

GLOBAL MONITORING OF DISEASE OUTBREAK PREPAREDNESS

Preventing the Next Pandemic

A Shared Framework



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ACRONYMS

AAS	African Academy of Sciences		
ACEGID	African Centre of Excellence for Genomics of Infectious Diseases		
AMR	Antimicrobial resistance (including antibiotic resistance)		
BARDA	Biomedical Advanced Research and Development Authority (U.S.)		
CBD	Convention on Biological Diversity (1992)		
CDC	U.S. Centers for Disease Control and Prevention		
CEPI	Coalition for Epidemic Preparedness Innovations		
CSO	Civil Society Organization		
CSR	Corporate Social Responsibility		
EID	Emerging Infectious Disease		
EIU	Economist Intelligence Unit		
EUAL	Emergency Use Assessment and Listing Procedure (WHO)		
FAO	Food and Agriculture Organization of the United Nations		
FENSA	WHO Framework of Engagement with Non-State Actors		
G20	Group of Twenty (International Forum)		
GEVIT	Global Ebola Vaccine Implementation Team		
GHRF	Commission on a Global Health Risk Framework for the Future		
GHSA	Global Health Security Agenda		
GHS Index	Global Health Security Index		
GOARN	Global Outbreak Alert and Response Network (WHO)		
HGHI	Harvard Global Health Institute		
HIV/AIDS	Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome		
IANPHI	International Association of National Public Health Institutes		
IASC	Inter-Agency Standing Committee (UN and non-UN humanitarian partners)		
ICG	International Coordinating Group		
IDA	International Development Association (World Bank's concessional fund)		
IDSR	Integrated Disease Surveillance and Response (CDC)		
IEG	Independent Evaluation Group (World Bank)		
IHR	International Health Regulations		
IMF	International Monetary Fund		
INFORM	Index for Risk Management		
IPCC	Intergovernmental Panel on Climate Change		
IRB	Institutional Review Board		
IWG	International Working Group on Financing Preparedness (World Bank)		
JEE	Joint External Evaluation (WHO)		
JHU	Johns Hopkins University		
LMIC	Low- and middle-income countries		

MERS-CoV	Middle East Respiratory Syndrome Coronavirus			
MTA	Material Transfer Agreement			
NAM	U.S. National Academy of Medicine			
NRA	National Regulatory Authority			
NIH	National Institutes of Health (U.S.)			
NTI	Nuclear Threat Initiative			
OECD	Organisation for Economic Co-operation and Development			
OIE	World Organisation for Animal Health (Office International des Epizooties)			
РАНО	Pan American Health Organization			
PEF	Pandemic Emergency Financing Facility (World Bank)			
PHEIC	Public Health Emergency of International Concern			
PIP	Pandemic Influenza Preparedness Framework			
PPDC	Pandemic Product Development Committee			
PQ	WHO Prequalification			
PSRT	Private Sector Roundtable (GHSA)			
PVS	Evaluation of Performance of Veterinary Services Evaluation (OIE)			
R&D	Research and development			
RAND Corporation	Research and Development Corporation			
REDISSE	Regional Disease Surveillance Systems Enhancement (West Africa)			
SARS	Severe Acute Respiratory Syndrome			
SDGs	Sustainable Development Goals (2030)			
SPP	Strategic Partnership Portal (WHO)			
TPP	Target Product Profile (WHO R&D Blueprint)			
UHC	Universal Health Coverage			
UN	United Nations			
UNAIDS	The Joint United Nations Program on HIV/AIDS			
UNICEF	United Nations Children's Fund			
USAID	United States Agency for International Development			
WEF	World Economic Forum			
WHA	World Health Assembly			
WHO	World Health Organization			

All dollar amounts in this report are U.S. dollars unless specified otherwise.

GLOSSARY

advance market commitments (AMCs)	A binding contract, typically offered by a government or other financial entity, used to guarantee a viable market for a product (e.g. vaccine or therapeutic) once it is successfully developed. Generally AMCs are used in circumstances where the cost of developing a new product is too high for the private sector without advanced purchases.	
antimicrobial resistance (AMR)	The ability of a microorganism (e.g. bacteria, viruses, fungi, and some parasites) to stop an antimicrobial (e.g. antibiotics, antivirals, or antimalarials) from working against it. Treatments thus become ineffective and infections persist. "Superbug" refers to a pathogen (especially a bacterium) that has developed resistance to the medications normally used against it (typically antibiotics).	
biochemistry	A branch of science that explores the chemical processes within and related to living organisms. It is a laboratory based science that brings together biology and chemistry. By using chemical knowledge and techniques, biochemists can understand and solve biological problems. (Biochemical Society 2017)	
biogeography	A branch of biology that studies the geographic distribution of plants and animals. It is concerned not only with habitation patterns but also with the factors responsible for variations in distribution. (Encyclopaedia Britannica 2017)	
biomarker	A biological molecule found in blood, other body fluids, or tissues that is a sign of a normal or abnormal process, or of a condition or disease. A biomarker may be used to see how well the body responds to a treatment for a disease or condition. Also called molecular marker and signature molecule. (National Cancer Institute 2017)	
biosecurity	An integrated approach that encompasses the policy and regulatory frameworks (including instruments and activities) that analyze and manage risks to food safety, animal life and health, and plant life and health, including associated environmental risk. Biosecurity covers the introduction of plant pests, animal pests and diseases, and zoonoses; the introduction and release of genetically modified organisms (GMOs) and their products; and the introduction and management of invasive alien species and genotypes. (FAO Committee on Agriculture 2003)	
core public health capacities	 Essential public health capacities that States Parties (countries) are required to have in place throughout their territories pursuant to Article 5 and 12, and Annex 1A of the IHR 2005. Eight core capacities are defined and these are listed in Annex 2B of this report. These core capacities are now also reflected in the Joint External Evaluation Tool, which can also be found in Annex 2B. 	
epidemic	The occurrence in a community or region of cases of illness or health-related events clearly in excess of normal expectancy. (<i>A Dictionary of Epidemiology</i> . Oxford. 2014)	
	Many epidemiologists use the terms outbreak and epidemic interchangeably, but the public is more likely to think that epidemic implies a crisis situation. (Porta 2008)	
	Epidemics caused by a new pathogen (i.e. new disease), may occur in one or more regions and not become pandemics. Pathogens causing these diseases include Ebola virus, coronaviruses like SARS and MERS-CoV, and <i>Aedes</i> -transmitted viruses like Zika and yellow fever.	

epidemiology	The study of the distribution and determinants of health-related states or events (including disease), and the application of this study to the control of diseases and other health problems. Methods of epidemiological investigations include surveillance, descriptive studies of distribution, and analytical studies of determinants. (World Health Organization 2017)		
Global Health Security Agenda (GHSA)	A partnership (launched in February 2014) of over 64 nations, international organizations, and non-governmental stakeholders to to help create a world safe and secure from infectious disease threats and elevate global health security as a national and global priority. (Global Health Security Agenda 2017b)		
IDA18	The 18 th replenishment of IDA (part of the World Bank Group) has \$75 billion for projects in the 75 poorest countries from July 1, 2017 to June 30, 2020. The concessional credits and grants are for projects that reduce poverty and foster sustainable economic development, including economic policy reform programs. The amount that a country can obtain from IDA is based on policy performance, but IDA's Crisis-Response Window can quickly give additional funds to countries to respond to disasters, including control of disease outbreaks. Under its IDA18 agreement with donors, the World Bank is to support: (i) "at least 25 IDA countries in developing pandemic preparedness plans," and (ii) "25 countries in developing frameworks for governance and institutional arrangements for multisectoral health emergency preparedness, response and recovery." (World Bank 2017)		
immunology	The study of the molecular and cellular components that comprise the immune system, including their function and interaction.		
indicator (as defined in this report)	A measurable variable used as a representation of an associated factor, quantity, or characteristic related to global health security		
International Health Regulations (2005)	A legally-binding instrument of international law that aims to a) assist countries to work together to save lives and livelihoods endangered by the international spread of diseases and other health risks, and b) avoid unnecessary interference with international trade and travel.		
	The purpose and scope of IHR 2005 are to prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade (World Health Organization 2007)		
in vitro	(Of a process) performed or taking place in a test tube, culture dish, or elsewhere outside a living organism		
in vivo	(Of a process) performed or taking place in a living organism		
Joint External Evaluation	A voluntary, collaborative process to assess a country's capacity under the IHR 2005 to prevent, detect, and rapidly respond to public health threats whether occurring naturally or due to deliberate or accidental events. (Global Health Security Agenda 2017a)		
JEE Alliance (Alliance for Country Assessments for Global Health Security and IHR Implementation)	A platform that brings together like-minded actors from different countries, sectors, organizations and other stakeholders involved in health security. Formed on 22 May 2016 in Geneva, Switzerland, it supports country assessment processes and the resulting work on building country capacity for health security. It promotes transparency in exchanging information, supports linking national planning and implementation to follow on the results of evaluations, and aims at creating innovative solutions and opportunities for supporting country capacity building. (JEE Alliance 2017)		

Likert scale	A five (or seven) point scale which is used to allow the individual to express how much they agree or disagree with a particular statement. Typically used to measure attitudes or opinions.	
microbiology	The study of all living organisms that are too small to be visible with the naked eye. The includes bacteria, archaea, viruses, fungi, prions, protozoa and algae, collectively know as 'microbes'. These microbes play key roles in nutrient cycling, biodegradation/ biodeterioration, climate change, food spoilage, the cause and control of disease, and biotechnology. (Microbiology Society 2017)	
monitoring framework (as defined in this report)	Evidence-based monitoring framework to track the performance of the international community and its key institutions in reducing a substantial global threat, and to regularly disseminate the results.	
	The monitoring framework encompasses four content domains (see Figure 1), namely:	
	1)Strengthening public health capacity as a foundation;	
	2)Improving science, technology, and access;	
	3)Reinforcing risk analysis and incentives for action;	
	4)Strengthening global mechanisms.	
One Health	One Health recognizes that the health of people is connected to the health of animals and the environment. The goal of One Health is to encourage the collaborative efforts of multiple disciplines-working locally, nationally, and globally-to achieve the best health for people, animals, and our environment.	
	For operational purposes, the World Bank and others define a collaborative One Health approach for strengthening systems to prevent, prepare, detect, respond to, and recover from infectious diseases and related hazards such as antimicrobial resistance, that threaten human health, animal health, and environmental health. One Health approach to surveillance and reporting is fundamental to improving global health security and development prospects. While using infectious diseases/AMR as a starting point, the scope of an operational definition of One Health can expand (e.g. to water and soil pollution, which have animal and environment connections).	
	A One Health approach is important because 60% of all infectious diseases in humans and 75% of emerging diseases are spread from animals. Moreover, 80% of bioterrorism agents are zoonotic. (Centers for Disease Control and Prevention 2017b)	
operational continuity	The ability of a system to continue working despite damages, losses or critical events. Arrangements for operational continuity are a key concern of pandemic preparedness. <i>Business continuity</i> is similar, but it may require stopping operations in order for the firm to survive.	
pandemic	An epidemic occurring worldwide, or over a very wide area, crossing international boundaries and usually affecting a large number of people. (Centers for Disease Control and Prevention 2017a)	
	The WHO uses the term 'pandemic' for infectious disease that affects many people in multiple countries and is spreading (epidemic) on at least two continents. Influenza and AMR are two known pandemic threats with potentially devastating impacts on economies, society, and public health.	
PVS Tool (Evaluation of Performance of Veterinary Services Tool)	A tool of the World Organisation of Animal Health (OIE) to assist veterinary services to establish their current level of performance, to identify gaps and weaknesses in their ability to comply with OIE international standards, form a shared vision with stakeholders (including the private sector), establish priorities and carry out strategic initiatives. (World Organisation for Animal Health 2013)	

preparedness	The knowledge and capacities developed by governments, public health agencies, response and recovery organizations, communities, businesses, and individuals to effectively anticipate, respond to and recover from the impacts of likely, imminent or current disasters, including epidemics and pandemics. A preparedness plan establishes arrangements in advance to enable timely, effective and appropriate responses to events or emerging disaster situations that might threaten society or the environment. Preparedness for the first and immediate response is called <i>emergency preparedness</i> . (UNISDR 2017)
public health emergency of international concern (PHEIC)	An extraordinary event which, as provided in the IHR 2005, (i) constitutes a public health risk to other States through the international spread of disease and (ii) potentially requires a coordinated international response public health risk. (World Health Organization 2007)
PVS Tool (Evaluation of Performance of Veterinary Services Tool)	A tool of the World Organisation of Animal Health (OIE) to assist veterinary services to establish their current level of performance, to identify gaps and weaknesses in their ability to comply with OIE international standards, form a shared vision with stakeholders (including the private sector), establish priorities and carry out strategic initiatives. (World Organisation for Animal Health 2013)
structural biology	The study of the molecular structure and dynamics of biological macromolecules, particularly proteins and nucleic acids, and how alterations in their structures affect their function. Structural biology incorporates the principles of molecular biology, biochemistry, and biophysics. (nature.com 2017)

virtual biobank	A virtual repository of data extracted from, and characterizing samples stored at, classical biobanks.Virtual biobanks are large databases and can provide high-resolution images of samples as well as other characteristic data. These virtual biobanks can be accessed via specialized software or web portals. Samples are stored in a decentralized manner. The use of virtual biobanks provides access, in the form of pre-collected data, without requiring access to the physical sample. This allows the sample's data to be more readily shared without fear of contaminating/destroying/transporting the sample. (Vaught, Kelly, and Hewitt 2009)	
zoonosis plural (zoonoses)	A disease or infection, which is naturally transmissible between animals and humans. According to OIE, 75% of emerging infectious diseases in humans are zoonotic (originate in animals). Some examples include: influenza (flu), MERS-CoV, SARS, Rift Valley fever, Ebola, rabies, tuberculosis, brucellosis, and leptospirosis. (adapted from OIE, WHO)	

PREFACE

Few natural hazards threaten more loss of life, economic disruption, and social disorder than serious infectious disease outbreaks. A pandemic of influenza or similarly transmissible disease could infect billions, kill millions, and knock trillions of dollars off global gross domestic product. Even a more contained epidemic could kill millions and cost tens or hundreds of billions of dollars (Commission on a Global Health Risk Framework for the Future 2016). Yet compared to the resources devoted to mitigating other global risks such as terrorism, climate change, or war, the global community invests relatively little to prevent and prepare for infectious disease outbreaks. The typical pattern of response can be characterized as a cycle of panic and neglect: a rushed deployment of considerable resources when an outbreak occurs, followed by diminishing interest and investment as memories of the outbreak fade. The consequent underinvestment in preparedness, and over reliance on reactive responses is enormously costly in terms of both lives and dollars, and aggravates global risk.

In the wake of major outbreaks since the beginning of the 21st century– including those of Ebola, Zika, avian flu (H5N1, H7N9, and other strains), Severe Acute Respiratory Syndrome (SARS), and Middle East Respiratory Syndrome Coronavirus (MERS-CoV) as well as the 2009 H1N1 flu pandemic – national and global health security have received increased attention. Efforts were launched to strengthen national public health systems and to reinforce international mechanisms for coordination and response. Yet there are still glaring gaps. The first line of defense is each country's veterinary and human public health systems' capacity to detect and promptly control an infectious disease outbreak. Given competing priorities, however, most countries have not devoted sufficient resources and attention to building such skills and infrastructure. As a result, most countries still do not meet their obligations as defined by the International Health Regulations in 2005. At a global level, steps have been taken to reinforce the ability of the World Health Organization, the World Organization for Animal Health, and other multilateral entities to support countries in preventing, detecting, and response appropriately. On the scientific front, initiatives such as the Coalition for Epidemic Preparedness Innovations (CEPI) hold great promise but are still at an early stage. As a result, we currently lack good diagnostic tools, vaccines, and therapeutics for many of the most threatening pathogens.

This is not an area in which there is significant debate about what to do; in fact, there is strong consensus on what actions are required. While varying in detail and emphasis, in the last two years, several major reports examined the response to the Ebola epidemic (World Health Organization 2015b; Commission on a Global Health Risk Framework for the Future 2016; Moon et al. 2015) and converged in their policy recommendations — strengthening national human and animal health systems as the first line of defense; reinforcing global coordination and capabilities; accelerating the development of diagnostics and vaccines; and improving information sharing and economic incentives. Moreover, many policymakers at national and international levels have accepted these recommendations and made commitments to implement them. The question is whether these commitments will be fulfilled or whether, given scarce resources, weak accountability for governments' failures to prevent epidemics, and more immediate priorities, we will once again slip into a cycle of neglect until the next outbreak occurs.

To help us escape from the damaging neglect phase between outbreak emergencies, this report provides an objective, evidence-based monitoring framework to track the performance of the international community and its key institutions in reducing a substantial global threat, and to regularly disseminate the results. This will help to clarify and increase accountability. Work is already underway to improve global health security at the country,

regional, and international levels by country governments, local and international institutions, civil society organizations, donor agencies, multilateral organizations and universities, and yet more needs to be done. The purpose of the proposed global monitoring arrangement is not to create entirely new bodies of research, but rather, wherever possible, to consolidate existing work into a comprehensive framework that can be shared widely and strategically to strengthen impact. By monitoring international-, regional-, and national-level actions to prevent, detect, and respond to infectious disease outbreaks, we can celebrate improvements, shine a light on outstanding gaps and weaknesses, and hold policymakers accountable. Routine, transparent, and objective monitoring will also help to ensure sustained financial support and effective prioritization from international organizations, donor agencies, national governments, and the private sector.

This report is a step towards developing such a shared framework and monitoring mechanism. It reflects the outcome of discussions involving over 50 international experts in veterinary and human public health, public policy, finance, and economic development from a meeting co-hosted by the National Academy of Medicine and the Harvard Global Health Institute on April 18th, 2017. These discussions were structured around a draft monitoring framework developed by the research team¹ and sought to build consensus around what should be monitored, and how an overall implementation approach could facilitate collaborative partnerships amongst a range of academic institutions, international organizations, think tanks, and public-health institutes in both developed and developing countries.

This report is primarily intended for the community of policymakers and researchers concerned about the rising risks of domestic, regional, and global infectious disease epidemics, and the collective failure to take the coordinated actions required to reduce such risks. These risks include the expected health, economic, and societal costs that are borne by countries, regions, and even all nations in the case of pandemics (which are worldwide epidemics). These risks also include the consequences of increasing antimicrobial resistance (AMR) and its spread within regions and globally. A necessary first step is to monitor whether a broad range of stakeholders are acting to prevent outbreaks from becoming epidemics, whether their capacities to respond to epidemics are robust, and whether preparedness to respond to pandemics and limit the resulting economic and health damage is improving. Analyzing the adequacy of these efforts is vitally important for the decisions of policymakers to invest in the public health and disaster-risk management capacities. Early and effective control of disease outbreaks prevents substantial health and economic costs whether or not the disease can spread globally and become a pandemic. Disease spread within a region can also be deeply impoverishing and should be prevented.

The capacities that reduce the risk of epidemics are an essential part of the arsenal required to mitigate pandemic risk. The investments made to mitigate these risks are also indispensable in reducing endemic disease burdens (such as malaria, tuberculosis, HIV and vector-borne diseases among others). A pandemic of influenza or similarly fast-growing contagion, as well as AMR, are natural hazards that pose a top global catastrophic risk to public health, economies, and societies — and they can even present an important existential risk to humanity. Public health capacities to detect and effectively control outbreaks and the prioritization of pandemic preparedness are necessary to reduce costly impacts on public health and economies, but they will not by themselves be sufficient for an adequate response, especially to a regional epidemic or a pandemic, which will require leadership, effective communications, and measures from sectors other than public health.

This report is intended to serve as an explanatory reference or baseline for future refinements of the indicators and evolution of the framework. Therefore, readers may choose to read the sections relevant to their particular professional domain. However, the report may also be used as an introduction to global health security policy issues.

¹ The initial development of indicators to monitor global health security and pandemic preparedness was undertaken by the Harvard Global Health Institute (HGHI), the Harvard Kennedy School (HKS), and Georgetown University. "Research team" in this report refers to researchers from these institutions.

EXECUTIVE SUMMARY

Few natural hazards threaten more loss of life, economic disruption, and social disorder than large-scale infectious disease outbreaks. An influenza pandemic or similarly transmissible disease¹ could infect billions, kill millions, and reduce trillions of dollars from global economic output. Even a more localized epidemic could lead to a catastrophic loss of life, GDP, and cost millions to contain (Commission on a Global Health Risk Framework for the Future 2016). The economic effects occur by closing businesses, schools, public offices, and often, the healthcare system itself. Further, effects of disease outbreaks include interruptions in transportation (of goods), trade, and travel. While most disease outbreaks are localized to a region, they can quickly become global, as we have seen with Ebola, Severe Acute Respiratory Syndrome (SARS), and Zika. With other related challenges, such as the rise in antimicrobial resistance (AMR) and deliberate human-engineered threats, we must ensure that a preparedness program is in place to combat these risks.

Compared to the resources devoted to mitigating other global risks such as terrorism, climate change, or war, the world invests strikingly little in infectious disease outbreak preparedness. The problem is not a lack of knowledge, as the public health community knows what steps are needed to mitigate risk. However, preventive measures are rarely prioritized. In fact, the typical pattern of infectious disease preparedness today can be characterized as a cycle of panic and neglect: a flood of resources during outbreaks followed by lack of interest and diminished investments. The resulting dependence on crisis-response is both costly and ineffective (in preventing the next outbreak).

The most recent Ebola outbreak in West Africa is a good example. Governments and response agencies poured more than \$3.6 billion into containment, 11,000 lives were lost, 28,000 were infected, and the regional economy lost \$2.2 billion in GDP in one year (Centers for Disease Control and Prevention 2016). Three years post-Ebola, funds to reduce future outbreaks have dwindled, and Ebola has all but disappeared from the news. Since 1976, dozens of Ebola outbreaks have struck Africa, and the next one is merely a question of time.

In addition to Ebola, we have a long and costly history with other infectious disease outbreaks. Just over the past 15 years, Zika, MERS-CoV, SARS, cholera, tuberculosis, HIV/AIDS, and various strains of the influenza virus have affected hundreds of millions of people around the world. One could argue that we have been lucky in avoiding a major pandemic, such as that of the 1918 influenza, which resulted in an estimated 50-100 million lives lost or 3-5% of the global population at that time, which today would be the equivalent of more than 200 million people.

Why do we fail to adequately invest in the prevention of disease outbreaks? We know that major disease outbreaks have an expected economic cost of tens of billions of dollars annually; yet, little preventive action is taken (Commission on a Global Health Risk Framework for the Future 2016). Indeed, following the Ebola outbreak in West Africa, more than 40 expert reports were written, each of which outlined, in strikingly similar ways, significant failures in the response of the international community and what needs to change to avoid the same mistakes. The Commission on the Global Health Risk Framework estimated that the costs of implementing robust measures would cost the world less than \$5 billion annually, which is far less than the cost of a major disease outbreak or pandemic (Commission on a Global Health Risk Framework for the Future 2016). A new course of action is needed. We must act to ensure the world is better prepared.

Sustained monitoring to drive preparedness. One way to spur action is to implement a global monitoring mechanism that tracks preparedness over time and holds key stakeholders accountable. Consistent public reminders of progress and gaps can be used strategically to increase investment in disease outbreak preparedness and inform the global public how much progress is being made. A global monitoring program can highlight weaknesses in our global efforts, and where additional resources or efforts may be needed. As political attention on pandemics fades, there is a corresponding loss of momentum on investments that can help keep the world safer. Therefore, sustaining and enhancing the energy that policymakers expend on this topic is vitally important. An independent, objective monitoring mechanism is one way to do so.

Co-benefits of monitoring preparedness. Sustained monitoring can also directly benefit all nations around the world by decreasing the chance that future outbreaks will develop into major epidemics or even pandemics. By spurring investment in essential public health capacities, human resources, and the infrastructure needed to prevent, detect, and contain infectious disease outbreaks, human health and economic development will benefit more broadly. Improvements in public health infrastructure, surveillance, detection, and response capabilities will benefit other health areas such as endemic disease management (including malaria, tuberculosis, HIV/AIDS, and vector-borne illnesses). Low-income regions and fragile states are likely to benefit the most from such investments as the positive spill-over into other health areas can be significant. According to experts, the total cost of disease outbreak risk mitigation could be as less than \$5 billion annually to substantially reduce the risk. This is also a fraction of what we spend on other serious risks to humanity, and a small fraction of the expected economic benefits which are estimated to be at least \$60 billion annually (Commission on a Global Health Risk Framework for the Future 2016).

Global monitoring to drive preparedness. Recognizing the value of such a monitoring mechanism, scholars from the Harvard Global Health Institute (HGHI) and Georgetown University, with input from scholars from around the globe, have developed a global monitoring framework. In April of 2017, HGHI and the National Academy of Medicine (NAM) convened more than 50 leading experts from around the world to review a draft monitoring framework with qualitative and quantitative indicators across a range of content areas.

During the April 2017 workshop, participants discussed the framework, indicators to track progress, operationalization of the monitoring, data collection, results dissemination, and a governance structure. To catalyze discussion, a draft framework consisting of a set of indicators was shared by a team comprised of researchers from HGHI, the Harvard Kennedy School, and Georgetown University. Because infectious disease outbreak preparedness is inherently multisectoral and requires both the private and public sectors, the monitoring framework had to reflect a "whole of society" approach. The proposed framework is meant to serve as a starting point which will evolve over time in response to experience and inputs from stakeholders as the monitoring work begins. The report that came out of the April 2017 workshop, entitled "Global Monitoring of Disease Outbreak Preparedness: Preventing the Next Pandemic," incorporates comments and feedback from the workshop, suggestions that followed from workshop participants, and input from other outside experts, totaling more than 350 unique comments.

Monitoring Framework and Coalition. A monitoring framework and the notion of a global coalition of institutions and organizations monitoring progress over time is consistent with the recommendations of the 2017 United Nations Secretary General's Global Health Crises Task Force. In the Task Force's final report, the group called for an independent, objective monitoring mechanism, highlighting the importance of regular monitoring to increase accountability and reform (Global Health Crises Task Force 2017). The April 2017 workshop participants similarly agreed with the Task Force that any monitoring program must be rigorous, independent, and reflect the best data and analysis possible.

We believe that a cohesive framework with a consistent set of indicators will facilitate collaboration among contributors and strengthen its impact. Regular, independent, and clearly communicated monitoring (using the proposed framework) will enable policymakers and civil society to better understand the risks and tradeoffs, and ultimately, to invest in preparedness more adequately.

The proposed framework is divided into four separate, interrelated domains:

- 1. Strengthening public health core capacity as a foundation;
- 2. Improving science, technology, and access;
- 3. Reinforcing risk analysis and incentives for action; and
- 4. Strengthening global mechanisms (such as the UN and WHO).

In each of the four domains, the report describes the indicators that will be critical to track. The indicators are a mix of country-level, regional, and international data. Where critical data elements are missing, new, original research will be needed. Wherever possible, existing data collection structures will be used for greatest efficiency and cost-effectiveness which in turn will minimize the burden on any given country, especially those with fewer resources. Because the field of disease outbreak monitoring and prevention is a dynamic one, we expect that the framework and the specific indicators that underlie it will evolve over time.

Four domains of the monitoring framework. The four domains of the framework cover a wide range of areas to be monitored. Starting with the first domain, the focus is on country-level readiness. **Domain 1** involves tracking public health systems, both veterinary and human, and their ability to perform the core functions of detecting, preventing, and responding to infectious disease outbreaks. In **Domain 2**, the focus is on improving investments in the science and technology needed to prevent, identify, and combat disease outbreaks. Here, tracking key issues like data-sharing, development of new diagnostics, vaccines, and therapeutics is critical. **Domain 3** focuses on risk assessment, and outlines an approach to tracking subnational, national, regional, and global risk. Much of the intellectual and analytical work for this domain is currently being performed by global scholars such as climate and health scientists, veterinarians, ecologists, economists, political scientists, anthropologists, those studying zoonoses⁷, and institutions developing health security indices. Finally, **Domain 4** of the framework will track progress among major international institutions, such as the WHO, the World Bank, and UN agencies, to ensure that the global governance mechanisms are better suited for identifying and responding to a crisis.

Research dissemination. Annual reports and other written outputs generated through the monitoring effort will paint a much-needed picture of the world's state of epidemic and pandemic preparedness. The work will provide a useful, evidence-based body of knowledge for decision-makers to allocate resources and set appropriate policies. Importantly, the monitoring framework will not duplicate existing work and data sources. Recognizing that existing programs already generate valuable data and analyses, the monitoring will build on, amplify, and coalesce these efforts. With a broad coalition of academic, institutional and other partners participating from around the world, a more complete picture of global epidemic preparedness will be generated, through a single lens and on a sustained basis.

A shared framework. This monitoring framework is designed to engage as many experts and institutions as possible from around the world in order to be effective. The goal, coming out of the April 2017 workshop, was to build a *Monitoring Coalition*, whose members contribute to data collection and analysis, report-writing and results dissemination, and jointly own the report. A planned *International Oversite Committee* will provide strategic direction to the initiative and assist in research dissemination and policy translation to political leaders (see Figure).

The way forward. Routine, transparent, and objective monitoring will ultimately help ensure sustained financial support and effective prioritization from international organizations, donor agencies, national governments, and the private sector. As one of the first comprehensive, objective monitoring frameworks that brings together multiple sectors in a participatory structure, this initiative is an important step forward in epidemic and pandemic preparedness.



¹ The rise of antimicrobial resistance (AMR) is a public health threat on the scale of an influenza pandemic.

² Zoonoses are the pathogens that spread from animals to humans and vice versa. 60% of new human infections originate in animals. Ebola, influenza, HIV, MERS-CoV and SARS all originated in animals.



INTRODUCTION & BACKGROUND

Few global threats are more daunting than infectious disease pandemics in terms of the potential catastrophic loss of life, damage to the world's economy and political systems, and impoverishment of communities (Commission on a Global Health Risk Framework for the Future 2016). Pandemics of highly virulent infectious diseases, such as the plague, cholera, and influenza, have swept human societies repeatedly, causing illness, death, economic chaos, and political and social disorder (see Annex 1 on the global costs and benefits of pandemic prevention). Despite the potentially cataclysmic threat to public health, society, and economies in all countries, the world is thoroughly underprepared to address this threat. The mismatch between the international health community's intentions and the actions that governments, the private sector, and civil society organizations take to increase health security is dramatic, and is exacerbated by poor pandemic risk awareness outside the public health domain. Similarly, limited risk awareness is the main reason why many countries remain unprepared to detect, report and contain local and regional epidemics. Even when an epidemic is well short of global, the impact can be devastating to the afflicted populations and economies. The West African Ebola outbreak in 2014 is an example of such a regional epidemic with significant economic, social, and health impacts. To date, there has been no coordinated, comprehensive, nor consistent monitoring of the world's capacity to mitigate disease outbreak risks. While infectious disease pathogens are a natural hazard to humans and livestock, their spread and harm they inflict can be significantly influenced by human action. The risks are directly increased by, for example, weak veterinary and human public health policies and infrastructure (including failures to invest sufficiently in vaccines despite very high expected benefits for public health and economies), neglect of whole-of-society preparedness to mitigate disease outbreak risks, unsafe and inadequate laboratory capacities, and failure to prepare for deliberate events (such as an intentional release of human-engineered pathogens).

The capacity building that is required to reduce epidemic and pandemic risks needs to become more visible and widely understood. One way to do so is to establish a durable mechanism to monitor performance in these capacities and to use those results to regularly remind the international community and civil society of the need for sustained prevention and preparedness efforts. Effective monitoring will identify weak spots in the world's readiness to prevent, detect, and respond to disease outbreaks, encourage the development of plans to address

shortcomings, and justify financial support to implement those plans. Such a monitoring mechanism should be established immediately, before the next infectious disease outbreak with epidemic or pandemic potential occurs.

The monitoring mechanism should also coordinate with other global health security and pandemic preparedness initiatives. One such example is the United Nations Global Health Crises Taskforce and the recommendations for improved monitoring put forth in its final report (Global Health Crises Task Force 2017). In addition, global monitoring must align with the Sendai Framework for Disaster Risk Reduction, the WHO's Joint External Evaluation (JEE), the action-planning and budgetary processes of countries as well as with the monitoring of the Global Health Security Agenda (GHSA), which now engages about one third of all countries. Unlike the intergovernmental initiatives, the monitoring envisaged under the framework is designed to be comprehensive and accessible to non-specialists. It would draw upon diverse academic and organizational resources in both developed and developing countries. It would also bring together evidence from varied sources and sectors, then independently analyze, synthesize, and disseminate findings.

A key characteristic of the proposed project is to engage researchers and public health professionals in low-, middle-, and high-income countries to form an international coalition of experts. Health security is inherently multisectoral, requiring the engagement of business, finance, veterinary and human public health services, law, medicine, biology, anthropology, communications, and other disciplines. It requires strategic engagement from each of these sectors as well as the cooperation of government departments responsible for healthcare, agriculture, livestock, wildlife, trade, travel, public safety, and national security. Broad, worldwide participation will help position this project to influence policy making and other actions to improve health security at the country, regional, and international levels. Additionally, the monitoring efforts must incorporate lessons from academia and across the global health field that have analyzed global health security systems, as well as responses to recent major contagions, such as the 2014-2016 West African Ebola epidemic, the 2013 MERS-CoV outbreak, the 2009 H1N1 flu pandemic, the 2004-2010 H5N1 panzootic avian flu, and the 2003 SARS outbreak. We need a shared monitoring framework that is sufficiently concise to foster understanding while drawing from a coherent and comprehensive vision for action and measurement.

The economic rationale for our effort is very strong (see Annex 1), and only enduring reform of the pandemic riskmanagement system will reduce the social and human toll from future infectious disease outbreaks. International public health authorities and governments have launched new initiatives (as outlined above and further below in this report), but their implementation, which has started only recently, will need to continue over the long-term. Sustaining prevention and preparedness will be impossible without robust monitoring of progress.

Everyone can benefit from being informed about progress in reducing microbial threats (including risks of AMR). We will succeed if we raise awareness of epidemic and pandemic risks and add to the evidence-based body of knowledge for decision makers. Risk awareness and well-communicated knowledge can trigger action to mitigate the expected costs of outbreaks, epidemics, and pandemics. In particular, policy-makers need to better understand all components of risk, including the social, cultural, and behavioral dimensions. Knowledge in these areas is partial as they have been seldom studied by anthropologists, economists, and social psychologists. Understanding behaviors during outbreaks is critical, considering that, for example, more than two-thirds of the high economic costs of a flu pandemic would be due to behaviors among healthy individuals. Effectiveness of disease control measures will depend on burial practices, for instance — but knowledge in this and other areas is surprisingly incomplete. More broadly, research on the ways in which communities, governments, and businesses can mitigate the costs of outbreaks is needed to inform effective communication strategies before, during, and after a disease outbreak. If risk communication is aligned along the four domains of the framework and understood across sectors, then its potential impacts can save many more lives and avert substantial damage to economies. Because pandemic

risk reduction involves nearly everyone in the world (by definition), communications between emergencies need to reach diverse audiences worldwide. The intended audiences for findings on our state of readiness and risk level lie in multiple sectors (including human and animal health, finance, business, government, academia, and the media), and the general public.

Monitoring and reporting can also sustain political support for financing of the core public health systems required for health security, which is one of "the single most important areas of productive investment on behalf of mankind" (World Bank 2014b). In 2015, leaders of the Group of 20 (G20) countries included health and economic security on the G20 agenda, together with the closely related health security and economic challenges posed by AMR. But other global issues will continue to emerge, and global health security may slide down the international policy priority list. Because sidelining of global health security is possible in the future and because epidemic threats that affect multiple countries or regions are also chronically underestimated, the international community needs lasting mechanisms for promoting sustained prevention and preparedness. The price of recurrent neglect is too high. Establishing a robust monitoring framework for tracking the microbial threat to humanity is timely and contributes one such lasting mechanism.

Most importantly, the potential benefits of health security arise on the global, regional, country, and community levels. In all four cases, having adequate core public health capacity means that lives are saved, disease is prevented, and economies stand to gain. All countries clearly benefit from reduced pandemic risk. In addition, when countries succeed in controlling outbreaks or epidemics that do not have potential to spread globally, the benefits can be substantial for multiple countries and regions (where the disease would have spread in the absence of public health capacities at the source of the contagion). Finally, if core public health systems function, then they bring large benefits to the country's own population and economy. Low-income communities with poor access to healthcare are disproportionately affected during epidemics; thus prevention of epidemics is likely to have pro-poor impacts.

RECENT ACTIVITIES TO STRENGTHEN GLOBAL HEALTH SECURITY

Over the past decade, the international community has taken steps to increase global health security. One step of note was the WHO adopting the revised and strengthened International Health Regulations (IHR 2005) with the goal of preventing and responding to acute public health risks that could cross borders and threaten people worldwide. The IHR are legally binding for all 194 Member States of the World Health Assembly (WHA), requiring countries to detect, assess, report, and respond to potential public health emergencies, and to develop the capacity to do so. Yet a decade later, most countries had not complied with the IHR, and the WHO could not objectively and independently ascertain compliance with the IHR, relying merely on countries' self-assessments.

In February 2014, nearly 30 countries launched the Global Health Security Agenda (GHSA), together with the WHO, the Food and Agriculture Organization of the United Nations (FAO), and the World Organisation for Animal Health (OIE). The initiative, which has received important support from the U.S. government and other countries,³ has since expanded to include over 63 countries, international organizations, and non-governmental stakeholders. GHSA partners aim to spur measurable implementation of the IHR and other global health security frameworks, such as the OIE's Performance of Veterinary Services (PVS) Pathway.⁴ Development of common agreed targets against which countries can assess their capacities to prevent, detect, and respond to outbreaks has been a significant achievement of the GHSA. The WHO has since used these targets in developing the metrics for the JEE. The GHSA has also been effective in securing high-level political commitment to prioritize health security within domestic budgets. Additionally, donor countries within the GHSA assist in mobilizing financial and technical assistance for capacity building, including support for communications and coordination of animal and human

public health systems through One Health⁵ approaches. Specific goals of the GHSA initiative include containing AMR; preventing and controlling zoonotic disease; improving biosecurity and biosafety systems; training a global health security workforce; establishing emergency operations centers; linking public health, law, and other sectors in preparedness for rapid responses to disease outbreaks; and enhancing medical countermeasures and personnel deployment (The White House Office of the Press Secretary 2015).

In 2015, the GHSA piloted a voluntary, external assessment of health security capacities in five countries to test the feasibility and acceptability of external assessments – something that had been done by OIE since 2006 for veterinary public health, but not for human public health. The pilot was successful, and the results were then incorporated into the WHO's new voluntary external assessment of IHR country capacity – the JEE. The JEE identifies gaps to help inform individualized country action plans and a framework to track progress. There are 19 assessment areas (see Annex 2A) based on the WHO IHR core capacity areas (see Annex 2B) (World Health Organization 2016c). As a result of this transparent, voluntary, and collaborative review process, progress is being made toward achieving IHR compliance. The WHO recommends follow-up country JEEs at least every five years. After the JEE, countries should receive technical assistance to develop a national action plan to fill identified gaps. The resources required to implement the action plans include financing from the country's budget, financing from external bilateral and multilateral partners, and technical assistance. The development of national action plans (and implementation roadmaps, in countries eligible for the U.S. government's GHSA funding) is only the first step, however. Mobilization of adequate financing and other implementation support is vital to ensure that priority gaps are rapidly and effectively filled.

The WHO, as the international standard-setting authority for the IHR Monitoring and Evaluation Framework (which includes the JEE process), set up a <u>Strategic Partnership Portal</u> (SPP) in 2017 to improve communications about global risks due to gaps in core public-health functions. The SPP is an accessible, protected platform for up-to-date JEE-related information, including countries' JEE reports. In 2016, the G7 ministers committed to "support, undergo, and share such evaluations with our partners," and called "on other countries to join in this collective effort, recognizing that partner coordination is key for efficient IHR strengthening, and acknowledging the value of providing necessary information to new initiatives to share information, such as WHO's SPP, while ensuring the information shared among the donors to be comparable and avoiding any fragmentation," (G7 2016). Tracking assistance from multiple partners when the receiving country has limited capacity or willingness to lead the preparation and implementation of the action plan is difficult; some countries may require support to track external assistance to the implementation of their action plans.

The JEE Alliance, which was formed in May 2016, has become an active network that supports the JEE process. Co-chaired by the governments of Finland and Australia, the JEE Alliance mobilizes actors concerned about health security, promoting the transparent exchange of information, national planning and implementation based on country JEEs, and innovative solutions for country capacity building. Membership is open to all countries, international organizations, financial institutions, and non-governmental actors willing to support external assessments and capacity building for health security. As of October 31st, 2017, the JEE Alliance had 64 members: 30 countries, 8 multilateral organizations, and 26 non-governmental organizations.

LESSONS FROM THE WEST AFRICAN EBOLA EPIDEMIC

As of December 2016, experts had conducted more than 40 analyses of the West African Ebola outbreak of 2014-2016 and the various failures associated with the international and national responses. It became very clear that a faster, more coordinated response would have prevented escalation of the outbreak into the crisis that caused more than 11,000 deaths and severe economic and social hardship for the populations of Guinea, Liberia, and

Sierra Leone (World Health Organization 2016b). These reports largely agreed on what went wrong and what needs to be done (Moon et al. 2017, 2015; Commission on a Global Health Risk Framework for the Future 2016).

The most significant failure in the Ebola response was the lack of compliance with the IHR. In a similar vein, the international community realized the inadequacy and unreliability of self-assessment of IHR compliance. A more robust means of verification was needed, along with adequate financing and technical assistance to help countries address gaps that might be identified. Countries experiencing an outbreak not only failed to report the outbreak swiftly and completely to the WHO but also failed to inform the public. A weak capacity to detect, diagnose, and correctly report an outbreak was only partly to blame. Economic reasons, including trade and travel considerations, likely also influenced government willingness to reveal disease outbreak information. During the Ebola epidemic, unjustified trade and travel restrictions did, in fact, hamper delivery of support to affected regions and thus slowed disease control and worsened the economic and health impacts. This not only cost lives but also impeded pharmaceutical research and development (R&D). In addition, effective strategies for mobilizing communities that had been developed during earlier Ebola outbreaks in Central Africa were not always applied in a timely fashion.⁶

International agencies play indispensable roles in responding to major emergencies of international concern, but Ebola postmortems found that their performance was poor or uneven at best. Various international agencies (including the WHO), government ministries, community leaders, and local and international non-governmental organizations interacted in poorly coordinated ways, leading to an inefficient and ineffective response that aggravated the crisis. Ensuring effective international coordination is a key responsibility of the WHO as the global public health authority, but it lacked the organizational culture for swift and decisive action when the magnitude of the epidemic became apparent, and struggled to collaborate and coordinate with multiple partners, particularly non-state actors (Gostin and Friedman 2014). Few mechanisms to ensure accountability were in place.

In sum, these analyses agreed that the world is underprepared for infectious disease outbreaks and that this will not change unless major reforms are implemented now, during the lull between infectious disease outbreaks with epidemic or pandemic potential.

OVERVIEW OF THE MONITORING PROJECT

In order to meet the need for a permanent, evidence-based monitoring mechanism devoted to global health security, HGHI and a coalition of academic partners initiated the development of a monitoring framework. This framework, the focus of this report, aims to guide data collection and analysis on a regular basis. The framework is comprised of qualitative and quantitative indicators. The team followed a deliberately consultative process so as to improve the quality of the framework by seeking inputs from experts and to encourage broad participation in the project, given that pandemic risk touches many disciplines and sectors – as well as all populations. Wide participation will be helpful in communicating the results of the monitoring; doing this well is very important. This shared framework will be used by a coalition of academic researchers and practitioners to generate evidence-based reports for decision makers in human and animal health, finance, industry, government, academia, the media, and the general public to spur collective action, investment and policy changes, and increased accountability. The framework is a living tool – it and its indicators will be periodically reviewed and revised, based on experience and consultations with the coalition of academic and implementation partners as well as other stakeholders. The monitoring initiative responds to, and aims to build on, the work of the UN Secretary General's Global Health Crises Taskforce, which in its July 2017 final report recommended that an independent monitoring mechanism track progress in global health security over time.



Figure 1. The monitoring framework: four content domains and implementation arrangements

The framework was developed to allow us to collectively track and examine the contours of global risk and preparedness over time, collect and analyze data in each domain, and ultimately strengthen global health security through channels of communication to relevant stakeholders. Data collection and analysis will draw upon existing initiatives and data sources wherever possible. Current country-level indices will be used and scaled as global indicators wherever possible, resulting in a global framework that aggregates available health security data and informs regular monitoring reports. The framework has already benefited from inputs by researchers and experts from low-, middle-, and high-income countries. The monitoring activities will be based on a broader community of practice, engaging researchers in diverse disciplines. This will not only enrich the evidence for the monitoring reports but also help mitigate the indifference to prevention and preparedness between emergencies. Maintaining a spotlight on progress in the most vulnerable regions is especially important because weak public health systems and ecological threats in these countries pose high risks to their populations and economies. In addition, undetected disease outbreaks and delayed disease control efforts may threaten the rest of the world.

The monitoring framework encompasses four content domains (Figure 1), namely:

- 1. Strengthening public health core capacity as a foundation;
- 2. Improving science, technology, and access;
- 3. Reinforcing risk analysis and incentives for action; and
- 4. Strengthening global mechanisms.

Figure 1 also shows the main policy mechanisms, official and private sector entities, and other global health security stakeholders for each of the four content domains. For example, Domain 1 encompasses the first line of defense actions and investments that are led and implemented by countries (with technical and financial support

from the international community), while Domain 4 addresses the strengthening of global mechanisms, for which international organizations such as the UN, WHO and OIE share the lead responsibility.⁷ A monitoring and reporting coalition of academic and research partners would collect and analyze the data, validate it, conduct relevant analyses, and regularly prepare comprehensive, evidence based global monitoring reports. Overall oversight and guidance would be provided by an international council.

Spotlight on Domain 1. While measures in each of the framework's four domains are required for increased health security, the first domain of the framework, public health systems, merits special attention. A key concern is that most low- and middle-income countries (LMICs) lack capacity in their veterinary and human public health systems to implement One Health approaches to disease control and prevention, and have limited prospects for improving this situation. Weak systems make stopping outbreaks at their source (often in LMICs) difficult and less likely to succeed. Workshop participants reiterated that these systems are both the first line of defense against pandemic threats and the area with the most severe and preventable lapses. Moreover, weak public health systems are significant causes of poverty among already-poor populations. Robust core public health systems offer both significant public health impacts for LMICs (Pierre-Louis et al. 2012; World Bank 2014a) and extraordinarily high economic returns (Jonas and Walford 2014).

DEVELOPMENT AND REVIEW OF THE FRAMEWORK

The initial draft framework drew on analyses of the recommendations put forth in several major reports⁸ on the response to the West African Ebola epidemic of 2014-2016, notably those by the Commission on Global Health Risk Framework, the Harvard-London School of Hygiene and Tropical Medicine Independent Panel, the WHO Ebola Interim Assessment Panel, and the UN High-Level Panel (see Annex 3 for examples from two of the reports). These analyses and recommendations have been an important impetus for the monitoring project. Experts agree on the most important things that need to be done, and have provided advice on the most effective and efficient implementation. If we want a more robust, resilient global health system able to manage infectious disease outbreaks, then major reforms are warranted and should be feasible, actionable, and measurable.

The draft indicators for each of the domains were, as much as possible, selected for their specificity, measurability, and relevance to spurring increased action. Since pandemic preparedness is inherently a multisectoral issue, the following report and its associated monitoring framework have been reviewed and discussed by a wide range of professionals from research centers, government departments, bilateral and multilateral organizations, corporations, and civil society.

To review the draft monitoring framework with experts and modify the indicators in light of expert input, NAM and HGHI co-hosted a workshop on April 18th, 2017, in Washington, DC. Attendees discussed the draft indicators in each of the four domains, ways in which to operationalize the framework, and strategies for communication and dissemination of results. Ahead of the workshop, participants received the draft framework and a list of questions to consider:

- What is the draft framework missing?
- How useful are the indicators? To what extent are they capturing what should be captured?
- What are the significant barriers to collecting any of the mentioned data?
- To what extent are the solutions to the issues posed already identified or efforts underway? How might these efforts inform the indicators at hand?
- How does the framework align, or not align, with the ability to assess and communicate risk?

The workshop followed Chatham House Rules, with no attributions made other than to those who made formal presentations, in order to encourage candid and wide-ranging discussion. Together with the written comments received before and after the workshop, discussion at the workshop informed revision of the monitoring framework. A total of 350 unique comments were received in writing and extracted from the workshop transcript. The list of workshop participants and other experts who provided advice on the framework and its indicators can be found in Annex 6.

Related work on preparedness, microbial risks, and other themes. The aggregate output of analytical work on pandemic risk, and policies and measures required to reduce that risk, has been very small, based in a handful of institutions, and of marginal importance within global health. This may seem paradoxical since preventing contagion is the quintessential global public good (International Task Force on Global Public Goods 2006). Against this backdrop of fluctuating neglect, there are two new important initiatives. The Nuclear Threat Initiative (NTI), along with Johns Hopkins University Center for Health Security, and the Economist Intelligence Unit (EIU), recently initiated development of a Global Health Security Index (described in Domain 3 below). The index will assess national capability to prevent and mitigate high-consequence biological events, taking into consideration political and socioeconomic risk factors, as well as the country's broader healthcare system, using publicly available data. Broader issues in monitoring of relevant policies and institutions were reviewed at a workshop in Geneva in March 2017, organized by Chatham House and the Graduate Institute, Geneva. Suggestions from this meeting included increased attention to improving the capacity of communities, One Health approaches to reducing zoonotic risks, and preventing unwarranted trade and travel restrictions. Participants at the April 2017 workshop held at the NAM (see Annexes 7 and 8) supported these key points as well. Notably, some important topics span several of the domains, for example, private sector engagement, risk communications, and community participation. Additionally, in Domain 1, the actions being monitored in Category A ("preventing outbreaks") and Category B ("responding to outbreaks") can usefully be grouped together because these functions overlap; the escalation of outbreaks into large-scale phenomena can be prevented only by effective and timely interventions.

Modifications of the framework after the workshop. The research team sought to address the wealth of substantive suggestions in revising the indicators and to document the multifaceted discussions in this report. Numerous additional indicators and complementary analyses were suggested, demonstrating the rich diversity of the subject matter, weak risk governance, and large knowledge gaps about vulnerability and preparedness. However, much of this additional work falls beyond the scope and resources of the monitoring project at this stage. The results of such complementary work by others could be incorporated into the monitoring reports as they become available and contribute to a richer and more compelling suite of monitoring efforts. At this stage, there was consensus that fewer indicators will likely mean greater impact ("less is more") and be more practical. The objectives and the design of the framework, as presented in this report, are becoming broadly shared, but the framework is not final. It is expected to evolve over time based on experience gained during the preparation of regular monitoring reports. To support possible future revisions, this report thus notes which suggestions were incorporated in the framework, as well as the reasons for setting aside other suggestions at this time.

Preparation of this report. After the research team revised the monitoring framework and drafted this report, eight leading experts reviewed its substantive and presentational aspects. While they focused in detail on the treatment of topics in their principal areas of expertise, most reviewers also contributed suggestions for other sections or even the entire report. This process significantly improved the clarity and quality of the report. The research team was able to fully incorporate the reviewers' comments (and thus improve the presentation of the framework) in most cases. Where this was not possible, the team clarified the rationale for specific aspects of the monitoring framework in subsequent discussions with the reviewers, and improved the explanation in the report of

these aspects of the framework. At the conclusion of this valuable review process, there were no unresolved substantive or presentational differences.

REPORT ORGANIZATION

This report is organized around the four main domains of the Monitoring Framework. Each of the Domains is addressed in a separate chapter (Chapters 1-4):

- 1. Strengthening public health core capacity as a foundation;
- 2. Improving science, technology, and access;
- 3. Reinforcing risk analysis and incentives for action; and
- 4. Strengthening global mechanisms.

Within each domain there are two or three categories of indicators and data collection. Each chapter begins with an overview of that domain area, what it intends to cover, and its purpose. Next, the chapter covers highlights from opening presentations on that domain made at the April 18th workshop. Opening presentations were meant to introduce the topic and provide a brief overview of progress in that area as well as the gaps that remain. Following the synopsis of the presentations, there is a discussion of the chosen indicators and content for that domain, including recommendations made by participants at the workshop and those that were submitted in writing. Included in these discussions are highlights of the main changes that were made to specific indicators and the rationale for such changes. Indicators were added, deleted, and or modified. The revised indicators are presented in tables within each chapter. Chapter 5, which follows the four domain chapters, looks forward and summarizes the discussions thus far on how best to establish an independent monitoring mechanism and what a governing structure might look like.

³ The U.S. government has been the main GHSA financier, providing \$1 billion to countries. Support from the Department of Defense, the State Department, the Centers for Disease Control and Prevention, and the United States Agency for International Development, has totaled between \$300 million-400 million per year. Additional funding was provided during the Ebola crisis.

⁴ The OIE PVS Pathway is a global program for the improvement of the quality of a nation's veterinary services and compliance with the OIE's quality standards.

⁵ One Health recognizes that the health of people is connected to the health animals and the environment. The goal of One Health is to encourage collaborative efforts of multiple disciplines – working locally, nationally, and globally – to achieve the best health for people, animals, and our environment. (CDC).

⁶ Previous outbreaks of Ebola have been controlled through early identification of cases through contact management, patient isolation, social mobilization, and safe burials.

⁷ As explained in Chapters 1-4 below, the indicators are grouped in two or three thematic categories within each domain.

⁸ See High-level Panel on the Global Response to Health Crises 2016; World Health Organization 2015b, 2015a; Checchi et al. 2016; Commission on a Global Health Risk Framework for the Future 2016; Moon et al. 2015; World Health Organization 2016c.



DOMAIN 1: STRENGTHENING PUBLIC HEALTH CORE CAPACITY AS A FOUNDATION

1

Public health systems, both veterinary and human, perform the core functions of detecting, preventing, and responding to infectious disease outbreaks. These essential public health functions have been accepted by public health authorities in national governments and international organizations (see Annexes 2A and 2C). Additionally, surveillance and diagnostic capacities, along with preparedness for rapid and effective responses to disease outbreaks and other emergencies, are part of the core public health functions required for compliance with the IHR. When there is little information on the capacities and how well they perform their functions, the economic and health risks to populations cannot be determined and may be unacceptably high.

Investing in public health infrastructure brings multiple benefits. The world benefits from greater health and economic security, since contagion and AMR are less likely to spread internationally. Countries benefit from the reduced threat of domestic spread of disease and AMR, avoidance of consequences associated with the reputation as an exporter of a dangerous disease, and improved capacity to prevent and control endemic diseases.

Knowing the performance of public health systems is the first essential step toward health security, just as vehicle inspections are the mainstay of road safety. When a large proportion of cars on the road do not have working brakes, headlights, steering, and other core functions, the safety of all road traffic is compromised. Periodic vehicle inspection will identify the measures needed to bring public safety to an acceptable level and are the basis for essential repairs. Domain 1 of the framework tracks the key systemic processes on which global health security depends, with the indicators divided into Categories A and B:

1A: Assessments of national animal and human health core capacities; and

1B: Building national animal and human health core capacities.

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The indicators address questions such as the following: Are core capacities to detect, prevent, and respond to outbreaks credibly assessed? Do authorities seek to improve the performance of core functions by preparing and implementing action plans based on the assessments? And are governments and donors providing sufficient technical and financial assistance for the investments that are required to improve public health capacity? Most of the data for indicators in Categories 1A and 1B should be available from the agencies that govern key parts of these processes: the WHO and OIE. Data on financing of investments in core capacities would be requested from the World Bank and other sources of support for government expenditures in the health sector, as well as the Organization for Economic Co-operation and Development (OECD), which tracks aid to health and health spending in considerable detail. Periodic assessments are needed to monitor progress, as well as ongoing gaps in legislation, regulations, infrastructure, trained workers or other capacities. Repeating the JEE and PVS assessments at least every five years would yield current information on the status of global health security capacities, which has not been available to date. Countries will be able to draw on repeated independent expert assessments using the JEE and the PVS tools to guide further public health capacity building. Given that building and assessing core capacities go hand in hand, the April 2017 workshop covered these two topics together.

Domain 1 also includes select indicators on Category C:

1C: Direct and indirect incentives to outbreak reporting

Prompt and complete reporting of diseases is critical to global health security. Without early intelligence on outbreaks, detection and subsequent disease control will be delayed. Thus, attainment of the most important objective of preparedness for response to outbreaks – containment at the source before spread – will be compromised and the resulting epidemic or pandemic will give rise to significant health, economic, and social costs. Reporting performance depends on whether a country has robust public health capacities to collect, analyze, and transmit complete information about the outbreak; prompt and complete reporting is, indeed, a requirement of the IHR.

Incentives provided by the international community are also of importance for performance of this core public health function. A country's reporting performance is likely to suffer if external assistance for outbreak control may be delayed and inadequate; if the WHO does not actively discourage unjustified trade and travel restrictions; and if the trade and travel sectors do not have carefully prepared responses to an outbreak but instead implement excessive and uncoordinated measures that unduly disrupt trade and travel. Such disincentives to reporting are key factors that worsen the performance of a country's public health system in controlling disease outbreaks. In addition to controlling outbreaks rapidly and efficiently, measures to build robust public health capacities (Categories 1A and 1B) and deliberate attention to incentives for reporting (Category 1C) will also serve to mitigate the economic costs of outbreaks, which have in the past fallen disproportionately on the poor.

OPENING PRESENTATIONS

The themes in Domain 1 were set out in presentations that traced the evolution of approaches to assessing and improving countries' public health capacities, outlined the assessment process, described the subsequent implementation of investments and other measures, and touched upon good practices. Dr. Mika Salminen (JEE Alliance, Director; Department of Health Security, National Institute for Health and Welfare, Finland) introduced the JEE tool and process, along with recent implementation experiences. Dr. Salminen has been closely involved in the development of the JEE and has traveled on JEE missions to six countries; he has been a core member of the JEE Alliance from the start. Next, Dr. Alain Dehove (Director of Finance, OIE) shared OIE's experience with independent external assessments of national veterinary services and animal health systems, which were developed

and conducted in the last ten years. Not only is veterinary public health capacity required to prevent and control zoonotic diseases and reduce pandemic risk, but OIE's systematic approach to assessments has helped guide the development of the JEE tool and the processes for using the tool. Dr. Oyewale Tomori (former President of the Nigerian Academy of Science) highlighted implementation aspects, such as the importance of close collaboration using One Health approaches in both human and veterinary public health systems; his presentation focused on public health systems in African countries. The main points in the presentations are summarized below.

TOOL FOR ASSESSING HUMAN PUBLIC HEALTH CAPACITIES: THE JOINT EXTERNAL EVALUATION

Dr. Salminen noted that the WHO and international community have only adopted the JEE as a tool to assess human public health capacities in 2016. Previously, the WHO relied on country self-reporting on capacities required for compliance with IHR. Since 2016, there have been four components in assessing public health capacities: yearly self-reporting to the WHO, an external evaluation conducted every three to five years, an after-action review, and simulation exercises. The country being assessed (the host country) normally approves public disclosure of the report with the JEE results, including through the WHO SPP. Disclosure is important since all countries have a vital interest in knowing the capacities in any one country in our increasingly interconnected world. Public health systems in countries are components of the broader regional and global health security systems, which are only as strong as their weakest links. As of December 2017, 67 countries have completed a JEE, with more planning to undergo the process (see Annex 4).



Figure 1.1. Capacity-assessment steps before, during, and after a JEE (actual duration in days, for the JEE for Finland in March 2017). *Source: Salminen slides*.

The host country leads in preparation and planning for the multistage JEE process (Figure 1.1). To carry out the JEE, external experts work closely with the team from the host country. This collaboration fosters transparency and country ownership of the process and the results. Once it volunteers for a JEE, the host country initiates a self-assessment, which should involve all relevant local stakeholders. But the new self-assessment differs from the

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former self-assessments of IHR compliance, which were mainly checklists about the presence of various institutional and regulatory arrangements relevant to IHR compliance. Whether a structure worked as intended, and how its functioning affected other public health functions, often remained unexamined and unknown under previous IHR compliance self-assessments. The JEE tool goes beyond checklists by providing tested and effective guidance on measuring capacity for performance of core public health systems. This guidance helps countries assign ratings on a five-step Likert scale; the color-scoring of performance by red, orange, yellow, and green helps communicate, at a glance, the levels of capacity (Table 1.1). The overriding aim of assigning scores in the JEE (and similarly for PVS) evaluations is to help communicate where capacity for performance in core functions is lacking and what and how much should be improved. The ratings also enable more reliable risk assessments, including cross-country comparisons of risk and identification of areas with high risk (as the workshop discussed in the session on Domain 3 of the framework).

Table 1.1. JEE assessment color-scoring system for core public health capacities.			
Capacity sections of the JEE tool overlap, but each is evaluated separately. The implementation status of each core capacity is a level of advancements, which is measured by a score on a scale of 1 to 5.			
Score/Color Code	Implementation Status	Description	
1	No capacity	Attributes of capacity are not in place.	
2	Limited capacity	Attributes of capacity are in development stage (some are achieved, and some are ongoing; however, the implementation has started).	
3	Developed capacity	Attributes of capacity are in place; however, there is the issue of sustainability, such as lack of inclusion in the operational place in National Health Sector Planning (NHSP) an/or lack of secure funding.	
4	Demonstrated capacity	Attributes are in place, sustainable for a few more years, and be measured by the inclusion of attributes or IHR (2005) core capacities in the national health sector plan.	
5	Sustainable capacity	Attributes are functional and sustainable, and the country is supporting other countries in their implementation. This is the highest level of the achievement of implementation of IHR.	

Source: WHO, 2016. Joint External Evaluation Tool: International Health Regulations (2005).

During a one-week visit to the country, experts on the JEE team review the self-assessment and other materials. The team then drafts its report, including an assessment of all indicators and priority actions, within two weeks. The host country then uses the report to develop its action plan to improve performance of core public health functions; implementation progress is then monitored through annual self-evaluations. JEE teams have found that the evaluation process is more valuable than the results because it brings together public health stakeholders from different sectors and departments, which does not happen often enough in many countries. The results are clearly more robust assessments of the performance of public health functions than the previous IHR compliance self-evaluations. The indicators generated in the JEE can serve to track changes and compare capacities within and across regions over time.

ALIGNMENT OF THE JOINT EXTERNAL EVALUATION AND THE PERFORMANCE OF VETERINARY SERVICES PATHWAY

Dr. Dehove explained that the OIE's PVS Pathway includes an external independent assessment of veterinary public health systems, a PVS Gap Analysis, quantification of the identified shortcomings, expert assistance to revise veterinary legislation, and several other tools, including an assessment of the national laboratory network for animal health to help countries improve the governance of veterinary public health.

Both the JEE and the PVS Pathway are grounded in international legal agreements: the JEE is linked to the IHR, and the PVS tool is based on shared international standards, definitions and benchmarks for national core capabilities, which are contained in the OIE Terrestrial Animal Health Code. The PVS tool now assesses 47 critical competencies (see Annex 2C). There are five possible levels of attainment for each competency, similar to the 5-point Likert scale used in the JEE. Draft PVS reports are peer-reviewed. Initially, many of these reports remained the confidential property of the government, but over time countries have disclosed the reports to donors and partners. Most countries now make their reports publicly available, including by requesting OIE to publish them on OIE's PVS Pathway website.

Since the PVS Pathway tools were introduced ten years ago, they have been used to carry out external assessments of veterinary public health capacities in many countries. Countries issued 152 requests to OIE for an assessment, and OIE completed 141 assessments as of April 2017. OIE has also completed 91 PVS Gap Analyses and 40 PVS follow-up evaluations. Stakeholders, subject-matter experts, country representatives, and donors examined the tenyear track record of PVS implementation and identified the following best practices:

- A participatory, supportive, and collaborative culture, rather than a prescriptive or critical one.
- A voluntary, country-driven process, focused on the systems and resources in the country to ensure sustainability.
- A simple tool that is both easy to use effectively and efficiently and is based on accepted OIE international standards.
- Rigorous selection and training by OIE of the independent external experts who carried out the evaluations, particularly experts' familiarity with country and regional specificities and needs. Notably, the evaluations were not done by OIE staff or by officials of the host country.
- Firm government commitment (from an OIE delegate or a minister) to use the PVS evaluation results when requesting a PVS mission; and understanding by the OIE delegate of the process and its requirements (time and human resources) before, during, and after the mission.
- Political will to accept and implement the recommendations of the PVS mission.
- Demonstration of the importance of quality veterinary services in facilitating trade negotiations.
- Adoption by the host country of OIE standards on veterinary public health capacities.
- Timely revisions of the tools, manuals, and report templates using regular feedback from experts to OIE, and continuous improvement (the PVS Tool is currently in its sixth edition).

IMPLEMENTING ACTION PLANS TO IMPROVE PUBLIC HEALTH CAPACITIES

Dr. Tomori highlighted that collaboration between veterinary and human public health services has always been part of the PVS initiative. OIE has encouraged veterinary and human public health services to share their evaluations and to jointly prepare action plans to address gaps. The opportunities to do so have expanded with the



Figure 1.2. Map of countries in Africa that have completed both the PVS and JEE assessment and those that have completed the PVS only.

growth of completed JEEs. In Africa, for example, the number of countries that have benefited from both PVS and JEE assessments has been rising rapidly (see Figure 1.1 and Table 1.2).⁹ It is worth noting that the WHO and OIE have collectively organized IHR-PVS Bridging Workshops. These workshops bring together national representatives of the veterinary and human public health services to share the outcomes of their respective assessments, review inter-sectoral coordination, and develop measures to strengthen their coordination at the human-animal health interface. Three such joint workshops have been organized as of April 2017.¹⁰

Dr. Tomori also noted that many countries with completed assessments face the difficult challenge of financing the necessary follow-up investments and other actions to reduce the performance gaps in core capacities identified in the assessments. In 2017, the World Bank began to develop a tool to analyze financing for health security so as to help decisions by the World Bank and other partners on allocation of their support (International Working Group on Financing Preparedness 2017). Governments and their donor partners have not financed investments in core public health functions adequately in the past, so these functions do not exist (or perform very poorly) in most developing countries. The health burden that results from weak public health functions is compounded by significant levels of poverty and economic losses. Investments in veterinary and human public health capacities would have extraordinarily high economic benefits and pro-poor development impacts (Annex 1).

Both veterinary and human public health systems have been grossly under-financed for decades in most developing countries. The resulting poor performance of these core systems has worsened public health, increased poverty, lowered investment and economic growth, and rendered compliance with IHR (2005) largely impossible for most developing countries.¹¹ Many countries in Africa, for example, have now completed the PVS process, but have not been able to make the investments necessary to reduce the gaps in performance identified in such assessments. This lapse contributes to repeated weak and delayed responses to outbreaks, including to outbreaks of diseases that are not specifically addressed in the PVS such as Ebola, meningitis, yellow fever, and Lassa fever. The costly consequences of neglecting public health capacities were evident in the West African Ebola epidemic in 2014. Six years before the epidemic, the governments of Guinea, Liberia, and Sierra Leone received assistance from the
World Bank and other partners in independent external assessments of their outbreak prevention and control capacities, which were used to prepare national action plans to improve performance of the most critical core public health functions. Once prepared, the plans sat on the shelf, although both the governments and their partners had agreed that improvement of capacities to control disease outbreaks was urgently needed. The investments in disease surveillance and outbreak control were not made even though they would have cost only \$26 million in the three countries, which is dwarfed by the ultimate cost of the Ebola epidemic (over \$10 billion, with the bulk of the costs borne by the affected countries). Compared to aid flows for health, the \$26 million requirement was modest, equivalent to less than 5% of the annual external assistance for the health sector in these three countries.¹²

External financing has been both scarce and volatile, contributing to its ineffectiveness and inefficiency. Donor agencies have not been held accountable for significant periods of neglect. Reactive, short-lived external financing, which favors emergency responses over core capacities for prevention, can further reduce sustainability and effectiveness. The perception that health security is a concern primarily for high-income countries and that "someone else will take care of the problem" is counterproductive. To offset such tendencies, two guiding principles are important. First, national action plans and other preparedness activities should emphasize proactive prevention. Second, robust national and local ownership of these action plans should be encouraged. A key sign of robust ownership of the plans is that they are fully funded, based on realistic costing of the investments, operations, maintenance, and other actions set out in the plans. Monitoring follow-up to the assessments is necessary to detect cases of resurgent neglect and to foster accountability. Documenting progress and gaps can provide incentives to governments and their partners to prioritize the development of capacity to prevent, detect, and respond to outbreaks during the long "peaceful" periods between emergencies. In any one country, awareness of the implementation track record will support better collaboration with international responders when outbreaks exceed domestic response capacity. Domestic capacity is important because even timely and competent external assistance to address an emergency cannot be fully effective if the underlying state of domestic preparedness is poor. More broadly, national capacities to prevent, detect, and respond to biological threats will always be the main determinants of the difference between the containment of an emerging infectious disease (EID) and the explosive beginning of a larger contagion with exponential growth. Global and regional health and economic security depends on all countries having strong national systems that can effectively contain contagion at the source.

DISCUSSION

Discussions at the workshop and other expert comments highlighted the relevance of Domain 1, which addressed key aspects of building veterinary and human public health capacities in all countries, with technical and financial support from the international community. There was agreement that the new processes to assess the performance of core public health capacities in all countries are among the most important steps taken in the last several years to avert another crisis like Ebola. The sustained pace and quality of PVS evaluations serve as precedents for the JEE program in the future, suggesting the importance of timely and appropriate support from the WHO and external partners to undertake the assessments. Participants also reviewed indicators to track completion of assessments of core public health capacities, monitor the action plans derived from the assessments, and identify actions to promote timely and complete reporting of disease outbreaks. Their review thus addressed each of the three categories of indicators in Domain 1. However, there were also overarching concerns about prospects for progress of countries in acquiring capacities to prevent and control contagion; this broader discussion is summarized in the next section. Subsequent sections review specific indicators in the three categories of Domain 1. The selected indicators reflect suggestions made at the workshop, additional written comments by the workshop participants and other experts, and the research team's further research.

Recurrent neglect of core public health functions. In reviewing the indicators of country-level actions for health security (especially Categories 1A and 1B), experts repeatedly cautioned about the recurrent neglect that could reverse the momentum built after the Ebola crisis. A vicious cycle of panic and neglect has recurred in the past. It is important to appropriately incentivize countries to both request assessments and then act on the recommendations. Moreover, weak support for health security from partner governments and non-governmental organizations could further diminish country interest in assessments and in follow-up action plans. Governments and international development agencies have not been held accountable for underfunding core public health systems in the past. The lack of accountability leaves the door open to two kinds of adverse consequences, especially for groups that have had little voice in policymaking. First, there may be numerous assessments showing risky gaps in essential capacities for preventing and controlling infectious diseases but little actual follow-up to build such capacities: preservation of the status quo. Curative healthcare and its management would then continue to absorb nearly all public funding for the health security and disproportionately harm the health and economic development prospects of poor populations and future generations.

Donors have rarely supported core public health systems in the past, especially veterinary systems, and workshop participants cautioned that this situation could continue. As recently as 2010, a global conference of the ministers of health and agriculture committed to sustain momentum in investments in core public health functions. More than 100 developing countries embarked on such action plans in 2006-2010 during the global avian flu response and realized how much more remained to be done (Barrett et al. 2010). Developing countries that had succeeded remarkably in controlling the spread of H5N1 avian flu, like Lao People's Democratic Republic (Lao PDR) and Nepal, requested technical and financial support for improving their core veterinary and human public health systems from multilateral development banks and other donors. However, they were repeatedly turned away because priorities had changed to emphasize health care systems (especially for women and children), training health workers, and control of ongoing epidemics of diseases like malaria, tuberculosis, and AIDS. Core public health capacities require far less funding than these programs, and generate higher economic returns than other public investments because they avert a large (and exponentially rising) disease burden and associated future economic costs. Control of specific endemic diseases and infectious diseases is both more effective and more efficient when core public health systems are robust.

Evaluation of the benefits of prevention of epidemics (or pandemics) always considers the low probability that an outbreak will occur in any one year. While the probability is low in any one country and in any one year, it is certainly not zero, based on the record of evidence and scientific knowledge. Globally, the expected rate of return on investments in core public health systems in all 139 developing countries was estimated between 57% annually (if only half of pandemics are prevented) and 86% annually (if all pandemics are prevented). Such extraordinarily high returns would be realized even if the probability of onset of a pandemic were just 1% in any one year, which corresponds to a once-in-a-hundred years event¹³ (World Bank 2012). Donors' preferences for projects with shorter timelines, readily visible results,¹⁴ and opportunities for ribbon-cutting and site visits to beneficiaries have unfortunately neglected less visible but more productive investments in core public health functions. Attention to independent assessments of public health systems in Domain 1 and to select follow-up actions will help to offset the perverse incentives, and lack of accountability, of those responsible for this cycle of neglect and panic. This cycle inexorably creates a need for wake-up calls, like the West African Ebola outbreak in 2014.

CATEGORY 1A. ASSESSMENTS OF NATIONAL ANIMAL AND HUMAN PUBLIC HEALTH CORE CAPACITIES

The indicators in Category 1A will track the pace of evaluations of public health capacities to prevent and control infectious disease contagions, including those caused by pathogens with AMR and similar major public-health threats of international concern. The processes for carrying out regular JEEs and PVS evaluations should help sustain prioritization of public health functions (the investments and operating expenditures required to deliver these functions), but the processes themselves require consistent support. The prospect of declining multilateralism and inter-governmental cooperation is problematic for global and regional health and economic security, which require relevant international organizations (WHO, OIE, and others) to show effective leadership.

Prevention and control of infectious diseases is a public good that requires collective arrangements to be provided, and whose value is on par with that of mitigating climate change and preventing global financial crises. It is also by far the most consequential global public good in health; when health security is available, all populations in all countries benefit. Thus, it is arguably the highest priority for WHO and OIE, as the competent international authorities for global public goods in health, to determine whether country capacities to detect and control contagion comply with internationally agreed standards, including the IHR. Self-reported compliance with IHR will be tracked as well.

The measures tracked in Category 1A (and the follow-on actions tracked in Category 1B) are key to achieving many of the Sustainable Development Goals (SDGs) which may be compromised as poor countries are disproportionately vulnerable to health insecurity and the economic shocks associated with contagion. The proposed set of indicators to monitor progress in Category 1A is set out in Table 1.2. The indicators refer to capacities in the public sector, in communities, and in civil society organizations (CSOs). The indicators respond to the widespread concern that the window of opportunity for reducing pandemic risk is closing and that neglect of prevention and preparedness is already setting in.¹⁵

A number of important concerns emerged during the discussion of the substantive and strategic cross-cutting issues related to Category 1A indicators. They are set out in the remainder of this section.

One Health. Participants considered indicator 2 to be appropriate for tracking PVS, especially since veterinary public health capacities are far weaker than human public health systems and administrative and budgetary constraints tend to hinder the collaboration that is necessary for effective and efficient disease control. The framework emphasizes prevention and early control of disease at the source. Given that most pandemic threats (and 80 percent of bioterrorism agents) have zoonotic origins, there should be robust governance of control of infectious diseases in livestock and appropriate monitoring of pathogens in wildlife. In addition, several experts suggested monitoring the extent and quality of collaboration between the animal health and human health sectors. Such indicators should measure action, not just capacities, and capture the activity, spending, and preparedness in both areas at the district and local levels. This is a high priority, but beyond the means and scope of the monitoring project at this stage. Monitoring of the follow-up to the PVS recommendations is already included, which should encourage capacity building on the veterinary side. More robust veterinary public health capacities than those that currently exist in developing countries are critical for joint and coordinated activities to prevent and respond to outbreaks, and to control AMR.

Environmental risks. Several experts noted that assessments of environmental risk were not included. The EcoHealth Alliance and the World Bank are developing tools for evaluating country capacities to reduce environmental drivers of infectious disease outbreaks. Once the tools are designed and tested, which may take several years, they should be considered for inclusion in the framework.

Table 1.2. Indicators for Category 1A: Assessments of national animal and human public health core capacities.		
Name	Definition	
1. JEE assessments	NUMERATOR: # of countries that have completed a JEE assessment in the last 5 years.	
	DENOMINATOR: 194 (number of WHO member states).	
2. PVS evaluations	NUMERATOR: Number of countries that have completed a PVS assessment in the last 5 years.	
	DENOMINATOR: 181 (number of OIE member countries).	
3. IHR implementation	NUMERATOR: Number of countries who report compliance with IHR at the World Health Assembly.	
	DENOMINATOR: All member states.	
	Compare these numbers with those of the JEE and PVS country assessments.	
	Identify gaps and/or differences in compliant countries with JEE and PVS scores.	
4. CSOs in country capacity for prevention of epidemics and pandemic preparedness	NUMERATOR: Number of countries with JEE/PVS less than 5 years old that covers CSO capacity topics. **	
	DENOMINATOR: Number of countries with JEE/PVS less than 5 years old.	
	** Topics examined: coverage of community-level engagement in prevention and preparedness activities, as well as a qualitative analysis of the numbers and types of CSOs directly contributing to national and international discussions on prevention and preparedness at country, regional and global levels.	
5. Quality and effectiveness of assessments	Aim would be to monitor quality and effectiveness of assessments and the assessment processes (noted above) through original and existing qualitative research, including case studies of impacts. This would complement tracking of delivery of assessments.	
6. CSO engagement in global health security	Trend in CSO campaigns for global health security, including attendance at World Health Assembly (WHA) to advocate for and otherwise contribute to global health security.	

Gaps in monitoring performance of health sector. Allocating resources in the health sector effectively and equitably has been a long-standing challenge. Monitoring and analyzing the performance of the various parts of the sector is essential to support policies that are effective, efficient, and equitable in promoting health. Many well-resourced initiatives are now underway to monitor progress toward universal access to quality healthcare, or Universal Health Coverage (UHC). A number of expert participants therefore suggested that UHC monitoring needs to be adapted, to balance concerns about services for existing patients with the parallel objective of reducing the expected number of future patients; this requires the minimization of the likelihood and severity of epidemics and pandemics. Prevention of and preparedness to respond to outbreaks requires effective public health systems that deliver the core functions of early detection, diagnosis, and prompt outbreak control. UHC monitoring should thus track whether populations increasingly benefit from core public health functions. Such a comprehensive approach would more meaningfully measure the health impacts of action (and inaction) by health ministries and their global health partners, thereby avoiding the biases of the current method, which limits the scope of the UHC metrics to ongoing healthcare programs for patients "today," without considering the impact of policy choices on

the volume of patients "tomorrow." The Ebola crisis and similar outbreaks have demonstrated that a short-sighted and incomplete approach to universal health coverage - one that ignores core public health functions instead of prioritizing them - is a deadly, costly, and impoverishing malpractice.

Visibility of core public health systems in analytical work. More comprehensive analytical work, including monitoring of performance of core public health systems, would provide multiple benefits. It would raise the profile of the public health capacities that are required for disease prevention, notably the core public health capacities needed for IHR. Health sector leaders have explained the chronic neglect of core public health functions by stating that the benefits are "invisible," which suggests a lack of accountability for equitable and productive use of resources. Acceptance of this explanation by top decision makers in the sector suggests that gross underfunding of prevention can and will continue, along with exclusion of core public health systems from UHC monitoring and other analytical work. More often than not, public health systems have been absent from health strategies and budgets, without any accountability for this omission. Even work on health systems (programs at the WHO, the World Bank, and elsewhere) has long excluded core public health capacities, with predictably adverse consequences for population health, health system vulnerability, investment, poverty, and economic growth, especially in the poorest countries. This discussion confirmed the importance of Category 1A. Indicators for monitoring analytical work related to risk assessments (in Domain 3) below would help to increase the visibility of core public health capacities.

Assessments of community capacities. The capacity of a country to prevent and control outbreaks depends substantially on what occurs within its communities, both where outbreaks start and where they may ultimately spread. Within communities, the core capacities to mitigate the impacts of outbreaks overlap substantively with concepts developed in recent years to measure resilience to shocks. Clearly, robust ability to detect, respond, and recover using available infrastructure, systems, and technology without external assistance (which is one definition of resilience) helps both to reduce the spread of outbreaks and to avert wider economic damage. Village veterinary and human health workers (who are often volunteers) can deliver highly valuable disease surveillance services if they have the knowledge and support to report disease events to the authorities. Thus, some experts suggested that Category 1A should also track community-level preparedness, particularly in poor countries most likely to face zoonotic disease outbreaks. Others recommended a metric for community engagement, such as support for community service organizations; the degree of media attention, public awareness, and education about zoonoses and other infectious diseases; and the percent of a nation's population with access to community health workers and village animal health workers as reported by leading non-governmental organizations. The team therefore modified the framework by adding a marker to review whether community and CSO capacities are addressed in the JEE and PVS; such a review and other analyses of CSO engagement at the country level would, however, require substantial resources.¹⁷

Sub-national capacities. Information relevant to tackling an outbreak that is available in the district and provincial branches of the public health service has often differed from information possessed by the national government. Similar to the case of community capacity for engagement in prevention and control of contagion (above), this dissonance between regional and national levels has implications for how the JEE teams work. JEE teams could help to improve communications between different levels of the public health sector by reaching out to the district and regional public health offices to make sure that regional and district views on gaps in performance of core public health functions are reflected in the evaluation.

CATEGORY 1B. BUILDING NATIONAL ANIMAL AND HUMAN PUBLIC HEALTH CORE CAPACITIES

The indicators in Category 1B track the steps in building core public health capacities by governments, with support from the WHO and the OIE, financing from official partners including the World Bank and other donors, and support from CSOs and the private sector. Both adequate funding and technical assistance are essential for closing the gaps between needs identified in the assessments and stronger capacity to prevent and control disease outbreaks. As noted above, when the assessments include capacities in CSOs and communities, the prospects for successful implementation would improve. Table 1.3 presents a set of indicators to monitor progress in Category 1B.

A number of concerns expressed at the April 2017 workshop have informed the development of the indicator set in Category 1B, as set out in the following sections.

Support to implementation of action plans. These indicators cover both domestic and external financing and support in the form of technical assistance. Some workshop participants cautioned that data on financing will be difficult to ascertain. Official sources of authoritative data on world economies, government expenditure, official development assistance, and health spending organizations – the OECD, the WHO, the World Bank, and the International Monetary Fund (IMF) – currently do not classify data they collect on public spending in a way that would show expenditures on core public health functions to implement the IHR and follow-up to PVS. Spending on a key global public good (pandemic prevention and preparedness) is thus currently not visible in official data from international public institutions, although the data series they create and maintain do track a number of categories of spending on health in nearly 200 countries. The gap is one that only an official international organization can close; it reflects the past periods of neglect of public health systems.

Financing for investments and other actions in countries with completed JEEs and PVS assessments should be tracked regularly because shortfalls and delays would be a strong sign that the international community is reverting to neglecting health security. Notably, the revised indicators only refer to financing for low-income countries, both to reduce the data collection burden and to prioritize a critical area, since these countries are more likely to have greater financing needs and difficulties finding resources than wealthier countries. Indeed, for all the financing indicators, the ultimate goal is coverage of all countries. This would allow estimating the total cost of providing the global public good of reduction of pandemic risk, which should then be compared to the estimates of expected benefits that would arise (which range from \$60 billion to \$570 billion annually, as noted in Annex 1). The indicators in Category 1B are currently defined to only track financing for middle- and high-income countries when time and resources permit and through collaborative efforts, including Georgetown University's initiative on financing for health security from governmental and non-governmental sources. Their objective is to account for all external assistance, including technical assistance that is important for public health system components such as laboratories.

Characteristics of financing indicators. The elapsed-time specification for action plan financing was adjusted to nine months, the same as in the recent report of the International Working Group on Financing Preparedness, but data collection will follow the good practice of aligning with the country's fiscal year and other practices adopted by donors to record the financial and technical assistance they provide (International Working Group on Financing Preparedness 2017). Progress of implementation of the health security financing assessment tool, which the World Bank is developing to support timely and robust follow-up to the JEE and PVS assessments, would be tracked, along with the financing requirements and commitments (including the sources of financing) (International Working Group on Financing Preparedness 2017). By tracking major external funding, the

Table 1.3. Indicators for Category 1B: Building national animal and human public health core capacities.	
Name	Definition
1. National action plant to reduce gaps identified in assessment(s) (JEE and/or PVS)	NUMERATOR: # of countries (broken down by income level) where government has formally adopted a national plan(s) with defined attributes (relevance, prioritization, realism, financing, community/private sector engagement) within 9 months of completion of assessment reports. DENOMINATOR: # of countries (broken down by income level) that have successfully undergone a JEE and/or PVS assessment.
 National action plans' coverage of community capacities in LMICs 	NUMERATORS (for 3 sub-indicators): Number of LMICs where National Action Plan considers (i) community preparedness, (ii) community human health workers and (iii) community animal health workers, (iv) evidence-based inclusion of behavioral response (data about public knowledge, views and current behaviors in connection to relevant aspects of the public health system and proposed measures for mitigation). DENOMINATOR: All LMICs with an adopted National Action Plan. Note: Consider separating low-income from middle-income countries for comparison
3. Domestic financing committed to a JEE-based action plan in an approved national budget in all countries	NUMERATOR: Number of countries with domestic financing in an approved budget for some or all JEE – identified gaps. DENOMINATOR: All countries that have successfully undergone a JEE assessment and disclosed the findings.
4. Domestic financing committed to a PVS-based action plan in an approved national budget in LMICs	NUMERATOR: Number of LMICs with domestic financing in an approved budget for some or all PVS- identified gaps (as set out in the quantitative data and objectives of the PVS Gap Analysis Reports). DENOMINATOR: All LMICs that have successfully undergone a PVS Gap Analysis and disclosed the findings. <i>Note: Consider separating low-income from middle-income countries for comparison.</i>
5A. External assistance for JEE-based action plan	NUMERATOR: # of LMICs that have obtained external financing and/or technical assistance to address some or all JEE-identified gaps. DENOMINATOR: All LMICs that have undergone a JEE assessment and disclosed the findings. Also look at domestic financing and technical in-kind assistance. <i>Note: Consider separating low-income from middle-income countries for comparison.</i>
5B. External assistance for PVS-based action plan	NUMERATOR: Number of LMICs that have obtained external financing and/or technical assistance to address some or all PVS-identified gaps. DENOMINATOR: All LMICs that have successfully undergone a PVS assessment and disclosed the findings. *Also look at domestic financing and technical in-kind assistance.
6. Burden sharing of assistance to LMICs	NUMERATOR: Financing from top 5 bilateral and private donors. DENOMINATOR: Financing from all external sources. <i>Note: Consider separating low-income from middle-income countries for comparison.</i>
7. Quality and effectiveness of capacity building efforts	Through the use of existing evaluation mechanisms and original research, assess the quality and effectiveness of (above noted) capacity building efforts following the JEE and PVS assessments and national action plans. Track quality of other relevant development assistance programs that address IHR-related capacities.
8. Public-Private Cooperation and Private Sector Advocacy	 (i) # of small, medium, and large companies promoting closing of JEE-identified gaps and /or GHSA (special emphasis on the local context) in each country with JEE action plan; participation at regional and national "marketplaces" responding to JEE/PVS gaps. (ii) Types, quality and effectiveness of public-private cooperation outputs (sample or all countries with JEE action plan and/or PVS gaps): Existence of action and inclusive in-country network, connecting in-country operators and public sector to organize and catalyze activity to support preparedness and response. Information sharing platform connecting public and private sectors, to support response, maintain risk awareness, and address economic and business risk posed by outbreaks. Private sector included in emergency response plans and within the Emergency Operations Center. Engagement of private sector in JEE/PVS planning, including addressing gaps identified in core public health capacities.
9. CSR leveraged for core public health capacity building at country level ("host country")	 # of countries where Fortune 100 companies are directing CSR resources toward building in public health core capacities. # of Fortune 100 companies directing CSR resources to public health core capacities. # of countries where small- and medium-sized companies directing resources (CSR) toward capacity building in public health core capacities. # of companies direction resources (CSR) toward capacity building in public health core capacities.

monitoring framework responds to the useful suggestion, made at the workshop, that donors be challenged to align their programs by increasing their funding for action plans as warranted by the findings of the assessments. For that to occur, countries need to take ownership of the assessment, and external partners must be prepared to quickly and adequately respond to country requests for such support. Funding availability as such may not be a constraint. For instance, the World Bank currently has \$25 billion per year for grants and soft loans for the poorest countries. The World Bank has estimated that investments and operations of core public health capacities that comply with IHR and OIE standards would cost \$1.4 billion per year in all low-income countries (Pierre-Louis et al. 2012). This amount is a small fraction of the funds already available in International Development Association (IDA).¹⁸

Government commitment. Given that revamping a nation's health system requires support from the highest levels of government, what would be a metric for good governance at the national level? The discussion was inconclusive on this point. The indicators in Categories 1A and 1B are designed to measure governance by including indicators of preparation of action plans and financing for their implementation. Over time, these indicators will track whether governments and their international partners were committed to improving health security and to what extent their actions were adequate (relative to the expected costs of pandemics). The analysis will not be country-specific; such analyses are outside the scope of the monitoring framework. Resources permitting, specific case studies on successful approaches to boosting government commitment to health security could be included in the monitoring report in the future.

Private-sector engagement. While financing by governments and their partners for the JEE and PVS-based Action Plans will be essential to progress, complementary actions by the private sector can reinforce country preparedness. Participants suggested monitoring how countries engage with the private sector. Indicators addressing these important concerns have been added to the framework, including the growth of membership of the Private Sector Round Table (PSRT) of the GHSA and support for country public health capacities from corporate social responsibility programs of the largest global firms. One suggestion, reflected above, was to focus on private sector involvement in preparedness as well as response at the time of an emergency. Tracking the involvement of the private sector in outbreak response would be a valuable step at the country level. Preparedness for such involvement would normally be a part of national and municipal disaster response planning. Since the list of indicators in Category 1B is large, however, the global framework will at this stage be limited to private sector engagement in preparedness, for which there is a continuing need, rather than tracking the relatively infrequent responses.

Tracking of select specific outcomes, in addition to robust systems. There is no doubt that preparing country action plans after JEE and PVS assessments is essential and should be tracked. Similarly, funding for implementation should also be monitored. Some experts felt, however, that, in addition, the framework should go a step further and track particular outcomes. This concern surfaced several times at the April 2017 workshop: to what extent is it appropriate, useful, and feasible to track specific country-level outcomes and aggregate them by region and globally? For instance, should there be global tracking of the number of epidemiologists and laboratory technicians trained, the number of emergency operations centers established, the extent of coverage by smartphones and social media and whether this is sufficient to help detect an outbreak and address fear, and whether there is protection for first responders or public health workers during an outbreak? The research team had struggled with this as well, and decided to keep the focus of the monitoring framework on the systemic measures that are required globally. The monitoring framework thus contains a set of vital actions that are required for specific outcomes and for the final results of effective and efficient outbreak response (as reflected in reduced health and economic costs). Most of these actions are the responsibility of specific agencies, therefore the monitoring framework will reveal gaps that are directly attributable to specific players. Monitoring select outcomes is highly relevant at the country and community levels, but selection and tracking of global outcome indicators

would be problematic at this stage. After several years of experience of implementing JEE- and PVS-based action plans in a large number of countries, selection of specific outcome indicators for global tracking may be revisited.

Focus on performance of core public health functions. The focus is on how the international community measures and improves the performance of core systems, rather than on traditional outcomes. This choice was supported by a recent analysis of outcome and output monitoring for the 72 public health projects financed by the World Bank from 2005 to 2013, as part of the international program for avian flu control and pandemic preparedness. The Independent Evaluation Group (IEG) reported the results of its analysis of the frameworks in these prevention and preparedness projects. On this basis, IEG recommended that monitoring frameworks for such projects should not include indicators of "traditional" outcomes like reduced disease prevalence. Instead, the focus of monitoring should be on public health system performance (such as production and analysis of surveillance and diagnostic reports; the number of, and results of, training in infection prevention and control; and the conduct and evaluation of simulation emergency responses), along with consistent tracking of the provision of inputs that are necessary for such capacities to improve and perform their essential functions (Independent Evaluation Group 2013). IEG's "most significant finding is that after 2010, the World Bank has not sustained the zoonotic disease risk management and pandemic preparedness agendas and failed to mainstream them into bank strategy and operations," (Independent Evaluation Group 2013).

Toward measurement of global outcomes. The JEE and PVS in fact deal with capacities of public health systems to perform their functions. Tracking outcomes in terms of the enhanced capacity of these systems is long overdue. Repeated JEE and PVS assessments and the resulting action plans could become the appropriate tools for reviewing the extent of non-governmental engagement, for instance by local universities and the private sector. Over time, the scores generated by the JEE and PVS (see Table 1.1 for the 5-point JEE scale) would be robust indicators of the final outcome of whether, and to what extent, the actions of the international community have improved our defenses against the microbial threat. Several experts cautioned that capacities may not always predict actual performance. Will these capacities take appropriate actions in an emergency? Clearly in the absence of capacity, there will be no effective action. JEE and PVS include predictors of performance, such as simulation exercise frequency and results. Participants also suggested analysis of, for instance, audits of five notifiable disease events in a country over the past year. After-action reviews of such incidents could help trace whether elements of the public health infrastructure responded swiftly and effectively. Such self-evaluations and assessments are important responsibilities of public health authorities at both national and global levels.

Relevance of outcome indicators. Select outcome indicators can be especially useful to communicate the case for prevention and preparedness to donors and finance ministers, but selection of indicators for this end would differ according to particular country circumstances. Even with improved underlying data, the number of such outcome indicators that would be meaningful to track at a global level is likely very limited. A global health security index (described in Chapter 3) will systematically explore these issues and expects to generate valuable data that can be used in the global monitoring effort. Other experts at the workshop felt that adding specific outcome measures would dilute this global monitoring effort and thus make it less useful. Instead, the monitoring framework emphasizes the essential systems and processes that are necessary for core public health capacities to develop and be sustained. Also, collecting data for numerous specific outcome metrics would be costly, difficult, and duplicative of other efforts. Instead, the research team has decided to highlight select outcome monitoring results from other researchers and competent public health authorities, such as the WHO, OIE, and CDC. Moreover, the team will seek to include indicators from monitoring of the Integrated Disease Surveillance and Response (IDSR), reviews of completeness of the IMF and World Bank's analyses of economic risks, and other existing processes that can capture change that should be occurring. While it does not seem appropriate or practical to add indicators to the framework, the monitoring reports would highlight the findings on outcomes from other, related initiatives.

These could include, for example, the results indicators from a major project in West Africa, the Regional Disease Surveillance Systems Enhancement (REDISSE).¹⁹

Performance of public health infrastructure in control of small outbreaks. There was concern that current assessments and policy debates primarily focus on the large public health emergency of international concern (PHEIC) type outbreaks. It may be more telling, however, to analyze responses to smaller, routine outbreaks – what the country learns from them and how it addresses unexpected problems. Such analysis would provide indicators of actual performance to complement the capacity indicators in the JEE of public health systems. Working with countries during and after small outbreaks could be a good opportunity to galvanize commitment to improving public health systems. Such opportunities are far more frequent than PHEICs. On the other hand, organizing such ad hoc joint external assessments may be more challenging than planning for more formal JEEs. While this point was not reflected in revisions of the indicators in Category 1B, it is important to retain for evolution of the JEE and to consider in developing simulations.

CATEGORY 1C. IMPROVING OUTBREAK REPORTING PERFORMANCE AND INCENTIVES

Experts endorsed the selection of the indicators for Domain 1 that relate to disease outbreak reporting, which is a core public health function. Reporting is key to the effectiveness and efficiency of infectious disease control, which is the overarching theme of Domain 1. Outbreak reporting is thus a quintessential function of public authorities in countries and, for diseases with epidemic or pandemic potentials, it is also required at the regional and global levels.

Performance of this function depends both on capacity (knowing where and what to report, capacity to diagnose the event or obtain such diagnosis) and on the willingness of governments to promptly and adequately share information on outbreaks. Hiding outbreaks of infectious diseases in livestock and humans is too common and ultimately highly damaging. When officials are not transparent about a disease outbreak (as is often the case when they are underprepared), consumers and producers will perceive heightened uncertainty. Reduced confidence in public authorities thus results in rational reactions by consumers and businesses that worsen the already high costs associated with delayed disease control. Delayed reporting of a zoonotic disease in animals can cause preventable human illness and deaths and result in humans serving as the sentinels for a livestock disease. A country's willingness to report diseases responds to incentives that are, in part, controlled by public health authorities. Table 1.5 shows the indicators for Category 1C.

Incentives to reporting and IHR compliance. Some noted that the private and commercial sectors would become aware of pandemic risk if a transparent index were developed to measure the risk of a country having an outbreak and not reporting it. Such an index would be similar to those used to characterize sovereign debt risk. Delayed reporting ultimately means heightened economic impact and this, in turn, would affect the cost of borrowing for countries. As part of its mandate to ensure global economic stability, the IMF's annual macroeconomic assessment should note if a country has significant exposure to risks due to low preparedness. Countries would then have a clear incentive to invest in capacity building because the IMF's assessment influences a country's access to capital. Another suggestion would be to link performance to access to the World Bank's Pandemic Emergency Financing Facility (PEF). These valuable suggestions can be in part reflected in work on risk assessments and analyses (discussed in Domain 3). They do highlight the paradox of providing incentives for actions by international institutions that should have been occurring without such incentives. The research team agrees with the experts' suggestions that progress in compliance with IHR could be a health indicator for the UN SDGs, though this may only occur when the next revision of the SDGs occurs in 2030.

Table 1.4. Indicators for Category 1C: Improving outbreak reporting performance and incentives.		
Name	Definition	
1. Availability of emergency financing (e.g., contingent components, pre-negotiated draw-down options, PEF)	NUMERATOR: # of LMICs with confirmed PHEIC that have obtained financial and other resources to promptly and adequately respond to outbreaks (incl. disease control and mitigation of impacts) DENOMINATOR: All countries with WHO-declared PHEIC. <i>Note: Consider separating low-income from middle-income countries</i> <i>for comparison. In years with no PHEIC declared, the indicator value</i> <i>is "not applicable." When five years of data are available (after 2023),</i> <i>the indicators can be a 5-year cumulative total and a moving average.</i>	
 Financial incentives system – contingency funds for prompt responses to emergencies in LMICs 	 Availability of WHO contingency funds (balance relative to the \$100m target amount). Availability of contingency funds for emergencies involving zoonotic outbreaks in animals in LMICs. Note: Consider separating low-income from middle-income countries for comparison. 	
3. WHO/UN accountability	WHO & UN to release statement against the imposition of unjustified restrictions on trade & travel in the case of a PHEIC. Assess and report on annually.	
4. Preparedness for trade and travel measures	World Trade Organization, Civil Aviation etc. development of standards & enforcement mechanisms for trade & travel restrictions.	

¹² According to the WHO Global Health Expenditure Database, external assistance for health in Guinea, Liberia, and Sierra Leone was \$627 million in 2009-2011; the action plans for capacity to control outbreaks proposed that the \$26 million investment should be made during a three-year period.

¹³ The World Bank's People, Pathogens and Our Planet: The Economics of One Health report estimated the resources required for good performance of public-health systems in 139 developing countries at \$3.4 billion annually (investments, operations, and maintenance in a steady state).

¹⁴ Prevented disease is considered an "invisible result" by health sector senior officials at the World Bank and elsewhere. Core public health systems have been absent from extensive analytical work on health systems and financing and have seldom received financing, although the term "core public health" suggests that priority treatment was warranted instead.

⁹ As of September 2017, OIE completed 51 initial PVS evaluations in Africa, while WHO and partners completed 22 JEE missions with 9 more being planned in Africa.

¹⁰ In total, WHO and OIE will have organized 10 IHR-PVS Bridging Workshops by the end of 2017, of which 4 were in Africa. About 30 other IHR-PVS Bridging Workshops are being considered for the coming two years (2018-2019).

¹¹ It has been estimated that more than two thirds of all 193 WHO Member States are non-compliant with the IHR (Gostin et al. 2016). Systematic implementation of the JEE is required to generate robust, reliable evidence of performance of core public health functions.

¹⁵ The JEE Alliance's monitoring indicators are expected to be finalized in the spring of 2018. The indicators in Table 1.2 will be adjusted to be fully consistent with the JEE Alliance indicators. The JEE Alliance indicators are expected to be more detailed and to monitor the JEE process in depth.

- ¹⁶ "Country" refers to 194 members of WHO and 181 members of OIE (see Annex 8). The requirement of IHR compliance is legally binding on all 194 WHO Member States. In practice, the small difference between lists of members of the UN, WHO, and OIE is immaterial. The more comprehensive country list is relevant to the monitoring since weak core public health capacity anywhere, regardless of formal status, reduces health and economic security for the rest of the world.
- ¹⁷ Workforce Development indicators of the JEE measure the need for basic training in applied epidemiology for local levels (beyond district and national levels). For the Field Epidemiology Training Program, the CDC has for many years trained Frontline Disease Detectives who work down at the sub-sub-national level. Geographic coverage of this cadre is also important and a key metric.
- ¹⁸ The financing requirement for public health systems in all 139 low- and middle-income countries was \$3.4 billion annually. World Bank loans and grants, totaling about \$60 billion per year, are intended to finance investments with the highest expected economic rates of return. Core public health systems have among the highest economic returns in any sector while they also cost-effectively and efficiently improve public health. (Pierre-Louis et al. 2012)
- ¹⁹ REDISSE, which was launched in 2016 with planned financing of \$310 million from IDA (the World Bank's concessional fund), will support strengthening of veterinary and human public health systems in 15 countries in the Economic Community of West African Countries.

²⁰ The OIE World Animal Health Information System (WAHIS) catalogs animal outbreaks.



DOMAIN 2: IMPROVING SCIENCE, TECHNOLOGY, AND ACCESS

2

Domain 2: Improving Science, Technology, and Access encompasses three main monitoring goals. The first is to monitor progress in the rapid sharing of epidemiological, clinical, and genomic data (including patient samples) on infectious disease outbreaks. The second goal is to track progress on national-level engagement in R&D, including capacity strengthening and R&D workforce development. The third goal is to track progress on life-saving vaccines, therapeutics, and diagnostics, and to identify barriers to completing these products and ensuring equitable access. These three goals serve complementary purposes. Creating incentives for countries to rapidly share data and samples, for example, can lead to better and faster scientific advancements. In addition, countries may be more likely to share data and samples if access to resulting products is guaranteed. By carefully tracking R&D investments, we can help ensure that lifesaving medical countermeasures are funded through licensure. Finally, by tracking progress in local and regional scientific capacity, disease surveillance and detection can be improved. Each of these goals represent categories within Domain 2 and are introduced in greater detail below.

2A: Rapid sharing of epidemiological, clinical and genomic data

We have not seen rapid, nor transparent, sharing of genomic sequence data and patient samples, especially during moments of crisis (such as Ebola in West Africa). There are multiple explanations for why such sharing does not occur, but one major reason is that medical technologies, therapeutics, and other scientific advancements developed in high-income countries are not often made available to those in LMICs, the origin of the samples.

The Pandemic Influenza Preparedness (PIP) Framework and the Nagoya Protocol are two advancements in the establishment of global standards for sample sharing and access, however progress in this area remains. The PIP was developed by WHO member states to balance the need for increased global access to influenza samples with the need of countries to retain the rights to, and benefits from, those samples. This global framework aims to facilitate the rapid sharing of sample-related data worldwide, however, a PIP-like sharing mechanism for pathogens

outside of influenza does not yet exist, and still others debate the effectiveness of the PIP (as was evidenced by the 2009 H1N1 outbreak). The Nagoya Protocol, born out of the UN Convention on Biological Diversity (CBD), was designed to create standards for the sharing of non-influenza genetic information as well as creating a benefit-risk-access framework. While voluntary, the <u>"Access Benefit-Sharing" Clearing House tool</u> was designed to facilitate implementation of the Protocol. PIP and the Nagoya Protocol (along with their associated tools) support increases in sample and data sharing and include access guarantees. The monitoring framework for this category will track progress in global standards for sample sharing, open data sharing mechanisms, and public domain research that supports data transparency.

2B: National engagement in research and capacity strengthening

Early and improved disease detection (surveillance and diagnostics) as well as R&D depend on strong collaborations between research institutions worldwide, especially in regions harder hit by EIDs of pandemic potential. Progress in transnational research collaborations can serve to strengthen local capacity while also incentivizing early and accurate reporting of EIDs of international concern. Numerous international research collaborations are underway and are significantly contributing to scientific advancements and new knowledge related to infectious disease dynamics; however more needs to be done. The phenomenon of 'parachute scientists' during an outbreak is far too common and expensive. During periods of non-crisis, LMICs would benefit from improvements in research laboratories and equipment, for example, improved research training opportunities, and post-training research-employment opportunities. Monitoring progress in this area will highlight the importance of research training, employment opportunities, and transnational research collaborations in epidemic and pandemic preparedness.

2C: Innovation in, and access to, medical countermeasures

The last few decades have brought significant advancements in R&D on EIDs of epidemic and pandemic potential. Recent advancements in biotechnology drawn from genetics, structural biology, immunology, biochemistry, epidemiology, and microbiology have fueled developments in a range of new vaccines, therapeutics, diagnostics, and platform technologies. Vaccines against microbial diseases improve the health of millions of people worldwide and have eliminated or significantly decreased the burden of several major diseases including smallpox, poliomyelitis, measles, and pertussis (whooping cough), among others. Yet, licensed vaccines and therapeutics still do not exist for most of the WHO's list of priority diseases of major epidemic threat (see Table 2.1). In addition, many would argue that one of the most important risk reducing measures to save lives in an influenza pandemic is a universal flu vaccine. Yet, consistent and adequate funding for that effort is also lacking. CEPI, a recent public-private partnership, represents a major milestone in advancing vaccine development for three priority pathogens (Lassa fever, MERS-CoV, and Nipah virus) and broader use platform technologies for vaccine development. However, more work needs to be done in vaccine R&D for other pathogens, including influenza, and in addressing other essential medical countermeasures such as diagnostics and therapeutics.

WHO's R&D blueprint. The WHO's R&D Blueprint, established in the wake of Ebola, is an effort to coordinate and fast-track global efforts in R&D for pandemic preparedness and a cross-cutting resource within this monitoring category. The R&D Blueprint assists researchers and developers by: a) increasing global coordination (through the Global Coordination Mechanism); b) prioritizing diseases²¹ (Figure 2.1) and creating target product profiles (TPPs) and roadmaps; c) fostering the exchange of epidemiological and related data; d) streamlining regulatory requirements; and e) setting standards (for clinical trial design and data sharing) (World Health Organization 2016a). One aspect of the R&D Blueprint is to assist in outlining appropriate regulatory and ethical pathways for clinical trial approvals during emergencies. The Emergency Use and Assessment Listing (EUAL) is the WHO

mechanism designed to create standards for clinical trial approvals and medical countermeasure deployment during emergencies. As of January 2017, the <u>WHO R&D Blueprint</u> prioritized a list of ten pathogens needing urgent R&D attention (not including influenza or tuberculosis, which are handled separately). Important to note is that the January 2017 list differs slightly from the 2016 list published in the Blueprint report. The 2016 list comprised of: (1) Crimean-Congo hemorrhagic fever; (2) Filovirus diseases (i.e. Ebola & Marburg virus); (3) highly pathogenic emerging coronaviruses relevant to humans (MERS-CoV & SARS); (4) Lassa Fever; (5) Nipah virus; (6) Rift Valley fever, and (7) R&D preparedness for a new disease. Also included were three additional diseases determined to be serious, necessitating further action as soon as possible: chikungunya, severe fever with thrombocytopenia syndrome, and congenital abnormalities associated with Zika virus.

Monitoring progress in scientific and technological innovations related to medical countermeasures and access provisions for all those in need will serve to a) target resources according to greatest need; b) highlight gaps and funding opportunities, and c) ensure that future clinical and scientific advancements (diagnostics, vaccines, therapeutics) are made available to those who need them (securing equitable access).

Table 2.1. WHO priority pathogens of major epidemic threat. 1. Arenaviral hemorrhagic fevers (including Lassa Fever*) 2. Crimean Congo Hemorrhagic Fever (CCHF) 3. Filoviral diseases (including Ebola and Marburg virus) 4. Middle East Respiratory Syndrome Coronavirus (MERS-CoV*) 5. Other highly pathogenic coronaviral diseases (such as Severe Acute Respiratory Syndrome (SARS)) 6. Nipah virus* and related henipaviral diseases 7. Severe Fever with Thrombocytopenia Syndrome (SFTS) 8. Zika 9. Disease X** *Viruses being address by CEPI, the Coalition of Epidemic Preparedness Innovations. **Any disease identified prior to the next review using the Blueprint's decision instrument. Source: http://who.int/blueprint/priority-diseases/en/

OPENING PRESENTATIONS

To commence the discussions for Domain 2, Dr. Richard Hatchett (CEO, CEPI) and Dr. Christian Happi (Professor of Biological Sciences, Redeemer's University, Nigeria) were asked to provide opening remarks. The presenters were asked to highlight progress and gaps within this domain and to provide any relevant context and examples of progress from their own organizations and beyond.

INNOVATIONS IN EPIDEMIC PREPAREDNESS

Richard Hatchett, CEO of CEPI, provided insight into the young coalition's scope of work since its establishment in 2016. CEPI is a partnership of public, private, philanthropic, and civil society organizations that aims to finance and coordinate the development of vaccines for high-priority public health threats. To this end, CEPI is creating vaccine platform technologies to respond rapidly to EIDs with pandemic or epidemic potential. To date, CEPI is focusing on Nipah virus, Lassa fever and MERS-CoV with the goal of bringing viable vaccine candidates to phase II development. According to Dr. Hatchett, the rapid sharing of genetic sequence data can jumpstart vaccine and therapeutic development and is one area where we have made the most progress within Domain 2. Interestingly, for the H7N9 influenza strain, the U.S. Biomedical Advanced Research and Development Authority (BARDA) was able to generate a candidate vaccine using reverse genetic techniques before obtaining extensive samples because the sequence data was made available. Despite a slow start, sharing clinical information did improve during the

West African Ebola outbreak. One reason for this was the WHO's teleconferences with healthcare providers overseeing Ebola with patients that were evacuated to the United States and Europe, enabling the rapid sharing of clinical experience managing such patients (including the anecdotal use of investigational therapeutics). These meetings and discussions with the WHO subsequently facilitated a joint effort to collect and analyze clinical data that was ultimately shared more broadly (Uyeki et al. 2016). But these successes have not been institutionalized. Unfortunately, despite efforts to establish a similar process during the Zika response, for various reasons such calls were never initiated. Zika, of course, presented different problems, with the patients affected being more widely distributed than those during the West African Ebola outbreak, and other informal collaborative networks materialized. Methods for establishing and capitalizing on such collaborative networks could be improved.

While CEPI's role in supporting vaccine development for EIDs aims to address an important global need directly, CEPI is also taking a holistic view on what will be needed in order to deliver vaccines in emergency settings. It is taking account of, and hopes to address, legal and regulatory requirements (and barriers), liability concerns and access issues. During the Zika outbreak, for example, public health officials argued that Zika is the kind of public health threat for which market forces would drive supply successfully, so the U.S. government response did not provide for advance purchases of (or other special provisions for) the Zika vaccine.²² This is one area that may need more careful attention in the future however. Moving forward, CEPI aims to play a critical role in organizing international efforts in the space between late preclinical development and Phase 2 clinical trials. According to Hatchett, this is an area that the U.S. government took years to address successfully in its own work developing and testing countermeasures.

Recently, CEPI and Duke University's Center for Policy Impact in Global Health conducted two pipeline analyses on products for use in emerging infectious disease outbreaks with epidemic or pandemic potential. CEPI focused on vaccines, while the Duke team focused on therapeutics and diagnostics. The analyses found that for some EIDs with epidemic or pandemic potential, there are many candidates in the pipeline, but for other diseases there are few or no candidates. Both analyses provide estimates of the financing required to move these candidates through the pipeline, and both of these analyses have been submitted for journal publication. Initially, CEPI is working to jumpstart the vaccine pipeline for three target pathogens: Nipah virus, Lassa fever, and MERS-CoV. According to Hatchett and other leaders, CEPI is still very much in its early stages, but the partnership could serve as a model for establishing an analogous organization in therapeutics or diagnostics. Given the high cost of vaccine development (e.g. \$750M - \$1B for a coronavirus vaccine as one example), more investments will be needed to complement the current scope of CEPI to ensure that more pathogens with epidemic potential are being properly addressed through R&D.

AFRICAN CENTRE OF EXCELLENCE FOR GENOMICS OF INFECTIOUS DISEASES (ACEGID)

Dr. Christian Happi, Professor of Biological Sciences, Redeemer's University, Nigeria, presented on progress being made through the African Centre of Excellence for Genomics of Infectious Diseases (ACEGID) as an example of a Nigerian research center actively collaborating with research institutions outside the U.S. and Africa. Funded by the WHO and the U.S. National Institutes of Health (NIH), the ACEGID is an effort to improve science, technology, and access related to the genomics of infectious diseases. As a consortium of institutions across West Africa and collaborators at several universities in the United States and United Kingdom, the mission is to develop African research capacity in genomics by building a critical mass of well-trained African scientists that can use genomics tools in efforts to eradicate infectious diseases. Current collaborators include the U.S. Defense Department, several private sector companies, and the University of Nebraska, the University of Cambridge, and the University of Edinburgh.



Figure 2.1. Pillars underlying rooted infectious diseases research collaborations. *Source*: Yozwiak et al. 2016. "Roots, Not Parachutes: Research Collaborations to Combat Future Outbreaks."

During the Ebola outbreak in Guinea, ACEGID developed an Ebola diagnostic tool, trained Guineans in how to use it, and made the tool available for communities in and outside of Guinea. The diagnostic tool was used to detect the first cases of Ebola in Sierra Leone and Nigeria (Nigeria did so within 6 hours of obtaining the first sample). This saved critical time because sending samples to Europe or the U.S. would have taken weeks. In addition, ACEGID worked with its partners to sequence viruses as they arrived and made these sequences publicly available. This was the first time that African researchers have contributed to open data access during an outbreak.

Since 2014, ACEGID has been running genomics training programs to increase research capacity throughout Africa and beyond. In a 2016 article in *Cell*, Yozwiak et al. argued that in the wake of Ebola, more researchers needed to build deeper roots in low-income countries to enable faster, better, and more accurate responses during infectious disease outbreaks. ACEGID was able to respond swiftly and effectively to diagnose and sequence samples because they already had established these "deep roots" with international collaborating institutions. Through ACEGID and beyond, more scientific "roots" in LMICs, and not "parachutes" landing in times of crisis, must be developed (see Figure 2.1).

DISCUSSION

Domain 2 of the monitoring framework revolves around three main categories, each of which aligns with the three goals of this domain noted above. The categories are as follows: 2A: Rapid sharing of epidemiological, clinical, and genomic data; 2B: National engagement in research, capacity strengthening and international collaborations; and 2C: Innovation in and access to medical countermeasures (vaccines, diagnostics, therapeutics and other health technologies).

The workshop discussion and subsequent written comments led to a number of changes in the monitoring framework for Domain 2. The research team has added new indicator categories, revised the wording of certain indicators, removed a few indicators, and in some cases shifted indicators to different sections within this domain. In a few cases, the suggestions could not be accommodated for a range of reasons (most often limitations on available resources for the monitoring or duplication with other sections). The modified qualitative and quantitative indicators are presented in the tables and discussion below. They encompass suggestions made by participant experts at the April 2017 workshop, written comments submitted following the meeting (by participants and other experts), and additional research conducted by the research team. The rationale for the indicators follows each table.

CATEGORY 2A. RAPID SHARING OF EPIDEMIOLOGICAL, CLINICAL, AND GENOMIC DATA

The central theme of this category is to monitor progress in data and sample sharing in order to advance science in medical countermeasures and patient access. Table 2.2 presents a set of qualitative and quantitative indicators proposed to monitor progress in this area. One reason why the sharing of samples and data has been inconsistent and delayed to date is that those who possess critical inputs (such as specimens, sequence data, or other clinical information) typically (and reasonably) seek something in return (i.e. publications, intellectual property rights, financial compensation, or other). This access component, which is often needed to ensure sharing, will be tracked in Categories 2B and 2C. The global need for access to information and samples must be balanced with country-specific desires for benefits. This balance of needs lies at the crux of both the PIP Framework and the Nagoya Protocol.

Global standards for sample sharing. Participants at the April 2017 workshop noted that while there has been significant progress in the sharing of genetic sequencing data, the same has not been true for sharing patient samples, such as serum, plasma or semen (i.e. to examine immunological or clinical biomarkers). More work needs to be done to address country-level barriers to sharing, for example, rights to samples. One participant suggested the possibility of creating an indicator to track the number of countries that do not share samples in a timely manner, making sure to define "timely." Others noted that there are important lessons to be learned from outbreaks other than Ebola, such as the recent outbreaks of Rift Valley fever, yellow fever, Zika, and multiple types of avian influenza. Indicators assessing outbreaks must also be able to measure the extent to which sharing occurs in addition to whether a platform for sharing exists. It was also suggested that an indicator is needed to assess sharing of animal samples because there are similar barriers to sharing reports of emerging animal diseases and large potential consequences for trade.

Because sample sharing directly relates to PIP and because there is overlap between the sharing of genetic information (Nagoya Protocol) and the sharing of patient samples, both are included in Category 2A. Increasing access to both patient samples and genetic sequencing data assist in R&D for vaccines, therapeutics, and diagnostics at the outset of a disease outbreak. The indicators for the establishment of global standards in sample sharing, are organized around the need for PIP-like sharing mechanisms for diseases other than influenza, the need

to track the speed of sharing by country governments, and progress made by the WHO in implementing tools and resources for countries to use material transfer agreements (MTAs) when sharing samples other than influenza viral isolates.

Table 2.2. Indicators for Category 2A: Rapid sharing of epidemiological, clinical, and genomic data.			
Name	Definition		
1. Global standards for sample sharing	 (i) Establishment of a WHO-led global system for sample sharing (similar to the PIP already agreed for influenza) for all diseases of pandemic potential as defined by the WHO outside of influenza. (ii) # of national governments who rapidly share samples and other disease-related data at the onset of an outbreak (include time measure). If sharing is delayed, investigate and report on reasons for delay. 		
	(iii) Track progress by WHO in implementing material transfer agreement (MTA) tools and sample sharing country assistance.		
2. Open data platforms	 (i) NUMERATOR: All diseases identified as high risk on the WHO Blueprint that have an open data sharing platform. DENOMINATOR: All diseases identified as high risk on the WHO Blueprint. (ii) # of platforms for open data sharing on additional pathogens and platforms that are non-pathogen specific (include virtual biobanks). (iii) Assessment of the quality and effectiveness of theses platforms for companies, researchers and national governments for R&D purposes and identification of gaps/ weaknesses. 		
3. Public domain research	 (i) Track advancements in candidate vaccines and other products developed using public domain data. (ii) Track advancements in the use of big data (including Google search term analyses) to accurately detect disease outbreaks and estimate EID prevalence rates (focus on R&D blueprint diseases and influenza). (iii) Track and public on other advancements in the field related to pen data sharing for epidemic preparedness. 		

Open data sharing and public domain research. The purpose of tracking progress and gaps in this area is to foster a culture of open data sharing to support preparedness for early and effective responses to disease outbreaks and for control of epidemics and pandemics (to contain their spread, mitigate their impact on public health, and reduce social and economic costs). Publicly shared information can be used to develop candidate vaccines, diagnostic tests, and other products, as well as broaden information access on emerging epidemics across the globe. Transnational research collaborations are also made easier through open access platforms. One comment at the workshop highlighted the need for accountability and incentives for action to be built into these indicators. While no one party is responsible for creating more and better open access platforms, continually monitoring progress in this area can help to create a more transparent data-sharing enviornment. A comment on public domain research suggested the need to coordinate with journal editors and other organizations to achieve open and immediate access to data. This is a topic which top-ranking medical journals are discussing as they try to identify mechanisms to incentivize sharing. It was noted that the Council of Medical Journal Editors recently declared that the rapid sharing of data during public health emergencies would not impede later research publication. There are also new journals, such as PLOS Currents: Outbreaks, that have agreed to peer review and publish relevant articles within days of submission during an emergency. While much progress has been made with respect to open data sharing through the establishment of online platforms for gene sequencing data sharing and other information regarding

samples, more needs to be done. The number, type and quality of open data sharing platforms will be tracked through the proposed set of indicators in Category 2A.

Biobanks. A biobank, a large collection of biological or medical data and tissue samples stored for research purposes, offers one solution to sharing clinical or other data across countries for epidemic and pandemic preparedness. One participant at the meeting noted that many experts in the field have voiced frustration about the lack of donor interest in supporting biobanks. Some of this lack of interest may be due to legal, administrative, and intellectual property concerns. One way to address this concern is through "virtual" biobanks in which actual samples are not stored but rather the genetic and other information contained in these samples are made available online or through other means. The emergence of relevant biobanks will be tracked under this category.

One Health. The importance of One Health approaches is a cross-cutting theme for this monitoring category. Since zoonotic diseases comprise 75% of new infectious diseases in human populations, and AMR spread in animals affects AMR spread in humans (and vice versa), it was suggested that viral and other sample data from animal populations also be monitored. HIV, influenza (including pandemic H1N1, H5N1, and H7N9 viruses), SARS, MERS-CoV, Ebola, Marburg virus, and Nipah virus are all zoonoses. Evidence suggests that the West African Ebola outbreak can be traced to increasing deforestation in Guinea (~more than 80%), which has brought wild animals (bats in particular) into closer contact with humans. The first reported case of Ebola was a child who had been playing within a bat-infested hollow tree in his back yard (World Health Organization 2015a). Surveillance of diseases among wild animals (including serum samples) can aid in human health R&D efforts. The OIE-WAHIS database has been added as a tracking tool for new information and data on animal diseases of pandemic potential and concern.

The <u>WAHIS Database Interface</u>, established by the OIE, is a good example of an open-access platform with zoonotic disease information. This data source includes follow-up reports and submissions of periodic information on 116 diseases. It was noted at the meeting that prioritization could focus on diseases with pandemic potential, rather than on all 116. Too often, it is difficult to obtain samples from animals and export them because such samples fall under the domain of the ministries of agriculture, trade, or commerce, all of whom may have differing priorities and policies. These ministries may also consider animal disease information as potentially threatening to trade, and not wish to share it publicly. There may also be insufficient funds to ship samples, as veterinary public health departments in virtually all LMICs are chronically underfunded. Including such an indicator in the monitoring framework could help increase awareness around the importance of zoonotic diseases and their interconnectedness with human public health.

CATEGORY 2B. NATIONAL ENGAGEMENT IN RESEARCH AND CAPACITY STRENGTHENING

Capacity building within and outside of national research institutions in LMICs as well as transnational collaborations is an important focus for Domain 2. While Domain 1 proposes to monitor progress in national capacity as defined through the JEE and PVS assessments and the IHR, Domain 2 focuses on national capacities specifically related to research and development for epidemic and pandemic preparedness. For many LMICs, the role of the public sector in R&D is crucial, if a country is to have any R&D at all, since private R&D spending is often limited. In addition, as noted by Dr. Christian Happi, African countries need to play a leading role in research, including disease diagnostics, in order to ensure faster and more efficient detection of infectious disease outbreaks. Through partnerships with major universities, such as in the field of genomics, this kind of capacity strengthening is possible. The table below reflects a set of indicators to monitor progress in research training opportunities,

regional and international research collaborations, and post-training research opportunities in LMICs with respect to epidemic and pandemic preparedness R&D.

Table 2.3. Indicators for Category 2B: National engagement in research and capacity strengthening.		
Name	Definition	
1. National engagement	 (i) National investment in epidemic and pandemic preparedness R&D as a % of total R&D budget (tracked over time to show progress and comparisons across countries). (ii) National policies on outbreak preparedness R&D. 	
2. R&D and applied epidemiology workforce development	 (i) NUMERATOR: All countries with composite score of 4 or 5 on the workforce development sub-section of the JEE. DENOMINATOR: All countries that have successfully undergone a JEE assessment and disclosed the findings. (i) Case studies on effectiveness of capacity building efforts (coverage as in (i), workforce skills for disease prevention and control, which is broader than narrow R&D). (ii) Capacity building efforts outside of the JEE that focus on R&D initiatives, including social and behavioral research. 	
3. Research training	# of LMICs with established training pathways for animal and human health research professionals in pandemic preparedness research:	
	 Animal and human health disease surveillance Laboratory diagnostics Research on EIDs (of pandemic potential/ disease dynamics Health security and national preparedness Social and behavioral research on epidemic and pandemic preparedness and response (knowledge, attitudes, behaviors, and practices) Note: For this area, build on existing research from ongoing capacity building programs worldwide. Original research is not recommended due to high acquisition costs. Examine low- and middle-income countries separately if possible. 	
4. Institutions, politics, and practices that foster health security research	Case studies of countries with growing research and professional opportunities (and how they did this successfully). Other indicators to be considered over time that are feasible and useful.	

National engagement. There are two proposed indicators to track progress in national engagement in R&D. These are meant to monitor national government policies and spending on R&D related to EIDs of international concern. The first is to measure the percentage of national R&D funding that is directed toward epidemic and pandemic preparedness. Though this may be difficult to assess, it would be useful to track over time and compare across countries to ensure that investments are being made, and that countries are being held accountable for building local capacities in R&D. In addition, national policies on disease outbreak R&D will be tracked. In relation to national investments, these policies can help to ensure that funds are properly distributed and that scientists are supported through training and employment opportunities. It could prove challenging to quantitatively monitor professional and scientific research in government-funded institutions globally because countries may be unwilling or unable to share that information, and it is currently not publicly available. Another area of research that is currently limited, but that has significant implications during an outbreak, concerns the social and behavioral dimensions of a disease outbreak in a given setting. Had there been a better understanding of burial practices,

eating habits, and social beliefs (around contagion) during the West African Ebola outbreak for example, the initial response would have been more effective. The global community will benefit from a deeper understanding of social, cultural, and behavioral dimensions of disease outbreaks (across countries). The more that national governments can support and engage in such research, the more useful it will be. Until R&D efforts become easier to track, the monitoring framework will include initially a few case studies on national R&D programs, including those that use One Health and other cross-disciplinary approaches to advance knowledge and technology for pandemic risk reduction.

R&D workforce development. In this section, indicators were added to more accurately track the development of a workforce dedicated to R&D. Workforce development includes capacity strengthening in the areas outlined in the JEE as well as research and development in the area of genomics and pathogen diagnostics. Efforts to build capacity following JEE assessments have not yet begun. Countries are still undergoing JEE and PVS assessments or developing national action plans on the basis of these assessments. However, some governments, such as those of the U.S., UK, and Australia, are actively engaged in capacity strengthening to improve R&D efforts worldwide. In addition, there is a relatively new initiative in Africa (started by the African Academy of Sciences and the New Partnership for Africa's Development Agency) called the Alliance for Accelerating Excellence in Science in Africa. This initiative aims to help drive Africa's research agenda across the continent and was initially funded with \$5.5 million from the Bill & Melinda Gates Foundation, the Wellcome Trust, and the UK Department for International Development (USAID), and the Australian Department of Foreign Affairs and Trade, are engaged in animal and human health (One Health) workforce development across Africa, Asia, and the Pacific. Rather than create new indicators in this section, the research team proposes using the existing body of knowledge generated by several international efforts to assess progress and gaps, as they relate to Domain 2.

Research training. Participants recommended greater refinement of the indicators in this category to clarify the specific research areas to be covered and priority regions of the world to track. If related indicators exist from other government funded programs, such as USAID's "One Health Workforce," those indicators should be used to inform this section. Participants at the workshop commented on the already high reporting burdens for many government-funded projects related to training and capacity building. Therefore, this monitoring mechanism should rely on existing, publicly available data wherever possible. It was also noted that there is a significant difference between low- and middle-income countries in terms of research capacity. It may be more informative therefore to distinguish between these two groups for the purpose of monitoring and reporting. One participant also noted that progress in this area may be difficult to track, which is another reason why assembling existing data to create a global understanding of research training in health security is recommended.

Health security research ecosystem. During the April 2017 workshop, participants suggested that in addition to creating more graduate-level training opportunities in infectious diseases and epidemic preparedness, more jobs and career opportunities need to be created to prevent employment emigration. Establishing R&D infrastructure with post-training employment opportunities could have a greater impact on the long-term development of animal and human health professional workforces within LMICs. Otherwise, newly trained professionals will seek work in other countries. It was also mentioned that while most of the indicators in this section focus on research capacity and infrastructure for dealing with potential pandemics, it might be useful to assess national research capacity for routine diseases. Such an indicator could encourage nations to develop their capacities during times of non-crisis, and, arguably, this infrastructure could be used during an outbreak. Similarly, a recommendation was made to measure the involvement of the local research community in determining what projects receive international funding. Due to the high cost of data acquisition, the research team proposes case studies and qualitative research

on post-training opportunities for researchers at this time. Over the long term, the research team recommends adding to this section as more easily accessible quantitative data become available.

CATEGORY 2C. INNOVATION IN AND ACCESS TO MEDICAL COUNTERMEASURES

Developing safe, effective vaccines, diagnostics, and therapeutics (also referred to as medical countermeasures), are critical components of epidemic and pandemic preparedness. Private companies, universities, and publicprivate partnerships such as CEPI, have all contributed to scientific, technological, and administrative advancements in R&D over the last several years. The WHO's R&D Blueprint has likewise made meaningful progress in R&D standard setting and coordination through its target product profiles, disease prioritization, advisory groups, and R&D roadmaps. Yet, none of these efforts will necessarily ensure successful deployment of medical countermeasures during an emergency, nor will they ensure access to all of those in need. The question of who should receive priority access to medical countermeasures in short supply, such as experimental therapies during the Ebola outbreak, is a difficult question that still needs to be resolved. The following table reflects a set of indicators to monitor progress in the development of appropriate medical countermeasures for WHO priority pathogens, progress in ensuring successful deployment of medical countermeasures during an emergency, and access to medical countermeasures including diagnostics for those in need. In addition to the WHO priority pathogens, progress on a universal flu vaccine will also be tracked. A universal flu vaccine could play a key role in reducing mortality and mitigating impacts from a severe influenza pandemic. Advancements in R&D as well as investments in this vaccine will be monitored and disseminated. Due to the number of indicators proposed for this category, the indicator rationale will focus on highlights from the discussion and recommendations only.

Product pipelines by pathogen (vaccines, diagnostics and therapeutics). With respect to tracking progress in vaccine and therapeutic advancements, it was noted that this indicator needs greater refinement. To properly determine pipelines, one needs to differentiate between preclinical, clinical phases (I, II, and III), and Phase IV (post-market surveillance). Within the pre-clinical phase, timelines can vary greatly, and candidate products may be numerous for a given pathogen, with no clear criteria for preferring one approach over another. The pre-clinical phase for vaccines includes: a) identification (discovery) of relevant antigens; b) creation of the vaccine concept; c) evaluation of vaccine efficacy through the use of in vitro and in vivo approaches; and d) manufacturing of the vaccine in line with Good Manufacturing Practice.²⁴ Due to the number of candidates and their varying stages of development, it would be useful to break this indicator down accordingly.

R&D costs. It was also noted that there is tremendous variability in the implementation cost of vaccines and therapeutics. Tracking financial estimates and commitments by pathogen will show where gaps exist and aid in prioritizing funding accordingly. A related proposal was to establish a platform to coalesce product pipeline information from funders across the public, private, and philanthropic sectors to help guide and coordinate investments. While investment in pandemic preparedness as a percent of total R&D budget is proposed as an indicator for Category 2B, the tracking of financial commitments in this category could be disaggregated by pathogen and phase of clinical development to provide a more detailed analysis.

Given the breadth and depth of medical countermeasure products in the pipeline, differentiating between the type of product (vaccine, diagnostic, therapeutic, or other technology), pathogen, and stage of development is recommended. Originally represented as a single indicator, this indicator grouping will now separately track progress in vaccine, therapeutic, diagnostic, and other health technologies separated by pathogen and phase of development. Using the Ebola vaccine R&D as an example of how monitoring in this area might look: as of 2016, there were seven candidates in the pipeline at various stages of clinical testing (Wellcome Trust-CIDRAP Ebola Vaccine Team B 2017). By disaggregating by product and phase of development, one can more easily track

and other nealth technologies).		
Name	Definition	
1A. Vaccines	# of the WHO R&D Blueprint priority disease candidate vaccines and also universal influenza vaccine candidates in the pipeline by phase of development: pre-clinical, Phase I, Phase II and Phase III, Phase IV, and licensed product (separate out by pathogen). Include cost information if available to assist funding prioritization.	
1B. Diagnostics	# of new and improvements to existing diagnostic technologies and tools available to increase the speed and accuracy of pathogen detection among WHO priority diseases (could also include platform diagnostics).	
1C. Therapeutics	# of candidate therapies among WHO R&D Blueprint priority diseases (including influenza) in the pipeline by phase of development: pre-clinical trials, Phase I, phase II and Phase III status (separate out by pathogen as appropriate).	
1D. Other health technologies	# of new technological advancements that enable faster disease detection, improved vaccine or therapeutic development or all the above.	
2. Clinical trials	 (i) Standards set by WHO for clinical trial designs in emergencies (i.e. ring vaccination²³ cluster-randomized with delayed arm among others) with consideration of ethics, safety and efficacy (especially when epidemics are declining). Focus on WHO list of priority diseases. (ii) Harmonization of clinical trial requirements across regions and worldwide prior to a PHEIC for R&D Blueprint priority diseases. (iii) # and type of regional coordinating bodies for NRAs. Focus on WHO priority diseases. (iv) # of clinical trial protocols reviewed by regional coordinating bodies on behalf of members. 	
3. R&D costs	 (i) Track investments in R&D: where it is going; where the gaps are (ongoing pipeline). (ii) Formation of a platform bringing together public-private entities to meet the needs of R&D. (iii) Track Pandemic Product Development Committee (PPDC) in prioritizing/mobilizing R&D funds. 	
4. Key regulatory approvals	 (i) Progress in executing the WHO's EUAL (Emergency Use and Assessment Listing) and pre- qualification (PQ) status for vaccines, diagnostics and therapeutics for high burden diseases in emergency settings. (ii) Harmonization of common technical document requirements across NRAs. (iii) Harmonization of NRA requirements for product registration and post-market surveillance by region and candidate product for priority diseases. (iv) Case studies on candidate vaccine regulatory approval processes and challenges. 	
5. Global manufacturing capacity	 (i) Volume of manufacturing for vaccines and therapeutics by product type for WHO priority diseases according to the R&D Blueprint for WHO priority diseases. Manufacturing will vary by type of vaccine and therapeutic and therefore should be measured accordingly. Establish a baseline and then track over time. (ii) Manufacturing timelines of candidate vaccines and therapeutics by pathogen and product where this information is available. Identify gaps. 	
6. Stockpiles	 (i) Gavi Alliance, UNICEF, and manufacture stockpiling plans for WHO priority diseases including influenza (international, regional and national). Note this information may be difficult to obtain. (ii) Number and quantity of stockpiles established for WHO Priority diseases by country and institution of purchase; determine how many are advanced market purchased by organization such as Gavi Alliance. Again, me be difficult to obtain. (iii) Disease modeling projections to assessment quantity of stockpile needed 	
7. Vaccine and therapeutic deployment strategies	Establishment of global strategy (i.e. WHO endorsed) for vaccine deployment in emergencies (by disease). Each disease will differ.	
8. Access	Percentage of target population(s) that has access to developed products (vaccines, therapeutics) by product and disease as monitored through international agreements and product deployment plans. Note: Data collection in this area may be difficult if the information is not made publicly available. It may also not be determined in advance; however, to the extent possible, global monitoring of access is encouraged.	
9. Public-private sector collaborations to remove R&D roadblocks	 # and type of public-private-academic collaborations between companies, international organizations (e.g. WEF and WHO) and academic institutions that tackle specific R&D roadblocks such as liability and indemnification, vaccine trials in emergency settings/bioethics, stockpiling strategies, global compensation schemes for adverse events (vaccines and therapeutics), bio-banking, etc. Assess the effectiveness of these collaborations in resolving the roadblocks. 	

Table 2.4. Indicators for Category 2C: Innovation in and access to medical countermeasures (vaccines, diagnostics, therapeutics and other health technologies).

progress and identify gaps. Additionally, it was suggested by participants to add an indicator to monitor financial commitments to help guide investments in R&D more strategically. Though this may be difficult to assess, greater transparency around R&D financial commitments juxtaposed against funding needs could help guide investments more strategically.

Clinical trials. To address the range of comments regarding the need for streamlining regulatory pathways, three indicators have been proposed. The first is to track transnational collaborations in clinical trial design and implementation. The second is to track progress in clinical trial design for emergency settings (a key issue that arose during the Ebola vaccine trials). The last of these indicators assesses national institutional review boards (IRBs) or national regulatory authority (NRA) participation in regional networks worldwide in order to monitor progress in harmonizing regulations for manufacturers in an emergency. If a regional coordinating body exists – such as the African Vaccine Regulatory Forum, which is a regulatory network founded by the WHO in 2006 that promotes communication and collaboration between African NRAs and ethics committees – this entity will be monitored. These kinds of coordinating bodies will be monitored through tracking the number of clinical trial protocols reviewed on behalf of members and the number of new protocols established, based on registrations on clinicaltrials.gov (U.S.) and EudraCT (EU).

It was also noted that clinical trial capacity could be tracked all the way through phases II and III (and not just phase I). An indicator to assess the use of IRBs – or rather, NRAs – that collaborate with other NRAs outside of the country could be established to ensure harmonization on a number of levels. An indicator to assess the number and type of regional coordinating bodies for NRAs has been added.

Regulatory streamlining. There were previously no specific indicators on regulatory approvals during emergency settings within the monitoring framework. While harmonization of clinical trial requirements overlaps with this section on regulatory approvals, there are a few differences. One is with respect to the WHO's EUAL. In addition, there is a need to harmonize post-market surveillance and product registry requirements. If companies must adhere to differing requirements by country, it could be prohibitively costly and time-consuming.

Still a work in progress, the EUAL could prove useful before and during future outbreaks of Ebola, as well as other disease outbreaks in which a candidate vaccine or therapeutic is in the pipeline. NRAs ideally should be harmonized with the EUAL and with one another, to the extent possible. If not, manufacturers will be burdened with multiple sets of regulations simultaneously, and delays will be unavoidable. In October 2016, the WHO Expert Committee on Biological Standardization released draft guidelines for NRAs and vaccine manufacturers on quality control and clinical evaluation of the safety and efficacy of Ebola vaccines for licensure. This kind of standardization will be needed for all priority disease vaccines and therapeutics. Using the Ebola vaccine as an example, to save time during a future outbreak, some countries could choose to accept WHO EUAL status or WHO prequalification (PQ) instead of in-country registration; however, WHO PQ standards require vaccine storage at -20°C which may be unfeasible for some vaccines. The rVSV-ZEBOV Ebola vaccine, for example, requires storage at -80°C. This is the kind of discrepancy that will need to be addressed for each medical countermeasure before WHO PQ and EUAL can become appropriate global regulatory mechanisms for products intended for use in public health emergencies.

Progress on the WHO's EUAL and PQ status will be monitored as part of the framework. In addition, regulatory requirements for vaccine candidates that are already in the pipeline (like Ebola and Zika) will be monitored to ensure progress is made with respect to regulatory approval processes. In addition, another proposed metric will track harmonization of Common Technical Document requirements across NRAs. It has been proposed to monitor progress on the establishment of global regulatory standards for other priority diseases.

Manufacturing capacity. A new category has been added in response to comments on the need to measure progress in vaccine and therapeutic manufacturing capacity worldwide. However, it was also noted that this can be challenging to measure. Manufacturing capacity varies by type of vaccine and therapeutic. One participant suggested measuring manufacturing capacity by existing vaccines (i.e. for Nipah virus) and creating a baseline from which to monitor over time. For many of the WHO priority diseases, current manufacturing capacity is non-existent, and this information needs to be made public. Given an anticipated surge in demand during a pandemic, manufacturing capacity will need to respond quickly. Identifying the specific gaps by pathogen and vaccine type will be useful for allocating necessary resources in advance.

Stockpiles. It was noted that stockpiling measures may be difficult to track, but could be useful for modeling and planning purposes. For example, to assist in overcoming financial barriers associated with vaccine development, the Gavi Alliance committed to purchasing 300,000 Ebola vaccine doses from Merck to stockpile. While this type of advance purchase is not sufficient to create meaningful incentives for pharmaceutical companies, it can at times, spur modest production when demand is not yet established. Participants at the Global Ebola Vaccine Implementation Team (GEVIT) Regional Workshop (convened in October 2015 by the WHO) discussed the possibility of using an International Coordinating Group (ICG) to manage Ebola vaccine stockpiles. The WHO, Médecins sans Frontières, the International Federation of Red Cross and Red Crescent Societies, and the United Nations International Children's Emergency Fund (UNICEF) all currently manage stockpiles for yellow fever, cholera, meningitis, and smallpox vaccines. The OIE has successfully developed and managed a "virtual vaccine bank" for emergency use in the control of livestock diseases; OIE also intermediates donations of rabies vaccines to developing countries, for vaccination of dogs as part of a campaign to reduce the high number of deaths from this preventable disease. Managing stockpiles for diseases with frequent outbreaks (like cholera and yellow fever) presents different challenges than those with more unpredictable and less frequent surges (like MERS-CoV and Nipah virus). How best to establish "just in case" stockpiles for less frequent outbreaks remains a challenge. As such, additional discussion is needed to determine how an ICG-like model could be used for managing vaccines for Ebola, Nipah virus, MERS-CoV or other diseases of epidemic or pandemic potential. Similarly, more modeling is needed to understand effective threshold quantities of a vaccine to stockpile. GEVIT plans to pursue research and modeling efforts to estimate future vaccine demands for Ebola specifically, and it may be beneficial to track progress on this work.

At the time of the April 2017 workshop, this category was not fully developed. Based on comments from the meeting and additional research, three indicators are proposed. These include: tracking progress on national and international stockpiling plans; monitoring stockpiles and advance market purchases (such as the purchase of 300K Ebola vaccine doses by Gavi Alliance from Merck); and disease modeling efforts to more accurately assess how much of a given product needs to be stockpiled.

Access. Another important measure for this category pertains to access to medical countermeasures (vaccines, therapeutics) during PHEICs. While it is crucial that new candidate vaccines and therapeutics be developed for priority diseases, it is equally important to ensure that the most vulnerable populations gain access. Access can be partially monitored through the development of frameworks like PIP and the Nagoya Protocol for WHO priority diseases (see Category 2A), however, there is also the broader question of how to prioritize distribution for therapeutics and vaccines during a PHEIC. It may be difficult to gather data on prioritization, but modeling exercises among international constituents can help to examine issues of equity and access.

R&D public-private sector collaborations. Developing effective vaccines, diagnostics and therapeutics are critical for epidemic and pandemic preparedness; however, ensuring that these products meet legal, administrative, and regulatory requirements in countries around the world, and that they can be successfully deployed during an

emergency, presents a different set of challenges. Overcoming these administrative, political, and legal barriers will require collaborations between the private and public sectors. In order to track progress in this area, the research team has proposed an initial indicator, which can be refined and/or expanded over time. The number and type of public-private-academic collaborations between companies, government research institutes, international organizations (e.g. OIE and WHO), civil society organizations (e.g. World Economic Forum (WEF)), and academic institutions (e.g. universities) that tackle specific R&D roadblocks will be monitored. These partnerships are likely to tackle multiple issues, including: liability and indemnification, vaccine trial design in emergency settings, stockpiling strategies, global compensation schemes for adverse events (vaccines and therapeutics), and biobanking of clinical samples. The success of these collaborations in resolving the above mentioned issues will also be assessed.

²¹ WHO criteria used for selection include: 1) human transmissibility (including population immunity, behavioral factors, etc.); 2) severity or case fatality rate; 3) spillover potential; 4) evolutionary potential; 5) available countermeasures; 6) difficulty of detection or control; 7) public health context of the affected area(s); 8) potential scope of outbreak (risk of international spread); and 9) potential societal impacts.

²² The anticipation that market forces would drive supply for Zika has not been realized as of yet. As the epidemic wanes, demand has slowed, and some companies are moving out of R&D.

²³ The vaccination of all susceptible individuals in a prescribed area around an outbreak of an infectious disease. Ring vaccination controls an outbreak by vaccinating and monitoring a ring of people around each infected individual. The idea is to form a buffer of immune individuals to prevent the spread of the disease.

²⁴ Good Manufacturing Practice is a system for ensuring that products are consistently produced and controlled according to quality standards. It is designed to minimize the risks involved in any pharmaceutical production that cannot be eliminated through testing the final product. (International Society for Pharmaceutical Engineering 2017)



DOMAIN 3: REINFORCING RISK ANALYSIS AND INCENTIVES FOR ACTION

3

Despite the proven potential for infectious disease outbreaks to cause extensive health and economic damage and disruption of daily life, the risks of infectious disease crises often remain opaque to decision makers outside of public health. Improving the awareness of pandemic and other health security risks among policymakers, the private sector, and society at large would be an indispensable first step toward better risk management.²⁵

The indicators in Domain 3 will track analytical work to assess risks from epidemics and pandemics in an authoritative way and use this work to improve risk management in countries and globally. The expectation is that existence of such analyses and communications of the results will incentivize investments in pandemic prevention and response. The indicators are grouped as follows:

3A: Country-level risk analysis and incentives for action; and

3B: Global risk assessment and incentives for action.

Clear communication of robust analyses of hazards and their expected consequences can motivate action to improve health security in communities, countries, and globally. Adequate visibility of infectious disease risks through transparent and reputable assessments can create incentives for action because political and economic actors can respond to risks that affect their interests. If governments understood the risk their countries face and how their preparedness efforts compare to their peers, they may invest in prevention and response capabilities. If civil society organizations had reliable information on the level of preparedness of their governments, they could more effectively hold their governments accountable. And if financial markets and firms could readily appraise the economic vulnerability associated with investing in a given region or industry, they could provide economic incentives for governments to improve national health security. In sum, risk awareness is the necessary first step toward good risk management.

Global public institutions with mandates to promote economic development and stability have communicated on pandemic risk sporadically, and long periods of complete silence about this global risk have been the norm. They have also neglected to mention in their country policy dialogue the risk of infectious disease outbreaks that can substantially damage public health and economies in multiple countries and regions. Unfortunately, this occurred between 2010 and the Ebola "wake-up call" in 2014. When the leading global financial institutions ignore epidemic and pandemic risks in their core programs of policy advice to countries, the entire membership of these institutions is ill-served. All countries need to be prepared to respond to a pandemic (by definition), and most countries have a vital interest in being prepared for epidemics, both for the sake of their own populations and for that of other countries (in the region and beyond).

OPENING PRESENTATIONS

The presentations illustrated how various components of pandemic risk can be analyzed and how the results of the analyses can be used to inform public policy and encourage public and private sector engagement in prevention of epidemics and in pandemic preparedness. They also reflected on the evolving nature of pandemic risk and how recent and ongoing work helps advance thinking about assessment of such risk. Presentations covered ongoing work to develop a robust measure of global health security, map disease hotspots, and communicate to policy-makers about the high economic and health benefits from early control of contagion. Some gaps in understanding of pandemic risk could only be filled by public authorities in a position to generate credible international risk assessments.

A ROBUST MEASURE OF GLOBAL HEALTH SECURITY

Tom Inglesby, the CEO and Director of the Center for Health Security at Johns Hopkins University presented the Center's work in developing a robust measure of global health security.

Indices have the capacity to inform the public and motivate progress by governments. By measuring and publicizing performance, indices can place domestic and international pressure on governments from political and economic actors (e.g., advocacy groups, capital market participants, investors, and firms). In other policy areas, indices such as the World Bank's 'Doing Business Index' have had positive effects by creating reputation-oriented incentives for better policy making. A similar approach may be helpful in global health security.

The NTI, the Johns Hopkins Center for Health Security, and the EIU, with support from the Open Philanthropy Project and the Robertson Foundation, have launched a pilot project toward the creation of a global health security index (GHS Index). The purpose of the global health security index is to create a country-level assessment, drawing on publicly available information, which can be applied to all countries and independently measured through a non-governmental process. A GHS Index would seek to motivate regular commitments, financing and accountability, influence government decision-making on a regular basis, and – ultimately – help break the cycle of panic and neglect associated with national pandemic preparedness. A GHS Index would complement, and not compete with, the JEE and PVS voluntary evaluations – drawing from those assessments where available but also assessing countries that have not performed either voluntary process.

In consultation with an international panel of experts, the GHS Index project team has now pilot-tested a comprehensive framework of national indicators in four countries. The indicators pertain to health security and related capabilities and were developed using publicly available data that can be applied to all countries. The components of the GHS Index assess countries' technical, financial, and political capabilities to prevent, detect, and respond to epidemics with international implications. The methodology for developing the GHS Index draws on

similar recent work, including the NTI Nuclear Security Index, which is an assessment of global nuclear security conditions in its fourth edition, and the National Health Security Preparedness Index, which measures U.S. states' progress in preparing for, preventing, and responding to potential health incidents and is now in its fourth iteration. The project team is now expanding the GHS Index to additional countries, with plans for the GHS Index to be available for 194 countries within 12-18 months, followed by regular updating.

The GHS Index will rely on publicly available data and will factor in JEE indicators to ensure a measure of consistency and credit for those countries that have conducted and published a JEE. It will also include non-JEE measures to factor in country commitments to transparency, political will, adherence to international norms, financing and accountability for pandemic preparedness, and broader measures associated with the country's healthcare system.

MAPPING PANDEMIC RISK

Peter Daszak, the President of the EcoHealth Alliance, discussed the methods used in disease hotspot mapping and how addressing the drivers of contagious pathogens is a cost-effective approach to preventing major epidemics.

Mapping disease hotspots. Biogeography can inform our understanding of infectious disease hazards. A team of researchers in 2008 created a database of some 600 emerging disease events and mapped them (Figure 3.1). After correcting the data for reporting bias, the team found that the number of events has been increasing in the second half of the twentieth century. Each year on average there were approximately five new emerging infectious diseases, including 2.6 new zoonotic diseases (Jones et al. 2008). Moreover, the rate of increase in the number of such diseases originating in wildlife was larger than for all emerging infectious diseases. Further, zoonotic spillover events (when an animal disease "spills over" into human populations) are not only costly, but the cost would increase exponentially in the next 50 years, with a conservative estimate of cumulative costs of \$3.5 trillion. Small outbreaks would account for 40 percent of those costs. The exponential rise of costs in the future suggested a very



Figure 3.1. Mapping emerging infectious disease (EID) events since 1945. Source: Daszak, Slide 4 & (Jones et al. 2008).

high return to early action, with a 20-year window when the world must act if the later, dramatic cost increases are to be averted (Pike et al., 2014).

Hotspot maps and related spatial analysis could assist in the distribution of resources for monitoring, prevention, and response by allocating resources to areas where diseases are more likely to originate. Geospatial analysis can also suggest where further studies are warranted of the factors behind a high outbreak propensity and vulnerability to outbreaks that are not quickly controlled. For example, human population densities and mobility show significant correlation with disease outbreak emergencies, as do mammalian species diversity and land use changes.

High returns from early control of contagion. From an economic perspective, addressing underlying drivers of contagion is a highly cost-effective approach to preventing pandemics. Investing in core public health capacity for both veterinary and human health has such a substantial payoff that it has been called "the most productive investment on behalf of mankind," (Fan, Jamison, and Summers 2016). Core public health capacity, if it is built and maintained, will detect and control outbreaks early and before they spread at an exponential rate. The cost-effectiveness of such investments is very high: spending just \$300 million a year over 10 years on pathogen discovery and on core public health systems in the most vulnerable countries results in a 5 percent reduction in the expected number of human cases and would save \$96 for every dollar invested. These investments would yield an extraordinarily high rate of economic return.

Improving the productivity of public spending. Evaluating the economic benefits from investments in health security can help remove political barriers to action. Economic arguments resonate with finance ministers who control the allocation of public funds. Equipped with evidence of the economic benefit of effective public health systems, finance ministers will be in a better position to argue for appropriate investment in veterinary and human public health capabilities, especially where such investments benefit agendas beyond health security. For any one country, global health security may be a minor concern that is far overshadowed by the difference public health systems will make to improve the health and livelihoods of the country's own population. Conversely, when the economic rationale for investment is not clear to finance ministries, chronic underfunding of core public health capacities is likely to persist, with protracted harm to population health.

Leveraging capital markets for health security. Infectious disease outbreaks can have substantial effects on the economic stability of a country and its region. Transparent assessments of economic vulnerability to infectious disease crises can thus support the efficient functioning of financial markets and expose the financial risk of lending to governments and companies. An adequate assessment of the contribution of infectious disease vulnerability to macroeconomic stability will allow market participants to incorporate these risks into their investment and lending decisions. This could affect sovereign borrowing rates, providing an additional incentive for finance ministries to make appropriate investments in strengthening health security.

ASSESSING ECONOMIC RISK OF INFECTIOUS DISEASE THREATS

Anas El Turabi, a health policy doctoral candidate at Harvard University, introduced the Domain 3 discussion on what methods are used to assess economic risk of infectious disease threats.

An overlooked economic risk. The very large economic costs of pandemics and outbreaks with pandemic potential are not generally well known among finance ministers. They have also been studied infrequently by macroeconomists. Economists have neglected the economic impacts as well since they mainly analyze healthcare costs and financing rather than broader prevention efforts. Macroeconomists have tended to dismiss pandemic risk as something rare or inconsequential and a problem that health economists should handle. But the economy-wide



Figure 3.2. A simplified model of the economic impacts of infectious disease outbreaks showing roles of changes in consumption (C), investment (I), exports (PE), production (P), and expenditure in the short- (ES) and long-term (EL). *Source*: El Turabi and Saynisch, Slide 5.

relevance of pandemic risk and its origins in the behavioral changes of consumers, producers, and workers places analyses of pandemic risk squarely within their expertise. The relatively small human-health toll of outbreaks is known better than the large economic costs; the public health impact may be small, but it usually dominates reporting on outbreak events. For example, that the 2015 MERS-CoV outbreak in South Korea caused 36 fatalities is well documented but that tourist arrivals declined by a staggering 54 percent over the subsequent two months is not. During the 2003 SARS outbreak in Hong Kong, tourist arrivals plummeted by 68 percent. These impacts on the tourist industry cascaded quickly to generate losses in other sectors. The economic damage from MERS-CoV in South Korea exceeded \$700 million, while the public health impact was vanishingly small. A dramatic economic toll alongside a decidedly modest public health impact was evident in the 2003 SARS outbreak as well: a global economic cost of \$30 to \$54 billion was associated with 8,000 cases, of which fewer than 800 were fatal. Though infectious disease outbreaks are material macroeconomic events, economists neglect them until after an outbreak occurs (Sands et al. 2016).

Bulk of costly impact from social responses, not from the disease. Social responses – reactions to an outbreak by consumers, workers, businesses, and governments – have been observed to drive the majority of the short-term economic impacts of disease outbreaks, as shown in the model of economic impacts of infectious diseases in Figure 3.2. During an outbreak, some firms may delay or rescind investment commitments and some firms may face sharply reduced demand. Tourism, travel, and discretionary spending (like hospitality and entertainment) have typically been most affected. Government policy and communications responses can have mitigating or exacerbating effects on the economic damage caused by an outbreak, particularly if the responses are poorly prepared and raise public anxiety. Uninfected individuals modify their behavior so as to avoid infection by, for

example, choosing to stay away from affected or crowded areas, workplaces, or schools. When workers stay home, their contribution to economic output will decline. Consumption (the demand for goods and services) will decline as well, especially for services like tourism, hospitality, restaurants, hotels, and travel. While some consumption may be deferred, most will be permanently lost from the economy. Consumers of services in sectors like travel and tourism can switch destinations or stay home during the outbreak, but they will not likely increase spending in these sectors after the crisis ends. Sharp drops in demand and a reduction in supply of goods and services that rely on workers' continued presence can cause short-term losses and longer-term effects, as some firms may go out of business (Brahmbhatt and Dutta 2008). Populations may differ markedly in how they respond to the same pathogen; for example, the social response during Saudi Arabia's 2013 MERS-CoV outbreak was far more muted than in South Korea in 2015. Reasons for this are unclear, posing a challenge for calibrating models of economic vulnerability resulting from outbreaks.

Need for credible international risk assessments. Credible technical expertise is essential for any risk assessment mechanism. Since many of the policies and institutions that are being assessed in countries are part of the government, involvement by official international authorities and organizations may be necessary to obtain robust and credible results. WHO's JEE and OIE's PVS, which address performance of core public health preparedness and response capacities, are two examples of credible risk assessments; however, these assessments focus primarily on animal and human public health capacities and, in the case of the JEE, are just getting started. About three quarters of all countries have not yet obtained an assessment through the JEE process (see map in Annex 4). Assessing broader factors that contribute to intrinsic risk, such as economic and financial conditions, governance, national infrastructure, and communications, are also important determinants of risk and need to be factored into analyses. The question of which authority is in the best position to do so accurately and transparently remains to be answered. The IMF and other public multilateral financing institutions with mandates to support economic development could develop tools to assess the vulnerability of different sectors because they have comparative advantage in this domain and because, as lending institutions, they also have an interest in supporting their borrowers' repayment capacity.²⁶ The IMF and the World Bank, along with other multilateral development banks and rating agencies, could then do the integration and produce an economic risk measure. Authoritative leadership by the international financial institutions (with mandates in promoting macroeconomic stability, international trade, and economic development) could build on the ongoing initiatives and undertake the analytical work required for robust economic vulnerability assessments (Figure 3.3).

Other initiatives to measure vulnerability. In 2016, a RAND Corporation report described an infectious disease vulnerability index based on many of the factors discussed above (Moore et al., 2016). Other organizations, such as Metabiota, have developed indices as well, using proprietary methods of blinding different inputs and data sources. Each of these projects has technical limitations due to poor availability of data and complexity of the underlying subject matter. Some of the shortcomings in the RAND Index, for example, were reliance on existing literature with no reference to data from the field; inadequate differentiation of vulnerability to different *types* of infectious diseases (e.g. due to differences in climate); and no consideration of income inequality *within* countries and of the composition of national industries (e.g. the relative contribution of tourism to GDP). It has been challenging to model population behavior responses and how trust in public institutions might affect risk. The vulnerabilities of different economic sectors have not been studied sufficiently. No agencies or professional groups have conducted systematic post-event economic evaluations. The topic appears to have fallen between the cracks: in the health sector, outbreaks are a marginal concern as their public health impact is modest, leading to minimal interest in documenting damage. Development economists may see such analyses as the responsibility of the health sector. Disciplinary divides between public health, the larger health sector, and various groups of economists makes it difficult to bring together all of these different risk analyses.



Figure 3.3. Proposed approach to assessment of economic vulnerability to infectious disease crises. Source: Based on Sands et al. 2006. "Assessment of Economic Vulnerability of Infectious Disease Crises."

DISCUSSION

The next section offers an overview of some of the broad topics related to assessing and communicating about pandemic risk that were discussed during the review of Domain 3 at the April 2017 workshop. The following sections then present the discussion points that relate directly to the indicators in Categories 3A and 3B of the monitoring framework.

CATEGORY 3A. COUNTRY-LEVEL RISK ANALYSIS AND INCENTIVES FOR ACTION

Mainstream economic analyses and, especially, macroeconomic analyses and projections, have so far not included economic vulnerability to infectious disease threats. Category 3A indicators respond to this frequent omission, which evolved in an era before the dramatic growth in international movement of people, livestock, and goods occurred. The omission has contributed to a persistent gross underestimation of infectious disease risk and consequently perpetuated the underinvestment in core public health capacities that has become increasingly evident. The Ebola outbreak is the most recent – and not the last – reminder of the devastating consequences of a reactive approach to infectious disease control. To help countries avoid such policy errors in the future, Category 3A indicators seek to encourage production of (and access to) authoritative evaluations of country vulnerability (Table 3.1). A secondary use (once such evaluations exist for many countries) would be to identify 'systemically important' countries and analyze possible measures to mitigate the risks associated with these countries' dominant role in the global economy and in certain sectors.

Table 3.1. Indicators for Category 3A: Country-level risk analysis and incentives for action.		
Name	Definition	
1A. Intrinsic risk: outbreak and risk	Existence and characteristics of country risk assessments.	
assessment	# of countries with risk assessment < 5 years old.	
	Quality aspects: sub-national/regional, dissemination, and use in-country.	
1B. Intrinsic risk: preparedness assessment	Existence and quality of preparedness assessment (PVS, JEE results).	
	Quality aspects: sub-national/regional, dissemination, and use in-country.	
2A. Economic vulnerability:	Existence and quality of economic vulnerability assessment.	
assessment	How robust? Validation and support from international financial institutions.	
2B. Economic vulnerability: use of assessment	Incorporation/deployment of economic vulnerability assessment into official macroeconomic assessments and planning.	
	Use of assessment, by official partners or by private sector.	
2C. Economic vulnerability: private sector	Engagement with private sector on economic vulnerability within key sectors and/or vulnerability of entire economy.	
3. Social vulnerability ²⁷ and resilience assessment	Existence and use of assessments, for health security or as part of disaster-risk management.	
	Creation of an evidence base that includes data about public knowledge, views and current behaviors in connection to relevant aspects of the public health system, disease outbreak containment, and proposed measures for mitigation (could be used for National Action Plans).	
	Note: methodology of assessments may vary and would be tracked as well, if relevant	
4. Corporate engagement	# of Fortune 100 companies engaged in risk analysis and incentives for action within and outside of their companies.	
Corporal social responsibility (CSR) engagement in risk analysis and incentives	# and type of companies directing CSR resources toward risk analysis and incentives for action.	
	Analysis of the CSK outputs.	

Country-level vulnerability assessments. A severe influenza pandemic or other similarly fast-transmitting contagion will likely have a large macroeconomic impact globally – an impact that has been assessed by the World Bank (2008) and others to amount to trillions of dollars of economic losses. But this prospect has not motivated commensurate action and resource allocation by the international community nor its multilateral organizations. Indeed, to reduce epidemic and pandemic risk, much depends on whether national leaders initiate actions in their own countries, in the interest of both its economy and its population. The international community should provide adequate technical and financial support for such actions, ideally in response to demand from countries. Category 3A indicators propose to track the extent and effectiveness of such assessments for country clients; as noted, such analyses have been rare to date.

Analyses tailored to country characteristics. In most country contexts, the global cost of a flu pandemic of \$6 trillion is not relevant, and, as a rather meaningless number, it will not sway policy decisions. Experts thus recommended that the monitoring framework emphasize progress on country-level analyses of economic and
societal vulnerabilities to outbreaks originating in the country or in neighboring countries as well as impacts of pandemics (when the whole world is affected). How do these risks change the economic growth prospects? What low-cost investments and plans can be made to reduce the risks? What is the country's critical infrastructure? Surprisingly, very few such analyses exist for developing countries, despite the setbacks in economic development that societal disruptions and associated economic shocks would bring.

Large analytical gaps. To date, the World Bank and the IMF have not examined health-related vulnerabilities. Their country-level economic risk-assessments and other macroeconomic analyses have taken note of devastating epidemic impacts, but did so only after outbreaks occurred. Neither the IMF nor the World Bank have helped countries to examine the policies that are required to reduce such highly preventable risks to the economy. The official reports of the IMF's Article IV consultations and country economic reports, which are prepared regularly, thus fail to adequately serve the IMF's and the World Bank's country clients and the international community by omitting a major catastrophic risk that can be significantly reduced by country-level policy actions. The Category 3A indicators will measure growth (or lack of growth) of a body of credible analyses of country-level risks to economies and societies in countries, and will track the use of such analyses.

Country specificities. Economic risk analysis and risk communication strategies should address specific characteristics of the economy. For instance, a collapse in tourist arrivals in the case of an outbreak in the country or in the region is a major vulnerability in many low-income countries dependent on tourism. Frequent air travel to and from a country and prevailing openness to foreign trade are also sources of risk, especially in high-income countries. Awareness of the risk could help increase financing for WHO health security programs and for public health systems in low-income countries. The absolute level of negative impacts would be greatest in high-income countries since their citizens travel the most, integration with global capital and goods markets tends to be high, and their economic losses from a global recession that would accompany a pandemic would be higher due to their higher per capita incomes. Mapping may be a useful tool for communicating this point to governments of richer nations, by disaggregating the risks of being at the epicenter of an outbreak from the risks of experiencing its spillover effects.

Vulnerability in low-income countries, communities, societies. In the face of epidemic threats, the resilience of a country's economy and the wellbeing of its population depend critically on the country's veterinary and human core public health system performance, participation in networks for diagnosis and sample sharing, and whether disaster risk management plans deal with public health emergencies.²⁸ This is relevant, especially, to poor countries with a history of zoonotic outbreaks. In addition, vulnerability assessments can encourage improved performance of public health systems in regions and municipalities. Several experts advised attention to specific sub-national regions and specific sectors, or even specific businesses, because such analyses could motivate the private sector and municipalities to consider ways to mitigate their liabilities. However, non-existent country-level and subnational economic risk analyses are just two of many analytical gaps. There are no indicators of societal risks, but it may be feasible and impactful to analyze such risks at the sub-national and community levels. The monitoring framework will track any emergence of such approaches and report on them. The monitoring framework will not duplicate any existing work on country-level risk such as the GHS Index, where country-level health security is the basic building block. The indicators for Category 3A in the table above are designed to track assessments of vulnerabilities and their use in policymaking, rather than particular outcomes of such analyses in specific countries. The monitoring reports plan to use the GHS Index and other analyses (as they become available) for any discussion of country-level and regional risks.

CATEGORY 3B. GLOBAL RISK ASSESSMENT AND INCENTIVES FOR ACTION

Global risk analyses can help policy-makers redirect scarce resources to areas of greatest need, for example, to build or strengthen veterinary and human public health systems in areas where the intrinsic risk of an infectious disease outbreak is high, but local capacity to respond is low. To date, no global risk assessments have been regularly prepared, despite the high and potentially catastrophic risk from a pandemic of influenza or similarly contagious disease. Table 3.2 lists the indicators in Category 3B: Global risk assessment and incentives for action.

Table 3.2. Indicators for Category 3B: Global risk assessment and incentives for action.		
Name	Definition	
1A. Intrinsic risk: maps and indices	Existence and quality of risk maps/indices: how many exist? How comprehensive and robust are they? Compare and contrast.	
1B. Intrinsic risk: dissemination and use of maps and indices	Analyses, dissemination and use of risk maps/indices. Use in official sector (e.g. incorporation into Sendai framework), use in private sector.	
2A. Preparedness mapping: maps and indices	Existence and quality of preparedness maps/indices: how many exist? How comprehensive and robust are they?	
2B. Preparedness mapping: dissemination and use	Dissemination and use of preparedness maps/indices. Use in official sector, use in private sector.	
Economic vulnerability: assessments by IFIs	Extent of appropriate inclusion of health security in official macroeconomic assessments: how and how often included in reports on IMF Article IV consultations, World Bank's Systematic Country Diagnostic and country economic reports, and similar official reviews of economic prospects and policies in countries, regions, and globally?	

Related analytical work. As noted, the recent RAND Corporation report has an excellent compilation of data on pandemic risk (Moore et al. 2016). Other relevant sources include the <u>Global Assessment Reports on Disaster Risk</u> <u>Reduction</u>, the Index for Risk Management (INFORM) tool for humanitarian crises and disasters, and the <u>Disaster Loss Databases</u>. Several experts recommended that analyses of risks from outbreaks and pandemics should be adequately incorporated into these broader exercises. For instance, global disaster risk reduction work should examine how health emergencies and biological hazards are integrated into national disaster risk prevention and mitigation plans. The monitoring framework will thus track whether this integration is occurring. Global disaster risk analyses may be useful for allocation of assistance by large donors and international organizations and in devising new mechanisms to promote prevention or improve the efficiency of responses.

Select data sources for risk assessments. Due to weak core public health systems, surveillance to generate information on disease risks (including those caused by AMR) is generally poor and, moreover, highly variable among developing countries. Animal disease surveillance barely exists in most developing countries because of the weakness of veterinary public health systems. However, ProMed, a non-governmental initiative, and the largest provider of outbreak information, is an important data source for analyses of disease risk; one commenter cautioned, however, that some ProMed information is edited and geographic coverage is far from universal. Another data source, the Emerging Infectious Disease Repository, mines data from a number of sources, including ProMed, and verifies data accuracy. The OIE-WAHIS has information relevant to economic vulnerability, such as data on animal diseases and emerging events, including those caused by zoonotic organisms. This data source

includes follow-up reports and submissions of periodic information on 116 diseases. The research team included these references and related analytical work in the monitoring framework. Other useful sources of information for risk assessment include the Department of Defense's Global Emerging Infections Surveillance and Response System, and USAID's Emerging Pandemic Threats Program, particularly its PREDICT Project, which focuses on detection and discovery of zoonotic diseases at the wildlife-human interface.

Promoting use of risk measures– **financial sector example.** Rating agencies charge countries for conducting a risk rating; as a result, more than 65 low-income countries have no financial ratings from prominent rating services. For pandemic risk, the situation will be similar, especially if leading international development organizations and governments continue to neglect pandemic risk. Even though the World Bank has shown that it is better for a country to be rated than unrated, when countries receive external financial support to pay for such ratings, many are still reluctant to have their financial sectors analyzed. One option, to overcome such obstacles, could be a centralized global mechanism, which would be owned by countries and supported by relevant multilateral organizations. Still, finding staff to conduct the ratings could be a challenge. Locating this function within an existing multilateral agency (IMF and/or World Bank) with qualified staff in place and synergy with the core functions of the agencies may be the most effective and sustainable option. Participants suggested at least three reasons for IMF and the World Bank to steward the economic analysis of vulnerability of their member countries:

- Perceived political neutrality of the international financial institutions whereas political considerations may from time to time influence the results of economic risk analyses, which could affect sovereign debt ratings, for instance.
- Credibility on macroeconomic and economic development issues whereas private sector or bilateral analyses could undermine the collaborative approach of the JEE process or raise questions about who could credibly conduct such analyses.
- Void may be filled by improvised measures of uncertain validity the private sector may develop its own approaches, which will not be transparent, if the global health community and institutions such as the IMF do not incorporate analyses of major economic risks within their mandate.

International cooperation. Official multilateral institutions have already incorporated other unconventional risk indicators in their assessments although these risks did not impose excessive fiscal imbalances or lead to incorrect monetary policies. Two recent examples are climate change and land use change. What enabled inclusion of these risk measures were political will and accountable leadership. Most low-income countries may have unsustainable fiscal imbalances, but most of the harm is borne by their own economies. The rest of the world is not affected because these countries' economies are not systemically important to the global economy. But they can be a source of pandemic risk if their public health capacities cannot stop the outbreak. When the outbreak spreads, it will impose costs in high-income countries that will be measured in trillions of dollars. The analyses of country policies and macroeconomic prospects prepared by the IMF under its Article IV only deal with the low-income countries' macroeconomic management perils. The public health policy stance of the country may potentially cause a multi-trillion dollar macroeconomic shock, but this is missing from the IMF's reports. The rationale for Article IV was to protect IMF members from instability originating in other countries, and yet its exclusion of pandemic risk fails to achieve this purpose.

Updating of methodology for monitoring macroeconomic risks. When the IMF was established in 1945, jet travel, which now enables unprecedented volume, speed, and range of travel by pathogens, was rare. After 70 years, the scope of the IMF's work under Article IV needs to be updated to align with the current risk profile of the global economy. A number of experts cautioned that if the World Bank, which collaborates closely with the IMF on

macroeconomic analyses, does not provide stewardship of pandemic risk assessments and does not integrate them into its regular country assistance, then the private sector and credit rating agencies will develop their own assessments, though they lack expertise in this type of risk. Official vetting of the assessments by a competent intergovernmental agency is needed. This would then guide work by the World Bank as it advises its country clients on analyses of risks and undertakes construction of risk indices.

GENERAL DISCUSSION POINTS

Types of risks. Three dimensions typically determine overall vulnerability to the health, community, and economic toll of infectious disease outbreaks. First is intrinsic risk, the risk that comes from the underlying probability that an outbreak will occur in any given country or context. Second, public health and health system core capacity risk is the probability that an outbreak will not be detected and controlled effectively. This risk relates to IHR and the JEE assessment scores and is a risk that increases when health systems are weak and core public health (human and animal health) capacities are functioning poorly. The third source of global risk is the economic vulnerability associated with an infectious disease outbreak of international concern. This risk arises from the interaction of the intrinsic risk and preparedness components with the specific mix of industrial and household economic activities that make up a country's economy. Certain sectors (e.g. travel and tourism) may be more likely to be adversely affected by certain outbreaks. Where these vulnerable sectors are major elements of the economy, the risks of significant economic disruption and loss are heightened. Experts noted that approaches to measure intrinsic risk and preparedness have been developed, although use of these approaches is uneven. For instance, most countries have not yet completed JEEs, and analyses of economic vulnerability of countries and of specific sectors remain largely unexplored, especially in developing countries. In response, the monitoring framework provides for tracking of any assessments of economic vulnerabilities that would be developed and carried out by leading global agencies.

Promoting risk management by countries – and globally. The indicators in Domain 3 aim to follow and encourage the conduct of analyses and assessments in two categories: (1) country-level risk analysis and incentives for action and (2) global risk assessment and incentives for action. While there is conceptual overlap between the two, they serve different purposes and clients. Raising and sustaining risk-awareness are fundamentally important objectives in all countries, and risk awareness benefits each country. Global risk analyses can help policy-makers steer scarce resources to areas of highest impact, such as support for core public health capacities in regions where outbreaks are most likely to occur and where capacity to control the outbreaks is low. They can also raise pandemic risk on the global policy agenda and thus prioritize global health security among global public organizations. Since public authorities and organizations have not been held accountable for past episodes of neglect, risk assessment is all the more important as an incentive for prevention and preparedness, both in countries and globally. Pandemic risk reduction is a quintessential global public good, and the place of universal health security on the global policy agenda should no longer be optional.

Impacts on livelihoods. Historically, infectious disease threats have been communicated principally as health and mortality risks. Although such outcomes clearly matter, they have been small compared to the ongoing health toll of other preventable diseases. But disease outbreaks have had adverse economic and social impacts that have imposed high costs on communities and businesses. In some cases, they have disrupted healthcare systems and reduced healthcare services for patients with conditions unrelated to the outbreak. The magnitude of the social and economic impacts of future outbreaks could be very large. The staggering costs of the ultimately contained outbreaks of SARS, H5N1 avian flu, Ebola, and MERS-CoV serve as a warning. The costs of future outbreaks will tend to grow in tandem with the increasing interconnectedness of national economies. The scale of economic impacts has been seldom consistently tallied, recorded, and communicated. This is a major shortcoming,

considering that for severe flu pandemic simulations, more than two thirds of the impacts are due to changed behaviors by the healthy, or so-called avoidance behaviors (Brahmbhatt and Jonas 2015; Brahmbhatt and Dutta 2008). Most recent estimates suggest that under conservative assumptions, the world's annualized losses from pandemics are already \$570 billion (see Annex 1), which is comparable to estimates of expected annual costs of climate change. Communicating these substantial economic risks is imperative, given their significance in analyses of macroeconomic risks and policy decision-making (Sands et al. 2016; Fan, Jamison, and Summers 2016).

Quantifying pandemic risk. A simple and robust measure of the economic threat can facilitate effective communication to decision makers. Pandemic risk is the annual expected economic losses that arise from a pandemic with low probability of occurrence but large, potentially catastrophic economic impacts. This risk is more than the estimated probability that a pandemic will occur; it also includes the economic damage. This measure of economic risk can be compared over time or among countries. For instance, a pandemic of severe influenza (or another readily transmissible disease) could cost the global economy \$6 trillion during its relatively brief spell of one to two years, with a rapid recovery in the post-pandemic period. The probability of onset of such a pandemic in any one year is, however, very small. If this annual probability is just 1%, such a pandemic is called a once-in-a-hundred-years event and the risk is \$60 billion per year. Pandemic risk is the annualized expected value of such losses.

Underestimating low-probability risk. So far, severe pandemics have been infrequent, with intervals longer than a human lifetime. The risk appears manageable. As a result, public officials tend to behave as if such events will never occur. The world underestimates the risks of infectious disease outbreaks, and devotes far too little to their prevention (Jonas 2013, Hoelscher & Blitzer 2007). This disastrous and ultimately very costly approach is sustained by the exclusion of disease outbreak risk factors from macroeconomic assessments. For instance, an empirical analysis of assessments for measuring threats to macroeconomic stability showed that such assessments tend to neglect infectious disease outbreak risk (Sands et al. 2016). Improved risk awareness among policymakers, businesses, and communities would be unambiguously beneficial.

Inevitable outbreaks, optional pandemics. A number of factors contribute to pandemic risk, many of which are amenable to both risk assessment and intervention to reduce risk. The risk of a pathogen with pandemic potential occurring in humans (emergence risk) gives rise to the risk of such a pathogen spreading in human populations (contagion risk) and causing damage (health risk, economic risk, societal risk). Prevention activity can reduce both emergence and contagion risk by lowering the opportunities for pathogens to start infecting humans and containing their spread. The possibility of exponential spread of disease makes activities for early control of contagion extraordinarily beneficial. It prevents exponentially rising costs of treating a large number of patients, and it also averts disease and suffering. Proven preventative measures include animal health surveillance, early detection in humans, and effective vaccination programs. In addition to reducing pandemic risks, preparedness measures help to strengthen the responsive health and societal systems that will reduce the vulnerability of communities to health and economic damage associated with any health emergency. Poor populations benefit disproportionately from responsive health systems and preparedness than those who are better off.

Mitigation of pandemic impacts. Pandemic preparedness will not prevent a pandemic, but it will reduce the costly impact on lives and economies. To what extent cost-mitigation efforts can succeed depends on policies and institutions, which can reduce the vulnerability of populations and economies. Fortunately, the scope for reduction of vulnerability is very large. Having a vaccine early and in large quantities (notably for influenza) will clearly help mitigate impact by as it would prevent infections of the people who are vaccinated and thus reduce the proportion of the population infected and the rate of spread of the contagion. Early availability of the vaccine is key; with current technologies, a vaccine may be available only after 4-6 months elapsed from the pandemic's onset.

Pandemic flu vaccine quantities would fall far short of optimal, so most of the world's population would not have access. Moreover, the bulk of the negative economic impacts and societal disruptions from major outbreaks stem largely from behavioral changes among the uninfected who avoid work, school, and international travel.

Reporting as an indicator of risk assessment. Several experts suggested that the indicators in Domain 3 should address whether a country promptly reports an outbreak, including disclosing truthful information to its people and reporting the event to the WHO or the OIE. This important issue is included in Category 1C (see Chapter 1). Indepth analyses of trade and travel implications (which both influence reporting performance) will be important contributions to analyzing risks and are already planned by the Graduate Institute Geneva/Chatham House team; the results will be incorporated in the monitoring report as they become available.

²⁵ Several workshop participants advised that framing the bottom-line of risk assessments as "vulnerability" instead of "risk" may elicit more constructive responses from policymakers, although the substantive meaning is the same and is usually measured by the value of expected annual loss.

²⁶ These institutions include the World Bank, the regional development banks (e.g., the Asian Development Bank, African Development Bank, the European Bank for Reconstruction and Development, and the Inter-American Development Bank), and the New Development Bank. The Global Fund (to Fight AIDS, Tuberculosis and Malaria) supports resilient and sustainable systems for health, recognizing that they prevent, at low cost, recurrent epidemics that are caused by late detection and poor control of contagion.

²⁷ Social vulnerability is composed of two parts: social fragility and social capacity to resist disaster and absorb loss ("resilience"). The main factors which influence these components include: depth of resources (including professional personnel, material, funds), social capital, beliefs and customs, frail and physically limited individuals (e.g. large aging population), and type and density of infrastructure and population. (See Zhao and Yang 2011).

²⁸ Health system resilience can be defined as "the capacity of health actors, institutions, and populations to prepare for and effectively respond to crises; maintain core functions when a crisis hits; and, informed by lessons learned during the crisis, reorganize if conditions require it." (See Kruk et al. 2015).



DOMAIN 4: STRENGTHENING GLOBAL MECHANISMS

4

International organizations are indispensable to managing epidemic and pandemic risk. Yet, as the most recent the Ebola crisis revealed, administrative delays, coordination deficiencies, and inadequate communication can cost the world valuable time and lives. Leading multinational businesses also play a significant role in disease outbreak risk management in that they develop response plans for their global enterprises and which can in turn, encourage others to do so as well. As noted in Chapters 1 and 3, these organizations can engage in supporting country-level preparedness, contributing to greater awareness of pandemic risk, and encouraging prevention and preparedness policies across states. To deliver on their mandate, international organizations need adequate resources including human, financial, organizational, and political support from their membership. In addition to tracking the health security initiatives of intergovernmental organizations, an improved global capacity to respond quickly and effectively to an outbreak and to mitigate disaster risk requires active participation by the private sector at the global level. International industry associations can be instrumental in sharing analyses among their members on the steps required to prevent and mitigate negative impacts of a pandemic. Domain 4 of the framework takes stock of both operational and organizational aspects (such as tracking flexible financing mechanisms, the establishment of emergency operational centers, and following through on WHO stated priorities) with the indicators divided into two categories:

4A: WHO operational and institutional reform; and

4B: UN system reform: operational & political.

The Global Outbreak Alert and Response Network (GOARN) was formed in 2000, and is a network of technical and public health institutions, laboratories, NGOs, and other organizations that work to observe and respond to epidemics. GOARN works closely with and under the WHO. The response network seeks to examine and study diseases, evaluate the risks associated with certain diseases, and improve global capacity to mitigate disease-

induced emergencies. The WHO coordinates international responses to outbreaks using resources from GOARN. The network's field missions have included the 2003 SARS outbreak in Asia, the 2009 H1N1 outbreak in the U.S. and Mexico, and most recently, the response to the 2014 Ebola outbreak in Guinea specifically.

In 2015, the WHO launched a reform campaign. The goals of this campaign include programmatic, governance, and managerial reform. For programmatic reform, the aim is to set priorities and subsequently allocate resources (both technical and financial) so as to avoid over commitment. Governance reform will clarify the WHO's role to promote greater coherence among the numerous global health players. Finally, managerial reform involves reevaluation of areas such as human resources, communications, finance, evaluation, accountability, and transparency and information management. The WHO also launched a new Health Emergencies Program in October 2016. Whether emergencies are the result of disease outbreaks, conflict, or disasters, the Health Emergencies Program seeks to assist countries to prepare for, prevent, respond to, and recover from emergencies quickly. The UN Global Health Crises Task Force has concluded its report and there are no firm plans for the UN to continue the global monitoring that the task force provided along with the preparation of its final report.

The state of public-private partnerships is highly relevant to preparedness for two major reasons. First, the private sector's capacity to contribute to emergency responses is often substantial only if adequate preparations are made in advance. Second, the private sector and its employees are often motivated to be prepared since pandemics are economically and socially costly. They have an incentive to encourage preparedness and even be part of it – for example, through simulation exercises, employee education, and community awareness.

Domain 4 also includes select indicators on:

4C: Private sector engagement in global coordination and capacity.

Recent private sector efforts include the GHSA PSRT and the WEF, the World Bank's PEF and commitments for actions during the World Bank International Development Association Replenishment Meeting (IDA18) period, and the WEF's Accelerator Project. This category also notes that the only known source of available funding for the time being is the World Bank, which is an official lender. The indicators fit into Category C because the mandate of the World Bank (and its IDA fund for the poorest countries) is to promote economic development of its member countries. The extraordinarily high economic returns from investments in public health capacities are due in large part to the fact that these capacities effectively mitigate economic damage in the private sector.

OPENING PRESENTATIONS

PAHO'S PERSPECTIVE ON INTERNATIONAL COORDINATION OF PREPAREDNESS AND DURING RESPONSES

Dr. Ciro Ugarte, the Director of Health Emergencies at the Pan American Health Organization (PAHO) introduced the Domain 4 discussion on the role of international organizations and public-private partnerships in supporting global health security and pandemic preparedness. His presentation suggested that increased transparency about the current state of preparedness at all levels would enhance national and global capacity to prevent, prepare for, and respond to health emergencies. Strengthening country capacity should be a priority (of global programs) because ultimately countries will need to be the first to respond to an endemic outbreak if it is to be effective and efficient (as noted in Chapter 1).

Inter-agency work. International actors, often called to intervene when a disaster exceeds the responsive capacity of the host country, or begins to cross borders, can help to fill the gaps in a country's response. The quality,

appropriateness, timeliness, and cost of external assistance all make a difference during major emergencies. Although a country's authorities are expected to coordinate an emergency response even in cross-country circumstances, cooperation from external responders is also necessary. Coordination and discipline among government and non-governmental actors and the coherence of their interventions have too often fallen short in the past. Analyses of international responses to major disasters (for example, the 2004 Indian Ocean tsunami, the 2010 Haiti earthquake, and the West African Ebola epidemic) have revealed that shortfalls in effectiveness are due to weak coordination and preparedness.

Lessons learned from 2009 H1N1 outbreak. The response to the 2009 H1N1 flu pandemic in the Americas illustrated both strengths and weaknesses in coordination. The WHO's GOARN missions, which provide technical assistance during public health emergencies, brought useful and timely information exchange in some countries during emerging outbreaks. However, GOARN resources were stretched when non-affected countries requested GOARN assistance, preventing other affected countries from receiving help. This led to poor communications between GOARN and the response team of the regional WHO organization, PAHO.

A comprehensive approach. A successful response requires unambiguous lines of authority, responsibility, and emergency operating procedures to be in place, broadly shared, and periodically exercised in peacetime. The primacy of national leadership of the overall response needs active support from international partners. Both national and international actors contribute to a response, but national roles can be delegated when parties agree. For instance, during the 2009 H1N1 flu outbreak, Mexico decided it did not have the time or resources to coordinate the overall response in the country, so it called upon PAHO to assume that role.

Given numerous international actors and networks, offers of assistance can overwhelm country authorities. Workshop participants felt that it was, indeed, a major problem that "everybody wants to play the role of coordinator and complain about a lack of coordination, but nobody wants to be coordinated." The resulting conflicts and delays divert substantial energy and resources away from the central task of responding to an outbreak. Political will and leadership are also important, sometimes more so than funding. Coordination problems have been recognized in the UN and the broader international emergency response community, resulting in sustained efforts to mitigate poor coordination, such as through the Cluster System²⁹ in the UN.

Traps to be avoided. The task of a coordinator of autonomous agencies or non-governmental organizations is challenging. Coordinators have made mistakes in the past, such as organizing many time-consuming meetings with little operational impact, allowing unproductive duplication of efforts or competition among partners, pursuing visibility instead of excellence, and making decisions on the basis of convenience rather than effectiveness. An effective and credible coordinator would not only avoid such traps, but also set realistic goals for the overall response. The coordinator requires adequate funding and other resources, especially where the national authorities have weak capacity.

Good information. Reliable information is critical for coordinating a multi-partner international response and can be more valuable than money and stockpiles of supplies and countermeasures. Many donors are ready to provide support when needed, but few have good information on what is needed. Often multiple actors are gathering information independently and then interpreting that information in different ways. Problems with information flow and response quality can be reduced by conducting joint field assessments with national experts and then jointly disseminating the information, analysis, and interpretation to all partners. In addition, the use of mobile data and crowd-sourcing could reduce costs and human resource barriers and potentially improve quality. Where Internet access is available and reliable, these may be appropriate uses of technology to improve assessments.

Profession expertise on site. Dr. Ugarte also suggested that response efforts tend to be hard to manage from offsite agency headquarters. An effective and efficient response is more likely if well-trained, on-the-ground staff work out of a local emergency operations center, with an interagency roster of experts to call on as needed. Responders based in the local emergency operations center are also in a good position to coordinate with national and international teams and initiatives. Teamwork is essential because neither WHO, nor any other single institution, can provide every needed resource.

Public-private partnership. The WHO's 2013 Partnership Contribution Implementation Plan and the 2016 Framework of Engagement with Non-State Actors provide guidance on coordination between the WHO and non-governmental partners. Positive results can already be seen across the Americas, including increased frequency of surveillance, reporting of virology data, and shipping samples to the U.S. CDC for testing and analysis. These initiatives are expected to strengthen coordination for preparedness and response capacity globally.

LAWS, SYSTEMS & PARTNERSHIPS – PANDEMIC PREPAREDNESS IN CHINA

Feng Cheng is a professor and director of the Global Health Program and Research Center for Public Health at Tsinghua University in Beijing. Professor Cheng emphasized the need for increased transparency of a nation's state of pandemic preparedness by providing the example of the Chinese government's response to the 2003 SARS outbreak which included a complete overhaul of the national public health system.

China and the experience of SARS. China's experience with pandemic preparedness and the country's response to the 2003 SARS outbreak offered lessons on the role of laws, systems, and partnerships. SARS was first detected in humans in Guangdong in 2002. By February 2003, it had spread to Singapore and Hong Kong, and by March 2003, it had appeared in Canada and the United States. A few months later, by July 2003, SARS had been detected in 29 countries. The economic impact was substantial globally, including in countries that had no reported cases of infection (see Annex 1). This outbreak prompted China to begin creating a system to respond more effectively to future infectious disease outbreaks.

Public health systems. As a first step, China's government established the necessary legal and regulatory infrastructures for preparedness activities. The resulting national system comprises of (1) a public health emergency command center to coordinate activities at the national, provincial, prefecture, and city levels with external organizations and other countries in the region (2) a nationwide reporting network for reporting infectious diseases and public health events (3) a nationwide pathogen laboratory network and (4) an emergency medical rescue team. This national system responds to both infectious disease outbreaks and other public health emergencies through 37 emergency medical teams distributed throughout China's 23 provinces. In December 2016, the Shanghai team was certified using the <u>WHO Global Emergency Medical Team</u> processes and checklists for deployment ready teams.

This newly instituted preparedness and response system in China was tested during several emergencies, including major earthquakes in 2008 and 2010, the 2009 H1N1 flu pandemic, the H7N9 avian flu outbreak that started in 2014, as well as Zika and MERS-CoV outbreaks. In addition, China has used this system to contribute to the international response to a yellow fever outbreak in Angola. Each incident has shown the high value of preparedness, but also revealed issues that require further attention, particularly regarding early detection, isolation, diagnosis, and treatment. China's capacities for pandemic prevention and response are now far greater, both relative to the pre-2003 levels and in absolute terms. Support from the international community has been integral to the system's development from the outset.

Partnerships. China continues to work closely with UN agencies and various non-government organizations and national academies, the Bill and Melinda Gates Foundation, and universities in Africa and the United States. China also engages in G20 initiatives. Under specific bilateral cooperation agreements, it has been working with the United States, countries in West Africa, and Nepal. There is a public-private partnership between the Ministry of Health and Sanofi Pasteur. The main challenge to sustaining such collaboration is funding; this has been a common constraint on health security-related partnerships in other countries as well.

DISCUSSION

The indicators in this domain address (1) WHO operational and institutional reforms, (2) UN operational and political reforms, and (3) global private-sector activities. These qualitative and quantitative indicators reflect suggestions made by participant experts at the April 2017 workshop, written comments by participant experts, and additional research conducted by the research team.

CATEGORY 4A. WHO OPERATIONAL & INSTITUTIONAL REFORM

Intergovernmental organizations like the WHO are extremely important when it comes to responding to a public health emergency. It is therefore imperative to assess the role of the WHO in the coordination of a global response to an emergency. The following table reflects a set of indicators that monitor WHO flexible financing, WHO emergency funds, the existence of an emergency center and inspector general position, transparency of information, and progress on WHO reform implementation.

The seminal Ebola reports all emphasized strengthening the WHO, with recommendations divided roughly into two categories: operational and institutional reform. Recommendations for operational reform focused on the WHO's readiness to respond rapidly to outbreaks, which includes running operations on the ground, issuing technical and normative guidance, and convening and coordinating other actors. Experts noted the need for the WHO to bolster its operational capacity, develop an emergency culture, and improve its ability to work with non-state actors such as humanitarian aid NGOs and private industry. The WHO has created a new Emergency Program to strengthen its overall operational capacity in health emergencies (see indicator 4A.3). Proposals for institutional reform addressed the organization in its entirety, looking beyond outbreak-related work (see indicator 4A.6). Recommendations included calls for a tighter focus on performing core functions; enhanced human resources at headquarters, regional, and country offices; the creation of accountability mechanisms; more appropriate financing (see indicators 4A.1 and 4A.2); and stronger leadership (see indicator 4A.5). A number of the reviews also highlighted the importance of the WHO maintaining its independence from the particular interests of any single member state or other powerful interest.

The discussion was wide ranging, as many participants felt that the WHO struggles with deeply rooted governance obstacles for multiple reasons, such as reliance on Member State priorities and restriction of funds. Given this challenge, it makes sense for the monitoring framework to include only a limited number of performance measures. One suggestion was that indicators could concentrate on (1) progress in building alliances outside of the WHO such as with civil society and other international organizations and (2) assessing how these alliances assist with changing funding restrictions and procedures and allowing the WHO to allocate more funds for core functions (instead of funds earmarked for a donor's favored health topic).

Another suggestion was to focus on tracking leadership, strengthening relationships with the private sector and other non-government organizations, increasing data availability, and improving media engagement. Others suggested tracking member countries' financial support of the WHO and contributions to emergency responses,

Table 4.1. Indicators for Category 4A: WHO operational & institutional reform.		
Name	Definition	
1.WHO flexible financing, general	NUMERATOR: non-earmarked funds provided to WHO by member countries & non-members.	
	DENOMINATOR: total contributions to WHO.	
	Also assess changes in the number and distribution of funds, and funding to regional offices.	
2.WHO emergency	NUMERATOR: \$ provided for emergency use (during year and cumulative).	
funds	DENOMINATOR: \$ requested for emergency use (e.g. \$1.24b requested for ongoing emergencies), during year and cumulative	
3. Emergency center	Creation of an emergency center to enhance the WHO's operational capacity & ability to issue technical/normative guidance & coordinate. Once fully established, monitor progress on implementation.	
	Assess quality and effectiveness of these emergency centers.	
4. Freedom of information	Increase transparency & accountability through a freedom of information policy. Once established, monitor requests and responses.	
5. Inspector general	Create an inspector general role; marshal more effective leadership. Once established, monitor effectiveness.	
6. WHO reform implementation	Assess progress towards the WHO defined priorities and recommendations for reform, including:	
	(i) Priority 1: defining clear business models for the WHO's work (1.1 Set clear direction for future and 1.2 link financing to value).	
	(ii) Priority 2: Align the WHO's operating model (2.1 review governance architecture, 2.2 align and optimize geographical footprint, and 2.3 strengthen vertical program integration).	
	(iii) Priority 3: Implement requisites for success (3.1. unlock potential of WHO Framework of Engagement with Non-State Actors (FENSA) 3.2 address internal fractures and divisions, 3.3. strengthen leadership and management skills, 3.4 implement mandatory mobility policy and 3.5 strengthen organization development capacity). Assess effectiveness of these reforms once implemented.	

mainly due to concern that a few countries provide most of the contributions while all other countries are "freeriders." This could be captured by indicators on country performance in meeting financial obligations to the WHO, the concentration of funding from the five top WHO donors, and the number of countries with large year-to-year increases in contributions. Given that underfunding of the WHO's core functions has long been a concern, the research team did not include in the revised framework many of the financing issues that were raised, maintaining only a few related indicators. Additional financing indicators are not feasible at this point. Moreover, they may require validation that improved quality and quantity of WHO funding correlates with greater preparedness.

The workshop discussions also emphasized that country-level preparedness will help the WHO be more effective. For instance, a growing proportion of countries with an emergency center in place will reduce the pressure on the WHO to assume operational roles for which it is not equipped. Further suggestions were to audit the five most recent international disease events in order to determine whether WHO followed optimal procedures and if its responses occurred on a sufficiently timely basis. Another recommendation was to track the WHO's ability to issue

staged warnings associated with infectious disease outbreaks. These were highly relevant comments, and should be considered at a later phase in the refinement of the monitoring framework. Other organizations should take on this important but separate task. Such performance measures could be part of the WHO's own reporting and evaluations.

Ultimately, the research team decided on a limited set of indicators, as modified after the workshop, that follow the WHO's activities in relation to global health security. This is not duplicative, but rather sets the WHO's role (as monitored by its mechanisms) in a broader context. In particular, the indicators will provide insight into the WHO's role as a convening power to whom countries respond in the event of an emergency and its role as coordinator of the public health response. However, one expert advised that the indicators do not explicitly measure the WHO's ability to announce when there is an outbreak of international concern and thereby trigger international action.

CATEGORY 4B. UN SYSTEM REFORM: OPERATIONAL & POLITICAL

The UN is another intergovernmental organization crucial to mitigating a public health emergency. Its role in global coordination is different from that of the WHO and therefore must also be highlighted and publicized. The following table reflects a set of indicators to monitor the UN's commitment to global health security and the creation of an accountability commission which would oversee monitoring and reporting efforts on global health security.

Table 4.2. Indicators for Category 4B: Operational & political UN system reform.		
Name	Definition	
1. Annual report	An annual report on global health security to the secretary general of the UN or the General Assembly (proposed).	
	Note: it is proposed to monitor whether there is an annual report; there are no plans at present for the UN to prepare a report on pandemic risks to its member states.	
2. Accountability commission	Appointment of an accountability commission to oversee monitoring and reporting efforts on global health security.	

Need for an annual report. Outbreaks can extend beyond the health sector and become humanitarian emergencies, which requires effective coordination between health and humanitarian aid organizations. Several of the reports suggested that existing entities for emergency coordination, namely the Inter-Agency Standing Committee (IASC) and the Office for the Coordination of Humanitarian Affairs, should continue to perform these functions (with the WHO coordinating the health cluster). In some cases, outbreaks may expand from health or humanitarian crises to economic and political emergencies that then threaten the security of all countries.

Accountability commission. A common recommendation was systematic reform in the UN system to ensure greater high-level political attention to the threat of outbreaks. Suggestions included: the creation of a high-level global health council at the UN General Assembly, a global health summit to be held in 2018 (see indicator 4B.1), the creation of a special global health committee on the UN Security Council, an accountability commission on outbreak preparedness and response (see indicator 4B.2), and the creation of a UN-wide task force. The UN Secretary-General has endorsed the creation of a one-year global health crisis task force with multi-stakeholder involvement, but has not endorsed creation of any other new body.

While participants agreed that the drafted indicators related to the UN were appropriate, some suggested adding priority setting at the global level. For instance, an expert suggested tracking the prioritization of health security in high-level policy fora, possibly by creating an annual indicator of where pandemic prevention and preparedness rank in the UN Security Council, G7, G20, and speeches by leaders of major multilateral development banks. However, the added value from tracking how the UN prioritizes global health security is uncertain, considering that the current UN priorities number at least 169 (which is the number of targets for the SDGs that are in place till 2030). While such an analysis could be revealing, the research team decided not to add such indicators at this time

CATEGORY 4C. PRIVATE SECTOR ENGAGEMENT IN GLOBAL COORDINATION AND STRENGTHENING GLOBAL MECHANISMS

In addition to the health security initiatives of the intergovernmental organizations like the WHO and the UN, , an improved global capacity to respond quickly and effectively to outbreaks and to mitigate disaster risk requires active participation by the private sector at the global level. The following table reflects a set of indicators to monitor private sector engagement in preparedness planning, World Bank funding for pandemic preparedness, the commitment of resources by companies outside of the World Bank, and finally the World Economic Forum's engagement in preparedness planning.

The private sector can contribute to strengthening global coordination and capacity through partnerships with critical international bodies, such as the WHO and UN, and with organizations, such as the World Economic Forum, which has taken on several projects to increase coordination between the public and private sector in pandemic preparedness efforts (see indicators 4C.1 & 4C.4). In addition, global coordination and capacity building will be enhanced if financial institutions like the World Bank and other entities commit financial resources toward pandemic preparedness and response. Examples include the World Bank PEF and IDA18 among others (see indicators 4C.2 and 4C.3).

The private sector's involvement in the prevention of, and response to, disease outbreaks is very diverse, and the existing indicators for global monitoring cannot adequately capture this heterogeneity. The public and private sectors share an interest in robust risk analyses, effective emergency response, and greater reliance on prevention and preparedness. Despite these shared interests, the private and public sectors differ greatly in terms of exposure, profit sources, operating capacities, motivations, and financial resources.

Many of these concerns have informed the indicators on private sector contributions in Domains 1-3 of the framework. Several experts suggested additional partnerships for Domain 4, namely to also assess civil society engagement, bilateral partnerships between countries, the performance of large NGOs and private funders, and the availability of development aid to start and sustain partnerships. The research team carefully considered these aspects, some of which were prominent in recent outbreaks. Such partnerships can be valuable, community and country contexts, but health-security specific global mechanisms are not required for effective partnerships with civil society organizations at the local level, nor are they warranted for bilateral cooperation. Accordingly, these concerns have been included in Domain 1, to be monitored in the context of improving country capacities and as a complement to the JEE processes. The additional partnerships that were suggested for monitoring likely would not be relevant in all countries or globally. As several experts noted, political considerations of governments may be the main drivers of such partnerships, which thus often have limited funding and time horizons. The evolution of these partnerships is more ad hoc than an intentional progression. The suggestion to track partnerships between countries and vaccine producers, pharmaceutical companies, and device makers and suppliers has informed the indicators on public-private partnerships in Domain 4 are only one dimension.

Table 4.3. Indicators for Category 4C: Private sector engagement in global coordination and strengthening
global mechanisms.

Name	Definition	
1. Private sector engagement in global coordination & capacity	 # of Fortune 100 companies that are engaged in preparedness planning with major international organizations such as the WHO, World Bank, UN. # of small- to medium-sized companies (across sectors) who are engaged in preparedness planning with major international organizations like WHO, World Bank and UN. 	
2. World Bank funding for pandemic preparedness	 (i) Amount of funding provided for pandemic. (ii) # of countries supported by PEF and IDA18 pandemic preparedness. (iii) Amount of funds disbursed for responses to epidemics. (iv) Effectiveness of these funds in building capacity/improving health security (as assessed through external evaluations). 	
3. Financing mechanisms other than the World Bank	 (i) # of institutions, donors, and/or countries that commit funds to global preparedness through a financing mechanism. (ii) Amount of funds committed. (iii) # of companies committing resources to global coordination efforts in health security. Monitor growth overt time and the ways in which private sector investment is improving coordination. 	
4. WEF engagement in global coordination & capacity	 # and type of activities related to global coordination and capacity around pandemic preparedness. Potentially may consider including (resources permitting): # of private sector members engaged in preparedness planning related to global coordination and capacity, quality and effectiveness of these programs and activities in driving impact. 	

Regional Organizations. Several participants highlighted the importance of regional bodies and their competencies, alliance building, and leadership capacities, whereas the indicators in Domain 4 only deal with international organizations that have global mandates. The research team considered whether adding regional capacity indicators was feasible at this stage and valuable. Adding regional entities would certainly enlarge the set of indicators. Yet, regional organizations are numerous. They include not only regional WHO organizations but also organizations linked to initiatives for economic integration. The capacities of these organizations are variable, and those that should serve low-income countries may be the weakest. At the same time, the principal responsibilities for public health rest with national governments or, in some countries, with subnational authorities. The operations of regional organizations typically address economic and security issues; where they have a formal or potential regional public health role, data collection on their activities in health security domains would be costly and of uncertain benefit. Moreover, the geographic scope of regional organizations varies greatly and may not necessarily correspond to the distribution of likelihood of infectious disease outbreaks.

Ultimately, the research team concluded that monitoring regional health security capacity is beyond the scope of the global framework at the initial stage. There is a case, however, for the relevant authorities to undertake specific reviews of regional capacities. In particular, the WHO's own readiness plans and simulations of responses to PHEIC could include plans for contributions of regional organizations. Joint external reviews of regional capacities would be a helpful complement to the coverage of countries' JEE results. The incentives for adequate preparedness of regional organizations would also be stronger if regional stakeholders (and not a global monitoring project) tracked preparedness in their region.

²⁹ Clusters are groups of humanitarian organizations, both UN and non-UN, in each of the main sectors of humanitarian action, e.g. water, health and logistics. They are designated by the IASC and have clear responsibilities for coordination (Humanitarian Response 2017).



REVISED SHARED MONITORING FRAMEWORK AND NEXT STEPS

5

In addition to raising issues specific to the four domains of the monitoring framework (Chapters 1-4), experts shared high-level suggestions necessary for the revision and, eventually, for the implementation of the framework and dissemination of findings. Workshop participants considered three objectives to be especially important in revising the monitoring framework. Namely, the monitoring should:

- 1. Convey that countries can actively reduce their vulnerabilities to infectious disease outbreaks and thereby also reduce associated risks to national economies, poor communities, and social structures;
- 2. Convey that pandemic prevention and preparedness involves many players at multiple levels; and
- 3. Change policymaker and stakeholder behaviors with regard to how a country uses its resources.

MONITORING TO DRIVE CHANGE

During the April 2017 workshop, several participants commented on the importance of framing indicators in such a way that will drive behavioral change and action. For example, one expert noted that quantitative "continuous" indicators rather than binary ones may be one way to drive behavioral change more effectively. The ability to assess progress over time may also be useful for a multiyear monitoring initiative. In some instances, such indicators could help motivate actions by acknowledging incremental progress. One example of this in effect is the Intergovernmental Panel on Climate Change's (IPCC) use of carbon emissions as an indicator to measure each country's incremental progress on actions to curb climate change. The revision team agreed and made such adjustments where feasible, taking into account the increased data requirements for continuous indicators. Detailed measurement of pandemic risk (and of the effectiveness of public health capacities to reduce this risk) should become progressively more feasible in the future as data availability on health security improves. For instance, as

more data on the JEE and PVS assessments are made public, policymakers, and donors will have better information to inform investment and planning decisions.

A number of experts also cautioned against having too many indicators and how this could make the monitoring costly, while not adding and possibly detracting value. Indeed, a recurrent problem in other fields has been that the expense of monitoring and measurement can spiral out of control, becoming an exercise in generating graphs and reports instead of supporting improved policies. As a result, the research team incorporated suggestions to try to identify a clear principal audience and political purpose for each indicator. Revision of the indicators has also sought to minimize the collection of new data, which is often costly and time-consuming for country-level indicators.

Everyone at the workshop agreed that, regardless of the ultimate form that reporting, and dissemination take, data collection and assessment must (1) engage developing country institutions and experts and (2) be overseen by an international coalition of independent, neutral, credible, and trusted organizations. Focused consultations with stakeholders in countries with inadequate public health systems will help improve understanding about the main obstacles to adequate budgeting for core public health functions; such obstacles illuminate areas for additional or more effective indicators or special studies. Tracking the financing for country public health capacities will encourage engagement by developing country stakeholders. Additionally, robust oversight is necessary to ensure that monitoring is transparent. Regardless of who takes on this task, monitoring must be independent, evidence-based and objective, with sufficient and sustained financing from the international bodies that are responsible for follow-up action to reduce high global risks to population health and economies.

Some suggestions sought to establish rewards for health security through the monitoring initiative, though in some cases such novel incentives are well beyond the immediate scope of the monitoring framework and thus were not incorporated into the framework per se. For example, one suggestion was that the global public health community should establish a fund to award cash prizes per reported incident of new strains of highly pathogenic influenza in poultry and swine. Another suggestion was that an influential academic institution should publish a report card of the top 100 companies involved in disaster preparedness and infectious disease research, and award prizes for the most improved from year to year. Improved accountability, whether through incentives or other mechanisms, is a key concern that is addressed throughout the framework, although the remaining scope for greater accountability is substantial. Two types of measures that were suggested at the workshop for future consideration are shown in Table 5.1.

Table 5.1. Examples of potential new incentives for increased effectiveness of responses.		
New incentives for good behaviors and disincentives for bad behaviors	Product development of new countermeasures	
i. Early reporting of outbreaks versus epidemics by national governments, and perhaps via global social media;	i. The pipeline of medical countermeasures that have entered clinical development;ii. Investment of people and funds by the	
ii. Imposing trade restrictions ³⁰ on disease- associated goods, such as live poultry, swine or bush meat, upon declaration of an outbreak by a country:	pharmaceutical industry in the development of countermeasures; iii. Number of doses of countermeasures stockpiled for clinical trials and epidemic	
iii. Implementation by national governments of travel restrictions on potential disease-carrying populations, and perhaps by international airlines; and	control and containment; iv. Funding for the last mile capacities needed to deliver countermeasures to highest risk areas; and	
iv. Participation in "disaster science" conducted by leading international groups at the time of an outbreak.	v. Financial contributions to CEPI above and beyond investments in national public health systems.	

Discussions at and after the workshop confirmed that the proposed monitoring framework is balanced and comprehensive. Reports on the results of the monitoring should not duplicate other work, but rather serve as a platform for related studies to be presented in a consistent manner. Many experts felt that ongoing analyses should complement the framework. This could include, for instance, case studies on how these indicators motivate change that results in lower outbreak risk and that produces a rate of return. Successful case studies showing high economic rates of return from surveillance, diagnostics, and other capacities that are needed to comply with IHR would encourage ministers of finance, for example, to seek financing from the World Bank and other multilateral banks for their country's increased investments in core public health capacities.

IMPLEMENTATION GOVERNANCE AND NEXT STEPS

This section synthesizes possible partnerships for monitoring and reporting pandemic preparedness indicators as identified from workshop participants and subsequent discussions with partners.

A long-term project of high importance. The difference between the magnitude of pandemic risk and the current modest and uneven prevention and preparedness efforts is so stark that this project is highly warranted. This proposed initiative is not a one-off exercise, and requires long-term commitment to continuous monitoring. The risk of potential pandemics is also ongoing and will undoubtedly change in years to come.

Anchoring the monitoring mainly in academic and research institutions – and at the same time engaging practitioners with field experience – will confer substantial benefits to the project and to the institutions. Such an arrangement would align well with the aims of universities to educate future leaders and to work for a better world for the younger generations that face higher lifetime odds of experiencing pandemics than older people. Additionally, the quality and reach of the monitoring will be improved since universities often deliberately promote collaboration across sectors and among disciplines. Such collaboration fits well with the inherently complex and multi-sectoral tasks of monitoring and reducing pandemic risk.

Monitoring stewarded by scientific authorities. Robust governance dedicated to scientific approaches could promote the effectiveness, credibility, and relevance of the proposed monitoring initiative. One proposal for the structure of this initiative, in addition to its broad participation by leading academic institutions, would be to have significant oversight by creating an international steering committee³¹ to oversee the implementation of the monitoring framework. This international steering committee could bring to bear its member's expertise in human public health, veterinary public health, government, business, economics, and disaster-risk management to provide strategic guidance, mobilize financial and other support for the project, and develop and implement dissemination strategies for reports and analyses. Collaboration with prominent international organizations such as the International Association for National Public Health Institutes could address select aspects of the project, from data collection and analysis to dissemination. The steering committee would also have adequate representation from non-OECD countries and expertise in veterinary public health and other fields outside medicine. This apex body could review progress of the monitoring and provide strategic advice. The steering committee would work with international financial institutions, G20, and other prominent fora to increase (and then sustain) prioritization of pandemic prevention and preparedness among policymakers, business leaders, and the public. Regardless of the precise governance structure that this initiative adopts, it will be invaluable to create a credible, international body that oversees the work and assists in high-level dissemination of key findings and annual reports as well as strategic planning for the initiative.

Coalition of International Partners and Academic Institutions. The importance of broad participation in the proposed monitoring initiative cannot be understated. In order to be effective, the initiative will need researchers

and public health professionals and institutions from around the world to participate in every stage of the process, from gathering and analyzing data to writing reports and disseminating findings. This process of engagement will be a cornerstone to increasing political will, behavioral change, and ultimately health security. During the workshop, participants expressed interest in becoming members of this coalition and assisting in data collection, analysis, and research translation. While the structure of this coalition still needs to be determined, it was felt that the initiative would benefit greatly from partnerships across the globe and across sectors. During the last session of the workshop, participants expressed great enthusiasm regarding a mechanism that is stewarded by an independent and apolitical organization and overseen by a credible, international body, with an international coalition of research and academic partners taking responsibility for the necessary monitoring and analytical work and regular production of monitoring reports.

ACHIEVING SUSTAINED MONITORING AND STAKEHOLDER PARTICIPATION

Sustainability of monitoring efforts. Experts offered suggestions for ways to promote the sustainability of the monitoring effort, draw on global expertise, and raise awareness of pandemic risks. Monitoring will be essential because it will provide regular reports on the status of the world's ability to reduce and respond to pandemic risk. Because the monitoring will generate objective information, the results should provide a substantial incentive to governments, the private sector, and international organizations to sustain momentum on improving health security. The monitoring project will be needed until such a time when:

- All countries have robust public health capacities that comply with IHR and meet OIE standards;
- Competent official agencies regularly analyze risks that weak public health capacities pose to economies and actively engage in reducing these risks;
- International organizations are positioned to rapidly and effectively support countries during major disease outbreaks and to foster development of countries' public health capacities; and
- Diagnostics, drugs, and vaccines for new diseases are available to mitigate the spread of contagion and its impacts on economies, communities, and public health.

The shared monitoring framework and its implementation will assist the international community in mobilizing the political will and financial resources needed to increase preparedness, reduce global risk, and improve core public health capacities worldwide. The four monitoring domains – (1) strengthening public health core capacity as a foundation (2) improving science, technology, and access (3) reinforcing risk analysis and incentives for action and (4) strengthening global mechanisms – work together to synergistically strengthen global health security. Together, these four domains, when monitored independently and objectively with the broad participation of experts across the globe, can provide the international community and stakeholders within countries with a comprehensive analysis of risk and readiness. Importantly, when the results of this monitoring are communicated regularly to policymakers, governments, businesses, the media, and the public, progress can be achieved. Through this global initiative, it will possible to break free of the vicious cycle of panic and neglect to a position of sustained action to reduce pandemic, AMR, and other microbial risks.

³¹ The role of a steering committee would be to form an international body that is strategic and advisory, and one that provides support to the project.

³⁰See provisions available at <u>World Trade Organization (WTO)</u> Agreement on the Application of Sanitary and Phytosanitary (SPS) <u>Measures</u>. They provide that countries cannot be prevented from adopting or enforcing measures that are necessary to protect human, animal, or plant life, subject to the requirement that these measures are not applied in a manner that is arbitrary or discriminatory between member countries.

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ANNEX 1

ESTIMATES OF GLOBAL PANDEMIC RISK AND COST OF PREVENTION

Examples of economic and health impacts of select outbreaks

Influenza. One of the four influenza pandemics in the last century, the 1918 influenza pandemic, was particularly severe. It infected over one third of the 2 billion people in the world at that time. The death toll was exceptionally high, and estimates range from 50 million to 100 million people worldwide (Taubenberger and Morens 2006).

HIV/AIDS. Since the mid-1970s, HIV/AIDS has killed more than 35 million people; coping with this protracted pandemic has already cost tens of billions of dollars and imposed high costs on communities. Fast-moving disease outbreaks will have disastrous economic consequences out of proportion to the health impact as consumers and businesses change their behaviors in response to the contagion. The bulk of the impact is not due to disease, but rather to the changed behavior of healthy uninfected people, which leads to rapid and possibly substantial changes in demand (as consumers stay away from stores, travel, and service establishments) and supply (as workers stay away from work).

SARS. An outbreak in 2003 of a new respiratory disease, SARS, infected 8,000 people worldwide, which was a very small health impact relative to the much greater daily toll of preventable illness. But the economic cost of SARS was high, as confirmed by estimates that range from \$30 billion to \$54 billion (Lee and McKibbin 2004).³²

MERS-CoV. The Middle East Respiratory Syndrome has continued to cause illness and death since it emerged in 2012, mainly because low standards of infection prevention and control in Saudi Arabia and other affected countries amplify the contagion (it spreads mainly in healthcare facilities). The MERS-CoV outbreak in 2015 South Korea illustrates how such a disease can be exported by a business traveler and cause major economic damage. In South Korea, there were 36 fatalities from MERS-CoV. Though all infections were acquired in hospitals, daily life came to a standstill as shops closed and people avoided going out. The episode reduced tourist arrivals in South Korea by a staggering 54 percent over the subsequent two months, as tourists from China and elsewhere chose to stay away due to perceived risks. The economic damage from MERS-CoV in South Korea exceeded \$700 million, while the public-health impact was small.

Ebola. The 2014-16 Ebola epidemic in West Africa took over 11,000 lives, disrupted healthcare, cost \$4 billion to contain (Centers for Disease Control and Prevention 2016), and inflicted \$6 billion of economic damage, mostly on already-poor communities (Smith et al. 2015; Zafar et al. 2016).³³

Estimates of pandemic risk. The magnitude of pandemic risk makes it a top global catastrophic risk and one of the main existential risk facing humanity (Organisation for Economic Co-operation and Development 2011). Expert estimates of the likely economic damage are invariably very high. They include a World Bank estimate that a severe flu pandemic (or a pandemic of another, similarly transmissible disease) could trigger a drop of 4.8% in world GDP (Burns, van der Mensbrugghe, and Timmer 2008). This would be a major global recession, with losses of \$6 trillion (based on world GDP of \$115 trillion in 2015). On an annualized basis, the risk of such a severe pandemic is \$60 billion, if the probability of onset of such a pandemic is just 1 percent in any year. The GHRF Commission also examined the threat to the global economy and reported that pandemic risk to the global economy is \$60 billion annually (Commission on a Global Health Risk Framework for the Future 2016).

Health impact comparable to tuberculosis and AIDS. A recent assessment of impacts of a severe influenza pandemic on health and economies concluded that the expected value of total pandemic costs is \$570 billion annually (Fan, Jamison, and Summers 2016). This result was associated with expected excess deaths of 720,000 annually, risk to the global economy of \$80 billion annually, and an expected value of excess mortality of \$490 billion annually. The cost of excess mortality was derived from empirical evidence on the subjective valuation of life. Adding the actual annual toll of seasonal flu (about 300,000) to the 720,000 death toll of a pandemic, the excess deaths due to flu are about 1 million (annualized). This impact is the same order of magnitude as the annual deaths from AIDS (1.6 million) or tuberculosis (1 million); both these epidemics are far costlier now than prevention of (and preparedness to respond to) the next flu pandemic – and immensely more costly than if they had been promptly and effectively controlled.

Annual economic damage comparable to climate change. The inclusive risk estimate is substantial - \$570 billion "and rising toward \$1 trillion" annually, which is equivalent to 0.7% of global income. The IPCC has stated that likely costs of climate change range between 0.2% and 2% of global income. Using these estimates, the price of inaction on pandemics is high - at least a third of the price of climate change, and as much as three times more costly than climate change. It is puzzling that these and similar results from other analysts have so far not motivated policy attention and adequate funding of global, regional, and country-level investments in prevention of pandemics and preparedness to mitigate their impacts.

Affordable prevention. An effective global infrastructure to prevent pandemics is affordable. Robust veterinary and human public-health systems in all countries are the principal component of this infrastructure and they are indispensable. Even if prevention fails and contagion spreads, this infrastructure will serve to mitigate costly impacts on public health and economies. The World Bank has estimated that veterinary and human public-health systems that perform their core functions would cost \$3.4 billion annually in all LMICs (Pierre-Louis et al. 2012). This annual expenditure would be sufficient for both investment and for operations and maintenance of these systems. Such spending would be equivalent to 2-3% of health budgets in the same countries, or to less than 2% of official development assistance.

Expected benefits far exceed costs. Estimates of the expected global benefit from pandemic risk reduction thus range from \$60 billion annually (if value of human life is excluded) to \$570 billion annually (if it is included). Using the lowest value in the range of costs, \$60 billion annually, the expected ratio of benefits to costs is 18:1. Investing \$1 of public funds every year in order to earn \$18 every year is clearly worthwhile and probably the most productive use of taxpayers' money. The comprehensive risk method yields an expected benefit: cost ratio of 160:1. To realize these substantial benefits, the world needs to spend \$3.4 billion annually. This spending would be highly effective, with extraordinarily high rates of return and improvement in health and human welfare. It would support the realization of the human right to health security on a global scale. The rate of return on investments in public health capacities for pandemic prevention and preparedness is exceptionally high and far above the returns on other public investments, which makes development of robust veterinary and human public-health systems the "most productive investment on behalf of mankind," (World Bank 2014b).

The extraordinarily high expected returns provide a strong economic rationale for funding core public health systems from multilateral banks and foreign aid. Moreover, robust public-health systems also have significant community and country-level co-benefits, such as reducing endemic disease burdens and enabling containment of AMR (in country and globally). The expected impacts include not only improved public health (reduced disease burdens in the human populations) but also faster progress toward universal health coverage, reduction of poverty, increased investment, increased livestock productivity and trade, sustained economic growth, and broad economic and social progress. These co-benefits would be additional to those that obtain from a reduction of pandemic risk.

Investments in veterinary and human public health systems in LMICs are more than amply justified by the benefits from pandemic risk reduction; they are also a highly productive use of public funds from the national perspective.

It should be an easy decision for all countries to cooperate and together invest in the necessary infrastructure for detecting contagion and mounting an effective and rapid response to disease outbreaks, especially since other public spending has much smaller economic and health benefits. The human right of health security is being denied to billions of people now and in the coming decades, and this is due mainly to weak governance of public health. Monitoring and reporting on pandemic risk management is a step that improves governance.

³² Another estimate of the cost of SARS was \$40 billion (Sidorenko and McKibbin 2009).

³³ Major disease outbreaks like those of Ebola and SARS were not pandemics but rather outbreaks or epidemics. A worldwide epidemic would be a pandemic (from the Greek pan = everywhere, and demos = people). Recent major outbreaks in poultry populations of novel influenza with pandemic potential were the H5N1 avian flu panzootic (from the Greek pan = everywhere, and zoo = animal; it spread widely to 4 continents) and the H7N9 avian flu epizootic (spread in China and other countries in Asia). These avian flu strains have caused rare sporadic infections in humans, but the virus could adapt and spread in humans, causing a pandemic.

ANNEX 2A

JEE ASSESSMENT AREAS

Public health core capacities are the public health competencies needed to effectively prevent, detect and respond to public health threats of international concern. These competencies are independent of whether a threat is naturally occurring, deliberate, or accidental (World Health Organization 2016d). There are 19 public health capacity assessment areas outlined in the JEE Tool (see below) to ensure core competencies. These originate from the IHR (2005) and are intended to provide measurable, actionable areas of competence in countries worldwide.

Public Health Core Capacities Assessed in the Joint External Evaluation Tool

- 1. National legislation, policy and financing
- 2. IHR coordination, communication and advocacy
- 3. Antimicrobial resistance
- 4. Zoonotic diseases
- 5. Food safety
- 6. Biosafety and biosecurity
- 7. Immunization
- 8. National laboratory system
- 9. Real-time surveillance
- 10. Reporting
- 11. Workforce development
- 12. Preparedness
- 13. Emergency response operations
- 14. Linking public health and security authorities
- 15. Medical countermeasures and personnel development
- 16. Risk communication
- 17. Points of entry
- 18. Chemical events
- 19. Radiation emergencies

Source: (World Health Organization 2016d)

ANNEX 2B

IHR CORE CAPACITIES

A. CORE CAPACITY REQUIREMENTS FOR SURVEILLANCE AND RESPONSE

- 1. States Parties shall utilize existing national structures and resources to meet their core capacity requirements under these Regulations, including with regard to:
 - a. their surveillance, reporting, notification, verification, response and collaboration activities; and
 - b. their activities concerning designated airports, ports and ground crossings.
- 2. Each State Party shall assess, within two years following the entry into force of these Regulations for that State Party, the ability of existing national structures and resources to meet the minimum requirements described in this Annex. As a result of such assessment, States Parties shall develop and implement plans of action to ensure that these core capacities are present and functioning throughout their territories as set out in paragraph 1 of Article 5 and paragraph 1 of Article 13.
- 3. States Parties and WHO shall support assessments, planning and implementation processes under this Annex.
- 4. At the local community level and/or primary public health response level

The capacities:

- a. to detect events involving disease or death above expected levels for the particular time and place in all areas within the territory of the State Party; and
- b. to report all available essential information immediately to the appropriate level of health-care response. At the community level, reporting shall be to local community health-care institutions or the appropriate health personnel. At the primary public health response level, reporting shall be to the intermediate or national response level, depending on organizational structures. For the purposes of this Annex, essential information includes the following: clinical descriptions, laboratory results, sources and type of risk, numbers of human cases and deaths, conditions affecting the spread of the disease and the health measures employed; and
- c. to implement preliminary control measures immediately.
- 5. At the intermediate public health response levels

The capacities:

- a. to confirm the status of reported events and to support or implement additional control measures; and
- b. to assess reported events immediately and, if found urgent, to report all essential information to the national level. For the purposes of this Annex, the criteria for urgent events include serious public health impact and/or unusual or unexpected nature with high potential for spread.

6. At the national level

Assessment and notification. The capacities:

- a. to assess all reports of urgent events within 48 hours; and
- b. to notify WHO immediately through the National IHR Focal Point when the assessment indicates the event is notifiable pursuant to paragraph 1 of Article 6 and Annex 2 and to inform WHO as required pursuant to Article 7 and paragraph 2 of Article 9.

Public health response. The capacities:

- a. to determine rapidly the control measures required to prevent domestic and international spread;
- b. to provide support through specialized staff, laboratory analysis of samples (domestically or through collaborating centers) and logistical assistance (e.g. equipment, supplies and transport);
- c. to provide on-site assistance as required to supplement local investigations;
- d. to provide a direct operational link with senior health and other officials to approve rapidly and implement containment and control measures;
- e. to provide direct liaison with other relevant government ministries;
- f. to provide, by the most efficient means of communication available, links with hospitals, clinics, airports, ports, ground crossings, laboratories and other key operational areas for the dissemination of information and recommendations received from WHO regarding events in the State Party's own territory and in the territories of other States Parties;
- g. to establish, operate and maintain a national public health emergency response plan, including the creation of multidisciplinary/multisectoral teams to respond to events that may constitute a public health emergency of international concern; and
- h. to provide the foregoing on a 24-hour basis.

B. CORE CAPACITY REQUIREMENTS FOR DESIGNATED AIRPORTS, PORTS AND GROUND CROSSINGS

1. At all times

The capacities:

- a. to provide access to (i) an appropriate medical service including diagnostic facilities located so as to allow the prompt assessment and care of ill travelers, and (ii) adequate staff, equipment and premises;
- b. to provide access to equipment and personnel for the transport of ill travelers to an appropriate medical facility;
- c. to provide trained personnel for the inspection of conveyances;
- d. to ensure a safe environment for travelers using point of entry facilities, including potable water supplies, eating establishments, flight catering facilities, public washrooms, appropriate solid and

liquid waste disposal services and other potential risk areas, by conducting inspection programs, as appropriate; and

- e. to provide as far as practicable a program and trained personnel for the control of vectors and reservoirs in and near points of entry.
- 2. For responding to events that may constitute a public health emergency of international concern

The capacities:

- a. to provide appropriate public health emergency response by establishing and maintaining a public health emergency contingency plan, including the nomination of a coordinator and contact points for relevant point of entry, public health and other agencies and services;
- b. to provide assessment of and care for affected travelers or animals by establishing arrangements with local medical and veterinary facilities for their isolation, treatment and other support services that may be required;
- c. to provide appropriate space, separate from other travelers, to interview suspect or affected persons;
- d. to provide for the assessment and, if required, quarantine of suspect travelers, preferably in facilities away from the point of entry;
- e. to apply recommended measures to dis-insect, de-rat, disinfect, decontaminate or otherwise treat baggage, cargo, containers, conveyances, goods or postal parcels including, when appropriate, at locations specially designated and equipped for this purpose;
- f. to apply entry or exit controls for arriving and departing travelers; and
- g. to provide access to specially designated equipment, and to trained personnel with appropriate personal protection, for the transfer of travelers who may carry infection or contamination.

ANNEX 2C

PVS CRITICAL COMPETENCIES

CHAPTER I - HUMAN, PHYSICAL AND FINANCIAL RESOURCES

Section I-1 Professional and technical staffing of the Veterinary Services Section I-2 Competencies of veterinarians and veterinary para-professionals Section I-3 Continuing education Section I-4 Technical independence Section I-5 Stability of structures and sustainability of policies Section I-6 Coordination capability of the Veterinary Services Section I-7 Physical resources Section I-8 Operational funding Section I-9 Emergency funding Section I-10 Capital investment

Section I-11 Management of resources and operations

CHAPTER II - TECHNICAL AUTHORITY AND CAPABILITY

- Section II-1 Veterinary laboratory diagnosis
- Section II-2 Laboratory quality assurance
- Section II-3 Risk analysis
- Section II-4 Quarantine and border security
- Section II-5 Epidemiological surveillance and early detection
- Section II-6 Emergency response
- Section II-7 Disease prevention, control and eradication
- Section II-8 Food safety
- Section II-9 Veterinary medicines and biologicals
- Section II-10 Residue testing
- Section II-11 Animal feed safety
- Section II-12 Identification and traceability
- Section II-13 Animal welfare

CHAPTER III - INTERACTION WITH INTERESTED PARTIES

- Section III-1 Communication
- Section III-2 Consultation with interested parties
- Section III-3 Official representation
- Section III-4 Accreditation/authorisation/delegation
- Section III-5 Veterinary Statutory Body
- Section III-6 Participation of producers and other interested parties in joint programmes

CHAPTER IV - ACCESS TO MARKETS

Section IV-1 Preparation of legislation and regulations Section IV-2 Implementation of legislation and regulations and compliance thereof Section IV-3 International harmonisation Section IV-4 International certification Section IV-5 Equivalence and other types of sanitary agreements Section IV-6 Transparency Section IV-7 Zoning Section IV-8 Compartmentalisation

OIE Tool for the Evaluation of Performance of Veterinary Services (2013) – 6th Edition © World Organisation for Animal Health

ANNEX 3

ILLUSTRATION OF ALIGNMENT OF RECOMMENDATIONS OF TWO REPORTS ON EBOLA RESPONSES

	Harvard - London School of Hygiene & Tropical Medicine Independent Panel	National Academy of Medicine (Commission on a Global Health Risk Framework for the Future)	
	Main Recommenda	tions	
Preventing major outbreaks	 Develop global strategy to invest in, monitor, and sustain national core capacities supported by transparent system for tracking and monitoring the results. Attain government agreement to regular independent, external assessments. Strengthen incentives for early reporting of outbreaks and science-based justifications for trade and travel restrictions. 	 Assess all countries' capacities independently; government participation in external assessments. The World Bank and development partners should deliver the core capacity plans with financial support for lower middle- and low-income countries. The International Monetary Fund to include pandemic risk in country economic and policy assessments, based on independently assessed IHR core capacities. The World Bank and other donors should declare that funding is conditional on independent assessments. WHO should establish a mechanism to generate a daily high priority watch list of outbreaks with public health emergencies of international concern potential to encourage necessary preparedness activities 	
Responding to major outbreaks	 Create a unified WHO Center for Emergency Preparedness and Response with clear responsibility, adequate capacity, and strong lines of accountability. Broaden responsibility for emergency declarations to a transparent, politically protected Standing Emergency Committee. 	 UN and WHO should establish clear mechanisms for coordination and escalation in health crises. WHO Center for Health Emergency Preparedness and Response to lead the global effort for outbreak preparedness and response. WHA should agree on protocols for avoiding suppression, delays in data/alerts, and protocols for avoiding unnecessary restrictions on trade or travel. WHO should create and fund a sustainable contingency fund of \$100 million through contributions determined pro-rata with assessed contributions from member states. 	
Producing and sharing data, knowledge, and technology	• Establish a global facility to finance, accelerate, and prioritize research and development.	 The WHO should galvanize acceleration of relevant R&D by establishing a Pandemic Product Development Committee (PPDC) to define priorities, mobilize, and allocate resources. The WHO should work with the global R&D stakeholders to catalyze commitment of \$1 billion per year to maintain a portfolio of projects in drugs, vaccines, diagnostics, personal protective equipment, and medical devices, coordinated under the PPDC. By end-2016, WHO to convene regulatory agencies, industry, and research stakeholders with the aim to streamline and standardize regulatory approvals and clinical trial protocols. 	
Governing the global system	 Institutionalize accountability by creating an independent Accountability Commission for Disease Outbreak Prevention and Response. Sustain high-level political attention through a Global Health Committee of the Security Council. Create a new deal for a more focused, appropriately financed WHO. Improve good governance of WHO through decisive, time-bound reform and assertive leadership. Improve WHO commendation of countries that rapidly publicly share information and publication of lists of countries that delay reporting. There should be economic incentives for early warning reporting. 	 Develop clear indicators of core public health system capacities for compliance with IHR. UN Secretary General should work with the WHO and other parts of the UN system to develop strategies for sustaining health system capabilities and infrastructure in fragile and failed states and in war zones, to the extent possible. WHA should agree on protocols for avoiding suppression/delays in data/alerts, and protocols for avoiding unnecessary restrictions on trade or travel. Progress of country-level and global reforms should be regularly monitored. 	

Sources: (Commission on a Global Health Risk Framework for the Future 2016; Moon et al. 2015)

ANNEX 4

WORLD MAP OF COMPLETED JEE ASSESSMENTS

(67 countries as of December 2017)



<i>Africa</i> (<i>n</i> = 28)			<i>Europe</i> (<i>n</i> = 10)	
Benin Botswana Burkina Faso Cameroon Chad Comoros Côte d'Ivoire Eritrea Ethiopia Gambia	Ghana Guinea Kenya Lesotho Liberia Madagascar Mali Mauritania Mozambique Namibia	Nigeria Senegal Sierra Leone South Africa South Sudan Uganda Tanzania (United Republic of) Zambia	Albania Armenia Belgium Finland Kyrgyzstan Latvia Liechtenstein Slovenia Switzerland Turkmenistan	
Eastern Mediterranean (n = 14)		South-East Asia $(n = 7)$	Americas (n = 2)	Western Pacific $(n = 6)$
Afghanistan Bahrain Jordan Kuwait Lebanon Morocco Oman	Pakistan Qatar Saudi Arabia Somalia Sudan Tunisia United Arab Emirates	Bangladesh Bhutan Indonesia Maldives Myanmar Sri Lanka Thailand	Belize USA	Australia Cambodia Korea (Republic of) Lao Peoples Democratic Republic Mongolia Vietnam
GLOBAL HEALTH SECURITY MONITORING AND REPORTING FRAMEWORK



Committee

MONITORING FRAMEWORK INDICATORS: ALL FOUR DOMAINS

1A: Assessments of national animal and human public health core capacities.					
Name	Definition				
1. JEE assessments	NUMERATOR: # of countries that have completed a JEE assessment in the last 5 years.				
	DENOMINATOR: 194 (number of WHO member states).				
2. PVS evaluations	NUMERATOR: Number of countries that have completed a PVS assessment in the last 5 years.				
	DENOMINATOR: 181 (number of OIE member countries).				
3. IHR implementation	NUMERATOR: Number of countries who report compliance with IHR at the World Health Assembly.				
	DENOMINATOR: All member states.				
	Compare these numbers with those of the JEE and PVS country assessments.				
	Identify gaps and/or differences in compliant countries with JEE and PVS scores.				
4. CSOs in country capacity for prevention of epidemics and pandemic preparedness	NUMERATOR: Number of countries with JEE/PVS less than 5 years old that covers CSO capacity topics. **				
	DENOMINATOR: Number of countries with JEE/PVS less than 5 years old.				
	** Topics examined: coverage of community-level engagement in prevention and preparedness activities, as well as a qualitative analysis of the numbers and types of CSOs directly contributing to national and international discussions on prevention and preparedness at country, regional and global levels.				
5. Quality and effectiveness of assessments	Aim would be to monitor quality and effectiveness of assessments and the assessment processes (noted above) through original and existing qualitative research, including case studies of impacts. This would complement tracking of delivery of assessments.				
6. CSO engagement in global health security	Trend in CSO campaigns for global health security, including attendance at World Health Assembly (WHA) to advocate for and otherwise contribute to global health security.				
1B: Building national animal and human p	ublic health core capacities				
 National action plant to reduce gaps identified in assessment(s) (JEE and/or PVS) 	NUMERATOR: # of countries (broken down by income level) where government has formally adopted a national plan(s) with defined attributes (relevance, prioritization, realism, financing, community/private sector engagement) within 9 months of completion of assessment reports.				
	DENOMINATOR: # of countries (broken down by income level) that have successfully undergone a JEE and/or PVS assessment.				

2. National action plans' coverage of	NUMERATORS (for 3 sub-indicators):
community capacities in Livites	Number of LMICs where National Action Plan considers (i) community preparedness, (ii) community human health workers and (iii) community animal health workers, (iv) evidence-based inclusion of behavioral response (data about public knowledge, views and current behaviors in connection to relevant aspects of the public health system and proposed measures for mitigation).
	DENOMINATOR: All LMICs with an adopted National Action Plan.
	<i>Note: Consider separating low-income from middle-income countries for comparison.</i>
3. Domestic financing committed to a JEE- based action plan in an approved national budget in all countries	NUMERATOR: Number of countries with domestic financing in an approved budget for some or all JEE –identified gaps.
	DENOMINATOR: All countries that have successfully undergone a JEE assessment and disclosed the findings.
4. Domestic financing committed to a PVS- based action plan in an approved national budget in LMICs	NUMERATOR: Number of LMICs with domestic financing in an approved budget for some or all PVS-identified gaps (as set out in the quantitative data and objectives of the PVS Gap Analysis Reports).
	DENOMINATOR: All LMICs that have successfully undergone a PVS Gap Analysis and disclosed the findings.
	<i>Note: Consider separating low-income from middle-income countries for comparison.</i>
5A. External assistance for JEE-based action plan	NUMERATOR: # of LMICs that have obtained external financing and/or technical assistance to address some or all JEE-identified gaps.
	DENOMINATOR: All LMICs that have undergone a JEE assessment and disclosed the findings.
	Also look at domestic financing and technical in-kind assistance.
	Note: Consider separating low-income from middle-income countries for comparison.
5B. External assistance for PVS-based action plan	NUMERATOR: Number of LMICs that have obtained external financing and/or technical assistance to address some or all PVS-identified gaps.
	DENOMINATOR: All LMICs that have successfully undergone a PVS assessment and disclosed the findings.
	*Also look at domestic financing and technical in-kind assistance.
6. Burden sharing of assistance to LMICs	NUMERATOR: Financing from top 5 bilateral and private donors.
	DENOMINATOR: Financing from all external sources.
	<i>Note: Consider separating low-income from middle-income countries for comparison.</i>

7. Quality and effectiveness of capacity building efforts	Through the use of existing evaluation mechanisms and original research, assess the quality and effectiveness of (above noted) capacity building efforts following the JEE and PVS assessments and national action plans. Track quality of other relevant development assistance programs that address IHR-related capacities.
8. Public-Private Cooperation and Private Sector Advocacy	 (i) # of small, medium, and large companies promoting closing of JEE- identified gaps and /or GHSA (special emphasis on the local context) in each country with JEE action plan; participation at regional and national "marketplaces" responding to JEE/PVS gaps. (ii) Types, quality and effectiveness of public-private cooperation outputs (sample or all countries with JEE action plan and/or PVS gaps): Existence of action and inclusive in-country network, connecting in- country operators and public sector to organize and catalyze activity to support preparedness and response. Information sharing platform connecting public and private sectors, to support response, maintain risk awareness, and address economic and business risk posed by outbreaks. Private sector included in emergency response plans and within the Emergency Operations Center. Engagement of private sector in JEE/PVS planning, including addressing gaps identified in core public health capacities.
9. CSR leveraged for core public health capacity building at country level ("host country")	 # of countries where Fortune 100 companies are directing CSR resources toward building in public health core capacities. # of Fortune 100 companies directing CSR resources to public health core capacities. # of countries where small- and medium-sized companies directing resources (CSR) toward capacity building in public health core capacities. # of companies direction resources (CSR) toward capacity building in public health core capacity buildin
1C. Improving Outbreak Reporting Perfo	formance and Incentives.
1. Availability of emergency financing (e.g., contingent components, pre- negotiated draw-down options, PEF)	 NUMERATOR: # of LMICs with confirmed PHEIC that have obtained financial and other resources to promptly and adequately respond to outbreaks (incl. disease control and mitigation of impacts) DENOMINATOR: All countries with WHO-declared PHEIC. Note: Consider separating low-income from middle-income countries for comparison. In years with no PHEIC declared, the indicator value is "not applicable." When five years of data are available (after 2023), the indicators can be a 5-year cumulative total and a moving average.

2. Financial incentives system – contingency funds for prompt responses to emergencies in LMICs	 (i) Availability of WHO contingency funds (balance relative to the \$100m target amount). (ii) Availability of contingency funds for emergencies involving zoonotic outbreaks in animals in LMICs. <i>Note: Consider separating low-income from middle-income countries for comparison.</i>
3. WHO/UN accountability	WHO & UN to release statement against the imposition of unjustified restrictions on trade & travel in the case of a PHEIC. Assess and report on annually.
4. Preparedness for trade and travel measures	World Trade Organization, Civil Aviation etc. development of standards & enforcement mechanisms for trade & travel restrictions.
2A. Rapid sharing of epidemiological, clinical & genomic a	lata.
1. Global standards for sample sharing	 (i) Establishment of a WHO-led global system for sample sharing (similar to the PIP already agreed for influenza) for all diseases of pandemic potential as defined by the WHO outside of influenza. (ii) # of national governments who rapidly share samples and other disease-related data at the onset of an outbreak (include time measure). If sharing is delayed, investigate and report on reasons for delay. (iii) Track progress by WHO in implementing material transfer agreement (MTA) tools and sample sharing country assistance.
2. Open data platforms	 (i) NUMERATOR: All diseases identified as high risk on the WHO Blueprint that have an open data sharing platform. DENOMINATOR: All diseases identified as high risk on the WHO Blueprint. (ii) # of platforms for open data sharing on additional pathogens and platforms that are non-pathogen specific (include virtual biobanks). (iii) Assessment of the quality and effectiveness of theses platforms for companies, researchers and national governments for R&D purposes and identification of gaps/weaknesses.
3. Public domain research	 (i) Track advancements in candidate vaccines and other products developed using public domain data. (ii) Track advancements in the use of big data (including Google search term analyses) to accurately detect disease outbreaks and estimate EID prevalence rates (focus on R&D blueprint diseases and influenza). (iii) Track and public on other advancements in the field related to pen data sharing for epidemic preparedness.

2B: National engagement in research	and capacity strengthening.
1. National engagement	 (i) National investment in epidemic and pandemic preparedness R&D as a % of total R&D budget (tracked over time to show progress and comparisons across countries). (ii) National policies on outbreak preparedness R&D.
2. R&D and applied epidemiology workforce development	 (i) NUMERATOR: All countries with composite score of 4 or 5 on the workforce development sub-section of the JEE. DENOMINATOR: All countries that have successfully undergone a JEE assessment and disclosed the findings. (i) Case studies on effectiveness of capacity building efforts (coverage as in (i), workforce skills for disease prevention and control, which is broader than narrow R&D). (ii) Capacity building efforts outside of the JEE that focus on R&D initiatives, including social and behavioral research.
3. Research training	 # of LMICs with established training pathways for animal and human health research professionals in pandemic preparedness research: Animal and human health disease surveillance Laboratory diagnostics Research on EIDs (of pandemic potential/ disease dynamics Health security and national preparedness Social and behavioral research on epidemic and pandemic preparedness and response (knowledge, attitudes, behaviors, and practices) Note: For this area, build on existing research from ongoing capacity building programs worldwide. Original research is not recommended due to high acquisition costs. Examine low- and middle-income countries separately if possible.
4. Institutions, politics, and practices that foster health security research	Case studies of countries with growing research and professional opportunities (and how they did this successfully). Other indicators to be considered over time that are feasible and useful.
2C: Innovation in and access to medic technologies).	al countermeasures (vaccines, diagnostics, therapeutics and other health
1A. Vaccines	# of the WHO R&D Blueprint priority disease candidate vaccines and also universal influenza vaccine candidates in the pipeline by phase of development: pre-clinical, Phase I, Phase II and Phase III, Phase IV, and licensed product (separate out by pathogen). Include cost information if available to assist funding prioritization.
1B. Diagnostics	# of new and improvements to existing diagnostic technologies and tools available to increase the speed and accuracy of pathogen detection among WHO priority diseases (could also include platform diagnostics).
1C. Therapeutics	# of candidate therapies among WHO R&D Blueprint priority diseases (including influenza) in the pipeline by phase of development: pre-clinical trials, Phase I, phase II and Phase III status (separate out by pathogen as appropriate).
1D. Other health technologies	# of new technological advancements that enable faster disease detection, improved vaccine or therapeutic development or all the above.

2. Clinical trials	 (i) Standards set by WHO for clinical trial designs in emergencies (i.e. ring vaccination²³ cluster-randomized with delayed arm among others) with consideration of ethics, safety and efficacy (especially when epidemics are declining). Focus on WHO list of priority diseases. (ii) Harmonization of clinical trial requirements across regions and worldwide prior to a PHEIC for R&D Blueprint priority diseases. (iii) # and type of regional coordinating bodies for NRAs. Focus on WHO priority diseases. (iv) # of clinical trial protocols reviewed by regional coordinating bodies on behalf of members.
3. R&D costs	 (i) Track investments in R&D: where it is going; where the gaps are (ongoing pipeline). (ii) Formation of a platform bringing together public-private entities to meet the needs of R&D. (iii) Track Pandemic Product Development Committee (PPDC) in prioritizing/ mobilizing R&D funds.
4. Key regulatory approvals	 (i) Progress in executing the WHO's EUAL (Emergency Use and Assessment Listing) and pre-qualification (PQ) status for vaccines, diagnostics and therapeutics for high burden diseases in emergency settings. (ii) Harmonization of common technical document requirements across NRAs. (iii) Harmonization of NRA requirements for product registration and post-market surveillance by region and candidate product for priority diseases. (iv) Case studies on candidate vaccine regulatory approval processes and challenges.
5. Global manufacturing capacity	 (i) Volume of manufacturing for vaccines and therapeutics by product type for WHO priority diseases according to the R&D Blueprint for WHO priority diseases. Manufacturing will vary by type of vaccine and therapeutic and therefore should be measured accordingly. Establish a baseline and then track over time. (ii) Manufacturing timelines of candidate vaccines and therapeutics by pathogen and product where this information is available. Identify gaps.
6. Stockpiles	 (i) Gavi Alliance, UNICEF, and manufacture stockpiling plans for WHO priority diseases including influenza (international, regional and national). Note this information may be difficult to obtain. (ii) Number and quantity of stockpiles established for WHO Priority diseases by country and institution of purchase; determine how many are advanced market purchased by organization such as Gavi Alliance. Again, me be difficult to obtain. (iii) Disease modeling projections to assessment quantity of stockpile needed
7. Vaccine and therapeutic deployment strategies	Establishment of global strategy (i.e. WHO endorsed) for vaccine deployment in emergencies (by disease). Each disease will differ.
8. Access	Percentage of target population(s) that has access to developed products (vaccines, therapeutics) by product and disease as monitored through international agreements and product deployment plans. Note: Data collection in this area may be difficult if the information is not made publicly available. It may also not be determined in advance; however, to the extent possible, global monitoring of access is encouraged.

9. Public-private sector collaborations to remove R&D roadblocks	# and type of public-private-academic collaborations between companies, international organizations (e.g. WEF and WHO) and academic institutions that tackle specific R&D roadblocks such as liability and indemnification, vaccine trials in emergency settings/bioethics, stockpiling strategies, global compensation schemes for adverse events (vaccines and therapeutics), bio-banking, etc.				
	Assess the effectiveness of these collaborations in resolving the roadblocks.				
3A: Country-level risk analysis and	incentives for action.				
1A. Intrinsic risk: outbreak and risk assessment	Existence and characteristics of country risk assessments.				
	# of countries with risk assessment < 5 years old.				
	Quality aspects: sub-national/regional, dissemination, and use in-country.				
1B. Intrinsic risk: preparedness	Existence and quality of preparedness assessment (PVS, JEE results).				
	Quality aspects: sub-national/regional, dissemination, and use in-country.				
2A. Economic vulnerability:	Existence and quality of economic vulnerability assessment.				
	How robust? Validation and support from international financial institutions.				
2B. Economic vulnerability: use of assessment	Incorporation/deployment of economic vulnerability assessment into official macroeconomic assessments and planning.				
	Use of assessment, by official partners or by private sector.				
2C. Economic vulnerability: private sector	Engagement with private sector on economic vulnerability within key sectors and/ or vulnerability of entire economy.				
3. Social vulnerability ²⁷ and resilience assessment	Existence and use of assessments, for health security or as part of disaster-risk management.				
	Creation of an evidence base that includes data about public knowledge, views and current behaviors in connection to relevant aspects of the public health system, disease outbreak containment, and proposed measures for mitigation (could be used for National Action Plans).				
	Note: methodology of assessments may vary and would be tracked as well, if relevant				
4. Corporate engagement	# of Fortune 100 companies engaged in risk analysis and incentives for action within and outside of their companies.				
5. Corporal social responsibility (CSR) engagement in risk	# and type of companies directing CSR resources toward risk analysis and incentives for action.				
	Analysis of the CSR outputs.				
3B: Global risk assessment and inco	entives for action.				
1A. Intrinsic risk: maps and indices	Existence and quality of risk maps/indices: how many exist? How comprehensive and robust are they? Compare and contrast.				
1B. Intrinsic risk: dissemination and use of maps and indices	Analyses, dissemination and use of risk maps/indices. Use in official sector (e.g. incorporation into Sendai framework), use in private sector.				

2A. Preparedness mapping: maps and indices	Existence and quality of preparedness maps/indices: how many exist? How comprehensive and robust are they?
2B. Preparedness mapping: dissemination and use	Dissemination and use of preparedness maps/indices. Use in official sector, use in private sector.
3. Economic vulnerability: assessments by IFIs	Extent of appropriate inclusion of health security in official macroeconomic assessments: how and how often included in reports on IMF Article IV consultations, World Bank's Systematic Country Diagnostic and country economic reports, and similar official reviews of economic prospects and policies in countries, regions, and globally?
4B: Operational & political UN system reform.	
1. Annual report	An annual report on global health security to the secretary general of the UN or the General Assembly (proposed).
	Note: it is proposed to monitor whether there is an annual report; there are no plans at present for the UN to prepare a report on pandemic risks to its member states.
2. Accountability commission	Appointment of an accountability commission to oversee monitoring and reporting efforts on global health security.
4A: WHO operational & institutional reform.	
1. WHO flexible financing, general	NUMERATOR: non-earmarked funds provided to WHO by member countries & non-members.
	DENOMINATOR: total contributions to WHO.
	Also assess changes in the number and distribution of funds, and funding to regional offices.
2. WHO emergency funds	NUMERATOR: \$ provided for emergency use (during year and cumulative).
	DENOMINATOR: \$ requested for emergency use (e.g. \$1.24b requested for ongoing emergencies), during year and cumulative
3. Emergency center	Creation of an emergency center to enhance the WHO's operational capacity & ability to issue technical/normative guidance & coordinate. Once fully established, monitor progress on implementation. Assess quality and effectiveness of these emergency centers.
4. Freedom of information	Increase transparency & accountability through a freedom of information policy. Once established, monitor requests and responses.
5. Inspector general	Create an inspector general role; marshal more effective leadership. Once established, monitor effectiveness.

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Workshop co-hosted by HGHI and NAM in Washington, D.C. on April 18, 2017

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WORKSHOP AGENDA

April 18, 2017 National Academy of Medicine

SESSION 1: OVERVIEW OF THE MEETING (WORKING BREAKFAST)

Chairs: Ashish K. Jha, Peter Sands and Victor Dzau

8:00 – 8:15am	Welcome from the Hosts and Introductions
	Victor J. Dzau (NAM) and Ashish K. Jha (HGHI)
8:15 – 8:25am	Briefing on the Graduate Institute of Geneva and Chatham House Meeting
8:25 – 8:40am	Rationale for a Common Monitoring Framework and the Need to Spur Action
	Peter Sands (HGHI)

SESSION 2: MONITORING PROGRESS IN PUBLIC HEALTH AS A FOUNDATION AND IHR CORE CAPACITY BUILDING

Chairs: Helene Gayle (McKinsey Social Initiative) and Rebecca Katz (HGHI)

8:40 – 9:05am Overview of the Monitoring Framework for IHR Core Capacity Building and Brief Presentations on Public Health as a Foundation and IHR Core Capacity Building

> Mika Salminen (JEE Alliance, Director, Department of Health Security, National Institute for Health and Welfare, Finland), Alain Dehove (Director of Finance, OIE), Oyewale Tomori (President, Nigerian Academy of Science)

9:05 – 9:45am Moderated Discussion on Key Metrics for this Area Task: Review the Monitoring Framework for Content Area 1. Discuss: What are we missing? Are the proposed indicators measurable? Do they capture what needs to be captured? Any challenges anticipated with data collection? Other concerns?

9:45 – 10:00 am Coffee Break

SESSION 3: MONITORING PROGRESS IN SCIENCE, TECHNOLOGY AND ACCESS Chairs: Gavin Yamey (Duke Global Health Institute) and Olga Jonas (HGHI)

11:15 – 11:30am Overview of Monitoring Framework for Risk Analysis and Assessment and Presentations on Risk Analysis and Assessment

Tom Inglesby (CEO and Director, Center for Health Security, Johns Hopkins University), Peter Daszak (President, EcoHealth Alliance), Anas El Turabi (Health Policy Doctoral Candidate, Harvard University)

11:30 – 12:30pm Moderated Discussion on the Framework for Monitoring Risk Analysis and Assessment

Task: Review the Monitoring Framework for Content Area 3. Discuss: What are we missing? Are the proposed indicators measurable? Do they capture what needs to be captured? Any challenges anticipated with data collection? Other concerns?

12:30 – 1:30pm Lunch

SESSION 5: MONITORING PROGRESS ON THE GLOBAL COMMUNITY AND PUBLIC-PRIVATE PARTNERSHIPS

Chairs: Stephen Morrison (CSIS) and Ashish K. Jha (HGHI)

1:30 – 1:45pm Presentation: Overview of the Monitoring Framework for Global Community and Public-Private Partnerships

Ciro Ugarte (Director, Health Emergencies, PAHO) and Feng Cheng (Professor, Tsinghua University Research Center for Public Health)

1:45 – 2:45pm Moderated Discussion on Monitoring the Global Community and Public-Private Partnerships

Task: Review the Monitoring Framework for Content Area 4. Discuss: What are we missing? Are the proposed indicators measurable? Do they capture what needs to be captured? Any challenges anticipated with data collection? Other concerns?

2:45 – 3:00pm Coffee Break

SESSION 6: COLLECTING AND DISSEMINATING DATA TO SPUR ACTION

Chairs: Ashish K. Jha (HGHI), Victor Dzau (NAM), and Peter Sands (HGHI)

- 3:00 4:15pm Group Discussion on Operationalizing the Framework: Collecting and Disseminating Data to Spur Action
- 4:15 4:30pm Wrap-up and Next Steps
- 4:30 6:00pm Reception
- 6:00 8:00pm Dinner

WHO AND OIE MEMBERS AND ECONOMIES BY INCOME GROUP (WORLD BANK, JULY 2017)

		Memb	er of			Memb	er of
Economy	Region	WHO	O IE	Economy	Region	WHO	O IE
Low-income (31 e	conomies)			Bangladesh	South Asia	•	•
Afghanistan	South Asia	•	•	Bhutan	South Asia	•	•
Benin	Sub-Saharan Africa	•	•	Bolivia	Latin America & Caribbean	•	•
Burkina Faso	Sub-Saharan Africa	•	•	Cabo Verde	Sub-Saharan Africa	•	•
Burundi	Sub-Saharan Africa	•	•	Cambodia	East Asia & Pacific	•	•
Central African Republic	Sub-Saharan Africa	•	•	Cameroon	Sub-Saharan Africa	•	•
Chad	Sub-Saharan Africa	•	•	Congo, Rep.	Sub-Saharan Africa	•	•
Comoros	Sub-Saharan Africa	•	•	Côte d'Ivoire	Sub-Saharan Africa	•	•
Congo, Dem. Rep.	Sub-Saharan Africa	•	•	Djibouti	Middle East & North Africa	•	•
Eritrea	Sub-Saharan Africa	•	•	Egypt, Arab Rep.	Middle East & North Africa	•	•
Ethiopia	Sub-Saharan Africa	•	•	El Salvador	Latin America & Caribbean	•	•
Gambia, The	Sub-Saharan Africa	•	•	Georgia	Europe & Central Asia	•	•
Guinea	Sub-Saharan Africa	•	•	Ghana	Sub-Saharan Africa	•	•
Guinea-Bissau	Sub-Saharan Africa	•	•	Guatemala	Latin America & Caribbean	•	•
Haiti	Latin America & Caribbean	•	•	Honduras	Latin America & Caribbean	•	•
Korea, DPR	East Asia & Pacific	•	•	India	South Asia	•	•
Liberia	Sub-Saharan Africa	•	•	Indonesia	East Asia & Pacific	•	•
Madagascar	Sub-Saharan Africa	•	•	Jordan	Middle East & North Africa	•	•
Malawi	Sub-Saharan Africa	•	•	Kenya	Sub-Saharan Africa	•	•
Mali	Sub-Saharan Africa	•	•	Kiribati	East Asia & Pacific	•	
Mozambique	Sub-Saharan Africa	•	•	Kosovo	Europe & Central Asia		
Nepal	South Asia	•	•	Kyrgyz Republic	Europe & Central Asia	•	•
Niger	Sub-Saharan Africa	•	•	Lao PDR	East Asia & Pacific	•	•
Rwanda	Sub-Saharan Africa	•	•	Lesotho	Sub-Saharan Africa	•	•
Senegal	Sub-Saharan Africa	•	•	Mauritania	Sub-Saharan Africa	•	•
Sierra Leone	Sub-Saharan Africa	•	•	Micronesia, FS	East Asia & Pacific	•	•
Somalia	Sub-Saharan Africa	•	•	Moldova	Europe & Central Asia	•	•
South Sudan	Sub-Saharan Africa	•	•	Mongolia	East Asia & Pacific	•	•
Tanzania	Sub-Saharan Africa	•	•	Morocco	Middle East & North Africa	•	•
Togo	Sub-Saharan Africa	•	•	Myanmar	East Asia & Pacific	•	•
Uganda	Sub-Saharan Africa	•	•	Nicaragua	Latin America & Caribbean	•	•
Zimbabwe	Sub-Saharan Africa	•	•	Nigeria	Sub-Saharan Africa	•	•
Lower middle-inc	ome (53 economies)			Pakistan	South Asia	•	•
Angola	Sub-Saharan Africa	•	•	Papua New Guinea	East Asia & Pacific	•	•
Armenia	Europe & Central Asia	•	•	Philippines	East Asia & Pacific	•	•

Member of					Memb	er of	
Economy	Region	WHO	OIE	Economy	Region	WHO	OIE
São Tomé and Principe	Sub-Saharan Africa	•	•	Dominican Republic	Latin America & Caribbean	•	•
Solomon Islands	East Asia & Pacific	•		Ecuador	Caribbean	•	•
Sri Lanka	South Asia	•	•	Equatorial Guinea	Sub-Saharan Africa	•	•
Sudan	Sub-Saharan Africa	•	•	Fiji	East Asia & Pacific	•	•
Swaziland	Sub-Saharan Africa	•	•	Gabon	Sub-Saharan Africa	•	•
Syrian Arab Republic	Middle East & North Africa	•	•	Grenada	Latin America & Caribbean	•	
Tajikistan	Europe & Central Asia	•	•	Guyana	Latin America & Caribbean	•	•
Timor-Leste	East Asia & Pacific	•	•	Iran, Islamic Rep.	Middle East & North Africa	•	•
Tunisia	Middle East & North Africa	•	•	Iraq	Middle East & North Africa	•	•
Ukraine	Europe & Central Asia	•	•	Jamaica	Latin America & Caribbean	•	•
Uzbekistan	Europe & Central Asia	•	•	Kazakhstan	Europe & Central Asia	•	•
Vanuatu	East Asia & Pacific	•	•	Lebanon	Middle East & North Africa	•	•
Vietnam	East Asia & Pacific	•	•	Libya	Middle East & North Africa	•	•
West Bank and Gaza	Middle East & North Africa			Lithuania	Europe & Central Asia	•	•
Yemen, Rep.	Middle East & North Africa	•	•	Macedonia, FYR	Europe & Central Asia	•	•
Zambia	Sub-Saharan Africa	•	•	Malaysia	East Asia & Pacific	•	•
				Maldives	South Asia	•	•
Upper middle-in	come (56 economies)			Marshall Islands	East Asia & Pacific	•	
Albania	Europe & Central Asia	•	•	Mauritius	Sub-Saharan Africa	•	•
Algeria	Middle East & North Africa	•	•	Mexico	Latin America & Caribbean	•	•
Argentina	Latin America & Caribbean	•	•	Montenegro	Europe & Central Asia	•	•
Azerbaijan	Europe & Central Asia	•	•	Namibia	Sub-Saharan Africa	•	•
Belarus	Europe & Central Asia	•	•	Nauru	East Asia & Pacific	•	
Belize	Latin America & Caribbean	•	•	Niue	East Asia & Pacific	•	
Bosnia and Herzegovina	Europe & Central Asia	•	•	Panama	Latin America & Caribbean	•	•
Botswana	Sub-Saharan Africa	•	•	Paraguay	Latin America & Caribbean	•	•
Brazil	Latin America & Caribbean	•	•	Peru	Latin America & Caribbean	•	•
Bulgaria	Europe & Central Asia	•	•	Romania	Europe & Central Asia	•	•
China	East Asia & Pacific	•	•	Russian Federation	Europe & Central Asia	•	•
Colombia	Latin America & Caribbean	•	•	Saint Lucia	Latin America & Caribbean	•	
Costa Rica	Latin America & Caribbean	•	•	Saint Vincent & the Grenadines	Latin America & Caribbean	•	
Croatia	Europe & Central Asia	•	•	Samoa	East Asia & Pacific	•	
Cuba	Latin America & Caribbean	•	•	Serbia	Europe & Central Asia	•	•
Dominica	Latin America & Caribbean	•		South Africa	Sub-Saharan Africa	•	•

Member of					Memb	er of	
Economy	Region	WHO	OIE	Economy	Region	WHO	OIE
Suriname	Latin America & Caribbean	•	•	Italy	Europe & Central Asia	•	•
Thailand	East Asia & Pacific	•	•	Japan	East Asia & Pacific	•	•
Tonga	East Asia & Pacific	•		Korea, Rep.	East Asia & Pacific	•	•
Turkey	Europe & Central Asia	•	•	Kuwait	Middle East & North Africa	•	•
Turkmenistan	Europe & Central Asia	•	•	Latvia	Europe & Central Asia	•	•
Tuvalu	East Asia & Pacific	•		Liechtenstein	Europe & Central Asia		•
Venezuela, RB	Latin America & Caribbean	•	•	Luxembourg	Europe & Central Asia	•	•
				Malta	Europe & Central Asia	•	•
High-income (59	9 economies)			Monaco	Europe & Central Asia	•	
Andorra	Europe & Central Asia	•	•	Netherlands	Europe & Central Asia	•	•
Antigua and Barbuda	Latin America & Caribbean	•		New Caledonia	East Asia & Pacific		•
Australia	East Asia & Pacific	•	•	New Zealand	East Asia & Pacific	•	•
Austria	Europe & Central Asia	•	•	Norway	Europe & Central Asia	•	•
Bahamas, The	Latin America & Caribbean	•	•	Oman	Middle East & North Africa	•	•
Bahrain	Middle East & North	•	•	Palau	East Asia & Pacific	•	
Barbados	Africa Latin America & Caribbean	•	•	Poland	Europe & Central Asia	•	•
Belgium	Europe & Central Asia		•	Portugal	Europe & Central Asia		•
Brunei Darussalam	East Asia & Pacific	•	•	Qatar	Middle East & North Africa	•	•
Canada	North America	•	•	Saint Kitts and Nevis	Latin America & Caribbean	•	
Chile	Latin America & Caribbean	•	•	San Marino	Europe & Central Asia	•	•
Chinese Taipei	East Asia & Pacific		•	Saudi Arabia	Middle East & North Africa	•	•
Curacao	Latin America & Caribbean	•	•	Seychelles	Sub-Saharan Africa	•	•
Cyprus	Europe & Central Asia	•	•	Singapore	East Asia & Pacific	•	•
Czech Republic	Europe & Central Asia	•	•	Slovak Republic	Europe & Central Asia	•	•
Denmark	Europe & Central Asia	•	•	Slovenia	Europe & Central Asia	•	•
Estonia	Europe & Central Asia	•	•	Spain	Europe & Central Asia	•	•
Finland	Europe & Central Asia	•	•	Sweden	Europe & Central Asia	•	•
France	Europe & Central Asia	•	•	Switzerland	Europe & Central Asia	•	•
Germany	Europe & Central Asia	•	•	Trinidad and Tobago	Latin America & Caribbean	•	•
Greece	Europe & Central Asia	•	•	United Arab Emirates	Middle East & North Africa	•	•
Hungary	Europe & Central Asia	•	•	United Kingdom	Europe & Central Asia	•	•
Iceland	Europe & Central Asia	•	•	United States	North America	•	•
Ireland	Europe & Central Asia	•	•	Uruguay	Latin America & Caribbean	•	•
Israel	Middle East & North Africa	•	•	# of membe	ers as of August, 2017	198	181

Economies are divided among income groups according to 2016 gross national income (GNI) per capita, calculated using the World Bank Atlas method. The groups are: low income (\$1,005 or less), lower middle income (\$1,006-\$3,955), upper middle income (\$3,956-\$12,235), and high income (\$12,236 or more). Some of the higher income economies listed are not states and as such are not members of international organizations. A number of them have attributes of sovereignty, including autonomous public health authorities.