The Neglected Dimension of Global Security: A Framework to Counter Infectious Disease Crises

DETAILS

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The Neglected Dimension of Global Security

A Framework to Counter Infectious Disease Crises

Commission on a Global Health Risk
Framework for the Future

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This report has been reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise. The purpose of this independent review is to provide candid and critical comments that will assist the Commission in making its published report as sound as possible and to ensure that the report meets International Oversight Group standards for objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the deliberative process. We wish to thank the following individuals for their review of this report:

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Although the reviewers listed above have provided many constructive comments and suggestions, they were not asked to endorse the conclusions or recommendations nor did they see the final draft of the report before its release. The review of this report was overseen by **David Challoner,** University of Florida. He was responsible for making certain that an independent examination of this report was carried out in accordance with International Oversight Group procedures and that all review comments were carefully considered. Responsibility for the final content of this report rests entirely with the Commission.

Preface

"Messieurs, c'est les microbes qui auront le dernier mot."
(Gentlemen, it is the microbes who will have the last word.)
—Louis Pasteur

While Louis Pasteur, the famed 19th-century microbiologist, may have literally spoken the truth, individuals, communities, and nations expect governments to use all the available tools of science and public policy to combat the threat of infectious disease. And where such tools are lacking, or poorly used, responsible leaders are expected to take action, plugging the gaps and enhancing execution.

Much has been done since the days of Pasteur to mitigate the threat of infectious diseases to individuals and humanity as a whole. Hygiene, water purification, vaccines, and antimicrobials have all contributed to great improvements in well-being and life expectancy. However, despite these advances, we have in the last few decades seen several large-scale outbreaks of infectious diseases, not only old foes—such as cholera and yellow fever—but new threats such as Ebola, severe acute respiratory syndrome (SARS), hantavirus, human immunodeficiency virus (HIV), and novel strains of influenza. A range of factors, including increasing population, economic globalization, environmental degradation, and ever-increasing human interaction across the globe, are changing the dynamics of infectious diseases. As a consequence, we should anticipate a growing frequency of infectious disease threats to global security.

We have not done nearly enough to prevent or prepare for such potential pandemics. While there are certainly gaps in our scientific defenses, the bigger problem is that leaders at all levels have not been giving these threats anything close to the priority they demand. Ebola and other outbreaks revealed gaping holes in preparedness, serious weaknesses in response, and a range of failures of global and local leadership. This is the neglected dimension of global security.

Part of the problem is the way this threat is perceived. Framed as a health problem, building better defenses against the threat of potential pandemics often gets crowded out by more visible and immediate priorities. As a result, many countries have underinvested in their public health infrastructure and capabilities. And global agencies, such as the World Health Organization (WHO) and the rest of the United Nations system, have lacked the focus and capacity to provide the required international support and coordination.

Yet, framed as an issue of human security, the current level of investment in countering this threat to human lives looks even more inadequate. There are very few threats that can compare with infectious diseases in terms of their potential to result in catastrophic loss of life. Yet nations devote only a fraction of the resources spent on national security to prevent and to prepare for pandemics.

Framed as a threat to economic growth and stability, the contrast is equally stark. Both the dynamics of infectious disease and the actions taken to counteract it can cause immense damage to societies and economies. And in a globalized, media-connected world, national borders are no barriers to real or perceived threats. Fears, whether rational or unwarranted, spread even more quickly than infections. And such fears drive changes in behavior and public policy, often leading governments to implement non-scientifically-based actions that exacerbate economic

impact, such as travel bans, quarantines, and blockades on the importation of food, mail, and other items. Yet both at the level of individual countries and at the global level, there has been remarkably little analysis and preparation for potential pandemics as a source of economic risk.

Moreover, while economic or financial problems in fragile or failed states pose very little direct risk to the rest of the world, infectious disease outbreaks in such states represent a direct threat. The lack of health care and public health capacity in these countries is both a disaster for their own populations and an acute vulnerability for the world as a whole. The recent Ebola outbreak showed how fragile post-civil-war nations can serve as incubators for infections of global pandemic potential. Guinea, Liberia, and Sierra Leone are far from being major engines of the African economy, let alone the global economy, but the sparks that came out of their remote jungles ignited an enormously expensive global reaction. Moreover, it could have been much worse. If Ebola had spread to much bigger, more globally integrated cities, such as Lagos, Nairobi, or Kinshasa-Brazzaville, it would have been a very different story. Indeed, we saw the impact of an infectious disease spreading rapidly through urban centers around the world in 2003 when SARS emerged from China.

It was against the backdrop of the Ebola outbreak that the Commission on a Global Health Risk Framework for the Future was conceived. While Ebola was the catalyst, the aim of this exercise was to look to the future, taking a broad view of the potential threats from infectious diseases, without putting particular emphasis on a single outbreak or agent. Indeed, our objective was to set out a framework of institutions, policy, and finance that would be resilient to a wide range of such potential threats, whether known—such as influenzas, coronaviruses, and haemorrhagic fevers—or as yet unknown.

The Commission was established in response to an urgent need. Eight philanthropic and government sponsors recognized the crisis of Ebola, the underlying neglect of health systems around the globe, and the associated peril for economies and security. Because of its extensive history of managing complex advisory studies, these sponsors asked the U.S. National Academy of Medicine (NAM, formerly the Institute of Medicine) to provide staff to support the Commission in carrying out its task in a comprehensive, rigorous, and objective manner. While the NAM provided staff expertise, the Commission's report should be regarded as independent of the NAM and all other organizations. The Commission's task was to provide peer-reviewed consensus recommendations based on evidence and expert opinion. The 17 members of the Commission include citizens of a dozen countries, and its peer reviewers are similarly balanced. Rather than following the well-established procedures of the NAM, the process and policies of the Commission were informed by them and customized to reflect the international nature of this effort and the constrained timeframe. An Independent Oversight Group, composed of 12 eminent and diverse leaders from Africa, the Americas, Asia, and Europe, provided oversight. To ensure that the Commission drew on insights and expertise across the globe, it was informed through a total of 11 days of public meetings held in Accra, Ghana; Hong Kong; London; and Washington, DC. More than 250 invited presenters offered their perspectives at these events.

The Commission's recommendations encompass three broad areas: first, reinforcing national public health capabilities and infrastructure as the foundation of a country's health system and the first line of defense against potential pandemics; second, reinforcing international leadership and coordination for preparedness and response; and third, accelerating research and development in the infectious disease arena. Together, these recommendations amount to a comprehensive, costed, and coherent framework to make the world much safer against the threat of infectious disease.

Inevitably, there will be discussion as to which of the Commission's recommendations are most important and which are the hardest to implement. Four observations are perhaps worth making in this context. First, a policy framework is most effective when the various elements combine to complement each other. Partial implementation makes even those elements that are put in place less efficacious. Second, we should heed the oft-learned lesson that, in this arena as in others, investment in prevention and preparation is worth much more than spending on response, and that the best response is a well-prepared response. Third, ultimately the fight against infectious disease outbreaks will be fought on the ground within specific communities, and the battle will only be won if these communities are engaged with and part of the response. Finally, science is our most powerful weapon in combating infectious diseases,

but the development of tools such as vaccines and diagnostics must be begun before the crisis occurs. Otherwise, the time it takes to deploy scientific tools effectively could be immensely costly in terms of lives and livelihoods.

So, while we should reinforce international mechanisms to lead, coordinate, and resource the response to infectious disease crises, including strengthening WHO's capabilities and creating contingency financing mechanisms through WHO and the World Bank, we should avoid the temptation to see such initiatives as being in any respect a complete answer. These may be the most visible actions, and perhaps the least difficult to achieve, but that does not mean they are the most important.

To make a truly significant impact in reducing the risks to humanity and to human prosperity, we must catalyze the building of stronger public health capabilities and infrastructure at a national level, even in failed and fragile states, and do so in a way that establishes effective community engagement. We do not underestimate the difficulties in achieving this, because it requires leadership at multiple levels and sustained financing. Yet this must be the top priority.

Neither do we underestimate the challenges of mobilizing additional funds for research and development in the infectious disease arena, or of achieving greater harmonization and efficiency in development and approval processes. Yet ultimately, we depend on science to enable us to counter potential pandemics. So we need to find the money and make our processes less complex and cumbersome.

Infectious disease pandemics represent one of the potent threats to humankind, both in terms of potential lives lost and in terms of potential economic disruption. The Commission's recommendations represent a framework for making the world much safer. Now the challenge is to make them happen.

Peter Sands, Chair
Commission on a Global Health Risk
Framework for the Future

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Contents

Acronyms and Abbreviations

AMR	antimicrobial resistance
CDC	U.S. Centers for Disease Control and Prevention
CERF	United Nations Central Emergency Response Fund
CFE	Contingency Fund for Emergencies
CHEPR	Center for Health Emergency Preparedness and Response
CHW	community health worker
CSO	civil society organization
DG	Director-General (World Health Organization)
DHIS-2	District Health Information System
DOD	U.S. Department of Defense
DTF	district task force
ED	executive director
EIS	event information site
FAO	Food and Agriculture Organization
FENSA	Framework for Engaging with Non-State Actors
FETP	Field Epidemiology Training Program
GDP	gross domestic product
GHRF	Commission on a Global Health Risk Framework for the Future
GHSA	Global Health Security Agenda
GOARN	Global Outbreak Alert and Response Network
HIV/AIDS	human immunodeficiency virus/acquired immune deficiency syndrome
IASC	Inter-Agency Standing Committee
ICMRA	International Coalition of Medical Regulatory Authorities
IHR	International Health Regulations
IMF	International Monetary Fund
IOG	International Oversight Group for the GHRF Commission
IOM	U.S. Institute of Medicine
IP	intellectual property
MERS	Middle East respiratory syndrome
MOH	Ministry of Health

NAM	U.S. National Academy of Medicine
NATO	North Atlantic Treaty Organization
NFP	national focal point
NGO	nongovernmental organization
NIH	U.S. National Institutes of Health
NTF	National Task Force
OCHA	United Nations Office for the Coordination of Humanitarian Affairs
OIE	World Organisation for Animal Health
PEF	Pandemic Emergency Financing Facility
PEPFAR	U.S. President's Emergency Plan for AIDS Relief
PHEIC	Public Health Emergency of International Concern
PHEOC	public health emergency operations center
PPDC	Pandemic Product Development Committee
PPE	personal protective equipment
R&D	research & development
RCF	Rapid Credit Facility
RCT	randomized controlled trial
SARS	severe acute respiratory syndrome
SDG	Sustainable Development Goal
SMS	short message service
TGB	Technical Governing Board
TLAC	total loss absorbing capacity
UN	United Nations
UNICEF	United Nations Children's Fund
UNMEER	United Nations Mission for Ebola Emergency Response
UNSG	United Nations Secretary-General
USAID	U.S. Agency for International Development
UVRI	Uganda Virus Research Initiative
WEF	World Economic Forum
WHA	World Health Assembly
WHO	World Health Organization

Executive Summary

Pandemics and epidemics have killed countless millions throughout human history. Highly virulent infectious diseases, such as the plague, cholera, and influenza, have repeatedly swept through human societies, causing death, economic chaos, and, as a consequence, political and social disorder. In the past 100 years, the 1918 influenza pandemic killed approximately 50 million (CDC, 2014); HIV/AIDS took the lives of more than 35 million (CDC, 2013). Although more recently-emerging epidemics, such as severe acute respiratory syndrome (SARS) in 2003, H1N1 in 2009—and, most recently, the Ebola epidemic in West Africa—have had lower death tolls, they have nevertheless had a huge impact in terms of both social and economic disruption.

It is clear that, despite extraordinary advances in medical science, we cannot be complacent about the threat of infectious diseases. The underlying rate of emergence of infectious diseases appears to be increasing, most likely due to the growing human population and consequent greater food production and animal–human interaction. Contagion risks are also larger as globalization and urbanization drive travel and trade, creating ever-increasing personal interaction and interdependence.

Infectious diseases remain one of the biggest risks facing humankind. Few events are capable of equal damage to human lives and livelihoods. Yet the global community spends relatively little to protect populations from the risks of pandemics. Compared with other high-profile threats to human and economic security—such as war, terrorism, nuclear disasters, and financial crises—we are underinvested and underprepared. This is the neglected dimension of global security.

The Ebola epidemic was both a tragedy and a wake-up call. The outbreak revealed deficiencies in almost every aspect of global defenses against potential pandemics. Disease surveillance proved inadequate. Alerts were escalated too slowly. Local health systems were quickly overwhelmed. Communities lost trust. Governments elsewhere in the world reacted haphazardly to the threat of contagion. The international response was sluggish, ill-coordinated, and clumsy.

Eventually, we made great progress toward containing Ebola, thanks to the courage and determination of health care workers and community leaders on the ground and a massive deployment of resources by the international community. But more lives were lost than should have been, and the economic costs were far greater than they could have been.

Before the memories of Ebola fade, we should heed this call. Global health security is a global public good—making each of us safer depends on making all of us safer; holes in one community's defenses are holes in all of our defenses. Global leaders must therefore commit to creating and resourcing a comprehensive global framework to counter infectious disease crises. We cannot afford to continue to neglect this risk to global security.

THE CASE FOR INVESTING IN PANDEMIC PREPAREDNESS

There is a strong case for investing more to make the world safer from the threat of potential pandemics. Although there are enormous uncertainties in modeling the risks and potential impact of infectious disease crises, the case is compelling no matter how it is calculated. The po-

tential losses in terms of human lives and livelihoods are immense. The economic costs alone can be catastrophic. By our calculation, the annualized expected loss from potential pandemics is more than $60 billion.[1] Against this, we propose incremental spending of about $4.5 billion per year—a fraction of what we spend on other risks to humankind. Framed as a risk to human security, this is a compelling investment. Framed as a risk to economic growth and stability, it is equally convincing.

Moreover, the risks of spending too much or too little are asymmetric. Even if we have overestimated the risks of potential pandemics, money invested to mitigate them will still be money well spent. Most of the investments we recommend will help achieve other high-priority health goals, such as countering antimicrobial resistance and containing endemic diseases like tuberculosis and malaria. Yet if we spend too little, we open the door to a disaster of terrifying magnitude. The Commission therefore recommends the following:

The G7, G20, and United Nations (UN), under the leadership of the UN Secretary General, should reinforce and sustain international focus and actions to protect human lives and livelihoods from the threat of infectious diseases by:

Recommendation A.1: Committing to implementing the framework set out in the report *The Neglected Dimension of Global Security: A Framework to Counter Infectious Disease Crises* and embodied in Recommendations B.1–D.3.

Recommendation A.2: Committing and mobilizing the incremental financial resources required to implement the framework, as set out in the report *The Neglected Dimension of Global Security: A Framework to Counter Infectious Disease Crises*, which amount to about $4.5 billion per year.

Recommendation A.3: Monitoring progress of implementation by commissioning an independent assessment in 2017 and every 3 years thereafter.

STRENGTHENING PUBLIC HEALTH AS THE FOUNDATION OF THE HEALTH SYSTEM AND FIRST LINE OF DEFENSE

Robust public health infrastructure and capabilities are the foundation of resilient health systems and the first line of defense against infectious disease outbreaks that could become pandemics. Yet far too many countries have failed to build the necessary capabilities and infrastructure. Even by their own internal assessments, 67 percent of the World Health Organization (WHO) member states fail to meet the requirements of the 2005 International Health Regulations (IHR) (WHO, 2015); objective external evaluations would almost certainly reveal even lower rates of compliance.

Previous international efforts to galvanize greater commitment to building resilient public health systems have largely failed. After every outbreak of infectious disease, there is a flurry of activity and reports, but political interest quickly wanes and other priorities dominate.

Building and sustaining strong health systems is achievable with leadership and commitment, at the national, provincial, and local levels, even in relatively poor countries. Countries like Uganda have demonstrated that creating resilient and effective public health systems that can identify and contain infectious disease outbreaks is not beyond reach. What is required is leadership. Governments must recognize that protecting against the threat of infectious disease is a fundamental part of their basic duty to protect their citizens.

Building effective public health systems requires more than surveillance systems, laboratory networks, and clinical capabilities. Engaging and communicating with communities is critical. Community awareness enhances surveillance. Trust and cooperation of the local population is a vital component of any response strategy.

Also essential is clarity about the benchmark attributes of a highly-functioning public health system and transparency about actual achievement against these benchmarks. Therefore, we need a clear definition of the core capacities required to deliver according to the IHR requirement—plus regular, rigorous, and objective assessments of delivery against these benchmarks. Publication of such assessments will enable civil society to hold governments accountable and facilitate prioritization and the monitoring of progress.

We make 10 recommendations about building more effective public health infrastructure and capabilities at

[1] All monetary figures in U.S. dollars.

the national level as the foundation of a more resilient health system and the first line of defense against potential pandemics.

First, we need clear definitions of the required infrastructure, capabilities, and benchmarks for effective functioning for a national public health system.

Recommendation B.1: The World Health Organization, in collaboration with member states, should develop an agreed-on, precise definition and benchmarks for national core capabilities and functioning, based on, and implemented through, the International Health Regulations and building on the experiences of other efforts, including the Global Health Security Agenda and the World Organization for Animal Health Terrestrial Animal Health Code by the end of 2016. Benchmarks should be designed to provide metrics against which countries will be independently assessed (see Recommendation B.2).

Second, we also need a regular, independent, and objective mechanism to evaluate country performance and to ensure publication of the results. This is essential for prioritization, progress monitoring, and accountability.

Recommendation B.2: The World Health Organization should devise a regular, independent, transparent, and objective assessment mechanism to evaluate country performance against the benchmarks defined in Recommendation B.1, building on current International Health Regulations monitoring tools and Global Health Security Agenda assessment pilots, by the end of 2016.

Third, all countries must agree to participate. Otherwise, we will encounter adverse selection, with those most needing evaluation declining to participate.

Recommendation B.3: By the end of 2016, all countries should commit to participate in the external assessment process as outlined in Recommendation B.2, including publication of results.

Fourth, to reinforce the incentive to participate in the assessment mechanism, international partners should make clear to countries needing assistance that support is subject to participation in this mechanism. For countries in need of external support to reinforce their core capacities, the assessment process will establish a clear starting point and enable prioritization of actions to fill gaps.

Recommendation B.4: The World Bank, bilateral, and other multilateral donors should declare that funding related to health system strengthening will be conditional upon a country's participation in the external assessment process.

To underscore the importance of pandemic preparedness as a way of protecting economic growth and stability, the International Monetary Fund (IMF) should routinely incorporate the results of the external assessment of national core capacities in its economic evaluations of individual countries. The IMF should also consider non-participation in the assessment process a signal of a country's lack of commitment to managing economic risk.

Recommendation B.5: The International Monetary Fund should include pandemic preparedness in its economic and policy assessments of individual countries, based on outcomes of the external assessment of national core capacities as outlined in Recommendation B.2.

The primary responsibility for achieving and sustaining public health infrastructure and capabilities of the required standard rests with national governments. We therefore call on national governments to develop and publish plans by mid-2017 (where plans do not already exist) to achieve benchmark status in the required core capacities by 2020. Plans should be comprehensive and realistic, addressing the challenges of sustainable financing and skills building.

Recommendation B.6: Countries should develop plans to achieve and maintain benchmark core capacities (as defined in Recommendations B.1). These plans should be published by mid-2017, with a target to achieve full compliance with the benchmarks by 2020. These plans should include sustainable resourcing components, including both financing and skills.

WHO should provide technical assistance to national governments seeking to rectify deficiencies in

their public health core capacities by building skills and transferring best practices.

Recommendation B.7: The World Health Organization (WHO) should provide technical support to countries to fill gaps in their core capacities and achieve benchmark performance. (Technical support will be coordinated through a WHO Center for Health Emergency Preparedness and Response; see Recommendation C.1.)

Because national governments must take responsibility for protecting their citizens from the threat of infectious disease, the primary source of funding for building and maintaining public health core capacities must be their own domestic budgets. This is also the best way of ensuring the funding is stable and sustained.

We therefore call on the governments of upper- and upper-middle-income countries to ensure that sufficient funding for public health systems is incorporated in their national budgets. Lower-middle- and low-income countries need to adequately invest in domestic core capacities. In addition, there may be a need for external assistance to rectify deficiencies and build capabilities. Importantly, even lower-income governments should seek to devise pathways to full domestic resourcing.

Recommendation B.8: National governments should develop domestic resourcing plans to finance improvement and maintenance of core capacities as set out in the country-specific plans described in Recommendation B.6. For upper- and upper-middle-income countries, these plans should cover all financing requirements. For lower-middle- and low-income countries, these plans should seek to develop a pathway to full domestic resourcing, with a clear timetable for achieving the core capacity benchmarks.

Given that lower-middle- and low-income countries are likely to need financial assistance in filling gaps and strengthening their public health systems, the World Bank should convene other multilateral donors, bilateral donors, and other philanthropic sources to cultivate financial support for such plans. This support should be contingent on (1) the plan's inclusion of a pathway to full domestic resourcing and (2) the recipient country's cooperation with the external assessment process (see Recommendation B.2).

Recommendation B.9: The World Bank should convene other multilateral donors (including the African Development Bank, Asian Development Bank, New Development Bank, United Nations Development Program, and Asian Infrastructure Investment Bank) and development partners by mid-2017 to secure financial support for lower-middle- and low-income countries in delivering the plans outlined in Recommendation B.6.

Fragile states, failed states, and warzones pose a particular problem for the maintenance of basic public health infrastructure and capabilities. For these situations, we recommend that the UN Secretary General takes the lead, working with WHO and other parts of the UN system to sustain at least minimal public health capacities within the context of the broader UN strategy for each particular circumstance.

Recommendation B.10: The United Nations (UN) Secretary General should work with the World Health Organization and other parts of the UN system to develop strategies for sustaining health system capabilities and infrastructure in fragile and failed states and in warzones, to the extent possible.

STRENGTHENING GLOBAL COORDINATION AND CAPABILITIES

While reinforcing the first line of defense at the country level is the foundation of a more effective global framework for countering the threat of infectious diseases, strengthening international coordination and capabilities is the next most vital component. Pandemics know no borders, so international cooperation is essential. Global health security is a global public good requiring collective action.

Ebola revealed significant shortcomings in the functioning and performance of the international public health system. Neither WHO, the UN system, nor regional entities escaped criticism. There were failures of execution, coordination, and leadership at multiple levels.

The Commission believes that an empowered WHO must take the lead in the global system to identify, prevent, and respond to potential pandemics. There is no realistic alternative. However, we believe that WHO must make significant changes in order to play this role effectively. It needs more capability and more resources, and it must demonstrate more leadership.

First, WHO needs to establish a dedicated and well-resourced operational center for coordinating preparedness and response. This should be a dedicated center, not a program—reflecting its status as a permanent and critical component of WHO's role. Furthermore, this center should be guided and overseen by a Technical Governing Board (TGB). The TGB should be chaired by the Director-General, but otherwise its composition should comprise members who are independent of and drawn from outside WHO on the basis of technical expertise.

Recommendation C.1: By the end of 2016, the World Health Organization should create a Center for Health Emergency Preparedness and Response—integrating action at headquarters, regional, and country office levels—to lead the global effort toward outbreak preparedness and response. This center should be governed by an independent Technical Governing Board.

The WHO Center for Health Emergency Preparedness and Response (CHEPR) will need sustainable funding. To achieve this, there should be an appropriate increase in member states' core contributions. These required contributions are a better resource than relying on voluntary contributions, which are often unpredictable and ultimately unsustainable, to support a core function of WHO.

Recommendation C.2: In May 2016, the World Health Assembly should agree to an appropriate increase in the World Health Organization member states' core contributions to provide sustainable financing for the Center for Health Emergency Preparedness and Response.

We support the World Health Assembly's resolution to create a $100 million contingency fund to enable rapid response to health emergencies, including infectious disease outbreaks. We believe one-off contributions or binding contingent commitments proportional to member state core contributions are the most efficient way to finance this fund.

Recommendation C.3: By the end of 2016, the World Health Organization should create and fund a sustainable contingency fund of $100 million to support rapid deployment of emergency response capabilities through one-off contributions or commitments proportional to assessed contributions from member states.

Ebola revealed weaknesses in WHO's coordination with other parts of the UN system. WHO and the UN should address the need for coordination, agreeing on effective mechanisms for crises that are primarily health-driven as well as those that pose broader humanitarian challenges. The composition of the TGB, which will include representation from other parts of the UN system, will facilitate this. Where a potential pandemic goes beyond the capacity of WHO and/or becomes a broader humanitarian crisis—or where the health challenges are just one element of a broader crisis—there should be an agreed-on escalation process, facilitating the UN Secretary-General's overall control of such situations.

Recommendation C.4: By the end of 2016, the United Nations (UN) and the World Health Organization should establish clear mechanisms for coordination and escalation in health crises, including those that become or are part of broader humanitarian crises requiring mobilization of the entire UN system.

Regional networks have an important role to play, complementing the regional structure of WHO. They can enhance cross-border cooperation, facilitate the sharing of scarce resources, and provide extra capacity in the event of outbreaks. WHO needs to recognize the value of such networks and improve its linkages with them.

Recommendation C.5: By the end of 2017, the World Health Organization should work with existing formal and informal regional and sub-regional networks to strengthen linkages and coordination, and thus enhance mutual support and trust, sharing of informa-

tion and laboratory resources, and joint outbreak investigations among neighboring countries.

The Ebola outbreak demonstrated the importance of non-state actors—from community leaders to international nongovernmental organizations and private-sector businesses. It also revealed many shortcomings in approaches taken at both the national and global level to engage with such players. WHO and individual national governments should proactively create mechanisms to engage with the various categories of non-state actors on preparedness and response. Waiting until the crisis hits is too late.

Recommendation C.6: By the end of 2016, the World Health Organization and national governments should enhance means of cooperation with non-state actors, including local and international civil society organizations, the private sector, and the media.

At the moment there is no formalized intermediate level of public alert below a Public Health Emergency of International Concern (PHEIC), which is an extremely rare event. The Commission believes that there would be merit in generating a daily "watch list" of outbreaks of PHEIC potential. The CHEPR should develop clear criteria to determine the outbreaks included in this list. This would raise awareness of the underlying pattern of potential threats and normalize the process of raising alerts.

Recommendation C.7: By the end of 2016, the World Health Organization (WHO) should establish a mechanism to generate a daily high-priority "watch list" of outbreaks with potential to become a Public Health Emergency of International Concern to normalize the process of reporting of outbreaks by country and encourage necessary preparedness activities. WHO should communicate this list to national focal points on a daily basis and provide a public summary on a weekly basis.

Self-interested and misguided behavior by individual countries can be an impediment to an effective international response to infectious disease threats, whether by delaying or suppressing data or alerts or by imposing excessive restrictions on travel and trade. We believe the global community should establish tougher norms and pursue greater compliance in these areas—and be prepared to "name and shame" where necessary.

Recommendation C.8: By the end of 2016, the World Health Assembly should agree on new mechanisms for holding governments publicly accountable for performance under the International Health Regulations and broader global health risk framework, as detailed in Recommendation B.2, including:

- **protocols for avoiding suppression or delays in data and alerts, and**
- **protocols for avoiding unnecessary restrictions on trade or travel.**

We support the World Bank's proposal to create a Pandemic Emergency Financing Facility as a complement to WHO's contingency fund. If innovative insurance and capital market mechanisms can be demonstrated to be both economically viable and practical, these could potentially represent an attractive new source of funds. While clearly politically challenging to implement, binding contingent commitments from donor governments represent an economic and flexible alternative.

Recommendation C.9: By the end of 2016, the World Bank should establish the Pandemic Emergency Financing Facility as a rapidly deployable source of funds to support pandemic response.

To ease fiscal pressure on governments that raise infectious disease outbreak alerts, and reduce the incentive to avoid doing so, the IMF should make clear that it is in a position to provide budgetary assistance when needed.

Recommendation C.10: By the end of 2016, the International Monetary Fund should ensure that it has the demonstrable capability to provide budgetary support to governments raising alerts of outbreaks, perhaps through its existing Rapid Credit Facility.

ACCELERATING RESEARCH AND DEVELOPMENT TO COUNTER INFECTIOUS DISEASES

As part of creating a more effective global framework to counter infectious disease threats, we need to strengthen our scientific and technical resources against these threats. This means accelerating research and development (R&D) in a coordinated manner across the whole range of relevant medical products, including vaccines, therapeutics, diagnostic tools, personal protective equipment, and instruments.

To ensure that incremental R&D has maximum impact in strengthening defenses against infectious diseases, we propose that WHO galvanize the creation of a Pandemic Product Development Committee (PPDC) to mobilize, prioritize, allocate, and oversee R&D resources relating to infectious diseases with pandemic potential. The chair of the PPDC should be an R&D expert appointed by the WHO Director-General, with the rest of the membership comprised of internationally recognized leaders with expertise in discovery, development, regulatory review and approval, and manufacturing of medical products. Although supported by WHO, the PPDC should operate independently and should be held accountable by the TGB. To facilitate this linkage, the chair of the PPDC should be a member of the TGB.

Recommendation D.1: By the end of 2016, the World Health Organization should establish an independent Pandemic Product Development Committee, accountable to the Technical Governing Board, to galvanize acceleration of relevant research and development, define priorities, and mobilize and allocate resources.

Accelerating R&D will require a significant financial investment. We recommend mobilization of about $1 billion per year (as part of the total investment proposed of $4.5 billion). Deployment of these funds, which we envision as being sourced from a variety of contributors, will be coordinated by the PPDC.

Recommendation D.2: By the end of 2016, the World Health Organization should work with global research and development stakeholders to catalyze the commitment of $1 billion per year to maintain a portfolio of projects in drugs, vaccines, diagnostics, personal protective equipment, and medical devices coordinated by the Pandemic Product Development Committee.

Enhancing the effectiveness of R&D requires agreement on protocols and approaches in a number of key aspects of the way R&D is conducted, including commitment to scientific standards during a crisis, engagement of communities, and harmonization of multiple aspects of development and approval, and manufacturing and distribution processes.

Recommendation D.3: By the end of 2016, the Pandemic Product Development Committee should convene regulatory agencies, industry stakeholders, and research organizations to:

- **Commit to adopting research and development approaches during crises that maintain consistently high scientific standards.**
- **Define protocols and practical approaches to engage local scientists and community members in the conduct of research.**
- **Agree on ways to expedite medical product approval, manufacture, and distribution, including convergence of regulatory processes and standards; pre-approval of clinical trial designs; mechanisms for intellectual property management, data sharing and product liability; and approaches to vaccine manufacture, stockpiling, and distribution.**

BUILDING A GLOBAL FRAMEWORK TO COUNTER INFECTIOUS DISEASE CRISES

For far too long, infectious disease has been the neglected dimension of global security. Few threats pose such risks to human life and well-being. Yet we have invested relatively little to counter such risks, and neither national nor global systems performed well when tested.

The Commission believes the time has come to reverse this neglect. The framework we propose has three key elements:

1. Stronger national public health capabilities, infrastructure, and processes built to a common standard and regularly assessed through an objective, transparent process fully consistent with international legal obligations under the IHR.

2. More effective global and regional capabilities, led by a reenergized WHO, through a dedicated CHEPR, coordinated effectively with the rest of the UN system, and supported by the World Bank and IMF.
3. An accelerated program of R&D, deploying $1 billion per year and coordinated by a dedicated committee.

These actions have a price tag. We estimate an incremental funding requirement of about $4.5 billion per year. This comprises:

- The upper end of the World Bank's 2012 estimated range of $1.9–$3.4 billion per year for the cost of upgrading national pandemic preparedness capabilities (World Bank, 2012).
- Our proposed figure of $1 billion per year for infectious disease prevention and response R&D (see Chapter 5).
- High-level preliminary estimates of costs for the establishment of WHO's CHEPR ($25 million), WHO's Contingency Fund for Emergencies ($25–$30 million) and the World Bank's Pandemic Emergency Financing Facility ($80–$100 million), which amount together to about $130–$155 million per year (see Chapter 4).

$4.5 billion is not a small sum, but neither is it beyond reach. In the context of estimated expected economic losses from pandemics of more than $60 billion per year, it is very good investment. Considering the potential threat to human lives, the case is even stronger.

REFERENCES

CDC (Centers for Disease Control and Prevention). 2013. *HIV/AIDS: Statistics overview.* http://www.cdc.gov/hiv/statistics/overview/index.html (accessed November 15, 2015).

CDC. 2014. *Reconstruction of the 1918 influenza pandemic virus.* http://www.cdc.gov/flu/about/qa/1918flupandemic.htm (accessed November 15, 2015).

World Bank. 2012. *People, pathogens and our planet: Volume 2—the economics of One Health*. Washington, DC: World Bank.

WHO (World Health Organization). 2015. *Implementation of the International Health Regulations (2005), Report of the Review Committee on Second Extensions for Establishing National Public Health Capacities and on IHR Implementation*. Sixty-Eighth World Health Assembly. Geneva: WHO.

1
Introduction

With failures occurring at all levels, the recent Ebola outbreak in West Africa exposed significant weaknesses in the global health system and culminated in a tragic humanitarian disaster. At the national level in affected countries, there was significant delay in acknowledging the magnitude of the outbreak. And after the outbreak was recognized, the international response was slow and uncoordinated. Mechanisms for the establishment of public–private partnerships were lacking. For example, the development of lifesaving medical products was reactive, rather than proactive. An easily mobilized reserve of funds to support the response was not available. Critical financial and human resources were slow to arrive or never arrived at all. Countries were reluctant to acknowledge the severity of the outbreak and obstructed early notification. Surveillance and information systems were not in place or failed to provide early warning.

All three affected countries lacked an adequately trained workforce, infrastructure, supplies, and the necessary medications to respond to the outbreak. Moreover, these three countries had never experienced an Ebola outbreak before making this an unexpected and more challenging situation to respond to. All this contributed to widespread fear and questioning of the ability and willingness of governments and humanitarian agencies to respond effectively, and, in many places, people were reluctant to seek health services (WHO, 2015a). These and many other factors contributed to an outbreak with devastating health, economic, and social impacts.

Past outbreaks of other diseases, including H1N1 influenza, severe acute respiratory syndrome (SARS), and human immunodeficiency virus (HIV), have also had significant economic and social impacts. These outbreaks, like Ebola, exposed weaknesses in national health systems and the global public health response, but did not galvanize the degree of reform required. This most recent Ebola outbreak triggered several initiatives calling for change:

- The World Economic Forum (WEF), in collaboration with the Boston Consulting Group, published *Managing the Risk and Impact of Future Epidemics: Options for Public–Private Collaboration* in June 2015. This report explored the role of public–private partnership when responding to epidemics, using lessons learned from the Ebola response (WEF, 2015).
- In January 2015, the World Health Organization (WHO) Executive Board's special session on Ebola adopted Resolution EBSS.R1, establishing an independent, expert panel to evaluate WHO's response to the Ebola crisis. The panel was established in March 2015 and released its report in July 2015 (WHO, 2015b).
- The Harvard Global Health Institute and the London School of Hygiene & Tropical Medicine set up the Independent Panel on the Global Response to Ebola to create actionable change through assessment of the global response. This report was released on November 23, 2015 (Moon et al., 2015).
- The United Nations (UN) High-Level Panel on Global Response to Health Crises was convened by UN Secretary-General Ban Ki-moon. This panel will make recommendations on the basis of a wide range of consultations across sectors and in affected communities, and will submit its final report to the Secretary-General in early 2016 (UN Secretary-General, 2015).

TABLE 1-1 Other Relevant Initiatives

Initiative	Affiliation	Description	Timeframe
Global Health Security Agenda	U.S. government in partnership with other nations, international organizations, and public and private stakeholders	Created to prevent, detect, and rapidly respond to threats of disease before they become epidemics.	Affirmed September 2014 Second Ministerial Meeting September 2015
Managing the Risk and Impact of Future Epidemics: Options for Public–Private Collaboration	World Economic Forum and Boston Consulting Group	Explored public–private partnerships when responding to epidemics using lessons learned from the Ebola response.	Report published June 2015
Independent Panel to Assess WHO's Response to Ebola Outbreak	World Health Organization (WHO)	Convened by the WHO Director-General to evaluate WHO's response to the Ebola crisis.	Report published July 2015
Independent Panel on the Global Response to Ebola	Harvard Global Health Institute and London School of Hygiene & Tropical Medicine	Determined necessary reforms to the global system for outbreak prevention and response, considering evidence from the Ebola epidemic.	Report published November 2015
UN High-Level Panel on Global Response to Health Crises	United Nations	Convened by the UN Secretary-General to make recommendations for strengthening national and international systems to prevent and manage future health crises.	Report to Secretary-General January 2016
Pandemic Emergency Financing Facility	World Bank Group	Proposed to hold financial resources for global health emergencies to allow for rapid deployment of equipment, medications, and human resources.	Will be presented in May 2016 at G7 meeting

SOURCES: GHSA, 2015; HGHI, 2015; WEF, 2015; WHO, 2015b; World Bank, 2015.

- Finally, to address deficiencies in the financing of outbreak response, the World Bank Group has launched an initiative to create a Pandemic Emergency Financing Facility (PEF). The PEF is expected to provide financial resources for global health emergencies to allow for the rapid deployment of equipment, medications, and human resources (World Bank, 2015).

For additional information on these relevant initiatives, see Table 1-1.

ORIGIN OF THE PRESENT REPORT

The National Academy of Medicine (NAM), internationally known for rigorous procedures to ensure independence and the ability to convene experts with broad multi-disciplinary reach, was encouraged by multiple stakeholders to assemble global experts to develop a plan for future preparedness and response to global infectious disease threats. After two planning meetings, the NAM became Secretariat for the Global Health Risk Framework for the Future (GHRF) initiative—an international, independent, evidence-based, authoritative, multi-stakeholder expert commission process to generate a comprehensive report with recommendations for improving governance and finance in matters of global health security pertinent to infectious disease outbreaks of international concern. The initiative received support from the Paul G. Allen Family Foundation, the Ford Foundation, The Bill & Melinda Gates Foundation, Mr.

Ming Wai Lau, the Gordon and Betty Moore Foundation, The Rockefeller Foundation, the U.S. Agency for International Development, and the Wellcome Trust.

CHARGE TO THE COMMISSION

The GHRF Commission was tasked with conducting a study and preparing a report to recommend an effective global architecture for recognizing and mitigating the threat of epidemic infectious diseases. While our report focuses on the preparedness and response to these infectious disease threats, we acknowledge that the implementation of our recommendations will also help address other global health concerns such as the increasing appearance and spread of antimicrobial resistance (AMR). For instance, the strengthening of surveillance systems and laboratory capacity that will help us be better prepared to respond to infectious disease outbreaks, will also facilitate early identification and actions to prevent further transmission of a resistant strain.

The complete statement of task is provided in Box 1-1. Four Institute of Medicine (IOM) workshops were held on the following topic domains to provide input for the Commission's final report:

1. Governance for global health,
2. Financing response to pandemic threats,
3. Resilient health systems, and
4. Research and development of medical products.

The Commission was asked to consider the evidence supplied by these four workshops, as well as literature already published on lessons learned from the recent Ebola outbreak and other outbreaks of global impact. It is important to note that the charge of this Commission was not to provide a comprehensive analysis of the lessons learned drawn from the recent Ebola outbreak, but to draw on previous work to develop an understanding of common lessons learned from different previous in-

BOX 1-1
Commission on Creating a Global Health Risk Framework for the Future

Statement of Task

An international, independent, multi-stakeholder expert commission will conduct a study and prepare a report to recommend an effective global architecture for recognizing and mitigating the threat of epidemic infectious diseases. The commission will receive input from four Institute of Medicine workshops that will be coordinated:

1. Governance for global health, which will explore global, national, and local capabilities, to include those required by the International Health Regulations (2005), to facilitate the collective action of the governmental, intergovernmental, corporate, and nonprofit sectors as they contribute to preparedness and response;
2. Financing response to pandemic threats, which will encompass public and private sector roles in financing preparedness, and response to epidemics. Financing mechanisms for public health surveillance, workforce mobilization and acquisition of medical commodities that can channel funds swiftly while minimizing transaction times and other expenses will be discussed;
3. Resilient health systems, which will include integrated surveillance and health information systems; workforce capacity; health system infrastructure; community, regional, and global partner engagement; and supply chain coordination and management; and
4. Research and development of medical products, which will assess the current product development platforms; explore incentives and infrastructure for product development, and conditions and needs for effective public–private partnerships; and address standards and approaches for regulatory harmonization and systems capacity.

The commission will consider the evidence supplied by these four workshops and the literature published on lessons learned on the current Ebola outbreak and other outbreaks of global impact such as H1N1 influenza, Middle East respiratory syndrome (MERS), and severe acute respiratory syndrome (SARS). The commission will deliberate and evaluate options in these four domains to strengthen global, regional, national, and local systems to better prepare, detect, and respond to epidemic infectious diseases. Interrelations among sectors will be studied. Conclusions and actionable recommendations will be offered to guide policy makers, international funders, civil society organizations, and the private sector, with the understanding that stakeholders may adapt and apply the recommended architecture to global health emergencies beyond epidemic infectious diseases. In an effort to minimize overlap and maximize synergy, the commission will coordinate as possible with other global initiatives that are developing recommendations for improving the response to future global public health threats.

fectious disease outbreaks to inform the Commission's recommendations. We strived to identify those lessons learned that could help us develop a framework that can effectively address future known or unknown infectious disease threats. Summaries of four IOM workshops developed to gather evidence for this study (as described later in this chapter) were published in January 2016 (see nam.edu/GHRF for more information). These summaries compile the experiences related to issues of health systems, governance, finance, and research and development as shared by participants including those from the recent Ebola outbreak.

The statement of task required that the Commission deliberate and evaluate options in these four topic domains to strengthen global, regional, national, and local systems to better prepare, detect, and respond to epidemic infectious diseases. The Commission was charged with offering conclusions and actionable recommendations to guide policy makers, international funders, civil society organizations, and the private sector.

STRUCTURE OF INITIATIVE

The initiative comprises an International Oversight Group (IOG), an independent Commission, and four IOM workshops that provided evidence to the Commission (see Figure 1-1).

International Oversight Group

The IOG, a body of leaders representing various stakeholders with relevant expertise and global representation, was formed to ensure the independence and objectivity of the Commission, and to protect integrity and maintain public confidence in the process. The IOG steered the Commission throughout the process, including by creating the charge to the Commission, approving the slate of Commissioners, guiding report review, and as-

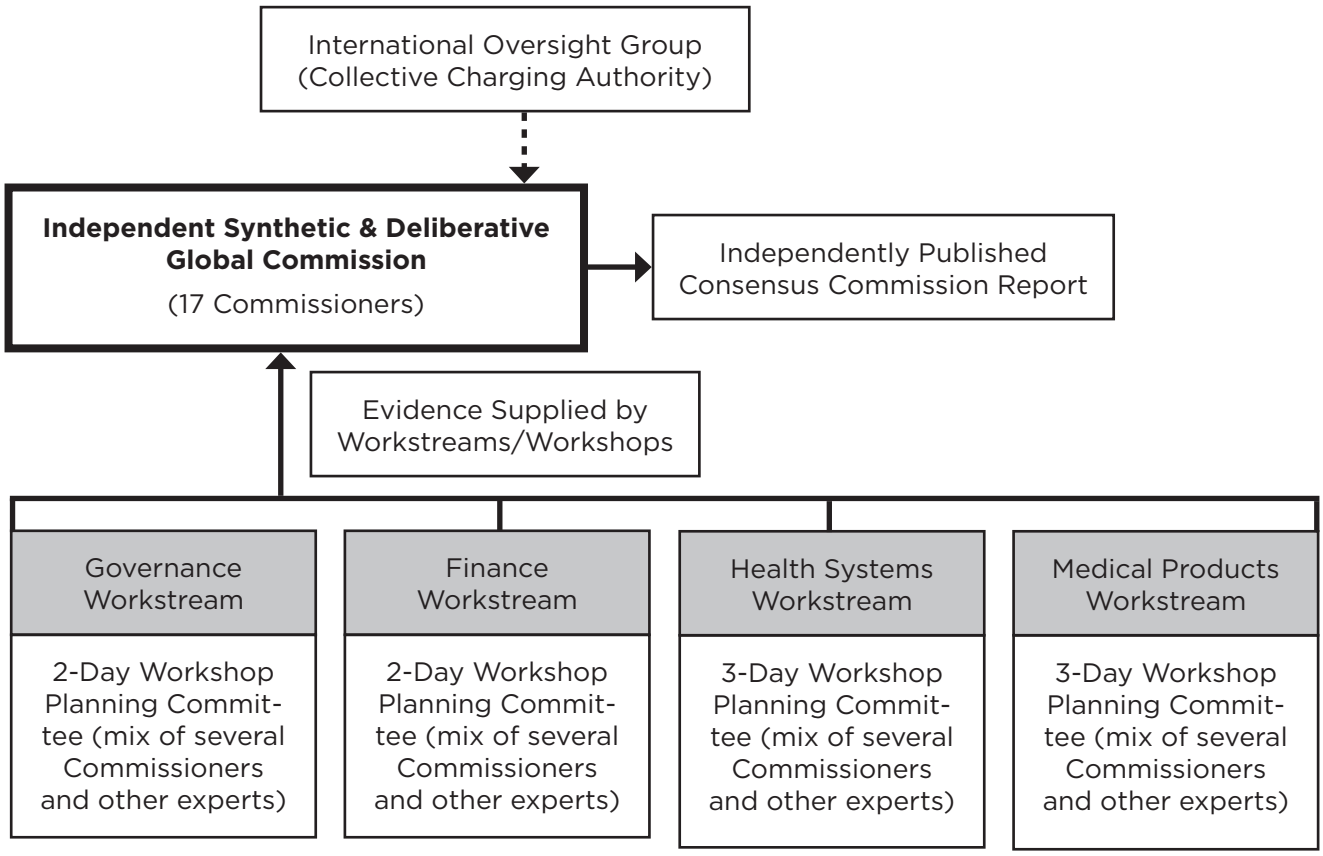

FIGURE 1-1 The structure of the Global Health Risk Framework for the Future initiative.

sisting in the dissemination process. The IOG was tasked to:

1. **Determine the scope of the study:** In preparation for this study, NAM staff worked with sponsors and technical advisors to develop a formal statement of task, which defined and bounded the scope of the study and the balance of perspectives needed on the Commission. The IOG reviewed the proposed statement of task to ensure that the task reflected the current global need for such a framework and made refinements as needed.
2. **Approve the Commission slate:** The NAM received and reviewed more than 150 nominations for commissioners. Commissioners were proposed for service based on their expertise, geographic representation, and availability to perform the task. The IOG assessed whether the expertise required was present in the slate proposed and evaluated the overall composition of the Commission in terms of different experiences and perspectives. The IOG also defined what constituted a conflict of interest and if its presence should prevent an individual from serving on the Commission. In addition, the IOG determined whether a conflict of interest was unavoidable and how it should be handled. A primary goal of this process was to ensure that Commissioners' points of view were balanced so that the Commission could carry out its charge objectively and credibly.
3. **Approve the Commission process for meetings, information gathering, deliberations, and report drafting:** The IOG approved the Commission's approach as outlined in the following section.
4. **Provide guidelines for the report review process:** As a final check on the quality and objectivity of the study, the IOG determined the characteristics of the external review process for the final report and provided suggestions for specific processes. The review process was structured to ensure that the report addressed its approved study charge and did not go beyond it, that the findings were supported by the scientific evidence and arguments presented, that the exposition and organization were effective, and that the report was impartial and objective. The IOG did not review the report draft or provide comments on the report conclusions or recommendations.
5. **Assist with the development of a dissemination strategy:** Dissemination of the final report is a key component for the success of this initiative. Therefore, the IOG assisted with identifying key decision makers and audiences, developing a dissemination strategy, and participating, if feasible, in its implementation.

The Commission

The Commission is made up of 17 experts drawn from different nations and representing a wide range of expertise, including governance; finance; disease control; surveillance; workforce mobilization; humanitarian and pandemic response; health systems; public–private partnerships; social science; and research, development, acquisition, and distribution. The Commissioners were screened for conflicts of interest in order to ensure their independence.

The Commission held three meetings and one public session (see Appendix A) during the course of its work in 2015. At these meetings, Commissioners took time to understand their charge, considered evidence, and formed recommendations.

The Workstreams

The Commission's deliberations were based in large part on the evidence gathered and discussed at four IOM workshops in late 2015 (see Appendix B for workshop agendas):

- August 5–7: A Workshop on Resilient and Sustainable Health Systems to Respond to Global Infectious Disease Outbreaks, Accra, Ghana
- August 19–21: A Workshop on Research and Development of Medical Products, Hong Kong, China
- August 27–28: A Workshop on Pandemic Financing, Washington, DC, United States of America
- September 1–2: Governance for Global Health—A Workshop, London, United Kingdom

Consultants

To fulfill its statement of task in regard to financing response to pandemic threats, the Commission worked with two consultants. They provided technical expertise in pandemic financing and modeling the business case for investing in preparedness for global health events. The consultants communicated with Commissioners via

conference calls, and Commission deliberations determined how the consultants' analysis would be incorporated into the final recommendations.

Other Sources of Information

Two consultation sessions were organized to complement workshop discussions and ensure that government, private-sector, civil society, and academia perspectives were captured:

- September 25, 2015: Session with members of the U.S. federal government, Washington, DC
- October 9, 2015: Webinar session with international and national representatives from multilateral organizations, academia, nonprofit, and private sector

The Commission also conducted consultations with WHO Director-General Margaret Chan on November 20, 2015, U.S. Centers for Disease Control and Prevention Director Thomas Frieden on October 21, 2015, and World Bank Group President Jim Yong Kim on November 12, 2015, to gather updated information about their respective organizations' current efforts on global health preparedness and response.

In addition to the workshops, Commission meetings, and consultations, the Commission conducted a literature review on infectious diseases, pandemics and pandemic risk, governance for health, finance, health systems, research and development, aid effectiveness, and existing global health frameworks, among other topics.

COORDINATION WITH OTHER INITIATIVES

The Commission also coordinated with many of the other global initiatives tasked with developing recommendations for improving the response to future global public health threats (see Table 1-1). It is important to note that, while some GHRF Commissioners contributed to other initiatives, this study preserved its high degree of independence and the integrity of its processes as outlined in this chapter.

REVIEW PROCESS

This report has been reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise. Reviewers were approved by the IOG. The purpose of this independent review was to provide candid and critical comments that will assist the Commission in making its report as sound as possible and to ensure that the report meets standards for objectivity, evidence, and responsiveness to its charge. Reviewers were asked to consider whether in their judgment the evidence and arguments presented were sound and the report was fully responsive to the charge, not whether they concurred with the findings. The Commissioners were expected to consider all review comments and to provide written responses, which were evaluated by the review coordinator. The report was not released to the sponsors or the public, nor was it disclosed until after the review process was satisfactorily completed and all Commissioners approved the revised draft. Furthermore, once the review process was successfully completed, no changes (other than minor editorial emendations) were made to the approved text. The review comments and draft manuscript remain confidential to protect the integrity of the deliberative process.

OVERVIEW OF THE REPORT

The remainder of this report is organized as follows:

- Chapter 2 builds the case for a greater investment in pandemic preparedness.
- Chapter 3 discusses the importance of national public health systems, including the need for objective and transparent assessment of national core capacities, for building and sustaining strong health systems, and for engaging and communicating with communities.
- Chapter 4 reviews the need to strengthen international capabilities for outbreak preparedness, alert, and response, including the role and responsibilities of WHO, coordination among global actors, a revamp of processes and protocols, and mobilization of global financial resources.
- Chapter 5 presents the importance of accelerating medical products research and development to counter the threat of infectious diseases and outlines a global strategy to facilitate this—including a plan to develop a Pandemic Product Development Committee, invest in a comprehensive portfolio of medical products, conduct research according to high scientific standards, and secure overarching global agreements.

- Chapter 6 reviews the steps necessary for building a framework for global health security and overcoming the associated financial challenges.

REFERENCES

GHSA (Global Health Security Agenda). 2015. https://ghsagenda.j20.org (accessed February 1, 2016).

HGHI (Harvard Global Health Institute). 2015. *HGHI and the London School of Hygiene & Tropical Medicine convene independent panel on the global response to Ebola.* http://globalhealth.harvard.edu/news/ebola_panel (accessed November 30, 2015).

Moon, S., D. Sridhar, M. A. Pate, A. K. Jha, C. Clinton, S. Delaunay, V. Edwin, M. Fallah, D. P. Fidler, L. Garrett, E. Goosby, L. O. Gostin, D. L. Heymann, K. Lee, G. M. Leung, J. S. Morrison, J. Saavedra, M. Tanner, J. A. Leigh, B. Hawkins, L. R. Woskie, and P. Piot. 2015. Will Ebola change the game?: Ten essential reforms before the next pandemic. The report of the Harvard–LSHTM Independent Panel on the Global Response to Ebola. *Lancet* 386(10009):2204-2221.

UN (United Nations) Secretary-General. 2015. *Secretary-General appoints high-level panel on global response to health crises.* http://www.un.org/press/en/2015/sga1558.doc.htm (accessed November 30, 2015).

WEF (World Economic Forum). 2015. *Managing the risk and impact of future epidemics: Options for public–private cooperation.* Geneva: WEF.

WHO (World Health Organization). 2015a. *Factors that contributed to undetected spread of the Ebola virus and impeded rapid containment.* http://www.who.int/csr/disease/ebola/one-year-report/factors/en (accessed September 1, 2010).

WHO. 2015b. *Report of the Ebola interim assessment panel.* Geneva: WHO.

World Bank. 2015. *Pandemic Emergency Facility: Frequently asked questions.* http://www.worldbank.org/en/topic/pandemics/brief/pandemic-emergency-facility-frequently-asked-questions (accessed November 30, 2015).

2
The Case for Investing in Pandemic Preparedness

The global community has massively underestimated the risks that pandemics present to human life and livelihoods, at least in terms of policy outcomes. The resources devoted to preventing and responding to such threats seem wholly inadequate to the scale of the risk. While it is impossible to produce precise estimates for the probability and potential impact of pandemics, it is not difficult to demonstrate a compelling case for greater investment. There are very few risks facing humankind that threaten loss of life on the scale of pandemics.

A pandemic could kill as many people as a devastating war, yet the resources committed to pandemic prevention and response are a fraction of the resources we commit to security. There are also very few risks that have greater potential for catastrophic economic impact—potentially on the scale of a global financial crisis—but the measures we are taking to avoid another financial crisis are of an entirely different magnitude.[1]

The costs of significantly upgrading the world's defenses against pandemics, while substantial, are not out of reach. The recent Ebola outbreak revealed many gaps and shortcomings in preparedness and the ability to respond effectively at both the national and global levels. These flaws in our defenses cost thousands of lives and meant that the ultimate cost of preventing Ebola from becoming a pandemic was much higher than it may otherwise have been. Ebola also demonstrated that being better prepared has huge benefits. For example, Nigeria contained the virus successfully, despite being a densely populated nation with many health and social challenges.

The Commission believes that commitment of an incremental $4.5 billion[2] per year would make the world much safer. This figure includes expenditures for strengthening national public health systems; funding research and development; and financing global coordination and contingency efforts, all of which are explored in greater detail in subsequent chapters. While it may be beneficial to spend more, investing at least this much would address the most urgent weaknesses in global health security. In addition to shoring up our defenses against pandemics, this investment would also yield enormous benefits in protecting the world against other health risks, such as antimicrobial resistance (AMR) and bioterrorism.

How does $4.5 billion per year stack up against the potential risks? The 1918 influenza pandemic killed approximately 50 million people (CDC, 2014) and arguably as high as 100 million in 1918–1920 (Johnson and Mueller, 2002). As a driver of incremental mortality in the last century, few other events even compare: total deaths from World War II are estimated to be between 35 and 60 million,[3] and HIV/AIDS has killed nearly 40 million people since the start of the epidemic (UNAIDS, 2014). Moreover, despite enormous advances in medicine and scientific understanding, and the containment of recent pandemic threats such as severe actue respiratory syndrome (SARS), H1N1 influenza, and, eventually, Ebola, we should not be complacent about future risks. The consensus among leading epidemiologists and public health experts is the threat from infectious diseases is growing. Emerging infectious disease events are increasing significantly over time (Jones, 2008), and, with an

[1] This section draws on "Modeling the Economic Threat of Pandemics" by Anas El Turabi and Philip Saynisch (see Appendix C).

[2] All monetary figures in U.S. dollars.

[3] Encyclopaedia Britannica, 15th ed., s.vv. "World Wars."

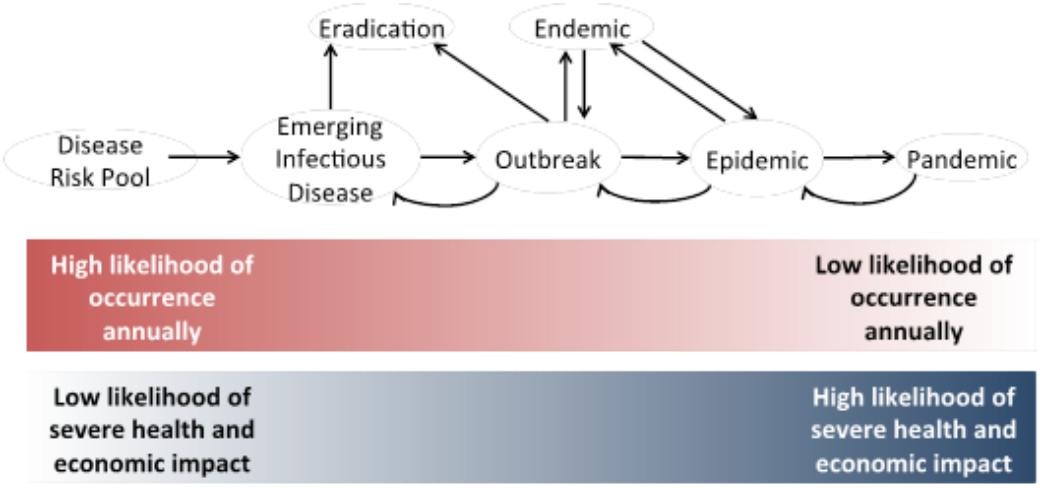

FIGURE 2-1 Spectrum of disease risk.
SOURCE: Figure created for the GHRF Commission by El Turabi and Saynisch, Harvard University.

ever-increasing global population, greater consumption of meat, and continuing increases in mobility and connectivity, the conditions for infectious disease emergence and contagion are more dangerous than ever. $4.5 billion annually equates to just 65 cents per person; with such a modest investment, we could better protect everyone in the world from such risks.

From an economic perspective, the argument is equally compelling. The World Bank has estimated the economic impact of a severe pandemic (that is, one on the scale of the influenza pandemic of 1918–1919) at nearly 5 percent of global gross domestic product (GDP), or roughly $3 trillion (Jonas, 2014). Some might see this as an exaggeration, but it could also be an underestimate. Aggregate cumulative GDP losses for Guinea, Liberia, and Sierra Leone in 2014 and 2015 are estimated to amount to more than 10 percent (UNDG, 2015; World Bank, 2014). This huge cost is the result of an epidemic that, for all its horror, infected only about 0.25 percent of the population of Liberia, roughly 0.25 percent of the population of Sierra Leone, and less than 0.05 percent of the population of Guinea (WHO, 2016), with approximately 11,300 total deaths (CDC, 2016). The Commission's own scenario modeling, based on the World Bank parameters, suggests that during the 21st century global pandemics could cost in excess of $6 trillion, with an expected loss of more than $60 billion per year (see Appendix C).[4]

Indeed, the economic impact of infectious diseases appears to be increasing as greater human and economic connectedness—whether through transnational supply chains, increased travel, or ubiquitous access to communication technologies and media—fuel contagion, both of the virus itself and of fear. Most of the economic impact of pandemics stems not from mortality but from behavioral change, as people seek to avoid infection (Burns et al., 2008). This behavioral change is driven by fear, which in turn is driven by a potent mix of awareness and ignorance. As Poincaré noted with respect to the plague, "the plague was nothing; fear of the plague was much more formidable" (Poincaré, 1905). The experience of SARS is instructive: viewed from the perspective of overall mortality, SARS infected "only" 8,000 people and killed less than 800 (WHO, 2003). Yet the economic cost of SARS has been estimated at more than $40 billion (Lee and McKibbin, 2004). At the peak of SARS, Hong Kong saw an 80 percent reduction in air traffic (Lee and McKibbin, 2004) and a 50 percent reduction in retail sales (Siu and Wong, 2004).

One reason that pandemics are so hard to predict, and their costs so hard to estimate, is that they are not discrete events, but represent the extreme end of a spectrum of infectious disease risks (see Figure 2-1). New infectious diseases emerge annually. Outbreaks, both of new infectious

[4] The expected loss refers to the amount that the global economy will lose each year of the century, on average. It is calculated by multiplying the probability of a loss occurring in any year by the size of the loss.

diseases and of known pathogens, occur many times every year. A small proportion of such outbreaks evolves into epidemics; others are contained, eradicated, or become endemic. An even smaller proportion of epidemics turns into pandemics. Therefore, pandemic risk should not be seen in isolation, but rather as part of a spectrum of escalating disease events, with both costs and potential for mitigation across the entire spectrum.

Viewed from this perspective, the task for policy makers is not just to reduce the likelihood and cost of pandemics as extreme right-tail events, but to reduce the economic and human costs across the whole spectrum of infectious disease threats. We should not become fixated on the probability of a "once-in-a-100-years" pandemic of the 1918–1919 influenza pandemic of severity. Much less virulent pandemics can still cause significant loss of life and economic impact. The influenza pandemics of 1958 and 1968, while far less deadly than the one in 1918–1919, are estimated to have cost 3.1 percent and 0.7 percent of global GDP, respectively (McKibbin and Sidorenko, 2006). Potential pandemics, that is outbreaks or epidemics that could become pandemics if not effectively contained, can also have enormous impact. Ebola, an epidemic that looked as if might have the potential to become a pandemic, has killed more than 11,000 people (CDC, 2016) and cost more than $2 billion (World Bank, 2014). While there is a high degree of uncertainty, the Commission's own modeling suggests that we are more likely than not to see at least one pandemic over the next 100 years, and there is at least a 20 percent chance of seeing four or more (see Appendix C).

Framed in this way, the investment case for pandemic preparedness and response rests not just on the probability and costs attached to a severe pandemic, but also on the likely costs to human lives and livelihoods across the spectrum of infectious disease threats. The apparent acceleration in the emergence of new infectious diseases underscores the need for a "One Health" approach, which recognizes the connection of human health to animal and plant health. Further outbreaks of new, dormant, or even well-known diseases are a certainty. More epidemics with the potential to become pandemics should be anticipated.

Among the known threats are multiple strains of influenza, coronaviruses, and vector-borne diseases—headlined by malaria but also including other endemic conditions that are still spreading because of climate change among other reasons. There is also always the possibility of re-emerging or completely new zoonotic viruses, or of different kinds of infectious threats, such as fungal infections, particularly in the context of growing AMR. Such potential pandemics are perhaps more frequent than is recognized; in the past 15 years, we have faced at least five: SARS, H5N1, H1N1, Ebola, and Middle East respiratory syndrome (MERS).

So, even if we downplay the likelihood of a catastrophic pandemic—and this would certainly be a mistake—there is a powerful case for investing more to minimize the frequency and mitigate the impact of potential pandemics. We appear to have been successful in preventing Ebola from becoming a pandemic, but at far greater cost in terms of lives and dollars than would have been necessary had we been better prepared.

Given the degree of uncertainty in this arena, it also makes sense to think about the relative costs of error—of investing too much or investing too little. If we overinvest, we will have upgraded primary health care and public health systems more than merited by the pandemic threat alone and spent more on vaccine and diagnostic research than strictly necessary. Yet it is hard to see this as wasted money. The core capabilities of primary care and public health systems are crucial to achieving many other health objectives. For example, reinforcing disease surveillance and response capabilities will have benefits for the management and treatment of endemic diseases, such as tuberculosis and malaria, which themselves cause significant loss of life and economic harm. Tuberculosis affects 8.5 million globally each year, reducing labor productivity by about 30 percent and reducing global GDP by about $12 billion per year (Fonkwo, 2008). Malaria affects approximately 150 million people each year (Global Burden of Disease Study 2013 Collaborators, 2015), and is estimated to reduce GDP for sub-Saharan African countries by some 10 percent (Sachs and Malaney, 2002). Such investments in the foundations of national health systems would also play a role in mitigating the threats to health security from noncommunicable diseases (Heymann et al., 2015). On the other hand, if we invest too little, we open the door to potential disaster.

The investment case for reinforcing global capabilities, rather than simply each country's own preparedness, does not depend on altruism, although such a moral argument clearly exists. To make themselves safer, rich countries must help the poorer parts of the world, because

global health security is truly a public good. Zoonotic transfers and outbreaks in even the poorest parts of the world can have global impact, as both HIV/AIDS and Ebola demonstrate.

It is instructive to take pandemics out of the medical context and think about the threat as a national security issue. For any one country, a pandemic is a threat that could kill hundreds and thousands every few years—and might potentially kill millions. Yet in most countries it attracts a small fraction of the resources devoted to national defense. Global military spending amounts to more than $2 trillion (CIA, 2015); many countries participate in highly structured and well-resourced international alliances, such as the North Atlantic Treaty Organization (NATO); and most countries regularly conduct exercises to test preparedness and response. As Bill Gates has pointed out, the contrast with the small amount of resources devoted to protecting humankind from potential pandemics is striking (Gates, 2015).

It is equally illuminating to consider pandemics as an economic risk. Despite the compelling evidence of the disruption caused by potential pandemics, their threat to economic stability typically receives very little attention from economic policy makers at either the national or international levels, and even fewer resources. Since the global financial crisis of 2008, policy makers have forced banks to dramatically increase their capital levels as a protection against future crisis, the cost of which is ultimately borne by society as a whole, through lower returns on equity or higher costs of credit. Consider the new total loss absorbing capacity (TLAC) rule, which applies only to the 27 largest banks in the world. The direct costs of this rule are estimated at $17 billion, and the resulting higher credit spreads are expected to cost approximately $20 billion in reduced GDP growth. This single component of the investment in preventing a future financial crisis dwarfs our Commission's proposed spending on pandemic risk (BIS, 2015).

Our point is not to argue that we spend too much or too little on other threats to security or economic stability, but rather to highlight out how relatively little we invest to protect the world from the threat of infectious diseases. One truth that holds across many different types of potentially catastrophic risks, including pandemics, is that prevention is far more cost-effective than response, and that the most effective response is a well-prepared response. In other words, spending money now will save money and lives later.

Recommendations:

The G7, G20, and United Nations (UN), under the leadership of the UN Secretary General, should reinforce and sustain international focus and actions to protect human lives and livelihoods from the threat of infectious diseases by:

Recommendation A.1: Committing to implementing the framework set out in the report *The Neglected Dimension of Global Security: A Framework to Counter Infectious Disease Crises* and embodied in Recommendations B.1–D.3.

Recommendation A.2: Committing and mobilizing the incremental financial resources required to implement the framework, as set out in the report *The Neglected Dimension of Global Security: A Framework to Counter Infectious Disease Crises*, which amount to about $4.5 billion per year.

Recommendation A.3: Monitoring progress of implementation by commissioning an independent assessment in 2017 and every 3 years thereafter.

REFERENCES

BIS (Bank for International Settlements). 2015. *Assessing the economic costs and benefits of TLAC implementation*. Basel, Switzerland: BIS.

Burns, A., D. van der Mensbrugghe, and H. Timmer. 2008. *Evaluating the economic consequences of avian influenza.* Washington, DC: World Bank.

CDC (Centers for Disease Control and Prevention). 2014. *Reconstruction of the 1918 Influenza Pandemic Virus.* http://www.cdc.gov/flu/about/qa/1918flupandemic.htm (accessed November 15, 2015).

CDC. 2016. 2014 *Ebola outbreak in West Africa—case counts.* http://www.cdc.gov/vhf/ebola/outbreaks/2014-west-africa/case-counts.html (accessed February 1, 2016).

CIA (Central Intelligence Agency). 2015. *The world factbook.* https://www.cia.gov/library/publications/the-world-factbook/geos/xx.html (accessed November 30, 2015).

Fonkwo, P. N. 2008. Pricing infectious disease: The economic and health implications of infectious diseases. *EMBO Reports* 9(Suppl 1):S13-S17.

Gates, B. 2015. The next epidemic—lessons from Ebola. *New England Journal of Medicine* 372(15):1381-1384.

Global Burden of Disease Study 2013 Collaborators. 2015. Global, regional, and national incidence, prevalence, and years lived with disability for 301 acute and chronic diseases and injuries in 188 countries, 1990-2013: A systematic analysis for the Global Burden of Disease Study 2013. *Lancet* 386(9995):743-800.

Heymann, D. L., L. Chen, K. Takemi, D. P. Fidler, J. W. Tappero, M. J. Thomas, T. A. Kenyon, T. R. Frieden, D. Yach, S. Nishtar, A. Kalache, P. L. Olliaro, P. Horby, E. Torreele, L. O. Gostin, M. Ndomondo-Sigonda, D. Carpenter, S. Rushton, L. Lillywhite, B. Devkota, K. Koser, R. Yates, R. S. Dhillon, and R. P. Rannan-Eliya. 2015. Global health security: the wider lessons from the West African Ebola virus disease epidemic. *Lancet* 385(9980):1884-1901.

Johnson, N. P. A. S., and J. Mueller. 2002. Updating the accounts: Global mortality of the 1918–1920 "Spanish" influenza pandemic. *Bulletin of the History of Medicine* 76:105-115.

Jonas, O. 2014. *Pandemic risk*. Washington, DC: World Bank.

Jones, K. E., N. G. Patel, M. A. Levy, A. Storeygard, D. Balk, J. L. Gittleman, and P. Daszak. 2008. Global trends in emerging infectious diseases. *Nature* 451(7181):990-993.

Lee, J. W., and W. J. McKibbin. 2004. *Estimating the global economic costs of SARS*. Washington, DC: The National Academies Press. Pp. 92-109.

McKibbin, W. J., and A. A. Sidorenko. 2006. *Global macroeconomic consequences of pandemic influenza*. Sydney, Australia: Lowy Institute for International Policy, The Australian National University.

Poincaré, H. 1905. *La valeur de la science*. Paris: Flammarion.

Sachs, J., and P. Malaney. 2002. The economic and social burden of malaria. *Nature* 415(6872):680-685.

Siu, A., and R. Y. C. Wong. 2004. *Economic impact of SARS: The case of Hong Kong*. Asian Economic Papers. Cambridge, MA: MIT Press.

UNAIDS (Joint United Nations Programme on HIV/AIDS). 2014. *Fact sheet 2014—global statistics.* http://www.unaids.org/sites/default/files/en/media/unaids/contentassets/documents/factsheet/2014/20140716_FactSheet_en.pdf (accessed February 1, 2016).

UNDG (United Nations Development Group)–Western and Central Africa. 2015. *Socio-economic impact of Ebola virus disease in West African countries*. Addis Ababa, Ethiopia: UNDG.

World Bank, 2014. *The economic impact of the 2014 Ebola epidemic: Short and medium term estimates for West Africa*. Washington, DC: World Bank.

WHO (World Health Organization). 2003. *Summary of probable SARS cases with onset of illness from 1 November 2002 to 31 July 2003.* http://www.who.int/csr/sars/country/table2003_09_23/en (accessed February 1, 2016).

WHO. 2016. *Ebola Situation Report—20 January 2016.* http://apps.who.int/ebola/current-situation/ebola-situation-report-20-january-2016 (accessed February 1, 2016).

3
Strengthening Public Health as the Foundation of the Health System and First Line of Defense

National public health systems are essential components of resilient health systems and the first line of defense against the threat of pandemic disease. Robust public health capabilities and infrastructure at a national level are thus the foundation of a global health risk framework. We acknowledge that public health cannot be considered in isolation.

Public health objectives can only be achieved within a highly-functioning and resilient health care system with effective primary care delivery (WHO, 2008b). Indeed, some would argue that public health and primary care are so interdependent and interlinked that talking about them as separate functions is counter-productive. Others would argue in favor of the distinction, because (a) primary care, as part of the health care system, is fundamentally patient-centered, whereas public health is focused on population health; and (b) some public health investments (e.g., laboratories, epidemiologists, health educators, etc.) are quite distinct from those of primary care and are often neglected. Whichever view one takes, both sets of capabilities and infrastructure are necessary to prepare and respond to the threat of infectious diseases. A primary health care system without the support of strong public health capabilities will lack the ability to monitor disease patterns and be unable to plan and mobilize the scale of response required to contain an outbreak. A public health system without strong primary care capabilities will lack both the "radar screen" to pick up the initial cases of an outbreak and the delivery system to execute an effective response strategy. In the context of countering the threat of infectious diseases, public health and primary care serve the same ultimate objective—improving the health security of individuals. Public health approaches this challenge from the macro level by looking at the health security of the population, cascading from the national level down to the community level. Primary care approaches the challenge from the perspective of providing clinical care to individual patients at the local community level.

In this chapter, we will focus on public health systems with the recognition that even countries with highly developed economies and sophisticated health systems have failed to invest in the infrastructure and capabilities necessary to provide essential public health services. Investment in public health is often hard to justify against other priorities, including other health priorities, because the achievements of good public health often take the form of crises averted and are therefore invisible. It takes a disaster like the recent Ebola outbreak to demonstrate the critical importance of this often unsung component of the health system.

Public health capacities at regional and international levels are also important, but national capacities are the foundation of an effective global health risk framework. Regional and global capabilities cannot compensate for deficiencies at the national or local level. Systemic deficiencies in national public health systems, especially the lack of functional disease surveillance and response systems, were key contributors to the length and severity of the Ebola outbreaks in Guinea, Liberia, and Sierra Leone (Kieny et al., 2014). And this is not a problem unique to low-income nations. Recent outbreaks of severe acute respiratory syndrome (SARS) and Middle East respiratory syndrome (MERS) demonstrated that even advanced economies are often unprepared to deliver an effective and timely response to public health emergencies.

Every national government must therefore take responsibility for building an effective public health system and be prepared to be held accountable, both by its own people and, given the externalities, by the international community. Indeed, the importance of national core capacities has been recognized by some individual governments and by the international community, as reflected in the 2005 International Health Regulations (IHR), which establish health security as a global public good (WHO, 2008a). Yet despite widespread agreement on the importance of public health, the global community has failed to deliver. Although countries like Uganda, which has contained several outbreaks of Ebola in the past 10 years, have demonstrated that even relatively poor countries can create effective public health systems, most countries fail against IHR according to even their own self-assessments (WHO, 2015c). Independent, objective assessments would undoubtedly paint an even darker picture.

The Commission believes it is imperative to turn fine words into action. Deficiencies in public health systems need to be identified and resolved. National governments must commit to rapid reinforcement of their public health core capacities. Public health should be treated as an integral part of national security—part of a government's fundamental duty to protect its own people. To force the pace and ensure accountability, we need (1) clarity on the core capacities required and definition of clear benchmarks; (2) objective, independent, and transparent assessment of a country's performance against these benchmarks to identify gaps; (3) clear national plans to achieve and sustain these benchmarks, including resourcing; (4) mobilization of resources at a national level, as well as through the international community to fill gaps and sustain benchmark core capacities; and (5) strategies to support minimum standards in fragile and failed states.

DESPITE SOME IMPROVEMENTS, MANY COUNTRIES HAVE FAILED TO BUILD THE NECESSARY PUBLIC HEALTH CAPACITIES

The importance of building strong public health systems was globally recognized following the SARS outbreak in 2002–2003 (GAO, 2004) and the emergence of avian influenza H5N1 in 2003–2004 (FAO and OIE, 2008). These outbreaks exposed weaknesses in detection, reporting, and response similar to deficiencies revealed by the Ebola outbreak. In response, the World Health Organization (WHO) member states agreed to implement the 2005 revisions of the IHR, committing to develop core capacities for detection, assessment, notification, and reporting of events to respond to public health risks and emergencies (WHO, 2008a) (see Table 3-1). This binding agreement also emphasizes the importance of containing emergencies locally.

One of the changes made to the original IHR when they were renewed in 2005 was the addition of a decision instrument to help national authorities determine whether a Public Health Emergency of International Concern (PHEIC) should be reported to WHO. The new instrument replaced a fixed list of specific diseases to report that failed to account for new or unknown threats. Since 2005, WHO has declared a PHEIC three times: the first in 2009 for the H1N1 pandemic; the other two in 2014 for polio and Ebola. H1N1 marked the first time the IHR (2005) were put to the test—and, once again, fragilities in national- and international-level response capacities were exposed, leading to doubts about the IHR mechanism itself.

To address concerns arising from the H1N1 response, WHO's Executive Board resolved in January 2010 to constitute a Review Committee with three key objectives (WHO, 2010):

1. assess the functioning of the IHR;
2. assess the ongoing global response to H1N1 (including the role of WHO); and
3. identify lessons learned to strengthen preparedness and response to future pandemics and public health emergencies.

The Review Committee, chaired by Harvey Fineberg (then president of the Institute of Medicine [IOM]), submitted its report to WHO in 2011, putting forth 3 overarching conclusions and 15 recommendations (WHO, 2011b). The report observed that core national and local capacities as required in the IHR were not operational in more than half the affected countries, with many lacking the ability to detect, assess, and report potential health threats. It also noted the lack of pathways for countries to ensure timely implementation of the requirements of the IHR.

In order to accelerate the implementation of core capacities introduced in the IHR, WHO developed a guide to support countries in assessment and planning.

TABLE 3-1 IHR Core Capacities and Components

IHR Core Capacities	Component of Core Capacity
1: National legislation, policy, and financing	• Legislative and policy framework, regulations, and administrative requirements or other government instruments covering animal health, food safety, emergency response, etc. • Appropriate budgetary support
2: Coordination and NFP communications	• Inter-ministerial coordination, IHR coordination through NFP, broader communication and advocacy across sectors
3: Surveillance	• Indicator-based surveillance, including early warning function for early detection • Event-based surveillance, including rumors and other ad hoc reports through formal or informal channels
4: Response	• Public health emergency response mechanisms, including a functional, dedicated command-and-control operations center; creation of rapid response teams, and case management guidelines • Infection prevention and control established and functional at national and hospital levels, including operational plans, guidelines and protocols; surveillance of high-risk groups and antimicrobial resistance
5: Preparedness	• Public health emergency preparedness and response plan developed and implemented; procedures, plans, or strategies to reallocate or mobilize resources; development of surge capacity • Priority public health risks and resources are mapped and utilized
6: Risk communication	• Policy and procedures for public communications; timely mechanisms for effective risk communication to media and the public, accessible and relevant information, education, and communication materials
7: Human resources	• Human resource capacity to implement core capacities (specific programs with allocated budgets to train workforce)
8: Laboratory	• Laboratory diagnostic and confirmation capacity for priority diseases (quality standards and guidelines); inventory of public and private laboratories available; access to networks of international laboratories to support outbreak investigation

NOTE: IHR = International Health Regulations; NFP = national focal point.
SOURCE: Adapted from WHO, 2015b.

WHO described in this document a range of activities to advocate for IHR implementation, mobilize resources, and monitor implementation plans (WHO, 2013). According to self-assessments by member countries for the years 2013 and 2014 (see Table 3-1 in Annex 3-1), overall improvement over the previous year was limited under several indicators. These assessments also provide further insight into the overall lack of health system capacity, especially in terms of preparedness, human resource capacity, and at points of entry (which includes ports, airports, and ground crossings), with countries in the African region reporting the lowest compliance. Despite some progress, 67 percent of countries self-assessed themselves as not being fully compliant with the IHR (WHO, 2015c).

ROBUST PUBLIC HEALTH CAPACITIES ARE ACHIEVABLE IN THE CONTEXT OF BUILDING AND SUSTAINING STRONG HEALTH SYSTEMS

Before the current West African Ebola outbreak, Uganda was the site of the largest Ebola outbreak in history, with

TABLE 3-2 Ebola Outbreaks in Uganda

Year	Response Timeline	Number of Cases	Number of Deaths
2000	38 days from first known case to preliminary investigation	425	224
2007	75 days from first known case to preliminary investigation	146	39
2011	1 day between case confirmation and response	1	1
2012	2 days between laboratory confirmation and response	24	17

SOURCE: Aceng, 2015.

425 reported cases in 2000 (CDC, 2001). Yet the outcome of this outbreak was distinctly more positive, because Uganda had in place an operational national health policy and strategic plan, an essential health services package that included disease surveillance and control, and a decentralized health delivery system (Mbonye et al., 2014). After 2000, Uganda's leadership realized that, despite the successful containment of the outbreak, a focus on strengthening surveillance and response capacities at each level of the national system would greatly improve the country's ability to respond to future threats (Aceng, 2015). Uganda has since suffered four additional Ebola outbreaks (CDC, 2014b), as well as one outbreak of Marburg hemorrhagic fever. However, due to its new approach, Uganda was able to markedly improve its detection and response to these public health emergencies (see Table 3-2).

The success of the Ugandan experience is founded in a deep political commitment to strengthen core capacities despite limited resources. The key elements of the strategy implemented in Uganda are described in Annex 3-2.

To build strong public health capacities that will allow detection, reporting, and response to infectious disease threats, countries should focus on revising public health law frameworks, strengthening public health infrastructure; building partnerships; using research evidence to inform program and policy decisions; engaging and improving communication with communities; and establishing a public health emergency operations center (PHEOC) (see Box 3-1).

An alternative, but essentially equivalent, blueprint for reinforcing public health capacities is embodied in the 11 "action packages" set forth in the Global Health Security Agenda (GHSA).[1] This multi-national initiative was launched in 2014, linking several member states, international organizations, and civil society together to prioritize health security activities and help countries to achieve core capacities of the IHR. The GHSA seeks to achieve coordinated action and undertake specific, measurable steps to prevent, detect, and respond quickly to emerging infectious diseases. To facilitate this goal, the 11 action packages provide guidance in areas ranging from prevention to detection to response (see Table 3-3). These packages include baseline assessments, planning activities, and monitoring and evaluation activities that break down the broad issues of global health security into more discrete and attainable goals. As of April 2015, 44 countries had signed on to at least 1 of the 11 action packages with a 5-year target goal, either committing themselves to meet core capacity criteria or assisting another country in need (IOM, 2015). For each action package, there are designated lead and contributing countries that will work together (Katz et al., 2015).

In addition to the country commitments for action packages, a peer assessment initiative began in 2015, with five countries, including Uganda, acting as pilots to measure their progress against each action package.[2] This process is separate from the IHR assessment, which is carried out by a country individually or in collaboration with a WHO regional office. Although the IHR assessment is a required part of the regulations, there is no system to hold countries accountable, and no penalty for abstaining.

In addition to the five countries that participated in 2015, several have committed to the GHSA assessment process for 2016. Important lessons can be learned from this initiative and the experience gathered from its pilot assessments. For instance, unlike the IHR, the GHSA addresses the importance of having a functional national vaccine delivery system that can be quickly adapted to new disease threats. Action package "Prevent 4" (see Table 3-3) sets a 5-year target of 90 percent coverage of

[1] For more information, see https://ghsagenda.org (accessed April 1, 2016).

[2] For more information on the pilots, see http://www.cdc.gov/globalhealth/security (accessed April 1, 2016).

BOX 3-1
Actions to Build Strong Public Health Systems

1. Revise public health law/policy framework
2. Strengthen public health infrastructure:
   a. Public health workforce
   b. Surveillance and information systems
   c. Laboratory capacity
3. Build partnerships
4. Use research evidence to inform decisions
5. Engage and communicate with communities
6. Establish a Public Health Emergency Operations Center

SOURCE: Adapted from IOM, 2003.

a country's 15-month-old population with at least 1 dose of measles vaccine (CDC, 2014a). This target was chosen because measles vaccination serves as a proxy indicator for the overall status of coverage for vaccine preventable diseases. A system to deliver vaccines nationwide safely and effectively is an essential component of an outbreak response plan.

Revising Public Health Law/Policy Frameworks[3]

Although there are many technical and resourcing challenges in building stronger public health systems, in many countries the fundamental impediments revolve around political commitment and governance. Government leaders need to recognize the importance of the overall health system, and public health in particular, to the nation's human and economic security, and to translate this recognition into budget priorities and concrete plans. Sustained political commitment at the highest levels is essential to devise policies and pass legislation to facilitate the implementation of core capacities, including establishment of national focal points (NFPs), development of laboratory networks and surveillance systems, and provision of adequate financial resources.

Failures of governance, most notably the flourishing of corruption, can be fatal to such efforts, diverting resources and distorting priorities. Of course, corruption and governance weaknesses are a problem for not only public health, but also every aspect of public services. Yet, given the level of governmental commitment required to build resilient health systems with adequate public health capabilities and infrastructure, this arena seems particularly vulnerable to such failures. Addressing the challenge of corruption is beyond the mandate of this Commission, but we recognize the reality of the problem. Civil society organizations, both local and international, as well as the international community, have critical roles to play in holding governments accountable, pressing for improvements in governance, and eradicating corruption.

Strengthening Public Health Infrastructure and Capabilities

Outbreaks cannot be effectively contained if they are not detected promptly. National public health systems must have the capacity to identify an outbreak and establish an alert system to trigger response and, if needed, seek support from regional and global levels. Countries should work to develop real-time detection and response systems, prioritizing elements that reinforce prevention, provide early detection, and enable effective response. Plans to reinforce public health infrastructure and capabilities will need to combine tactical actions delivering short-term improvements with more strategic initiatives to build capacity over the longer term.

Public Health Workforce

Without a skilled, motivated, and well-supported health workforce, no health system can achieve its goals. Yet the world faces a global health workforce crisis—characterized by widespread shortages of skilled personnel, uneven distribution of skills, and, in many situations, poor working conditions (Campbell et al., 2013; WHO, 2006). Many countries lack relevant skills in a range of disciplines essential to public health, including epidemiology, biological and health sciences, veterinary

[3] For the purposes of this discussion, we use the framework set out in Box 3-1.

TABLE 3-3 Global Health Security Agenda Action Packages

Prevent 1	Antimicrobial Resistance
Prevent 2	Zoonotic Disease
Prevent 3	Biosafety and Biosecurity
Prevent 4	Immunization
Detect 1	National Laboratory Systems
Detect 2 & 3	Real-Time Surveillance
Detect 4	Reporting
Detect 5	Workforce Development
Respond 1	Emergency Operations Centers
Respond 2	Linking Public Health with Law and Multisectoral Rapid Response
Respond 3	Medical Countermeasures and Personnel Deployment

SOURCE: Adapted from Standley et al., 2015.

science, psychology, anthropology, and biostatistics. Outbreak planning requires skills outside the medical arena, such as logistics, security, and communications. Building workforce capacity to sustain an effective and responsive public health system is one of the most profound health challenges for many countries. Therefore, countries should commit to developing and implementing a workforce-strengthening strategy and plan that includes training programs for public and veterinary health professionals. Countries should also expand existing initiatives, such as the U.S. Centers for Disease Control and Prevention's (CDC's) Field Epidemiology Training Programs (FETPs), which are already being implemented in several countries. Public health workforce strengthening should occur at the community, district, and other subnational levels and through the establishment of national networks to share critical resources and knowledge across public, private, and nonprofit sectors. Countries should also strive to link with regional and global networks to share resources and best practices, participate in training exercises, and collaborate on research studies.

Disease Surveillance and Information Systems

Effective surveillance is critical to containing infectious disease outbreaks. Disease surveillance and health information systems should be developed with the long-term vision of creating nationwide, interoperable, and interconnected platforms that are capable of collecting, aggregating, and analyzing information at every level of the health system (community, district, other subnational, and national levels). Such systems should be able to support both indicator-based (syndromic) surveillance and event-based surveillance. Increased access to new information technology has increased surveillance capacity even in countries with limited resources and should be fully exploited (IOM, 2007). Electronic surveillance tools should be implemented and standardized across the country to transmit information to a central hub that can be accessed in real-time by surveillance staff at every level. For instance, the common use of mobile phones has allowed early detection and response to outbreaks in remote areas (Rosewell et al., 2013).

Surveillance data should be collected in a way that allows integration with data coming from other health and non-health sources, which facilitates the decision-making process by confirming or providing more detail on a specific event. Therefore, countries should avoid the creation of parallel systems, instead seeking to ensure interoperability between existing and new systems. Continuous training is essential, and training guidelines and materials should be updated regularly based on changing needs and priorities.

Strengthening disease surveillance systems would allow countries to comply with IHR requirements and report the occurrence of a PHEIC within 24 hours of receiving indicatory information. Country surveillance guidelines should include procedures and reporting templates to comply with these obligations.

Laboratory Capacity

An effective nationwide laboratory network is another key component of a highly-functioning public health system. Such a network needs to be able to systematically identify, collect, and transport specimens to labo-

ratories with adequate equipment and personnel to carry out reliable testing. Diagnostic capacity should be developed for at least a core list of pathogens (based on the country's major public health risks). A tiered network should be integrated with the disease surveillance system at every level of the health care system to ensure that information reaches decision makers quickly. Collaboration and communication between human and animal laboratory systems is also vital.

Technological innovation promises more cost-effective and rapid diagnostics. However, it also requires trained biomedical engineers—a scarce resource that is critical to the functioning and integrity of a high-quality laboratory network. Development partners, who provide training, offer technical support for accreditation processes, and aid in the acquisition and maintenance of laboratory equipment, have been essential in resource-limited countries. Community involvement has been equally important in disease surveillance and transportation of laboratory sample efforts, as shown by the experience in Uganda (see Annex 3-2).

Countries should ensure that adequate diagnostic capacity is available either within the country (within the public or private sector), or via a collaboration mechanism established at the regional or global level. To facilitate outbreak response, a catalog of laboratory resources should be developed and made available across the health sector and other sectors involved. Progress at this level will require, as mentioned earlier, the development of national plans for diagnostic approaches that include protocols to handle specimens and apply diagnostic tests. Evaluation against predetermined performance targets is key to monitoring progress and guiding improvement.

Building Partnerships

Government public health agencies are the cornerstones of the public health system, but they cannot work in isolation. To deliver an adequate response during outbreaks, they need to build and maintain partnerships with other public, private, and nonprofit sectors and work closely with communities and community-based organizations.

Within the Health Sector

Countries should make the most of available resources by analyzing the strengths, needs, and challenges of existing systems and avoiding creation of parallel structures. There are already too many examples of vertical interventions in health systems that fail to strengthen the system as a whole (Atun et al., 2008). Effective integration of health care delivery and public health is essential, because outbreaks are typically first detected through primary health care, and because the health care delivery system is critical to executing a response strategy. Such integration must include both public and private health care delivery systems, which play a large role in many countries, because the first (or "index") case in a potential epidemic could be seen first in either system, or could move between them. For example, the first human cases of H5N1 in Laos (Puthavathana et al., 2009) and MERS in Thailand were seen by private hospitals (Schnirring, 2015). Similarly, the first cases of H1NI in Ghana and Ebola in Nigeria were discovered by private clinics (Freeman, 2014).

It is also important that countries move toward institutionalization of a One Health approach, which integrates veterinary and agriculture practitioners with the public health system (Coker et al., 2011). Globally, a One Health approach has become well established, with the creation of the Global Early Warning System, a platform developed by the World Organisation for Animal Health (OIE), WHO, and the Food and Agriculture Organization of the United Nations (UN) to improve early warning on animal diseases and zoonoses worldwide.[4] The One Health approach is also an explicit component of the GHSA, embedded, for example, in the action packages on zoonotic diseases and laboratory networks.

Across Sectors

Effective response to a potential pandemic requires deployment of a broad range of skills and assets beyond the health arena. Governments should therefore engage with key players in non-health sectors, such as private companies and civil society organizations, to establish clear communication and coordination at the national, subnational, and district levels. It is key to establish these mechanisms before the emergence of a health crisis.

Working with Development Partners

National governments must ensure that their partnerships with international development partners focus on national capacity building that prioritizes country

[4] See http://www.who.int/zoonoses/outbreaks/glews/en (accessed April 1, 2016).

ownership and accountability for health systems based on national plans and aspirations. Development partners should, in turn, respect and support countries' ownership of health plans and priorities. (For more on country relationships with development partners, see the Rwanda case study in Annex 3-3.)

Working at the Regional Level

National governments should also foster regional approaches to complement country-level efforts, as regional strategies have proved to be an efficient way to address limitations in national resources and skills and bring an element of cultural competency and epidemiological familiarity. Regional initiatives also build trust across professional communities, thereby facilitating communication in times of crisis. The Mekong Basin Disease Surveillance Network, which was established in 2000, is an example of regional collaboration among six countries in Southeast Asia. With a semiformal friendship- and trust-based relationship, the network enables cross-border collaboration and, most importantly, "joint outbreak investigation and control" when outbreaks occur along the border (Phommasack et al., 2013).

Regional capacity should also be built through the expansion of efforts such as the CDC's FETP, the creation of professional registries, the establishment of laboratory networks, regional mutual assistance agreements, and regional preparedness exercises. WHO regional offices have a key role to play at this level, facilitating coordination between regional health players and supporting regional initiatives.

Using Research Evidence to Inform Program and Policy Decisions

Health systems research is a core function of a learning health system that can continuously assess performance and identify responsive solutions. Lack of capacity for health systems research is a major weakness in many low-income countries (Decoster et al., 2012). Each country should have research capacity built into its health system planning and budget. Social sciences research would help public health leaders understand the social, behavioral, and anthropological aspects of disease preparedness and response, such as effective strategies to engage communities in outbreak detection and control and communicate threats and required responses. The recent Ebola outbreak clearly illustrated the importance of robust representative studies on knowledge, attitudes, and practices regarding Ebola to inform policies and development of effective communication strategies (Laverack and Manoncourt, 2015).

Engaging and Communicating with Communities

Epidemics are shaped by a range of factors that include multiple socio-cultural and economic dimensions. Public health practitioners and policy makers cannot succeed in their endeavors to prevent or respond to infectious disease threats without working closely with communities. Considerable "buy in" and support is essential, as little can be achieved if people are unwilling to accept vaccinations or to consume medications. Public health programs requiring collective behavioral change to interrupt the transmission of infectious disease need the active support and involvement of the communities they wish to assist. Indeed, there are many cautionary cases of communities rejecting public health interventions, sometimes in violent ways. The deaths of several health workers and journalists during the outbreak of Ebola in Guinea in September 2014 are a tragic illustration of extreme negative responses to public health interventions.

Public trust and confidence is a precondition for successfully preventing and containing outbreaks and epidemics. Yet trust can be extremely difficult to build where corruption or other governance failures are prevalent. Where health systems are weak and people question the motives underpinning messages promoting healthy behaviors, public trust and confidence in the work of government and international agencies tend to be minimal, fragile, or absent. It is thus vital that time is taken to engage with, and learn from, local people in an open and flexible way. Such long-term, ongoing engagements not only help create the space for healthy social norms to be established, but also enable pathways that facilitate necessary coordination and mobilization in the event of an outbreak. The recent outbreaks of Ebola in Guinea, Liberia, and Sierra Leone illustrate this point. Doubt, fear, and distrust informed many local people's responses to interventions proposed by governments and international agencies (Dhillon et al., 2015). In some places, this contributed to, and exacerbated, the transmission of the virus (MSF, 2014), while simultaneously reinforcing preexisting distrust in health authorities.

It is also important to acknowledge and celebrate positive outcomes from community engagement. In Uganda,

BOX 3-2
Engaging Communities for Outbreak Preparedness and Response

Before a Major Outbreak

Useful methods to foster engagement include the following:

- Regular meetings with local leaders to discuss aspects of infectious disease prevention and control (with staff from the national Ministry of Health being made aware of these meetings and contributing to them).
- Influential leaders (including political leaders, village health care workers, and religious figures) could also be given training in public health practices and encouraged to report possible cases to nearby health facilities when cases emerge.
- Communication campaigns (involving written and aural media) may also be effective ways to boost surveillance capacity.

During an Outbreak

Communities can be very effective as the first line of surveillance, actively tracking down and reporting unusual events, as well as managing and containing outbreaks. Useful approaches include the following:

- Responders could engage communities through mass meetings, community mapping exercises, training, and active case finding. In West Point, Liberia (Fallah, 2015), for example, community town hall meetings and "foot soldiers" usefully contributed to surveillance.
- Harnessing local activism (e.g., identifying local community members to be activists, training them, and deploying them in the community) can help build ownership and responsibility among communities in containing outbreaks.
- Space should be created to enable local leaders to take the lead in designing and developing communication campaigns and social mobilization efforts.
- Great care should be taken to devise strategies enabling the most politically and economically marginal populations (who are vulnerable to infection and often systematically ignored) to be included.
- Task-shifting and sharing with proper training could allow non-specialists to provide care (e.g., psychosocial support).

After an Outbreak

Nothing is more damaging to trust than for government officials, international nongovernmental organizations, and multilateral donors to take no interest in the challenges facing communities in the wake of an outbreak or epidemic. Every effort should be made to maintain links, follow up on families affected by outbreaks, and to solicit feedback about serious issues. In the case of Ebola, for example, it is vital that efforts are made to monitor the long-term health and well-being of those who have survived, while also assessing the social and economic impact of the outbreak for those who have lost members of their family to the infection.

for example, most outbreaks are detected through community surveillance systems in which influential community leaders are trained to alert village health teams as soon as they detect any unusual occurrences of death (Aceng, 2015). Ultimately, communities played a vital role in disease surveillance and implementation of countermeasures during the Ebola outbreak. Using a bottom-up approach, public health authorities were able to devise ways to influence deep-seated cultural practices and behaviors related to burial rites, caring for the sick, and social gatherings, which were key contributors to the mitigation or containment of the outbreak (Aceng, 2015). Box 3-2 offers guidance on how to engage communities before, during, and after infectious disease outbreaks.

Community-based service providers (of health, education, and security, among others), local government officials, elected members, staff working at local nongovernmental organizations (NGOs), and anthropologists are well placed to liaise with local people. These professionals recognize the need to work with a range of influential people in many roles and understand the importance of developing trusting relationships. They also have many valuable skills, including fluency in the local language, as well as the willingness to talk, listen, and observe to acquire a thorough understanding of the range of perspectives that make up the local culture. Also essential is a willingness to let go of preconceived ideas and recognize that local people may well be able to come

up with novel solutions to contain outbreaks and resolve complex public health issues. Anthropologists are well placed to identify deep sociocultural conditions that may impact the course of the overall epidemic and the response at multiple critical points; they should describe the practical relevance and applicability of their findings to facilitate acceptance and implementation of their recommendations (Abramowitz, 2014).

Effective communication is a critical component of preparedness and response to outbreaks. Preventing and containing infectious disease presents particular challenges because options for interrupting transmission are often limited, and it is crucial that change occurs at speed. Therefore, communications should be approached as a progressive, adaptable process, rather than a monolith of simple messaging.

Public health officials should develop context-specific approaches that recognize the influence of history, culture, and social forces in their population. For more information about the influence of history in the response of the community to containment measures implemented during outbreaks of infectious diseases, see Annex 3-4. Social media offers promising tools to reach different groups with appropriate messaging. However, messaging must be carefully researched and framed for the context and cultural practices of the targeted audience. Simple, standardized messages grounded in a biomedical understanding of contagion can be ineffective if they ignore these factors. In fact, recent experiences in West Africa (Chandler et al., 2015), as well as in past outbreaks of Ebola in Uganda (Hewlett and Hewlett, 2008) show how oversimplified messaging can reinforce rumors and anxieties, discourage active engagement with local social realities, and erode opportunities to identify changes that are appropriate as well as practical and socially effective.

Establishing a Public Health Emergency Operations Center

To ensure effective response to an infectious disease outbreak, countries need a well-resourced PHEOC. In the event of a crisis, the PHEOC will integrate public health services with other parts of the health system and incorporate resources from outside the health sector into an emergency management model to implement the outbreak response plan (WHO, 2015a). The PHEOC will be responsible for coordinating all sectors involved in delivering the response plan, including those beyond the health sector, as well as the training and deployment of emergency workforce resources. To be effective, the PHEOC will need to be well established, with appropriate resources and financing, and to have developed and tested the required coordination mechanisms in advance, preferably through rehearsals. The PHEOC should have direct access to national disease surveillance and laboratory systems and possess infrastructure to enable rapid analysis of information to inform decision making. The PHEOC should also work with development partners and regional and global networks to identify where international support is most needed and coordinate its delivery to affected communities.

NATIONAL GOVERNMENTS' RESPONSIBILITY TO PROTECT THEIR OWN PEOPLE AND PLAY THEIR PART IN PROTECTING HUMANKIND BY IMPLEMENTING THE INTERNATIONAL HEALTH REGULATIONS

National governments must take the responsibility to prevent, detect, and control infectious diseases outbreaks; to protect their own populations; and to play their part in protecting global health security. This goal can only be achieved in full when countries have built effective public health services, operating as an integral part of resilient health systems and capable of recognizing, reporting, and arresting the spread of infectious diseases. This cannot be achieved overnight. To ensure that national governments are equipped to achieve this goal, the Commission proposes a set of recommendations.

Clear Definition of Core Capacities and Benchmarks

A clear definition of public health core capacities and functioning is needed to enable countries to develop concrete plans and facilitate compliance with the IHR. Establishing benchmarks is also key for conducting robust, objective assessments and identifying gaps, which in turn will allow prioritization of expenditures and enable accountability.

Recommendation B.1: The World Health Organization, in collaboration with member states, should develop an agreed-on, precise definition and benchmarks for national core capabilities and functioning, based on, and implemented through, the International

Health Regulations and building on the experiences of other efforts, including the Global Health Security Agenda and the World Organization for Animal Health Terrestrial Animal Health Code by the end of 2016. Benchmarks should be designed to provide metrics against which countries will be independently assessed (see Recommendation B.2).

It should not be necessary to open the IHR to renegotiation to determine new definitions and benchmarks, because these could be developed through informal means, such as by an Annex or through the Director-General's (DG's) operational benchmarks for implementing the IHR (Gostin et al., 2015). The need for a clear roadmap that moves away from implementation checklists was also identified by the IHR Review Committee on Second Extensions for Establishing National Public Health Capacities and on IHR Implementation and approved by World Health Assembly (WHA) Resolution 68.5.

Objective, Independent, and Transparent Assessment of Individual Country Performance Will Enable Prioritization and Reinforce Accountability

In 2011, WHO issued a comprehensive IHR Core Capacity Monitoring Framework and accompanying monitoring tool to all member countries to enable them to assess their capacities (WHO, 2011a). This tool contains 13 sections and more than 100 subsets of information. WHO has received detailed self-assessment reports from the member countries since 2011 on an annual basis. During the past 5 years, 98 percent of all states parties have responded to the monitoring questionnaire at least once (WHO, 2016). The monitoring tool has enabled countries to understand the significance of complying with the IHR and has also lent a measure of in-country accountability. There is greater awareness of health security issues and the necessity to build core capacities. Most countries have instituted an NFP and established a communication link between the country and WHO focal points. This in itself is a vast improvement over the pre-2005 IHR period.

Thus, while the IHR have undoubtedly been a valuable legal instrument (WHO, 2011b), the WHO monitoring tool and its subsequent revisions, though developed by experts, do not provide clear guidance for countries on how to prioritize implementation actions. While many have focused on training human resources, building surveillance systems for reporting of outbreaks, establishing reporting and review mechanisms, and creating rapid response teams for containing outbreaks, others have focused on less critical elements—for instance, procuring thermoscans for screening at airports.

The IHR reports submitted by member states have limited credibility, primarily because they are self-assessments. Furthermore, the WHO monitoring tool only allows for binary yes-or-no answers to many questions. For example, under Core Capacity 1 for the category "National Legislation," many countries would need to revise several laws to be truly "compliant" with IHR requirements. However, for instance, updating a Public Health Act without any changes to other laws, such as the wildlife or environment laws, would allow them to report themselves as compliant. Or, for example, under Core Capacity 2, for "Coordination and NFP Communications," multisectoral task forces may have been constituted, but their meetings are often irregular and not conducted until after an outbreak has occurred. Likewise, while NFPs have been established, they are often small units lacking infrastructure, trained personnel, and adequate budgets.

Recommendation B.2: The World Health Organization should devise a regular, independent, transparent, and objective assessment mechanism to evaluate country performance against the benchmarks defined in Recommendation B.1, building on current International Health Regulations monitoring tools and Global Health Security Agenda assessment pilots, by the end of 2016.

Proposed Structure of the Assessment

We propose the following structure for the assessment.

The objective assessment should be overseen by an independent panel appointed by the Technical Governing Board of WHO's Center for Health Emergency Preparedness and Response (CHEPR) and answerable first to the WHO DG and ultimately to the Executive Board and the WHA. (WHO CHEPR is a key element of our recommendations for WHO and discussed at length in the next chapter.) This body will be responsible for defining metrics and developing instruments and tools to measure progress on implementation of core capacities. This panel will build on the IHR current assessment

mechanism and lessons learned from other initiatives, such as the GHSA experience.

Because it will not be possible at the start to conduct assessments of every country simultaneously, the panel should prioritize countries most in need of an external assessment. Countries should also have the ability to request an external assessment. Ultimately, assessments should be conducted on an annual basis, but we recognize that getting to this point will take some time. Peer representatives from both within and outside the region should play a key role in conducting panel reviews. The panel should develop an annual report to present to the WHA (which should also be made public) that should include progress on the implementation of core capacities and indicators that track notification and verification of events, communication, and coordination with NFPs.

The assessment tools should be approved by the WHA and measure performance in two main areas:

1. implementation of core capacities (including national legislation, coordination and NFP communications, surveillance, response, preparedness, risk communication, and laboratory capacity); and
2. early detection, notification, and response to outbreaks.

Discussion of the results of this assessment should include members of the country under assessment in order to ensure agreement on recommendations for support and follow-up.

In designing the details of this assessment mechanism, the panel should draw on the experience of analogous assessment mechanisms from outside the health sector, such as the World Bank's *Doing Business* reports, which are detailed assessments of the regulatory and infrastructure environment for establishing a business, or the Financial Action Task Force Mutual Evaluation mechanism, which is a peer-review process focused on the effectiveness of anti–money laundering systems and regulations. In both examples, the assessments are rigorous, objective, and transparent and serve a powerful purpose in galvanizing policy.

We recognize that such assessment processes inevitably generate frictions and disputes about methodology. The Commission is fully aware of the debates (Bialik, 2009) following WHO's *World Health Report 2000* (WHO, 2000). Our objective here is not to create a ranking, nor to assess overall health system performance, but to provide a focused assessment of critical public capacities with the goal of enabling prioritization and accountability. Rigorous, objective, and transparent assessment will help identify weaknesses and illuminate opportunities to improve national prevention, detection, and response systems.

Recommendation B.3: By the end of 2016, all countries should commit to participate in the external assessment process as outlined in Recommendation B.2, including publication of results.

Without appropriate incentives, countries may seek to avoid objective and transparent assessment and thereby continue to neglect their health system capacities and infrastructure. One potential way to encourage participation in the assessment mechanism is to make external funding from the World Bank and/or other partners contingent on participation.

Recommendation B.4: The World Bank, bilateral, and other multilateral donors should declare that funding related to health system strengthening will be conditional upon a country's participation in the external assessment process.

Another potential mechanism for encouraging countries to meet domestic and international obligations around pandemic preparedness should be for the World Bank and International Monetary Fund (IMF) to include assessments of pandemic preparedness in their country assessments. As discussed in Chapter 2, infectious disease outbreaks represent a substantial threat to countries' economic prosperity. Appropriately reflecting the risk associated with under-preparedness in assessments of macroeconomic stability would allow economic actors to take such risks into account when making decisions about investments and loans. Access to capital through development banks, capital markets, or foreign direct investment may be adversely affected if countries are known to have underdeveloped pandemic prevention and response capacities. If the IMF routinely included the outcomes of external assessments of national pandemic preparedness in its reviews of countries' economic and financial situations, countries keen to engage in global financial markets would have to pay heed. Those that chose to avoid external assessment would risk adverse signaling.

Recommendation B.5: The International Monetary Fund should include pandemic preparedness in its economic and policy assessments of individual countries, based on outcomes of the external assessment of national core capacities as outlined in Recommendation B.2.

Primary responsibility for achieving and sustaining public health capacities to the required standard rests with national governments. We therefore call on governments to develop and publish plans by mid-2017 (where plans do not already exist) to achieve benchmark status in the required core capacities by 2020. These plans should be comprehensive and realistic, addressing the challenges of sustainable financing and skills building.

Recommendation B.6: Countries should develop plans to achieve and maintain benchmark core capacities (as defined in Recommendations B.1). These plans should be published by mid-2017, with a target to achieve full compliance with the benchmarks by 2020. These plans should include sustainable resourcing components, including both financing and skills.

Country plans should also be aligned with global initiatives that share similar objectives, such as the Sustainable Development Goals (SDGs) adopted in September 2015 by the UN General Assembly under the title *Transforming Our World—The 2030 Agenda for Sustainable Development*.[5] This initiative represents a global compact and movement that will be the vehicle for mobilizing and galvanizing country and global actors for concerted action on national and global issues. The SDGs will be used for holding country leaders accountable and can also act as the entry point for bringing the global health security agenda into the routine work of the UN, including the Security Council.

To assist national governments in developing and implementing plans to build stronger core capacities, WHO should provide technical assistance, ensuring the transfer of best practices.

[5] SDG3, which is to "ensure healthy lives and promote well-being for all at all ages," has three specific goals—(3.d) on outbreak preparedness and response, (3.b) on vaccines, research and development and (3.c) on health financing and health workforce recruitment, development and retention. See https://sustainabledevelopment.un.org/post2015/transformingourworld (accessed April 1, 2016).

Recommendation B.7: The World Health Organization (WHO) should provide technical support to countries to fill gaps in their core capacities and achieve benchmark performance. (Technical support will be coordinated through a WHO Center for Health Emergency Preparedness and Response; see Recommendation C.1.)

Financing the Required Improvements in National Public Health Systems

Public health services are an integral part of any health system and a key driver of health system resilience. However, public health is often starved of investment, even relative to other parts of the health system (RWJF, 2013). Why is this?

One reason is a certain level of invisibility of outcomes, as explained earlier in this chapter. Avoiding outbreaks is a negative achievement. Building resilience can be difficult to measure and easy to undervalue. As in the Biblical parable of the house on the sand and the house on the rock, weak foundations are only exposed when the storm hits (Matthew 7:24–27).

Secondly, national resource constraints and competing priorities mean that investment in strong and resilient health systems, which deliver benefits over the long term, often gets crowded out amid clamor for spending in areas where the benefits are more immediately and directly obvious. This problem is particularly acute in the poorest countries, but it is not unique to them. Even rich countries have this challenge. It takes a crisis like Ebola to reveal the enormous social and economic costs of neglecting the fundamental infrastructure and capacities of national health systems.

Thirdly, the prioritization of global aid agendas and financing mechanisms can create challenges in building coherent and resilient health systems. A focus on specific diseases (vertical programs) and other health-related targets, which prevails in much of the international development assistance community, can lead to neglect and fragmentation of the underlying health system (Flessa and Marx, 2016; Oliveira and Russo, 2015). For understandable reasons, many donors take a deliberately narrow focus, channeling their resources and energies toward meeting sharply defined program targets for specific diseases. Such single-minded focus helps deliver short-term results. However, a profusion of narrowly focused initiatives, each pursuing specific program goals

without much attention to linking the public health and health care delivery systems, can create a kind of "tragedy of the commons," as Garrett Hardin described in 1968 (Hardin, 1968).

This phenomenon was somewhat evident in West Africa during Ebola. Before the epidemic, and despite neglected and fragile health systems, vertical program funding had enabled gains in specific indicators, such as child and maternal health and immunization. Yet during Ebola, health systems collapsed and those specific gains from vertical programs were reversed, at least in part. Neglecting the foundation makes the gains from other health programs extremely fragile.

Reinforcing health system resilience and preparedness at the level of individual countries will require sustained incremental spending, given the significant gaps in capacities and infrastructure of many countries. Estimating the scale of incremental investment required is challenging, as the available information on each country's current status is far from perfect, and the costs of upgrading capacities will vary substantially among different countries. Even taking these challenges into account, however, it is obvious that significant investment is needed to strengthen national systems. Currently, only one-third of countries report themselves to be fully compliant with IHR guidelines (WHO, 2015c), and even this may be an overstatement, given that compliance is self-assessed and benchmarks broadly defined.

The most credible estimate of the costs of reinforcing national capacities and infrastructure to achieve IHR compliance comes from a 2012 World Bank report, which concluded that achieving compliance for only low- and middle-income countries would cost between $1.9 and $3.4 billion[6] per year (World Bank, 2012). This figure includes expenditures on a range of essential functions across both human and animal health sectors.[7] For human public health systems, these include the costs of strengthening surveillance and diagnostic capacities, as well as upgrading disease control measures. For veterinary health services, the costs of surveillance, biosecurity, diagnostics, and control, as well as culling and resultant compensation, are included, along with the costs of enhancing wildlife surveillance, diagnosis, and disease control.

While the World Bank estimates might be based on imperfect data, there is good reason to believe that they reasonably represent the scale of investment required. A 2009 estimate by the IOM/National Research Council Committee on Achieving Sustainable Global Capacity for Surveillance and Response to Emerging Diseases of Zoonotic Origin concluded that an annual expenditure of $1.34 billion would be needed annually through 2020 to address the pandemic threat of avian influenzas alone (IOM and NRC, 2009). It thus seems reasonable that strengthening national systems to address the broader threat posed by all potential pandemic disease agents will cost even more. Indeed, taking into account the need to upgrade capacities in many higher-income countries—as well as the low- and middle-income countries included in the World Bank analysis—it is likely that the overall investment gap today is nearer the upper end of the World Bank estimates ($3.4 billion). This amount is in addition to other investments recently proposed for health systems strengthening. For example, the Lancet Commission on Investing in Health proposed an incremental investment in health systems strengthening of $17 billion per year to 2035; however, this estimate did not include the resource demands to prepare for new infectious threats, such as pandemic influenza (Jamison et al., 2013).

In considering potential sources of such incremental funding, two key considerations are sustainability and externalities. Health systems resilience should be viewed by all countries as an ongoing requirement, rather than a one-off effort, so the funding approach needs to be sustainable. Furthermore, given that it is the foundation of health security, spending on public health infrastructure and capacities such as surveillance systems and laboratory networks should be seen as a component of national security expenditures, and therefore as an integral part of a government's fundamental duty to protect its people. A country's investment in public health capabilities and

[6] All monetary figures in U.S. dollars.

[7] The estimates were developed following a 2-year process of research and expert consultation, involving the collection of budget data from 88 countries. Estimates of required spending were disaggregated by service and disease type in order to produce global estimates of the expenditures needed to meet WHO/OIE standards, and estimates of annual spending were extrapolated to the full set of 139 low- and middle-income countries. The report emphasized a One Health approach, entailing interdisciplinary collaboration among systems focused on human, animal, and environmental health. This approach to pandemic preparedness can be justified on two grounds: first, zoonotic diseases constitute the bulk (more than 60 percent) of emerging infectious diseases; and second, many of the elements of One Health strategies, such as national laboratory networks, would be applicable to any emerging disease threat.

infrastructure also creates positive externalities, because other countries will benefit from the resulting reduction in infectious disease risk (and, conversely, the failure to make such investments creates negative externalities). The presence of such powerful externalities underscores the logic of high-income countries supporting low-income countries in making these investments.

In this context, we suggest the following:

- High-income and upper-middle-income countries must make achievement of the IHR core capacities a central part of the government's expenditure, most likely funded through general resources or possibly via dedicated taxes.[8] Civil society will be able to hold governments accountable for devoting sufficient resources to achieving IHR compliance through the mechanism of independent assessment described in Chapter 3. For countries in these income brackets, it also makes sense to establish emergency contingency funds where they do not already exist. Such funds could cover a broader range of potential emergencies than pandemics alone.
- Lower-middle-income and low-income countries should discuss with their multilateral and bilateral partners the appropriate balance of domestic resource mobilization and external support (which might be directed at helping upgrade capacities and infrastructure, contingent on local governments' commitments to maintain support thereafter). This could be achieved through a range of options, including:
    1. individual country-level negotiations with donor partners around national plans to rectify gaps;
    2. negotiations under the umbrella of existing multi-country initiatives, such as the GHSA and the World Bank–funded Laboratory Network in 18 countries in east, central, and southern Africa;
    3. through the creation of a new fund, with grants and/or loans linked to commitment to ongoing financial support from domestic resources; and
    4. a combination of Options 1 and 2, with the World Bank providing overall coordination to minimize duplication and gaps.

We believe Option 4 provides the optimal blend of flexibility for funding efforts in lower-middle- and low-income countries. This would enable the global community to build on the momentum of initiatives such as the GHSA, leveraging other, more focused health financing vehicles such as Gavi and the Global Fund and drawing on new potential sources of financial support, such as the New Development Bank and the Asian Infrastructure Investment Bank. We believe Option 3, a dedicated fund specifically focused on pandemics, would not be optimal, given that the investment we envisage is so integrally entwined with the reinforcement of the overall health system and overlaps with initiatives to target other health challenges, such as antimicrobial resistance (AMR).

Whatever the initial balance between domestic and donor spending, there should be a plan to reduce reliance on external funding through domestic resource mobilization. Building and sustaining local health system resilience should be seen as a core function of the national government and integral part of the budget. For example, the visible economic growth reported in many African countries should also be reflected in growing health expenditure.

For fragile and failed states, where local governments are not in a position to develop or execute such plans (let alone fund them), there should be a strategy for building and sustaining the most critical public health capacities to the extent possible. This will also be true where governments systematically ignore their responsibilities, pay only lip service to them, or allow implementation to be fatally undermined by corruption. Given that each of these situations has unique characteristics, this report refrains from prescribing a single approach to addressing and resourcing such challenges. However, it is clearly in the interest of global health security to incorporate consideration of infectious disease preparedness and response challenges in determining the UN or broader international strategy toward such situations.

Irrespective of a country's income level, the health systems investments described here should be guided by:

- a clear definition of the core capacities required (see Recommendation B.1);
- rigorous, objective, and transparent assessment of current performance against these defined capacities (see Recommendation B.2); and

[8] For example, the IOM/National Research Council Committee on Achieving Sustainable Global Capacity for Surveillance and Response to Emerging Diseases of Zoonotic Origin suggested a possible tax on the meat trade (IOM and NRC, 2009).

- clear and detailed plans to rectify gaps, including the costs of upgrading core capacities and a model for sustainable funding.

Recommendation B.8: National governments should develop domestic resourcing plans to finance improvement and maintenance of core capacities as set out in the country-specific plans described in Recommendation B.6. For upper- and upper-middle-income countries, these plans should cover all financing requirements. For lower-middle- and low-income countries, these plans should seek to develop a pathway to full domestic resourcing, with a clear timetable for achieving the core capacity benchmarks.

Recommendation B.9: The World Bank should convene other multilateral donors (including the African Development Bank, Asian Development Bank, New Development Bank, United Nations Development Program, and Asian Infrastructure Investment Bank) and development partners by mid-2017 to secure financial support for lower-middle- and low-income countries in delivering the plans outlined in Recommendation B.6.

Recommendation B.10: The United Nations (UN) Secretary General should work with the World Health Organization and other parts of the UN system to develop strategies for sustaining health system capabilities and infrastructure in fragile and failed states and in warzones, to the extent possible.

CLOSING REMARKS

While the public health component of a health system is the first line of defense against the threat of infectious diseases, it has been seriously neglected by even the most advanced economies. Strengthening public health capacities should be a health security priority for governments and the global community. To achieve this, WHO, in coordination with member states, should develop clear standards and benchmarks for national core capacities and functioning and devise a regular, independent, and transparent assessment mechanism to evaluate countries' compliance.

At the country level, political will is essential to develop and implement plans to achieve and maintain benchmark core capacities. For resource-limited countries and fragile and failed states, the World Bank should develop finance mechanisms in collaboration with other multilaterals and development partners to support these efforts. This funding should be conditional upon a country's compliance with the external assessment mechanism. WHO should play an important role in providing technical expertise to support countries in the implementation of such plans. Strengthening public health systems will not only prevent a future outbreak from spinning out of control, but also support other critical efforts to combat global health threats, such as AMR.

CHAPTER 3 ANNEX

ANNEX 3-1

TABLE 3-4 Status of Core Capacities by Region for the Years 2013 and 2014

	% of Countries in Compliance	Global		AFRO		AMRO		EMRO		EURO		SEARO		WPRO	
N	Year	2013	2014	2013	2014	2013	2014	2013	2014	2013	2014	2013	2014	2013	2014
1	Legislation	70	78	41	60	77	74	75	82	84	86	84	88	80	84
2	Coordination	73	80	57	67	79	81	77	83	76	82	77	87	83	83
3	Surveillance	80	85	69	77	87	89	84	83	83	87	77	81	85	90
4	Response	79	83	66	72	84	85	78	81	85	87	77	81	88	86
5	Preparedness	63	71	40	53	67	71	62	65	73	78	69	75	78	78
6	Risk Communication	72	77	51	61	77	81	67	72	80	79	79	86	88	85
7	Human Resources	60	63	45	56	68	68	69	68	52	53	69	74	72	72
8	Laboratories	76	82	69	73	79	83	76	74	80	84	77	88	80	87
9	Points of Entry	54	62	23	35	64	67	55	63	68	67	60	58	68	78
10	Zoonosis	81	86	67	68	91	87	86	85	86	92	92	96	80	87
11	Food Safety	71	76	47	43	74	76	75	77	85	93	81	81	79	83
12	Chemical	53	57	29	28	55	54	53	53	77	79	50	50	57	62
13	Radio Nuclear	51	60	28	36	53	54	60	62	80	86	37	35	49	57

NOTE: AFRO = Regional Office for Africa; AMRO = Regional Office for the Americas; EMRO = World Health Organization (WHO) Eastern Mediterranean; EURO = WHO Europe Regional Office; SEARO = WHO South East Asia Regional Office; WPRO = Western Pacific Regional Office.
SOURCE: Adapted from WHO, 2016.

ANNEX 3-2

Uganda Case Study

Political Commitment: National Legislation and Development Plans

Following the 2000 Ebola outbreak and based on results from an assessment of the vertical surveillance strategy in place at the time, a 5-year strategic plan for the health sector was developed and implemented (MOH, 2000). This assessment indicated that investment and improvement on the existing passive, limited approach to collecting surveillance information and the less-than optimal coordination and communication between the district, regional, and national levels would result in reducing the threat, morbidity, and mortality of epidemics through an early-warning system and quick response (Lukwago et al., 2012; Phalkey et al., 2013). As part of the new strategy, Uganda moved to strengthen WHO's "Integrated Disease Surveillance and Response Strategy."

Coordination and Collaboration

The Ugandan system is coordinated by a standing multidisciplinary and multisectoral National Task Force (NTF) that meets monthly to review surveillance data and update preparedness plans; during an outbreak, the NTF meets daily (Aceng, 2015). It is led by the Director General of the Ministry of Health (MOH), and its members are drawn from various fields of expertise, including epidemiology, veterinary medicine, communication, and laboratory science—all from various ministries within the government, the military, the Office of the Prime Minister, research institutions and universities; representatives from WHO and the CDC; and participants from civil society and NGOs such the Uganda Red Cross and Médecins Sans Frontières (Aceng, 2015).

A PHEOC was recently established to assist the NTF and the district task forces (DTFs) created by coordinating emergency capacities through receiving, evaluating, and distributing information collected from

surveillance activities, laboratories, and communication networks (Bourchert et al., 2014). The PHEOC is activated immediately following outbreak detection (Aceng, 2015).

Community Engagement

Social mobilization has been critical to Uganda's success. Local leaders and various professionals are involved throughout the discussion and are trained on basic principles of identifying certain diseases, such as Ebola (Lamunu et al., 2004). Respect for cultural traditions and understanding of knowledge, attitudes, and beliefs of the affected area shapes the mobilization effort, and the government works closely with the United Nations Children's Fund and the Uganda Red Cross to engage traditional healers and religious leaders to support social mobilization efforts (Aceng, 2015; Lamunu et al., 2004; Mbonye et al., 2014).

Integrated Disease Surveillance System

The disease surveillance system functions at all country levels: national, sub-national, district, and sub-district. A DTF exists in all 112 districts of the country. Its membership is comprised of political, health, and community leaders and relevant technical advisors, led by the politically elected Chairman of the Local Council (Borchert et al., 2011). There are designated surveillance and laboratory focal persons at the district and regional levels who regularly receive and review surveillance information (Aceng, 2015). Village health teams are responsible for 20–30 households and were established as an integral component of the national strategic plan to improve access to care, social mobilization, governance coordination, and community-based preventive or rehabilitation services (Aceng, 2015; MOH, 2000, 2015).

Information Systems and Use of Technology

Data from all health facilities in the country are shared with providers and health workers through a weekly epidemiological bulletin produced by the MOH Epidemiology and Surveillance Division and Resource Center. A comprehensive short message service (SMS) alert system is established to boost surveillance, with members of the District Rapid Response Teams, the District Surveillance Officer, and the hub coordinator sending texts to the system, which then forwards alerts to all members of the NTF. The SMS reporting system and a specimen tracking system are accessible to the PHEOC through the District Health Information System (DHIS-2), which is used to report national health data and provide real-time monitoring and evaluation through an online platform. Access to the DHIS-2, which is now linked up with the SMS facility data transmission system, allows the PHEOC to be the primary center of communication and the coordination site of response decisions and subsequent implementation by the NTF in an emergency (Bourchert et al., 2014). The use of standardized forms for data collection, as well as a specific individual assigned to data management for each outbreak, allows for coordinated management and dissemination of information to health care workers and the public (Aceng, 2015).

Infrastructure and Laboratory Capacity

Laboratory services are available beginning at the health sub-district level and grow increasingly more complex in scaling up the health system, with approximately 1,700 health facilities providing basic minimum laboratory services (Kiyaga et al., 2013). A biosafety level 3 laboratory at the Uganda Virus Research Institute (UVRI), funded in part by the CDC after a 2007 Ebola outbreak, allows for fast turnaround and identification of samples (Aceng, 2015; Mbonye et al., 2014; MOH, 2000). Samples are concurrently sent to the CDC for testing. The decentralized laboratory network allows for isolation units to be set up when the need arises, allowing for quick control and containment. Upon confirmation, a daily situation report called the "Sitrep" is produced and distributed, and WHO is notified immediately (Aceng, 2015).

As many health facilities have only basic laboratory services, a National Sample and Results Transport Network was established to allow for quick and efficient transport of samples, coordinated by the Central Public Health Laboratory. Funded in part by the Global Fund, the transport network identified 77 hubs throughout the country with enhanced laboratory capacity (Aceng, 2015; Global Fund, 2014; Kiyaga et al., 2013). The hubs act as a coordinating center and serve approximately 20–40 health facilities in a 30–40 km radius around the hub (Kiyaga et al., 2013). Each hub is serviced by a motorbike rider who visits 4–8 hubs on a given day. They reach every facility at least once per week, delivering the previous week's results and picking up samples (Aceng, 2015; Kiyaga et al., 2013; Mbonye et al., 2014). In emergency situations, riders for each hub are on reserve to pick up

TABLE 3-5 Uganda Strategy Building of Core Capacities

Uganda Strategy	IHR Core Capacities
5-year strategic plan	1 – National Legislation, Policy and Financing
National Task Force, district task forces and public health emergency operations center	2 – Coordination and National Focal Point Communication
Integrated Disease Surveillance and Response System with community involvement (village health teams)	3 – Surveillance
Coordination mechanisms and Rapid Response Teams	4 – Response
Outbreak response plans developed	5 – Preparedness
Use of media, radio, and development of messages respectful of cultural traditions	6 – Risk Communication
Comprehensive nationwide training strategy	7 – Human Resources
Strong laboratory capacity and transportation network	8 – Laboratory

SOURCE: Summary of Aceng, 2015.

samples, and transport them to the postal service, Posta Uganda, for transportation to UVRI. This process in its entirety is designed to take less than 24 hours (Aceng, 2015). SMS alerts are sent to the hub coordinator at each point to notify them of specimen registration, UVRI receipt, and release of results, with data in parallel tracked through DHIS-2 (Aceng, 2015).

Health Workforce Capacity

Currently the country is implementing a comprehensive training in all the 14 Regional Referral Hospitals to build standby Case Management Teams readily available to support respective districts as need arises. These will further serve as the decentralized monitoring and evaluation centers for Integrated Disease Surveillance and Response countrywide. Surveillance efforts are boosted with the CDC's FETP. This program trains field epidemiologists in investigating any unusual deaths or occurrences, and these field epidemiologists are deployed with surveillance officers to assist with contact tracing (Aceng, 2015).

Community health workers (CHWs), who comprise the village health teams, are trained on standardized clinical and community case definitions, reporting of any unusual events, and surveillance activities to enable early reporting from the community level to their respective attachment health facilities (Aceng, 2015; Lamunu et al., 2004; MOH, 2015).

Communication and Education

CHWs serve as a valuable link between the community and the health sector. For example, in cases where the patient is kept in isolation, CHWs brief families on a daily basis and contact burial teams to bury the dead with dignity while maintaining adherence to outbreak control practices (Aceng, 2015). The media is well utilized with daily radio discussions, "aggressive" documentary screenings of previous outbreaks, and widely circulated posters and dissemination (Aceng, 2015; Lamunu et al., 2004).

Summary

In summary, taking the lessons learned from the 2000 Ebola outbreak, Uganda started a process of building public health core capacities that strengthened its surveillance and response systems, which significantly improved the outcome of several subsequent Ebola outbreaks. As shown in Table 3-5, these key elements implemented aligned very well with the core capacities included in the legally binding IHR.

ANNEX 3-3

Rwanda Case Study

Where needed, governments should work with development partners to strengthen health systems capacity with an approach that focuses on country ownership and accountability. Rethinking the current approach to aid implementation and management in building health

systems can bring about significant improvement in the breadth and quality of care provided, as well as in countries' social and economic development. This is demonstrated best through the study of Rwanda and how the country has transformed its circumstance beginning from the ruins of the 1994 genocide to being "the only country in the region on track to meet each of the health-related millennium development goals by 2015" (Farmer et al., 2013).

The Vision 2020 policy, Rwanda's comprehensive national plan, provides a clear, long-term development path and objectives for moving forward post-genocide. These comprehensive and transparent development plans allow for coordination among the government, donors, and implementing partners. Critical to the progress achieved is the strict adherence to country ownership and accountability, maintained in an effort to further national capacity building by "reducing the country's dependence on external aid" (MoFEP, 2000). The Rwanda Aid Policy, published by the Ministry of Finance and Economic Planning in 2006, explicitly states, "The Government will decline any or all offers of assistance where it considers transaction costs to be unacceptably high, alignment to government priorities to be insufficient, or conditionalities to be excessive" (MoFEP, 2006). This ensures investment in national systems and institutions—investment that is beneficial to countries with weak institutional capacity (UN Office of the Special Envoy for Haiti, 2012).

This does not mean, however, that vertical funding from programs such as the Global Fund or the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) should be turned away. Instead, funds can be harnessed to build and strengthen platforms for integrated service delivery (Walton, 2004). In Rwanda, funds from PEPFAR, the Global Fund, and the U.S. Agency for International Development (USAID) were used to launch the Human Resources for Health program to combat shortages in health personnel with investments in health facilities and training (Binagwaho et al., 2013). Leveraging shared infrastructure, such as supply chain and procurement systems, laboratory capacity, health personnel, and information management also enabled greater efficiency in the system through improved access to care at lower cost (Farmer et al., 2013; Porter et al., 2009). Finding opportunities for funders to work in alignment with the government's agenda have proven successful, with dramatic changes observed in poverty, life expectancy, spread of infectious disease, and child mortality (Binagwaho et al., 2014).

The Vision 2020 policy emphasizes reduction of inequality through improved access to high-quality health care and education, especially for previously neglected rural communities (MoFEP, 2000). Often, despite millions of dollars in aid, individuals who rely on the help of national institutions see little improvement in their situations. In the case of Sierra Leone, a country hugely impacted by the ongoing Ebola outbreak despite more than $712 million in aid, only 5 percent was funneled into national systems, therefore bypassing communities who would stand to benefit most (Office of the Secretary-General's Special Adviser on Community Based Medicine and Lessons from Haiti, 2015). Rwanda has addressed this issue by implementing and managing its own effective system to track donor disbursements, based on recommendations from the Paris Declaration of Aid Effectiveness (UN Office of the Special Envoy for Haiti, 2012). Utilizing donors' external aid-tracking systems instead of letting governments take ownership in tracking disbursement "undermines the government's appropriation of the process and the validity of the figures" (UNDP, 2010). Including aid management and documented delivery in policy recommendations, such as in Rwanda's Donor Performance Assessment Framework, allows for effective, timely, and high-quality data on aid programs and management (MoFEP, 2010). This holds the performance of donors accountable against "a set of established indicators on the quality and volume of development assistance," ensuring the establishment of transparent dialogue, and "allow[s] for comparison, individual reflection on performance, accountability and peer pressure" among all involved partners (MoFEP, 2010). These data are essential for enabling the government to make evidence-based decisions to strengthen the public sector and effectively deliver public services (UN Office of the Special Envoy for Haiti, 2012). Rwanda observed 58 percent of its aid channeled into country systems in 2010, allowing for vast progress to be made in building and strengthening the country's health system (UN Office of the Special Envoy for Haiti, 2012).

From this experience, we can also learn that bridging gaps in access to care for marginalized communities can be accomplished with community-based interventions quickly and at low cost. As of 2012, approximately 91

percent of the country was enrolled in the national community-based insurance scheme with subsidized premiums and co-payments on an income-based tiered payment structure that allowed for the poorest enrollees to obtain access to health care (Farmer et al., 2013). Strengthening community-based interventions by scaling up numbers of community health workers was accomplished rapidly and at low cost. These personnel are considered essential for bridging the health care worker gap through providing treatment, monitoring, surveillance, referral, and reporting services, and allowing for strong community linkages to be formed with the national health care system (Binagwaho et al., 2014). Rwanda's inclusion of clear guidelines for financing, management, and delivery in its national policy has indeed helped overcome disparities in access to high-quality health care. It is important to keep in mind for the future that, as in the Ebola response, we have witnessed that where high-quality care was provided, Ebola patients survived. This is strong testimony to a national policy that builds a resilient, country-owned health system, thereby preventing future spread of disease and saving countless lives.

ANNEX 3-4

Acknowledging the Roots of Resistance and Distrust of Containment Measures

To understand community resistance and distrust of containment measures in Guinea, Sierra Leone, and Liberia during the Ebola epidemic, it is important to understand the history of public health approaches in the region. During the 2014 Ebola epidemic, journalists noted that establishing a cordon sanitaire was "a tactic unseen in a century" (McNeil, 2014). But restrictive and authoritarian tactics were used throughout the previous century by both colonial and independent governments. Outbreaks of yellow fever, smallpox, cholera, and bubonic plague joined the chronic affliction of malaria, and were met with a host of restrictive or punitive measures, including the destruction of housing, highly restrictive building codes and outright segregation, quarantine, isolation, and fines for infractions. These were all applied in discriminatory fashion, sparing Europeans in a manner that rankled Africans.

Ethnographic research as well as a survey of radio and print media suggest that citizens of all three countries have long-lived memories of prior campaigns to wall-off villages afflicted by smallpox, Lassa fever, influenza and even vector-borne diseases—such as plague, trypanosomiasis, and malaria.

In all three countries, wars had weakened already rickety public health systems, which were largely focused on restrictive and punitive measures and included little in the way of care; this was especially true in the eastern reaches of the "trizone area" in which the three countries come together. In Sierra Leone, the arsenal of measures taken to halt smallpox and malaria in the colonial period sounds eerily familiar to those seen in the recent Ebola response. These included fines (there was a two-pound fine levied on households "hiding" victims; the threat of mandatory quarantine within contagious disease "hospitals" with little in the way of medical or nursing care; other legal actions in 1914–1915, there were 1,333 "mosquito larva court cases," even though the ditches and puddles remained ubiquitous); more futile and corrosive attempts to segregate Freetown; and efforts to restrict population movements (Cole, 2015; Rashid, 2011; Spitzer, 1968; Tomkins, 1994).

Similar approaches were adopted in French West Africa. Yet although the "sanitarians" were obsessed with disease control, this did not mean they were effective at controlling disease. Plague was in the end halted by more DDT and therapeutic advances, than by quarantine, travel bans, or the destructions of housing. Similar control-only approaches were applied to smallpox, and were often resisted (Greenough, 1995). Although the case-fatality of the disease varied widely, the primary approach to smallpox put all the emphasis on control rather than care: quarantine, isolation, ring vaccination, and walling off affected villages, which were sometimes razed. In both 1967 and 1968, Sierra Leone had the world's highest incidence of smallpox among "all countries reporting to the World Health Organization" (Hopkins et al., 1971).

Caregiving did not, however, fit readily into the conceptions of the "sanitarians" of tropical medicine. Obsessed with disease control, they paid scant heed to supportive care. Their intense focus on containment and control and lack of interest in care left a potent legacy that undoubtedly influenced communities' reactions to actions taken in the context of Ebola. Coupled with tensions remaining from recent conflicts in each of the three countries and the corrosive effects of corruption on public trust, this history of control-oriented public

health created a very challenging context for community engagement (Dhillon et al., 2015; Pellecchia et al., 2015; Richards et al., 2015).

Two lessons leap out: first that caregiving is an essential component of an outbreak response strategy, in part because it is the right thing to do, and in part because it is essential to enlisting community support; and second, that effective community engagement requires understanding the context, including the history, that will inform people's attitudes and behaviors.

REFERENCES

Abramowitz, S. 2014. *Ten things that anthropologists can do to fight the West African Ebola epidemic*. Somatosphere. http://somatosphere.net/2014/09/ten-things-that-anthropologists-can-do-to-fight-the-west-african-ebola-epidemic.html (accessed December 15, 2015).

Aceng, J. 2015. *Managing epidemics, the Ugandan experience.* Presentation at "Global Health Risk Framework: A Workshop on Resilient and Sustainable Health Systems to Respond to Global Infectious Disease Outbreaks," Accra, Ghana, August 5–7, 2015.

Atun, R., S. Bennett, and A. Duran. 2008. *When do vertical (stand-alone) programmes have a place in health systems?* Copenhagen: WHO.

Bialik, C. 2009. Ill-conceived ranking makes for unhealthy debate. *Wall Street Journal*. http://www.wsj.com/articles/SB125608054324397621 (accessed February 1, 2015).

Binagwaho, A., P. Kyamanywa, P. E. Farmer, T. Nuthulaganti, B. Umubyeyi, J. P. Nyemazi, S. D. Mugeni, A. Asiimwe, U. Ndagijimana, H. Lamphere McPherson, J. d. D. Ngirabega, A. Sliney, A. Uwayezu, V. Rusanganwa, C. M. Wagner, C. T. Nutt, M. Eldon-Edington, C. Cancedda, I. C. Magaziner, and E. Goosby. 2013. The human resources for health program in Rwanda—a new partnership. *New England Journal of Medicine* 369:2054-2059.

Binagwaho, A., P. E. Farmer, S. Nsanzimana, C. Karema, M. Gasana, J. de Dieu Ngirabega, F. Ngabo, C. M. Wagner, C. T. Nutt, T. Nyatanyi, M. Gatera, Y. Kayiteshonga, C. Mugeni, P. Mugwaneza, J. Shema, P. Uwaliraye, E. Gaju, M. A. Muhimpundu, T. Dushime, F. Senyana, J. B. Mazarati, C. M. Gaju, L. Tuyisenge, V. Mutabazi, P. Kyamanywa, V. Rusanganwa, J. P. Nyemazi, A. Umutoni, I. Kankindi, C. Ntizimira, H. Ruton, N. Mugume, D. Nkunda, E. Ndenga, J. M. Mubiligi, J. B. Kakoma, E. Karita, C. Sekabaraga, E. Rusingiza, M. L. Rich, J. S. Mukherjee, J. Rhatigan, C. Cancedda, D. Bertrand-Farmer, G. Bukhman, S. N. Stulac, N. M. Tapela, C. van der Hoof Holstein, L. N. Shulman, A. Habinshuti, M. H. Bonds, M. S. Wilkes, C. Lu, M. C. Smith-Fawzi, J. D. Swain, M. P. Murphy, A. Ricks, V. B. Kerry, B. P. Bush, R. W. Siegler, C. S. Stern, A. Sliney, T. Nuthulaganti, I. Karangwa, E. Pegurri, O. Dahl, and P. C. Drobac. 2014. Rwanda 20 years on: Investing in life. *Lancet* 384:371-375.

Borchert, M., I. Mutyaba, M. D. Van Kerkhove, J. Lutwama, H. Luwaga, G. Bisoborwa, J. Turyagaruka, P. Pirard, N. Ndayimirije, and P. Roddy. 2011. Ebola haemorrhagic fever outbreak in Masindi District, Uganda: Outbreak description and lessons learned. *BMC Infectious Diseases* 11(1):357.

Bourchert, J., J. Tappero, R. Downing, T. Shoemarker, P. Behumbiize, J. Aceng, I. Makumbi, M. Dahlke, B. Jarrar, B. Lozano, S. Kasozi, M. Austin, D. Phillippe, I. Watson, T. Evans, T. Stotish, S. Dowell, M. Iademarco, R. Ransom, A. Balajee, K. Becknell, D. Beauvais, and T. Wuhib. 2014. *Rapidly building global health security capacity—Uganda Demonstration Project, 2013*. Atlanta, GA: U.S. Centers for Disease Control and Prevention.

Campbell, J., G. Dussault, J. Buchan, F. Pozo-Marin, M. Guerra Arias, C. Leone, A. Siyam, and G. Cometto. 2013. *A universal truth: No health without a workforce. Forum report.* Geneva: Global Health Workforce Alliance and WHO.

CDC (Centers for Disease Control and Prevention). 2001. Outbreak of Ebola hemorrhagic fever—Uganda, August 2000–January 2001. *Morbidity and Mortality Weekly Report* 50:73-77.

CDC. 2014a. *Global Health Security Agenda: GHSA Immunization Action Package* (GHSA Action Package Prevent-4). http://www.cdc.gov/globalhealth/security/actionpackages/immunizationap.htm (accessed on December 18, 2015).

CDC. 2014b. *Outbreaks chronology: Ebola virus disease.* http://www.cdc.gov/vhf/ebola/outbreaks/history/chronology.html#thirty (accessed January 4, 2016).

Chandler, C., J. Fairhead, A. Kelly, M. Leach, F. Martineau, E. Mokuwa, M. Parker, P. Richards, A. Wilkinson, and P. Ebola Response Anthropology. 2015. Ebola: Limitations of correcting misinformation. *Lancet* (London, England) 385(9975):1275-1277.

Coker, R., J. Rushton, S. Mounier-Jack, E. Karimuribo, P. Lutumba, D. Kambarage, D. U. Pfeiffer, K. Stark, and M. Rweyemamu. 2011. Towards a conceptual framework to support One-Health research for policy on emerging zoonoses. *Lancet Infectious Disease* 11(4):326-331.

Cole, F. 2015. Sanitation, disease and public health in Sierra Leone, West Africa, 1895–1922: Case failure of British colonial health policy. *Journal of Imperial and Commonwealth History* 43(2):238-266.

Decoster, K., A. Appelmans, and P. Hill. 2012. *A Health Systems Research mapping exercise in 26 low- and middle-income countries: Narratives from health systems researchers, policy brokers and policy-makers*. Geneva: Alliance for Health Policy and Systems Research.

Dhillon, R. S., and J. D. Kelly. 2015. Community trust and the Ebola endgame. *New England Journal of Medicine* 37(9):787-789.

Fallah. M. 2015. *Community-based initiative: The miracle of west point slum and Needowein Ebola outbreak*. Presentation at "Global Health Risk Framework: A Workshop on Resilient and Sustainable Health Systems to Respond to Global Infectious Disease Outbreaks," Accra, Ghana, August 5–7, 2015.

FAO (Food and Agriculture Organization) and OIE (World Organisation for Animal Health). 2008. *The global strategy for prevention and control of H5N1 highly pathogenic avian influenza*. Rome: FAO.

Farmer, P. E., C. T. Nutt, C. M. Wagner, C. Sekabaraga, T. Nuthulaganti, J. L. Weigel, D. B. Farmer, A. Habinshuti, S. D. Mugeni, J.-C. Karasi, and P. C. Drobac. 2013. Reduced premature mortality in Rwanda: Lessons from success. *British Medical Journal* 346:20-22.

Flessa, S., and M. Marx. 2016. Ebola fever epidemic 2014: A call for sustainable health and development policies. *European Journal of Health Economics: Health Economics in Prevention and Care* 17(1):1-4.

Freeman, C. 2014. Did this doctor save Nigeria from Ebola? *The Telegraph*. http://www.telegraph.co.uk/news/worldnews/11174750/Did-this-doctor-save-Nigeria-from-Ebola.html (accessed December 18, 2015).

GAO (U.S. Government Accountability Office). 2004. Asian SARS outbreak challenged international and national responses. *Emerging Infectious Diseases.* GAO-04-564.

The Global Fund. 2014. *TB and HIV concept note: Investing for impact against tuberculosis and HIV*. Geneva: The Global Fund.

Gostin, L. O., M. C. DeBartolo, and E. A. Friedman. 2015. The International Health Regulations 10 years on: The governing framework for global health security. *Lancet* 386(10009):2222-2226.

Greenough, P. 1995. Intimidation, coercion, and resistance in the final stages of the South Asian smallpox eradication campaign, 1973-1975. *Social Science and Medicine* 41(5):633-645.

Hardin, G. 1968. The tragedy of the commons. *Science* 162(3859).

Hewlett, B., and B. Hewlett. 2008. *Ebola, culture, and politics: The anthropology of an emerging disease.* Belmont, CA: Thompson Wadsworth.

Hopkins, D. R., J. M. Lane, E. C. Cummings, and J. D. Millar. 1971. Two funeral-associated smallpox outbreaks in Sierra Leone. *American Journal of Epidemiology* 94(4):341-347.

IOM (Institute of Medicine) 2003. *The future of the public's health in the 21st century.* Washington, DC: The National Academies Press.

IOM. 2007. *Global infectious disease surveillance and detection: Assessing the challenges: Workshop summary*. Washington, DC: The National Academies Press.

IOM. 2015. *International infectious disease emergencies and domestic implications for the public health and health care sectors: Workshop in brief*. Washington, DC: The National Academies Press.

IOM and NRC (National Research Council). 2009. *Sustaining global surveillance and response to emerging zoonotic diseases*. Washington, DC: The National Academies Press.

Jamison, D. T., L. H. Summers, G. Alleyne, K. J. Arrow, S. Berkley, A. Binagwaho, F. Bustreo, D. Evans, R. G. A. Feachem, J. Frenk, G. Ghosh, S. J. Goldie, Y. Guo, S. Gupta, R. Horton, M. E. Kruk, A. Mahmoud, L. K. Mohohlo, M. Ncube, A. Pablos-Mendez, K. S. Reddy, H. Saxenian, A. Soucat, K. H. Ulltveit-Moe, and G. Yamey. 2013. Global health 2035: A world converging within a generation. *Lancet* 382(9908):1898-1955.

Katz, R., E. Sorrell, C. Standley, A. Vaught, and J. Fischer. 2015. *Mapping the Global Health Security Agenda to existing international and domestic frameworks*. Poster presentation at the 2015 Preparedness Summit, Atlanta, GA, April 2015.

Kieney, M.-P., D. Evans, G. Schmets, and S. Kadandale. 2014. Health-system resilience: Reflections on the Ebola crisis in Western Africa. *WHO Bulletin of the World Health Organization* 92(12):850.

Kiyaga, C., H. Sendagire, E. Joseph, I. McConnell, J. Grosz, V. Narayan, G. Esiru, P. Elyanu, Z. Akol, W. Kirungi, J. Musinguzi, and A. Opio. 2013. Uganda's new national laboratory sample transport system: A successful model for improving access to diagnostic services for early infant HIV diagnosis and other programs. *PLoS ONE* 8(11):e78609.

Lamunu, M., J. Lutwama, J. Kamugisha, A. Opio, J. Nambooze, N. Ndayimirije, and S. Okware. 2004. Containing a haemorrhagic fever epidemic: The Ebola experience in Uganda (October 2000–January 2001). *International Journal of Infectious Diseases* 8(1):27-37.

Laverack, G., and E. Manoncourt. 2015. Key experiences of community engagement and social mobilization in the Ebola response. *Global Health Promotion* 1-4.

Lukwago, L., M. Nanyunja, N. Ndayimirije, J. Wamala, M. Malimbo, W. Mbabazi, A. Gasasira, I. N. Nabukenya, M. Musenero, and W. Alemu. 2012. The implementation of integrated disease surveillance and response in Uganda: A review of progress and challenges between 2001 and 2007. *Health Policy and Planning* CZS022.

Mbonye, A. K., J. F. Wamala, M. Nanyunja, A. Opio, I. Makumbi, and J. R. Aceng. 2014. Ebola viral hemorrhagic disease outbreak in West Africa—lessons from Uganda. *African Health Sciences* 14(3):495-501.

McNeil, Jr., D. G. 2014. Using a tactic unseen in a century, countries cordon off Ebola-racked areas. *New York Times*, A10. http://www.nytimes.com/2014/08/13/science/using-a-tactic-unseen-in-a-century-countries-cordon-off-ebola-racked-areas.html (accessed April 1, 2016).

MoFEP (Ministry of Finance and Economic Planning). 2000. *Rwanda Vision 2020*. Kigali, Rwanda: Republic of Rwanda.

MoFEP. 2006. *Rwanda aid policy*. Kigali, Rwanda: Republic of Rwanda.

MoFEP. 2010. *Donor performance assessment framework (DPAF) FY 2009-2010*. Kigali, Rwanda: Republic of Rwanda.

MOH (Ministry of Health). 2000. *Health sector strategic plan 2000/01-2004/05*. Kampala, Uganda: Ministry of Health.

MOH. 2015. *National village health teams (VHT) assessment in Uganda*. Kampala, Uganda: Ministry of Health.

MSF (Médecins Sans Frontières). 2014. *Pushed to the limit and beyond: A year into the largest ever Ebola outbreak.* https://www.doctorswithoutborders.org/sites/usa/files/msf143061.pdf (accessed February 1, 2016).

Office of the Secretary-General's Special Adviser on Community Based Medicine and Lessons from Haiti. 2015. *Building health systems and increasing resilience to crises: Lessons from Rwanda*. New York: United Nations.

Oliveira, C., and G. Russo. 2015. Vertical interventions and system effects; have we learned anything from past experiences? *Pan African Medical Journal* 21.

Pellecchia, U., R. Crestani, T. Decroo, R. Van den Bergh, and Y. Al-Kourdi. 2015. Social consequences of Ebola containment measures in Liberia. *PLoS ONE* 10(12):e0143036.

Phalkey, R. K., S. Yamamoto, P. Awate, and M. Marx. 2013. Challenges with the implementation of an integrated disease surveillance and response (IDSR) system: Systematic review of the lessons learned. *Health Policy and Planning* CZT097.

Phommasack, B., C. Jiraphongsa, M. Ko Oo, K. C. Bond, N. Phaholyothin, R. Suphanchaimat, K. Ungchusak and S. B. Macfarlane. 2013. Mekong Basin Disease Surveillance (MBDS): A trust-based network. *Emerging Health Threats Journal* G:10.

Porter, M. E., S. Lee, J. Rhatigan, and J. Y. Kim. 2009. Partners in Health: HIV care in Rwanda. *Harvard Business School Case* 709474. Boston, MA: Harvard Business School Press.

Puthavathana, P., K. Sangsiriwut, A. Korkusol, P. Pooruk, P. Auewarakul, C. Pittayawanganon D. Sutdan, R. Kitphati, P. Sawanpanyalert, B. Phommasack, K. Bounlu, and K. Ungchusak. 2009. Avian influenza virus (H5N1) in human, Laos. *Emerging Infectious Diseases* 15(1):127-129.

Rashid, I. 2011. Epidemics and resistance in colonial Sierra Leone during the First World War. *Canadian Journal of African Studies* 45(3):415-439.

Richards, P., J. Amara, M. C. Ferme, P. Kamara, E. Mokuwa, A. Idara Sheriff, R. Suluku, and M. Voors. 2015. Social pathways for Ebola virus disease in rural Sierra Leone, and some implications for containment. *PLoS Neglected Tropical Diseases* 9(4):e0003567.

Rosewell, A., B. Ropa, H. Randall, R. Dagina, S. Hurim, S. Bieb, S. Datta, S. Ramamurthy, G. Mola, A. B. Zwi, P. Ray, and C. R. MacIntyre. 2013. Mobile phone-based syndromic surveillance system, Papua New Guinea. *Emerging Infectious Diseases* 19(11):1811-1818.

RWJF (Robert Wood Johnson Foundation). 2013. *Return on investments in public health*. Princeton, NJ: RWJF.

Schnirring, K. 2015. *Thailand reports first MERS case; South Korea adds 3*. Center for Infectious Disease Research and Policy. http://www.cidrap.umn.edu/news-perspective/2015/06/thailand-reports-first-mers-case-south-korea-adds-3 (accessed December 18, 2015).

Spitzer, L. 1968. The mosquito and segregation in Sierra Leone. *Canadian Journal of African Studies* 2(1):49-61.

Standley, C. J., E. M. Sorrell, S. Kornblet, J. E. Fischer, and R. Katz. 2015. Implementation of the International Health Regulations (2005) through cooperative bioengagement. *Frontiers in Public Health* 3:321.

Tomkins, S. M. 1994. Colonial administration in British Africa during the Influenza epidemic of 1918–19. *Canadian Journal of African Studies* 28(1):60-83.

UN (United Nations) Office of the Special Envoy for Haiti. 2012. *Can more aid stay in Haiti and other fragile settings? How local investments can strengthen governments and economies*. New York: United Nations. http://lessonsfromhaiti.org/download/Report_Center/osereport2012.pdf (accessed January 4, 2016).

UNDP (United Nations Development Programme). 2010. *Aid information management systems in post-conflict and fragile situations: A comparative study*. Discussion draft. New York: UNDP.

Walton, D. A., P. E. Farmer, W. Lambert, F. Léandre, S. P. Koenig, and J. S. Mukherjee. 2004. Integrated HIV prevention and care strengthens primary health care: Lessons from rural Haiti. *Journal of Public Health Policy* 25:137-158.

World Bank. 2012. *People, pathogens and our planet: Volume 2—the economics of One Health*. Washington, DC: World Bank.

WHO (World Health Organization). 2000. *The World Health Report 2000: Health systems: Improving performance*. Geneva: WHO.

WHO. 2006. *The World Health Report 2006—working together for health*. Geneva: WHO.

WHO. 2008a. *International Health Regulations (2005) Second Edition*. Geneva: WHO.

WHO. 2008b. *The World Health Report: Primary health care "now more than ever."* Geneva: WHO.

WHO. 2010. *Implementation of the International Health Regulations (2005) draft plan for the first review of the functioning of the International Health Regulations (2005) in relation to pandemic (H1N1) 2009*. Geneva: WHO.

WHO. 2011a. *IHR Core Capacity Monitoring Framework: Checklist and indicators for monitoring progress in the development of IHR core capacities in states parties*. http://www.who.int/ihr/IHR_Monitoring_Framework_Checklist_and_Indicators.pdf (accessed January 4, 2016).

WHO. 2011b. *Implementation of the International Health Regulations (2005): Report of the Review Committee on the Functioning of the International Health Regulations (2005) in relation to Pandemic (H1N1) 2009*. Sixty-Fourth World Health Assembly. Geneva: WHO. P. A64.

WHO. 2013. *Guide for acceleration of IHR implementation of States Parties. Enhanced desk review of national IHR core capacities, action plan development, and stakeholder mobilization. Global capacities alert and response*. Geneva: WHO.

WHO. 2015a. *Framework for a Public Health Emergency Operations Center*. Geneva: WHO.

WHO. 2015b. *IHR Core Capacity Monitoring Framework: Questionnaire for monitoring progress in the implementation of IHR core capacities in states parties. Global capacities alert and response*. Geneva: WHO.

WHO. 2015c. *Implementation of the International Health Regulations (2005), Report of the Review Committee on Second Extensions for Establishing National Public Health Capacities and on IHR Implementation*. Sixty-Eighth World Health Assembly. Geneva: WHO.

WHO. 2016. *Global Health Observatory data—International Health Regulations (2005) Monitoring Framework*. http://www.who.int/gho/ihr/en (accessed February 1, 2016).

4
Strengthening the Global and Regional System for Outbreak Preparedness, Alert, and Response

While reinforcing the first line of defense at the country level is the foundation of the global health risk framework, strengthening international capabilities for outbreak preparedness, alert, and response is a second vital component. Improving and maintaining international capabilities is essential because infectious disease outbreaks quickly transcend national borders. Infectious disease outbreaks also require response strategies that extend beyond health—encompassing areas such as transportation, commerce, trade, finance, law, and communication.

Swift and strong coordination among a diverse set of global actors is required across a broad range of outbreak preparedness and response actions, including management of logistics and deployment of international medical teams (see Annex 4-1 for other essential functions needed for outbreak preparedness and response at the international level).

Global action is an imperative because pandemic prevention and response are global public goods. Outbreak identification, prevention, and control efforts by one country benefit not only that country, but all countries (Jonas, 2013). Weaknesses in one country endanger not only the local population, but all of humanity. Global health security is the opposite of a zero-sum game—benefits obtained by one country do not reduce benefits available to others, but actually increase them. However, as with all public goods, global health security suffers from free-rider incentives and coordination challenges (Frenk and Moon, 2013; Jonas, 2013). Therefore, strong international norms and collaboration are essential.

To ensure that critical functions for pandemic preparedness and response are performed well at the international level, the Commission recommends major changes to current global and regional arrangements. We believe that the World Health Organization (WHO) should play the leading role in coordinating pandemic preparedness and response, consistent with its constitutional mandate. Yet WHO needs to play this role much more effectively. To achieve this, WHO should:

1. recognize the significance of its role by creating a robust operational entity and contingency fund that can respond adequately to potential pandemics;
2. improve its ability to coordinate and cooperate with others in the global health landscape, including other United Nations (UN) agencies, regional networks, and non-state actors; and
3. redesign key protocols that would encourage early alerts and reporting and enable swift international response.

The Commission also believes that the multilateral finance agencies, such as the World Bank and International Monetary Fund (IMF), must play a leading role in mobilizing global financial resources in response to potential pandemics.

STRENGTHENING WHO'S CAPACITY FOR OUTBREAK PREPAREDNESS AND RESPONSE

With a constitutional mandate to be the global leader in disease surveillance, outbreak investigation, and response, WHO has the authority and obligation to play a significant role in delivering a range of essential functions (see Annexes 4-1 and 4-2 for more detail), including pro-

viding technical assistance and aid in emergencies.[1] In addition to its constitutional mandate, WHO's role is enshrined in the major treaty governing global health security, the International Health Regulations (IHR). The World Health Assembly (WHA) has also adopted numerous resolutions supporting WHO's mandate.[2]

However, the Ebola crisis exposed many weaknesses in WHO's leadership and capabilities. Most notably, WHO did not help mobilize personnel, materials, and finances rapidly or at scale, despite clear evidence that the outbreak had overwhelmed the capacities of both states and nongovernmental organizations (NGOs) (MSF, 2015). There were communication and coordination breakdowns among WHO, other agencies, and actors in the affected countries. There was duplication between humanitarian and outbreak clusters, causing confusion and inefficiencies.

To fulfill its constitutional mandate and regain the trust of governments and the public, WHO must make significant changes, strengthening its organizational and operational capabilities to lead and support outbreak preparedness and response while ensuring sound governance principles (Gostin, 2014).

WHO Center for Health Emergency Preparedness and Response

The Commission considered four potential models of governance for global health security that were presented at a September 2015 Institute of Medicine workshop on governance for global health.[3] Details on these models are provided in Annex 4-3 and in the published report of the workshop, *Global Health Risk Frameworks: Governance for Global Health: Workshop Summary* (NASEM, 2016). To summarize briefly:

- Model A proposes that WHO strengthen execution of its responsibilities for outbreak preparedness and response through improvements to existing structures.
- Model B proposes the creation of a WHO center for humanitarian and outbreak management, overseen by a dedicated board, to give WHO more robust operational capabilities for outbreak preparedness and response.
- Model C proposes that WHO execute a strategic and operational role in a health emergency under the formal mechanisms of the UN system.
- Model D proposes that the UN create a new interagency entity for global health risks that would encompass capabilities not only from WHO, but also from other UN agencies, such as the Food and Agriculture Organization (FAO) and the United Nations Children's Fund (UNICEF).

Assessing the Models

Model D is clearly sub-optimal. Creating an additional UN entity would dilute WHO's credibility and form overlaps and duplication in partnerships, ties with health ministries, and legal authorities. Moreover, without established relationships and access to WHO's other capabilities, the new entity would find it difficult to manage the essential link between improving preparedness and managing outbreak response.

The reforms suggested for Model A are necessary, but not sufficient. More significant changes are required to ensure that WHO can fulfill its mandate effectively.

The Commission proposes an approach based mainly on Model B, with elements of Model C. Under this approach, WHO would have a new center with clear responsibility, resources, and capabilities to take the lead on outbreak preparedness and response, while taking advantage of the UN system's assets and being held accountable by a separate board chaired by the WHO Director-General (DG). Establishing this center, with a dedicated board, would strengthen WHO by providing a much stronger focal point for outbreak preparedness and response, and by establishing more apolitical governance and accountability arrangements for this vital component of WHO's role.

In fact, several other initiatives, including WHO's Ebola Interim Assessment Panel, have proposed models along broadly similar lines, incorporating elements of Models B and C (see Annex 4-4 for a snapshot of the proposals). Moreover, the DG has already begun to implement changes based on these proposals and input from member states (see Table 4-1). Specifically, the DG has already taken steps to create a program that would

[1] See Article 2 of the WHO constitution for specifics on its roles and responsibilities (WHO, 2006).

[2] Just to name a few, the World Health Assembly (WHA) resolution 58.1 on health action in relation to crises and disasters; WHA 59.22 on emergency preparedness and response; and WHA 65.2 on WHO's response and role as the health cluster lead in meeting the growing demands of health in humanitarian emergencies.

[3] This workshop was held in London on September 1–2, 2015. For more information, see http://www.nap.edu/catalog/21854/global-health-risk-framework-governance-for-global-health-workshop-summary (accessed March 24, 2016).

TABLE 4-1 Reform of WHO's Work in Outbreaks and Emergencies

Reform	Description
A Unified WHO Program for Outbreaks and Emergencies	Fully integrates the functions and units across country, regional, and headquarter levels that work on outbreaks, on emergencies, and on risk analysis and assessment under the IHR. Includes a platform to provide operational and logistics support for preparedness and response operations in communities and countries.
Global Health Emergency Workforce	Promptly and efficiently deploys workforces (comprising national responders, international responders from networks and partnerships, responders from UN agencies, and WHO standing and surge capacity) for service in countries that request or accept such assistance, for adequate periods of time, and with adequate resources.
WHO Contingency Fund for Emergencies	Provides initial funding that is flexible, sustainable, complementary to existing and planned mechanisms, accountable, adequate, available, accessible, and designed to prevent a given event from escalating into to an emergency.
R&D Blueprint for Infectious Diseases with Epidemic Potentials	Maps existing knowledge and good practices, identifies gaps, and establishes a roadmap for R&D preparedness.
Reinforcing the IHR	Supports development of priority IHR core capacities as an integral part of resilient health systems to enable rapid detection and effective response to disease outbreaks and other hazards. Ensures improved functioning and effectiveness of the IHR through the creation and report of the Review Committee to examine the role of the IHR in the Ebola outbreak and response.

NOTE: IHR = International Health Regulations; R&D = research and development; UN = United Nations; WHO = World Health Organization.
SOURCE: Adapted from WHO, 2015c.

effectively integrate functions and units—across country, regional, and headquarter levels—that work on infectious disease outbreaks, on emergencies, and on risk analysis and assessment under the IHR.[4] Although the Commission welcomes such steps, we propose some modifications and areas of emphasis.

Program Versus Center

The Commission agrees that a new operational entity should be established within WHO to bring together and strengthen its capabilities to manage and coordinate preparedness and response. However, we believe it should be developed and described as a "center," rather than a "program," as we understand it is currently envisioned. WHO has numerous important programs that aim to advance global health. Yet we believe it is important to distinguish WHO's entity for outbreaks and health emergencies. This should be firmly established as a permanent part of the WHO system and given sufficient and sustainable funding to fulfill WHO's leadership mandate.

Specifically, we propose that WHO should establish a Center for Health Emergency Preparedness and Response (CHEPR). The CHEPR would operate in a nimble, scientific, and apolitical manner, coordinating operational information and resources for strategic management of infectious disease outbreaks and other public health events and emergencies, including the growing threat of antimicrobial resistance (AMR). Similar to what has been proposed by other post-Ebola reform initiatives, the CHEPR would have robust capabilities to manage surveillance for outbreaks and events, risk assessment, planning and execution of response, assessment of IHR functions and compliance, coordination with partners, risk communication, quality assurance, and monitoring (Moon et al., 2015; WHO, 2015a,g).

Moreover, the CHEPR should coordinate the global health emergency workforce (WHO, 2015d). To facilitate this, it should strengthen the Global Outbreak Alert and Response Network (GOARN), which pools human and technical resources from existing institutions and networks to support international outbreak identification, confirmation, and response. GOARN has faced challenges in scaling up responses to outbreaks, given

[4] Personal communication, Director-General Margaret Chan, World Health Organization, November 20, 2015.

limited numbers of staff and the challenges of finding personnel who are ready to deploy rapidly and possess relevant experience (WHO, 2015f). The CHEPR should strengthen and expand GOARN, integrating national, regional, and global capabilities to reduce the current over-reliance on a limited group of partners. It should also ensure that members are trained and engaged in different stages and tasks of preparedness and response, including sharing information on alerts, risk assessments, integrated data management, logistics and communications, and field-based administrative procedures and protocols.

Although the CHEPR should operate within the WHO Secretariat and be led by an Executive Director, it should be overseen by a Technical Governing Board (TGB), as detailed below.

Executive Director and Staff

An Executive Director at the level of Deputy DG should lead the CHEPR, and the post should be filled through an external, open recruitment. The CHEPR staff should have a variety of skills in areas such as management, health security, public health systems, epidemiologic surveillance, medical anthropology, risk communication, clinical medicine, health information technologies, logistics, security, and technology. In addition, staff should have excellent leadership competencies and a thorough understanding of diverse cultures, laws, and governance.

Technical Governing Board

The Executive Director should report to a merit-based and multidisciplinary TGB. The TGB should be chaired by the DG, who should nominate members strictly on the basis of their technical expertise—not on member state representations. Members should come from various countries, regions, and sectors, including civil society organizations (CSOs), academia, and the private sector. Additionally, the TGB should include representatives from the UN and possibly the World Bank to enable multisectoral support and coordination of WHO's efforts. Some of the members of the TGB should head technical committees linked to the board. For example, a member of the TGB should head the panel tasked to oversee the assessment of national core capacities (see Chapter 3 for more on this panel). Similarly, a member of the TGB should head a committee tasked to prioritize diseases and research and development (R&D) needs (see Chapter 5 for more on the Pandemic Product Development Committee). Members of these committees should be appointed by the DG based on their expertise and should be mostly external to WHO. TGB responsibilities should include the following:

- Recruit, appoint, support, and evaluate the CHEPR Executive Director.
- Ensure the CHEPR's fiscal integrity and preserve and protect its assets, including allocating, prioritizing, and safeguarding funds such as WHO's Contingency Fund for Emergencies (CFE) (discussed later in this chapter).
- Ensure that the CHEPR's policies and processes are current, properly implemented, well prioritized, and of high quality.
- Regularly review the latest information on threats that have the potential to become a Public Health Emergency of International Concern (PHEIC), drawing from the high-priority "watch list" of outbreaks (discussed later in this chapter).
- Make recommendations to the DG, including when to call an emergency committee and declare a PHEIC (although the DG should still retain the legal power to make final decisions on both of these matters).
- Oversee implementation of mechanisms to reinforce and monitor country reporting and compliance with the IHR.
- Oversee implementation and deployment of the global emergency workforce.
- Hold the CHEPR accountable by setting clear standards and objectives, monitoring and evaluating performance, and issuing periodic reports, which should be made public.
- Report to the WHO Executive Board and the WHA on the progress of the CHEPR.[5]

Integration Across All WHO Levels

WHO regional and country offices play important roles in promoting and coordinating efforts to counter infectious disease outbreaks. However, some WHO regional offices have faced challenges in working effectively with countries, with WHO headquarters, and with each other

[5] Additionally, as stated in Recommendation A.3, an independent review of the entire global health framework, including an assessment of the performance of the TGB, should be conducted in 2017 and every 3 years thereafter.

(WHO, 2013). The discordant relationships were evident in the recent Ebola crisis, hindering swift and effective outbreak response (Gostin and Friedman, 2015). Additionally, recent surveys found that most WHO staff, especially at the headquarters level, view coordination and cooperation among headquarters and regional offices as not adequate (PWC, 2013; WHO, 2012). Although the WHO constitution gives WHO's governing bodies and the DG formal authority over the regional bodies, in practice, they have limited influence on the conduct or staffing of regional offices because authority rests with the regional directors, who are elected by regional member states (Clift, 2014). The election process makes the regional directors accountable first to their region's health ministers, rather than to headquarters, thereby impeding WHO's ability to act as a unified organization (Fineberg, 2014; Gostin and Friedman, 2015). The resulting lack of coordination is a particular hindrance when WHO needs to act decisively and swiftly in response to an outbreak.

To prepare and respond to outbreaks effectively, WHO must be able to speak and act coherently and consistently across all levels. Therefore, all relevant departments at WHO headquarters should be moved to the CHEPR, and equivalent structures and operating systems should be established at the regional level. Specifically, existing functions for health security and emergencies in regional offices should be merged (if this has not already been done) and vertically integrated under the CHEPR command-and-control structure. Further, the regional directors should only have "dotted-line" geographic oversight of these regional functions. Comparable systems should be set up at the national level as well, with linkages to the regional level, along similar lines as the regional and headquarters centers (but adapted as suitable for the country context).

Recommendation C.1: By the end of 2016, the World Health Organization should create a Center for Health Emergency Preparedness and Response—integrating action at headquarters, regional, and country office levels—to lead the global effort toward outbreak preparedness and response. This center should be governed by an independent Technical Governing Board.

Financing WHO's Leadership Role in Pandemic Preparedness and Response

Providing Funding Support for the CHEPR

The CHEPR must be supported with adequate resources to effectively perform its role in preparing for and responding to a potential PHEIC. Within the constraints of this exercise, we have had neither the access to information nor the time to construct detailed estimates of the additional resources required for the CHEPR or the extent to which WHO might be able to fund this incremental expenditure from savings elsewhere. Moreover, as noted earlier in the chapter, the CHEPR's role would extend beyond infectious disease threats to cover other health emergencies, such as the growing threat of AMR or biological terrorism. The resource requirements arising from this broader role are beyond the scope of this report.

For WHO to perform successfully its leadership role in countering the threat of infectious diseases, it needs stable and sufficient funding for the CHEPR. The Commission believes that the incremental funds needed should be acquired through an increase in WHO core contributions earmarked for this purpose, rather than through voluntary contributions, because preparedness and response to health emergencies must be supported as an ongoing core function of WHO. Analysis of WHO's budget allocation for responding to public health emergencies shows that funding has been responsive and erratic in the past, following a "boom-bust" pattern (Hoffman, in press).

The Commission is aware that there has been considerable debate about the adequacy of WHO's overall core funding from assessed contributions, because it has remained flat in nominal terms for more than two decades (WHO, 2011). However, we have not attempted to address this broader issue, because it involves aspects of WHO's mandate and performance that are beyond this Commission's charge. For the purposes of estimating an aggregate level of funding required by the Commission's proposals, we have assumed that an increase in the core contributions from countries of 5 percent, or roughly $50 million[6] over 2016–2017, would suffice to cover the incremental operational costs involved in the formation of the CHEPR. This corresponds to the increase recommended by WHO's Ebola Interim

[6] All monetary figures in U.S. dollars.

Assessment Panel (WHO, 2015g) and to the increase in spending proposed for "preparedness, surveillance and response" in WHO's Proposed Programme Budget for 2016–2017 (WHO, 2015e).

Recommendation C.2: In May 2016, the World Health Assembly should agree to an appropriate increase in the World Health Organization member states' core contributions to provide sustainable financing for the Center for Health Emergency Preparedness and Response.

Providing Contingency Funding for Emergency Response

In addition to financing the CHEPR, there is a need for contingency funding to enable WHO to respond more rapidly to potential pandemics and to fill a critical gap from the onset of an emergency until resources from other financing mechanisms begin to flow, such as from the UN's Central Emergency Response Fund (CERF) and donors.

The WHA has already approved the creation of a $100 million contingency fund, the WHO CFE, which aims to support WHO's initial response to outbreaks and emergencies (WHO, 2015h). Financing for this mechanism appears somewhat uncertain. The proposed approach is via voluntary contributions, yet thus far pledges from member states amount to less than one-third of the sum required. Deployment of the CFE would be triggered at the DG's discretion based on a justified, technically valid, budgeted request from the WHO incident manager, with initial funds to be made available with only minimal bureaucratic stipulations. Funding will be available for up to 3 months for deployment of emergency health personnel, coordination of medical response and transportation of personnel and supplies, information technology and analytical support of emergency response efforts, and creation and operation of field offices (WHO, 2015h). To ensure accountability and transparency, the CFE is subject to WHO's Financial Regulations and Financial Rules, and all income and expenditures from the fund will be reported annually to the WHA and donors and posted on the WHO website.

The Commission supports this proposal, as it offers the DG flexibility to move rapidly to respond to an outbreak, either after having declared a PHEIC or even before. Accountability for disbursements could be achieved through oversight by the TGB. Ultimately, the CFE's disbursement would also be constrained by the need to maintain good faith with member states, ensuring their continued willingness to fund replenishment. The proposed quantum of $100 million appears reasonable as a first source of funding that would complement other sources of emergency funding such as the World Bank's proposed Pandemic Emergency Financing Facility (PEF) (discussed later in this chapter), the UN's CERF, and contingency funds held by other agencies (e.g., UNICEF, the Global Fund), at a regional level, or by individual member states.

Because the purpose of the CFE is to provide immediate and flexible financial resources in the event of an emergency, the CFE needs to be fully funded in advance or have immediate access to funds. There are at least four possible routes to achieving this:

1. Via an increment to the biennial assessed contributions: The problem with this route is that with, say, a further 5 percent increment to assessed contributions, it would take 2 years to fund the mechanism. Thereafter, the fund would either be in surplus or deficit depending on whether or not any disbursements were made. It does not seem optimal to fund a contingency vehicle via a regular payment mechanism.
2. Via voluntary contributions: This is the route currently envisioned by WHO. The challenge here is securing sufficient contributions.
3. Via committed one-off initial contributions, assessed pro rata with the core assessed contributions: In this route, each member state would make a contribution to the fund in line with and in addition to its share of core assessed contributions. This could either be on the basis of actual cash contributions or via binding contingent commitments to fund the CFE. In the event of the DG's triggering the contingency fund, WHO could raise money from banks immediately against these binding commitments. Following deployment of all or part of the contingency fund, the DG would then ask for a replenishment round on the same basis.
4. Via an insurance scheme: The potential role for pandemic insurance is discussed in more detail below with respect to the World Bank's PEF. However, insurance is unlikely to be optimal for the CFE, given that the purpose of this fund is to have immediate discretionary funding flexibility. It would seem dif-

ficult and certainly costly to structure an insurance arrangement that pays out on a sufficiently early discretionary trigger, particularly when the DG controls the trigger and receives the payout.

Given the potential for deficits (or surpluses) under Option 1, the potential shortfall and inequity under Option 2, and the costs and technical difficulties attending Option 4, the Commission recommends Option 3 as the optimal approach to funding the WHO CFE.

Recommendation C.3: By the end of 2016, the World Health Organization should create and fund a sustainable contingency fund of $100 million to support rapid deployment of emergency response capabilities through one-off contributions or commitments proportional to assessed contributions from member states.

COORDINATING WITH GLOBAL ACTORS

To carry out its leadership responsibilities more effectively, WHO needs to improve its ability to coordinate across all three levels of the organization and with others in the global health landscape. These global actors include the UN, formal and informal regional networks, local and international CSOs, the private sector, and the media. Rather than waiting for the next outbreak, the WHO should proactively build relationships with these actors to identify their roles and responsibilities and establish ways of working together to leverage their strengths and improve coordination.

The UN

Coordination mechanisms among WHO and other UN agencies should be strengthened to enhance outbreak preparedness and control. The Ebola outbreak showed that agencies within the UN Health Cluster failed to communicate and coordinate well with each other—or with other international, governmental, and nongovernmental actors—resulting in delayed, misinformed, or inadequate response efforts. For example, the UN Mission for Ebola Emergency Response (UNMEER) was created even though other regional and sub-regional entities, such as the Sub-Regional Ebola Operations and Coordination Center, and existing resources could have been leveraged to provide more timely and effective response efforts.[7] To avoid such duplicative and costly efforts, responsibilities and accountabilities need to be made clear through common protocols and regular communication and strengthened through practice exercises.

Under the global health risk framework, the default or routine operations of the CHEPR should remain within WHO and be overseen by the TGB. However, when a crisis escalates to the extent that it poses a high-level global health threat or evolves into a much broader humanitarian crisis, WHO should then play its role within a broader effort led by the UN Secretary General (UNSG). Because UN representatives would serve on the TGB, the UN would always be informed about possible threats that could require broader UN system support. In the case of such a high-level threat, the TGB (chaired by the DG) should report to the UN-led effort to ensure an integrated, holistic response. The UN would provide leadership and coordinate the efforts of the international community to support affected countries via the Inter-Agency Standing Committee (IASC), chaired by the Emergency Relief Coordinator. This would help ensure the appropriate level of political and financial commitment and facilitate intensified responses from other UN agencies.

Recommendation C.4: By the end of 2016, the United Nations (UN) and the World Health Organization should establish clear mechanisms for coordination and escalation in health crises, including those that become or are part of broader humanitarian crises requiring mobilization of the entire UN system.

Regional Networks (Formal and Informal)

As we argued in Chapter 3, national capacities for disease surveillance and outbreak investigation and control are the first line of defense against potential pandemics.

[7] "UNMEER was established on 19 September 2014 after resolutions from the United Nations General Assembly and the United Nations Security Council on the Ebola virus disease outbreak in West Africa. […] The mission functioned by bypassing existing mechanisms, rather than by engaging the United Nations cluster system. While the approach was adapted in countries where the United Nations Resident Representative was engaged with the system, there were other instances where the wider United Nations system was not effectively involved and pillars of work were not coordinated with the cluster structure. A number of stakeholders at country level also reported that the mission was unwieldy, and said that it took two critical months to establish itself at the height of the epidemic when parts of the existing cluster system could have been used instead" (WHO, 2015g).

However, despite the IHR commitments, many countries fall short. Regional and sub-regional networks, both formal and informal, can play a key role in addressing and mitigating these deficiencies by spreading best practices, providing economies of scale, and improving cross-border cooperation. For example, regional manufacturing and stockpiling of medical products and equipment may be more efficient and practical than national efforts. In a similar vein, health worker shortages in one country might be alleviated by neighboring countries. As discussed in Chapter 3, regional professional registries, laboratory networks, mutual assistance agreements, and preparedness exercises against potential scenarios could complement global approaches, with the advantages of proximity, cultural competency, and epidemiological familiarity.

While WHO's regional offices have contributed significantly to outbreak preparedness and control, some neighboring countries find it difficult to work together under WHO structures because they belong to different WHO regions (WHO, 2013). Examples include Thailand and the Mekong Basin countries, Myanmar and China, and Indonesia and Malaysia/Singapore. However, in the past two decades, countries have formed less formal regional or sub-regional networks, such as Southern African Centre for Infectious Disease Surveillance in Africa, the Mekong Basin Disease Surveillance, the Association of Southeast Asian Nations in Southeast Asia, and the Middle East Consortium on Infectious Disease Surveillance in the Middle East. These networks have built trust and developed formal and informal communication flows that enable rapid and continuous communication when outbreaks occur and joint investigations when outbreaks affect border areas. These sub-regional networks should be interwoven with WHO regional offices, which would enable a strong and prompt collaborative response to pandemics.

Recommendation C.5: By the end of 2017, the World Health Organization should work with existing formal and informal regional and sub-regional networks to strengthen linkages and coordination, and thus enhance mutual support and trust, sharing of information and laboratory resources, and joint outbreak investigations among neighboring countries.

Non-State Actors

Many non-state actors can and do play significant roles in protecting global health. These actors bring diverse resources, capabilities, and infrastructure. WHO is currently working to fully adopt the Framework for Engaging with Non-State Actors (FENSA) (WHO, 2015i). FENSA is intended to promote engagement among WHO and non-state actors and encourage non-state actors to use their own activities to protect and promote public health. Building on FENSA, WHO CHEPR should actively engage non-state actors, especially local and international civil society organizations, the private sector, and the media.

Local and International CSOs

As noted in Chapter 3, local and international CSOs—such as community-based, nongovernmental, and faith-based organizations, as well as academic and research institutions—often have a valuable grasp of the realities on the ground and a vital role to play in ensuring that the perspectives of those directly affected by outbreaks are heard. Working closely with anthropologists with long-term knowledge of affected regions or subject specific knowledge can be a particularly effective way of not only identifying local and regional challenges to containing outbreaks, but also finding locally acceptable and practical solutions to complex issues emerging on the ground. Representatives from civil society could help WHO with reporting of cases, adapting and readjusting approaches during disease outbreaks, realigning priorities, and establishing and disseminating standards, such as those related to research. Moreover, CSOs should be encouraged and supported to play advocacy and watchdog roles at country and global levels. They have demonstrated the ability to bring issues of global and national concern to the forefront, capturing the attention of political leaders and funders, as exemplified in the case of HIV/AIDS (UNAIDS, 2012). WHO should develop protocols and build formal and genuine relationships with local and international civil society groups so that both sides know when and how these actors can contribute most effectively.

Private Sector

The private sector has traditionally provided funding and supplies during emergencies, but private companies have a broad range of other assets, expertise, and capabilities

that can augment the public-sector response. The private sector can bring expertise and resources to help with research and development of medical products, transportation of supplies, educational campaigns, construction of treatment units, development and deployment of innovative technology and infrastructure to support responses, logistics and supply chain issues, data management, and financial services (WEF, 2015).

However, private-sector players often do not know the best ways to help, so their contributions have often been ad hoc and inconsistent. WHO CHEPR should build relationships with private companies to harness their capabilities in the event of a public health emergency. The key is to define roles and mechanisms for coordination. The private sector must be informed of priorities in order to align its efforts with the UN and WHO, other companies, governments, and other non-state actors. For example, WHO should engage with airline and trade industries so that their actions align with the IHR as much as possible. With such relationships and alignments in place, companies would know how to contribute effectively and exchange information smoothly with WHO CHEPR and other actors in the event of an outbreak.

Media

The media plays a critical role in communicating to the public about an outbreak. In order to communicate effectively—with the goal of promoting safe behaviors and controlling the spread of the disease—messages must be unified, accurate, evidence-based, well-framed, and timely. The most important aspect of good communication is openness and transparency, which will help gain the trust of the public. When messages are poor, they can create or exacerbate mistrust, generate anxiety, and foster rumors and conspiracies. These outcomes may inadvertently encourage behaviors that make a difficult situation even worse. To prevent this from happening, WHO CHEPR should ensure that it has staff with anthropological, social media, and crisis communication expertise who can work closely with media agencies.

Recommendation C.6: By the end of 2016, the World Health Organization and national governments should enhance means of cooperation with non-state actors, including local and international civil society organizations, the private sector, and the media.

REDESIGNING PROCESSES AND PROTOCOLS

WHO should redesign processes and protocols to reinforce the effectiveness of the IHR. In Chapter 3, the Commission recommends that WHO devise a regular independent, transparent, and objective assessment mechanism to evaluate country performance. In this section, we go further to recommend mechanisms that would help ensure that countries report cases and facilitate appropriate international response. We also comment on the type of leadership needed to ensure that such changes are made and sustained.

A High-Priority "Watch List" of Outbreaks

One of the main responsibilities of WHO CHEPR should be to ensure that outbreaks are properly detected and prioritized. Currently, there are some mechanisms in place that aim to fulfill this function. For instance, at national focal points (NFPs), health officials are expected to notify and report potential PHEICs to WHO under the IHR decision instrument for notifications, which member states are required to use. Furthermore, the WHO Global Alert and Response team[8] meets each weekday morning to review incoming reports from official and unofficial sources for suspected outbreaks and unknown diseases and for outbreaks undergoing verification and containment. The team then decides on the actions needed for these reports. If a notification has been deemed a potential PHEIC, WHO is expected to provide NFPs with timely updates through a secure event information site (EIS) (WHO, 2008). If a notification is deemed internationally significant,[9] the WHO DG convenes an emergency committee of subject-matter experts who provide advice and recommend an evidence-based response. Emergency committees typically make recommendations about whether to declare a PHEIC, but the ultimate decision rests with the DG.

Despite these mechanisms, countries are often reluctant to report novel infections. A major reason is that

[8] This team includes WHO Country Offices, WHO Sub-Regional Response Teams, WHO Regional Offices, the Alert and Response Operations Centre team in Geneva, and disease specialists (WHO, 2015b).

[9] This is based on six main criteria: (1) unknown disease; (2) potential for spread beyond national borders; (3) serious health impact or unexpectedly high rates of illness or death; (4) potential for interference with international travel or trade; (5) strength of national capacity to contain the outbreak; and (6) suspected accidental or deliberate release (WHO, 2015b).

reporting could be seen as failure in the countries' surveillance or the wider global alert and response program (IOM and NRC, 2009). Thus, reporting has implications for national prestige and reputations. Moreover, news of a potential PHEIC can sometimes provoke excessive responses such as travel and trade restrictions, which can adversely impact a state's economy. However, the Commission stresses that it is vital to instill the global norm of early detection and rapid reporting of potential PHEICs. Delayed reporting can cause grave consequences, as some outbreaks need immediate attention to prevent them from becoming epidemics and even pandemics. Prompt alerts enable swift, early, and strong response, which can save lives and money.

To instill the norm of early reporting and encourage necessary preparedness activities for potential PHEICs, the CHEPR should identify and communicate to NFPs the top priority outbreaks that have the potential to become a threat and need careful monitoring. This "watch list" should be drawn from the daily reports the CHEPR receives from official and unofficial sources and should be prioritized based on a rigorous and transparent risk assessment. The CHEPR should communicate the priority watch list through the EIS every day, so that regions and countries could not only see what the CHEPR is monitoring, but also access information to help them ascertain the degree to which interventions and resources should be mobilized. Through this mechanism, alert and response teams at all levels would be better prepared and more easily held accountable. For example, if a high-priority outbreak remained on the list for a while without any response from the affected country, the WHO CHEPR could step in and facilitate technical support as necessary. A summary of this priority watch list should also be made public through the WHO website, perhaps on a weekly basis. We recognize that publishing lists of potential PHEICs might trigger overreaction and public fears. However, if such a list were published every day, it would quickly become normalized and would destigmatize the reporting of outbreaks.

Recommendation C.7: By the end of 2016, the World Health Organization (WHO) should establish a mechanism to generate a daily high-priority "watch list" of outbreaks with potential to become a Public Health Emergency of International Concern to normalize the process of reporting of outbreaks by country and encourage necessary preparedness activities. WHO should communicate this list to national focal points on a daily basis and provide a public summary on a weekly basis.

Protocols for Holding Governments Publicly Accountable

Because of the critical consequences of delayed or nonreporting, WHO CHEPR should create a mechanism to hold accountable countries that try to suppress or delay reporting. Countries that share information quickly should be lauded and supported (for example, through budgetary assistance from the IMF, as discussed later in this chapter). Countries that are not transparent and forthcoming in their notifications should be publicly named. In both instances, the WHO weekly epidemiological report should contain details on how a report was obtained and appropriate commendations.

Similarly, the CHEPR should create protocols to dissuade member states and the private sector from implementing unnecessary restrictions on trade and travel. In past outbreaks, many countries and airline carriers restricted travel, commerce, and trade. Although there are strong political motivations for harsh measures, the IHR create binding legal obligations to act in an evidence-based manner, following WHO's recommendations regarding "additional measures." Travel restrictions can be highly counterproductive. When borders close and commercial flights discontinue, global actors have difficulty providing essential resources to the affected areas, delaying response efforts and sometimes creating an even greater humanitarian and health care emergency (Heymann et al., 2015). Further, travel restrictions could drive affected patients underground, making it challenging to deliver treatment and potentially allowing the disease to spread more rapidly in the isolated area—eventually putting surrounding areas at even greater risk. It is also worth noting that some borders are difficult to regulate, meaning travel restrictions may not effectively contain the disease. Thus, although travel bans offer an illusion of safety, they also lead to prejudice and stigma around those in affected areas and delays in robust response efforts.

To prevent travel bans, relevant stakeholders, such as the International Air Transport Association and the World Trade Organization, should be engaged prior to the next outbreak. Strong understanding and communication of the consequences of travel restrictions, as

well as cooperation among relevant stakeholders and the public, is crucial. If travel bans are implemented without scientific justification, protocols such as publicly disclosing those countries should be established.

Recommendation C.8: By the end of 2016, the World Health Assembly should agree on new mechanisms for holding governments publicly accountable for performance under the International Health Regulations and broader global health risk framework, as detailed in Recommendation B.2, including:

- **protocols for avoiding suppression or delays in data and alerts, and**
- **protocols for avoiding unnecessary restrictions on trade or travel.**

Creating a well-resourced CHEPR, establishing the CFE, and reinforcing coordination and alert mechanisms would enable WHO to be a more effective leader in pandemic preparedness and response. However, the Commission recognizes that strong individual leadership by the DG is also essential. The DG must have the right personal attributes and must be empowered by member states to use them. As the next DG election approaches, member states should carefully consider the leadership qualities that will enable WHO to fulfill its vital role within the global health risk framework. These attributes include:

- the ability to reenergize and refocus the organization around its core priorities, making it simultaneously more effective and efficient;
- the relationship-building and influencer skills needed to build constructive relationships with other actors, such as other multilateral agencies and non-state actors; and
- the stature and courage to hold their own with other global leaders, to accept accountability, and to hold countries accountable.

For their part, member states must give the DG the resources and support to enable effective global leadership, even when this entails making tough trade-offs, standing behind unpopular decisions, and calling individual countries to account.

MOBILIZING GLOBAL FINANCIAL RESOURCES IN RESPONSE TO POTENTIAL PANDEMICS

When an infectious disease outbreak has the potential to become an epidemic or pandemic, speed of response is vital. This means mobilizing financial resources swiftly to support the overall response strategy. For many countries, the government's own contingency resources will be the primary source of such funds; however, in situations where challenges overwhelm domestic resource capabilities, international financing support is needed. The experience of Ebola demonstrated that mobilizing such contributions can take time, so it makes sense to have contingency financing arrangements in place to ensure a rapid and effective response. Moreover, the availability of such contingency support arrangements could help to mitigate incentives to delay or suppress alerts at the national level. As discussed earlier in this chapter, WHO's CFE represents one source of such emergency funding, but at $100 million, it is of quite limited scale. To mobilize financial resources of greater scale requires that the World Bank and the IMF also have appropriate arrangements.

An Emergency Contingency Fund for Pandemic Response

The Commission welcomes the World Bank's creation of the PEF, because, given the nature of pandemics, it is essential that significant external resourcing can be made available without delay. Although the governments of high-income countries and other donors would undoubtedly respond again to assist a low-income country, the Ebola experience illustrates that mobilizing such resources can take considerable time given considerations such as legislative approval. In our view, the PEF should be the second source of immediate funding from international sources, following quickly on the heels of WHO's CFE. Although there is no precise science to determining the size of the PEF, the figure of $1 billion seems not unreasonable.

It could be argued that rather than having both a CFE and PEF, there should be only one fund. However, the Commission believes these two funds serve distinct and complementary purposes. The CFE is designed to enable WHO itself to respond quickly and flexibly to outbreaks with pandemic potential. This fund is deliberately discretionary to maximize flexibility and speed of

response. It is also constrained to funding WHO's activities. The PEF would be triggered less often and with less discretion but would deploy far greater funds to a broad array of accredited responders (including WHO). Merging the CFE and the PEF would limit the DG's flexibility and slow disbursement. Extending the CFE to encompass the greater scale and scope of the PEF would require WHO to fund third parties at a scale it cannot manage. Such funding is already a core function for the World Bank. Creating a separate entity would simply add cost and bureaucracy. That said, it is clearly important that WHO and the World Bank work closely together to optimize the deployment of the CFE and PEF. Indeed, they will also have to coordinate with other contingency funding arrangements within the UN system, such as the CERF.

The need for the PEF to be available quickly after an outbreak has been identified as having pandemic potential is an important consideration in determining the appropriate financing mechanism. There are a number of options.

Option 1: One-Off Cash Contributions or Binding Contingent Commitments from Member States of Other Donors

This option has the advantages of immediacy and certainty. Where cash has been contributed, it will be immediately available. Where a commitment is in the form of a binding contingent commitment, the World Bank will be able to raise funds quickly and cost-effectively from the capital markets against that commitment. The disadvantage of this option is that it would require further support from governments of advanced economies and donors, some of whom may not be able to operate on a contingent commitment basis due to constitutional or other legal constraints (although there may be scope to devise near legally-binding contingent commitments, structured so that they can be made binding extremely rapidly). In principle, this approach simply brings forward and makes much more efficient the usual process of calling on advanced economies and other donors when a crisis occurs. However, the political reality of asking governments to contribute or commit substantial sums before a crisis is in sight makes this option quite challenging.

Option 2: Insurance

Pandemic insurance is certainly worth pursuing, and considerable progress has been made in developing this option. The key will be whether it will prove cost-effective and practical. To be cost-effective, disaster insurance of this kind typically needs an objective parametric trigger (e.g., an earthquake, or rainfall below a certain amount). Discretionary triggers tend to result in much higher premiums. Given the uncertainties that inevitably surround the early phases of an infectious disease outbreak, this is somewhat problematic. By the time it is objectively clear that a pandemic is taking place (e.g., via a clear impact on mortality data), it may be too late. We are aware that considerable progress has been made in defining and agreeing potential triggers, but the test will be how these work well in practice.

There are three other issues that need to be considered. Given that life insurers and their reinsurers already bear mortality risk relating to pandemics and hold capital against extreme changes in mortality risk, it can be argued that they should be trying to reduce the extreme mortality risk in their balance sheets. This would suggest they should be prepared to pay for a response mechanism like the PEF that reduces the risk of an outbreak turning into a pandemic, rather than be paid for it. This is the logic underpinning the idea discussed in the next chapter on financing research and development. If insurance regulators were prepared to recognize that financing the PEF would reduce the mortality risk that insurers face, then it might be possible to fund the facility much more cost-effectively. At the very least, these considerations should be factored into the pricing negotiations.

Additionally, to the extent that insurance premiums are paid by advanced economies and donors on behalf of low-income countries, one must consider whether this is the best use of constrained overseas aid budgets. Paying such premiums might save the advanced economies from having to offer support should a pandemic occur, but would do little to change the reality and the risks for the country itself. It may be better to spend the money on helping to rectify gaps in health system capabilities.

On the other hand, a clear benefit of using insurance for the PEF is that involvement of the private sector typically drives an intense focus on improving data and can create powerful incentives to mitigate risk—and may ultimately catalyze the development of a private market in pandemic insurance. These dynamics constitute pow-

erful arguments for pursuing insurance options. Better data gathering and modeling will certainly contribute to better preparedness. Creating stronger incentives for governments to invest in pandemic preparedness is certainly desirable. However, it should also be noted that incentives are different with pandemics. For other kinds of natural disasters, such as earthquakes or drought, afflicted countries have to rely on altruism when seeking external support. There is no powerful externality. When a potential pandemic occurs, other countries will help out of self-interest, not just altruism—and this means there is less incentive to pay for insurance. The challenge of defining a clear event and the impact of externalities on incentives suggest we may need to be cautious about the prospects of developing a private market in pandemic insurance.

Option 3: Pandemic Bonds

Pandemic bonds work almost like pandemic insurance in reverse, but are addressed to different investors. With pandemic insurance, one pays a premium and gets a cash payout if a pandemic occurs. With pandemic bonds, an investor issues a bond in exchange for cash and extinguishes the debt if a pandemic takes place. As with pandemic insurance, the challenge is whether it is possible to identify a trigger that is both objective and early. Extreme mortality bonds, from which pandemic bonds are derived, are triggered by defined changes in mortality. In the case of a pandemic, this trigger would be too late for the purposes of the PEF. As with insurance, for pandemic bonds to be cost-effective as a funding mechanism for the PEF, it will be necessary to identify triggers that are simultaneously parametric and early. We understand that this is precisely what the World Bank and its private-sector partners have been working together to achieve.

Assessing the Options

Given these considerations, the Commission thinks that Option 1 would be the optimal way to finance the PEF if economic efficiency were the only consideration. However, we acknowledge it will be difficult to secure financial commitments of this magnitude and to overcome the legal constraints on contingent commitments that some governments face. We also recognize the broader benefits of engaging the private sector on data analytics and incentives. If the pricing of the innovative solutions in Options 2 or 3 can be made economically attractive, then it might be possible to combine these options, using funds from Option 1 as the early-release component and funds from Options 2 and 3 somewhat later. With such a combined structure, it would be important to ensure that the pricing of the insurance and bond components reflects the fact that they benefit from the existence of the component of the PEF funded by Option 1.

Recommendation C.9: By the end of 2016, the World Bank should establish the Pandemic Emergency Financing Facility as a rapidly deployable source of funds to support pandemic response.

Emergency Budgetary Assistance

The WHO CFE and the World Bank PEF are designed to fund emergency response, rather than offset the economic impact of a crisis. The feasibility of developing financial mechanisms to mitigate broader economic impacts on an afflicted country is often discussed, not least because concerns about potential economic consequences can lead governments to delay reporting. However, it is difficult to see how either the insurance industry or capital markets could provide cost-effective mechanisms to achieve this objective, given the potential scale of the impact, the difficulty of establishing objective early triggers, and the degree of perverse incentives.

Yet it would make sense for the IMF to consider revising eligibility and triggers for the Rapid Credit Facility (RCF) to ensure it is clear that this facility is available to provide budgetary assistance for countries reporting infectious disease outbreaks. The RCF is designed to provide rapid concessional financial assistance with limited conditionality to low-income countries facing an urgent balance-of-payments need (IMF, 2015). The RCF streamlines the IMF's emergency assistance, provides significantly higher levels of concessionality, and can be used flexibly in a wide range of circumstances. While the RCF could not offset the entire economic impact a country facing a potential pandemic, it could help ease the pressure on the government of a low-income country faced with rapidly escalating spending requirements and plummeting tax revenues. Moreover, this could make it clear that declaring an outbreak to have epidemic or pandemic potential might help mitigate the incentives to delay such a decision.

In addition, although insurance is unlikely to provide

a complete answer, national governments might want to encourage critical industries to take out appropriate business interruption insurance to mitigate the direct impact on individual firms and thus on the economy as a whole. Levels of business interruption insurance coverage in many countries appear remarkably low (Swiss Re, 2015).

Recommendation C.10: By the end of 2016, the International Monetary Fund should ensure that it has the demonstrable capability to provide budgetary support to governments raising alerts of outbreaks, perhaps through its existing Rapid Credit Facility.

CLOSING REMARKS

Strengthening international coordination and capabilities is vital to countering the threat of infectious diseases on a global scale. The recent Ebola outbreak revealed significant shortcomings in WHO's operational capacity and leadership, as well as in timely disbursements of funds and resources. To reinforce international coordination and capabilities for outbreak preparedness, alert, and response, WHO should play a leading role in the global system by creating a well-resourced center overseen by a TGB and improving coordination with other global actors, including other UN agencies, regional networks, civil society organizations, and the private sector. There is also a need to redesign protocols to incentivize reporting of outbreaks and encourage necessary preparedness activities. Finally, the development of contingency support arrangements is essential to ensure that a rapid and effective response is not hindered by lack of funds. Global actors together must carry out these critical functions to effectively prepare and respond to major infectious disease outbreaks. The next chapter discusses the need to accelerate R&D to counter the threat of infectious diseases.

CHAPTER 4 ANNEX

ANNEX 4-1
Essential Functions for Effective Outbreak Preparedness and Response

Global actors must carry out several essential functions for effective outbreak preparedness and response (see Table 4-2). These functions can be divided into three major categories.[10] The first overarching category encompasses functions related to the management of externalities across countries to prevent or mitigate deleterious health effects that arise from one country and might affect another. This effort requires strong coordination among stakeholders to ensure timely response to threats that spread across borders. In recent years, the global health landscape has expanded to include multiple actors ranging from national governments, the UN system, multilateral development banks, public–private partnerships, and international and local civil society organizations to the private sector. While these transformations have opened doors to different and innovative resources, coordination of these multiple actors has become particularly important and challenging in responding to a PHEIC. If actors and efforts are uncoordinated and unchecked, competition, duplication, and poor quality tend to emerge.

Another overarching category is the production of global public goods, particularly knowledge-related goods. In the context of infectious disease outbreaks, examples include defining and evaluating standards for national core capacities and setting priorities for research and development of medical products, among others. This would help global actors work together to achieve common goals in an efficient and accountable way.

Finally, there is a need to mobilize aid to areas where national governments are unwilling or unable to provide protection. For example, when an infectious disease outbreak occurs in a fragile state, financial and resource support will be needed. Even outside fragile states, there may be cases when a country is acutely overwhelmed by a crisis. In these cases, the deployment of emergency response funds and technical cooperation from the international community may be needed. At present, there has been conversation about the creation of emergency response funds at WHO and the World Bank, but no mechanisms have been put into place.

It is important to note that for these functions to perform well, good governance must be observed. Good governance for global health is accountable, transparent, responsive, equitable and inclusive, effective, efficient, and participatory (Gostin, 2014), and should extend from local communities to multinational organizations. However, achieving this ideal can be challenging in the context of infectious diseases because they can evolve into a broader social crises, drawing in political processes and leaders. These officials have the ultimate responsibility for ensuring not only needed health care but also all other services expected of governments before, during, and after crises. Hence, governance for global health needs to integrate a broad array of technical and political inputs. The foundation should be scientific, but the ultimate accountability lies in the political domain. A challenge for the design of systems of governance for global health is to coordinate these accountability functions in such a way that they remain distinct, but are also synergistic. A hierarchy of power and authority needs to be designed such that the best technical advice effectively and efficiently serves the operational and political.

ANNEX 4-2
WHO's Strengths and Weaknesses as the Global Leader in Pandemic Prevention and Control

WHO's constitution mandates that it be the global health leader in disease surveillance, outbreak investigation, and response.[11] In fact, the primary rationale for establishing WHO in 1948 was to control cross-border infectious diseases. To facilitate the management of PHEICs, WHO may use legal and technical tools to set international norms and guidelines for member states in preventing and responding to potential PHEICs. For

[10] These categories were adapted from Frenk and Moon, 2013.

[11] The constitution of WHO states clearly WHO's mandate to play key roles in managing PHEICs. See Article 2 for specifics on the roles and responsibilities defined for WHO (WHO, 2006).

TABLE 4-2 Essential Functions for Outbreak Preparedness and Response at the Global Level

Categories of Essential Functions	Sub-Functions	Examples Specific to Outbreak Preparedness and Response
Management of externalities across countries	Coordination for preparedness and response and deployment of surveillance and information sharing	Coordination and communication within and among stakeholders for preparedness and response, including: • National governments • Regional groups • WHO • UN agencies • Civil society organizations • Foundations • Multilaterals/bilaterals • Public–private partnerships and private sector (e.g., for surveillance, payments, medical products, logistics, distribution, transport, communications) • OIE/FAO on zoonotic threats, "One Health" Reinforce system for coordinating response to alerts/outbreaks (e.g., Global Outbreak and Response Network, global health workforce, emergency operations centers, plans for joint readiness exercises, laboratory networks that meet a standard of accreditation, equitable distribution of medical products, etc.) • Enhance surge capacity (e.g., emergency doctors) • Declare a PHEIC in a timely manner
Production of global public goods	Development of international standardization, priority and rule setting, guidelines regarding best practices, and evaluation of actors and actions	Define standards for national core capacities (not just the IHR, but also incorporating key elements of GHSA), including measurable metrics Develop guidelines for best practices in reinforcing national core capacities Create system of independent, objective, and transparent assessment of national core capacities, including response plans (akin to GHSA assessment process), so that governments can be held accountable Set priorities for R&D of medical products Establish standards and agreements for R&D issues (e.g., not nationalizing vaccines during emergencies)
Mobilization of global solidarity	Provision of aid, including development financing, technical cooperation, humanitarian assistance, and agency for the dispossessed	Provide financial support to low-income countries seeking to enhance national core capacities Provide financial and other resource support for failed states Develop and deploy emergency response funds

NOTE: FAO = Food and Agriculture Organization of the United Nations; GHSA = Global Health Security Agenda; IHR = International Health Regulations; OIE = World Organisation for Animal Health; PHEIC = Public Health Emergency of International Concern; R&D = research and development; UN = United Nations; WHO = World Health Organization.
SOURCE: Framework adapted from Frenk and Moon, 2013.

example, the IHR allow WHO to work with affected countries in outbreak investigation, assess the risk, and facilitate timely declaration of the status of the outbreak.[12] Additionally, many resolutions developed by the WHA, which convenes health ministers from 194 member states, request WHO to work on PHEICs as well as capacity building for epidemic and pandemic response. These requests show the authority and legitimacy that WHO already holds in this area.

Further, WHO has social credibility as the leading agency to manage global health issues, especially epidemics and pandemics. Past successes in controlling several high-profile infectious diseases, including plague, smallpox, and malaria, have made WHO a highly socially respected organization when it comes to dealing with disease outbreaks. In 1966, WHO initiated action to carry out a worldwide smallpox eradication program. Historically, the program remains one of the greatest achievements of WHO. Although the 2009 H1N1 pandemic and recent Ebola outbreak may not be good success cases for WHO, it nevertheless continues its role as global health leader.

WHO also has a wide network that allows it to work closely with various actors on outbreak preparedness and response. Within its organization, WHO has an extensive network of 6 regional and 145 country offices. WHO has strong linkages and close collaboration with agencies responsible for preparedness and response in member states, as well as access to thousands of the best public health experts around the world. Additionally, WHO actively engages with various UN mechanisms, which are key drivers in humanitarian crises, including the UN Office for the Coordination of Humanitarian Affairs (OCHA), the UN Executive Committee on Humanitarian Affairs, the Global Humanitarian Platform, the UN Economic and Social Council, and other initiatives and entities as relevant to play major roles in health cluster–related issues. WHO also engages in dialogue with all stakeholders involved in humanitarian assistance and works to keep health high on the political/humanitarian agenda. Outside the UN framework, WHO cooperates with a wide network of humanitarian partners worldwide, including the Red Cross and Red Crescent movement, Collaborating Centers, universities and other academic institutions, CSOs, and senior public health experts. Other key partners are intergovernmental institutions such as the African Union, the Council of Europe, and the International Organization of Civil Protection.

Although WHO must lead the effort in outbreak preparedness and control, it currently lacks the organizational capacity to deliver a full emergency public health mechanism (see Table 4-3). With its bureaucratic and vertical structures, WHO cannot perform efficiently. For example, overall coordination among the headquarters and regional offices is poor (WHO, 2013). The separation of humanitarian and outbreak control work has led to confusion and duplication of activities.

Additionally, WHO predominantly works with the ministries of health for each country, and not as much with other actors. Although it does have channels to work with CSOs and the private sector, coordination and engagement could be improved, especially as the number of actors in the global health landscape increases. Working with other actors is crucial to expand WHO's capacity to manage emergencies and other difficult and complex health problems. Such capacity is becoming more important in the past few decades when health issues have been linked to complex socio-economic and political issues.

Political undercurrents influence global health issues. This is not surprising, as health has come to be thought of

[12] In the IHR (2005), Article 13 notes the following: "(3) At the request of a State Party, WHO shall collaborate in the response to public health risks and other events by providing technical guidance and assistance and by assessing the effectiveness of the control measures in place, including the mobilization of international teams of experts for on-site assistance, when necessary. (4) If WHO, in consultation with the States Parties concerned as provided in Article 12, determines that a public health emergency of international concern is occurring, it may offer, in addition to the support indicated in paragraph 3 of this Article, further assistance to the State Party, including an assessment of the severity of the international risk and the adequacy of control measures. Such collaboration may include the offer to mobilize international assistance in order to support the national authorities in conducting and coordinating on-site assessments. When requested by the State Party, WHO shall provide information supporting such an offer" (WHO, 2008). Further, in Article 49, it says "(6) The Director-General shall communicate to States Parties the determination and the termination of a public health emergency of international concern, any health measure taken by the State Party concerned, any temporary recommendation, and the modification, extension and termination of such recommendations, together with the views of the Emergency Committee. The Director-General shall inform conveyance operators through States Parties and the relevant international agencies of such temporary recommendations, including their modification, extension or termination. The Director-General shall subsequently make such information and recommendations available to the general public" (WHO, 2008).

TABLE 4-3 Strengths and Challenges of WHO as the Role of Health Cluster Lead in PHEICs

Strengths	Challenges
1. WHO's roles and mandate for PHEICs are clearly identified (by constitution and the IHR)	1.1 WHO's bureaucracy and capacity need to be much improved to respond to such a huge mandate.
	1.2 There are other agencies with competing roles, and WHO should collaborate with them.
2. Legal and technical tools (e.g., IHR)	2.1 WHO governing structures are vertical and bureaucratic and have inadequate capacity to fully implement the legal and technical tools.
3. WHO's social credibility and capacity	3.1 WHO is facing challenges to recruit and maintain capable staff; this threatens its social credibility.
	3.2 WHO's bureaucratic governance systems limit its collaboration, mainly with the public sector.
	3.3 Health issues become more and more politicized.
4. WHO's own financial resources, based on assessed contribution	4.2 The assessed contribution is becoming a smaller and smaller proportion of the WHO budget, and thus WHO has less freedom in its spending.

NOTE: IHR = International Health Regulations; PHEIC = Public Health Emergency of International Concern; WHO = World Health Organization.

as a tradable commodity (Labonté and Gagnon, 2010). However, politicizing the health discussion in WHO has gradually eroded the most important social asset of the organization—that is, trust among its members. As trust dwindles, it has become more difficult for WHO's networks and member states to work together to fight potential pandemics. There is fear that political influences shroud decisions that are ostensibly based on technical expertise.

Finally, WHO has had limited freedom in how it uses resources. Since the early 1990s, WHO has depended more on voluntary contributions. Voluntary contributions have become its main source of income, accounting for 80 percent or more of its expenses, and are earmarked so that WHO does not have much control over how to use the funds (WHO, 2014).

As these challenges reveal, WHO's performance in preparedness and response for PHEICs needs improvement. Decisions should be based on rigorous scientific input and shielded from major political interferences. WHO also needs to become more nimble and proactive, breaking down vertical or duplicative structures and providing robust and flexible operational capacity. Finally, an accountability mechanism is needed to evaluate and enhance WHO's performance.

ANNEX 4-3
Four Potential Models of Governance for Global Health Security

The Commission considered four models of governance for global health security.[13] These models are neither mutually exclusive nor exhaustive of all possibilities for global health governance. All of these models recognize that business as usual is not an option.

Model A: A Reformed WHO[14]

This model assumes that WHO would continue to have operational responsibility for outbreak preparedness and response through improvements of existing structures. Reforms may include distinctly separating technical departments and those dealing with governance; limiting the position of the DG to a single term; modifying the structure and staffing requirements of regional and country offices; and adjusting funding arrangements to ensure that WHO can fulfill core functions. These re-

[13] These models were presented at the Institute of Medicine Workshop on Governance for Global Health on September 2, 2015. For more information, see http://iom.nationalacademies.org/Activities/PublicHealth/MicrobialThreats/2015-SEP-01.aspx (Accessed February 1, 2016).

[14] This model is based on the Chatham House Working Group on Health Governance's recommendations for reforming WHO (Clift, 2014).

forms rely on the member states to be motivated to push for fundamental reform.

Model B: WHO Plus[15]

This model proposes that WHO would continue to have operational responsibility for outbreak preparedness and response but would significantly revamp its organizational and operational capacity to deliver a complete emergency public health response. To achieve this, WHO would create a center for humanitarian and outbreak management attached to WHO and under the authority of the DG that combines strategic, operational, and tactical capabilities for emergency, humanitarian, and the IHR functions. This center would be designed to respond quickly to different kinds of outbreaks and emergencies. The routine and crisis modes, and the transition between them, would be governed by the center's director, in consultation with the DG, and guided by an independent board in such a way as to create transparency and ensure effectiveness. The center would also strengthen coordination across all three levels of WHO as well as with the UN humanitarian system. In order to support this activity, an increased health security budget within WHO, as well as an increased political commitment from member states, would be required.

Model C: The Executive Agency Model

In this model, the UN system would create an enabling environment in which WHO, potentially through a center for humanitarian and outbreak management, takes the lead in the health sector and executes a strategic operational and tactical role in a health emergency. This model aims to take advantage of WHO's expertise and legitimacy, while allowing it to tap into the UN's higher level of authority for command and control and political support. This model would be activated only when a multisectoral global response is required to reduce health risk.[16] These reforms rely on WHO to formally coordinate with UN programs and funds under the framework of OCHA and harmonize with NGOs under the IASC framework.

Model D: A New, Separate Entity Under the UN

This model assumes that the current mandate on global health risks contained in WHO's constitution is either unclear or insufficient and that WHO cannot or should not deal with global health risks. Rather, outbreak preparedness and response measures should be drawn from other UN-system assets and authorities. In effect, the UN would create an interagency entity for global health risks, under the UNSG. This entity would encompass capabilities not only from WHO but also from the FAO, UNICEF, the United Nations Development Programme, World Food Programme, and others.

ANNEX 4-4

Models for Reforming WHO's Work on Outbreak Preparedness and Response

Since the Ebola crisis, several initiatives have proposed different types of models for reforming WHO's work on outbreak preparedness and response. Each initiative recognizes that WHO must strengthen its capacity during outbreaks and that the health emergencies and outbreak response functions should merge. Additionally, the initiatives urge better integration of these functions across all three levels of WHO, as well as some kind of oversight mechanism. However, each proposal also suggests different elements for the operational entity's governance and funding structure (see Table 4-4).

[15] This model is based on the Ebola Interim Panel's proposal (WHO, 2015g).

[16] For example, in cases when an infectious disease is known and the national capacities are fragile, or when the disease is unknown and the national capacities are low, a multisectoral development response would be required within the UN Development Assistance Framework, with WHO taking the lead in the health sector. Alternatively, in cases when the infectious disease is unknown and national capacities are fragile, OCHA would coordinate a multisectoral humanitarian response, with WHO taking the lead in the health cluster (NASEM, 2016).

TABLE 4-4 A Comparison of Proposed WHO Reform Models for Outbreak Preparedness and Response

Initiative	Center/Program	Declaration of PHEIC	Role of the United Nations	Oversight Mechanism	Funding
WHO's Ebola Interim Assessment Panel	Center for Health Emergency Preparedness and Response, led by an ED who reports to the DG	DG supported by Emergency Committee, with introduction of an intermediate level PHEIC option that can be declared at an earlier stage of crisis ahead of a full PHEIC	When a crisis escalates to a point where it poses a high-level global health threat requiring greater political and financial engagement, the UNSG should consider the appointment of a Special Representative of the UNSG or a UN Special Envoy with a political and strategic role to provide greater political and financial engagement	An independent board would guide the development of the center and report on its progress to the WHO Executive Board, WHA, and the UN IASC	Increased assessed contributions by 5 percent
Harvard Global Health Institute and London School of Hygiene & Tropical Medicine's Independent Panel on the Global Response to Ebola	Center for Emergency Preparedness and Response, led by an ED who reports to the DG and Board of Directors	A newly developed WHO Standing Emergency Committee, chaired by DG	If initial response does not succeed and an outbreak becomes a humanitarian crisis (threatening not only public health, but also political, economic, and social stability), OCHA should provide third line of defense. Also the UN should appoint an "accountability commission," and the UN Security Council should establish a global health committee	A Board of Directors would oversee the center. Members would include broad representation of governments from each WHO region, scientific expertise, operational responders from all sectors, and funders	Protected and adequately resourced through a dedicated revolving fund Standing Emergency Committee is funded by assessed contributions to protect against undue donor influence
WHO's Advisory Group on Reform of WHO's Work in Outbreaks and Emergencies	Programme for Outbreaks and Emergencies Management, led by an ED who reports to the DG	Not specified, most likely DG	The UN and the WHO Program should work closely to build mechanisms to enhance surge capacity. In many instances, WHO will act as part of a larger UN Humanitarian Country Team	External, independent oversight body established by the DG would monitor performance of the Programme (and operational platform). May report to the WHO Executive Board, WHA, and UNSG	Steady-state financing; will explore options to increase allocations for the core budget of WHO so the Programme can receive predictable funding

NOTE: DG = Director-General; ED = Executive Director; IASC = Inter-Agency Standing Committee; OCHA = UN Office for Coordination of Humanitarian Affairs; PHEIC = Public Health Emergency of International Concern; UN = United Nations; UNSG = UN Secretary-General; WHA = World Health Assembly; WHO = World Health Organization.

SOURCES: Moon et al., 2015; WHO, 2015a,g.

REFERENCES

Clift, C. 2014. *What's the World Health Organization for?* Final report from the Centre on Global Health Security Working Group on Health Governance. London: The Royal Institute of International Affairs.

Fineberg, H. 2014. Pandemic preparedness and response—lessons from the H1N1 influenza of 2009. *New England Journal of Medicine* 370:1335-1342. http://www.nejm.org/doi/full/10.1056/NEJMra1208802?af=R&rss=currentIssue& (accessed November 2, 2015).

Frenk, J., and S. Moon. 2013. Governance challenges in global health. *New England Journal of Medicine* 368(10):936-942.

Gostin, L. O. 2014. *Global health law*. Cambridge, MA: Harvard University Press.

Gostin, L. O., and E. Friedman. 2015. A retrospective and prospective analysis of the west African Ebola virus disease epidemic: Robust national health systems at the foundation and an empowered WHO at the apex. *Lancet* 385(9980):1902-1909.

Heymann, D. L., L. Chen, K. Takemi, D. P. Fidler, J. W. Tappero, M. J. Thomas, T. A. Kenyon, T. R. Frieden, D. Yach, S. Nishtar, A. Kalache, P. L. Olliaro, P. Horby, E. Torreele, L. O. Gostin, M. Ndomondo-Sigonda, D. Carpenter, S. Rushton, L. Lillywhite, B. Devkota, K. Koser, R. Yates, R. S. Dhillon, and R. P. Rannan-Eliya. 2015. Global health security: The wider lessons from the West African Ebola virus disease epidemic. *Lancet* 385(9980):1884-1901.

Hoffman, S. J. In press. A*nalysis of WHO budget allocations to emergency response functions 2002–2017*. [Personal communication with Steven Hoffman on November 4, 2015.]

IMF (International Monetary Fund). 2015. *Factsheet—IMF Rapid Credit Facility.* https://www.imf.org/external/np/exr/facts/rcf.htm (accessed November 29, 2015).

IOM (Institute of Medicine) and NRC (National Research Council). 2009. *Sustaining global surveillance and response to emerging zoonotic diseases*. Washington, DC: The National Academies Press.

Jonas, O. 2013. *Pandemic risk*. Background Paper. World Development Report 2014: Risk and Opportunity: Managing Risk for Development.

Labonté, R., and M. Gagnon. 2010. Framing health and foreign policy: Lessons for global health diplomacy. *Globalization and Health* 6:14.

Moon, S., D. Sridhar, M.A. Pate, A. K. Jha, C. Clinton, S. Delaunay, V. Edwin, M. Fallah, D. P. Fidler, L. Garrett, E. Goosby, L. O. Gostin, D. L. Heymann, K. Lee, G. M. Leung, J. S. Morrison, J. Saavedra, M. Tanner, J. A. Leigh, B. Hawkins, L. R. Woskie, and P. Piot. 2015. Will Ebola change the game? Ten essential reforms before the next pandemic. The report of the Harvard-LSHTM Independent Panel on the Global Response to Ebola. *Lancet* 386(10009):2204-2221.

MSF (Médecins Sans Frontières). 2015. *Pushed to the limit and beyond.* Paris: MSF.

NASEM (National Academies of Sciences, Engineering, and Medicine). 2016. *Global health risk framework: Governance for global health: Workshop summary*. Washington, DC: The National Academies Press.

PWC (PricewaterhouseCoopers). 2013. *WHO evaluation reform staff survey analysis*. http://www.who.int/about/who_reform/whoreform-stage2evaluation-appen2-pwc-2013.pdf?ua=1 (accessed April 27, 2016).

Swiss Re (Swiss Reinsurance Company). 2015. *Sigma—underinsurance of property risks: Closing the gap*. Zurich, Switzerland: Swiss Reinsurance Company.

UNAIDS (Joint United Nations Programme on HIV/AIDS). 2012. *UNAIDS guidance for partnerships with civil society, including people living with HIV and key populations*. Geneva: UNAIDS. http://www.unaids.org/sites/default/files/en/media/unaids/contentassets/documents/unaidspublication/2012/JC2236_guidance_partnership_civilsociety_en.pdf (accessed November 29, 2015).

WEF (World Economic Forum). 2015. *Managing the risk and impact of future epidemics: Options for public–private cooperation*. Geneva: World Economic Forum, in collaboration with Boston Consulting Group.

WHO (World Health Organization). 2006. *Constitution of the World Health Organization. Basic Documents. Forty-fifth edition. Supplement*. Geneva: WHO.

WHO. 2008. *International Health Regulations (2005) Second Edition*. Geneva: WHO. http://www.who.int/governance/eb/who_constitution_en.pdf (accessed November 20, 2015).

WHO. 2011. *Financing of the World Health Organization.* Geneva: WHO. http://apps.who.int/gb/ebwha/pdf_files/EBSS/EBSS2_ID2-en.pdf (accessed November 20, 2015).

WHO. 2012. *Supplementary Paper to JIU/REP/2012/6&7: Review of Management, Administration and Decentralization in the World Health Organization (WHO). Analysis of the Results of WHO Staff Survey, Joint Inspection Unit*. https://www.unjiu.org/en/reportsnotes/Other%20related%20documents/Suppl_Doc_Staff%20Survey%20analysis_15%20November%202012.pdf (accessed December 11, 2015).

WHO. 2013. *Review of management, administration and decentralization in the World Health Organization, report by the Joint Inspection Unit*. http://apps.who.int/gb/ebwha/pdf_files/EB132/B132_5Add6-en.pdf (accessed December 11, 2015).

WHO. 2014. *Proposed programme budget 2014-2015*. http://www.who.int/about/resources_planning/A66_7-en.pdf (accessed December 15, 2015).

WHO. 2015a. *Advisory group on reform of WHO's work in outbreaks and emergencies—first report.* http://www.who.int/about/who_reform/emergency-capacities/face-to-face-report.pdf (accessed December 1, 2015).

WHO. 2015b. *Emergency preparedness and response—event verification*. http://www.who.int/csr/alertresponse/verification/en (accessed November 20, 2015).

WHO. 2015c. *Follow up to the World Health Assembly decision on the Ebola virus disease outbreak and the Special Session of the Executive Board on Ebola: Roadmap for action*. http://www.who.int/about/who_reform/emergency-capacities/WHO-outbreasks-emergencies-Roadmap.pdf (accessed December 16, 2015).

WHO. 2015d. *Global health emergency workforce*. http://apps.who.int/gb/ebwha/pdf_files/WHA68/A68_27-en.pdf (accessed December 16, 2015).

WHO. 2015e. *Proposed programme budget 2016-2017*. http://apps.who.int/gb/ebwha/pdf_files/WHA68/A68_7-en.pdf (accessed November 20, 2015).

WHO. 2015f. *Meeting between GOARN Steering Committee (SCOM) and the chair for the Advisory Group on Reform of WHO's work in outbreaks and emergencies*. http://www.who.int/about/who_reform/emergency-capacities/Meeting-report-GOARN-Steering-Committee-17-Sept-2015.pdf (accessed December 16, 2015).

WHO. 2015g. *Report of the Ebola interim assessment panel—July 2015*. Geneva: WHO.

WHO. 2015h. *WHO Contingency Fund for Emergencies*. Geneva: WHO. http://www.who.int/about/who_reform/emergency-capacities/contingency-fund.pdf (accessed December 16, 2015).

WHO. 2015i. *WHO's engagement with non-state actor*s. http://www.who.int/about/collaborations/non-state-actors/en (accessed November 22, 2015).

5
Accelerating Research and Development to Counter the Threat of Infectious Diseases

The increasing threat of emerging and reemerging infectious disease outbreaks demands research and development (R&D) of effective and fit-for-purpose tools and technologies, such as vaccines, drugs, diagnostics, personal protective equipment (PPE), and medical devices. Recent epidemics have highlighted gaping holes in our ability to rapidly deploy medical products that will not only help identify and contain outbreaks, but also care and treat those affected. To ensure successful resolution of the next major outbreak with minimal loss of life, we must have a more robust R&D strategy.

This strategy should include, at a minimum, a defined coordinating entity; an investment plan for a comprehensive portfolio of medical products; convergence of regulatory requirements across countries or regions for testing, approval, and licensure of new products; agreements on access to intellectual property (IP), if any, and to data and materials, manufacturing capacity, and distribution channels; and the incorporation of social and political considerations for the successful adoption of technologies and best practices at local levels. Experience has demonstrated that without substantial community engagement and anthropological research, effective technologies may not be readily and swiftly adopted to curtail spread of disease (Tindana et al., 2007).

A PANDEMIC PRODUCT DEVELOPMENT COMMITTEE TO DRIVE THE R&D STRATEGY

Readiness for infectious disease outbreaks requires ongoing investment in research in myriad disciplines, including basic biomedical research to understand the etiology of disease, the causative agents, the symptomatology, clinical research to test for safety and efficacy of potential new vaccines and drugs, and anthropological research to identify the contributing social and cultural factors. Crucially, the development of appropriate PPE, point-of-care diagnostics, and a portfolio of novel therapeutic agents, including for antimicrobial resistance (AMR), and vaccine constructs that can be quickly brought to scale, must take place before a crisis strikes, rather than in the midst of an outbreak.

In parallel, population, policy, and implementation research is needed to understand the population factors, policies, and delivery systems that work best for scaling up interventions to improve the delivery of biomedical interventions (Jamison et al., 2013). In particular, social research, involving local capacity building where necessary, must be undertaken at vulnerable hotspots to anticipate potential outbreaks, generate vital information about the causes of infection, and develop a body of work that can usefully inform the design and implementation of interventions in future emergencies. It is clear that such a comprehensive approach will only succeed with the contributions of multiple parties working toward common goals.

Pandemic Product Development Committee

In times of global health emergency, the R&D community—academia, government, industry, and civil society—must be galvanized as a cohesive group to swiftly determine the necessary biomedical interventions. For example, in the short term, identification and diagnosis of the pathogen, as well as selection of existing tools to treat and control the infection and curtail AMR,

are critical. However, it is likely that current technologies will prove insufficient or ineffective, and, therefore, a massive effort to find the needed tools must be undertaken (Balasegaram et al., 2015; Jamison et al., 2013). When there is no pressing emergency, the R&D community has to continue to develop knowledge and have products ready for scale-up and distribution. These activities must be coordinated to ensure effective prioritization, maximize the possibility of success, reduce redundancy and cost, and save lives. However, to date, there are only weak coordinating mechanisms to perform these activities, despite longstanding recognition of this unmet need (CEWG, 2012; CHRD, 1990; CIPIH, 2006). The consequences of the lack of coordination were exposed again in the recent Ebola outbreak, causing confusion about how best to approach and implement response efforts and thereby contributing to inefficiencies (WHO, 2015c).

In line with its constitutional mandate to direct and coordinate international health work, the World Health Organization (WHO) should galvanize the acceleration of relevant R&D to counter infectious disease threats by establishing a high-level, broad-based expert panel, an independent Pandemic Product Development Committee (PPDC), which would be accountable to the Technical Governing Board, or TGB (see Chapter 4 for more on the TGB). The PPDC would be independent of WHO, and make decisions according to the advice and views of its members, appointed for their technical expertise, not under the direction of WHO. Such a coordinating entity would help fill the unmet need by pinpointing existing capabilities, identifying gaps, and determining priorities for a concerted global effort to develop, test, manufacture, and distribute the relevant medical products in cases of emergency.[1] The PPDC should be focused primarily on diseases of pandemic or epidemic potential, including coronaviruses and influenza viruses, among others. The committee's roles and responsibilities should include identifying R&D priorities to tackle high-risk pathogens[2] and monitoring the distribution of funds allocated to the PPDC in line with these priorities. Additionally, the PPDC would be charged with drafting the emergency preparedness plan that outlines R&D roles and responsibilities as part of the overall response. Specifically, this plan would provide a clear roadmap for all willing contributors to the effort, including, but not limited to, identifying existing technologies and best practices; determining "who does what when"; selecting and enabling a central emergency point of contact; establishing and implementing a far-reaching, trustworthy communications strategy; and maintaining close contact with on-the-ground responders, governments, industry, scientists, clinicians, and civil society, among others. Domain experts from key stakeholder organizations should be called on to support the many activities the PPDC undertakes, but the PPDC would not be charged with direct management of any specific projects. The TGB should assess the PPDC performance on a yearly basis.

The Commission recognizes that the PPDC must consider the impact of AMR on preparedness efforts. As we have seen with human immunodeficiency virus (HIV), tuberculosis, and other infections, resistance will eventually develop, creating an added challenge for combatting disease and disability. AMR is the by-product of indiscriminate use of antibiotics in the animal industry and human medical practice. Indeed, it is a manmade disaster (IOM, 2010) due to gross misuse of high-quality drugs as well as widespread use of counterfeit antibiotics in many parts of the world. Thus, although the focus of the PPDC must be addressing pandemic threats, the actions it takes can and must be aligned with steps to address resistance. This synergy will serve patients, communities, and countries well.

The WHO Director-General should appoint the chair of the PPDC and, in collaboration with the chair, appoint the committee members. The chair should be an R&D expert who is also a member of the TGB and would help spearhead resource mobilization. Members should include, at most, 15 internationally recognized leaders who have expertise in discovery, development, regulatory review and approval, and manufacturing of medical products. These experts should be affiliated with pharmaceutical and biotechnology companies, foundations, academia, research institutions, clinics, and patient

[1] WHO is in early stages of developing a new R&D Blueprint with similar aims to capture existing knowledge and good practices, identify gaps, and create a roadmap for R&D preparedness, but does not have an entity like the PPDC to take the lead (WHO, 2015a).

[2] A panel of scientists and public health experts convened by WHO has developed an initial list of disease priorities needing urgent R&D attention, which will form the "backbone" of the new WHO Blueprint for R&D Preparedness (WHO, 2015d). The list of priority diseases includes Crimean Congo hemorrhagic fever, Ebola virus disease, Marburg hemorrhagic fever, Lassa fever, Middle East respiratory syndrome (MERS) and severe acute respiratory syndrome (SARS) coronavirus diseases, and Nipah and Rift Valley fever.

and civil society groups.[3] The members should serve in their personal capacity in a process that is transparent and balanced. In addition, to ensure impartial decision making, members must disclose any conflicts of interest or potential conflicts of interest before a decision is made on the matter involved, and should be prohibited from voting (other than by offering information) on any decision in which there is a conflict. Information about the members, including those that could be determined to have a potential conflict of interest, should be published on the WHO website.

Further, a few WHO representatives should participate and provide secretariat support for the PPDC. While the Commission appreciates the complexity of creating and implementing such a group, the clear expectation is that the secretariat would have an enabling role and would be highly sensitive to the importance of ensuring minimal, albeit adequate, spending on administrative infrastructure, thus maximizing the amount of funds devoted to R&D needs. These representatives must have high-level technical expertise and relevant experience in R&D of medical products and possess experience derived from tenure in industry, academia, and/or relevant government agencies.

Recommendation D.1: By the end of 2016, the World Health Organization should establish an independent Pandemic Product Development Committee, accountable to the Technical Governing Board, to galvanize acceleration of research and development, define priorities, and mobilize and allocate resources.

ACCELERATING R&D BY INVESTING $1 BILLION PER YEAR

Achieving significant acceleration in R&D related to pandemic and epidemic diseases requires significant amounts of new money. Because it is critical to use the best science to strengthen global defenses against the threat of potential pandemics, the Commission recommends targeting incremental spending of $1 billion[4] per year for at least 15 years. Used synergistically with existing and new expenditures in the public and private sectors, these funds would provide a strong foundation for the development and production of an armamentarium of medical tools, including diagnostics, vaccines, drugs, equipment, and techniques, to build and sustain R&D preparedness capacity for rapid response to global infectious disease outbreaks.

The $1 billion figure can be compared to the scale of a small–medium pharmaceutical company's R&D portfolio of promising drugs and vaccines for key target diseases that are in various stages of development.[5] At this size, when there is an outbreak of a known pathogen, much of the early research work would have been completed, and it will then be possible to move some of the products quickly to clinical testing, regulatory approval, production, and deployment.

To build better defenses against the threat of pandemics, we must step up the pace and scale of R&D on infectious diseases. It is imperative, therefore, to invest in a portfolio of platform technologies and facilities, using public funds where necessary and appropriate and leveraging commercially driven investment where possible. Given the accelerating emergence of new pathogens and the reemergence or geographic spread of previously contained agents, the program must support simultaneous development of multiple platforms. In some cases, it will make sense to take products through to full commercialization; in others, where the threat is more distant, it may be optimal to pause at a certain point, leaving full development and licensing until the threat appears more proximate.

It is important to note that the PPDC's role should go beyond purely pharmaceutical R&D. The PPDC should shape and oversee an R&D program that encompasses equipment; instruments and tools, such as low-cost diagnostic kits; surveillance systems; and PPE. The PPDC should also help streamline the product development infrastructure required to enable accelerated clinical trials and approvals, as well as promote innovations to enhance manufacturing technology and capacity and deployment systems. However, the PPDC would not deliver the products itself—delivery would be carried out by whomever is allocated the responsibility. The Biomedical

[3] Although WHO has had difficulties in directly engaging with non-state actors, such as private-sector companies, the Commission believes that with the adoption of the Framework for Engaging with Non-State Actors (FENSA) and Recommendation C.6 (explained in Chapter 4), WHO can take genuine steps to engage non-state actors for this effort.

[4] All monetary figures in U.S. dollars.

[5] The $1 billion figure is derived from Commission expertise and does not include a precise number for each product in the portfolio, as the number and types of products fluctuate in any given year, making it unrealistic to make such calculations.

Advanced Research and Development Authority of the U.S. Department of Health and Human Services, which has experience managing the advanced procurement and development of medical countermeasures for pandemic influenza and other emerging infectious diseases, would be a valuable source of know-how and best practices for the PPDC. The recent Ebola crisis revealed many deficiencies in the global product armory, from diagnostics to vaccines to PPE—and this is for a virus discovered nearly 40 years ago. Only now are we approaching the successful development of an effective vaccine.

In a sense, we should take an approach akin to that of advanced defense organizations, which anticipate future threats, envision countermeasures, and invest in R&D, both directly and by galvanizing private industry. For example, the U.S. Department of Defense (DOD) spends $70 billion on R&D (AAAS, 2015). Indeed, reflecting its assessment of future threats to the U.S. population, the DOD has been one of the larger sources of funding for infectious disease research. Comparison with defense R&D also helps put the $1 billion figure in perspective. As we argued in Chapter 2, the global community invests far less in protecting human lives and livelihoods from the threat of infectious diseases than it does in countering other threats, such as wars, terrorism, and financial crises.

By coordinating incremental R&D investments, we can maximize their impact. We anticipate that the $1 billion would comprise two different components: one portion would come from stakeholders who delegate decision making on deployment of finances to the PPDC, the second from other stakeholders who retain control over the deployment of funds, but work closely with the PPDC to achieve better coordination. Through collaborative shaping and prioritizing of discrete research programs into an overall R&D strategy, the PPDC would help ensure focused efforts in areas of maximum impact across the infectious disease spectrum, not just areas that happen to be commercially viable or fit existing research agendas. The optimal balance between the two components of funding would be determined in detailed discussion with potential contributors.

Investments in Three Key Areas

The PPDC, in coordination with other funders, would aim to deploy the funds in the following three key areas:

1. **Development and strengthening of core functions.** These are investments in infrastructure and capabilities needed by all R&D stakeholders, such as high-throughput screening, formulation technology, manufacturing capacity, and building strong local research capacity where outbreaks are likely to occur.
2. **Targeted expansion or acceleration of ongoing R&D projects.** Recent outbreaks have shown the need to create and test potential new platforms for vaccines and novel drugs past Phase I (safety) trials and primed for Phase II (efficacy) trials once a potential emergency is identified. Investment in and development of platforms already being pursued by government agencies, industry, and foundations would allow a nimble, "plug and play" strategy because process development, chemistry, manufacturing, regulatory controls, and analytics would already be in place. Likewise, investments in effective surveillance technologies; point-of-care diagnostics; PPE; medical devices; and population, policy, and implementation research are also strongly needed. Again, expansion or strengthening of existing investments in these areas is paramount.
3. **Innovation.** Without new scientific knowledge and the synergistic integration of multiple disciplines, new product development and disease-prevention strategies would be impossible. For example, it is imperative to identify new targets for antibiotic development; find ways to potentiate immunological responses; craft strategies to integrate "omics" into tool development; develop continuous manufacturing techniques; validate novel clinical trial designs; integrate information and communication technologies into strategies that better track the emergence and diagnosis of global health threats; and discover new platforms that would have broad applicability to identify, prevent, and/or treat infectious diseases with pandemic potential.

Taken together, these three investment areas can produce technologies that are fit-for-purpose and a comprehensive strategy to address threats nimbly and quickly.

Sources of Funding

The Commission envisions that the $1 billion for R&D could be drawn from five potential sources[6]:

[6] A detailed roadmap on how the funds are mobilized, coordinated, sustained, allocated, and monitored is beyond the scope of this report and will be ultimately up to the PPDC to decide on these

1. **Direct contributions from national governments, foundations, and the private sector, including private finance from outside the health care sector** (see potential source number 5). Such investments have the advantage of leverage and have proven very successful in creating public–private partnerships such as Gavi, the Global Health Innovative Technology Fund, the Global Alliance for TB Drug Development, the Drugs for Neglected Diseases initiative, and the Medicines for Malaria Venture, among others.
2. **From R&D budgets devoted to national security.** The role of the DOD, such as through the Defense Advanced Research Project Agency and Defense Threat Reduction Agency, is a model. More countries should recognize that infectious diseases represent significant threats to national security and deploy resources accordingly.
3. **From existing public, philanthropic, and university R&D budgets in the health arena, particularly funds for pandemic threats.** When combined, these can boost the individual investment capacity and create important synergies. This potential amplification would help address the severe constraints on current budgets.
4. **By catalyzing private-sector R&D.** Economic drivers enable R&D for infectious diseases for which there is strong market demand—these include, for example, nosocomial infections and yearly flu vaccines. However, sustained private investment for R&D for potential pandemics that may or may not surface or for which testing and licensure is difficult is unlikely. Nevertheless, the private sector has demonstrated a willingness to contribute to the global effort in myriad ways, including through donation programs, by activating R&D capacity in times of crises, and by providing infrastructure support, human resources, and direct funding—making them important contributors to these efforts (WEF, 2015).
5. **Generating new sources of private finance from outside the health care sector.** All sectors of the economy suffer the consequences of a serious epidemic or pandemic. Therefore, all businesses have a direct interest in supporting tax-funded public spending to mitigate this significant threat. For some types of businesses, there are even more direct connections. For example, the insurance industry faces a significant risk, given the potential impact on mortality; travel and tourism stand to suffer, given the sector's acute vulnerability to restrictions on travel which might be imposed, as well as to voluntary infection avoidance behaviors; and, of course, the meat and poultry trades face the threat of losses due to disease or mandatory culling in the event of an outbreak. One specific example of a novel funding source that could be worth investigating arises from the fact that life insurers hold capital against extreme mortality risk scenarios, among which pandemics are the most likely events. In principle, firms offering life insurance products should be able to reduce their exposure to such risks by funding research, which accelerates the R&D of products that reduce the likelihood of mass mortality pandemic events. If regulators were to approve reductions in reserve requirements faced by such firms due to a lowered risk of pandemic-related mortality, funding such research would appear doubly attractive. Such ideas undoubtedly warrant further exploration.

Recommendation D.2: By the end of 2016, the World Health Organization should work with global research and development stakeholders to catalyze the commitment of $1 billion per year to maintain a portfolio of projects in drugs, vaccines, diagnostics, personal protective equipment, and medical devices coordinated by the Pandemic Product Development Committee.

ENSURING CONSISTENT STANDARDS FOR RESEARCH DURING CRISES

When a major outbreak occurs, appropriate medical products may be not fully developed or ready for deployment to affected areas. Therefore, there is a strong need to rapidly develop and evaluate investigational therapies during outbreaks, to identify those that benefit patients, and to protect against those that cause harm. To test these therapies and products, researchers have used

mechanisms. The Commission recognizes the challenges in raising this scale of funds proposed and achieving the level of coordination envisaged. However, the Commission believes that accelerating R&D in this arena is of such importance that this is worth trying.

a variety of approaches to conduct studies (Borio et al., 2015). Some of these approaches have led to uninterpretable results and invalid conclusions. Some have also resulted in misunderstandings and suspicion on the part of participants due to poor engagement with communities. In this section, the Commission discusses the need for researchers to conduct scientifically rigorous research studies and to engage locals for studies conducted in community settings.

Commitment to Scientific Standards

The Commission recognizes the natural tension between the immediate needs of health care workers in the field having to treat the sick and the imperative to conduct trials and studies to ascertain the safety and efficacy of new medical interventions. Society has an obligation to provide immediate help to those in need and to protect health care workers and first responders. But example after example—including the AIDS pandemic, SARS, MERS, and the recent Ebola outbreak—also show that in conducting clinical trials for new vaccines or drugs, society must ensure that in all instances, particularly during health emergencies, these studies are scientifically sound and justifiable and yield interpretable data and strong, valid conclusions.

Researchers must conduct trials under rigorous scientific and ethical principles. Randomized controlled trials (RCTs) offer robust methodology with low probability of bias or confounding. RCTs also best utilize the limited number of experimental interventions by obtaining the most valid and reliable results for the benefit of current and future patients (Kalil, 2015). If data are poor and controls are weak or nonexistent, information about how experimental products may be helping or harming current patients remains unknown, offering no benefit to future patients and potentially causing harm.

Different and innovative trial designs can be—and are—employed to allow for interpretable, scientifically sound results. For vaccines, two examples of such trial design include the immediate-versus-delayed-vaccination and "ring" vaccination trials, which were conducted in Sierra Leone and Guinea, respectively, during the Ebola outbreak (WHO, 2015b). For therapeutics, the National Institutes of Health's (NIH's) medical countermeasures study contains multiple intervention arms with just one placebo (i.e., standard-of-care) group. This "adaptive" design allows trial arms to stop early where there is demonstrated toxicity or lack of efficacy (Borio et al., 2015). During public health emergencies, these adaptive trial designs may help balance the need for scientifically valid information and rapid results. However, no trial will benefit the public if data and results are not shared in a timely manner so that they can be reviewed and validated by external investigators and regulators. Therefore, regardless of the trial design, data and results of all trials must be shared promptly and transparently.

To conduct these trials, a strong local clinical trial infrastructure is paramount. Unfortunately, in many resource-poor countries, particularly in hotspots for emerging infectious diseases, trained staff, appropriate technical support, and adequate physical facilities are completely lacking—hampering the swift movement of potentially useful products from Phase I or Phase II into Phase III trials. Preparedness for trials requires appropriate physical infrastructure, a trained health care workforce, established and functional ethics committees, expertise in social sciences, community mobilization, and sustainable basic public health capacity, such as surveillance and basic laboratories. This takes time and resources. If we are to be ready for the next outbreak, we need to assess the current research and public health capacities of vulnerable areas and invest in building this infrastructure. The PPDC could provide guidance on the funding and delivery mechanisms of such an effort.

Engaging Communities in Research

When researchers design and conduct studies in community settings, strong local engagement and buy-in is imperative at every step along the way. Involving local people, particularly key opinion leaders and scientists, is of critical importance; in many communities, for example, local healers as well as religious and peer leaders are enormously influential (Awunyo-Akaba, 2015). Open, bilateral, or multilateral information exchange from the outset will create trust, promote discussion, help address local concerns or misperceptions, and ensure that study participants are treated with utmost respect and consideration.

As researchers seek to enroll participants in studies, care must be taken to ensure that participants are fully informed and educated about all aspects of the protocol. This process is not always straightforward (Geissler and Molyneux, 2011; Parker and Allen, 2013), but it is essential. Informing study participants necessarily requires

proficiency in the local language, regular dialogue with study participants, meetings with experienced local scientific investigators, and an understanding of the way in which the political reality shapes participation at the local level (Sow, 2015). Every effort should be made to inform local leaders, as well as civil society groups, about the science of the disease and the rationale underpinning the design of the particular clinical trial. Such an approach is not only invaluable in itself—it also helps to mitigate rumors and misunderstanding.

A program run by the Kenya Medical Research Institute–Wellcome Trust Research Programme usefully illustrates the way in which study participants in international health research acquire relevant knowledge before consenting to participation in a trial. This program engages local community facilitators, health care professionals, and local people to create consent forms that are socially and culturally sensitive to local needs (Boga et al., 2011). By bringing together community stakeholders, the initiative confronts concerns about research head-on and incorporates potential solutions into the consent process. Concerns can range from understanding of controls and placebos to sample storage and use, among other scientific or process-based issues (Boga et al., 2011).

The emphasis on creating and maintaining open dialogue between those doing the research and those participating in the study is critical. Under its Communication for Development initiative, the United Nations Children's Fund (UNICEF) encourages social mobilization as an effective approach to informing communities. This approach brings together local stakeholders to learn about particularly relevant issues through open dialogue (UNICEF, 2015). Opening up a conversation allows researchers to address local anxieties and fears, alter their messaging accordingly, and ensure that people truly understand the purpose of the research.

Even if there are effective medical products available following the conclusion of a study, the products are useless if they are received with suspicion, rejected by those residing in affected areas, and ultimately not adopted for use. Widespread fear and anxiety, occasionally leading to violent rejection of mass drug administration for control of neglected tropical diseases, as in the case of schistosomiasis (Hastings, 2016; Muhumuza et al., 2015; Parker et al., 2008) and lymphatic filariasis (Kisoka et al., 2015; Parker and Allen, 2013), usefully illustrates this point. Thus, researchers must establish and maintain relationships with local individuals to effectively move a study or product forward. Further, strong communication must be matched with successful service delivery to be effective. In order to achieve this, researchers and product developers must engage local logistics support, supply chain experts, and those with knowledge of the specific social contexts in which supplies will be delivered and dispensed (Hall, 2015).

SECURING OVERARCHING GLOBAL AGREEMENTS TO EXPEDITE APPROVAL, MANUFACTURE, AND DISTRIBUTION

Under the coordinating leadership of the PPDC, R&D stakeholders should pre-negotiate global agreements to facilitate timely and appropriate implementation and distribution of a range of tools and infrastructure during a global infectious disease outbreak. Without agreement on regulatory approval and review, manufacturing and distribution mechanisms, indemnification, IP and data sharing, to name a few, effective medical products may not reach those in need.[7]

Convergence of Regulatory Processes and Regulatory Science Standards

Regulatory agencies must continue to work toward common rules, agree on best practices, and establish standards that will define how products for emergencies are reviewed and approved. Currently, each country has its own distinct processes of reviewing and approving the safety, efficacy, and quality of medical products. Understanding and navigating the diverse regulatory systems can be cumbersome and complex, causing delays in deploying products to patients. A streamlined process across regulatory systems would lead to important efficiencies.

The problem of discordant regulatory systems was illustrated during the H1N1 outbreak, when each country's national regulatory authority—understandably—imposed its own regulatory process for approving, authorizing the importation, and overseeing the distribution of vaccines. Processes ranged from one-time waivers of certain rules to detailed requirements for pediatric subgroup data, regulatory assessments capacity, quality

[7] The Commission recognizes that the following section does not lay out an exhaustive roadmap of how to achieve these agreements. Such a roadmap requires extensive discussion and analysis among various stakeholders and is beyond the scope of this report.

control preparedness and capacity, and post-marketing safety surveillance and field assessment of efficacy and immunogenicity (Halabi, 2015). Additionally, in over half of the beneficiary countries, prequalification of a vaccine by WHO was not sufficient to obtain regulatory approval, while in others, albeit relatively few, national laws stated that products donated by the UN did not require national registration (WHO, 2010). The distinct requirements that varied across countries adversely affected efficacious donation and distribution, as it took time for manufacturers and other entities to access, understand, and sift through the information on the countries' regulatory processes and negotiate with regulators.

Regulatory convergence does not require nations to give up their autonomy, but rather helps them come together quickly to address the following questions: How can countries divide the tasks associated with a product review and work together to ensure that prescribing information is aligned? How can regulators align expectations of what is required in regulatory submissions for product review and approval? How can they move toward more common data and evidence standards? What are the knowledge base and the regulatory tools necessary for more streamlined oversight?

Some steps have been taken to achieve better regulatory convergence. In the most recent Ebola outbreak, regulators from around the world, including Health Canada, the United Kingdom's Medicines and Healthcare Regulatory Agency, the U.S. Food and Drug Administration, and the European Medicines Agency, worked together with local regulators to speed preparation for trials in West Africa (EMA, 2014; WHO, 2015c). Another example is the International Coalition of Medical Regulatory Authorities (ICMRA), which is a voluntary, executive-level entity that provides direction for a range of areas that are common to many regulatory authorities' missions (Skerritt et al., 2015). While ICMRA is still in its nascent stages, it may be a promising example in regulatory convergence, alignment, and standards development.

Pre-Approval of Clinical Trial Designs and Master Protocols

R&D stakeholders should discuss and agree on the different possible designs for clinical trials and protocols that are scientifically valid and appropriate for emerging infectious diseases. This would expedite the evaluation of investigational products during emergencies and allow therapies shown to be safe and effective to reach patients more quickly.

Currently, the process of approving clinical trial designs and protocols during an outbreak is not streamlined. This was apparent during the recent Ebola outbreak, when researchers worldwide diverged on the types of clinical trials to undertake and wrote protocols that took time to be approved in the three affected West African countries (WHO, 2015c).

The process of testing an investigational product would be more efficient if research clinical designs and protocols that took account of uncertainty were outlined and approved prior to emergencies and then adapted to the specific outbreak. Pre-approved clinical designs have been used successfully, such as when Médecins Sans Frontières assessed the validity of new rapid diagnostic tests during a meningitis outbreak, which reported no harm to participants and enhanced the ability of researchers to respond in a timely manner (Schopper et al., 2015). A move toward common protocols (Borio et al., 2015) and sharing designs and protocols broadly within the research community would allow researchers to be ready to test investigational products at the onset of a crisis. The International Severe Acute Respiratory and Emerging Infection Consortium, which provides a platform for researchers to share and download research protocols and data tools useful in epidemics, could help facilitate the pre-approval process and sharing of protocols (ISARIC, 2015).

Mechanisms for Managing Intellectual Property and Sharing of Data and Reagents

Transparent mechanisms for managing IP and sharing of data and materials are needed for efficient R&D processes during major outbreaks. Withholding valuable information, including negative results, is a disservice to the R&D effort; such behavior delays progress in the fight against the pandemic, wastes time and resources, and stifles collaboration (Heymann et al., 2015).

An example of a mechanism to streamline activities is WHO's Pandemic Influenza Preparedness Framework, which seeks to improve and strengthen the sharing of influenza viruses with human pandemic potential (WHO, 2011). This requires manufacturers to agree on a standard material transfer agreement that regulates the terms under which countries agree to donate influenza samples, the entities authorized to receive and research

them, and the corresponding sharing of resulting vaccines and other IP. This framework oversees the sharing of H5N1 and other influenza viruses with human pandemic potential, but does not apply to non-influenza biological materials. This type of framework of sharing specimens could be expanded to other threats.

Likewise, data and other information related to R&D should be made available in a public domain to avoid duplicative costs and wasted effort. There are examples, such as GlaxoSmithKline's data transparency model,[8] the Global Alliance for Genomics and Health,[9] and the Biomarkers Consortium,[10] that have made important strides to ensure that information is promptly available to the public. In addition, the NIH, the U.S. National Science Foundation, The Bill & Melinda Gates Foundation, and the Wellcome Trust, among others, have established guidelines for data sharing by grantees. These models should to be expanded to make data sharing and speedy publication the norm.

Reasonable Protection Against Product Liability Claims

Stakeholders must agree on the degree to which manufacturers should be indemnified against liability claims during an emergency. Without realistic protection, many manufacturers will halt the production of medical products, and patients will not receive timely proper care or treatment.

Experience has shown that manufacturers require protection. During the H1N1 outbreak, for example, vaccine manufacturers required that all purchasers or recipients indemnify them for adverse events resulting from use of the vaccine, unless the failure was due to discrete manufacturing specifications (Halabi, 2015). In other cases, some manufacturers will not authorize the use of a vaccine for a clinical trial if they are not insured against legal liabilities or in the absence of clear agreements for protection. Even in situations where a manufacturer agrees in principle to donate to WHO or other UN agencies to protect from potential liability claims, it might not do so in certain countries if such vaccine is not duly licensed (GAO, 2008). Other legal barriers include those related to preexisting advance market commitment agreements, which affect the ability to enter into additional contracts once a pandemic has been declared, or those related to approval and registration procedures with national regulatory authorities (Halabi, 2015).

Identification and Contracting Manufacturing Platforms and Facilities

The PPDC should establish mechanisms to quickly identify and contract manufacturing platforms and facilities before and during a crisis. Such manufacturing capacity is not widely available, particularly in developing countries. Only a few areas of the world, such as Australia, Europe, Japan, and North America, have plants for manufacturing influenza vaccine (Halabi, 2015). In fact, the capacity for vaccine production is severely limited compared with the number of doses that would be required for a future pandemic.

Manufacturing takes time, resources, and expertise; different facilities are needed for different products. Therefore, accurate and detailed information on capabilities and output yields is crucial so that, in the event of a pandemic, R&D stakeholders will know if and when they can contribute to scale-up, how to produce the greatest possible quantity of medical products in a timely manner, and when and how to scale down safely after the threat disappears. Demand forecasting and clarification of stockpiling plans are also important in ensuring adequate production of drugs and vaccines. Spare manufacturing capacities may be needed to accommodate mass manufacturing of products, as well as testing investigational products. For example, GlaxoSmithKline has plans to share a manufacturing site where the scientific and pharmaceutical communities can come together to draw expertise and knowledge from the facility—from vaccine design through manufacturing (GSK, 2015).

If adequate manufacturing capacity is unavailable in an affected country, regional manufacturing and stockpiles could facilitate production and distribution of medical products to populations in need. In fact, specific centralized production facilities in countries with capable regulatory authorities and a track record for high-quality standards may be preferable in some areas for ensuring public health benefit in terms of quality, timelines, economies of scale, and affordability. These locations should be determined prior to an emergency. Indeed, it is reasonable to assume that attempting to build manufacturing and distribution infrastructure during an

[8] For more information, see http://www.gsk.com/en-gb/behind-the-science/innovation/data-transparency (accessed March 24, 2016).
[9] For more information, see https://genomicsandhealth.org (accessed March 24, 2016).
[10] For more information, see http://www.biomarkersconsortium.org (accessed March 24, 2016).

emergency will not yield best results—far from it. Taking guidance from national defense–enterprise preparedness strategies, the PPDC should consider finding ways to maintain a geographically distributed "warm industrial base" that is primed for quick scale-up of medical product manufacturing, deployment, and delivery where such products are most needed.

Access and Distribution of Stockpiles of Vaccines, to Reach Those at Greatest Risk

A global access framework should be developed to ensure that the right drug is delivered to the right place and population at the right time. As noted before, the sobering truth is that there is limited capacity for producing potentially lifesaving vaccines, and not everyone is able to get needed medical products at the same time (Yamada, 2009). This requires difficult decisions about who gets the medical products first.

The ability to pay should not determine where products are distributed, as in the case of a country that wishes to stockpile vaccines for its low-risk population. Rather, those who are at the greatest risk and in imminent danger during a crisis—whether they are frontline health workers or a vulnerable local population—should have priority. This means that, in order to ensure equitable access and distribution of vaccines to those in need, countries must refrain from nationalizing their vaccine manufacturing output. This was illustrated during the H1N1 outbreak in 2009, when governments with preexisting contracts sought to preserve the capacity of firms located within their territorial borders to inoculate their own citizens before giving or selling to other countries (Fidler, 2010). The rationale, which is understandable, was that the governments had an obligation to their citizens before exporting vaccines to other populations. However, the reality was that these populations were at very low risk and the prioritization was incongruent with good public health policy.

To ensure access, a process for stockpiling supplies of premanufactured material should be developed. In addition, prices need to be such that the most vulnerable people, who tend to be the poor, can afford the medical products. Contributions from high-income countries to offset the cost of vaccines for countries and populations who cannot afford to pay for them is critical, as are tiered pricing schemes, donations, and other mechanisms that can ensure access to prevention, care, and treatment.

Recommendation D.3: By the end of 2016, the Pandemic Product Development Committee should convene regulatory agencies, industry stakeholders, and research organizations to:

- **Commit to adopting research and development approaches during crises that maintain consistently high scientific standards.**
- **Define protocols and practical approaches to engage local scientists and community members in the conduct of research.**
- **Agree on ways to expedite medical product approval, manufacture, and distribution, including convergence of regulatory processes and standards; pre-approval of clinical trial designs; mechanisms for intellectual property management, data sharing and product liability; and approaches to vaccine manufacture, stockpiling, and distribution.**

CLOSING REMARKS

It should be self-evident that scientific research must play a critical role in the global framework for countering the threat of infectious diseases. Yet to be able to react promptly to outbreaks with the potential to become pandemics by deploying new medicines, diagnostic tools, and instruments at pace, we need more R&D in this arena, and we need it to be better coordinated. To achieve this, the Commission recommends that WHO establish a dedicated entity, the PPDC, to define priorities, mobilize and allocate resources, and oversee progress. We recommend targeting incremental R&D spending of $1 billion per year, to be coordinated by the PPDC. This proposed budget does not include expenditures for AMR, although it is expected that innovative drugs supported by the PPDC may help address AMR. The Commission also recommends a number of actions to ensure that R&D during crises sustains the highest scientific standards, that communities are effectively engaged in R&D processes, and that many of the impediments to swift development, approval, and deployment of new medical products are tackled in advance.

REFERENCES

AAAS (American Association for the Advancement of Science). 2015. *R&D budget and policy program—historical trends in federal R&D*. http://www.aaas.org/page/historical-trends-federal-rd (accessed November 15, 2015).

Awunyo-Akaba, J. 2015. *Linkage between "country-led" & "community-owned."* Presentation made at "Global Health Risk Framework: Workshop on Research and Development of Medical Products," Hong Kong, China, August 20.

Balasegaram, M., C. Brechot, J. Farrar, D. Heymann, N. Ganguly, M. Khor, Y. Levy, P. Matsoso, R. Minghui, B. Pecoul, L. Peilong, M. Tanner, and J. A. Rottingen. 2015. A global biomedical R&D fund and mechanism for innovations of public health importance. *PLoS Medicine* 12(5):e1001831.

Boga, M., A. Davies, D. Kamuya, S. M. Kinyanjui, E. Kivaya, F. Kombe, T. Lang, V. Marsh, B. Mbete, A. Mlamba, S. Molyneux, S. Mulupi, and S. Mwalukore. 2011. Strengthening the informed consent process in international health research through community engagement: The KEMRI-Wellcome Trust research programme experience. *PLoS Medicine* 8(9):e1001089.

Borio, L., E. Cox, and N. Lurie. 2015. Combating emerging threats—accelerating the availability of medical therapies. *New England Journal of Medicine* 373(11):993-995.

CEWG (Consultative Excerpt Working Group on Research and Development: Financing and Coordination). 2012. *Research and development to meet health needs in developing countries: Strengthening global financing and coordination.* Geneva: WHO.

CHRD (Commission on Health Research for Development) 1990. *Health research. Essential link to equity in development*. New York: Oxford University Press.

CIPIH (Commission on Intellectual Property Rights, Innovation and Public Health). 2006. *Public health, innovation and intellectual property rights*. Geneva: WHO. http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf (accessed December 17, 2015).

EMA (European Medicines Agency). 2014. *Ebola outbreak: EMA to review experimental medicines to support treatment decisions*. http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2014/09/news_detail_002176.jsp&mid=WC0b01ac058004d5c1 (accessed November 30, 2015).

Fidler, D. P. 2010. Negotiating equitable access to influenza vaccines: Global health diplomacy and the controversies surrounding avian influenza H5N1 and pandemic influenza H1N1. *PLoS Medicine* 7(5):e1000247.

GAO (U.S. Government Accountability Office). 2008. *Influenza pandemic: Efforts underway to address constraints on using antivirals and vaccines to forestall a pandemic*. http://www.gao.gov/new.items/d0892.pdf (accessed October 10, 2015).

Geissler, P. W., and C. Molyneux. 2011. *Evidence, ethos and experiment: The anthropology and history of medical research in Africa*. Oxford: Berghahn Books.

GSK (GlaxoSmithKline). 2015. GSK to establish global vaccines R&D centre in the US. https://www.gsk.com/en-gb/media/press-releases/2015/gsk-to-establish-global-vaccines-randd-centre-in-the-us (accessed February 1, 2016).

Halabi, S. 2015. Obstacles to pH1N1 vaccine availability: The complex contracting relationship between vaccine manufacturers, WHO, donor and beneficiary governments. In *The Public Health Response to 2009 H1N1*, edited by M. Soto and M. Higdon. Oxford: Oxford University Press.

Hall, S. 2015. *Presentation for manufacturing and stockpiling*. Presentation made at "Global Health Risk Framework: Workshop on Research and Development of Medical Products," Hong Kong, China, August 20.

Hastings, J. 2016. Rumours, riots and the rejection of mass drug administration for the treatment of schistosomiasis in Morogoro, Tanzania. *Journal of Biosocial Science*.

Heymann, D. L., L. Chen, K. Takemi, D. P. Fidler, J. W. Tappero, M. J. Thomas, T. A. Kenyon, T. R. Frieden, D. Yach, S. Nishtar, A. Kalache, P. L. Olliaro, P. Horby, E. Torreele, L. O. Gostin, M. Ndomondo-Sigonda, D. Carpenter, S. Rushton, L. Lillywhite, B. Devkota, K. Koser, R. Yates, R. S. Dhillon, and R. P. Rannan-Eliya. 2015. Global health security: The wider lessons from the West African Ebola virus disease epidemic. *Lancet* 385(9980):1884-1901.

IOM (Institute of Medicine). 2010. *Antibiotic resistance: Implications for global health and novel intervention strategies: Workshop summary*. Washington, DC: The National Academies Press.

ISARIC (International Severe Acute Respiratory and Emerging Infection Consortium). 2015. *Protocols and data tools*. https://isaric.tghn.org/protocols (accessed October 20, 2015).

Jamison, D. T., L. H. Summers, G. Alleyne, K. J. Arrow, S. Berkley, A. Binagwaho, F. Bustreo, D. Evans, R. G. A. Feachem, J. Frenk, G. Ghosh, S. J. Goldie, Y. Guo, S. Gupta, R. Horton, M. E. Kruk, A. Mahmoud, L. K. Mohohlo, M. Ncube, A. Pablos-Mendez, K. S. Reddy, H. Saxenian, A. Soucat, K. H. Ulltveit-Moe, and G. Yamey. 2013. Global health 2035: A world converging within a generation. *Lancet* 382(9908):1898-1955.

Kalil, A. 2015. *Selecting study designs to discover new therapies during infectious disease outbreaks*. Presentation made at "Global Health Risk Framework: Workshop on Research and Development of Medical Products," Hong Kong, China, August 20.

Kisoka, W. J., B. P. Tersbøl, D. W. Meyrowitsch, P. E. Simonsen, and D. L. Mushi. 2015. Community members' perceptions of mass drug administration for control of lymphatic filariasis in rural and urban Tanzania. *Journal of Biosocial Science* 48(1):1-19.

Muhumuza, S., A. Olsen, A. Katahoire, and F. Nuwaha. 2015. Understanding low uptake of mass treatment for intestinal schistosomiasis among school children: A qualitative study in Jinja district, Uganda. *Journal of Biosocial Science* 47(4):505-520.

Parker, M., and T. Allen. 2013.Will mass drug administration eliminate lymphatic filariasis? Evidence from northern coastal Tanzania. *Journal of Biosocial Science* 45(4):517-545.

Parker, M., T. Allen, and J. Hastings. 2008. Resisting control of neglected tropical diseases: Dilemmas in the mass treatment of schistosomiasis and soil-transmitted helminths in north-west Uganda. *Journal of Biosocial Science* 40(2):161-181.

Schopper, D., A. Dawson, R. Upshur, A. Ahmad, A. Jesani, R. Ravinetto, M. J. Segelid, S. Sheel, and J. Singh. 2015. Innovations in research ethics governance in humanitarian settings. *BMC Medical Ethics* 16:10.

Skerritt, J., J.C. de Moura Oliveira, A. Arora, G. Rasi, A. Rys, P. O'Mahony, L. Pani, T. Kondo, H. Hurts, M. C. M. Ling, M. Hela, I. Hudson, and M. Hamburg. 2015. The International Coalition of Medicines Regulatory Authorities (ICMRA). *WHO Drug Information* 29(1). http://www.who.int/medicines/publications/druginformation/WHO_DI_29-1_RegulatoryCollaboration.pdf (accessed November 15, 2015).

Sow, S. 2015. *Clinical assessment: Practical consideration and community engagement*. Presentation made at "Global Health Risk Framework: Workshop on Research and Development of Medical Products," Hong Kong, China, August 20.

Tindana, P. O., J. A. Singh, C. S. Tracy, R. E. G. Upshur, A. S. Daar, P. A. Singer, J. Frohlich, and J. V. Lavery. 2007. Grand challenges in global health: Community engagement in research in developing countries. *PLoS Medicine* 4(9):e273.

UNICEF (United Nations Children's Fund). 2015. *Communication for Development (C4D): Social mobilization*. http://www.unicef.org/cbsc/index_42347.html (accessed October 10, 2015).

WEF (World Economic Forum). 2015. Managing the risk and impact of future epidemics: Options for public–private cooperation. Geneva: WEF.

WHO (World Health Organization). 2010. *Main operational lessons learnt from the WHO pandemic influenza A(H1N1) vaccine deployment initiative*. http://www.who.int/influenza_vaccines_plan/resources/h1n1_vaccine_deployment_initiaitve_moll.pdf (accessed October 10, 2015).

WHO. 2011. *Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits*. Geneva: WHO. http://apps.who.int/iris/bitstream/10665/44796/1/9789241503082_eng.pdf (accessed October 10, 2015).

WHO. 2015a. *WHO R&D blueprint*. http://www.who.int/medicines/ebolatreatment/public_consult_platform-tech021115.pdf (accessed October 10, 2015).

WHO. 2015b. *Report of the SAGE working group on Ebola vaccines and vaccination with provisional recommendations for vaccination*. http://www.who.int/immunization/sage/meetings/2015/october/2_WHO_SAGE_WG_ebola_vaccines_and_immunization_MPP_VM_AMHR.pdf?ua=1 (accessed November 30, 2015).

WHO. 2015c. *WHO Ebola Research and Development Summit*. http://apps.who.int/iris/bitstream/10665/183557/1/WHO_EVD_Meet_HIS_15.3_eng.pdf (accessed December 3, 2015).

WHO. 2015d. *WHO publishes list of top emerging disease likely to cause major epidemics*. http://www.who.int/medicines/ebola-treatment/WHO-list-of-top-emerging-diseases/en (accessed December 15, 2015).

Yamada, T. 2009. Poverty, wealth and access to pandemic influenza vaccines. *New England Journal of Medicine* 361:1129-1131.

6
Building a Framework for Global Health Security

The world needs a stronger, more resilient framework for global health security. The Ebola crisis revealed deficiencies in almost every aspect of how we defend humankind against the threat of infectious diseases. Disease surveillance was inadequate, and outbreak alerts were slow. Local health systems were quickly overwhelmed. Local communities lost trust. The World Health Organization (WHO) was slow to respond and lacked capabilities and resources. The broader international response took too long and was poorly coordinated. There were gaps and shortfalls in diagnostics, therapeutics, vaccines, and protective equipment; there were inadequacies in logistics, communications, and governance. Ultimately, we will contain Ebola, but at far too great a cost in lives, resources, and economic disruption.

The next potential pandemic may be far more contagious and far more fatal. So, while the memories of Ebola are fresh—and we should not forget that the epidemic is not yet over—we should grasp the opportunity to shore up our defenses. We must create a global health risk framework capable of protecting human lives and livelihoods worldwide from the threat of infectious disease. We have neglected this aspect of global security for far too long.

First, we must recognize the scale of the risk. As we argued in Chapter 2, infectious diseases represent a massive threat to human life and economic well-being. Given the increasing rate of emergence of new infectious diseases and the increasing inter-connectivity of people and economic activity, the underlying risks and potential impact are probably increasing. We need to understand and counter the risks across the whole spectrum of infectious diseases—from emergence and outbreak to epidemics and, ultimately, pandemics. Second, we must acknowledge the degree to which we have neglected this risk. Compared with other threats to human security or economic security, such as war, terrorism, or financial crises, we have devoted far less resources to countering the threat of potential pandemics. We are underinvested and underprepared in almost every dimension, from national capacities and infrastructure to global capabilities and coordination to product research and development.

Creating a resilient framework that better protects humankind will require determined leadership. As we set out in Chapters 4 and 5, it will require leadership at the global level to make WHO much more effective, to enhance the role of the multilaterals and the United Nations in this arena, and to mobilize the funds required to improve the core capacities of poorer countries and accelerate research and development (R&D). As we outlined in Chapter 3, it will require leadership at the national government level to build and sustain effective public health infrastructure and capabilities as core foundation of the overall health system. If ensuring the security of the public is the first duty of a government, then protecting against infectious disease is a security imperative.

Creating this framework will also require money. We believe the global community should commit to spend about $4.5 billion[1] per year to rectify deficiencies in local health systems, enhance global capabilities and coordination, and accelerate R&D. This is not a small sum, but compared with the cost of potential pandemics, and compared with what we spend on other risks,

[1] All monetary figures in U.S. dollars.

the investment case is certainly compelling. Moreover, the framework we propose will yield benefits beyond countering the threat of infectious diseases. More resilient local health systems and a more effective global health architecture will also fortify against other pressing global health challenges, such as antimicrobial resistance (AMR) and endemic diseases like malaria.

Infectious diseases represent an enormous threat to humankind. Few other events can kill as many people or destroy an economy so quickly. We have neglected this risk. Our ability to identify, prevent, and respond to potential pandemics is full of flaws and weaknesses. Yet this is a solvable problem. With leadership and a commitment of roughly $4.5 billion per year, we can make the world much safer.

In this chapter, we gather the threads of the financing discussion to show how the figure of $4.5 billion is derived and how it could be sourced. We then close with a brief discussion of what should happen next.

THE OVERALL FINANCING CHALLENGE

To make the world much safer from the threat of pandemics, the global community should commit to investing roughly $4.5 billion per year in prevention, detection, and preparedness efforts, including research and development. Put differently, for an annual investment of approximately 65 cents per person, we could substantially improve our defenses against one of the biggest threats facing humankind.

To arrive at the figure of $4.5 billion in required incremental funding, we aggregated four components:

1. The upper end of the World Bank's 2012 estimated range of $1.9–$3.4 billion for the cost of upgrading national pandemic preparedness capabilities (World Bank, 2012).
2. Our proposed figure of $1 billion per year for infectious disease prevention and response R&D (see Chapter 5).
3. A 5 percent increase in the WHO core assessment to fund the Center for Health Emergency Preparedness and Response (CHEPR), which would amount to approximately $25 million per year (see Chapter 4).
4. A stylized funding cost of WHO's Contingency Fund for Emergencies (CFE) of roughly 25–30 percent, which assumes net funding costs of 2 percent and full drawdown on a non-repayment basis, plus subsequent replenishment of the fund every 4 years. For the proposed contingency fund of $100 million, this amounts to about $25–$30 million per year.[2]
5. A stylized funding cost of the World Bank's Pandemic Emergency Financing Facility (PEF) of 8–10 percent, based on an effective net funding cost of 2 percent plus annualized deployment costs of 6–8 percent, assuming that PEF loans are made as a mixture of concessionary loans and grants every 4 years; or, alternatively, that the PEF is funded through an insurance mechanism with premiums around this level. For the proposed PEF of $1 billion, this amounts to about $80–$100 million per year.[3]

The amount of incremental spending proposed is not precise, for four principal reasons.

First, we do not have a robust assessment of the gaps in national core capacities for infectious disease prevention and detection. The World Bank's 2012 estimate of $1.9–$3.4 billion was the result of a very extensive process of consultation and data gathering around what would be needed to upgrade low- and middle-income countries' capacities to the level required to be compliant with International Health Regulations (IHR) (World Bank, 2012). This is obviously quite a wide range, and it excludes any upgrading that might be required in more advanced economies, as well as investments in health systems that extend beyond those strictly required by the IHR guidelines. It also excludes increases in relevant spending at a national level since 2012, including the international response to the Ebola epidemic and the Global Health Security Agenda.

[2] Annualized funding costs for the CFE and PEF were calculated using the following assumptions. For the CFE, net funding costs were estimated at 2 percent (calculated as 3 percent minus 1 percent yield on undeployed funds), and all funds were assumed to be spent in year 4. Thus, over a 4-year cycle, a $100 million contingency fund would cost 100 × .02 × 4 = $8 million. Further, assuming that the full $100 million is spent over a 4-year cycle, this brings the total to $108 million, annualized as $27 million.

[3] For the PEF, net funding costs were again estimated at 2 percent, and the full amount of the fund ($1 billion) was assumed to be loaned out every 4 years, for 1 year (i.e., to year 5). Thus, the funding cost over 5 years for the PEF is 1,000 × .02 × 5 = $100 million. Note that this approach treats money loaned in year 5 as new money, because the first tranche will be deployed at end of year 4. Additionally, we deduct the return on investment for the year in which the funds are disbursed, adding 1,000 × .03 × 1 = $30 million. Finally, we allow for 25–35 percent of the value of the $1 billion fund being written off every time it is deployed, totalling $250–$350 million. These inputs give a 5-year cost of $380–$480 million, annualized to $74–$96 million.

Second, much of the incremental spending on national health systems relates to capabilities and infrastructure (such as laboratory networks and surveillance tools) that are also required to mount an effective response to other health issues, such as AMR and endemic diseases like malaria. As a consequence, the World Bank's estimate of the cost of upgrading health systems capabilities effectively double-counts the cost of some components.

Third, some elements of the incremental spending proposed are necessarily subjective, with a large element of uncertainty in their determination. This is most obvious with the proposals for incremental expenditure on the R&D component. We are confident that it makes sense to spend more than is currently being allotted to product R&D in the infectious disease arena, and that the increase in expenditure would have to be substantial in order to make any meaningful difference. However, there is clearly no formula that converts a quantum of incremental investment into specific product outcomes with certainty. That said, comparison with other publicly funded R&D efforts suggests that our figure of $1 billion is not unreasonable. For example, global funding for HIV prevention research was $1.25 billion as of 2014 (RTWG, 2015).

Finally, the cost of the WHO contingency fund and the World Bank PEF depend on the financing structure, how often they are utilized (and subsequently replenished), and whether the funds are deployed as loans or grants. As a result of this uncertainty, we have made stylized estimates of their annualized costs to enable us to create an overall aggregate figure for the cost of these funding facilities. However, when compared with our proposals for annual spending on health systems strengthening and R&D, these numbers are relatively small contributors to the overall cost figure. As a result, the impact of this uncertainty on the total will be small.

These considerations and caveats notwithstanding, providing an indicative single overall figure—$4.5 billion per year—gives a sense of the scale of the financing challenge. Moreover, this number is grounded in current best evidence as to the costs of health systems improvement and is comparable to other R&D efforts of comparable scale.

There are good reasons to believe that investment to reduce the global threat posed by pandemics represents exceptional value for money, when health and economic returns on investment are considered. Analysis of the response to the Ebola outbreak in Sierra Leone highlights the health gains that come from being able to respond more rapidly to infectious disease outbreaks. A recent study found that international support to Sierra Leone helped avert more than 50,000 cases of Ebola, with the potential to avert a further 12,500 had this support been mobilized 1 month earlier (Kucharski et al., 2015). Considering only the benefits to economic growth (rather than human life), estimates by the World Bank suggest that investment to strengthen national health systems to IHR standards would yield a positive return on investment in all plausible scenarios (World Bank, 2012). Likewise, swift deployment of funds to fight an outbreak can yield extraordinary returns. For example, Nigeria spent approximately $13 million responding to the Ebola outbreak, and, while Guinea, Liberia, and Sierra Leone each lost several percentage points of gross domestic product (GDP) as a result of Ebola, Nigeria suffered minimal economic losses (World Bank, 2014). A 2 percent reduction in Nigeria's 2014 GDP would have translated to an economic loss of nearly $12 billion (World Bank, 2015).

Set against the scale of the threat to lives and the global economy, there is a compelling case for investing the incremental $4.5 billion per year we propose to prevent, detect, and better prepare to respond to pandemics. Even if the investments we recommend were to reduce our estimate of the expected economic loss from pandemics of more than $60 billion by only 10 percent, which seems extremely conservative, spending $4.5 billion per year would reduce expected losses by more than $6 billion. Moreover, as argued earlier, these investments would also contribute to the achievement of other health goals, such as countering the threat of AMR and containing endemic diseases like malaria and tuberculosis.

Set in contrast to what the world spends on other risks to human lives and livelihoods, the case gets even stronger. As we pointed out in Chapter 2, the risk is not that that we will spend too much; the risk is that we will continue to spend too little—with potentially disastrous consequences.

In the rest of this section, we briefly summarize the approach to determining each of these five components of expenditure and present potential funding options.

Financing Stronger National Core Capacities

In Chapter 3, we argued that reinforcing core capacities and infrastructure at the national level so that countries

are better able to prevent infectious disease outbreaks (or detect outbreaks and respond before they escalate to the level of an epidemic or pandemic) is a top priority. Doing so will require significant incremental expenditure and is the largest component of our recommendations.

As explained in Chapter 3, estimating the scale of the required incremental investment is difficult, because information about each country's current status is far from perfect and benchmark definition is insufficiently precise. The best analysis of the costs of reinforcing national capabilities and infrastructure to achieve IHR compliance stems from a World Bank (2012) study, *People, Pathogens and Our Planet*. This study concluded that achieving compliance for low- and middle-income countries would cost $1.9–$3.4 billion per year.

In considering how to meet this gap, a key requirement is sustainability. Health systems resilience is an ongoing commitment, not a one-off effort. Moreover, given that it is the foundation of health security, spending on public health infrastructure and capabilities should be seen as a central component of national security expenditures, an integral part of a government's fundamental duty to protect its people. As set out in Chapter 3, we therefore recommend:

- High-income and upper-middle-income countries must make achievement of the IHR core capacities a core part of the government's expenditure. Civil society can hold governments accountable through the mechanism of independent assessment described in Chapter 3. Such countries should also establish emergency contingency funds.
- Lower-middle-income and low-income countries should determine, in dialogue with multilateral and bilateral partners, the appropriate balance of domestic resource mobilization and external support (which might be directed at helping upgrade capabilities and infrastructure, contingent on local governments' commitments to maintain support thereafter). The World Bank should work with other multilaterals and bilateral donors to catalyze and coordinate such support.
- For fragile and failed states, the UN, the World Bank, and WHO should work together to determine appropriate strategies for sustaining health systems infrastructure and capabilities to the extent possible.

Across all countries, incremental investment in health systems should be guided by:

- a clear definition of the core capacities required (as set out in Recommendation B.1);
- rigorous, objective, and transparent assessment of current performance against these defined capacities (as envisioned in Recommendation B.2); and
- clear and detailed plans to rectify gaps, including the costs of upgrading core capacities and a model for fulfilling the funding needs (as required by Recommendation B.6).

Funding Stronger Global Coordination, Preparedness, and Response

In Chapter 4, we argued that, in addition to reinforcing national capabilities and infrastructure, it is necessary to strengthen regional and global capacities to enable better coordination and response. Among other things, we recommend the formation of the WHO CHEPR and support the establishment of the WHO CFE and the World Bank's PEF. These three elements require the following incremental financing:

- WHO CHEPR: Although the discussion around WHO's core funding involves considerations beyond the remit of this Commission, we recommend that the CHEPR be financed through an increment to assessed contribution, rather than via voluntary contributions, because we see the CHEPR as essential to WHO's fulfillment of a core part of its mandate. We have not sought to develop an independent estimate of the incremental funding requirement for the CHEPR, but have taken as an estimate the 5 percent figure suggested by the Report of the Ebola Interim Assessment Panel (WHO, 2015a) and consistent with the additional funding for "preparedness, surveillance and response" in WHO's Proposed Programme Budget for 2016–2017 (WHO, 2015b). This amounts to about $25 million per year.
- WHO CFE: We support the creation of WHO's CFE as a highly flexible, immediately available fund of $100 million. As outlined in Chapter 4, we believe the most appropriate way of funding the CFE would be through one-off initial contributions, assessed pro rata with the core assessed contributions, in the form of either actual cash contributions or binding contingent commitments.

- World Bank PEF: We also support the creation of the World Bank's PEF of $1 billion. As with WHO's CFE, we see binding contingent commitments as being the most cost-effective way of funding this facility, although we recognize that such mechanisms can pose problems for some partner governments. Innovative insurance and capital market solutions could be attractive, if demonstrated to be economic and practical.

Financing Accelerated Product Research, Development, and Delivery

In Chapter 5, the Commission recommends targeting incremental spending of $1 billion per year to reinforce the global ability to respond to infectious disease threats through science. The objectives are to enhance our capacity to detect infectious disease outbreaks through better diagnostics, strengthen our ability to control such outbreaks through better containment and protection tools, and accelerate our ability to respond through faster development and deployment of vaccines and therapeutics. This differs from conventional pharmaceutical R&D, in a number of ways:

- It includes equipment, instruments, and tools, such as low-cost diagnostic kits, surveillance systems, protective equipment, and delivery mechanisms.
- It incorporates investment and innovation in product development infrastructure to facilitate accelerated clinical trials and approval processes.
- It encompasses sustainment of flexible manufacturing capacity and deployment mechanisms, because rapid scale-up of vaccine manufacture and quick delivery to the field are likely to be critical.

The figure of $1 billion is indicative rather than precise. The scope and priorities of the overall program will have to be defined by the Pandemic Product Development Committee (PPDC) we describe in Chapter 5. This will also have to take account of concurrent initiatives, such as the proposed Global Vaccine-Development Fund and AMR efforts. Yet while the $1 billion figure might be indicative, the need for significantly greater spending is definitive. Ebola revealed deficiencies in many aspects of our product armory, including diagnostics, protective equipment, therapeutics, and vaccines—and we have known about Ebola for nearly 40 years.

We anticipate that the $1 billion will comprise a mixture of pooled funding, from which contributors will delegate deployment to the PPDC, and coordinated funding, where contributors retain control over funds deployment but collaborate through the PPDC to achieve better coordination. The Commission envisions that the $1 billion for R&D could be drawn from five potential sources:

1. direct contributions from national governments, foundations, and the private sector;
2. from R&D budgets devoted to national security;
3. from existing public, philanthropic, and university R&D budgets in the health arena;
4. by catalyzing private-sector R&D; and
5. by generating new sources of private finance from outside the health care sector, such as the life insurance, travel, and tourism and meat and poultry trade sectors. Here, there is scope for exploring innovative financing solutions.

Conclusion on Financing

The Commission believes that there is a powerful argument for committing greater resources to counter the threat of pandemics. For around $4.5 billion per year, we could make the world much safer. At more than $3 billion, by far the biggest component of this incremental spending arises from the imperative to upgrade the public health infrastructure and capabilities of national health systems. We are convinced that greater investment in prevention, identification, and preparedness offers compelling returns. Most of this funding should derive from local domestic resources, both because health security should be a key priority for any government and because this will ensure long-term sustainability. However, low- and lower-middle-income countries, as well as failed and fragile states, will require international support to fill the gaps in required infrastructure and capabilities. The second largest component of the $4.5 billion is the proposed incremental $1 billion for product R&D. To have stronger weapons with which to fight new or reemerging infectious diseases, we need to step up the pace of R&D, and do so in a coordinated manner. Finally, there is the need to reinforce and refocus WHO, so that it can play a more effective leadership role, and to ensure that WHO and the World Bank are ready and able to deploy funds quickly when a crisis occurs.

REVERSING NEGLECT: THE CHALLENGE OF ACTION

Pandemics represent too big a threat to ignore. Yet the world has largely done so. Taking a hard look at what we have actually achieved in terms of prevention, preparedness, and response, it is hard to escape the conclusion that we have neglected this aspect of global security. The time has come to reverse this. Doing so will require determined leadership, funding, and collaboration. We must seize this opportunity to make the world safer.

Yet we know that political commitment to devoting resources to such a task will wane as memories of the last infectious disease crisis fade. This is why we believe global leaders should commit now to commissioning an independent report in 2017, and again 3 years later. This is how we can be held accountable for what we deliver and what we let slip.

The actions we recommend are achievable. The funding we envision remains a fraction of what is spent on other risks. A much stronger, more resilient global framework to combat the threat of infectious disease is within our reach. The challenge is whether we have the leadership to make it happen.

REFERENCES

Kucharski, A. J., A. Camacho, S. Flasche, R. Glover, W. J. Edmunds, and S. Funk. 2015. Measuring the impact of Ebola control measures in Sierra Leone. *Proceedings of the National Academy of Sciences* 112(46):1436-1437.

RTWG (HIV Vaccines & Microbicides Resource Tracking Working Group). 2015. *HIV prevention research & development funding trends, 2000–2014: Investing in innovation in an evolving global health and development landscape*. New York: AVAC. http://www.avac.org/resource/hiv-prevention-research-development-funding-trends-2000-2014-investing-innovation-evolving (accessed January 4, 2016).

WHO (World Health Organization). 2015a. *Report of the Ebola interim assessment panel—July 2015*. Geneva: WHO.

WHO. 2015b. *Proposed programme budget 2016-2017*. http://apps.who.int/gb/ebwha/pdf_files/WHA68/A68_7-en.pdf (accessed November 20, 2015).

World Bank. 2012. *People, pathogens and our planet: Volume 2—the economics of One Health*. Washington, DC: World Bank.

World Bank. 2014. T*he economic impact of the 2014 Ebola epidemic: Short and medium term estimates for West Africa*. Washington, DC: World Bank.

World Bank. 2015. Data: Nigeria. http://data.worldbank.org/country/nigeria (accessed November 20, 2015).

Appendix A
Public Session Agenda

July 29, 2015
National Academy of Sciences Building
2101 Constitution Avenue, Lecture Room
Washington, DC

Objectives:

- The International Oversight Group will present the Statement of Task to the Commission and make any clarifications if needed.
- The expert panel will address issues of governance, finance, resilient health systems, and medical products research and development when responding to infectious disease outbreaks of international concern at the global, regional, national, and local levels. The Commission will consider the different perspectives presented as they develop the approach for this study.

9:00–9:05 am	**Opening Remarks** *Peter Sands*, Commission Chair
9:05–10:00	**Background of the Initiative** *Victor Dzau*, President, National Academy of Medicine; Chair, International Oversight Group (IOG)
	Reflections from IOG Members *Hugh Chang*, Director, Strategy, Planning & Management for Global Development, Gates Foundation [by video-teleconference] *Shigeru Omi*, President, Japan Community Health Care Organization [by phone] *Tan Chorh Chuan*, President, National University of Singapore; IOG member [by phone]
	Charge to the Commission *Judith Rodin*, President of The Rockefeller Foundation; Vice-Chair of the IOG
	Q and A from Commission
10:00–10:40	**Landscape of Other Global Initiatives** *Ramesh Rajasingham*, United Nations High Level Panel on Global Response to Health Crises

Barbara Stocking [by video-teleconference] and *Ilona Kickbusch*,
Independent Panel to Assess World Health Organization's (WHO's) Response to Ebola

Q and A from Commission

10:40–10:50 **Break**

10:50 am–1:00 pm **Panel: Lessons Learned on Issues of Governance, Finance, Resilient Health Systems, and Medical Product Research and Development on the Preparedness and Response to Infectious Disease Outbreaks of International Concern**

This panel will inform the commission about key challenges and lessons learned for the preparedness and response to infectious disease outbreaks of international concern. Specifically, the panelists will respond the following questions:

- What were the key issues on governance, finance, resilient health systems, and medical products research and development that were the most challenging to overcome for your organization/country/community when responding to an infectious disease outbreak of international concern?
- Are there any key lessons learned from past outbreaks or health emergencies that you have been able to implement in your response and that have improved the control of epidemics?
- What are the most important aspects or evidence that this commission should consider throughout the course of the study?

10:50 **Introduction to the Panel**
Patrick Kelley, Director, Board on Global Health, National Academies of Sciences, Engineering, and Medicine

11:00 **The United Nations Response**
David Nabarro, United Nations Special Envoy on Ebola [video presentation]

11:15 **The World Health Organization's Role**
Christopher Dye, WHO Team Lead for Epidemiology and Information Management in the Ebola Response

11:30 **Preparedness and Response at the Regional Level**
Ron St. John, Consultant, WHO MERS Incident Manager

11:45 **The National Government's Capacity to Detect and Respond to a Public Health Emergency of International Concern**
Stephen Gaojia, Head of the Ebola Emergency Operations Centre, Sierra Leone

12:00 pm **Role of Communities—Achieving Real Community Understanding and Ownership of the Response**
Juliet Bedford, Anthrologica

12:15	**The Role of the Private Sector—The World Economic Forum Report "Managing the Risk and Impact of Future Epidemics: Options for Public–Private Cooperation"** *Trish Stroman*, The Boston Consulting Group
12:30	**Q and A from the Commission and IOG members**
1:00	**Adjournment of Public Session** *Peter Sands*, Commission Chair

Appendix B
Workshop Agendas

HEALTH SYSTEMS WORKSHOP

August 5–7, 2015
La Palm Royal Beach Hotel
Accra, Ghana

Wednesday, August 5, 2015 (Day 1)

8:30–8:50 am **Welcome**
Michael Myers, Managing Director, The Rockefeller Foundation; Co-Chair, Workshop Planning Committee
Francis Omaswa, Executive Director of the African Centre for Global Health and Social Transformation; Co-Chair, Workshop Planning Committee

Opening Remarks
Aba Bentil Andam, Vice President, Ghana Academy of Arts and Sciences Representative

8:50–9:10 **Overview of the National Academy of Medicine's Global Health Risk Framework Initiative**
Patrick Kelley, Director, Board on Global Health, Institute of Medicine (IOM), USA

Session I: Opening Plenary: Lessons from a Historical Perspective
Session Moderator: *Gabriel Leung*, Dean, Li Ka Shing Faculty of Medicine, The University of Hong Kong; Workshop Planning Committee

9:10–10:30 **Case Study Panel Presentation**
Rob Fowler, Physician, University of Toronto, Canada
Jane Ruth Aceng, Director General of Health Services, Ministry of Health, Kampala, Uganda
Trish M. Perl, Division of Infectious Diseases, Department of Medicine, Johns Hopkins University, USA

10:30–11:00 **Break**

Session II: Building Health Systems Resilience
Session Moderator: *Francis Omaswa*

11:00–11:45 **Building Sustainable Health Resilience: A Systems Approach**
Michael Myers

11:45 am–12:30 pm **Discussion with Attendees and Case Study Panelists**

12:30–1:30 **Lunch**

Session III: Focus Area Discussions

1:30–3:30 **Breakout Discussions by Focus Area**

Focus Area 1: Disease Surveillance Systems
Facilitators: *David Fitter,* Epidemiologist, Emergency Response and Recovery Branch, U.S. Centers for Disease Control and Prevention (CDC)
Oyewale Tomori, President, Nigerian Academy of Science; Workshop Planning Committee

Focus Area 2: Local and Regional Workforce Capacity
Facilitator: *Stella Anyangwe*, Honorary Professor in Epidemiology, School of Health Systems and Public Health, University of Pretoria

Patrick M. Nguku, African Field Epidemiology Network, Nigeria Field Epidemiology and Laboratory Training Program
Abdulsalami Nasidi, Director General, Nigerian Centre for Disease Control
Jim Campbell, Director, Health Workforce, World Health Organization (WHO) Executive Director, Global Health Workforce Alliance

Focus Area 3: Health Care and Public Health Integration
Facilitator: *P. Gregg Greenough*, Research Director, Harvard Humanitarian Initiative, Harvard School of Public Health

Koku Awoonor-Williams, Regional Director of Health Service for the Upper East Region of Ghana

Focus Area 4: Community Engagement
Facilitator: *Ben Adeiza Adinoyi*, Africa Zone Health and Care Coordinator, International Federation of Red Cross and Red Crescent Societies; Workshop Planning Committee

Mosoka Fallah, Co-Principal Investigator: Ebola Natural History Study; US-Liberian Research Partnership/NIAID, Liberia
Janet Nakuti, Senior Program Officer, Monitoring and Documentation, Raising Voices, Kampala Uganda

3:30–4:00 **Break**

Session IV: Plenary: Report Out
Session Moderator: *Michael Myers*

4:00–4:45	**Report Out by Facilitators**
4:45–5:30	**Large Group Discussion**
5:30	**Adjourn**
5:30–7:00	**Reception**

Thursday, August 6, 2015 (Day 2)

8:30–8:45 am **Welcome**
Michael Myers
Francis Omaswa

Opening Remarks
Delanyo Dovlo, Director, Health Systems and Services Cluster, WHO Africa Regional Office

Session V: Cross-Sector Engagement in Building Systems to Support Health
Session Moderator: *Ann Marie Kimball*, Senior Consulting Fellow, Royal Institute of Foreign Affairs, Chatham House; Workshop Planning Committee

8:45–10:15 **Panel Discussion: Cross-Sector Engagement**

Public Health
Peter Lamptey, Distinguished Scientist and President Emeritus, FHI360

Mental Health
Inge Petersen, Professor of Psychology, University of KwaZulu-Natal, South Africa

Health Care
Kumanan Rasanathan, Senior Health Specialist, United Nations Children's Fund (UNICEF)

Business/Private Sector
Graham Davidson, Managing Director, Simandou Project, Guinea, Rio Tinto
Nana Yaa Afriyie Ofori-Koree, Foundation and Sustainability Manager, Vodafone Ghana Foundation

Nongovernmental Organization (NGO)/Civil Society
Saran Kaba Jones, Founder and Executive Director, FACEAfrica, Liberia

10:15–10:45 **Break**

10:45–11:45 **Discussion with Attendees: Reaction to Panel Discussion**

11:45 am–12:45 pm **Lunch**

Session VI: Focus Area Discussions

12:45–3:15 **Breakout Discussions by Focus Area**

Focus Area 1: Health Information Systems
Facilitator: *Paul Biondich*, Research Scientist, Regenstrief Institute, Inc.

Kate Wilson, Director of Digital Health Solutions, PATH, USA

Focus Area 2: Incorporating Global Reserve Teams on the Ground
Facilitator: *Jim Campbell*

Ian Norton, Foreign Medical Teams Working Group, WHO, Australia
Lewis Rubinson, Director, Critical Care Resuscitation Unit, University of Maryland, USA

Focus Area 3: Health Care Delivery and Supply Chain
Facilitator: *David Sarley*, Senior Program Officer, The Bill & Melinda Gates Foundation

Lloyd Matowe, Director, Pharmaceutical Systems Africa
Raj Panjabi, CEO of Liberian NGO Last Mile Health

Focus Area 4: Leadership and Management
Facilitator: *Dan Hanfling*, Contributing Scholar, University of Pittsburgh Medical Center, USA

Ali Ardalan, Associate Professor and Chair, Disaster and Emergency Health Academy, Tehran University of Medical Sciences, Iran

3:15–3:30 **Break**

Session VII: Plenary: Report Out
Session Moderator: *Francis Omaswa*

3:30–4:30 **Report Out by Facilitators**

4:30–5:15 **Large Group Discussion**

5:15 **Adjourn**

Friday, August 7, 2015 (Day 3)

9:00–9:15 am **Welcome**
Michael Myers
Francis Omaswa

Session VIII: Synthesizing Components to Build Resilient Health Systems
Session Moderators: *Michael Myers*
Francis Omaswa

9:15–9:45	**Building Integrated, Sustainable, and Resilient Health Systems—Reflections from the Workshop Planning Committee** Planning Committee Panelists *David Fitter* *Ann-Marie Kimball* *Ben Adeiza Adinoyi* *Aba Bentil Andam*
9:45–10:15	**Discussion with Attendees**
10:15–10:30	**Break**
10:30–11:30	**Building Integrated, Sustainable, and Resilient Health Systems—A Reaction Panel** *Peter Lamptey* *Raphael Frankfurter*, Executive Director, Wellbody Alliance *Delanyo Dovlo* *Daniel López-Acuña*, Former Director for Recovery and Transition, Cluster of Health Action in Crisis, WHO *Marie Claire Tchecola*, Nurse, Donka Hospital, Conakry, Guinea (Translation by Pascale Krumm, Health Communications Office, CDC)
11:30 am–12:00 pm	**Wrap Up and Discussion with Attendees**
12:00	**Closing Remarks** *Patrick Kelley* *Michael Myers* *Francis Omaswa*
12:15	**Workshop Adjourned**

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RESEARCH AND DEVELOPMENT OF MEDICAL PRODUCTS WORKSHOP

August 19–21, 2015
Cheung Kung Hai Conference Centre
Hong Kong

Wednesday, August 19, 2015 (Day 1)

8:40 am	**Welcome** *Gabriel Leung*, Li Ka Shing Faculty of Medicine, The University of Hong Kong *Victor Dzau*, National Academy of Medicine

Keynote Lecture
Margaret Chan, WHO

Session I: Incentives and Development Models
Moderator: *Tachi Yamada*, Frazier Life Sciences

Objectives:

- Review existing incentives, business models, and partnership approaches that support the research and development of medical products for emerging infectious diseases.
- Identify shortcomings in existing regulatory and financial incentives, and highlight promising ideas for improvements that can help advance the development of medical products for emerging infectious diseases.
- Discuss challenges to building and sustaining more effective business models and public private partnerships; explore promising approaches and identify key attributes of a well working collaborative approach.

9:30 **Segment A: Existing and Promising Incentives**

Keynote Lecture
BT Slingsby, Global Health Innovative Technologies Fund

Panel Discussion
Lynn Marks, GlaxoSmithKline
Rajeev Venkayya, Takeda Pharmaceuticals
Kevin Outterson, Boston University

10:50 **Break**

11:00 **Segment B: Sustainable and Effective Business Models and Public–Private Partnerships**

Keynote Lectures
David Reddy, Medicines for Malaria Venture
Krishna Ella, Bharat Biotech International Limited

Panel Discussion
Mel Spigelman, TB Alliance
Graeme Bilbe, Drugs for Neglected Diseases Initiative
Peter Dull, The Bill & Melinda Gates Foundation

12:30 pm **Lunch**

Session 2: Science and Regulatory Convergence and Capacity
Moderator: *Maria Freire*, Foundation for the National Institutes of Health

Objectives:

- Review and characterize the needs and gaps in current scientific tools, technologies, and capacities to develop and evaluate products.

- Highlight promising common platforms to enable nimble and rapid development and evaluation of products.
- Discuss whether and how discordant regulatory specifications hinder efficient development and evaluation of medical products, and possible approaches for convergence.
- Characterize the critical needs of country regulatory authorities in times of public health emergency and discuss potential strategies regulators and international organizations can take to help address these needs.
- Discuss potential strategies for encouraging the sharing of knowledge, clinical, and clinical trial data to speed clinical assessment of investigational products for emerging infectious disease.

1:30 **Segment A: State of the Science**

Keynote Lectures
Michael Pfleiderer, Paul-Ehrlich-Institut, Federal Institute for Vaccines and Biomedicines
Trevor Mundel, The Bill & Melinda Gates Foundation

Panel Discussion
Margaret Hamburg, National Academy of Medicine
Rudi Pauwels, BioCartis NV
Charles Goldstein, Becton Dickinson
Adel Mahmoud, Princeton University
Craig E. Colton, 3M Personal Safety Division

3:00 **Segment B: Sharing of Data and Reagents, Intellectual Property and Liability**

Keynote Lecture
Anthony So, Duke University

Panel Discussion
Michelle Mulder, South African Medical Research Council
Lynn Marks, GlaxoSmithKline
Reid Adler, Practical Innovation Strategy

4:20 **Break**

4:30 **Segment C: Global Regulatory Convergence and Capacity**

Keynote Lectures
Margaret Hamburg
Hans-Georg Eichler, European Medicines Agency

Panel Discussion
Raymond Chua, Singapore Health Sciences Authority
Mike Ward, WHO

6:00 **Adjourn**

Thursday, August 20, 2015 (Day 2)

Session 3: Clinical Assessment
Moderator: *Maria Freire*

Objectives:

- Examine barriers to the clinical assessment of the safety and efficacy of investigational medical products in communities experiencing a public health emergency from an emerging infectious disease.
- Discuss a framework for determining when investigational products should be subjected to controlled clinical assessment and when they should be used more broadly under other mechanisms.
- Describe responsible and adaptive clinical trial designs that could be developed for use in times of public health emergencies and discuss ethical considerations associated with the possible options.
- Consider ethical and methodological standards that may be used to determine optimal trial designs for assessing the readiness of investigational medical products prior to broader deployment during public health emergency.
- Highlight strategies for engaging communities during times of public health emergency to determine how and when to undertake controlled clinical assessment and, where trials are used, to facilitate rapid and fair enrollment in trials for investigational products.

9:00 am **Segment A: Ethical Principles and Methodological Framework for Clinical Trial Designs**

Keynote Lectures
Andre Kalil, University of Nebraska Medical Center
Fred Binka, University of Health and Allied Sciences, Ghana

Panel Discussion
Luciana Borio, U.S. Food and Drug Administration (FDA) (via video conference)
Paul Stoffels, Johnson & Johnson
Mike Levine, University of Maryland School of Medicine
Peter Kilmarx, Fogarty International Center, National Institutes of Health
Rob Califf, U.S. FDA (via video conference)

11:00 **Break**

11:10 **Segment B: Practical Considerations and Community Engagement**

Keynote Lecture
Samba Sow, Center for Vaccine Development, Mali

Panel Discussion
Joan Awunyo-Akaba, Future Generations International, Ghana
Beth Bell, U.S. CDC
Fred Binka

12:30 pm **Lunch**

Session 4: Manufacturing, Stockpiling and Deployment
Moderator: *Tachi Yamada*

Objectives:

- Characterize the needs and gaps in current manufacturing, stockpiling, and supply chain mechanisms for medical product development and deployment during public health emergencies.
- Highlight promising approaches for delivery and deployment of products that are manufactured outside of an affected region during public health emergencies.
- Discuss the ethical considerations of different manufacturing approaches and deployment capabilities.

1:30 **Segment A: Manufacturing and Stockpiling**

Keynote Lecture
Rajeev Venkayya, Takeda Pharmaceuticals

Discussion Panel
Krishna Ella, Bharat Biotech International Limited
Shanelle Hall, UNICEF

2:50 **Break**

3:00 **Segment B: Supply Chain Mechanisms and Deployment**

Keynote Lecture
David Ripin, Clinton Health Access Initiative (CHAI)

Discussion Panel
Shanelle Hall
Rajeev Venkayya

4:00 **Adjourn**

Friday, August 21, 2015 (Day 3)

Session 5: Top Priorities for Facilitating Medical Product Research and Development
Moderators: *Maria Freire*
Tachi Yamada

Objectives:

- Examine the ethical and practical considerations for setting priorities to facilitate medical product research, development, and availability.
- Discuss potential strategies for developing a structure and process to select priorities for medical product research, development, and availability.
- Discuss potential strategies for encouraging collaboration and information sharing among private companies to speed research and development for top priorities.
- Explore how to align regulatory considerations, development milestones, and financing models for designated top priorities.

9:00 am **Summary Lecture**
Tachi Yamada

Panel Discussion
Robin Robinson, Biomedical Advanced Research and Development Authority, U.S. Department of Health and Human Services (via video conference)
Peter Kilmarx
Paul Stoffels
Glenda Gray, South African Medical Research Council

11:20 **Closing Remarks**
Ceci Mundaca-Shah, National Academies of Sciences, Engineering, and Medicine

11:30 **Adjourn**

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PANDEMIC FINANCING WORKSHOP

August 27–28, 2015
National Academy of Sciences Building
2101 Constitution Avenue NW
Washington DC

Thursday, August 27, 2015 (Day 1)

8:00–8:30 am **Breakfast available**

Session I: Welcome and Overview
Objective: To introduce the agenda and give an overview of the workshop's key themes.

8:30–9:00 **Welcome and Introductions**
Prashant Yadav, Vice President and Senior Research Fellow, William Davidson Institute, University of Michigan
Victor Dzau, President, National Academy of Medicine

9:00–10:30 **International Cooperative Action on Pandemics**
Moderator: *Olga Jonas*, Economic Adviser and Coordinator, Operational Response to Avian and Pandemic Influenzas, World Bank

Gordon Woo, Catastrophist, Risk Management Solutions
Jordan Tappero, Director Division of Global Health Protection, U.S. CDC
Eduardo González Pier, Vice Minister Integration and Development, Ministry of Health, Mexico
Aron Betru, CEO, Financing for Development

10:30–10:45 **Break**

Session II: Marshaling Funding for Preparedness and Response

Objective: To discuss different options for making funding available in low- and middle-income countries during a pandemic and the circumstances that favor certain options over others.

10:45–11:45 **Pandemic Emergency Funds: The WHO Contingency Fund, the World Bank, and IMF Financing Facilities**

Moderator: *Peter Sands*, Former Group CEO, Standard Chartered PLC

Katherine DeLand, Chief of Staff, Ebola Response, WHO
Chris Lane, Division Chief, Low-Income Countries Strategy, Policy and Review, IMF
Priya Basu, Manager, Development Finance, The World Bank Group

11:45 am–1:15 pm **Adapting Insurance Products for Pandemic Risk**

Moderator: *Panos Varangis*, Global Lead, Agricultural Finance and Disaster Risk Finance, Finance and Markets Global Practice, IFC

Olivier Mahul, Program Manager, Disaster Risk Financing & Insurance, World Bank
Nikhil da Victoria Lobo, Head, Global Partnerships, Americas, Swiss Re
Simon Young, GeoSY Ltd.
José Ángel Villalobos, Senior Insurance Specialist, World Bank
Gunther Kraut, Financial Solutions Life, Munich Re (by video)

1:15–2:15 **Lunch**

2:15–3:45 **Innovative Financing for Preparedness and Response**

Moderator: *Juan Costain*, Lead Financial Specialist, World Bank

Paolo Sison, Director Innovative Finance, Gavi, The Vaccine Alliance
Christopher Egerton-Warburton, Partner, Lion's Head Global Partners
Lelio Marmora, Executive Director, UNITAID
Adam Bornstein, Specialist Innovative Health Financing, The Global Fund

3:45–4:00 **Break**

Session III: Identifying Triggers and Modelling Risk

Objective: To discuss a verifiable trigger for payout and a suitable group to adjudicate triggers, to understand what models can tell us about pandemic risk.

4:00–5:30 **Modelling and Triggers for Payout**

Moderator: *Prashant Yadav*

Nathan Wolfe, CEO, Metabiota
Martin Meltzer, Lead, Health Economics and Modeling Unit, U.S. CDC
Gordon Woo
Nita Madhav, Principal Scientist, Research and Modelling, AIR Worldwide

5:30 **Adjourn**

All participants and guests are invited to a reception in the Great Hall immediately following the meeting.

6:30 **Dinner in the National Academy of Sciences Building for speakers, moderators, and invited guests**

Friday, August 28, 2015 (Day 2)

8:30–9:00 am **Breakfast available**

9:00–9:15 **Welcome and Overview**
Prashant Yadav

Session IV: Management and Administration of Funds
Objective: To understand the constraints on donors and discuss how financial tools can be designed to encourage risk sharing and crowding in; to discuss the administrative burden emergency payments place recipient country governments.

9:15–10:45 **Financing Challenges In-Country**
Moderator: *Peter Sands*

Tendai Biti, Former Minister of Finance, Zimbabwe
Gordon Liu, Yangtze River Scholar, Professor of Economics, National School of Development, Peking University
Victor Bampoe, Deputy Minister of Health, Ghana
James Kollie, Deputy Minister for Fiscal Affairs, Ministry of Finance and Development Planning, Liberia

10:45–11:00 **Break**

11:00 am–12:30 pm **Donor Considerations and Crowding-In**
Moderator: *Trish Stroman*, Partner and Managing Director, BCG

Tore Godal, Special Advisor, Office of the Prime Minister, Norway
Jennifer Adams, Deputy Assistant Administrator, Bureau for Global Health, USAID
Gargee Ghosh, Director Development Policy and Finance, The Bill & Melinda Gates Foundation
Erin Hohlfelder, Policy Director Global Health, ONE Campaign

12:30–1:30 **Lunch**

Session V: Financing Preparedness and Giving Incentives
Objective: To explain how financial incentives can be used to encourage preparedness and health systems development.

1:30–3:00 **The Investment Case for Preparedness and the Role of the Private Sector**
Moderator: *Eduardo González Pier*, Vice Minister Integration and Development, Ministry of Health, Mexico

Staci Warden, Executive Director Center for Financial Markets, Milken Institute
Trish Stroman
Daniel Hanna, Managing Director, Head of Public Sector and Development Organisations: Africa, Americas and Europe, Standard Chartered Bank
David Crush, Manager, IFC

3:00–3:15 **Break**

3:15–4:45 **Incentives and Preparedness**
Moderator: *Milan Brahmbhatt*, Senior Fellow, World Resources Institute

Richard Gregory, Senior Policy Advisor, Global Health Security, DfID
David Nabarro, Secretary General's Special Envoy on Ebola, UN (by video)
George Gao, Deputy Director-General, China CDC
Hans Troedsson, Assistant Director General for General Management, WHO

4:45–5:00 **Closing Remarks**

5:00 **Adjourn**

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GOVERNANCE FOR GLOBAL HEALTH WORKSHOP
September 1–2, 2015
Wellcome Trust—Gibbs Building
London, United Kingdom

Tuesday, September 1, 2015 (Day 1)

8:00–8:30 am **Registration and Continental Breakfast**

8:30–8:40 **Welcome**
Jeremy Farrar, Director, Wellcome Trust
*David Relma*n, Chair of the Forum on Microbial Threats, IOM; Professor of Microbiology and Immunology, Stanford University

8:40–8:55 **Overview of the Global Health Risk Framework Initiative**
Patrick Kelley, Director, Board on Global Health, IOM

8:55–9:00 **Keynote Introduction**
David Relman

9:00–9:30 **Keynote Remarks: Governance for Global Health—Engaging Intergovernmental Organizations to Achieve Collection Action**
Keizo Takemi, Member of Japanese Parliament

Session I: Definition of Governance for Global Health and Lessons Learned from Outbreaks of the Past

Session Moderator: *Ximena Aguilera*, Director, Center of Epidemiology and Public Health Policies, Universidad del Desarrollo, Chile

Objectives:

- Illuminate key elements of "good" governance for global health.
- Examine compliance enhancing mechanisms to drive good governance and implementation of existing international norms.
- Synthesize lessons learned from recent infectious disease outbreaks and opportunities to strengthen governance for global health.
- Identify ways in which International Health Regulations (IHR) can be modified to achieve its intended purpose.

9:30–10:10 **Part 1: Elements of Good Governance for Global Health**

Presentations
David Fidler, Professor of Law, Indiana University
Alejandro Thiermann, President, Terrestirial Animal Health Code Commission, World Organisation for Animal Health (OIE)

10:10–10:30 **Discussion**

10:30–10:45 **Break**

10:45–11:45 **Part 2: Lessons Learned from Outbreaks of the Past**

Case Study Panel
David Heymann, Head/Chair, Public Health England/Chatham House
Harvey Fineberg, President, Moore Foundation
Joanne Liu, President, Médecins Sans Frontières

11:45 am–12:45 pm **Discussion**

12:45–1:30 **Lunch**

Session II: Challenges in Governance for Global Health for Fragile States

Session Moderator: *Oyewale Tomori*, President, Nigerian Academy of Science

Objectives:

- Compare and contrast different governance approaches for fragile health systems vs. other areas and identify where new approaches are relevant.
- Identify how to measure and define success of governance for global health for areas with weak political systems and economies.

1:30–2:10 **Presentations**
Paul Wise, Professor of Pediatrics and Health Policy, Stanford University School of Medicine; Senior Fellow, Freeman-Spogli Institute for International Studies, Stanford University
Mark Heywood, Executive Director, Section27 (South Africa)

2:10–2:40 **Discussion**

Session III: Challenges in Current Design of Global Health Governance
Session Moderator: *Margaret A. Hamburg*, Former Commissioner, U.S. FDA

Objectives:

- Highlight ways WHO and member states can be better equipped to address global outbreaks.
- Discuss recent proposals made to enhance global preparedness and response.
- Identify how global security initiatives and frameworks can work together to boost preparedness and response.

2:40–4:30 **Presentations**
Charles Clift, Senior Consulting Fellow, Center on Global Health Security, Chatham House
Margaret Chan, Director General, WHO
Colin McIff, Senior Health Attaché, U.S. Mission, Geneva
Dame Barbara Stocking, President, Murray Edwards College

4:30–4:50 **Break**

4:50–6:00 **Panel Discussion**

6:00–6:15 **Concluding Remarks**
David Relman

6:15 **Adjourn**

Wednesday, September 2, 2015 (Day 2)

8:30–9:00 am **Registration and Continental Breakfast**

9:00–9:15 **Summary of Day One**
David Relman

Session IV: Models of Governance for Global Health
Moderator: *Larry Gostin*, University Professor of Global Health Law, Georgetown University

Objectives:

- Illuminate goals of governance systems considering domains from the international, national, regional, and local levels.
- Compare and contrast four potential models of governance for global health, including key features of organizational structure, funding, legitimacy, authority, and accountability.
- Identify a broad array of stakeholders and effective methods for integrating and leveraging partner engagements for strong governance for global health.

9:15–10:05	**Part 1: Systems for Governance: How Should They Fit Together?** **Presentations** *Claude de Ville de Goyet*, Consultant to UN and Former WHO/Pan American Health Organization Emergency Preparedness Director *Ron St. John*, WHO Consultant
10:05–10:20	**Break**
10:20–11:10	**Presentations** *Ben Anyene*, Chairman, Health Reform Foundation of Nigeria *Rebecca Marmot*, Vice President, Global Partnerships, Unilever
11:10 am–12:10 pm	**Panel Discussion**
12:10–1:00	**Lunch**
1:00	**Part 2: Laying Out Some Governance Options: The Work of Concurrent Panels and Debate**
1:00–1:40	**Insights from Concurrent Initiatives** *Peter Piot*, Director, London School of Hygiene & Tropical Medicine *Joy Phumaphi,* Executive Secretary of African Leaders Malaria Alliance, Member of UN High-Level Panel on Global Response to Health Crises
1:40–1:50	**The Debate: Introduction** Moderator: *Larry Gostin*
1:50–2:10	**Model 1: WHO Status Quo** *Charles Clift*
2:10–2:30	**Model 2: "WHO Plus"** WHO with an attached center for humanitarian and outbreak management under the line authority of the WHO Director-General and with strategic, operational, and tactical roles. It combines both strategic and operational missions within the WHO-Geneva culture. *Ilona Kickbusch*, Director, Global Health Programme, Graduate Institute of Geneva
2:30–2:50	**Model 3: The Executive Agency Model** WHO as the host for a center for humanitarian and outbreak management operating under the authorities of the UN Secretary-General and executing strategic, operational, and tactical roles. (This taps the expertise of WHO but draws from a higher level of authority for command and control and political support.) It would insulate the Center from the WHO culture and the politics of the World Health Assembly but derive vast technical benefits. *Yasushi Katsuma*, Dean, Graduate School of Asia-Pacific Studies, Waseda University

2:50–3:10 **Model 4: The Model of the UN Office for the Coordination of Humanitarian Assistance**
A separate agency.
Daniel López-Acuña

3:10–4:00 **Panel and General Discussion**
Moderator: *Harvey Fineberg*

Featured Reactors
Kenji Shibuya, Professor and Chair of Global Health Policy, University of Tokyo
Ann Marie Kimball, Senior Consulting Fellow, Chatham House

4:00–4:15 **Break**

Session V: Other Considerations in Governance for Global Health
Moderator: *Chris Elias*, President, Global Development, The Bill & Melinda Gates Foundation

Objectives:

- Synthesize best practices for translating research and lessons learned into actions for governance for global health.
- Identify financing mechanisms that help mobilize and maintain good governance and steer policy directions.

4:15–5:15 **Panel Discussion**
Tim Evans, Senior Director, Health, Nutrition and Population Global Practice, World Bank
Jeremy Farrar
Daniel López-Acuña

5:15–5:45 **Open Discussion**

5:45–6:00 **Concluding Remarks**
Eileen Choffnes, Scholar, Board on Global Health, IOM
Ceci Mundaca-Shah, Senior Program Officer, Board on Global Health, IOM
David Relman

6:00 **Adjourn**

Appendix C
Modeling the Economic Threat of Pandemics

Anas El Turabi and Philip Saynisch
Harvard University

Predicting the likely economic losses associated with future pandemic events is challenging. Pandemics are rare events, and we have relatively few data points to inform predictive models, with only three observed influenza pandemics in the 20th century.

We can, however, use the limited data we have to help us get a sense of the scale of likely losses. We can start, for example, by estimating how many pandemics we might see this century. We know that the 20th century saw three pandemics, so it might be reasonable to assume that there is around a 3 percent chance that a pandemic might occur in any given year. This means that, while on average we might get three pandemics each century, because of random variation, some centuries might get more and some might get fewer. We can use simulation models to give us a feel for how much the number of pandemics each century might vary due to random chance, and doing this gives us the distribution shown in Figure C-1.[1]

One important feature of this chart is that, although we would expect to see three or fewer events the majority of the time, there is a chance of the world experiencing more. Indeed, the 19th century saw five pandemics of cholera alone, which, although not directly comparable to the situation today, gives us a sense that the order of magnitude predicted by our model is reasonable.

Our model probably represents a conservative estimate of the risk of pandemic events; that is to say, there are reasons to believe the true risk could be higher. Our model uses data from the 20th century; however, a key conclusion of this report is that the risk of pandemic events is higher than it has been before and without further action is likely to continue to rise (see Box C-1).

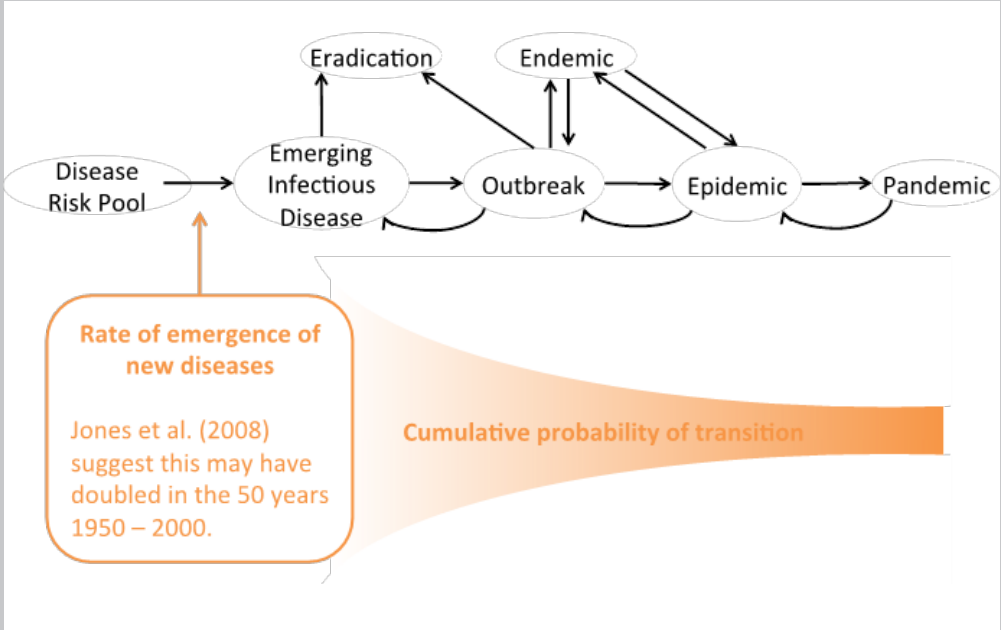
To estimate the scale of economic losses associated with future pandemics, we can apply the same strategy of using what we know about previous pandemics to model the impact of future pandemics. Previous work has estimated the economic loss that occurred as a result of each of the 20th-century pandemics as 0.7–4.8 percent of global gross domestic product (GDP) (McKibben and Sidorenko, 2006). We can use these estimates to develop models of how much damage might be done to the global economy during future pandemics. Again, we use simulation models that take into account the uncertainty associated with the number of pandemics that might happen, as well as uncertainty associated with the damage done by pandemics when they strike. Using the same approach we used for modeling the number of events per century, we model the economic losses of these events throughout a century and use these estimates to get a distribution of expected annual losses[2] (see Figure C-2).

[1] We use simulation to estimate the distribution of expected pandemic events per century by running 10,000 simulations of random draws from a binomial distribution, where the number of events, X, is distributed $X \sim Bin(100,(3/100))$. In doing this we are simulating the losses that might occur in 10,000 centuries and aggregating the results to show us how likely it is that we see different numbers of events per century, on average. Our principal modeling assumptions are that the probability of an event occurring in any year is fixed at 3 percent (derived from the observation of three influenza pandemics in the 20th century) and that the probability of an event occurring in any year is independent of whether events occurred in other years that century.

[2] This model uses simulation to estimate the distribution of expected

BOX C-1
Why Might the Risk of Pandemic Events Be Rising?

Two factors principally affect the number of pandemics that might occur in any period of time. The first is the rate of emergence of new infections and the second is the chance that these diseases evolve into more serious outbreaks (transition probabilities); both of these factors have increased in recent years.



SOURCE: Figure created for the GHRF Commission by El Turabi and Saynisch, Harvard University.

The rate of new infectious diseases has been rising over the past century, with more than 330 emerging infectious diseases being reported between 1940 and 2004. The principal source of new infectious diseases since 1950 has been from zoonotic transmission—the crossing over of diseases from animal species to humans (Jones et al., 2008). A number of factors have contributed to this including greater use of intensive animal farming methods, increased human and animal densification, and increased population immunodeficiency as a result of HIV/AIDS and malnutrition (Jones et al., 2008). At the same time, these factors combined with Increased levels of migration, trade and transport, and the challenge of rising levels of antimicrobial resistance have made it easier for new infectious diseases to evolve through pre-pandemic states. All these trends are likely to continue, and without concerted effort, the threat raised by pandemic events is likely to rise. At the same time, the economic damage associated with pandemics continues to be extensive, even when disease case fatality rates are low.

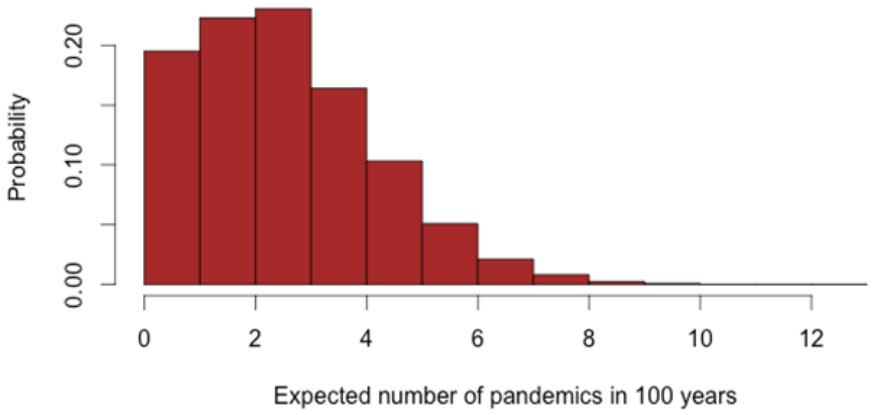


FIGURE C-1 Distribution of expected number of pandemics in the 21st century.
SOURCE: Figure created for the GHRF Commission by El Turabi and Saynisch, Harvard University.

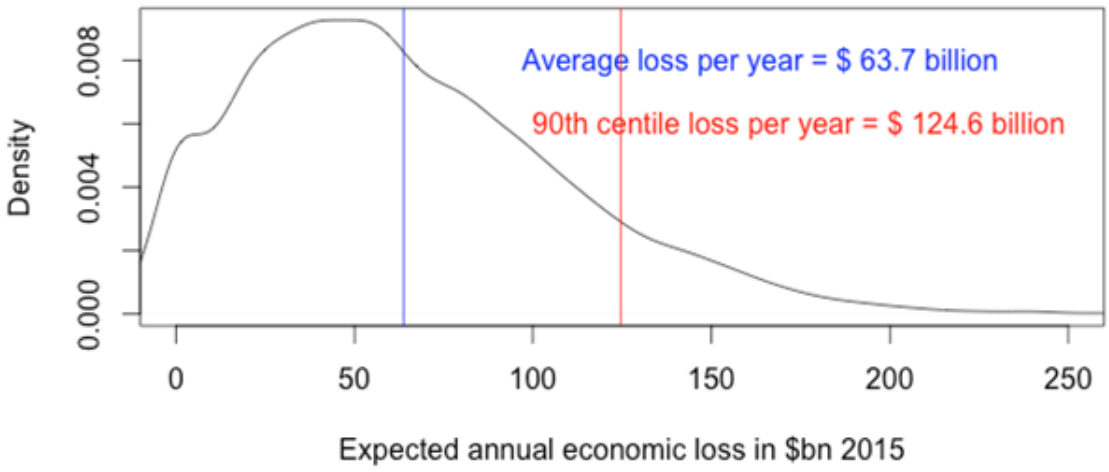


FIGURE C-2 Distribution of expected economic losses due to pandemics in the 21st century.
SOURCE: Figure created for the GHRF Commission by El Turabi and Saynisch, Harvard University.

We can see that our model estimates an average loss to the global economy of more than $60 billion per year—or more than $6 trillion per century. Again, an important feature of the distribution of expected economic losses is that they exhibit a long right tail; that is to say, there is a nontrivial chance of seeing much more extreme losses. For example, the model predicts a 10 percent chance that average losses this century will be more than $120 billion per year. Indeed, it is because our model accommodates for the possibility of these rarer but more extreme outcomes that our estimate of average losses is higher than the $30 billion calculated by the World Bank.

No model can perfectly predict the economic losses that will arise from future pandemics, and all models have their limitations. Our model is dependent on the validity and accuracy of our input data and the assumptions we make about how representative these data are of the underlying pandemic phenomena (frequency of occurrence and impact).[3] Although our input data are not perfect (in that they relate to events stretching back to 1918 that may be of less relevance today), they are the same figures that a number of authorities, including the World Bank, have used when estimating the economic impact of pandemic events (Jonas, 2014). Additionally, using different input figures derived from those used by commercial insurers, as well as using different models to account for the uncertainty of these estimates, has little effect on the scale of our estimates.[4] Put more plainly, the story remains the same, even when we use alternative input data and different statistical models.

A number of limitations mean that our model probably underestimates the economic threat of pandemic disease events. First, our model only estimates the risk associated with pandemics, and takes no account of the burden of pre-pandemic events such as outbreaks and epidemics, which are substantial. Second, our model assumes the risk of pandemic events this century will be broadly the same as they were in the 20th century; in reality, however, the risk of pandemic events is probably

economic losses due to pandemic events per century, which we then report in annualized form. It achieves this by first simulating for each year in a century whether a pandemic occurs (X) by drawing randomly from a Bernoulli distribution with a probability of 3 percent (X~*Bern*(0.03)). If an event occurs, the economic losses for that event are randomly drawn from a normal distribution with mean and standard deviation derived from the global GDP losses calculated by McKibben and Sidorenko for 20th century influenza pandemics (0.7 percent, 3.1 percent, and 4.8 percent) applied to a global GDP figure of $74 trillion U.S. dollars (the International Monetary Fund estimate for global GDP for 2015). These draws are repeated for each year in a century to give a total loss for that simulated century. The results of 10,000 such simulations are then aggregated to give the distribution of expected losses per century, and these results are then divided by 100 to give the annualized expected losses presented above.

[3] This includes our parametric assumptions about the underlying distributions from which the historical data are realized.

[4] We explored alternative parameterizations of the distributions of economic losses (uniform and beta) using alternative sources for economic loss inputs (Jonung and Roeger, 2006) and found that our expected annualized losses remained in the range of $60–$65 billion U.S. dollars with a similar right-tailed distribution as found in our main analysis. Using models which explored expected costs over shorter time horizons than 100 years led to no change in the average expected loss but greater uncertainty of expected losses, producing heavier-tailed distributions.

greater now and rising (see Box C-1). Finally, our model only predicts the economic losses associated with the first year after a pandemic event, while previous research suggests that the economic impact of pandemics probably extends 3 to 4 years (McKibben and Sidorenko, 2006). Our estimates might thus be considered conservative.

So, given the range of estimates for the economic losses as a result of pandemic events, which number should we have in mind when considering the risk posed to the global economy? In one sense it does not matter. All of the proposed figures, from $30 billion to more than $120 billion, represent losses large enough to warrant concerted action. And, with only one-third of countries declaring that they have met the standards for infectious disease control mandated by the International Health Regulations (WHO, 2015), it is clear that we have failed to invest properly to address these risks. On the other hand, there is good reason to believe that our model represents a conservative estimate of the losses that will occur, so we may be justified in focusing on the higher numbers. The argument for this approach is strengthened when we consider the asymmetric consequences of over- versus under-investment in pandemic prevention and response and the tendency of societies to be risk averse. Governments, because they are responsible for the protection of citizens' welfare, are especially likely to be risk averse to outcomes with potential to cause catastrophic damage to the health and prosperity of their nations. For these reasons, it may be reasonable to consider our estimate of expected annual losses from the global economy of $60 billion per year a "low" realistic estimate.

REFERENCES

Jonas, O., 2014. *Pandemic risk*. Washington, DC: World Bank.

Jones, K. E., N. G. Patel, M. A. Levy, A. Storeygard, D. Balk, J. L. Gittleman, and P. Daszak. 2008. Global trends in emerging infectious diseases. *Nature* 451(7181):990-993.

Jonung, L., and W. Roeger. 2006. *The macroeconomic effects of a pandemic in Europe—a model-based assessment*. Brussels, Belgium: European Commission.

McKibben, W. J., and A. A. Sidorenko. 2006. *Global macroeconomic consequences of pandemic influenza.* Sydney, Australia: Lowy Institute for International Policy.

WHO (World Health Organization). 2015. *Implementation of the International Health Regulations (2005). Report of the review committee on second extensions for establishing national public health capacities and on IHR implementation.* Geneva: Sixty-Eighth World Health Assembly.

Appendix D
Biographical Sketches of Commission Members, Consultants, and Staff

COMMISSION MEMBERS

Peter Sands, M.P.A. (*Chair*) is a senior fellow at the Mossavar-Rahmani Center for Business and Government at Harvard Kennedy School. He is also lead non-executive director of the Board of the United Kingdom's Department of Health. Mr. Sands was Group Chief Executive of Standard Chartered Bank from November 2006 to June 2015. He joined the Board of Standard Chartered PLC as Group Finance Director in May 2002. Before his appointment as Group Chief Executive he was responsible for Finance, Strategy, Risk and Technology and Operations. Prior to joining Standard Chartered, Mr. Sands was a director with worldwide consultants McKinsey & Company. He had been with McKinsey since 1988 where he worked extensively in the banking and technology sectors in a wide range of international markets. He was elected a partner in 1996 and became a director in 2000. Prior to joining McKinsey, he worked for the United Kingdom's Foreign and Commonwealth Office. Mr. Sands graduated from Oxford University and holds a Master's in Public Administration from Harvard University, where he was a Harkness Fellow.

Oyewale Tomori, D.V.M., Ph.D. (*Vice Chair*) is President of the Nigerian Academy of Science and pioneer Vice-Chancellor of Redeemer's University, Nigeria. He is a Fellow of the Academy of Science of Nigeria, a Fellow of the College of Veterinary Surgeons of Nigeria, Fellow of the Royal College of Pathologists of the United Kingdom, and Fellow of the American Society of Tropical Medicine and Hygiene. Dr. Tomori received his D.V.M. from the Ahmadu Bello University in 1971 and his Ph.D. in Virology of the University of Ibadan in 1976.

He became the Head of the Department of Virology at the University of Ibadan in 1984, leading research efforts that focused on field and laboratory investigations of viral infections in Nigeria. Dr. Tomori's research interests include a wide range of human viruses, and zoonotic and veterinary viruses including the Yellow fever virus, the Lassa fever virus, the poliomyelitis virus, the measles virus, the Ebola virus and a hitherto unknown virus, the Orungo virus, the properties of which he elucidated, and registered with the International Committee of Virus Taxonomy.

In 1994, he was appointed as the Regional Virologist for the World Health Organization (WHO) Africa Region (AFRO). During a 10-year tenure with WHO-AFRO, he set up the African Regional Polio Laboratory Network, comprised of 16 laboratories, providing diagnostic support to the global polio eradication initiative. The Network was a forerunner of other regional diagnostic laboratory networks for measles, Yellow fever, and other viral hemorrhagic fevers. It was while he was with WHO-AFRO that he participated in the investigation of viral infections, such as Ebola hemorrhagic fever, Lassa fever, Yellow fever, and Marburg in various African countries—including Democratic Republic of the Congo, Liberia, Nigeria, and Uganda.

Dr. Tomori is the recipient of several awards and honors. He was recognized in 1981 by the U.S. Centers for Disease Control and Prevention (CDC), with the U.S. Department of Health and Human Services Public Health Service Certificate for contribution to Lassa fever research, and in 1990 he was the recipient of the Nigerian National Ministry of Science and Technology Merit Award for excellence in medical research. In 2002, he received the Nigerian National Order of Merit (NNOM), the country's highest award for academic and intellectual attainment and national development.

Dr. Tomori has served on several advisory bodies including the Board of the BioVaccines Limited in

Nigeria, WHO Eastern Mediterranean Regional Polio Certification Committee and WHO Strategic Advisory Group of Experts (SAGE). He currently serves on the Nigerian Expert Review Committee on Polio Eradication and Routine Immunization, WHO Africa Regional Polio Certification Committee, WHO Advisory Committee on Variola Virus Research, WHO Polio Research Committee, WHO Group of Experts on Yellow Fever Disease and the International Steering Committee of the International Consortium on Antivirals (ICAV), Canada.

Ximena Aguilera, M.D., is Director of the Centre of Epidemiology and Public Health Policies at the Faculty of Medicine Clínica Alemana–Universidad del Desarrollo in Chile. She was Senior Advisor in Communicable Diseases at the WHO Regional Office for the Americas (2008–2010) where among other duties she coordinated the technical response to the influenza A (H1N1) pandemic. Previously she was the Chief of Health Planning Division at the Ministry of Health in Chile (2005–2008) and Head of the Department of Epidemiology at the same institution (1999–2005). Dr. Aguilera was the Chilean representative during the negotiations on the revision of the International Health Regulations (IHR), and official delegate for Asia-Pacific Economic Forum Health Working Group, and for Mercosur sub-working group on health. In addition, she was primarily responsible for pandemic preparedness and for the implementation of the IHR (2005) at the Ministry of Health of Chile. Dr. Aguilera has worked as consultant for the WHO Regional Office for the Americas, the United Nations Development Fund, the Inter-American Development Bank and the World Bank in several countries in Latin America and participated in the WHO mission in response to the severe acute respiratory syndrome (SARS) outbreak in China (2003). She has been a member of the Advisory Committee of the Global Outbreak Alert and Response Network of WHO.

Irene Akua Agyepong, Dr.P.H., MBChB, M.P.H., FGCPS, is a public health physician from Ghana employed by the Ghana Health Service. She has also taught and supervised students part time in the University of Ghana School of Public Health since its inception in 2004. In 2012, the Ghana Health Service seconded her full time to the Department of Health Policy, Planning, and Management of the University of Ghana's School of Public Health. Prior to this she was Regional Director of Health Services in the Ghana Health Service Greater Accra region from 2004 to 2012, and before that District Director of Health for the Dangme West district. She was Professor to the Prince Claus Chair in Development and Equity from 2008 to 2010 at the University of Utrecht in the Netherlands, based in the Julius Center of the University Medical Center. She was chair of the 11-member Board of Health Systems Global, an international membership society for the promotion and development of the field of health policy and systems research globally from 2012 to 2014. She has been a member (since 2006) and Chair (2009–2013) of the Scientific and Technical Advisory Committee of the Alliance for Health Policy and Systems Research.

Dr. Agyepong has an MBChB from the University of Ghana Medical School, a Master's of Public Health from the Liverpool School of Tropical Medicine, Part I of the West Africa College of Physicians and Surgeons in Public Health, and a Doctorate in Public Health from the University of North Carolina at Chapel Hill School of Public Health. She is a Foundation Fellow of the Ghana College of Physicians and Surgeons.

Yvette Chesson-Wureh, J.D., obtained a Juris Doctorate law degree with honors from the North Carolina Central University (NCCU) School of Law where she was also featured in "Who's Who in American Law Schools" 1988 Edition. She is a recipient of several awards and certifications including a certificate in Mediation/Arbitration from Bowie State University. A member of several professional associations both in the United States and Liberia, Dr. Chesson-Wureh is a member of the United States Supreme Court Bar, The U.S. Federal District Bar, The Association of Female Lawyers of Liberia (AFELL) where she serves on the Board, and a current member of the Board of Tax Appeals of Liberia, the first such board in Liberia. She is Board President of Isis-Women's International Cross Cultural Exchange (Isis-WICCE), based in Uganda.

An advocate and a champion of women's rights and gender equality, she was the Manager in 2009 of the International Women's Colloquium for Women's Empowerment, Leadership Development, International Peace and Security, which was co-convened by H.E. President

Ellen Johnson Sirleaf of Liberia and H.E. President Tarja Halonen of Finland. Dr. Chesson-Wureh successfully collaboratively plans and manages highly visible national and international events such as the UN High Level Panel meeting in Liberia, ECOWAS 20 years of Peace Meeting, and The Inauguration of the President of Liberia. She is a successful advocate and lobbyist for immigration reforms at the U.S. Congress, U.S. Department of State, and White House.

Dr. Chesson-Wureh is currently the Establishment Coordinator of the Angie Brooks International Centre (ABIC) for Women's Empowerment, Leadership Development, International Peace and Security headquartered in Liberia, which is the concrete outcome of the International Colloquium. Dr. Chesson-Wureh initiated the "Women's Situation Room" (WSR) and implemented it in collaboration with more than 40 women and youth groups for the Liberian elections in 2011.

As the chief executive officer of ABIC, Dr. Chesson-Wureh ensured that ABIC was situated on the front line of the Ebola response in Liberia. As a non-governmental organization (NGO) ABIC initiated projects on awareness and sensitization in both urban and rural communities with partners such as United Nations Development Programme, United Nations Population Fund, African Women's Development Fund, Urgent Action Fund, The African Union and the Liberian Ministry of Health. Dr. Chesson-Wureh serves on the Presidential Advisory Council on Ebola, gives legal advice to the Government of Liberia on the Ebola vaccine and is Legal Advisor to the Traditional Council of Liberia. ABIC also supported the work of the Liberian doctors treating Ebola.

Paul Farmer, M.D., Ph.D., chairs the Department of Global Health and Social Medicine at Harvard Medical School and is a co-founder and Chief Strategist of Partners In Health (PIH), an international nonprofit organization that since 1987 has provided direct health care services and undertaken research and advocacy activities on behalf of those who are sick and living in poverty. He also is professor of medicine and chief of the Division of Global Health Equity at Brigham and Women's Hospital.

Dr. Farmer began his lifelong commitment to Haiti in 1983 while still a student, working with dispossessed farmers in Haiti's Central Plateau. He served there for 10 years as medical director of a charity hospital, L'Hôpital Bon Sauveur. With PIH over the past 26 years, Dr. Farmer has led colleagues working in 12 sites throughout Haiti and 12 additional countries around the globe. For more than a decade, the Department of Global Health and Social Medicine has integrated research and teaching programs with PIH service activities, establishing direct feedbacks between clinical interventions and biosocial analyses. The work has become a model for health care for poor communities worldwide and provides the basis for developing a science of global health delivery implementation.

Dr. Farmer is the recipient of numerous honors, including the Margaret Mead Award from the American Anthropological Association, the American Medical Association's Outstanding International Physician (Nathan Davis) Award, the John D. and Catherine T. MacArthur Foundation Fellowship, and, with his PIH colleagues, the Hilton Humanitarian Prize. He is a member of the National Academy of Medicine and of the American Academy of Arts and Sciences. Dr. Farmer holds M.D. and Ph.D. degrees from Harvard University. In addition to his leadership roles at Harvard Medical School, Brigham and Women's Hospital, and Partners In Health, he is the United Nations Special Adviser to the Secretary-General on Community Based Medicine and Lessons from Haiti.

Maria Freire, Ph.D., is the President of Foundation for the National Institutes of Health. She comes to the Foundation from the Albert and Mary Lasker Foundation, where she served as President since 2008. Prior to joining the Lasker Foundation, Dr. Freire served as President and CEO of the Global Alliance for TB Drug Development from 2001 to 2008, Director of the Office of Technology Transfer at the National Institutes of Health from 1995 to 2001, and led the Office of Technology Development at the University of Maryland at Baltimore and the University of Maryland Baltimore County from 1989 to 1995. Dr. Freire received her Bachelor of Science degree at the Universidad Peruana Cayetano Heredia in Lima, Peru, and her Ph.D. in Biophysics from the University of Virginia. She has also completed post-graduate work in immunology and virology at the University of Virginia and the University of Tennessee, respectively. Dr. Freire has devoted her career to improving health and health research on a global scale.

Julio Frenk, M.D., M.P.H., Ph.D., became the sixth President of the University of Miami on August 16, 2015. From 2009 to 2015, he was Dean of the Harvard T.H. Chan School of Public Health and T & G Angelopoulos Professor of Public Health and International Development, a joint appointment with the Harvard Kennedy School of Government. Dr. Frenk served as Minister of Health of Mexico from 2000 to 2006, where he pursued an ambitious agenda to reform the health system, with an emphasis on redressing social inequality. He was the founding Director-General of the National Institute of Public Health of Mexico and has held leadership positions at the Mexican Health Foundation, the World Health Organization, The Bill & Melinda Gates Foundation, and the Carso Health Institute. Dr. Frenk holds a medical degree from the National Autonomous University of Mexico, as well as a Master's of Public Health and a joint doctorate in Medical Care Organization and in Sociology from the University of Michigan. He has received five honorary doctorates and is a member of the American Academy of Arts and Sciences, the U.S. National Academy of Medicine, and the National Academy of Medicine of Mexico. Dr. Frenk is the author of 34 books and monographs, 75 book chapters, 152 articles in academic journals, and 126 articles in cultural periodicals and newspapers. In September of 2008, he received the Clinton Global Citizen Award for changing "the way practitioners and policy makers across the world think about health."

Lawrence O. Gostin, J.D., is University Professor, Georgetown University's highest academic rank conferred by the University President. Dr. Gostin directs the O'Neill Institute for National and Global Health Law and is the Founding O'Neill Chair in Global Health Law. He served as Associate Dean for Research at Georgetown Law from 2004 to 2008. He is Professor of Medicine at Georgetown University and Professor of Public Health at the Johns Hopkins University.

Dr. Gostin is the Director of the World Health Organization (WHO) Collaborating Center on Public Health Law & Human Rights. The WHO Director-General has appointed Dr. Gostin to high-level positions, including the International Health Regulations Roster of Experts and the Expert Advisory Panel on Mental Health. He served on the Director-General's Advisory Committee on Reforming the World Health Organization, as well as numerous expert advisory committees on the Pandemic Influenza Preparedness Framework, smallpox, and genomic sequencing data. He is a member of the WHO/Global Fund Blue Ribbon Expert Panel entitled The Equitable Access Initiative to develop a global health equity framework. Dr. Gostin also serves on the Independent Panel on the Global Response to Ebola (Harvard University/London School of Hygiene & Tropical Medicine).

Dr. Gostin holds a number of international academic professorial appointments: Visiting Professor (Faculty of Medical Sciences) and Research Fellow (Centre for Socio-Legal Studies) at the University of Oxford, United Kingdom; the Claude Leon Foundation Distinguished Scholar and Visiting Professor at the University of Witwatersrand, Johannesburg, South Africa; and the Miegunyah Distinguished Visiting Fellow and Founding Fellow of the Centre for Advanced Studies (Trinity College), University of Melbourne. Dr. Gostin serves as Secretary and a member of the Governing Board of Directors of the Consortium of Universities for Global Health.

Dr. Gostin holds numerous editorial appointments in leading academic journals throughout the world. His principal position is the Health Law and Ethics Editor, Contributing Writer, and Columnist for the *Journal of the American Medical Association*. He is also Founding Editor-in-Chief of *Laws* (an international open access law journal). He was formerly the Editor-in-Chief of the *Journal of Law, Medicine & Ethics*.

Dr. Gostin holds four honorary degrees. In 1994, the Chancellor of the State University of New York conferred an Honorary Doctor of Laws Degree. In 2006, Her Majesty Queen Elizabeth II and the Vice Chancellor awarded Cardiff University's (Wales) highest honor, an Honorary Fellow. In 2007, the Royal Institute of Public Health (United Kingdom) designated Dr. Gostin as a Fellow of the Royal Society of Public Health (FRSPH). In 2012, the Chancellor of the University of Sydney—on the nomination of the Deans of the Law and Medical Schools—conferred a Doctor of Laws (honoris causa) in the presence of two Justices of Australia's highest court—Justices Kirby and Haydon.

Dr. Gostin is an elected lifetime member of the National Academy of Medicine (formerly the Institute of Medicine). He has served on the National Academies of Sciences, Engineering, and Medicine's Board on

Health Sciences Policy, the Board on Population Health and Public Health Practice, the Human Subjects Review Board, and the Committee on Science, Technology, and Law. He chaired the Academies' Committee on Global Solutions to Falsified, Substandard, and Counterfeit Medicines. He has chaired Academies' committees on national preparedness for mass disasters, health informational privacy, public health genomics, and human subject research on prisoners.

The National Academy of Medicine awarded Dr. Gostin the Adam Yarmolinsky Medal for distinguished service to further its mission of science and health. He received the Public Health Law Association's Distinguished Lifetime Achievement Award "in recognition of a career devoted to using law to improve the public's health" presented at the U.S. Centers for Disease Control and Prevention. The New York Public Health Law Association conferred the Distinguished Lifetime Achievement Award for extraordinary service to improve the public's health.

Dr. Gostin is also a lifetime elected Member of the Council of Foreign Relations (providing independent advice to governments on foreign policy) and a Fellow of the Hastings Center (for bioethics and public policy). Internationally, Dr. Gostin received the Rosemary Delbridge Memorial Award from the National Consumer Council (United Kingdom) for the person "who has most influenced Parliament and government to act for the welfare of society." He also received the Key to Tohoko University (Japan) for distinguished service for human rights in mental health.

Dr. Gostin has led major law reform initiatives in the United States, including the drafting of the Model Emergency Health Powers Act (MEHPA) to combat bioterrorism and the "Turning Point" Model State Public Health Act. He is also leading a drafting team for the World Health Organization and International Development Law Organization, Advancing the Right to Health Through Public Health Law.

Dr. Gostin's proposal for a Framework Convention on Global Health—an international treaty ensuring the right to health—is now part of a global campaign, endorsed by the United Nations (UN) Secretary-General and Director of the Joint United Nations Programme on HIV/AIDS (UNAIDS).

In the United Kingdom, Dr. Gostin was the Legal Director of the National Association for Mental Health, Director of the National Council of Civil Liberties (the United Kingdom equivalent of the ACLU), and a Fellow at Oxford University. He drafted the current Mental Health Act (England and Wales) and brought several landmark cases before the European Court of Human Rights.

Dr. Gostin's latest books are *Global Health Law* (Harvard University Press, 2014; Chinese translation due in 2016); *Public Health Law: Power, Duty, Restraint* (University of California Press, 3rd ed. forthcoming 2016); *Public Health Law and Ethics: A Reader* (University of California Press, 2nd ed., 2010); *Law and the Health System* (Foundation Press, 2014); *Principles of Mental Health Law & Practice* (Oxford University Press, 2010).

Paul Farmer, Partners In Health, says of his latest book: *Global Health Law* is "more than the definitive book on a dynamic field. Gostin harnesses the power of international law and human rights as tools to close unconscionable health inequities—the injustices that burden marginalized populations throughout the world. Gostin presents a forceful vision, one that deserves a wide embrace."

In a 2012 systematic empirical analysis of legal scholarship, independent researchers ranked Dr. Gostin 1st in the nation in productivity among all law professors, and 11th in impact and influence.

Gabriel Leung, M.D., M.P.H., became the 40th Dean of the Li Ka Shing Faculty of Medicine at The University of Hong Kong in 2013. Dr. Leung, a clinician and a respected public health authority, concurrently holds the Chair of Public Health Medicine. Previously he was Professor and Head of Community Medicine at the University and served as Hong Kong's first Under Secretary for Food and Health and fifth Director of the Chief Executive's Office in government.

Dr. Leung is one of Asia's leading epidemiologists, having authored more than 400 scholarly papers and edited numerous journals. His research defined the epidemiology of two novel viral epidemics, namely severe acute respiratory syndrome-coronavirus in 2003 and influenza A (H7N9) in 2013. While in government, he led Hong Kong's policy response against the 2009 influenza A (H1N1) pandemic. Dr. Leung currently directs the University's World Health Organization (WHO) Collaborating Centre for Infectious Disease Epidemiology

and Control. He was inaugural Chair of the Asia Pacific Observatory on Health Systems and Policies during 2010–2014. He regularly advises national and international agencies, including WHO, World Bank, Asian Development Bank, and the Chinese Center for Disease Control and Prevention.

Francis Omaswa, MBChB, MMed, FRCS, FCS, is the Executive Director of the African Centre for Global Health and Social Transformation (ACHEST), an initiative based in Uganda and promoted by a network of African and international leaders in health and development. Until May 2008, Dr. Omaswa was Special Adviser to the WHO Director General and founding Executive Director of the Global Health Workforce Alliance (GHWA). Before joining GHWA, he was the Director General for Health Services in the Ministry of Health in Uganda during which time he was responsible for coordinating and implementing major reforms in the health sector in Uganda which included the introduction of Sector-Wide Approaches (SWAps), quality assurance, and decentralization. Dr. Omaswa has a keen interest in access of the poor to basic health care and spent 5 years in the rural Ngora hospital testing approaches for this. He is active in the global health community, and served as founding Chair, and later served as Vice-Chairman, of the Global Stop TB Partnership Board; was one of the architects of the Global Fund to Fight AIDS, Tuberculosis and Malaria and served as Chair of the Portfolio and Procurement Committee of the Global Fund Board; was a member of the steering committee of the High Level Forum on Health-Related Millennium Development Goals; and participated in the drafting the Paris Declaration on Aid Effectiveness. Dr. Omaswa is a graduate of Makerere Medical School, Kampala, Uganda, a Fellow of the Royal College of Surgeons of Edinburgh, founding President of the College of Surgeons of East, Central and Southern Africa, is a Senior Associate at the Johns Hopkins Bloomberg School of Public Health, International Member of the National Academy of Sciences, USA and Fellow of the Uganda Academy of Science.

Melissa Parker, DPhil, is Reader in Medical Anthropology at the London School of Hygiene & Tropical Medicine. During the Ebola outbreak, she created an online portal—the Ebola Response Anthropology Platform—that helps health workers and anthropologists work more effectively together by providing rapid, practical information about the socio-cultural, historical, economic, and political dimensions of Ebola. Over the past 25 years, she has undertaken multi-disciplinary and collaborative research in African and European settings. A unifying theme is the study of global health and international development. Research questions have typically emerged from extensive periods of ethnographic fieldwork, and engage with global health policies and practice. Topics investigated include HIV/AIDS in the United Kingdom, mental health in war zones, health-related quality of life in Kenya, female circumcision in Sudan, and the control of neglected tropical diseases in Sudan, Tanzania, and Uganda.

Sujatha Rao, M.A., M.P.A., joined the Indian Administrative Service in 1974. In her career span of 36 years, she worked in the health sector since 1988–1993 when she was deputed to the Ministry of Health and Family Welfare, Government of India as Director and later as Joint Secretary. From 1993–1996 she worked as Secretary, Family Welfare in Government of Andhra Pradesh and from 1998–2003 she was deputed again to work as Joint Secretary in the Ministry of Health and Family Welfare, Government of India. In 2004 she was nominated by the Government of India as Member Secretary of the National Commission on Macroeconomics, which was co-chaired by Union Ministers of Health and Finance. The report of this commission became the basis for much of the health sector reform. In 2005, after a short stint as Secretary of Health in the state government, she was back again to the federal government as Additional Secretary and later Secretary and Director General Department of AIDS Control from 2005 until 2009. Ms. Rao was posted as Union Secretary, Ministry of Health and Family Welfare in 2009 until her retirement from government service on November 30, 2010.

Ms. Rao was nominated as Vice-Chairman of the Global Advisory Group on Nursing and Midwifery by WHO as a public health expert for 2000–2001. She was elected as chairperson of the Portfolio Committee of the Global Fund to Fight AIDS, Tuberculosis and Malaria for two years (2007–2009). In 2008, she was invited to be a member of the six-member Global Advisory Panel of The Bill & Melinda Gates Foundation, on which she served until 2011. She was the founding board member of the Public Health Foundation of India and worked

on its board from its inception in 2006 until 2011. She was Co-chair of WHO's Advisory Panel on Developing a Global Health Systems Research Strategy, Geneva, 2011. She represented India on the Boards of WHO, Global Fund, and the Joint United Nations Programme on HIV/AIDS.

She is currently a Trustee of the Population Council International, New York, 2011; Member of the Advisory Board of the Ministerial Leadership Program of the Harvard School of Public Health, Member of the Economic Reference Group on HIV/AIDS, and Member of the Chief Minister's Advisory Council on Health.

Ms. Rao did her post-graduation from Delhi University and has a Master's Degree in Public Administration from Harvard University. She was also a Takemi Fellow at the Harvard School of Public Health during 2001–2002. In 2012, she was a Gro Harlam Brundtland Senior Leadership Fellow at the Harvard School of Public Health, USA. Ms. Rao has published several papers and articles on health and public policy matters. She was a co-author of the *India Health Report* published by Oxford University Press in 2003.

Daniel Ryan, M.A.,[1] is head of R&D–Life, Health & Big Data at Swiss Re, having joined in August 2010. He was previously head of Mortality Consulting and Research at Towers Watson, and was the founder and principal investigator for 8 years of an innovative research group for insurers and reinsurers that addressed key issues on mortality and morbidity risk, product innovation and forward-looking scenario development. Mr. Ryan leads a multi-disciplinary group that is engaged in research collaborations on such topics as pandemic risk modeling, behavioral economics, genetic testing, and the relative importance of risk factors and treatments in different diseases in driving further increases in life expectancy. His research group was expanded in 2014 with the establishment of the Big Data & Smart Analytics Centre. The Centre has responsibility across the different risk classes covered by Swiss Re from individual risk to natural catastrophes to corporate liability. The Centre acts as a catalyst on the use of structured and unstructured data sources by Swiss Re to develop new analytical techniques that enhance underwriting capabilities. Mr. Ryan has an M.A. in Medical Sciences from Cambridge University, and was on the World Economic Forum's Global Agenda Council for Ageing for 4 years.

Jeanette Vega, M.D., M.P.H., Ph.D., has been the Director of Fonasa, the National Chilean Public Health Insurance Agency since March 2014. Dr. Vega has more than 20 years of experience in international health. Her areas of expertise include social determinants of health, health equity, and health systems. Prior to being appointed as Director of Fonasa by President Michelle Bachelet, Dr. Vega served as Managing Director of Health at The Rockefeller Foundation. She was Vice Minister of Health in Chile, between 2008 and 2010, leading the country's 13-step agenda for equity in health. Before that, Dr. Vega served as a Director at the World Health Organization in Geneva, where she led the equity in health agenda, looking at the social determinants of health and health systems. Dr. Vega started her career as a medical doctor in Chile specializing in Family Medicine. She has a master's degree in Public Health from the Universidad de Chile and a Ph.D. in Public Health from the University of Illinois at Chicago.

Suwit Wibulpolprasert, M.D., is a general practitioner, public health specialist, administrator, and policy advocate. He began his career as a director and practitioner in four rural district hospitals in Thailand from 1977–1985. Later, he was the Director of the North Eastern Public Health College, Director of the Food and Drug Administration Technical Division, Director of the Bureau of Health Policy and Plan, Assistant Permanent Secretary, Deputy Permanent Secretary, and the senior expert in Disease Control of the Ministry of Public Health. His current position is the vice chair of the International Health Policy Foundation.

He has been proactively working in public health area for more than three decades from the grassroots of the health system to the highest policy level. In parallel with working for the development of health in country, he is a global health leader who is well-known in the public eye as the forefront fighter to protect the benefit of the poor. His experiences which gain from real actions and hard work contribute significantly in Thailand's health system development.

He plays important roles in many humanitarian emergencies in Thailand as follows:

[1] During his declaration of potential financial conflicts of interests to the other Commissioners and for the International Oversight Group, Mr. Ryan noted his employment by Swiss Re.

1. In Avian influenza outbreak in Asia, there was a breakthrough strategy in disease surveillance which never occurred before. The first joint investigation between two neighboring countries was done and the information was shared transparently under support from the Mekong Basin Disease Surveillance Network (MBDS) and he is a key person who facilitates this initiation and bilateral collaboration as a co-founder of MBDS.
2. In Thailand's policy development and implementation in pandemic influenza preparedness, as the chair of the National Pandemic Influenza Preparedness (PIP) Plan Development Committee, he and relevant stakeholders recognized the importance of the preparedness in the systematic approach to prepare for Thailand's capacity in all key areas. It started from the development of the first national plan for PIP, including other emerging infectious diseases and considering this plan to build on the country's capacity in dealing with other humanitarian emergencies. All jigsaws have been mapped including research and development, strengthening surveillance and the International Health Regulations core capacities, improving the health care system and human resources for health based on One Health concept. A good example of this comprehensive strategy is Thailand's long vision on vaccine security in pandemic crisis. The domestic development of influenza vaccines has been launched in parallel with the policy to drive vaccine demand.
3. As the co-founder and the first chair of APAIR (Asia Pacific Avian Influenza Research), he and his team have been working on multinational and multidisciplinary researches ranging from biomedical, health economics, and social sciences. This research will be the essential input for national policy development and support the implementation in our country.
4. In terms of health system development and strengthening, he is one of the most experienced health system specialists and has involved and contributed in Thailand's health system development. He always reiterates that Thailand's health system has to be resilient and capable to support and deal with health emergencies. Therefore many programs have been implemented to prepare health facilities and health system to be well-established for humanitarian crisis.

At global level, he was the Vice Chair of the WHO Executive Board and the Vice Chair of the board of the Global Fund to fight AIDS, Tuberculosis and Malaria. He is a member of the Chatham House "GH governance in the future." He is knowledgeable and well understood in GH governance. His valuable experience at the global level, his dedication for Thailand's health system development, and his work to support developing countries will be beneficial for the further development of the global risk framework. He is the real actor from the ground who believes that "The secret of getting things done is to act."

Tadataka "Tachi" Yamada, M.D.,[2] is a Venture Partner with Frazier Healthcare Partners. Prior to joining Frazier he was Executive Vice-President, Chief Medical and Scientific Officer and a Board Member of Takeda Pharmaceuticals. Dr. Yamada has served as President of The Bill & Melinda Gates Foundation Global Health Program. In this position, he oversaw grants totaling more than $9 billion in programs directed at applying technologies to address major health challenges of the developing world, including tuberculosis, HIV, malaria, and other infectious diseases, malnutrition, and maternal and child health. He was formerly Chairman, Research and Development, and a member of the Board of Directors of GlaxoSmithKline and before that he was Chair of the Department of Internal Medicine and Physician-in-Chief at the University of Michigan Medical Center.

Dr. Yamada holds a bachelor's degree in history from Stanford University and obtained his M.D. from New York University School of Medicine. In recognition of his contributions to medicine and science he has been elected to membership in the National Academy of Medicine (United States), the Academy of Medical Sciences (United Kingdom), and the National Academy of Medicine (Mexico) and he has received an honorary appointment as Knight Commander of the Most Excellent Order of the British Empire (KBE). He is a Past-President of the Association of American Physicians and of the American Gastroenterological Association and he has served as a member of the President's Council of Advisors on Science and Technology and the Advisory Committee to the Director of the National Institutes of

[2] During his declaration of potential financial conflicts of interests to the other Commissioners and for the International Oversight Group, Dr. Yamada noted that he holds financial positions in Takeda Pharmaceuticals.

Health. He is currently Vice Chair of the Council of the National Academy of Medicine and serves on the Board of Directors of the Clinton Health Access Initiative.

INTERNATIONAL OVERSIGHT GROUP

Victor J. Dzau, M.D. (*Chair*) is the President of the National Academy of Medicine (NAM), formerly the Institute of Medicine (IOM). He is Chancellor Emeritus and James B. Duke Professor of Medicine at Duke University and the past President and CEO of the Duke University Health System. Previously, Dr. Dzau was the Hersey Professor of Theory and Practice of Medicine and Chairman of Medicine at Harvard Medical School's Brigham and Women's Hospital, as well as Chairman of the Department of Medicine at Stanford University.

Dr. Dzau has made a significant impact on medicine through his seminal research in cardiovascular medicine and genetics, his pioneering of the discipline of vascular medicine, and his leadership in health care innovation. His important work on the renin angiotensin system (RAS) paved the way for the contemporary understanding of RAS in cardiovascular disease and the development of RAS inhibitors as widely used, lifesaving drugs. Dr. Dzau also pioneered gene therapy for vascular disease, and his recent work on stem cell paracrine mechanisms and the use of microRNA in direct reprogramming provides novel insight into stem cell biology and regenerative medicine.

In his role as a leader in health care, Dr. Dzau has led efforts in health care innovation. His vision is for academic health sciences centers to lead the transformation of medicine through innovation, translation, and globalization. Leading this vision at Duke, he and his colleagues developed the Duke Translational Medicine Institute, the Duke Global Health Institute, the Duke-National University of Singapore Graduate Medical School, and the Duke Institute for Health Innovation.

As one of the world's preeminent academic health leaders, Dr. Dzau advises governments, corporations, and universities worldwide. He has been a member of the Council of the IOM and the Advisory Committee to the Director of the National Institutes of Health (NIH), as well as Chair of the NIH Cardiovascular Disease Advisory Committee and the Association of Academic Health Centers. He served on the Governing Board of the Duke-National University of Singapore Graduate Medical School and the Board of Health Governors of the World Economic Forum and chaired its Global Agenda Council on Personalized and Precision Medicine. He also served as the Senior Health Policy Advisor to Her Highness Sheikha Moza (Chair of the Qatar Foundation). Currently, he is a member of the Board of Directors of the Singapore Health System, the Expert Board of the Imperial College Health Partners, United Kingdom, and the International Advisory Board of the Biomedical Science Council of Singapore. In 2011, he led a partnership between Duke University, the World Economic Forum, and McKinsey, and he founded the International Partnership for Innovative Healthcare Delivery and currently chairs its Board of Directors.

Among his honors and recognitions are the Gustav Nylin Medal from the Swedish Royal College of Medicine; the Max Delbruck Medal from Humboldt University, Charité, and the Max Planck Institute; the Commemorative Gold Medal from the Ludwig Maximilian University of Munich; the Inaugural Hatter Award from the Medical Research Council of South Africa; thePolzer Prize from the European Academy of Sciences and Arts; the Novartis Award for Hypertension Research; the Distinguished Scientist Award from the American Heart Association (AHA); and the AHA Research Achievement Award for his contributions to cardiovascular biology and medicine. He has received numerous honorary doctorates and has been named among *Modern Healthcare*'s 50 Most Influential Physician Executives and Leaders, as well as among the 100 Most Influential People in Healthcare. Recently, he was awarded the Public Service Medal by the President of Singapore.

Judith Rodin, Ph.D. (*Vice Chair*) is President of The Rockefeller Foundation, one of the world's leading philanthropic organizations. She was previously President of the University of Pennsylvania, and provost of Yale University. Since joining the Foundation in 2005, Dr. Rodin has recalibrated its focus to meet the challenges of the 21st century and today the Foundation supports and shapes innovations to expand opportunity worldwide and build greater resilience by helping people, communities and institutions prepare for, withstand, and emerge stronger from acute shocks and chronic stresses. The Foundation accomplishes these goals through work that advances health, revalues ecosystems, secures livelihoods, and transforms cities.

A widely recognized international leader in academia, science, and development issues, Dr. Rodin has actively participated in influential global forums, including the World Economic Forum, the Council on Foreign Relations, Clinton Global Initiative, and the United Nations General Assembly. Dr. Rodin is also a member of the African Development Bank's High Level Panel and a Board member of the Alliance for a Green Revolution in Africa (co-created by The Rockefeller Foundation). In November 2012, New York Governor Andrew Cuomo named Dr. Rodin to co-chair the NYS 2100 Commission on Long-Term Resilience following Superstorm Sandy.

A pioneer and innovator throughout her career, Dr. Rodin was the first woman named to lead an Ivy League Institution and is the first woman to serve as The Rockefeller Foundation's president. A research psychologist by training, she was one of the pioneers of the behavioral medicine and health psychology movements. Dr. Rodin is the author of more than 200 academic articles and has written or co-written 15 books. She has received 19 honorary doctorate degrees and has been named one of Crain's 50 Most Powerful Women in New York. She has also been recognized as one of Forbes Magazine's World's 100 Most Powerful Women 3 years in a row.

Dr. Rodin serves as a member of the board for several leading corporations and nonprofits including Citigroup, Laureate Education, Inc., Comcast, and the White House Council for Community Solutions. Dr. Rodin is a graduate of the University of Pennsylvania and earned her Ph.D. in Psychology from Columbia University.

Fazle Hasan Abed, LL.D., is the founder and chairperson of BRAC. After Bangladesh's war for independence, he established BRAC to rehabilitate returning refugees in a remote area in northeastern Bangladesh. Under his leadership, within four decades, BRAC grew to become the largest development organization in the world. In 2010, he was appointed Knight Commander of the Most Distinguished Order of St. Michael and St. George by the British crown in recognition of his services to reducing poverty in Bangladesh and internationally, and was also appointed to the Eminent Persons Group for the Least Developed Countries by the United Nations Secretary General Ban Ki-moon. Dr. Abed is a founding member of Ashoka's Global Academy for Social Entrepreneurship. He was educated in both Dhaka and Glasgow Universities and has received many honorary degrees, including from Yale University (2007), Columbia University, the University of Oxford, and Princeton University.

Dr. Abed has been honored with numerous national and international awards for his achievements in leading BRAC, including the Trust Women Hero Award (2014), Spanish Order of Civil Merit (2014), Leo Tolstoy International Gold Medal (2014), CEU Open Society Prize (2013), Inaugural WISE Prize for Education (2011), Entrepreneur for the World Award (2009), David Rockefeller Bridging Leadership Award (2008), Inaugural Clinton Global Citizen Award (2007), Henry R. Kravis Prize in Leadership (2007), Palli Karma Shahayak Foundation (PKSF) Award for lifetime achievement in social development and poverty alleviation (2007), UNDP Mahbub ul Haq Award for Outstanding Contribution to Human Development (2004), Gates Award for Global Health (2004), Gleitsman Foundation International Activist Award (2003), Schwab Foundation's Social Entrepreneurship Award (2003), Olof Palme Prize (2001), InterAction Humanitarian Award (1998), and Ramon Magsaysay Award for Community Leadership (1980).

Arnaud Bernaert, M.B.A., is Senior Director of Global Health and Healthcare Industries at World Economic Forum. Prior to World Economic Forum, Mr. Bernaert was Senior Vice President at Royal Philips in charge of Global Strategy, Business Development, and mergers and acquisitions for Philips Healthcare, the $13 billion in sales unit of Royal Philips based in Boston. Formally the senior vice president and chief financial officer for Philips Home Healthcare Solutions, Mr. Bernaert joined Philips in 2005 from Baxter Healthcare, where he acted as the European Regional Controller for Baxter $2.5 billion business. Personal A finance M.B.A. from HEC Paris by education, Mr. Bernaert has accumulated more than 20 years of experience in the health care industry, and more recently completed about 25 merger and acquisitions transactions with a particular focus on targets in the space of Home Healthcare, Clinical Decision Support, Imaging and Image Guided Intervention and Treatment.

Chris Elias, M.D., M.P.H., is the President of the Global Development Program at The Bill & Melinda Gates Foundation where he leads the foundation's ef-

forts in a diverse range of program areas aimed at finding creative new ways to ensure solutions and products get into the hands of people in poor countries who need them most. Focusing on areas with the potential for high-impact, sustainable solutions that can reach hundreds of millions of people, Dr. Elias oversees Global Development's portfolio in Agriculture Development; Emergency Response; Family Planning; Financial Services for the Poor; Maternal, Newborn, & Child Health; Nutrition; Polio Eradication; Vaccine Delivery; and Water, Sanitation & Hygiene. A common theme of these programs is innovative and integrated delivery, including an emphasis on strengthening of primary health care systems.

Dr. Elias's professional background is in public health and medicine. Prior to joining the Gates Foundation in February 2012, he worked in various positions and countries for international nonprofit organizations, most recently serving as the president and CEO of PATH, an international, nonprofit organization dedicated to improving the health of people around the world by advancing technologies, strengthening systems, and encouraging healthy behaviors.

Dr. Elias holds an M.D. from Creighton University, having completed postgraduate training in internal medicine at the University of California San Francisco, and an M.P.H. from the University of Washington, where he was a fellow in the Robert Wood Johnson Clinical Scholars Program. He currently serves on various advisory boards, including the National Academy of Medicine and the University of Washington Global Health External Advisory Board.

Jeremy Farrar, Ph.D., is Director of the Wellcome Trust, a global charitable foundation dedicated to improving health by supporting the brightest minds in science, the humanities and social sciences, and public engagement. Before joining the Trust he was Director of the Oxford University Clinical Research Unit in Vietnam, where his research interests were infectious diseases, tropical health, and emerging infections. He has contributed to more than 500 peer-reviewed scientific papers and has served on several World Health Organization and other international advisory committees. Dr. Farrar was appointed Officer of the Most Excellent Order of the British Empire in 2005 for services to tropical medicine, and he has been awarded the Memorial Medal and the Ho Chi Minh City Medal by the Government of Vietnam, the Frederick Murgatroyd Prize for Tropical Medicine by the Royal College Physicians and the Bailey Ashford Award by the American Society for Tropical Medicine and Hygiene. He is a Fellow of the Academy of Medical Sciences and a Fellow of the Royal Society.

Shigeru Omi, M.D., Ph.D., is President of Japan Community Healthcare Organization (JCHO). He was the former Regional Director of the Western Pacific Regional Office at the World Health Organization (WHO) from 1999 to 2009, and the President of the 66th World Health Assembly. Dr Omi has held a wide range of positions in the field of medicine and public health. After graduation from medical school in 1978, he worked as a Medical Officer in the Bureau of Public Health of Tokyo Metropolitan Government. The job included an assignment as the sole medical doctor on remote islands in the Pacific, where he worked under difficult conditions and with limited resources. From this field activity, he proceeded in 1987 to do research on the molecular biology of the hepatitis B virus at the Division of Immunology, Jichi Medical School. During 1989–1990, Dr. Omi served as Deputy Director in the Office of Medical Guidance and Inspection, Bureau of Health Insurance, in the Ministry of Health and Welfare, Japan.

Dr. Omi joined the WHO Western Pacific Regional Office in Manila, Philippines, in 1990 as the Responsible Officer for the Expanded Programme on Immunization (EPI). Dr. Omi spearheaded the regional poliomyelitis (polio) eradication initiative in the Western Pacific Region. In 1995, he was promoted to the position of Director of the Division of Communicable Disease Prevention and Control, a post he held until 1998. In 1998–1999, Dr. Omi was a professor of public health at Jichi Medical School, Japan. In February 1999, Dr. Omi assumed the position of the WHO Regional Director for the Western Pacific.

It was during Dr. Omi's first term as Regional Director that WHO played the lead role in combating the outbreak of severe acute respiratory syndrome (SARS), the first emerging and readily transmissible disease of the 21st century. More than 95 percent of the SARS cases occurred in the Western Pacific Region. He spearheaded efforts to contain SARS by both tackling the medical issues and addressing the sensitive political concerns inherent in such events. Dr. Omi also gave special empha-

sis to tuberculosis during his first term by making the "Stop TB" program one of the Region's flagship projects. Dr. Omi was elected to a second term as Regional Director in January 2004. Much of Dr. Omi's work in his second term focused on working with the WHO Member States and various partner agencies to avert a potential influenza pandemic.

Paul Polman, M.B.A., M.A., has been CEO of Unilever since January 2009. Under his leadership Unilever has an ambitious vision to fully decouple its growth from overall environmental footprint and increase its positive social impact through the Unilever Sustainable Living Plan. He is Chairman of the World Business Council for Sustainable Development, a member of the International Business Council of the World Economic Forum, a member of the B Team and sits on the Board of the United Nations (UN) Global Compact and the Consumer Goods Forum, where he co-chairs the Sustainability Committee.

Mr. Polman has been closely involved in global discussions on action to tackle climate change and the Post-2015 development agenda. He served on the International Council of the Global Commission on the Economy and Climate, under former Mexican President, Felipe Calderon, whose flagship report "New Climate Economy" demonstrates that lasting economic growth can be achieved at the same time as reducing the immense risk of climate change. At the invitation of the UN Secretary-General, Mr. Polman also served on the High Level Panel on the Post-2015 Development Agenda, presenting recommendations on the successor to the Millennium Development Goals. Other roles include UK Business Ambassador by invitation of UK Prime Minister David Cameron, member of the Global Taskforce for Scaling up Nutrition, Counsellor of One Young World. Mr. Polman was co-chair of the B-20 Food Security Task Force.

Since 2010, Mr. Polman has been a non-executive director of the Dow Chemical Company.

In recognition of his contribution to responsible business, Mr. Polman has received numerous awards and recognition, including the Atlantic Council Award for Distinguished Business Leadership (2012), WWF's Duke of Edinburgh Gold Conservation Medal (2013), the Centre for Global Development's Commitment to Development Ideas in Action Award (2013), the Rainforest Alliance Lifetime Achievement Award (2014) and the UN Foundation's Champion for Global Change Award (2014).

He earned a B.B.A./B.A. from the University of Groningen, Netherlands, in 1977 and an M.A. in Economics and an M.B.A. in Finance/International Marketing from the University of Cincinnati in 1979. He has been awarded honorary degrees from a number of universities, including Newcastle, Liverpool, Groningen, and the University of Cincinnati.

Mirta Roses Periago, M.D., is Senior Advisor Global Health, Latin American and Caribbean Representative to the Global Fund Board (AIDS, Malaria, Tuberculosis) and Special Envoy Global Network NTDs. From 2003 to 2013, she was Pan American Health Organization (PAHO) Director, becoming the first woman to head the world's oldest international health organization and the first female World Health Organization (WHO) Regional Director. Prior to assuming this office, she served two terms as Assistant Director of PAHO (1995–2003) being responsible for the direct supervision of all PAHO/WHO Country Offices in the Americas, forming part of WHO's Directors of Programme Management Group (DPMs) and Global Programme Management Group (GPMG). She also served as PAHO/WHO Representative in the Dominican Republic (1988–1992) and in Bolivia (1992–1995). She started her international career with PAHO/WHO in 1984 as Chief, Surveillance Unit, Caribbean Epidemiology Center (CAREC) in Trinidad and Tobago serving all Caribbean countries, and moved as epidemiologist to the Dominican Republic (1986–1987).

Dr. Roses Periago earned her M.D. from the National University, Córdoba, Argentina, in 1969, completing her specialization in tropical medicine at the Universidade Federal de Bahia, Brazil, in 1971. Her graduate studies also include a diploma in public health (1974) and a specialization in epidemiology (1982) at the School of Public Health, University of Buenos Aires, Argentina, as well as the specialist degree in clinical medicine and epidemiology of infectious diseases at the University of Buenos Aires in 1976.

Shen Xiaoming, M.D., Ph.D., graduated from Wenzhou Medical College in 1984. He secured a Ph.D. from Shanghai Second Medical University (SSMU, current name Shanghai Jiao Tong University School of

Medicine after merging with Shanghai Jiao Tong University in 2005) in 1991 and joined its faculty of pediatrics. He undertook his fellowship in Albert Einstein College of Medicine. He was promoted to full professor upon his returning to Shanghai in 1996.

Dr. Shen was Director General of Shanghai Children's Medical Center, a join tertiary health care provider between Shanghai Municipal Government and a U.S.-based charity Project HOPE. He was the President of Xin Hua Hospital affiliated to SSMU and President of SSMU until he joined Shanghai Municipal Government as Director General of Shanghai Municipal Education Commission. He was elected as Vice Mayor of Shanghai in January 2008.

As a developmental pediatrician, Dr. Shen launched the first childhood lead poisoning program in China and established an epidemiology-based model for lead poisoning prevention. Dr. Shen successfully introduced newborn hearing screening to China and is currently running the largest and most efficient newborn hearing screening program in the world. He also introduced Nelson's *Textbook of Pediatrics* to China by translating the 17th edition of the textbook into Chinese. He also functions as the Director of the World Health Organization Collaborative Center for Neonatal Health Care.

He holds memberships in numerous professional scientific organizations and served as President of Asian Pacific Society for Newborn Screening, Vice Chairman of Chinese Society of Child Health Care, and Honorary Chairman of Shanghai Pediatric Society. He also took the editorial positions in more than 10 academic journals.

He is the author of more than 200 scientific articles and chapters in books. He has lectured extensively worldwide, and been a visiting or adjunct professor at many institutions, including The University of Hong Kong, Queensland University of Technology and given numerous named lectureships. To recognize Dr. Shen's contribution to the promotion of child heath internationally, he was granted an Honorary Doctor Degree by University of Paris 5 in 2005, and is the first Asian scholar to receive this degree in the 300-year history of the University of Paris 5. He also received an Honorary Doctor Degree from University of Nebraska Medical Center in 2010. He is an Honorary Fellow of American Academy of Pediatrics, one of very few pediatricians from outside the United States and the first pediatrician from China to receive this honor.

Tan Chorh Chuan, M.B.B.S., Ph.D., is President of the National University of Singapore (NUS). He concurrently serves as the Chairman of the Board of the National University Health System. Dr. Tan's additional appointments include Deputy Chairman of Singapore's Agency for Science, Technology and Research (A*STAR); Senior Advisor to the Governing Board of Duke-NUS Graduate Medical School; and Member, Board of Directors of the Monetary Authority of Singapore.

A renal physician, he obtained his medical training at NUS, and research training at the Institute of Molecular Medicine, Oxford. He was Dean of the NUS Faculty of Medicine from 1997 to 2000. He served as the Director of Medical Services, Ministry of Health, from 2000 to 2004, where he was responsible for leading the public health response to the 2003 severe acute respiratory syndrome (SARS) epidemic. He held the positions of NUS Provost, then Senior Deputy President from 2004 to 2008. He also played a key role in setting up the Duke-NUS Graduate Medical School, in his capacity as Deputy Chairman of the Governing Board from 2004 to 2007. As the inaugural Chief Executive of the National University Health System in 2008, he brought the NUS Medical and Dental Schools and the National University Hospital under single governance.

Dr. Tan is a key leader in Singapore's Biomedical Sciences Initiative since its inception in 2000, for which he was awarded the National Science and Technology Medal in 2008. He also received the following National Day Awards from the Singapore government: the Public Service Star in 2003 for outstanding contributions to overcoming SARS in Singapore; the Public Administration Gold Medal in 2004 for his work as Director of Medical Services in the Ministry of Health; and the Meritorious Service Medal in 2015. Other awards include the Dr. John Yu Medal from the George Institute for Global Health, Australia; the Albert Schweitzer Gold Medal from the Polish Academy of Medicine; Honorary Doctor of Medicine from King's College; Honorary Doctor of Science from Duke University; Honorary Doctor of Science from Loughborough University; Achievement Medal from the Singapore Society of Nephrology, and the 1996 Singapore Youth Award.

Dr. Tan, who has been a member of the World Economic Forum's Global University Leaders Forum (GULF) since 2008, was appointed its Chairman from

2014–2016. He also sits on the World Economic Forum's Science Advisory Committee. He was the Chairperson of the International Alliance of Research Universities, a consortium of 10 leading research-intensive universities from 2008–2012.

Dr. Tan was elected to the U.S. National Academy of Medicine in 2015. He was previously a Commonwealth Medical Fellow, Wellcome Fellow, University of Oxford, and a Visiting Scholar to Wolfson College, Oxford. He is a Fellow of the Royal College of Physicians of Edinburgh, Royal College of Physicians of London, the American College of Physicians, elected Fellow of the Polish Academy of Medicine and Fellow of the Royal Geographical Society, United Kingdom.

Miriam Were, MBChB, Dr. PH., M.P.H., is the current Chancellor of Moi University in Kenya and a Trustee of the Kenya Medical Women Association. She is also the Co-Founder of UZIMA Foundation that has a focus on Youth Empowerment. She was formerly chairperson of the National AIDS Control Council (NACC) Kenya, under the Office of the President that coordinates the national HIV/AIDS response in Kenya. She was also the Chairperson of the African Medical and Research Foundation (AMREF) Board. Dr. Were also served on the Advisory Board of the Kenya Anti-Corruption Commission (KACC) as well as on the MAP International Board of Directors based in Georgia, USA, among others.

Dr. Were was Director of the United Nations Population Fund Country Support Team (UNFPA/CST) for East and Central Africa and Anglophone West Africa, based in Addis Ababa, Ethiopia. Prior to that she also worked as the World Health Organization Representative in Ethiopia and Chief of Health and Nutrition in the United Nations Children's Fund (UNICEF), Ethiopia. Professor Were was recruited to UNICEF from the Department of Community Health in the Faculty of Medicine, University of Nairobi where she was Head of Department. While in the Department, she initiated the Community-Based Health Care (CBHC) project in Kakamega of which she was the Director from 1976 to 1982. This project won the UNICEF Maurice Pate Award of 1978, the first time an African institution had won this award. Dr. Were qualified as a Medical Doctor from the University of Nairobi. Subsequently, she obtained her M.P.H. and Dr.PH. from the Johns Hopkins University.

CONSULTANTS

Anas El Turabi, BMChB, MPhil., is a primary care physician and doctoral candidate in health policy at Harvard University. He received his B.A. with Honors in Physiological Sciences and his medical degree from the University of Oxford, and an M.Phil. with Distinction in Clinical Science from the University of Cambridge. He has a background in health policy and global health, having spent 2 years working at the Department of Health (England) and with the World Health Organization on issues of global health research governance and health research system evaluation. He has also held an honorary research fellowship at RAND Europe and has previously worked in strategy consultancy.

Philip Saynisch is a doctoral student in Health Policy at the Harvard Business School and Graduate School of Arts and Sciences, concentrating in management. His research interests include consumer models of patient behavior and topics in provider decision making. He is currently engaged in projects exploring the use of patient-facing tools for reporting information on the price and quality of care, and in surgeon decision making around organ transplantation. Additionally, he is part of an ongoing project studying the impact of patient-centered medical home reforms in primary care on patient outcomes. He received his bachelor's degree from the University of Pennsylvania in 2009. Prior to joining the Health Policy program, he worked in the Center for Outcomes Research at the Children's Hospital of Pennsylvania, and as a research assistant in the Wharton School's Department of Health Care Management.

STAFF

Carmen C. Mundaca-Shah, M.D., Dr.P.H., is a Senior Program Officer with Board on Global Health at the National Academies of Sciences, Engineering, and Medicine. She is currently directing the Multi-Stakeholder Initiative for Creating a Global Health Risk Framework for the Future. Prior to directing this study, she was the study director for the Academies' Board on the Health of Select Populations report *Beyond Myalgic Encelphalomyelitis/Chronic Fatigue Syndrome: Redefining an Illness.* She also served as a postdoctoral fellow with the Academies' Board on Global Health on the Outcome and Impact Evaluation of Global HIV/AIDS Programs Implemented Under the Lantos-Hyde Act

of 2008. Prior to joining the Academies, Dr. Mundaca-Shah was employed as head of the Surveillance Center of the Emerging Infections Program in the U.S. Naval Medical Research Unit 6 in Lima, Peru. In that role, she led the successful implementation of a technology-based disease surveillance system (Alerta) at sites across the nation and the initial phase of a project sponsored by the U.S. Southern Command to expand Alerta to five other countries in South America. Alerta is a partnership involving the Peruvian Navy and the U.S. Navy. Dr. Mundaca-Shah also led the collaborative syndromic surveillance pilot implementation in the Peruvian Ministry of Health. She was part of the Early Warning Outbreak Recognition System (EWORS) Working Group and participated in several studies, including a field visit to evaluate the performance of the system in Lao People's Democratic Republic. She obtained her M.D. from San Marcos University, Lima, Peru, and her M.P.H. and Dr.P.H. degrees from the Uniformed Services University of the Health Sciences, Bethesda, Maryland. Her dissertation work focused on developing a framework to guide the implementation of disease surveillance systems in developing countries. Dr. Mundaca-Shah completed a certificate in emerging infectious disease epidemiology at the University of Iowa.

V. Ayano Ogawa, S.M., is a Research Associate on the Board on Global Health at the National Academies of Sciences, Engineering, and Medicine. Prior to the Academies, she was a Senior Research Analyst for the U.S. Agency for International Development, where she helped country officers develop and strengthen global health initiatives in Southeast Asia and sub-Saharan Africa. She previously supported health communication campaigns on a global scale at U.S. Fund for United Nations Children's Fund and Sesame Workshop, and worked in health and education sectors in various countries, including in Bangladesh, South Africa, and Taiwan (as a Fulbright Fellow). She holds a B.A. in Public Health from Johns Hopkins University and an S.M. in Social & Behavioral Sciences with a concentration in Health Communication from the Harvard T.H. Chan School of Public Health.

Priyanka Kanal was a summer intern working at the National Academies of Sciences, Engineering, and Medicine. Currently, she studies Public Policy, Economics, and Global Health at Duke University. She previously interned for the OpenPharma Index, a pharma transparency initiative at Duke's Kenan Institute for Ethics. She has also conducted research with Duke's Nicholas School of the Environment on the link between reemerging infectious diseases in the United States to water quality and sanitation.

Mariah Geiger was a Senior Program Assistant on the Board on Global Health at the National Academies of Sciences, Engineering, and Medicine. She recently graduated from Macalester College, receiving a B.A. in International Studies with a concentration in Community and Global Health. At Macalester, she founded and chaired Voices on Mental Health, an organization dedicated to reducing stigma around mental health issues. The organization received Macalester's 2015 Civil Discourse Award. She was a 2014 Ronald E. McNair Scholar at the University of Minnesota, where she worked on the Padres Informados/Jóvenes Preparados (Informed Parents/Prepared Young People) project, a community-based participatory research initiative designed to fight tobacco use among Latino youth.

David Garrison is a Senior Program Assistant for the Board on Global Health at the National Academies of Sciences, Engineering, and Medicine. He joined the Academies after 1 year in San Luis Potosí, Mexico, where he taught English and interned with Mexico's Ministry of Economy. In his first months at the Academies, he played a supporting role in the finance workstream of the Global Health Risk Framework initiative. He received his bachelor's degree from Vanderbilt University, with majors in economics and Spanish language.

Patrick W. Kelley, M.D., Dr.P.H., joined the Institute of Medicine (IOM) in July 2003 as the Director of the Board on Global Health. He also served from 2004 to 2015 as Director of the Board on African Science Academy Development. Dr. Kelley has overseen a portfolio of the IOM expert consensus studies and convening activities on subjects as wide ranging as: the evaluation of the U.S. emergency plan for international AIDS relief (PEPFAR); the U.S. commitment to global health, sustainable surveillance for zoonotic infections; substandard, falsified, and counterfeit drugs; innovations in health professional education; cardiovascular disease preven-

tion in low- and middle-income countries; interpersonal violence prevention in low- and middle-income countries; and microbial threats to health. He also directed a unique capacity-building effort, the African Science Academy Development Initiative, which over 11 years strengthened the capacity of eight African academies to provide independent, evidence-based advice their governments on scientific matters.

Prior to joining the National Academies of Sciences, Engineering, and Medicine, Dr. Kelley served in the U.S. Army for more than 23 years as a physician, residency director, epidemiologist, and program manager. In his last U.S. Department of Defense (DOD) position, Dr. Kelley founded and directed the DOD Global Emerging Infections Surveillance and Response System (DOD-GEIS). This responsibility entailed managing surveillance and capacity-building partnerships with numerous elements of the federal government and with health ministries in more than 45 developing countries. He also founded the DOD Accession Medical Standards Analysis and Research Activity and served as the specialty editor for a landmark two-volume textbook titled: *Military Preventive Medicine: Mobilization and Deployment*. Dr. Kelley is an experienced communicator, having lectured in English or Spanish in more than 20 countries. He has authored or co-authored more than 75 scholarly papers, book chapters, and monographs and has supervised the completion of more than 25 book-length IOM consensus reports and workshop summaries. While at the IOM he has obtained grants and contracts for work conducted by his unit from more than 60 governmental and nongovernmental sources. Dr. Kelley obtained his M.D. from the University of Virginia and his Dr.P.H. in epidemiology from the Johns Hopkins School of Hygiene and Public Health. He has also been awarded two honorary doctoral degrees and is board-certified in preventive medicine and public health.