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GLOBAL HEALTH SECURITY AGENDA AND THE INTERNATIONAL HEALTH REGULATIONS: MOVING FORWARD

Rebecca Katz, Erin M. Sorrell, Sarah A. Kornblet, and Julie E. Fischer

The launch of the Global Health Security Agenda (GHSA) in February 2014 capped over a decade of global efforts to develop new approaches to emerging and reemerging infectious diseases—part of the growing recognition that disease events, whether natural, accidental, or intentional, threaten not just public health, but national, regional, and global security interests. In 2005, the United States, along with other Member States of the World Health Organization (WHO), adopted the revised International Health Regulations [IHR (2005)]. The IHR (2005) conferred new responsibilities on WHO and the global health community to coordinate resources for capacity building and emergency response, and on the now-196 States Parties to develop the core capacities required to detect, assess, report, and respond to potential public health emergencies of international concern. Both GHSA and the IHR aim to elevate political attention and encourage participation, coordination, and collaboration by multiple stakeholders, while leveraging previously existing commitments and multilateral efforts. GHSA and the IHR (2005) are platforms for action; how efforts under each will complement each other remains unclear. Mechanisms that measure progress under these 2 overlapping frameworks will aid in focusing resources and in sustaining political momentum for IHR implementation after 2016.

ON FEBRUARY 11, 2014, THE UNITED STATES, in partnership with international institutions and more than 2 dozen other nations, launched the Global Health Security Agenda (GHSA) to accelerate progress toward a world where all countries can prevent, detect, and respond to public health emergencies. The launch of GHSA capped more than a decade of policy initiatives to address emerging and reemerging infectious diseases, reflecting the growing recognition that disease outbreaks (whether natural, accidental, or intentional) not only threaten public health but can represent transnational security threats requiring new collaborative responses. GHSA aims to promote commitments and events toward specific actions, accelerating measurable progress toward global public health objectives by elevating issues of global health security.

Emerging and reemerging diseases such as HIV, H5N1 highly pathogenic avian influenza, SARS (severe acute respiratory syndrome), and MERS-CoV (Middle East respiratory syndrome coronavirus) demonstrate that public health events take a toll that goes well beyond human lives, affecting economic, societal, and political stability. Changes associated with socioeconomic development, from new agricultural practices to urban crowding and suburban sprawl, create conditions that allow communicable diseases to spread among and between humans, domesticated animals, and wildlife. Trade and rapid transit now link a global network of international cities, fueling economic growth but also increasing the risk that diseases of any origin may spread rapidly through a highly mobile population. The ease with which disease can spread through travel and trade

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means that the entire international community may be affected when a disease emerges in any corner of the globe—a crisis anywhere may become a problem everywhere. The global population benefits if a country where a pathogen emerges is able to contain the outbreak before it becomes a national or international public health event. Conceptually, rapid disease detection and reporting allow for timely response, saving lives and preventing cross-border impact.

US and international decision makers have sought new strategies to detect and respond to emerging infections since the 1990s, resulting in new programs, policies, and international agreements. The US government created the President's Emergency Plan for AIDS Relief (PEPFAR), realigned programming at the Centers for Disease Control and Prevention (CDC) to emphasize global disease detection and response, launched the US Agency of International Development (USAID) Emerging Pandemic Threats program, and expanded Cooperative Threat Reduction programs at the Departments of State and Defense to address biological threats in Africa, the Middle East, and Asia—programs that, taken together, have dramatically increased the number of US technical personnel working overseas in programs to prevent, detect, and respond to infectious disease threats.¹ US government funding for global health increased concomitantly, climbing from about \$1.7 billion in fiscal year 2001 to a total of about \$9 billion annually in fiscal years 2010 to 2013 (driven primarily by spending on HIV/AIDS through PEPFAR).²

At the same time, the impact of emerging and reemerging infectious diseases helped catalyze new commitments at the global level. Some of these arose from concerns about the deliberate use of biological weapons in the wake of the 2001 anthrax assaults in the United States. At the 2002 G8 Summit, countries agreed to launch the Global Partnership Against the Spread of Weapons and Materials of Mass Destruction (GP), a 10-year \$20 billion initiative to prevent terrorists, or states that support them, from acquiring or developing weapons of mass destruction. (GP, which has grown to include 28 partners, has allocated roughly \$21 billion worldwide and has been extended beyond 2012.) In 2012, under US chairmanship, the GP established a Biological Security Sub-Working Group (BSWG) to promote reduction of risks associated with biological threats, regardless of cause.³ In the Biological Weapons Convention Forum, delegates at Meetings of Experts expanded dialogue to include cooperation for disease surveillance, preparedness, and response to public health emergencies.

Other efforts focused on overhauling traditional frameworks for international public health cooperation to enable rapid outbreak detection and response. The 2003 SARS outbreak spurred WHO's Member States to adopt the revised International Health Regulations in 2005 [IHR (2005)] after nearly a decade of debate on the most appropriate technical and legal frameworks for confronting emerging and reemerging diseases. The spread of highly pathogenic H5N1 avian influenza catalyzed the launch of

the International Partnership on Avian and Pandemic Influenza (IPAPI) in late 2005, although the global community did not agree to the Pandemic Influenza Partnership Framework until 2009, and issues of sample and benefit sharing remain contentious.

These programs and agreements created momentum for approaching infectious disease threats on a new global scale, engaging a broader group of public and private sector stakeholders. In September 2011, US President Barack Obama announced at the United Nations General Assembly that the US had signed an agreement with WHO on global health security, urging "all nations to join us in meeting the WHO's goal of making sure all nations have core capacities to address public health emergencies in place by 2012."⁴

However, gaps remained: While many countries strengthened their capabilities for disease detection and response under IHR (2005), only about 20% reported that they had fully met their obligations by the June 2012 target date.⁵ US government programs and resources to enhance global public health preparedness continued to expand in the absence of a whole-of-government strategy to guide and measure the impact of investments.⁶

The launch of the Global Health Security Agenda in early 2014 and the US government's accompanying commitment to specific overarching targets in global health security⁷ attempt to address both of these challenges by reinvigorating capacity-building efforts and accelerating progress toward global public health preparedness, including fully implementing IHR (2005) worldwide.

This article describes how and where IHR and GHSA intersect, how success in both will be measured, and what GHSA means for sustaining IHR implementation after the final 2-year extension period in 2016.

THE INTERNATIONAL HEALTH REGULATIONS (2005)

In May 2005, the 58th World Health Assembly (WHA) agreed to revise the International Health Regulations.⁸ The revised International Health Regulations [IHR (2005)], which entered into force for most countries in June 2007, aim 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."⁸ These goals echo historical agreements but encompass a much more ambitious set of actions. The now-196 States Parties (including all 195 WHO Member States) agreed to a new standard of reciprocal responsibility among nations and committed to developing the core capacities required to detect, assess, report, and respond to any public health event that might cross borders, whether of natural, accidental, or deliberate origin.⁸

Binding Obligations

The IHR (2005) conferred new responsibilities on WHO and the global health community to share resources, information, and expertise to help nations prepare for and respond to health emergencies. Annex 1 of the IHR (2005) outlines the functional capabilities States Parties must develop in order to detect and respond effectively to public health events. This framework offers national officials latitude in determining how best to achieve these capabilities in the context of existing systems and anticipated risks.

The regulations themselves define only a few specific steps that States Parties must take to achieve IHR obligations, such as appointing a National Focal Point (NFP), accessible at all times (24 hours a day, 7 days each week), to serve as the main point of communications between WHO and government officials on all aspects of IHR implementation. The IHR also mandate transparent and timely reporting of public health events and require countries to develop and maintain “the capacity to detect, assess, notify and report” such events through appropriate laboratory and diagnostic capacities; the ability to conduct epidemiologic investigations at the community level; a national emergency response plan backed by adequate logistical support; communications among health officials at every level, across government sectors, and with WHO; and rapid response teams capable of responding to public health events within 48 hours.

Countries must develop legal and regulatory mechanisms to ensure all IHR (2005) obligations will be met. This means translating the international agreement into laws that are relevant and manageable for public health officials, starting at the national level and going all the way down to the local level. This is especially true in federalist countries like the US, where the core capacity requirements (eg, surveillance, response, reporting) are often a local or intermediate government responsibility.

Ensuring that every country possesses the capacity to detect and respond to a public health event before it spills across borders helps protect national, regional, and global security interests. The IHR (2005) framework resonates with US global health and biological security priorities. Many US government agencies now include the IHR (2005) in disease surveillance and response capacity-building strategies.^{9,10}

Measuring Progress under IHR (2005)

In 2010, WHO published the IHR (2005) Core Capacity Monitoring Framework and an accompanying IHR Monitoring Tool to help national health officials self-assess progress against country-level indicators for capacity building for 8 core capacities (national legislation, policy, and financing; coordination and NFP communications; surveillance; response; preparedness; risk communications; human resources; laboratory), at points of entry, and for 4 specific hazards in addition to priority infectious diseases

(zoonotic, food safety, chemical, and radiological and nuclear events).

Within each country-level indicator, WHO identified attributes associated with increasingly sophisticated capabilities against which countries can compare their own progress, both for internal planning and to use in reporting on IHR implementation to WHO. These define baseline capacities, programs, policies, or capabilities while still allowing countries wide latitude in defining how these activities and operational plans fit into the context of their national priorities and systems. Attributes are sorted into capability levels: prerequisite, or foundational capacities are categorized as < 1; Level 1 as inputs and processes; Level 2 as outputs and outcomes; and Level 3 as “additional” attributes that reflect advanced achievement (primarily the ability to share lessons learned with the international community).¹¹ WHO has also developed other tools to assist countries in IHR implementation, including guidance on implementing national legislation and establishing an IHR national focal point.¹²

Seven years after the IHR (2005) entered into force, little sharing of best practices has occurred between regions. Many nations lack the resources and expertise to develop actionable national IHR plans; the undefined costs and broad scope of achieving compliance initially created a barrier to marshaling donor assistance effectively. States Parties agreed to report to WHO by June 2012 whether they had achieved the required core capacities to implement the regulations, or whether they would require at least one 2-year extension to meet their IHR obligations. Over 80% of nations—including many at high risk of emerging infectious disease outbreaks and other public health crises—requested such an extension and still face significant challenges in achieving the IHR core competencies.

In June 2014, States Parties are required again to report to WHO whether they have fully achieved the IHR core capacities (determined by self-assessment using WHO guidance) or will require another 2-year extension. This provides an opportunity to assess global and granular progress in achieving the targeted IHR capacities and to determine what still needs to be done for the 118 countries that successfully requested the first 2-year extension as well as for those that have not developed—let alone implemented—concrete plans.⁵

HOW GHSA AND IHR (2005) INTERSECT

GHSA aims to elevate political attention and encourage multistakeholder participation, coordination, and collaboration while leveraging previously existing commitments and multilateral efforts such as IHR (2005) and the World Organisation for Animal Health (OIE) Animal Health Codes.¹³ Documents published by the White House since February 2014 describe the US government’s overarching target for numbers of partner countries and the general

milestones that the US government will use to measure its own progress.¹³ The agenda itself includes 9 distinct objectives intended to accelerate progress toward global capacity to prevent, detect, and respond to infectious disease threats. Eight of these 9 objectives (enumerated in Tables 1 through 3) relate in whole or in part to IHR capacity-building efforts; the ninth (“launching, strengthening and linking global networks for real-time biosurveillance”) refers to the promotion of “interoperable, networked” systems for real-time sharing of public health surveillance information and specifically to linking such networks to

regional disease detection hubs, an approach not advocated in the IHR agreement or the state-centric IHR core capacity-building guidance.

The 3 areas into which the GHSA objectives are grouped—prevent, detect, and respond—obviously overlap with the core capacity requirements to detect, assess, report, and respond described in the IHR agreement. Although the IHR (2005) do not refer to prevention, many attributes described in the WHO IHR Core Capacity Monitoring Framework (eg, laboratory biosecurity and biosafety, surveillance for antimicrobial resistance, hazard assessment

Table 1. GHSA and IHR Overlap for “Prevent”

GHSA Objectives (1-3)		Recommended Actions Under GHSA Objectives	IHR	Overlap
1	Prevent the emergence and spread of antimicrobial drug-resistant organisms	Reduce factors that enable antimicrobial resistance (AMR); improve surveillance for AMR; promote appropriate and responsible use of antibiotics in all settings.	Not explicitly described in the IHR agreement; the IHR Monitoring Framework (Response) calls for development of AMR surveillance systems to prevent transmission of antibiotic-resistant organisms in hospitals in the context of infection prevention and control.	Partial
	Prevent the emergence and spread of emerging zoonotic diseases	Reduce factors that enable emergence of zoonotic disease threats; increase surveillance for novel zoonotic diseases; promote safe practices in livestock production and animal marketing.	The IHR Monitoring Framework names zoonotic diseases a priority hazard, listing attributes that address multisectoral coordination between animal and human public health stakeholders to improve information sharing and integrated response to zoonotic events.	Yes
	Strengthen international regulatory frameworks governing food safety	Develop strategies to improve food safety.	The IHR agreement does not address strengthening international regulatory frameworks for food safety, but the IHR Monitoring Framework specifically names food safety as a priority hazard, listing attributes that address capacities for food safety and foodborne events monitoring and coordination between food safety stakeholders (including national liaisons to international food safety organizations) and the IHR National Focal Point.	Yes
2	Promote national biosafety and biosecurity systems	Develop multisectoral approaches to manage biological materials, including identifying, securing, monitoring, and storing dangerous pathogens in a minimum number of facilities; frameworks to advance safe and responsible conduct of research.	Not mentioned in the IHR agreement, but the IHR Monitoring Framework Laboratory Core Capacity includes attributes that broadly address laboratory biosafety and biosecurity, including the need for national guidance, biorisk assessments, and training.	Yes
3	Reduce the number and magnitude of infectious disease outbreaks	Establish effective programs for vaccination against epidemic-prone diseases and nosocomial infection control.	The IHR agreement addresses response to rather than prevention of outbreaks, but does call for nations to develop functional capabilities to respond to and control infectious disease outbreaks; the IHR Monitoring Framework includes attributes related to stockpiling and distribution of medical countermeasures.	Partial

Table 2. GHSA and IHR Overlap for “Detect”

GHSA Objectives (4-7)		Recommended Actions Under GHSA Objectives	IHR	Overlap
4	Launch, strengthen, and link global networks for real-time biosurveillance	Establish monitoring systems that can predict and identify infectious disease threats.	Strengthening surveillance is a key component of IHR, with attributes and milestones defined in Core Capacity 3 (Surveillance) in the IHR Monitoring Framework.	Yes
		Establish interoperable, networked information-sharing platforms and bioinformatic systems and networks that link to regional disease detection hubs.	While IHR explicitly addresses the process of notifying WHO IHR focal points of potential public health emergencies of international concern detected through national-level surveillance, neither the agreement nor the Monitoring Framework call for linking biosurveillance data to a regional hub.	No
5	Strengthen rapid and transparent reporting in the event of health emergencies of international concern	Strengthen capabilities for accurate and transparent reporting to WHO, OIE, and FAO during emergencies.	The IHR agreement requires States Parties to notify WHO of events rapidly (within 24 hours of assessing that an event may constitute a potential public health emergency of international concern).	Yes
	Strengthen sample sharing in the event of health emergencies of international concern	Rapid sample and reagent sharing between countries and international organizations.	The IHR agreement addresses sample sharing only by implication; the IHR Monitoring Framework under Laboratory (Core Capacity 8) calls for shipment of specimens for confirmatory testing by international reference laboratories.	Partial
6	Develop and deploy novel diagnostics	Strengthen country and regional diagnostic capacity at the point-of-care and point-of-need.	IHR does not explicitly call for the development and deployment of novel, point-of-care diagnostics.	No
	Strengthen laboratory systems	Strengthen laboratory systems capable of safely and accurately detecting dangerous pathogens with minimal biorisk.	IHR Annex 1 lists national-level support for laboratory testing as an element of the core functions (detect, assess, report, and respond); the IHR Monitoring Framework calls for nations to strengthen laboratory systems to detect and confirm priority diseases safely and reliably (with details focusing primarily on strategic coordination of national diagnostic laboratories).	Yes
7	Train and deploy biosurveillance workforce	Build capacity through trained disease detectives and laboratory scientists.	Core Capacity 7 (Human Resources) of the IHR Monitoring Framework addresses developing and sustaining a workforce for surveillance and response (including field-trained epidemiologists).	Yes

and mitigation) can be classified as supporting the GHSA “prevent” objective (Figure 1).

Prevent Avoidable Epidemics

GHSA aims to avert avoidable epidemics by helping nations prevent the emergence and spread of antimicrobial resistance (AMR) and emerging zoonotic diseases; strengthening international regulatory frameworks governing food safety; promoting national biosafety and biosecurity systems; and reducing the number and magnitude of infectious disease

outbreaks through vaccination programs and enhanced nosocomial infection control. Tables 1 through 3 demonstrate if and where these items are addressed in IHR.

Detect Threats Early

GHSA calls for nations to develop capacities for early detection, characterization, and transparent reporting of biological threats. GHSA calls for launching, strengthening, and linking global networks for real-time “biosurveillance,” strengthening the global norm for rapid and transparent

Table 3. GHSA and IHR Overlap for “Respond”

GHSA Objectives (8-9)		Recommended Actions Under GHSA Objectives	IHR	Overlap
8	Develop an interconnected global network of emergency operations centers	Establish emergency operations centers.	The IHR agreement calls for coordination and logistical support from the national level for rapid response. The IHR Monitoring Framework Core Capacity 4 (Response) address public health emergency management procedures for command, communications, and control; the development of a dedicated command and control operations center is categorized as a Level 3 or “additional” capability. There are no references to connections between such centers.	Partial
	Develop multisectoral response to biological incidents	Establish trained, functioning, multisectoral rapid response teams, with access to a real-time information system.	The IHR agreement calls for development of multisectoral response capacities at all levels, including development of rapid response teams that can be deployed within 48 hours; Core Capacity 4 (Response) of the IHR Monitoring Framework also refers to development of trained multisectoral rapid response teams that can be deployed within 48 hours of an urgent event.	Yes
		Develop capacity to attribute the source of an outbreak.	Neither the IHR agreement nor Monitoring Framework addresses attribution of deliberate events.	No
9	Improve global access to medical and nonmedical countermeasures during health emergencies	Strengthen capacity to plan for, produce or procure, and deploy personal protective equipment, medications, vaccines, and technical expertise and to deploy nonmedical countermeasures.	Core Capacity 5 (Preparedness) of the IHR Monitoring Framework refers to development of accessible national stockpiles and resource management during public health emergencies; attributes address national (rather than global) resources.	Yes

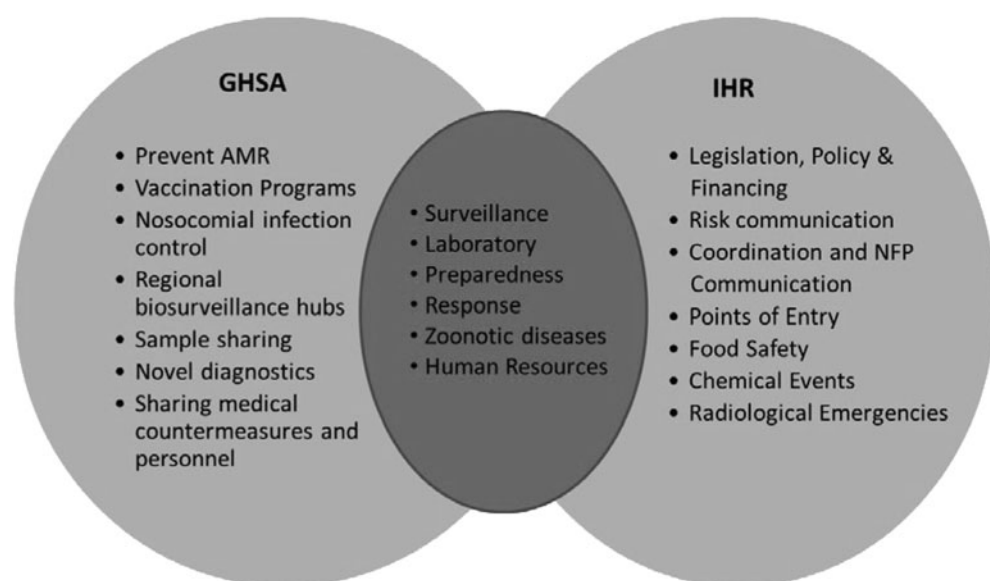


Figure 1. Diagram of GHSA Objectives and IHR Core Capacities

reporting to international organizations, rapid sample sharing, developing and deploying novel diagnostics, strengthening laboratory systems, and training and deploying an effective biosurveillance workforce.

Respond Rapidly and Effectively

GHSA calls on countries to develop an interconnected global network of emergency operations centers, with multisectoral rapid response teams; to develop abilities to make attribution assessments; and to improve global access to medical and nonmedical countermeasures during health emergencies (including policies and frameworks to share personnel and medical countermeasures with international partners).

MEASURING SUCCESS

The US has set overarching national targets under the GHSA framework that include an aggressive 5-year goal of working with at least 30 partner countries (covering an estimated 4 billion people) to build sufficient capacity to protect their populations—and ultimately the global population—against infectious disease threats.⁷ The US has outlined specific objectives, metrics, and milestones to set priorities and measure progress across agencies and initiatives.

To accomplish this task, the US government has proposed overarching targets that are measurable and “failable,” such as achieving immunization of at least 90% of the country’s 1-year-old children against measles, or establishing a reference laboratory capable of testing reliably for at least 3 of the WHO-designated AMR priority pathogens. However, specific metrics for most of the main objectives have not yet been clearly defined. One of the main questions is the source of information for such metrics: Will monitoring and evaluation depend on national self-assessments and self-reporting (as for the IHR Monitoring Tool)? Or will one or more external entities step up to collect data that can be used to credibly measure success toward the targets? It is not clear how many GHSA partner countries would willingly adopt the US targets and metrics—and would find external evaluation acceptable and valuable—rather than proposing their own measures of success based on national action plans in the local context. What might constitute baseline measurements for many of these policies and programs also remains unclear, creating a challenge for measuring the acceleration of progress under the priority areas shared by IHR, GHSA, and any other related initiatives.

Annual reports from States Parties on IHR implementation have been proposed as a proxy baseline measurement for GHSA metrics. However, IHR implementation is measured through yearly self-reporting by countries, using the IHR Monitoring Tool (which links to the 20 country-level indicators and 256 associated attributes classified by capability levels in the IHR Monitoring Framework). The self-

assessments measure binary responses (yes/no) on achievement of each attribute across all of the 8 core capacities, 4 hazards, and points of entry, in the context of the capability rankings at Levels <1, 1, 2, or 3. Countries must indicate that they have achieved all of the attributes under capability Levels 1 and 2 for each country-level indicator, and for all of the country-level indicators in each specific core capacity, to be deemed as having fully achieved that core capacity: Achieving all of the core capacities means that the IHR have been fully implemented. The IHR Monitoring Tool primarily measures high-level activities or outcomes (eg, the country-level indicator for routine indicator-based surveillance with an early warning function includes the attribute, “timely reporting from at least 80% of all reporting units takes place”). At the national level, determining whether or not attributes have been achieved requires communications across sectors and levels, as well as the use of more specific monitoring and evaluation criteria in many specific technical areas to serve as a basis for responding to the IHR Monitoring Tool questions.

Lessons can be drawn from this experience in developing more specific metrics for the GHSA objectives and targets. For example, many low- and middle-income countries have requested and received support from WHO regional offices and subject matter experts at WHO headquarters to conduct field assessments for all core capacities, creating an extensive pool of knowledge on practices, utility, and drawbacks of in-depth gap assessments that must address not only entire public health systems, but supporting capacities in animal health, transportation, trade, and other sectors. With this experience, WHO reduced the extensive protocol for field assessments to a more manageable desk review tool that can be distributed to key stakeholders at all levels and then integrated into a national assessment under the leadership of the IHR national focal point.

The experiences with national self-assessments under IHR also point to the challenges in finding a balance between prescriptive metrics that might not fit all national or regional contexts and metrics that can be applied flexibly in almost any context but rely heavily on the expertise, resources, and time available to the individual ultimately responsible for completing any assessments. The IHR Monitoring Framework itself resulted from requests by national stakeholders for more specific guidance on how to evaluate progress toward the core capacity requirements that are described functionally in Annex 1 of the IHR agreement.

Ultimately, the metrics most likely to be useful in assessing whether and how GHSA accelerates progress toward global health security are those that combine measurements of processes, such as developing a targeted infrastructure or human resource capacity, with performance-based assessment tools that evaluate functional outcomes, such as the time between the index case of a priority disease and the first reports of the event to the appropriate level for action, or the number of reported cases supported by laboratory confirmation. Examples can be drawn usefully from systems

that have already been tested internationally to measure progress toward disease control and prevention targets, and from the setting of international standards that can be adapted nationally for certification or accreditation processes.

While many of the 256 attributes outlined under the monitoring framework align with GHSA targets, they are not one and the same. For example, no specific attributes under the IHR Core Capacity Framework address effective programs for vaccination against epidemic-prone diseases. A detailed assessment of how the GHSA targets and objectives align and can be measured with IHR attributes is provided in Supplementary Table 1 (available online at www.liebertonline.com/bsp).

IHR Post-2016

Technically, the last self-assessment reporting deadline for IHR implementation described in the IHR agreement will come in June 2016, but the process of monitoring the development, strengthening, and sustaining of IHR (2005) core capacities is not expected to end with the final 2-year extension period. WHO is developing guidance on post-2016 reporting and implementation support, as well as elaborating on the process for evaluating, collaboratively revising, and supporting national action plans for those States Parties that submit a 2-year extension request in June 2014. One of the most important steps to ensure success in meeting the requirements of the IHR (2005) is to measure acceleration through measuring and *understanding* baselines. Clearly, financial resources will be required to scale up programs for disease detection and response, building on existing systems. However, resources can also include the sharing of best practices and lessons learned, as well as the analysis of structural obstacles that prevent national health officials from achieving their goals for capacity building, event detection and verification, and effective responses. By finding areas of overlap between the objectives of IHR and GHSA, and by developing tools and forums to share information on capacity building and lessons learned in public health preparedness, the US and its partners in GHSA have the opportunity not just to accelerate progress toward global health security, but to build a blueprint for sustaining those gains well beyond 2016.

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