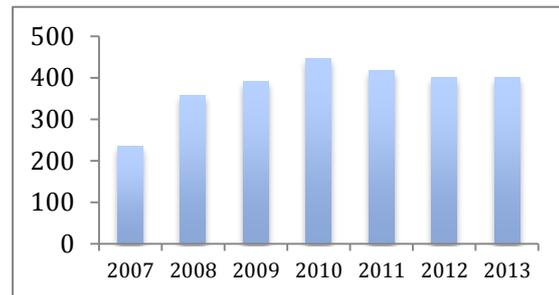
Philanthropic investments in global health R&D comprise a little more than one-fifth of total funding. And just two foundations – the Wellcome Trust and the Bill & Melinda Gates Foundation— account for nearly all of this contribution<sup>30</sup>. Both organizations have broad global views of the product development pipeline for diseases they fund, conduct considerable due diligence prior to funding, and continue to influence product decisions for funded projects.

At the Gates Foundation, grantmaking decisions are usually made internally by Foundation staff, although some funding decisions may be outsourced to Product Development Partnerships (PDPs) or organizations such as the Foundation for NIH, which manages the Grand Challenges program. The Wellcome Trust has an internal staff structure that’s similar to the Gates Foundation and many of their funding decisions are made by external committees.

## Industry

Biotechnology and pharmaceutical companies are integral to product development and innovation. Prior to the 1980s, these companies played an enormous role in developing life-saving treatments for infectious diseases, but the epidemiological transition to non-communicable diseases and the push for profits changed their positioning. Citing high research costs, poor returns, and onerous regulations, drugmakers have lagged in finding needed treatments for the infectious diseases plaguing dozens of poor countries.

**Figure 3. Industry Funding for GHPD**



In the late 1990s, the public sector emerged as a strong partner to industry, a move that dramatically sparked engagement and activity. In FY 2013, pharmaceutical companies spent \$400 million on global health R&D and that number continues to increase through expanding research initiatives<sup>31</sup> (Figure 3).

## Product Development Partnerships

Product Development Partnerships (PDPs) are independent, nongovernmental organizations that manage large product portfolios in a number of diseases and interventions. Over 16 PDPs<sup>32</sup> cover the focus areas of HIV, malaria, tuberculosis and neglected tropical diseases (NTDs). PDPs have been termed “intermediaries” as they collect and consolidate funding, primarily from national governments and philanthropies, and then partner with academic researchers and private companies. The primary advantages of the PDPs are 1) understanding and working across the pharmaceutical discovery, development, delivery continuum, and 2) the speed and flexibility to fill gaps and partner with minimal bureaucracy. About 20% of total funding (\$482 million) from charities and governments was programmed through PDPs in 2013<sup>33</sup>.

## Purchase Funds

Purchase funds play an important role in shaping the product market for needed drugs, vaccines and diagnostics as they provide a vital procurement link that has been missing from other efforts. The creation of entities such as the Global Alliance for Vaccines and Immunization (GAVI) and the Global Fund for AIDS, Tuberculosis and Malaria in the early 2000s brought billions of dollars of financing to the improvement of health delivery systems and purchasing power to poor countries for lifesaving drugs, vaccines, and diagnostics.

Over 500 million children have received DPT-HIB, Hepatitis B, measles, rotavirus, and pneumococcal vaccines thanks to GAVI, saving 7 million lives. GAVI follows the Advanced Market Commitment (AMC) process that provides an assured market to pharmaceutical companies that will create and mass produce pneumococcal vaccines that meet developing country needs.

## New Models of Global Health R&D

The Global Health Innovative Technology (GHIT) Fund is a unique collaboration between the Government of Japan, five of Japan’s largest pharmaceutical companies, the Bill & Melinda Gates Foundation and the United Nations Development Program. Founded in 2013, the GHIT Fund has increased Japan’s R&D contributions to infectious diseases more than five-fold in one year, from US\$2.4 million in 2012 to more than US \$12 million in 2013.

While the GHIT Fund views global health as an investment with tangible returns, it treats its R&D grants as an investment without a financial return. The pharmaceutical companies that contribute to

GHIT are encouraged to work across sectors and leverage international partnerships to develop new products.

In just two-and-a-half years since it was formed, GHIT has invested in the development of more than 40 new products, with allocations totaling more than US \$50 million. As of 2015, GHIT is advancing six clinical trials in Burkina Faso, the Republic of Côte d'Ivoire, Tanzania, Uganda, Thailand, Peru, and Bolivia, and two more clinical trials will begin in 2016. The first product is scheduled to complete development in 2018. As a novel model for funding product development, GHIT is transforming the portfolio for infectious disease products for Japan and the global community.

Similar to GHIT, the Global Health Investment Fund (GHIF), headed by the Bill & Melinda Gates Foundation, aims to increase collaboration between investors and provide long-term funding for GHPD<sup>34</sup>. Launched in late 2013, GHIF will finance late-stage clinical trials of high-impact drugs, vaccines, and diagnostic tools, specifically focused on reducing childhood death rates. Sponsors and partners include pharmaceutical companies, charities, investment banks, and governments. GHIF has yet to publicly announce its first investment.

## Global Health R&D Ecosystem

Global investments in technology and R&D are pivotal to supporting innovation, and must be well-managed to effectively create and produce life-saving treatments. We need to find innovative methods to translate and customize health interventions and products to local settings, and engage communities so that these treatments are administered in the long-term.

The World Health Organization plays a substantial role in this effort. In some cases, it occasionally serves as de facto regulators for countries lacking a recognized national regulatory agency, and frequently creates policies for the use of new drugs, vaccines and diagnostics. Both of these processes are essential for moving an infectious disease drug, vaccine or diagnostic into the marketplace. But few would call these processes innovative or even efficient.

On a more global scale, there is no mechanism for creating and maintaining a “rational” portfolio of pharmaceutical products. While that work is in the domain of the funders and it is unrealistic to expect the champion of a specific new drug or vaccine to step back from their proprietary interests, more can be done to better coordinate a global portfolio to reduce duplication and focus resources on the highest value projects.

## Conclusion

The leading developed nations and philanthropies have identified innovation as a key strategy for controlling, eliminating, and eradicating infectious diseases. The global ecosystem that would align those strategies and bring efficiency to that effort does not currently exist.

The emergence of new institutions, partnerships, and funding streams focusing on infectious diseases is proof that there is political will and hope for the eradication of these maladies. However, it is still not sufficient. A significant increase in funding for the discovery, development and delivery of new drugs, vaccines and diagnostics and enhanced global collaboration would create a much-needed sea change in GHPD.

The scientific community, especially in countries heavily burdened by infectious diseases, needs a more enabling environment to access resources and share knowledge that can contribute to new treatments and disease control efforts. Partnerships need to be forged and sustained to capitalize on resources and to build capacity for R&D on emerging infectious diseases like Ebola, MERS, and SARS. We need to view all global infectious diseases as a public health emergency that warrants a coordinated international response.

# Appendix B: Interviews with Top Global Health Product Development Funders

## I. Objective

Interview top funders in global health product development (GHPD) to better understand how GHPD fits into their overall infectious disease strategies, how they convert strategy into grants to product developers, and the barriers—“bottlenecks”—they and their grantees experience.

## II. Methodology

This study was conducted with an inductive approach using qualitative research. Seven interviews were conducted using a semi-structured interview method. The data were collected, coded and analyzed for key themes. The results are presented in this appendix.

### A. Interview Selection

The target groups consisted of 1) top public GHPD funders who are G7 members, and 2) top philanthropic funders.

#### *Public Funders*

The top ten public funders were identified using the 2014 G-FINDER study “Neglected Disease Research and Development: Emerging Trends”<sup>35</sup>. Six of the top ten funders are members of the G7. Invitations were issued to the six G7 members, and five were interviewed. The interview with Canada was unable to be interviewed due to scheduling. The only G7 members not among the ten largest public funders in 2013 were Japan and Italy.

#### *Ten Largest Public R&D Funders*

1. United States
2. European Commission
3. United Kingdom
4. France
5. India
6. Germany
7. Australia
8. Netherlands
9. Canada
10. Brazil



#### *Ten Largest Funders who are G7 Members*

1. United States
  2. European Commission
  3. United Kingdom
  4. France
  5. Germany
  6. \*Canada
- \*Unable to be interviewed due to scheduling.

The five G7 members interviewed comprise 86% of public GHPD funding, and 57% of total funding.

#### *Philanthropic Funders*

The top ten philanthropic funders were identified using the 2014 G-FINDER study<sup>36</sup>. Funders who contribute more than 10% of the total philanthropic funding were chosen for the study. The Bill & Melinda Gates Foundation (75%) and the Wellcome Trust (19%) were invited to participate.

### *Ten Largest Philanthropic R&D Funders*

1. Gates Foundation
2. Wellcome Trust
3. Gavi
4. MSF
5. Fundacio La Caixa
6. UBS Optimus Foundation
7. MMRF
8. amfAR
9. Medicor Foundation
10. General public



### *Philanthropic R&D Funders (>10% of total sector)*

1. Gates Foundation
2. Wellcome Trust

The combined funding of the respondents is US\$2.48 billion or 77% of the total 2013 funding.

## B. Interview Methodology

### *Interview Guide*

High-level experts in government agencies and the two philanthropies were identified through GHIT. An interview guide was developed based on direction from the Global Health Working Group and used for all interviews. Three questions guided the research:

1. What is the role of product innovation in the control, elimination, and eradication of infectious diseases for different funders?
2. What approaches do different funders use for the discovery, development and delivery of product innovation?
3. What are the bottlenecks to achieving these product innovation strategies?

### *Data Collection*

Seven interviews were held. Qualitative data were collected in one to one, semi-structured interviews via telephone in August – September 2015. An independent researcher with over 20 years of experience in GHPD was hired to conduct the interviews and the analysis. Each interviewee gave verbal informed consent to participate in the study prior to being interviewed.

*This semi-structured interview is aimed at learning more about your organization's strategy and decision-making process for funding of the discovery, development, and delivery of global health innovation. The information from the interview will be used solely to inform the work of the GHWG. No presentation or discussion of an individual organization's strategy and decision-making processes would be shared outside the use of the GHWG. A public report summarizing aggregate observations may be developed. Do you consent to be interviewed?*

The notes were typed into the interview guide by the consultant during the interview, and were reviewed for completeness and clarity immediately afterward. A daily interpretive analysis was conducted on the interview days to ensure integrity of the data with the passage of time.

### *Data Analysis*

A thematic analysis approach<sup>37</sup> was used to analyze and interpret the data. Provisional insights referencing the three guiding questions were recorded, and a list of initial codes was developed. Following completion of the interviews, the raw interview notes were coded. The primary codes included:

- The role of product development in the control of infectious diseases
- Methods for determining product development strategy
- Sources of information used for product development strategy formation

- Methods for providing funding to product developers
- Decision-making processes for product development project grants
- Sources of information used for grant-level decision making
- Lessons learned from Ebola
- Barriers or “bottlenecks” to converting their strategy into results
  - Funding
  - Regulatory
  - Collaboration
  - Knowledge sharing
  - Links to Delivery/Target Product Profiles (TPPs)
  - Focus and momentum

For coding of the barriers, each phrase was first coded as “barrier.” These phrases were then sub-coded as to the type of barrier as noted above. The barriers were analyzed for frequency of occurrence across interviews.

### III. Results

#### A. Global Health Product Development Strategy Formation

##### *Focus on infectious diseases*

Each government and foundation interviewed devotes considerable resources to global health, and infectious disease control, elimination, and eradication figure prominently in their programs. The stated rationales for significant investments in infectious disease differ, but fall into two categories: 1) ensuring global stability and security, and 2) addressing global inequities. This rationale is driven by political imperatives, as in the case of Ebola, and by evidence of disease burden, as in the cases of HIV, tuberculosis and malaria.

*“Why does the government fund anything? To remain stable and productive.”*

*“Our approach is based on solid epidemiology. We examine the data, and decide where to intervene to make the most impact.”*

##### *Focus on innovation*

Each government and foundation interviewed features innovation prominently in its strategies to control, eliminate and eradicate infectious diseases. All stated that the available tools to fight these diseases are inadequate; effective vaccines are not yet available for the biggest killers, the available drugs do not fit modern technology product profiles, and very few of the powerful diagnostic technologies available are suitable for the developing world. In addition, the respondents represent countries and foundations with extremely strong research bases. The desires to expand the impact of those scientific resources beyond national borders and to help the poor were cited frequently as reasons to focus on innovation.

*“[W]e try to use R&D as a basis to propel innovation and commit ourselves to internationalizing our innovation system.”*

*“Our strategy is based on scientific approaches. Let’s develop the best science and see where that leads us to impact on a disease.”*

Respondents stressed that progress against infectious diseases has been made, but innovation is necessary to maintain control efforts and to expand toward elimination and eradication. The theme of “market failure” was cited frequently by respondents as the reason that government and philanthropic involvement and funding are critical.

*“We have made progress but we have major gaps in the tools needed to fight infectious diseases.”*

*“[N]o vaccine for TB, no malaria vaccine with high efficacy, no single dose radical cure for malaria. We have not yet cracked the science that will get to the solutions.”*

*“For poverty-related diseases, there is a market failure. The proper incentives for the pharma industry do not exist.”*

### *How innovation strategies are developed*

Government respondents report that in addition to scientific evidence, political interests are major drivers of their innovation strategies. Politicians decide strategy at the highest levels, and provide direction to the agencies charged with controlling infectious diseases. Advocates lobby politicians and government agencies for their ideal solutions. The political agenda is melded with the scientific expertise of agency leaders to form specific innovation strategies. Examples cited include:

- United States - The primary themes of government are security and stability so emerging threats such as Ebola are a political priority.
- France - The politicians in France pushed for innovative financing, leading then-president Jacques Chirac to propose an airline tax to fund global health R&D. This money (over US \$1 billion) is provided to UNITAID, which grants money to specific projects.
- United Kingdom – In the product development space, the U.K. government highly values collaboration with other donors.
- European Commission – The EC focuses on funding science that is conducted by partnerships between European countries.

The two largest philanthropic funders of GHPD are the Bill & Melinda Gates Foundation (U.S.) and the Wellcome Trust (U.K.). Their strategies are formed internally by Trustees and staff, with varying degrees of external input. Both foundations described their strategies as evidence based, relying on rigorous analysis to drive their decision-making.

All the responses on this high-level strategy formation cited drivers that are primarily internal to the government or foundation. It was not until specific product development strategies were discussed that respondents cited the importance of external sources of information and collaboration.

## **B. Approaches to the Discovery, Development and Delivery of new Drugs, Vaccines and Diagnostics**

Each funder reported using different mechanisms to convert its innovation strategies into product development activities. Some work across the spectrum of product development from discovery through delivery, while others focus primarily on the discovery and development phases.

The largest funders reported using a mix of intramural funding, investigator-initiated grants, contracts with companies and suppliers, and grants to product development partnerships (PDPs) to achieve their innovation strategies. Smaller funders, or those with few technical staff, report primarily programming their funding through PDPs because they have their own technical staff and many independent experts advising them. Funds like UNITAID and GHIT also serve this role.

The majority of government respondents stated that they have more than one agency in the country funding product development. Research agencies usually fund more basic research and discovery activities across the spectrum of infectious diseases, and are less often funders of late stage clinical trials. The overseas development assistance agencies often fund product development aimed specifically at new vaccines, drugs and diagnostics. Biosecurity agencies focus resources on emerging diseases and emerging threats. It is common for several agencies in one country to be funding similar R&D work with little internal communication.

The funders were asked how they obtain information about the global portfolio of infectious disease products. Responses were similar among funders. They reported that technical staff attend scientific meetings and stay abreast of the scientific literature. These activities provide numerous opportunities for bilateral talks each year when funders exchange information and, in some cases, set up collaborations. WHO frequently convenes meetings on product development topics; for example, they convened meetings around the Phase 3 trial design and regulatory review of the GSK malaria vaccine, and they convened a meeting of donors and product developers working on Ebola R&D in 2015. Several respondents pointed out that funders use a very similar group of scientific experts for guidance and review and that this helps to carry information between different funders. When asked if they felt there was duplication in the global portfolio, respondents said they feel there may be a small amount, but stressed that some amount is important to increase scientific validity.

### C. Barriers to Global Health Product Development

Respondents were asked to identify the major barriers to achieving their GHPD strategies. This was first asked as an open-ended question. Following this question, a specific follow-up question was asked on the effectiveness of current knowledge sharing and collaboration efforts around the management of the global portfolio of drugs, vaccines and diagnostics. The barriers are presented in order of priority as determined by the frequency with which they were cited by respondents.

#### *Funding*

Lack of sufficient funding for R&D was cited as the most significant barrier by each interviewee. Raising new funds was seen as difficult as there are many competing needs and priorities for governments. The view expressed by many was that more money in the system would provide greater returns than any other potential intervention.

*“It is a long and expensive process to develop drugs, vaccines, and diagnostics. The costs are a problem over time.”*

*“Industry is not set up to automatically engage based on their business model. We have to be creative to incent their involvement.”*

*“The bottlenecks identified are usually things money can solve.”*

#### *Regulation*

One specific policy arena cited by several funders as a barrier is the regulatory ambiguity in the licensure of products that will be used in developing countries that lack a strong national regulatory agency. One respondent noted that the regulatory process for malaria vaccines was being created as the lead vaccine was in clinical trials. Several respondents noted that regulatory processes are accelerated when faced with outbreaks like Ebola, but for endemic diseases and AMR they are still a source of significant delays.

*“The most pain is in countries that don’t have NRAs [National Regulatory Authorities] and experience with clinical trials.”*

*“It [international regulatory system] has never worked well. We should take the lessons learned from Ebola. Maybe the G7 could be a key player in this.”*

### *Review Processes*

Government respondents explained that they are directly accountable to politicians and citizens for their investments. Part of that accountability is addressed through peer review processes. Respondents said that peer review creates a conservative approach where it is challenging to introduce new ideas, especially when the science behind the product is very complex. Two respondents expressed that the research community makes it challenging to fund a smaller number of large projects (needed to solve complex problems) because of the fear of losing funding. Other respondents stressed that each “disease community” operates very differently and it is hard to generalize from one to the next. Nearly all funders interviewed used the peer review process to determine funding decisions, but many expressed concerns that this may not be the best way to make product development decisions.

*“Many reviewers are siloed in fields they know very well, but they do not have the multi-disciplinary view required for product development.”*

### *Linkages to Delivery*

Many of the funders of innovation stated that they have a more natural fit with the discovery and development phases and not as much with the delivery space. They rely on others to develop Target Product Profiles aimed at bringing the field’s needs into product development considerations. There is a feeling expressed by some respondents that the TPPs do not really represent the realities of the situations in clinics and hospitals but rather represent a researcher’s interpretation of what is needed. Some funders worry that the TPP process may not fully take into account the psychosocial factors that can make or break the introduction and scale-up of a new intervention. This lack of confidence limits their ability to use the TPPs in product development decision making.

### *Momentum*

Respondents noted that maintaining focus and momentum on initiatives in a political environment could be very challenging. Several respondents from government agencies stated that the political environment tends to react to issues that have the greatest public concern. It was noted that significant funds were allocated to Ebola during the height of the outbreak, but that those funds are diminishing as the current risk recedes. As most of the burden of infectious diseases is in developing countries and most of the funding is in high-income countries, the public accountability for that spending will never be as strong. Respondents stressed the importance of the focus that the G7 could bring as it would raise the accountability level above that of any one nation.

*“All are enthusiastic at the beginning. The problem is maintaining momentum over time.”*

*“Pandemics are disruptive. This is also true for malaria and more standard diseases. There is a huge imbalance of lives lost – we don’t want to over focus on pandemics.”*

### *Collaboration and Knowledge Sharing*

Specific questions on barriers in collaboration and knowledge sharing were asked following the open question on barriers, as these two areas have been a focus for the G7.

All respondents stressed that any proposed collaboration solutions be framed in terms of the problem that needs to be solved. Are efforts being duplicated? Can resources be invested more efficiently? Are there critical gaps that need investment?

Several respondents stated that their own governments or organizations are working to ensure a coordinated approach within their country or organization, but few cited known problems of significance when examined globally. Two respondents felt there is some duplication of effort in product development but could not name specifics. Others stated that they did not think there was a problem with duplication of activities and one simply stated that there is no evidence this is a problem. Several respondents stressed that some amount of duplication is healthy competition, and raises the validity of the results.

On the subject of duplication, respondents were more concerned with what they viewed as duplication in the “global architecture.” Examples of duplication of collaboration and information sharing efforts were cited, such as duplication of effort for the Global Health Primer and the Global Health Observatory. Funders are expected to participate in these efforts, and several of those interviewed were frustrated by the time and attention needed to make those agreements and try to make their reporting systems interoperable.

Three cautions were expressed in the interviews about creating new collaboration and knowledge sharing platforms. The first is the view that most initiatives aimed at “coordinating” the players and activities almost always add work and time without bringing the desired benefits of efficiency and effectiveness. The second was that any additional coordinating mechanisms should build on existing initiatives rather than creating something new and should have WHO at the center. The third was that most funders would not pool funds, or turn over their decision making to third parties. In addition, several respondents questioned whether the behaviors and decisions of the dominant funders would actually change in response to additional information or collaboration initiatives.

Respondents cited an “enormous amount of noise” in the system around new funding mechanisms, new frameworks, new collaboration platforms, etc. The conflicting briefings provided by advocacy groups to policy makers contributes to the churn, and dilutes the focus and energy of funding agencies.

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