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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[1]. 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[2]. 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[3].

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 trematodiases	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 helminthiases	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)[5]. 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[6]. The compounding effect of increasing AMR and a slowdown of new antibiotics discovery have created new challenges for treating infectious diseases.

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[4].

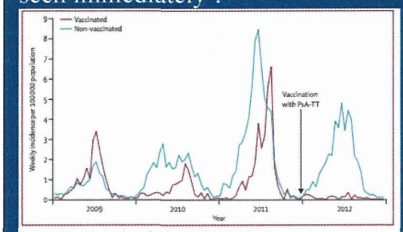


Figure 3: Incidence of reported cases of meningitis in Chad, 2009–12
Vaccination with PsA-TT was undertaken in patients aged 1–29 years at the end of 2011 (arrow). PsA-TT=serogroup A meningococcal polysaccharide-tetanus toxoid conjugate vaccine.

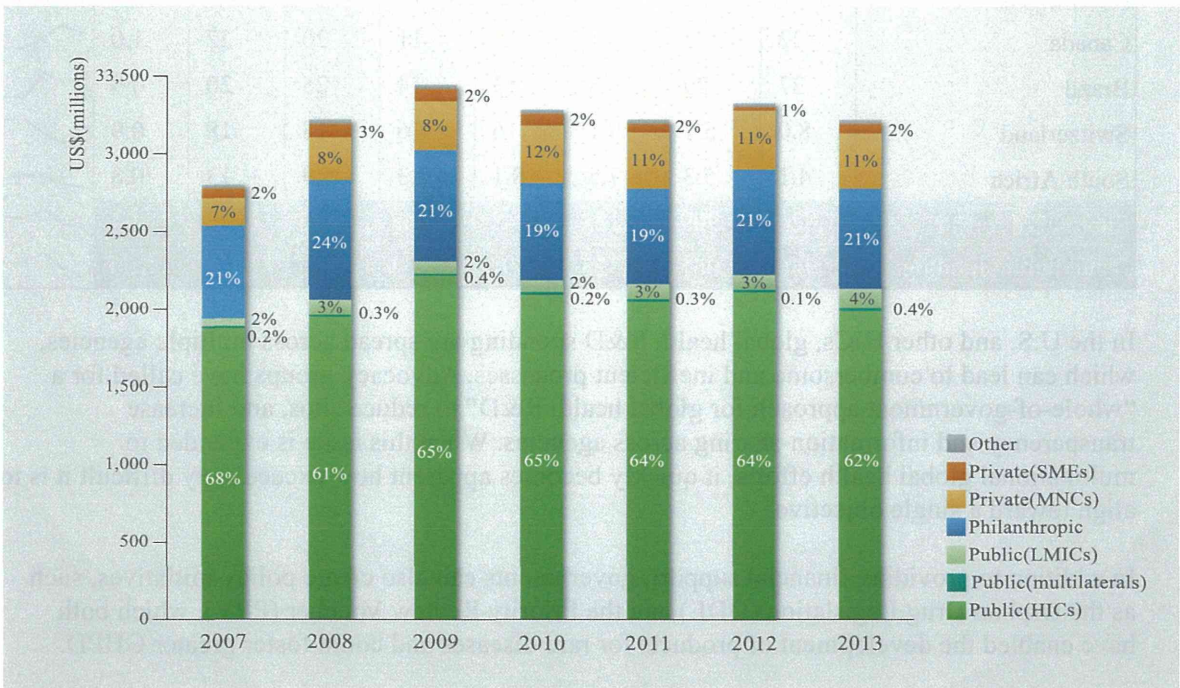
To counter the lack of a commercial incentive, governments and foundations are increasingly partnering with industry to convert important scientific research into needed products. This investment has grown dramatically to US $3.2 billion in 2013[7], and the pipeline of products has increased substantially 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 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[8] (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	
Europian 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

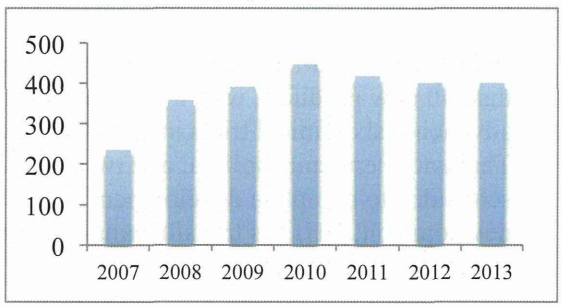
Philanthropic investments in global health R&D comprise a little more than one-fifth of total funding. And just two foundations – the Wellcome Trust and the Bill & Melinda Gates Foundation— account for nearly all of this contribution[9]. Both organizations have broad global views of the product development 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[10] (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[11] 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[12].

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[13]. 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

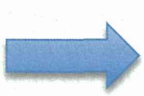
The target groups consisted of 1) top public GHPD funders who are G7 members, and 2) top philanthropic funders.

Public Funders

The top ten public funders were identified using the 2014 G-FINDER study "Neglected Disease Research and Development: Emerging Trends"[14]. 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

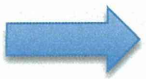
The five G7 members interviewed comprise 86% of public GHPD funding, and 57% of total funding.

Philanthropic Funders

The top ten philanthropic funders were identified using the 2014 G-FINDER study[15]. 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



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[16] 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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IV章　マヒドン皇子賞会議発表資料

Policy Recommendations for the 2016 G7 Summit in Japan: Toward Resilient and Sustainable Universal Health Coverage (UHC)

Date: Wednesday, January 27, 14:00–17:00
Venue: Lotus Suite 7, 22nd Floor
Centara Grand & Bangkok Convention Centre at CentralWorld

Objectives:
At this side event, members of the GHWG will present their draft policy recommendations for the G7 Ise-Shima Summit in May 2016 with an emphasis on governance for global health in response to and in preparation for health crises. Each sub-group of the GHWG will also present key findings from their studies that have been conducted to provide an evidence base for the GHWG policy recommendations.

Expected output/outcome:
The expected outputs from this side meeting are two fold: 1) To obtain comments and feedback from PMAC participants on draft policy recommendations for the G7 Ise-Shima Summit; and 2) to synergize the G7 process with the on-going global health policy debates to develop a concrete action plan for the G7 Summit agenda.

Program:

14:00-14:05 **Opening Remarks** [5 minutes]

Keizo Takemi, *Member, House of Councillors, Japan; Senior Fellow, JCIE* [Chair]

14:05–14:15 **Overview of Policy Recommendations for the G7 Summit from the GHWG** [10 minutes]

Kenji Shibuya, *Professor and Chair, Department of Global Health Policy, Graduate School of Medicine, University of Tokyo* [Moderator]

14:15–15:30 **Session 1**: Building Governance Architecture for Global Health to Improve Preparedness and Response [75 minutes]

Global Health Governance: Analysis and Lessons Learned from the Ebola Virus Disease Outbreak and the Identification of Future Response Options [15 minutes]

Hideaki Shiroyama, *Dean, Graduate School of Public Policy, University of Tokyo*

Yasushi Katsuma, *Dean, International Studies Program, Graduate School of Asia-Pacific Studies (GSAPS); Director, Institute of Asia-Pacific Studies, Waseda University*

Japan's New Direction for Global Health Cooperation in the Era of the Sustainable Development Goals [7 minutes]

Tomohiko Sugishita, *Senior Advisor on Health, JICA*

Hidechika Akashi, *Director, Bureau of International Medical Cooperation, National Center for Global Health and Medicine (NCGM)*

Toshiro Kumakawa, *Chief Researcher, Department of Health and Welfare*

Services, National Institute of Public Health (NIPH)

Comments [5 minutes each]

Lawrence O. Gostin, *Faculty Director, Linda D. and Timothy J. O'Neill Professor of Global Health Law; Professor, Georgetown Law, Georgetown University, USA*

Discussion on practical steps for the G7 Summit

15:30–15:55 **Session 2**: Strengthen UHC to Sustain Health Care Systems in Ageing Populations [25 minutes]

Global Ageing, UHC and Governance [7 minutes]

Reiko Hayashi, *Director, Department of International Research and Cooperation, National Institute of Population and Social Security Research*

Resilience of Japan's UHC after the Great East Japan Earthquake and Financial Crisis [5 minutes]

Naoki Kondo, *Associate Professor, Department of Health and Social Behavior, School of Public Health, University of Tokyo*

Comments [3 minutes each]

Yuki Murakami, *Health Economist, OECD*

Alex Ross, *Director, WHO Centre for Health Development (WHO Kobe Centre)*

15:55–16:25 **Session 3**: Promote Research and Development (R&D), and System Innovations for Global Health [30 minutes]

Fostering Global Health Innovation [7 minutes]

B.T. Slingsby, *Executive Director and CEO, Global Health Innovative Technology Fund (GHIT)*

Comments [5 minutes each]

Discussion on practical steps for the G7 Summit

16:25-16:55 Plenary discussion [30 minutes]

Comments [5 minutes each]

William Summerskill, *Senior Executive Editor, The Lancet, UK*

16:55–17:00 Wrap up by Kenji Shibuya [5 minutes]

Protecting human security:
Proposals for the G7 Ise-Shima Summit

"Never again can we have another Ebola"

Kenji Shibuya, MD, DrPH
www.ghp.m.u-tokyo.ac.jp

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Human security

- The recent Ebola crisis highlights the importance of focusing more attention on human security—at both individual and population levels—in global health debates.
- Human security complements national security, focusing on individual and community security.
- Human security is both a top-down and a demand-driven bottom-up process.
- Health is a core element of human security.
- UHC serves as an instrument to link individual and population security.

Competing Challenges

Human security challenges	We will:
•Terrorism •Refugee and migration crises •Climate change •Disease epidemics	1. Provide track 2 ideas to the G7 track 1 process 2. Put global health high on the 2016 G7 agenda • Identify the key global health challenges which the G7 can address • Propose concrete actions that can have larger impact despite limited new resources

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