

establishing a new organization through the strong political initiative of the UN Secretary-General to serve as a measure to counter the infectious disease, such as UNMEER in the case of the Ebola virus disease. Moreover, in cases where serious crises are dealt with, it is also conceivable that a UN peacekeeping operation (PKO), military, or other security maintenance organization in the security community may also be utilized. In the present case, a resolution was passed by UN Security Council to endorse the establishment of UNMEER, and it had the advantage of being effective in heightening awareness of the international community because of its binding power and high political importance. If the approach (top-down logistical approach that restricts state sovereignty to a certain extent) taken by the Department of Field Support (DFS), which is in charge of PKOs, is implemented successfully, a quick and efficient response may be executed. However there are also elements that place the operation in a tense relationship from the perspective of democracy. Outbreaks classified as Type 5 are extraordinary cases and the establishment of a new permanent organization is not desirable. It is important that cases be dealt with using organizations for limited periods with clear mandates. It should be noted that UNMEER, which was responsible for the Ebola response, was disbanded after having achieved its mission, and the subsequent authority to coordinate the overall response has been handed over to the WHO Director-General.

### *(2) Coordination and Cooperation Issues to be Considered and the Person Responsible for the “Switch Function”*

The following two points must be emphasized. First, an issue in terms of operation in the cases of outbreak types 3, 4, and 5 is that coordination and cooperation between the health security community and the humanitarian community are important because the objectives, subjects, and organizational culture differ for each community. The issue of coordination between the humanitarian and health security communities is present not just within the WHO, but also in relationships between the WHO and other organizations within the UN system, working together in the health sector or in clusters.

Second, because circumstances may change, the necessary patterns of coordination and cooperation need to be continuously reassessed based on changing situational categories. For example, there is continuity in changes of circumstance that necessitate a switch from Type 3 to Type 4 (switching includes personnel from ordinary times to emergency mode). Accordingly, it is important that there be a “switch” that alters the patterns of coordination and cooperation discontinuously by taking into account ongoing circumstances. Particularly in cases where a coordinating entity is already present under an existing framework such as a UNCT Resident Coordinator, it is necessary to allow for honorable replacement with a Humanitarian Coordinator or a new coordinating entity such as UNMEER. For this reason, it may also be necessary to prepare in advance a protocol that enables smooth switches. Ultimately, the person responsible for the “switch function” should be the UN Secretary-General under the leadership of the UN headquarters based on a comprehensive determination.

### **3.1.3 Building Financing Mechanisms for Procurement During Times of Emergency**

In order to make timely responses, it is necessary to have in place a financial mechanism that is readily available. However, the absence of any framework for procuring funds to be used immediately during an emergency in the health sector contributed to the delayed response. Existing organizations such as OCHA depend on voluntary contributions, so budgeting takes time, and the delayed response was also one of the reasons for establishing UNMEER to be led by the UN Secretary-General following resolutions of the Security Council and the General Assembly.

Such problems in responding to the Ebola outbreak were taken up at the 68<sup>th</sup> WHO General Assembly in 2015 where it was agreed that a USD100 million Contingency Fund for

Emergencies (CFE) would be set up within WHO. The disbursement of CFE funds is at the discretion of the WHO Director-General, and the building of a fund that can be immediately mobilized is indispensable for timely responses during emergencies<sup>23</sup>. However, this was designed for only three months worth of expenses required for deploying WHO staff. In addition, the possibility has also been pointed out that this amount may not even be sufficiently secured from member countries. Accordingly, other funding frameworks and tools need to be prepared.

As a mechanism for supplementing the CFE, the discussion led by the World Bank to establish a Pandemic Emergency Facility (PEF) underway is important, as it is a financing mechanism including the involvement of private insurance. The budget scale of the PEF is still under discussion at the World Bank, but it is estimated to be approximately USD 500 million. In its actual design, there is the issue of the trigger parameters, which are the criteria for providing funding. More specifically, (1) there is the issue of timing for PEF intervention and (2) the issue of the criteria for disbursement (for private insurance to get involved, criteria based on quantifiable data is a prerequisite, but such data is not always available particularly in the early stages of health crises). First, concerning (1), the issue is that if the payment is to take place too early, then there is an increased likelihood that multiple payments may have to be made, which makes the insurance rate higher; but if the payment is to be made too late, then the payment amounts increase while the insurance rate might become lower. Second, concerning (2), in case where data is unavailable for private insurance payouts, a pool of funding by donors may be needed where a certain degree of discretion is permissible under the World Bank, separate from the amount afforded by private insurance. In addition to the CFE and PEF, OCHA's CERF may also be utilized if the situation is determined to be a humanitarian issue. So, in addition to the relationship between CFE and PEF, the interrelationship between these and the CERF also needs to be considered.

Furthermore, there is the issue of how to build a financing mechanism for researching and development, for example vaccines during times of emergency. As the case of the recent Ebola virus disease outbreak showed, when responding to infectious diseases, existing vaccines and other such technology need to be dispersed throughout society, but research and development on new technologies, such as new vaccines was also needed. This point has also been recognized in the WHO's Roadmap for Action (WHO, 2015c). An option for the future is to have such research and development make use of the vitality of the private sector and have more diverse public-private partnerships (PPP) constructed<sup>24</sup>. For example, the Global Health Innovative Technology Fund (GHIT Fund) is one such effort in the upstream stage of development. A framework is needed to connect such upstream research and development funding with downstream activities such as the broad distribution of existing vaccines.

In Alignment with such diverse funding frameworks, as discussed in sections 3.1.1 and 3.1.2, a financing mechanism should be built that allows for rapid and timely disbursement without any gaps or discontinuities so that funds may be provided that will enable situation and stage-based responses during times of emergency.

### **3.2 Strengthening Health Systems During Ordinary Times**

It is important that health system strengthening during ordinary times be supported so that an early warning may be signaled to prevent outbreaks before they happen. Also, information collection and systematic infrastructure for responding during emergencies to specific infectious diseases can be utilized by the health system during ordinary times as well in a cross-sectional manner to address diseases. Therefore, it is important that the governance structure and design of response measures in times of emergencies be closely linked to reinforcing the health system during ordinary times.

### *3.2.1 Strengthening IHR Core Capacities*

#### *(1) Strengthening IHR Implementation at the Country Level*

In order to respond to infectious diseases, it is necessary that the IHR core capacities be built up in countries when strengthening a health system. Currently, in AFRO, not one country has completed implementation of building the minimum core capacities for IHR (WHO AFRO, 2015). Of the eight IHR core capacities<sup>25</sup>, it is particularly essential that surveillance, human resources, and laboratory services be strengthened and built so that stage-based decisions may be made about situations. Along with a framework seamlessly linking a variety of levels (communities⇒local governments⇒countries⇒regions⇒international), partnerships also need to be created with the private sector to strengthen surveillance, laboratory services, and human resources. It is necessary that the range of information to be reported be expanded (a surveillance system needs to be reconsidered so that not just cases where there is concern about PHEIC, but also events spanning a variety of alert levels, are ascertained).

#### *(2) Strengthening Responses at the Regional and International Levels for IHR Implementation in Countries*

In order to strengthen IHR implementation at the country level, responses at the following such regional levels must be enhanced. First, there is the need for the augmentation of WHO regional offices. In order to build up staffing, as WPRO has done, it is important that “truly international” staff be employed based on an ability to ensure diversity and capabilities. To achieve this, reforms may be necessary, for example, that impose an obligation on all regional agencies to hire on the basis of ability a certain percentage of their staff from outside the region. However, this does not mean that the independence per se of regional offices is bad (during the SARS response, WPRO’s discretion enabled early containment). Also, verification of effectiveness of strategic frameworks, for example WPRO’s Asia Pacific Strategy for Emerging Diseases (APSED) and AFRO’s Integrated Diseases Surveillance and Response (IDSR) in IHR implementation, which have already been launched by regional agencies, also appears to be needed.

Second, regional monitoring must be strengthened (for example, the establishment of a version of the CDC for the Africa Union (AU)<sup>26</sup>). These activities need to be linked with actors other than those in the public sector. Public-private partnerships (PPP) are particularly important for the utilization of information (challenges include how to effectively absorb information from activities conducted by MSF and others at the regional and grassroots level) and for strengthening preparedness at the local level (training on responding to disasters)<sup>27</sup>.

At the international level, departments within the WHO concerned with health security need to be strengthened. Current debate is focused on coordination between departments involved with emergencies and humanitarian issues, and those concerned with health security, but if continuity between times of emergency and ordinary times is taken into consideration, then it is also important to rank the strengthening of IHR core capacities as one element of strengthening health systems in so as to ensure coordination between health security departments and health system departments.

### *3.2.2 Coordination Among Diverse Organizations Laterally Supporting IHR Enhancement*

It is considered necessary to build a cooperative framework such that organizations and frameworks besides the health sector directly and indirectly support IHR enhancement.

As a condition for building a cooperative framework, it is necessary to recognize that the IHR is based on an “all hazard” approach. The commitment of organizations in a variety of fields, such as development, trade, disaster prevention, and security, are needed for an all hazard

response. To ensure such a commitment from a diverse range of organizations, it is necessary to have commitment not just at the level of the health minister, but also from the top national level.

As WHO presence at the country level is not necessarily sufficient, it is difficult for the WHO to play a direct role in the enhancement and monitoring of IHR implementation in all countries. It is important that international organizations active in the field such as UNDP and UNICEF acknowledge that the building up of IHR core capacities contributes to overall strengthening of the health systems of developing countries, and play the role of monitoring whether the IHR requirements of core capacities are met.

In addition, there is the issue of what to do about measures involving unnecessary trade restrictions that may potentially be adopted by neighboring countries when a certain country reports information that may constitute a PHEIC. With regard to this, a framework may be strengthened to check the appropriateness of measures under the IHR, and coordination may be pursued with actors in other sectors such as World Trade Organization (WTO)<sup>28</sup>. The WTO's Sanitary and Phytosanitary (SPS) Agreement states that when national standards are adopted that are stricter than international standards, the national standards must be scientifically justified. For example, in the case where Europe instituted trade restrictions during a cholera outbreak in Africa, the WTO's SPS Committee deliberated the restrictions including a scientific debate on the risk these measures pose to public health, which resulted in the trade restrictions being lifted (WHO and WTO Secretariat, 2002).

Moreover, it is possible to embed functions supporting IHR core capacity construction into new systematic frameworks for emergency responses. For example, with the PEF, imposing IHR implementation as an insurance term can promote domestic implementation of IHR and necessitates an evaluation of IHR implementation by third-party assessment for insurance premiums, thereby ensuring transparency in implementation and incentivizing IHR implementation in developing countries. However, because the payment of funds is contingent on damage, there remain concerns that moral hazards may arise in which the weaker a country is (with insufficient IHR implementation), the easier it will be to receive funds in the end.

In addition, it is also important that there be coordination among frameworks for aid and cooperation from the perspective of security, which has been developed bilaterally and multilaterally. Collaboration with initiatives such as the Global Health Security Agenda (GHSA) is also possible. The GHSA is a multilateral framework led by the United States, which has stated that it will achieve its goals in a minimum of 30 countries over the next five years, and has declared that it will invest USD1 billion in 17 countries toward this effort. The United States has called for donor countries to participate in the GHSA, and at the G7 Summit in 2015, it was agreed that aid would be provided to 60 countries overall, including countries in West Africa<sup>29</sup>. Although the countries targeted are limited, this initiative can contribute to rapid build-up of IHR core capacities. The merit of this kind of initiative is that it has a strong political commitment from the perspective of security and is useful for bridging the gap with issues that are not able to be carried out under existing frameworks. However, on the other hand, the demerits include dependence on political momentum, and the challenge of institutionalization to extend such efforts sustainably.

### *3.2.3 Building a Comprehensive Funding Framework for Health Systems*

It is also important that the World Bank coordinate not only with emergency response frameworks such as the PEF, but also with aid frameworks for ordinary times implemented by the International Development Association (IDA). Funding frameworks that mainly specialize in specific infectious diseases, such as the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) and Gavi,-the Vaccine Alliance, may also be utilized. For example, although GFATM's targets are limited, one-third of its expenditures support comprehensive and horizontal elements such as the strengthening of health systems(GFATM 2015), and it is also conceivable that such allocations may be extended through links with funding frameworks that support health systems through other horizontal elements.

There are multiple options for actors to lead initiatives pertaining to strengthening systems for comprehensive funding frameworks. Such efforts may be addressed by the World Bank or led by the GFATM, which currently has a large amount of funding designated for specific infectious diseases. Or, these efforts may be undertaken by the UNDP, which has a significant presence in the field in developing countries, and divisions may also be established concerning health systems mainly for strengthening IHR core capacities in frameworks for health aid collaboration such as the International Health Partnerships (IHP)+, which aims to coordinate aid in the health sector for the purpose of coordinating a variety of initiatives. It is also possible to strengthen coordination with security policies.

#### **4. Future Challenges**

This paper presented issues to be addressed and lessons learned based on analysis of the process of the response to the Ebola virus disease outbreak, and proposed options for addressing global health governance.

Currently, international interests and assessments appear to be focused on improving organizational coordination between health security and humanitarian aid, which is necessary for responding to infectious diseases such as Ebola, and on the necessity for the general strengthening of health systems. However, the focus on improvement of organizational coordination has been narrowed down to mainly improvements within the WHO, and consideration needs to be given to issues related to organizational coordination across the entire UN system, including OCHA and UNDG members.

Also, it is important that responses to such specific infectious diseases are positioned within cross-sectional and comprehensive reinforcement of health systems, which makes such monitoring possible, and are linked to strengthening health systems in countries as well as to universal health coverage (UHC). Generally speaking, an emergency response depends on the health system employed during ordinary times, which provides the systematic infrastructure for information collection and response. On the other hand, the systematic infrastructure for information collection and response that is developed for use in emergency response can also be able utilized during ordinary times. Furthermore, improving the efficiency of emergency responses allows for resources to be secured to expand access to health systems during ordinary times. However, the paths for undertaking such linkages differ depending on the country. On this point, Japan is able to play a significant role on account of its experience in realizing UHC in responding to a variety of infectious diseases, such as tuberculosis.

In addition, the debate over funding is currently focused on vertical funding mechanisms in the sense of being for emergencies and specific infectious disease. However, if the issue of global health governance is understood from a long-term perspective, what is important is how to construct a comprehensive and horizontal funding mechanism. For example, the GFATM maintains a set allocation for responding to specific infectious diseases, but it has begun to expand that scope by strengthening horizontal aid for health systems. It is necessary to promote such moves encouraging vertical funding mechanisms to employ horizontal funding elements.

Although it has been discussed in the debate over PHEIC, a point that has not been sufficiently delved into is the issue of constructing mechanisms for collecting information about events that occur at levels below PHEICs and how to control the unnecessary restrictions on trade or in other areas. With regard to these, further research is necessary as to whether the IHR needs to be revised, whether it needs to be adapted in terms of operation, or whether considerations are needed with other systems such as funding frameworks or the WTO. In addition, the importance of the UN Secretary-General and the Chief of Staff at the UN Headquarters as the people responsible for the “switch function” from ordinary times to emergencies that involves a change in leadership roles where an event develops past a certain stage was recognized, but the remaining issue is how to institutionalize such mechanisms at the international level.

Furthermore, responses must also be considered in line with specific scenarios in cases where an outbreak occurs not in a vulnerable country such as where the Ebola outbreak spread, but, for instance, in big countries in Asia such as China and India, where pandemics develop due to a different infectious diseases (airborne diseases or something more contagious). The table in section 3.1.2 needs to be utilized to review a variety of stage-based response modes in keeping with the terms of global health governance by conducting reviews on the capacity to respond to specific infectious diseases at multiple levels (national, regional and international) in coordination with the situational categories based on the competence of the country (high or low) where the outbreak has occurred and the type of infectious disease.

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<sup>1</sup> WHO website, Ebola Situation Report - 18 November 2015.

<http://apps.who.int/ebola/current-situation/ebola-situation-report-18-november-2015>

<sup>2</sup> WHO, 2015a.

<sup>3</sup> MSF, 2015, p.6-7.

<sup>4</sup> Under IHR regulations, a PHEIC is defined as an extraordinary event which is determined (i) to constitute a public health risk to other States through the international spread of disease and (ii) to potentially require a coordinated international response.

<sup>5</sup> SG Statement, 2015.

<sup>6</sup> However, it has also been indicated that a segmented governance structure is not necessarily an obstacle, and it also has the advantage of robustness in terms of flexibility and adaptability (Keohane and Victor (2011), Shiroyama et al (2011)).

<sup>7</sup> Briand et al (2014), Gostin (2014), Gostin and Friedman (2014), Kruk et al (2015), Friedman, and Hougendobler (2015) Burkle (2015), Heyman et al. (2015), Garrett (2015), etc.

<sup>8</sup> Formerly, the Institute of Medicine (IOM).

<sup>9</sup> The WHO Ebola Interim Assessment Panel (2015, p.15, Box) pointed out the following as the reasons for the WHO's PHEIC delay: (1) country factors (weak health systems, insufficient community mobilization, unsafe practices in burials, etc.), (2) country politics (concern about political and economic impact), (3) WHO politics/dilemmas (concerns about challenging governments, understandable worries about economic and trade implications, hesitation since the H1N1 response, lack of data, etc.), (4) WHO's organizational culture (it has a technical, normative culture, not accustomed to dealing with such large-scale, long-term and multi-country emergency responses occurring in member states), and (5) international community (it failed to heed warnings because previous Ebola outbreaks were small and contained; there was no intermediate level of warning between outbreak and the declaration of a PHEIC).

<sup>10</sup> WHO stated that it does not fully agree with the WHO Ebola Interim Assessment Panel's assessment that a PHEIC determination was delayed. While it acknowledged "the understanding of the international community is that a PHEIC determination should act as an international alert signal for disease outbreaks of this nature," it stated that this understanding is not "entirely accommodated by the current IHR criteria." but it supported the recommendation to consider intermediate alert to mobilize international response (WHO Secretariat, 2015, para.10)

<sup>11</sup> Density of physicians (total number per 1000 population, latest available year)

[http://www.who.int/gho/health\\_workforce/physicians\\_density/en/](http://www.who.int/gho/health_workforce/physicians_density/en/)

<sup>12</sup> Coordination among international organizations is carried out by the Inter-Agency Standing Committee (IASC), which is chaired by OCHA's Under-Secretary-General and Emergency Relief Coordinator (OCHA serves as the Secretariat).

<sup>13</sup> As for the nationalities of staff affiliated with the regional office in the African, United States and European regions, 80% have been hired from within the same region (by contrast, WPRO is more diversified, having employed approximately 40% of its staff from within the same region, somewhat less than 30% from Europe and 16% from the United States). This point relies on research conducted by Kayo Yasuda.

<sup>14</sup> The Director General prior to Gro Harlem Brundtland attempted to strengthen coordination between Headquarters and the regional offices during her term, but there is still a low level of movement of personnel among the regional offices and between the Headquarters and regional offices. For instance, in 2013, approximately 80% of personnel transfers were within the same regional office, 15% between Headquarters, and movement among the regional offices was a mere 7%. This point relies on research conducted by Kayo Yasuda.

<sup>15</sup> The WHO's medium-term strategic plan for 2008-2013 was revised in the backwash of the 2008 financial crisis, resulting in the initially allocated budget for IHR implementation in 2010-2011 being slashed by roughly half (the original USD98 million was reduced to USD54.84 million). WHO, 'Proposed Programme Budget 2010-2011', 2009, pp.3-5. This point relies on research conducted by Kayo Yasuda.

<sup>16</sup> The MSF General Director stated, "WHO should have been fighting the virus not MSF."

<sup>17</sup> In fact, after the PHEIC declaration, carriers suspended flights. So, from the second meeting of the IHR emergency committee and thereafter recommendations were repeatedly issued that restrictions on overseas travel and trade, particularly bans on travel abroad and flights, lead to economic loss and isolation of the country where the outbreak occurred (2<sup>nd</sup> meeting), and hinder personnel responding to Ebola (4<sup>th</sup> meeting), so such measures should not be taken. Statement on the 4th meeting of the

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- <sup>18</sup> At the time of H1N1, criticism was leveled that the agency issued a PHEIC even though the fatality rate was a mere 0.2% (Gostin, 2014).
- <sup>19</sup> Polio is also an infectious disease but as experience has been accumulated in responding to it, the response has also been implemented in cooperation with the humanitarian sector. This was not the case for Ebola.
- <sup>20</sup> WHO Ebola Interim Assessment Panel (2015) also stated it was clear that leadership at the UN Secretary General level was needed in September 2014. However, it goes on to state that when large-scale health crises arise in the future, the UNMEER model is not appropriate and strongly opposes the establishment of a UN Mission. It points out that an emergency coordinator may be set up at the regional level for operations and that the Sub-regional Ebola Operation Coordination Centre (SEOCC) could have coordinated the Ebola response. (WHO Ebola Interim Assessment Panel (2015), para77-81).
- <sup>21</sup> The need for emergency grading levels is also recommended in the WHO Panel's report. A PHEIC determination is a single binary decision, and the Panel recommends that the IHR Review Committee for Ebola consider the possibility of alerts at an intermediate level to mobilize the international community (WHO Ebola Interim Assessment Panel, 2015, para.23).
- <sup>22</sup> Although established within the WHO, it is an independent organization. It provides centralized management of units and functions at all levels, national, regional and the WHO Headquarters. Discussions have been held about the necessity for having this program cite PHEIC cases and IHR contact points (WHO Advisory Group, 2015, para. 6)
- <sup>23</sup> In September, the WHO and World Bank held a meeting on global pandemic financing. Also, the WHO's Contingency Fund is scheduled to be discussed at a financing dialogue in November 2015. Other modes of structuring financing with humanitarian cases is being coordinated with IASC (WHO Secretariat, 2015, para. 30).
- <sup>24</sup> This point relies on research conducted by Sayako Kanamori , Jonas Kemp and Charlotte Sauter.
- <sup>25</sup> (1) national legislation, policy and financing, (2) coordination and NFP communication, (3) surveillance, (4) response, (5) preparedness, (6) risk communication, (7) human resources, (8) laboratory services.
- <sup>26</sup> Although it is to be established soon, issues have also been raised as to what extent it will be able to carry out its activities with a staff of 11 personnel and funding of 6.9 million.
- <sup>27</sup> This point relies on research conducted by Sayako Kanamori , Jonas Kemp and Charlotte Sauter.
- <sup>28</sup> There have been discussions that this sort of approach may be useful in preventing surrounding countries from adopting overly restrictive measures on the movement of people and goods during IHR implementation.
- <sup>29</sup> Although the response will also be limited using conventional means for procuring funding, the defense sector is also a potential source of public funding. The US government's budget for health security in 2016 is \$13.7 billion, of which \$2.5 billion has been allocated for bio-defense, pandemics and other all-purpose preparedness. It has been pointed out that such a budget allocation may also be useful in developing vaccines. This point relies on research conducted by Sayako Kanamori , Jonas Kemp and Charlotte Sauter.

# Public-Private Partnerships for Strengthening Global Health

Sayako Kanamori (Japan Institute for Global Health), Jonas Kemp (Stanford University), Charlotte Sauter (University of Cologne)

## Overview - Challenges in Global Health Governance

Based on lessons from the responses to the Ebola outbreak, group 6 will assess the global health governance landscape in order to identify major challenges that require new thinking and reform in the governance structure. Authors will analyze recent trends and propose areas of reform needed to respond to changing needs and priorities in global health and health security, with a focus on the role of Japan and the G7.

## Major questions

- What are the recent trends of public sector involvement and public-private partnerships (PPPs) in the area of global health?
- What are the lessons learned to effectively respond to disasters and how can global health incorporate them in order to create a resilient governance structure?
- How can the private sector contribute to develop a strengthened governance structure in the area of global health?

## Additional questions

- What are the options for PPPs for R&D during an emergency (the Partnership)?
  - Structure : What is an ideal structure for the Partnership? How will the Partnership work with WHO and its internal reform?
  - Style: What kind of leadership is needed for the Partnership?
  - Skill: What kind of core competencies is needed for the Partnership?
  - Staff: What are the motivations and incentives for the Partnership members?
  - Shared value : What should be the vision and mission of the Partnership?
  - Strategy: How does the Partnership prioritize R&D issues? What does the Partnership develop strategies?
  - System: How does the Partnership share the materials (pathogens, etc) and results of the R&D outcomes?
  - Size: What is an ideal level of funding that the Partnership manage - is US\$ billion enough or not? If not, why and what is an ideal level?

## 1. Introduction

### 1.1 Drastic changes in the global health community

Over the last few decades, the landscape of the global community has changed dramatically.

The range of issues has become more diverse, particularly with the proposed transition from 8 Millennium Development Goals (MDGs) to 17 Sustainable Development Goals (SDGs). The number and variety of players has increased to include not only the United Nations (UN), recipient and donor governments, and civil societies, but also emerging governments and the private sector, including business. The level of funding for all areas of development has increased sharply, from US \$58.5 billion in 1990 to US \$150.4 billion in 2013 [1], and development assistance for health (DAH) has quintupled in the same period [2]. Finally, approaches to tackling health problems have also become diversified – from traditional funding, to innovative financing mechanisms such as IFFIm and World Bank Green Bonds, to various initiatives like PEPFAR, the Muskoka Initiative, and Malaria No More.

The recent Ebola outbreak reminds us, however, that such an eclectic environment does not always provide more effective solutions. We must also consider the importance of strengthened governance and management at global, regional, national and community levels.

## **1.2 The rise of public-private partnerships**

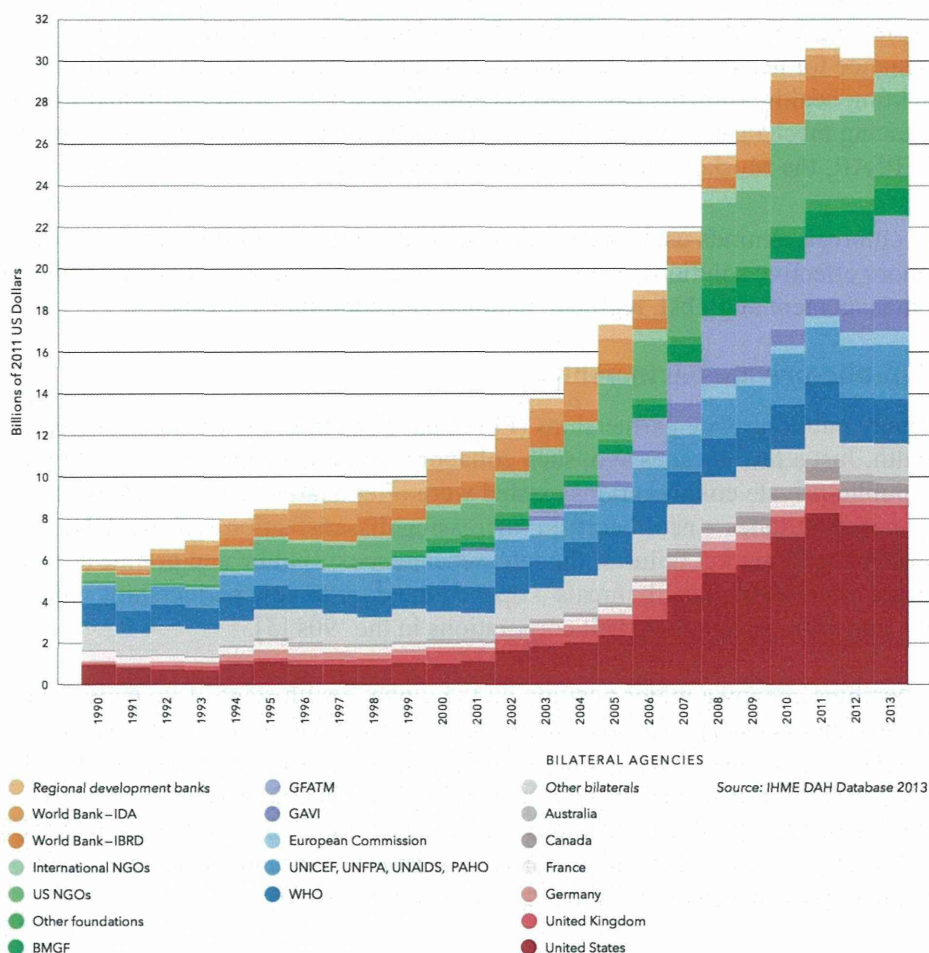
In recent years, many public-private partnerships (PPPs) have arisen in the field of development assistance for health. Just a few decades ago, such collaborations were quite rare. Prior to the 1980s, what few public-private collaborations existed were often marked by distrust and conflict [3]. However, changing attitudes – neoliberalism; increasing dissatisfaction with the UN; recognition of global health market failures, the interdependence of public and private actors, and the broad nature of emerging health threats – opened the door to new partnerships with NGOs in the ‘80s, and with private for-profit corporations in the ‘90s [3].

Today, these partnerships occupy a major position on the global health stage. Two major PPPs – Gavi, the Vaccine Alliance (GAVI); and The Global Fund to Fight AIDS, Tuberculosis, and Malaria (Global Fund) – provided 17.8 percent of all DAH in 2013, for a combined total of US \$5.5 billion [2]. Meanwhile, private sector involvement in global health has grown in other ways too, with NGOs and private US foundations providing another US \$6.9 billion in DAH in 2013, or 21.9% of worldwide totals [2]. Going forward, private actors and partnerships will have an integral role to play in strong global health governance system.

**Figure 1: DAH by channel of assistance, 1990-2013 [2]**

**FIGURE 2**

DAH by channel of assistance, 1990-2013



## 2. The role of public-private partnerships in global health today

Despite the proliferation of PPPs in global health today, the term “public-private partnership” is still a relatively ambiguous term encompassing a variety of arrangements. It is beyond the scope of this paper to rigorously define a framework for understanding which global health partnerships do or do not constitute “true” PPPs. However, in the interests of providing clarity while still allowing for the wide range of partnerships operating in global health today, we will adopt the broad guidelines proposed by Reich: a global health PPP should 1) include at least one for-profit and one not-for-profit organization, 2) distribute efforts and benefits among core partners, and 3) commit to creating social value in the form of improved health [4].

### 2.1 Types of global health PPPs

PPPs for global health engage in a wide variety of different ventures (Figure 2). Possible objectives include (but are by no means limited to) product development, distribution of donated or subsidized products, or strengthening health services [5].

**Figure 2: Variety of PPPs in Global Health**

Objective	Example of Partnership
Product development partnerships (PDPs)	PATH Malaria Vaccine Initiative
Distribution of donated or subsidized products	Mectizan Donation Program
Strengthening health services	Gates Foundation and Merck's Botswana Comprehensive HIV/AIDS Partnership

### **2.1a Vertical and horizontal partnerships**

In the early 2000s, most global health PPPs arose as narrowly focused vertical programs, with very specific disease targets or technical specialties [6]. GAVI, for example, has worked to improve immunization rates since 2000, while the Global Fund has fought AIDS, TB, and malaria since 2002. The Gates Foundation, a strong supporter of both of these initiatives and many others, has long favored such a technocratic approach to solving global health problems [6-7].

These large vertical partnerships have demonstrated the benefits of the model, with substantial successes in their scope of action. GAVI estimates that its efforts have supported the immunization of 539 million children and helped avert 7.1 million future deaths as of 2014 [8]; the Global fund supports programs that have provided 8.1 million AIDS patients with antiretroviral therapy, have treated and tested 13.2 million TB patients, and have distributed 548 million insecticide-treated nets as of July 2015 [9]. Both have been rated highly by the UK Department for International Development (DFID) on measures of value for money within their areas of expertise [10].

However, the vertical approach is not without its drawbacks. Some critics warn that partnerships with too narrow a focus run the risk of creating “islands of excellence in seas of underprovision” [11], while others suggest that even “excellence” might be too strong a word, and perhaps “sufficiency” would be more appropriate [12]. Semantics aside, there is a range of evidence indicating that the benefits of vertical efforts can often be to the detriment of local health systems more broadly. Reviews of specific initiatives indicate positive effects on service delivery for those services targeted by PPPs, but also a number of external negative effects including distortion of national priorities, additional burdens on inadequate national capacity, inefficiency through duplication and parallel services, imbalances in the utilization of the health workforce, and interruption of routine services [13-15].

Over the last decade, many organizations have shown increasing interest in moving towards horizontal models, with broader goals of health systems strengthening (HSS). The 2007 WHO framework for action on health systems cites HSS as an agenda item of utmost importance [16]. It is generally recognized that to achieve large-scale health goals, such as the health-related MDGs or SDGs, attention to HSS must be a priority area for global health actors. Indeed, building strong health systems will be a vital first step in working towards Japan and world goals of worldwide universal health coverage (UHC). Even some staunchly vertical organizations, including GAVI and the Global Fund, have opened windows to HSS support, recognizing that better systems are needed to effectively deliver their disease-specific interventions [17-18].

However, in their current state most HSS initiatives are still underdeveloped. Many partnerships

have struggled to define the scope of activities that fall under “health systems strengthening.” The WHO health systems framework provides a starting point, but it is broad and open to a variety of interpretations. Critics have suggested that, in too many cases, so-called HSS activities have been little more than a means for partnerships to achieve their own specific, narrow health targets, rather than a truly comprehensive attempt to improve health systems [13]. However, going too far in the opposite direction may also be problematic: for example, early HSS attempts by the Global Fund have been described as “‘messy’ and ‘inconsistent,’” with substantial financial support for activities that were “diffuse and difficult to define” [19]. This tension – between maintaining expertise in a narrow mandate, and expanding to a comprehensive HSS platform – has plagued major HSS initiatives from both GAVI and the Global Fund since their inception [6-7].

GAVI’s current HSS initiatives provide a useful encapsulation of much of the current debate around HSS. The GAVI HSS window offers a suite of grant options for prospective applicants, categorized under the six building blocks of the WHO framework [17]. Proponents of the system cite a “‘niche focus on eliminating health system bottlenecks’” impeding immunization coverage [19] with sufficient flexibility to have impacts beyond that narrow mandate [13,20], and a commitment to the principles of aid effectiveness outlined in the Paris Declaration, including national ownership, alignment, and harmonization [20]. But critics suggest that despite GAVI’s rhetoric about holistic HSS support, its activities continue to skew the global HSS agenda unfairly in favor of the technocratic “Gates approach” [7].

### **2.1b Product development partnerships**

Product development partnerships (PDPs) represent an important subset of the global health PPP landscape, distinguished from other partnerships by a focus on research and development of new medicines for neglected diseases [21]. Data from the G-FINDER Public Search Tool recognizes 16 major PDPs active as of 2013, receiving total funding in that year amounting to US \$482 million [22]. While this is a drop in the bucket relative to total global pharmaceutical R&D spending – for example, Pharmaceutical Research and Manufacturers of America members report spending US \$51.6 billion on R&D in 2013 [23] – results from many PDPs have so far been positive.

PDPs have been and continue to be integral in bringing private-sector innovation to bear on neglected diseases. The public health community has long recognized that pharmaceutical R&D is strongly biased in favor of products targeting affluent markets in high-income countries, leading to a market and policy failure that ignores diseases of poverty despite the massive worldwide burden of such diseases [24]. By linking pharmaceutical companies with government and nonprofit organizations invested in global public health, PDPs offer incentives to align private-sector resources and capacity with public-sector interests. Several new products have come to market over the past decade, such as combination therapies for various diseases from the Drugs for Neglected Diseases Initiative (DNDi) [25], or a new meningitis vaccine from the PATH Meningitis Vaccine Project (see Box 1).

However, the PDP model is not without limitations. Observers have noted the need for diversified funding sources - from 2007 to 2013, for example, the Gates Foundation has provided approximately half of all funding to PDPs each year [22]. Diverse and unrestricted funding is necessary to ensure that PDPs can operate flexibly without being tied to a single donor’s strategy [26]. Moreover, while PDPs have succeeded in bringing private-sector attention to neglected diseases on a partnership-by-partnership basis, they offer only a limited resolution to the fundamental flaws in the pharmaceutical incentive structure, which still broadly preclude the development of affordable treatments for diseases of poverty [27]. A serious attempt to restructure these incentives could bolster the development of such vital products even further.

In Japan, the Global Health Innovative Technology (GHIT) Fund operates on a business model intended to alleviate this problem. Founded in 2013, the GHIT Fund utilizes an investment strategy based on sustainably engaging the private sector in Japan and worldwide, while ensuring product accessibility once developed [28]. The Fund's commitment to encouraging partnerships around the world for a range of high-impact products signals a move to expand the scope of private sector engagement with global health R&D, and the Fund portfolio already supports a range of new projects.

Moreover, Incentives for Global Health has for several years advocated for a global Health Impact Fund (HIF), another innovative solution to pharmaceutical incentive problem. Pharmaceutical companies who partner with HIF would commit to selling a product at cost worldwide, as well as provide free licenses after a 10-year reward period; in return, HIF would pay partner companies from a reward pool, in proportion to the actual measured health impact of their product [29]. Such a financial apparatus could both encourage private interest in neglected diseases and ensure that the products developed reach their intended markets, thus promoting even further PDP collaboration in the future. In particular, the market realities in middle-income countries often make it difficult for PDPs to reconcile the profit interests of commercial partners with the affordable provision of products in these areas; the HIF could greatly mitigate this problem [30].

#### **Box 1: PATH Meningitis Vaccine Project (MVP)**

Despite the high need for group A meningococcal meningitis vaccinations in Africa, for many years no manufacturers stepped up to develop an affordable solution. Recognizing the unmet need, PATH and the WHO collaborated on the Meningitis Vaccine Project (MVP), a public-private partnership for the development, testing, and licensing of a new meningitis vaccine.

While the components and technology existed prior to the MVP, the challenge lay in finding partners willing to take the economic risk of developing a product for an impoverished market [31]. With the support of a ten-year grant from the Bill & Melinda Gates Foundation, PATH located three such partners: SynCo Bio Partners BV, the Serum Institute of India Limited (SIIL), and the U.S. Food and Drug Administration's (FDA's) Center for Biologics Evaluation and Research. Each partner contributed something unique and vital to the development process: key vaccine components, production capacity, and conjugating technology, respectively [31].

The partnership involved an exchange of nonexclusive, sublicensable licenses for key technologies between PATH, the FDA, and SIIL, an unusual arrangement in vaccine manufacturing [32]. The final product, MenAfriVac, launched in late 2010 at a cost of less than US \$0.50 per dose, and within a few months mass vaccination campaigns reached over 19 million people in three countries [33]. The results demonstrate that the MVP succeeded in bridging the gap between a critical public health need and the commercial interests of the pharmaceutical companies involved.

## **2.2 Keys to a successful partnership**

Several essential factors underlying PPP success or failure are well understood. At the most basic level, strong partnerships should have a clear and mutually agreed-upon goal, a pre-defined division of labor, and a sharing of both benefits and risks acceptable to all partners [34]. Multiple commentators have specifically emphasized the importance of transparency, accountability, and clarity in common understandings between partners [34-35]. Moreover, good PPPs are not static structures – the best work to actively maintain and adjust their partnerships in order to achieve maximum impact [35-36].

Attempting to coordinate public and private sector entities presents its own unique set of



opportunities and challenges. The complexity of many global health problems demands a range of skills and competencies that neither the public nor private sector can individually provide [4]. Thus, strong partnerships can create innovative solutions by offering the best of both worlds: the resources, technical expertise, flexibility, and management skills of the private sector, combined with the legitimacy, legal and regulatory assets, and development experience of the public sector [37]. However, creating such a partnership also necessitates aligning divergent interests, i.e. the public good and corporate bottom lines. As such, partners must actively acknowledge their differences in interest and strive to generate mutual benefit, through programs that improve public health while still offering corporate partners a return on investment or an opportunity to expand business interests [35,37].

Additionally, it is utterly essential that global health PPPs, like other international development agents, adhere closely to the principles of effective aid outlined in the Paris Declaration, particularly ownership, alignment, and harmonization. As outlined in the previous section, too often a myopic focus on a particular program can have negative effects on the broader health system, leading to distorted priorities, burdens on strained capacities, and inefficiencies. By contrast, for example, positive reactions to GAVI's HSS window have highlighted successes in strengthening in-country coordination and producing well-aligned funding proposals [20]. The international community continues to call for placing national plans at the center of aid agendas, moving, in the words of Dr. Paul Farmer, "from 'aid' to 'accompaniment'" [38].

Other recommendations for strong partnerships, drawn from independent evaluations of major PPPs, include focus on a comparative advantage distinct from other global health actors, maintaining a secretariat of the appropriate size and structure, and practicing good performance management with continuous internal assessment [35].

### **3. The role of the private sector in global health today**

While a substantial fraction of private sector engagement in the global health arena occurs through PPPs, these partnerships by no means represent the full extent of private involvement in the field. Nor does "private sector" refer exclusively to for-profit corporations: many other private entities, including NGOs and foundations, are also major suppliers of development assistance for health, and play major roles in a wide variety of PPPs. Each of these entities occupies a different niche in the global health ecosystem.

#### **3.1 For-profit corporations**

Perhaps unsurprisingly, even in the modern global health landscape, certain sectors of private industry remain antagonistic to public health progress, such as the tobacco and alcohol industries and segments of the food industry [39]. However, attention to corporate social responsibility (CSR) has become increasingly widespread over the past 20-30 years [40], and in turn many corporations are more attuned to issues of international health and development than ever before.

CSR in the pharmaceutical industry provides a key example, with obvious relevance to global health. Engagement includes targeted research arrangements through PDPs, as discussed in the previous section, but this reflects only one dimension of pharmaceutical CSR activities. A survey of several major pharmaceutical companies found that other common CSR activities included product donation and/or differential pricing, improving local distribution capacities, engaging private or informal healthcare providers, and mobile health (mHealth) initiatives [41]. These activities may involve working with other corporate partners, such as telecommunications companies for mHealth [41]. Some companies also provide personnel: for example, Pfizer's Global Health Fellows Program sends employee volunteers to global partner sites in order to

transfer knowledge and build capacity [42].

Some other companies outside the health sector have also mounted initiatives contributing to global health. For example, Google.org, the charitable arm of Google, provides funding to a variety of global health actors, and also manages programs such as Google Crisis Response and, previously, Google Flu and Dengue Trends. Moreover, the advent of the sustainable development era has brought new corporate initiatives to the playing field, such as Impact 2030, a business-led collaboration intended to encourage corporate volunteerism in service of the SDGs. However, various observers have cautioned that better evidence is needed to understand the efficacy of CSR initiatives, particularly in the global health context [41,43-44].

### 3.2 NGOs

Non-governmental organizations, or NGOs, comprise a hugely diverse spectrum of private groups outside of traditional for-profit corporations (Figure 3). Within global health, these groups operate in numerous different capacities, with various objectives.

**Figure 3: Variety of NGOs in Global Health [45]**

Type of NGO	Example
Humanitarian aid	Doctors Without Borders (MSF)
Philanthropic foundation	Bill and Melinda Gates Foundation
Membership organization	Global Health Council
Consulting	John Snow, Inc.
Academic research	Johns Hopkins Center for Global Health

Historically, the position of NGOs in the global health landscape was initially somewhat contentious, with some derogatory commentators referring to NGOs as “pressure groups” [3]. Criticisms of NGOs working in global health remain today, including accusations of bypassing governments or undermining democracy, limited accountability and transparency, or poor relationships with national health systems and community organizations [46]. Yet the presence of NGOs has grown into an undeniable force in the global health arena.

In addition to their individual activities, NGOs have played a major role in many important global health partnerships. For example, PATH engages in a range of different PDPs, and both Rotary International and the Gates Foundation have been important partners with Japan and other national and international bodies in the fight to eradicate polio. The significant funding power of the Gates Foundation, in particular, has arguably been a driving factor behind the proliferation of vertical global health initiatives in the past 15 years [7].

An interesting and increasingly important function of NGOs in global health is in disease surveillance. Analyses have indicated improvements in outbreak discovery and public communication over the past 20 years, though gains vary regionally [47]. NGOs have advanced disease surveillance through innovative initiatives, such as the internet-based reporting systems HealthMap and the International Society for Infectious Diseases’ ProMED, and through efforts to coordinate independent surveillance programs in a “network of networks,” such as the Nuclear Threat Initiative’s CORDS program. NGOs have also provided on-the-ground intelligence in emerging situations, as Doctors Without Borders did in the wake of the 2010 Haiti earthquake [48] and in the current Ebola crisis [49].

## **4. Partnerships and private-sector responses to global health emergencies: lessons from the Ebola crisis**

The international response to the ongoing Ebola outbreak, particularly the response of the WHO, has been widely criticized by both outside actors [49] and the WHO itself [50]. Yet a wide variety of private actors stepped in to provide critical support in the emergency response, with at least 150 companies participating in various capacities [51]. Taking explicit steps to coordinate these corporations' resources and expertise could prove invaluable in strengthening preparedness, response capacity, and recovery efforts in the face of future public health emergencies.

### **4.1 Disaster preparedness**

The scale of the current Ebola crisis stems in part from the reality that none of the nations experiencing the brunt of the outbreak were equipped to deal with a disaster of this magnitude. All three are recovering from recent civil wars, leaving their health systems poorly positioned to respond to such a massive emergency [52]. In this sense, the increasing global focus on health systems strengthening activities also represents a long-term investment in preventing future crises. Partnerships should focus on building national capacity to create strong, self-sufficient local health systems [38], which can in turn take the lead in emergency response situations and reduce reliance on international resources.

At the community level, in particular, partnerships focused on local disaster preparedness education can have a valuable impact. Such partnerships have already seen success in other disaster management contexts. For example, communities in West Sumatra, Indonesia, with a disaster preparedness team trained by the partnership P3DM fared better than those without following the 2009 Sumatra earthquake (see Box 2). This strategy should also be applicable to global health emergencies. Disaster preparedness education can provide communities with the tools to mount their own immediate response in an emergency situation, and involving community members directly in the response effort creates important ties to the larger health system [38]. Keeping in mind the rampant mistrust of and hostility towards health workers in the Ebola crisis [52], cultivating these community connections may be an essential facet of effective response preparation.

Another avenue for the improvement of disaster readiness lies in better coordination with pharmaceutical companies for product development. A key failure in the Ebola response has been the dearth of treatments and lack of a vaccination available for the disease. Although Ebola has been known to the scientific and medical communities for nearly 40 years, only the severity of the current situation has brought any serious attention to R&D. Existing partnerships have made efforts to step in and fill this gap, to be sure. For example, Gavi pledged \$300 million as of December 2014 to purchase Ebola vaccines for affected nations [53]. Various other new partnerships have also been formed in order to expedite drug and vaccine development [54-56]. But the scramble to create the necessary new arrangements in the midst of a crisis has been inefficient and costly. As one commentator noted, "A crisis is not the time to be exchanging business cards" [51].

Coordinating efforts to facilitate PDPs prior to an outbreak could greatly smooth the development process in the event of an actual emergency [51]. Of course, the underlying incentive issues in the pharmaceutical industry also limit R&D interest in diseases like Ebola until they threaten the developed, not just the developing, world [53]. Restructuring these incentives, through an initiative like the HIF, could bolster preparatory coordination by creating a pre-existing structure to facilitate preemptive or emergency product development in cases of crisis.

**Box 2: Public-Private Partnership for Disaster Management in West Sumatra, Indonesia (P3DM)**

In the wake of the 2005 earthquake and tsunami in Nias, North Sumatra, the NGO Mercy Corps founded P3DM in September 2008, with the aim of educating local communities in risk management strategies. Mercy Corps, which has actively worked to reduce poverty in Indonesia since 1999, collaborated with Kogami, a tsunami alert community, and other local private sector companies, and received funding from OFDA-USAID and Boeing Corporation for the program [57]. P3DM planned to create local disaster risk reduction in partnership with two local government districts in West Sumatra, and in twelve schools over a two-year period [58].

P3DM also built disaster preparedness teams (DPTs) in each village, and provided recovery, rehabilitation, and reconstruction services [57]. The program was tested unexpectedly by the September 2009 Sumatra earthquake, but a final report says that communities with a DPT were significantly better prepared than others [57].

Through this program, locals were prepared with knowledge of secure locations and appropriate steps to take in an emergency situation. DPTs trained through P3DM, as well as the follow-up program PREPARE SumBar, learned to prepare funding applications, engage in budget discussions, and manage funds. Note, however, the program was not without its difficulties: insufficient government staff, issues with coordination, and challenges securing funding for certain activities all hampered the partnership's efforts [57].

## **4.2 Response capacity**

In the event of an emergency, time is of the essence. Private for-profit companies can often act more efficiently and flexibly than the public sector, due to better management and reduced administrative overhead [59-60]. As such, they are in a prime position to contribute to disaster response efforts, in contrast to the traditional view that disaster management is primarily a public good [60-61].

Private aid contributions in the Ebola crisis reveal a variety of ways for companies to add value to response efforts. For example, in-country operators (i.e. businesses with a local presence in affected areas) were positioned to take on a first-responder role, and contributed resources, training, advocacy, local knowledge, and vital services [51,59]. Other companies offered valuable domain-specific expertise, such as logistics and transportation, communications tech, R&D, or financial services [51]. In a crisis such as this one, where early responders were stretched to the breaking point while the world dragged its collective feet [49], the power of quick local action and expert support to change the course of the outbreak cannot be overstated.

Yet across all levels of private sector involvement, poor coordination has hampered even the best-intentioned response efforts. Previous examinations of successful partnerships stress the importance of clearly defined objectives and responsibilities and effective communication channels [60], as well as strong organizational arrangements to promote mutual coordination [61]. Often, the ad hoc nature of Ebola response partnerships prevented partners from fully realizing these ideals. A lack of communication between the public and private sectors left local responses disjointed, created “solutions” that failed to meet core needs (particularly in technology), and rendered many private actors unsure how to engage at all [51].