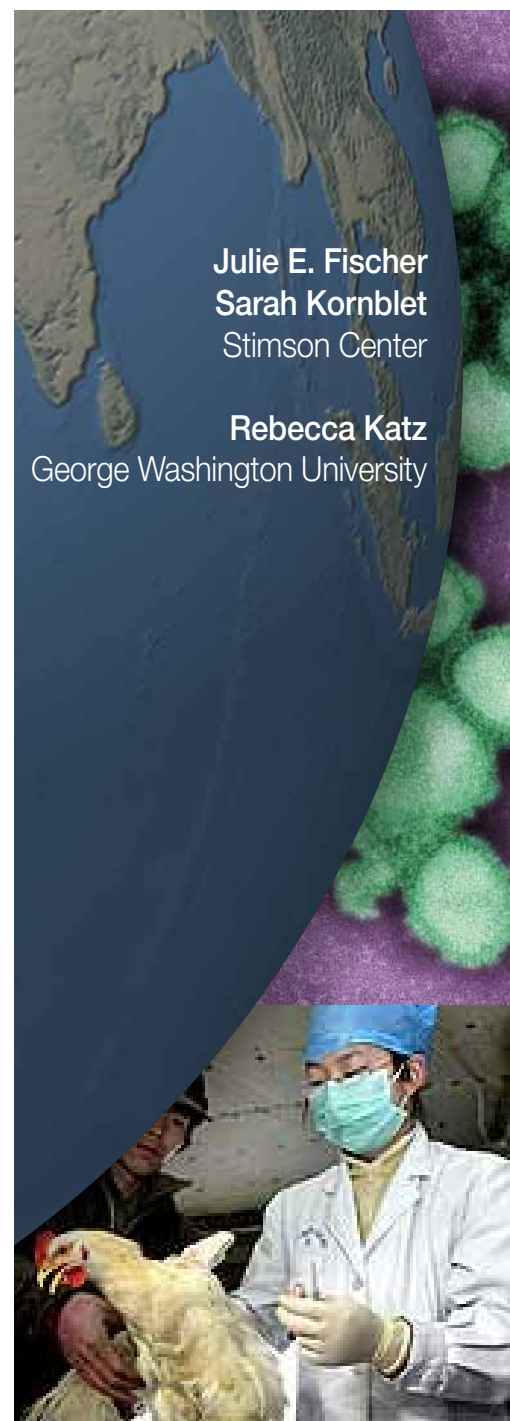




STIMSON



The International Health Regulations (2005): Surveillance and Response in an Era of Globalization



Julie E. Fischer
Sarah Kornblet
Stimson Center

Rebecca Katz
George Washington University



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Stimson Global Health Security Program

Julie E. Fischer, PhD

Sarah Kornblet, JD, MPH

School of Public Health and Health Services, George Washington University

Rebecca Katz, PhD, MPH

1111 19th St NW

12th Floor

Washington DC 20036

<http://www.stimson.org>

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EXECUTIVE SUMMARY

In an era of routine air travel and disease multipliers born of human behaviors, a public health crisis anywhere in the world is a potential problem everywhere.

For over one hundred years, nations have negotiated measures to prevent cross-border disease spread. Approaches that endured through the twentieth century focused on protecting international trade and travel by harmonizing the public health measures taken at ports, and on protecting public health through notification procedures for a few specific diseases. Over time, these agreements lost significance as the handful of diseases they addressed faded as threats to global commerce. Traditional regimes had no answer to newly emerging infections such as HIV or to re-emerging infections like multidrug-resistant tuberculosis that spread in more virulent form or to new populations.

In 1995, the Member States of the World Health Organization (WHO) agreed on the need for better disease surveillance and response tools on a global scale. A decade later, in the wake of the international SARS epidemic and the spread of a deadly “bird flu,” WHO’s governing body accepted the dramatically revised International Health Regulations [IHR (2005)].

Transforming international public health cooperation

The IHR (2005) focus on containing public health threats where and when they occur, rather than solely at ports and borders. They emphasize flexible responses to any potential public health emergency of international concern, instead of preset measures for specific diseases. The revised regulations also confer new obligations on countries to report health crises in a timely and transparent way, and new responsibilities and authorities on WHO to coordinate international responses to these crises.

Most significantly, the agreement requires all 194 States Parties to strengthen and maintain core capacities for disease detection, assessment, reporting, and response – capacities that are very uneven worldwide. Countries must develop the legal and regulatory mechanisms, physical infrastructure, human resources, and tools and processes necessary to ensure that all IHR (2005) obligations can be met, all the way down to the community level. This demands long-term cooperation across disciplines and sectors. The revised regulations entered into force in 2007, beginning a two-year planning phase followed by a three-year implementation period. (Nations may request up to two 2-year extensions if they fall short of the 2012 deadline for compliance.)

Building global health security at home and abroad

The US formally accepted the IHR (2005) on 3 December 2006 through an Executive Agreement by the President. Nineteen Federal agencies, led by the Department of Health and Human Services (HHS), worked with the White House to craft the US position during the IHR revision process. Fewer play active roles in implementing the regulations. The HHS Assistant Secretary for Preparedness and Response (ASPR) leads these efforts, coordinating the review, assessment, and notification of potential public health events and promoting domestic

implementation and compliance. US disease detection and response capabilities rely heavily on state and local public health capacities. Communications between the state and Federal levels and across sectors remains a serious challenge. Despite these perennial challenges, the US is generally assumed to be well within the requirements for IHR (2005) compliance.

The outlook is less rosy in other regions. The IHR (2005) framework assumes that countries will build their national public health surveillance and response capacities on the foundations of functional health systems. Many weak states fall short of this prerequisite, and a larger number of low and middle income states face solvable but serious gaps. The onus is on national public health leaders to define how they will implement the regulations, and to find the necessary resources. The IHR (2005) created no formal finance mechanism to support implementation. The scope of capacity-building and the lack of defined metrics present a quandary for donors who are uncertain about what it might mean to help partner nations fund IHR compliance.

The global disease detection and response network is only as strong as the weakest link. Article 44 of the revised regulations encourages states to collaborate “to the extent possible” in detecting and responding to health crises, and in sharing technical, logistical, financial, and legal support to help other states implement the IHR (2005). As the largest bilateral donor of health assistance, US leadership and responsibilities in this area are preeminent. The US recently initiated a more robust dialogue among states at various levels of economic development, with the ultimate goal of cultivating IHR (2005) capacity-building partnerships.

Aligning local public health and global biosecurity priorities

Many countries have begun to invest in strong health systems at home and abroad. Reliable public health surveillance lies at the foundation of efficient health systems, and at the core of the IHR (2005). The IHR framework offers the global health community a template for cooperative capacity-building efforts that build local capabilities for evidence-based health policies *and* reinforce measures to prevent naturally, accidentally, or deliberate released infections from spreading internationally.

This is no guarantee of long-term success. The IHR directly touch on politically charged issues from individual rights to state sovereignty. The legal mandate of the revised regulations may be a tool to empower health ministers within their own governments, but can also be perceived as an unfunded mandate on nations with other health priorities. Building the necessary capacities will require sustained commitment from national leaders inside and beyond the health sector, as well as consistent funding over the long-term.

US agencies – even those that have engaged in capacity-building for decades – will require new strategies to measure progress in building global disease detection and response capabilities. This includes a whole-of-government assistance strategy that breaks down programmatic silos among security, science, and health actors.

INTRODUCTION

In an era of routine air travel, robust international trade, and disease multipliers born of human behaviors, a public health crisis anywhere in the world is a potential problem everywhere. Emerging infectious disease outbreaks of the past two decades pressed policy makers to strengthen the health systems designed to protect people and nations. The SARS epidemic, in particular, evoked widespread recognition that better disease surveillance and response tools are needed on a global scale.

For over one hundred years, nations have negotiated measures to prevent cross-border disease spread. Approaches that endured through the twentieth century focused on notification procedures for a few specific diseases, allowing nations to implement control measures at ports and borders. These agreements emphasized the protection of international trade and travel from inconsistent public health policies as much as the protection of the public's health from imported diseases. Over time, as the handful of diseases that they aimed to control faded as threats to public health and commerce, the regulations themselves lost significance.¹

The emergence of infectious diseases from hemorrhagic fevers to HIV highlighted the need for a new brand of international public health cooperation, flexible enough to anticipate the unexpected and strong enough to respond to potential emergencies before they spill across borders. In 2005, the Member States of the World Health Organization (WHO) agreed to the dramatic overhaul of the International Health Regulations (IHR). The revised IHR went into effect in 2007, creating a new urgency for all 194 States Parties to develop systems capable of detecting and responding to *any* public health threat. The 2009 H1N1 influenza pandemic tested these systems, and the willingness of states to report potential public health emergencies of international concern quickly and transparently. Although this first real test proved a qualified success in terms of information-sharing and cooperation under the revised regulations, the fallout included a backlash against the very institutions that had marshaled an unprecedented public health response.²

This white paper outlines the context for revising the IHR, describes the building blocks for global disease detection and response capabilities, and discusses the implications of the revised IHR for the United States as a domestic obligation and a platform for global health engagement. The purpose of this paper is to provide a basic framework for understanding the background and status of the regulations. This includes a brief historical overview of international public health cooperation, as well as the practical and political challenges to forging a truly global network for public health surveillance and response today.

Health Regulations in Historical Context

Globalization is not a new phenomenon. In the 19th century, East-West shipping costs plunged as new technologies transformed land and sea transport and key Asian economies opened their markets. People and everyday goods suddenly moved easily among expanded trade networks.³ Health risks also spread via the water and railways. As commerce intensified in the early 1830s, cholera – a devastating diarrheal disease endemic to South Asia – reached the growing cities of Europe and North America for the first time. The emerging infection spread in terrifying waves that left tens of thousands dead and incited social unrest. Governments responded by imposing variously stringent quarantine and isolation measures, built on equally varied “pre-germ theory” assumptions about how cholera spread.⁴

In 1851, France convened delegates from ten other European nations and Turkey to explore the possibility of standardizing quarantine regulations for cholera, as well as yellow fever and plague. Although this first International Sanitary Conference yielded no enduring agreements, it established that disease control could indeed be a suitable matter for diplomatic negotiations. This laid the groundwork for thirteen more International Sanitary Conferences though 1938, marked by progressively broader state participation and better scientific understanding of communicable disease transmission.⁵ By the late 19th century, delegates had framed assumptions that would remain at the heart of international disease control regimes for decades:

- Quarantine policies at points of entry/exit should be harmonized to minimize unnecessary and unpredictable interference with trade and travel;

IHR Timeline

- 1830s
New trade patterns allow cholera to spread from South Asia to Europe and North America, leaving hundreds of thousands dead
- 1851
France convenes the first International Sanitary Conference to explore agreement on harmonizing quarantine regulations for cholera, plague, and yellow fever
- 1892
Delegates to the seventh conference ratify the first International Sanitary Convention
- 1918-1920
“Spanish flu” pandemic kills 50-100 million people worldwide
- 1902 -1935
States create intergovernmental institutions [Pan American Sanitary Bureau (1902), Office International d’Hygiene Publique (1907), Health Organization of the League of Nations (1920)] to coordinate international public health measures
- 1948
World Health Organization (and its governing body, the World Health Assembly, WHA) created
- 1951
WHA consolidates existing international sanitary conventions into the singular International Sanitary Regulations (covering plague, cholera, yellow fever, smallpox, typhus, relapsing fever)
- 1969
The renamed International Health Regulations (1969) replace prior agreements; revisions eliminate but do not add diseases
- 1995
Ebola virus outbreak in Central Africa captures global attention; WHA calls upon WHO Director-General to overhaul the IHR
- 2003
SARS spreads from China to 25 other countries via air travel
- 2005
WHA adopts the revised International Health Regulations (2005)
- 2007
IHR (2005) enter into force in 194 countries, beginning 5-year assessment and capacity-building period
- 2009
Pandemic H1N1 influenza A tests IHR (2005)

- Nations need some mechanism to report outbreaks of mutually high-priority diseases to other countries that might be affected; and
- States must develop and maintain adequate public health capacities – a continually evolving standard – to protect themselves from imported outbreaks.⁶

In 1892, delegates to the seventh conference ratified the first International Sanitary Convention. Although this first agreement focused narrowly on quarantine measures for cholera along specific shipping routes, more agreements on cholera followed. Conferees ratified a convention on plague control measures in 1897. A 1903 action combined these into a single International Sanitary Convention. Throughout the next five decades, participating states negotiated a variety of measures to control health risks considered particularly likely to affect travel and trade (with an emphasis on diseases originating in Asia and the Middle East, reflecting the apprehensions of the maritime powers).⁷

Those faced with implementing such measures soon recognized that new intergovernmental institutions would be needed. Regional organizations in Europe and the Americas and the short-lived health offices of the League of Nations tested mechanisms to manage international public health reporting obligations. Major and minor conflicts could disrupt progress. Civilian and troop movements in the wake of World War I helped propagate cross-border epidemics on a devastating scale, including the 1918 “Spanish flu” pandemic that killed 50-100 million people worldwide.⁸ During World War II, Allied forces cooperatively addressed diseases of military importance, forging successful strategies to control risks such as malaria even as infectious diseases from typhus to tuberculosis resurged in war-ravaged Europe.⁹

These organizational experiences and fresh memories of health catastrophes underlay the creation of WHO as a specialized agency of the United Nations in 1948. The WHO constitution asserted the “health of all peoples is fundamental to the attainment of peace and security,” and established the organization’s authority to direct and coordinate international health activities under the direction of its policy-making arm, the World Health Assembly (WHA).¹⁰ In 1951, WHA member states agreed under the authority of Article 21 of the WHO Constitution to consolidate the various conventions and regulations still in force into the International Sanitary Regulations,ⁱ a single standard for notification of and public health responses to potentially infectious travelers or goods.¹¹ As opposed to previous “opt in” treaties that had been notoriously difficult to enforce and required states to give express consent to be obligated by international law, the new “opt out” regime in the WHO Constitution automatically bound all Member States to monitor, report, and control specific diseases within their borders.¹² WHO revised those parts of previous conventions that had become obsolete and consolidated the new regulations around six infectious diseases: smallpox, relapsing fever, typhus, cholera, plague and yellow fever.¹³ In 1969, the regulations were updated and renamed the

ⁱ Article 21 of the WHO Constitution allows the World Health Assembly to adopt measures within specific focus areas, including prevention of the international spread of disease. Article 22 of the WHO Constitution states that these WHA-adopted regulations become legally binding on Member States without any further action (e.g., ratification) unless they notify the Director-General of rejection or reservations within a specified time – this is known as the “opt out” clause.

International Health Regulations [IHR (1969)].¹⁴ Their fundamental thrust – preventing the spread of specific diseases while protecting trade and travel – remained unchanged.

By that time, antibiotics, vaccines, and pesticides had already changed the equation for these historically relevant pathogens. Naturally occurring smallpox would be eradicated only a few years later, and the WHA correspondingly revised the IHR (1969) for the last time in 1981 to exclude smallpox from the list of notifiable diseases. By that time, the scope of the IHR (1969) had narrowed to the three original priority diseases (yellow fever, plague, and cholera), leaving the core of the regulations intact in the absence of an obvious alternative. Thanks to public health and clinical advances, leaders in developed countries no longer considered the three diseases serious threats to domestic public health. The political will to uphold the regulations waned among resource-rich states, encouraging the indifference of less-developed nations that had little to gain from self-reporting. The global health landscape continued to evolve. Changing human, animal, and vector behaviors and environmental pressures gave rise to new health risks. Experts began to report an average of one newly discovered infectious disease of public health significance each year. The IHR (1969) had no answer to emerging infections such as Ebola virus or to re-emerging infections such as dengue fever that spread to new populations or returned to old ground in more virulent form.¹⁵ Most importantly, the regulations had no means to adjust to an explosion in international air travel that now sees an estimated 2.2 billion passengers each year.¹⁶

The Changing Global Health Landscape

Global health experts needed to look no further than the health and development crisis of HIV/AIDS to validate their fears about the threat of emerging infections. In 1981, the US Centers for Disease Control and Prevention (CDC) reported seeing for the first time a cluster of unusual pneumonias in homosexual men. The number of diagnosed cases climbed quickly among high-risk groups in the US and Europe.¹⁷ Doctors working in Uganda (and in Europe with patients from or linked to East and Central Africa) soon described similar patterns of opportunistic infections and aggressive cancers in previously healthy individuals.¹⁸ Accumulating evidence pointed to an underlying infection that had reached epidemic proportions over decades in urbanizing sub-Saharan Africa without triggering any official alarms until human behaviors spread the slow-progressing disease internationally. In 1983, WHO convened its first meeting on AIDS (acquired immune deficiency syndrome), initiating global surveillance for the virus eventually termed HIV (human immunodeficiency virus). Many nations reacted quickly and independently, requiring travelers to undergo HIV tests before entry, prohibiting HIV-infected foreigners from temporary or permanent residency, and authorizing law enforcement officials to turn away anyone who appeared to be infected.¹⁹ (The US only lifted its ban preventing entry of HIV-positive individuals into the country in January 2010).²⁰

By the mid 1990's, the Clinton Administration began to focus on two issues at the nexus of health and security: the potentially destabilizing effects of catastrophic HIV/AIDS prevalence on severely affected countries, and domestic vulnerabilities to natural or deliberate epidemics.²¹ These concerns reflected mounting public anxiety about microbial threats in the US and beyond. In 1995, WHA members adopted two resolutions tasking the WHO Director-General

with new responses to emerging and re-emerging infectious diseases. The first requested the revision of the IHR to achieve “maximum protection against the international spread of disease with minimal interference with traffic and trade.”²² The second called on WHO to develop and implement worldwide strategies for rapid containment of emerging and re-emerging infectious diseases, including strengthening national capacities for disease detection and response.²³ WHO created the Division of Emerging and Other Communicable Diseases (since succeeded by other structures) to coordinate these programs.²⁴ In January 2000, the UN Security Council recognized HIV/AIDS in sub-Saharan Africa as an international peace and security issue.²⁵ A few months later, the White House took the similarly unprecedented step of designating infectious diseases a threat to US national security.²⁶ Collectively, these actions signaled a “securitization” of health issues that, while still contentious in many quarters, leveraged new resources and political will to tackle public health risks on a global scale.

By the 1990s, experts had begun to call for a more robust and flexible international regime. With neither technical consensus nor a clear political mandate, they began painstakingly laying the groundwork for a truly global disease detection network – and an unprecedented level of international public health cooperation. Nevertheless, it took 10 years of intergovernmental negotiations, pilot testing, re-evaluation, and regional consultations, as well as another emerging infection crisis, to overcome political and procedural challenges to overhauling the IHR.²⁷ The latter came in November 2002, when rumors hinted at an epidemic of atypical pneumonia in China’s Guangdong Province. For a variety of reasons, China failed to disclose the emergence of the disease that would become known as SARS (severe acute respiratory syndrome) to the international community until a physician who had treated infected patients in Guangdong Province developed symptoms himself while visiting Hong Kong. He infected at least 13 guests and visitors to the hotel where he stayed, seeding disease clusters in healthcare workers, patients, and their close contacts in Hong Kong, Vietnam, Singapore, and Canada. SARS ultimately spread to about 25 countries, largely via air travel, before public health interventions interrupted the outbreak – which caused about 8000 cases, almost 800 deaths, and economic losses estimated at \$30-50 billion.^{28,29} WHO’s Director-General delved into the unfinished toolkit for global health governance, issuing advisories about SARS-affected regions and coordinating international efforts to understand and contain the outbreak. Because SARS was not a notifiable disease under the extant IHR (1969), China had no legal obligation to report cases to WHO, and WHO had no legal authority to require information from China in response to unofficial reports. These bald facts in the face of international recriminations helped reinvigorate the IHR revision process after nearly a decade of debate.³⁰

IMPLEMENTING THE INTERNATIONAL HEALTH REGULATIONS (2005)

In May 2005, the 58th World Health Assembly adopted the revised regulations, which entered into force for most countries on June 15, 2007.³¹ The IHR (2005) 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,” a goal that echoes the earlier regimes but encompasses a much more ambitious set of actions. The regulations legally bind the 194 States Parties (including all 193 WHO Member States) to a new standard of reciprocal responsibility among nations.³²

The revised IHR emphasize containing public health threats when and where they occur, conferring new obligations on countries to prepare for health crises, and new responsibilities and authorities on WHO to coordinate the international public health response. The success of this more flexible approach depends on national and sub-national capacities for disease detection, assessment, reporting, and response – capacities that are very uneven worldwide. For this reason, the IHR (2005) 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. The revised regulations create a framework for disease reporting while also defining what constitutes adequate local disease detection and response capacities.

The revised regulations also incorporated human rights principles. The IHR (2005) require nations approach domestic implementation with full respect for human rights and freedoms, as defined under the UN Charter and the WHO Constitution. When states are required to take measures for travelers suspected of carrying a contagious illness, this must be done through “the least intrusive and invasive medical examination that would achieve the public health objective of preventing the international spread of disease.”³³

Points of entry: Of the requirements in the revised regulations, those for points of entry most closely adhere to the spirit of earlier agreements. States Parties must still take action to control public health risks at borders, from routine inspection and certification practices to emergency preparedness for controlling the spread of diseases via shipping or air travel.³⁴ However, this does not apply equally to all ports and border crossings. The revised regulations allow national officials to identify the specific points of entry that will comply with the IHR (2005) core capacity requirements. WHO documents these in a published list of certified ports (that include air, land, and sea).³⁵ This gives nations the flexibility to concentrate on developing the sanitation services and public health competencies demanded by the IHR (2005), a challenging task for even well-resourced countries, at the points of entry they judge most vulnerable. Whether most States Parties will ultimately opt to include most major points of international transit remains an open question.

In other ways, the revised regulations diverge sharply from previous regimes. The table below illustrates the changes between the 1969 and 2005 version of the IHR, followed by detailed descriptions of actions and authorities under the revised regulations.

Table 1: Comparing the IHR (1969) and IHR (2005)

Area of focus	IHR (1969)	IHR (2005)
Type of threats	Specific infectious diseases	Any public health emergency of international concern (biological, chemical, radiological/nuclear, or other)
Focus of activities	Control disease outbreaks at ports and borders without hampering trade and travel	Detect, report, and contain any public health threats at ports, borders, and anywhere they might occur within national borders to prevent international spread, while minimizing impact on trade and travel
Risk assessment	Short list of diseases of historical significance (cholera, plague, yellow fever)	Decision instrument to evaluate the risks and potential impact of the public health event, prompting notification to WHO, where emergency committee of experts evaluates risk
Response	Pre-determined public health controls at points of entry	Flexible, evidence-based responses adapted to nature of threat
Communications	Nations identify appropriate authorities on an ad hoc basis	Notifications to and from WHO via designated IHR National Focal Points
National capacity requirements	Public health and infection control measures at ports of entry	Capability to detect, assess, report, and respond to public health threats in near-real time at national and community level

Risk assessment: WHO may declare any natural, accidental, or deliberate event a “public health emergency of international concern” (PHEIC) if it has the potential to affect health across national borders. This includes events of any origin, whether biological, chemical, radiological, nuclear or other disasters.

Previous regimes offered little flexibility, but also little ambiguity, in identifying an actionable crisis. The IHR revision process presented stakeholders with a quandary: in a system designed to detect emerging infections and other unpredictable events, what signals should national public health officials measure and report? Working groups finally incorporated one traditional tool: a short list of always notifiable diseases. Countries must always report outbreaks of smallpox, wild-type poliovirus, novel human influenza strains, and SARS to WHO under the IHR (2005).³⁶ However, they also created an innovative “Decision Instrument” to help countries assess whether an event constitutes a potential PHEIC (see Appendix 1). During unfolding public health crises, including outbreaks of important epidemic-prone diseases, the Decision Instrument algorithm that comprises Annex 2 of the IHR (2005) guides authorities through a series of questions:

- Is the public health impact of the event serious?
- Is the event unusual or unexpected?
- Is there a significant risk of international spread?
- Is there a significant risk of international travel or trade restrictions?

If the event meets any two of the four criteria, States Parties must notify WHO of a potential PHEIC.

Although WHO must consult with the relevant government(s), the Director-General determines whether an event constitutes a PHEIC based on available information, including the advice of an “Emergency Committee” of subject matter experts that she can convene in response to the crisis. The Emergency Committee can also provide guidance on appropriate national health responses. The Director-General issues such guidance as “temporary recommendations” which automatically expire after 3 months unless extended, modified, or terminated earlier.³⁷ Since the new regulations entered into force in 2007, only one PHEIC has been declared: the 2009 H1N1 influenza pandemic, discussed in detail below.³⁸

Sharing information: Each Member State must appoint a National Focal Point (NFP) to be accessible at all times (24 hours a day, 7 days each week) as the point of contact during health crises, and for all information regarding IHR (2005) implementation. The NFP provides a channel for open dialogue on public health risks and capacities among states, and fosters a sense of accountability to WHO. The NFP network offers a new and invaluable tool for communicating about international health risks and response.

In response to lessons learned during the SARS crisis, WHO can now seek information on unfolding public health events rather than passively awaiting official notification. WHO may take into account information from two previously off-limits sources: reports from national officials about public health risks *outside* of their own territories, and reports from unofficial sources, such as nongovernmental organizations, traditional media, or internet-based information networks. WHO can also request that national officials verify such reports within 24 hours. If the State Party refuses to collaborate despite evidence an event may constitute a PHEIC, WHO can share even unofficial information with other countries as necessary to coordinate an effective international response. To encourage the flow of information *and* protect against immoderate reactions, WHO must protect the confidentiality of information for countries that willingly report potential PHEICs unless it is necessary to disclose “for the purposes of assessing and managing a public health risk.”³⁹

Capacity-building: None of these new measures can actually improve the quality of global public health cooperation if national health authorities lack the ability to detect, assess, report, and respond to evolving public health events. When the revised regulations entered into force in 2007, States Parties began a two-year assessment period to evaluate their core capacities in these areas, and to develop an operational plan for strengthening and sustaining public health capabilities as necessary. Annex 1 of the revised regulations outlined where and how these core capacity requirements apply:

- *What is covered:* surveillance, reporting, notification, verification, response and collaboration activities;
- *Where:* from the national to the local level, and at points of entry;

- *How:* through appropriate laboratory and diagnostic capacities; ability to conduct epidemiological 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 teams to respond rapidly to emerging public health events – all on a 24/7/365 basis.⁴⁰

The Annex 1 requirements emphasized building on existing public health strategies, rather than creating a stand-alone system. Although Annex 1 provides a level of detail unprecedented in previous international agreements, it outlines high-level competencies rather than specific pathways to compliance. WHO and its regional offices have continued to develop guidance to States Parties on how these core capacity requirements might be met and measured since 2007. In the interim, many officials adopted national or regional benchmarks, one basis for the confidential report on progress toward IHR core capacities due each year to WHO. In early 2010, WHO published an IHR (2005) Monitoring Framework that mapped country-level indicators for capacity-building in eight categories, from the very specific (such as a human resources work plan) to broad areas such as national surveillance, preparedness, and response capabilities. These created a standard for comparison that still allows states wide latitude in connecting the core competencies to skills, activities, and operational plans.⁴¹

Countries must develop legal and regulatory mechanisms to ensure that 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 (e.g., surveillance, response, reporting) are often a local or intermediate government responsibility. WHO has developed a toolkit to help national authorities establish a legislative and regulatory framework for the IHR functions, including examples of national legislation and regulations already adopted by some Member States. Nevertheless, no matter how comprehensive, the guidance guarantees neither political will nor adequate legal resources to overhaul a national legal framework for public health. Different countries are using different mechanisms, including new legislation or regulations, memoranda of understanding between levels of government, and various other legal tools to ensure compliance, often on top of a contradictory patchwork of pre-existing public health laws.

Pathways to Implementation

Figure 1 illustrates the timeline for implementing the IHR (2005). This timeline hints at the challenges in achieving the promise of the IHR.

IHR (2005) Implementation Timeline

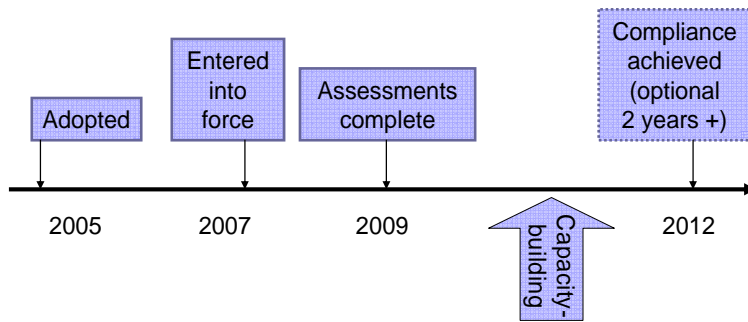


Figure 1. The revised regulations entered into force in mid-2007, launching a two-year period for nations to assess their existing disease detection and response capacities. States Parties must achieve compliance with core competency requirements by 2012, or request up to two optional two-year extensions.

First, many poor countries – already carrying heavy burdens of endemic and epidemic-prone diseases – will have a hard time meeting the core capacity requirements by 2012, the initial 5-year deadline for compliance. (Nations may request up to two 2-year extensions). Most national health authorities aim to achieve the rapid disease detection, reporting, and response capabilities outlined in Annex I of the revised IHR, but often lack political backing and resources. In practical terms, the legal mandate of the regulations gives health ministers leverage to request the resources necessary to meet IHR obligations. However, the onus is on country leaders to find the resources needed to implement the regulations.

Article 44 of the revised regulations encourages states to collaborate “to the extent possible” in detecting and responding to potential PHEICs, and in sharing technical, logistical, financial, and legal support to help other states implement the IHR (2005).⁴² Despite this, donors have been slow to roll out comprehensive assistance packages to help resource-constrained countries achieve the core capacities. Part of this is the tremendous scope of the challenge: strengthening public health surveillance and response systems from the top down to the community level requires a skilled health workforce, infrastructure, tools, and cross-sector communications and coordination. Few countries have openly shared information on their internal IHR (2005) implementation practices, such as lessons learned in capacity-building and from exercises and events. Evaluations of national and regional readiness remain inherently subjective. Without a standard global blueprint for achieving the core competencies, national public health authorities must map their own courses. Just figuring out where to start can be a daunting task.

Ultimately, each of the 194 States Parties may develop a unique but perfectly valid public health strategy for achieving IHR (2005) compliance. The capacity building required for disease surveillance and response in order to increase global health capacity will require a great deal of investment, but the IHR (2005) created no formal fund to help low and low-middle income countries make those investments. The lack of well-defined metrics and indicators presents a

quandary for donors who are uncertain about what it might mean to help partner nations fund IHR compliance. Recognizing this limitation, the US recently initiated a more robust dialogue among states at various levels of economic development, with the ultimate goal of cultivating IHR (2005) capacity-building partnerships.

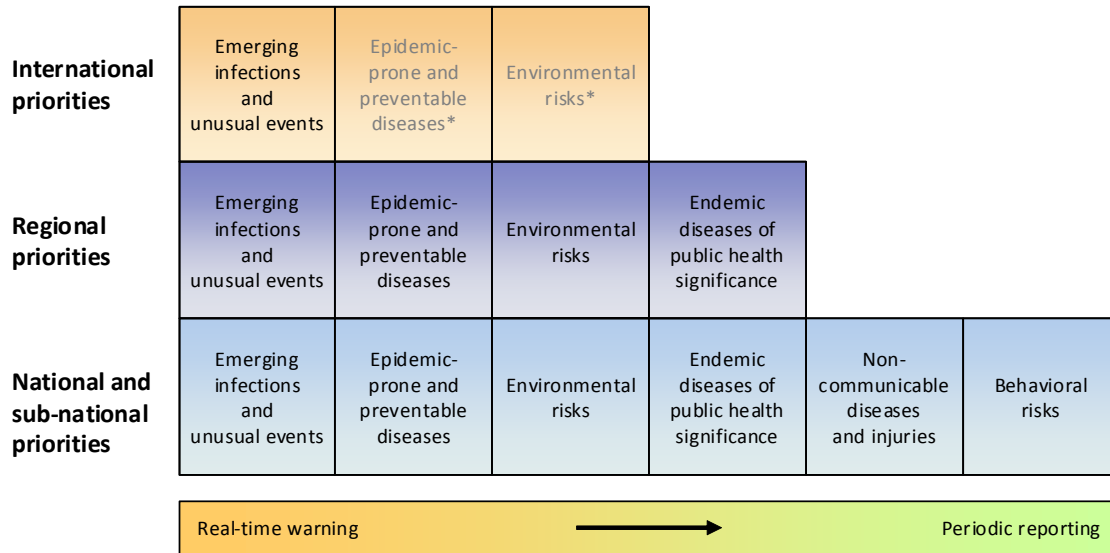
The second set of challenges regard state sovereignty. The socioeconomic impact of SARS helped tip the balance between the benefits of international cooperation and objections that IHR provisions would compromise national sovereignty. (This sea change mirrored developments in other areas of international policy, such as environmental law, where the majority of actors increasingly favored transnational responses to global threats rather than piecemeal cooperation between nation-states).⁴³ However, the act of adopting the revised regulations did not erase concerns that transparent reporting might impinge on national security. The IHR directly touch on politically charged issues, such as balancing individual rights against the public good to control the spread of disease, or preventing economic disruption during the discovery phases of a potential public health event. The legal mandate of the revised regulations may be a tool to empower health ministers within their own governments, but can also be perceived as an unfunded mandate on nations with other health priorities.

Perhaps more significantly, the IHR (2005) contain no formal enforcement mechanism or penalty for failing to comply. In fact, the WHO Constitution does not provide for sanctions against states, even for non-compliance with binding resolutions.⁴⁴ Compliance with the IHR (2005) relies in part on national leaders' recognition that containing public health threats when and where they occur – and helping other countries build the capacities to do so themselves – serves everyone's mutual interests.⁴⁵ Information and communications technologies play an important role in encouraging transparent and timely reporting. Numerous events of the last decade have demonstrated that even authoritarian regimes face serious challenges in suppressing "chatter" where mobile phones and internet access have become widespread. New public- and private-sector search engines comb internet records for evidence of unusual illnesses or behaviors that might foreshadow a public health crisis. The revised regulations give national leaders a mechanism to report potential public health crises before the news can be disclosed – or exaggerated – by unofficial sources. The increasing certainty that States Parties not acting in good faith will eventually be outed serves as a "shaming mechanism" to reinforce the revised IHR. Ultimately, all states risk economic penalties in lost travel and trade if a public health crisis occurs. Reporting under the IHR (2005) transparently and adhering to WHO's temporary recommendations at least gives states leverage in disputes over unduly imposed trade or travel restrictions, should these reach a forum such as the World Trade Organization.

SURVEILLANCE AT THE CORE: THE BUILDING BLOCKS OF GLOBAL HEALTH

Reliable public health surveillance lies at the foundation of efficient health systems, and at the core of the IHR (2005). Public health surveillance consists of systematic and ongoing collection, analysis, interpretation and timely dissemination of health data. The revised IHR set parameters for establishing adequate public health surveillance. Valid and accurate information allows decision makers to assess population health status, identify public health risks, gauge the magnitude and scope of threats, set priorities, evaluate interventions, track long-term trends, and shape the research agenda – in short, to take all of the steps necessary to plan and implement evidence-based health actions.⁴⁶ If all 194 States Parties achieve the IHR core capacities and participate fully in the IHR decision-making schemes, public health officials will have an integrated surveillance network designed to detect and, to the extent possible, control the spread of disease on a global scale.

Most global health initiatives – such as internationally funded responses to HIV/AIDS, tuberculosis, or malaria – include some public health surveillance component. Surveillance systems limited to a single disease or risk factor, while capable of improving the effectiveness of focused interventions, rarely spill over into improved general disease surveillance. Deliberately integrated disease surveillance programs can simultaneously target multiple diseases of local, regional, or global public health significance. The IHR (2005) address a subset of public health surveillance efforts: systems to detect, assess, and report emerging infections and other unusual health threats. Figure 2 illustrates the tiered relationship between public health surveillance targets by priority levels and by the urgency of the health actions that the information triggers. This framework also highlights how public health surveillance for emerging infections and unusual events, which demand speedy investigations, may fall outside the reach of targeted surveillance for diseases representing the greatest local burdens.



*IHR (2005) prioritize a subset of these threats

Figure 2. This graphic arrays public health surveillance targets by urgency of action, illustrating how international priorities (such as detecting emerging infections and unusual events) may represent only a subset of regional and national priorities, but build on the same foundation of core public health surveillance functions.

Types and elements of public health surveillance

The same principles underpin surveillance for any disease, condition, or behavioral risk, whether HIV or heart disease. Most public health surveillance efforts use specific case definitions to track the occurrence of high-priority diseases. For example, many countries have some system to register newly diagnosed cases of HIV, in order to estimate the incidence of HIV and target behavioral intervention programs to high-risk populations. Influenza surveillance looks for the predictable (seasonal increases in disease incidence) and the uncertain (the emergence of novel strains with the potential to cause unusually severe or widespread outbreaks). Although many public health systems monitor clinical syndromes, such as acute diarrheal or respiratory illnesses, diagnosis ultimately requires reliable laboratory testing validated through routine quality control and assurance practices.⁴⁷

Major disease control efforts such as the Global Polio Eradication Initiative depend on national and sub-national disease surveillance to identify outbreaks, facilitating cost-effective vaccination of vulnerable populations. This initiative, a public-private partnership between WHO, the US CDC, UNICEF, and Rotary International, with financial support from the Bill and Melinda Gates Foundation, also illustrates the growing complexity of stakeholder relationships in global health. Clearly, non-governmental organizations and public-private partnerships contribute to disease surveillance and response efforts, making the IHR (2005) platform – with its explicit recognition of private sector actors – an even more vital tool for developing a common vocabulary for building clinical, diagnostic, and epidemiological capacities that transcend disease-specific programs.

In outreach to potential partners on the value of supporting IHR compliance, certain distinctions about different categories of public health surveillance should be clear. For example, passive surveillance relies on clinics, hospitals, and laboratories to report notifiable diseases to authorities. Such provider-driven networks can be cost-effective, but central authorities have little control over system sensitivity and data quality. Active surveillance, on the other hand, prompts health authorities to collect or request information from healthcare providers or laboratories. Health initiatives that demand active surveillance often compensate for the additional technical workload by supporting surveillance officers directly, either through local hires or by bringing in outside experts, yielding better quality data. The disadvantage is the cost, which in poor countries and even poorer communities of wealthy countries may not be sustainable.

The IHR (2005) aim to build the capacities for ongoing “event-based” public health surveillance from the ground up, which requires real-time capacities in data collection, assessment, and response that might otherwise be a luxury. For example, conditions such as non-communicable diseases and injuries or behavioral risks do not generally require urgent health actions; the collection and analysis of information for such conditions over weeks, months, or years is perfectly acceptable. The response to epidemic-prone or emerging diseases must be more prompt, ideally using near-real-time data collection, analysis, and rapid dissemination to produce guidance for timely and effective health actions.⁴⁸

Decision makers have increasingly placed new demands on public health surveillance systems to provide early detection of outbreaks. Also referred to as early warning, scenario-based, or event-based surveillance – efforts to detect public health risks before they affect large populations depend on the ability to identify and investigate case reports, analyze patterns, and process data in a timely way.⁴⁹

All disease surveillance efforts depend upon adequate infrastructure (including clinical and laboratory facilities and mechanisms for collecting and disseminating data); tools, such as appropriate protocols, diagnostic tests, and equipment; and workers with adequate skills and knowledge. Even when single-disease surveillance programs operate in the same geographic area, funding and technical restrictions often functionally segregate workers and diagnostic resources into completely unrelated systems. Whether in sub-Saharan Africa or North America, a country may host dozens of public health surveillance programs that collect data on single diseases of local or global importance. Their findings often remain within operational silos in the absence of information-sharing networks. This is a serious concern. First, decision makers may see only a fragmented picture of health events at any given time. Second, skilled health and laboratory workers are a finite resource in every region. Developed countries often seek to amplify public health warning signals by knitting together information from a variety of clinical, laboratory, and other sources, often through automated reporting. Low-tech approaches can work as well. Examples from the WHO African Region and individual nations, such as the Philippines and Guatemala, have shown integrated disease surveillance and response strategies can target many high-priority diseases at once by emphasizing cross-training of personnel at the

appropriate levels (community, health facility, district, national, and supra-national) and equipping them with the appropriate skills, resources, and tools.⁵⁰

What does “capacity-building” mean in public health surveillance?

WHO, other international organizations, and bilateral donors – including the US CDC and the Department of Defense – have engaged partner nations to build disease detection and response capacities over decades. Capacity-building spans the national to the local level, emphasizing public health activities such as epidemiological investigations, laboratory diagnosis, specimen transport, clinical management, information management, communications systems, administration, and the legal/policy environment. In some cases, building infrastructure means actually constructing entire laboratory facilities from the ground up. More often, initiatives ensure that local facilities have the equipment, supplies, skilled personnel, and support systems necessary to detect and report cases of the disease or diseases targeted by that surveillance program. Training plays an essential role, from short courses in case detection or diagnostic techniques to multi-year post-graduate programs that support high-quality epidemiological investigations. For example, CDC developed the Field Epidemiology (and Laboratory) Training Programs based on the model of the US Epidemic Intelligence Service. This training combines classroom and field activities, with CDC providing technical and financial assistance to help partner ministries of health launch their own programs. Trainees attain skills and professional credentials while providing the “shoe leather” to investigate public health events.⁵¹ Mature FE(L)TP efforts, such as Thailand’s, extend training opportunities to professionals from less-developed neighboring states, further expanding international communities of practice. The mature programs are intended to be self-sustaining, as graduates of the program take over the training tasks, allowing CDC to phase out its direct participation in stages. The partner nations gradually assume leadership of the programs, building indigenous epidemiological capacity and professional networks.

Sustainable capacity building relies not only on the long-term availability of resources, but on the perception that the systems are useful. This, in turn, means the information from public health surveillance systems must be accessible and useful for routine decision-making as well as crisis response.⁵² For single diseases or conditions, it is a relatively straightforward process to identify the chief data consumers, and to validate the quality of data. Testing the ability of public health surveillance systems to detect and present useful information for unexpected crises is more complicated. The ability of such systems to detect seasonal epidemics or clusters of disease (such as food-borne illnesses) at the community level can serve as a proxy to assess the sensitivity, specificity, and utility of reporting.⁵³

The IHR (2005) establish goals for general public health surveillance capacities, rather than for a specific disease or condition. This is a new development, even for organizations that have engaged in capacity-building for decades. Most have historically measured inputs such as funding, or outputs such as training sessions in the absence of a gold standard for measuring outcomes objectively. US agencies such as the CDC and the military that engage in long-term training or laboratory programs jointly operated with partner nations are in the process of identifying more robust indicators, such as tracking the number of diagnostic tests that can be performed within a country over time.⁵⁴

IMPLICATIONS OF THE IHR (2005) FOR THE UNITED STATES

The US formally accepted the IHR (2005) on 3 December 2006 through an Executive Agreement by the President. Federal officials entered one reservation to the IHR (2005): the US would comply only “to the extent that the implementation of [the] obligations come[s] under the legal jurisdiction of the Federal Government.” With that caveat, they committed to recommending that the 50 states implement the IHR obligations under their jurisdictions.⁵⁵ This so-called “Federalism Reservation” reflects the language in the 10th Amendment of the US Constitution, which reserves to the states or the people any power not granted to the federal government.⁵⁶ Public health generally falls to the responsibility of the states.

The US also filed three understandings (i.e., interpretations) of the IHR (2005). The first affirmed the US understanding that State Parties have an obligation to report potential PHEICs to WHO regardless of their origin or source, and whether the release of biological, chemical, or radio-nuclear material was natural, accidental, or deliberate.⁵⁷ The second stipulated that the US would not be obligated to report evidence to WHO of a potential PHEIC if such notification would interfere with the US Armed Forces’ ability to “operate effectively in pursuit of US national security interests.”⁵⁸ The final understanding asserted that the revised regulations do not create judicially enforceable private rights. The latter understandings, echoed by several other nations, effectively reinforced state sovereignty in the context of the regulations.

Domestic Implementation

Nineteen different Federal agencies, led by the Department of Health and Human Services (HHS) with oversight by the White House National and Homeland Security Councils, participated in crafting the US position during the IHR (2005) revision process. Fewer play active roles in implementing the regulations. The HHS Assistant Secretary for Preparedness and Response (ASPR) leads these efforts, coordinating the review, assessment, and notification of potential PHEICs and promoting domestic implementation and compliance. The HHS Secretary’s Operations Center serves as the US IHR National Focal Point.

Table 2: US Federal Agencies Involved in IHR 2005 Negotiations

▪ Central Intelligence Agency	▪ Department of Justice	▪ Nuclear Regulatory Commission
▪ Department of Agriculture	▪ Department of State	▪ Office of Management and Budget
▪ Department of Commerce	▪ Department of the Treasury	▪ Office of Science and Technology
▪ Department of Defense	▪ Department of Transportation	Policy
▪ Department of Energy	▪ Department of Veteran’s Affairs	▪ US Agency for International Development
▪ *Department of Health and Human Services	▪ Environmental Protection Agency	▪ US Trade Representative
▪ *Department of Homeland Security		▪ United States Postal Service

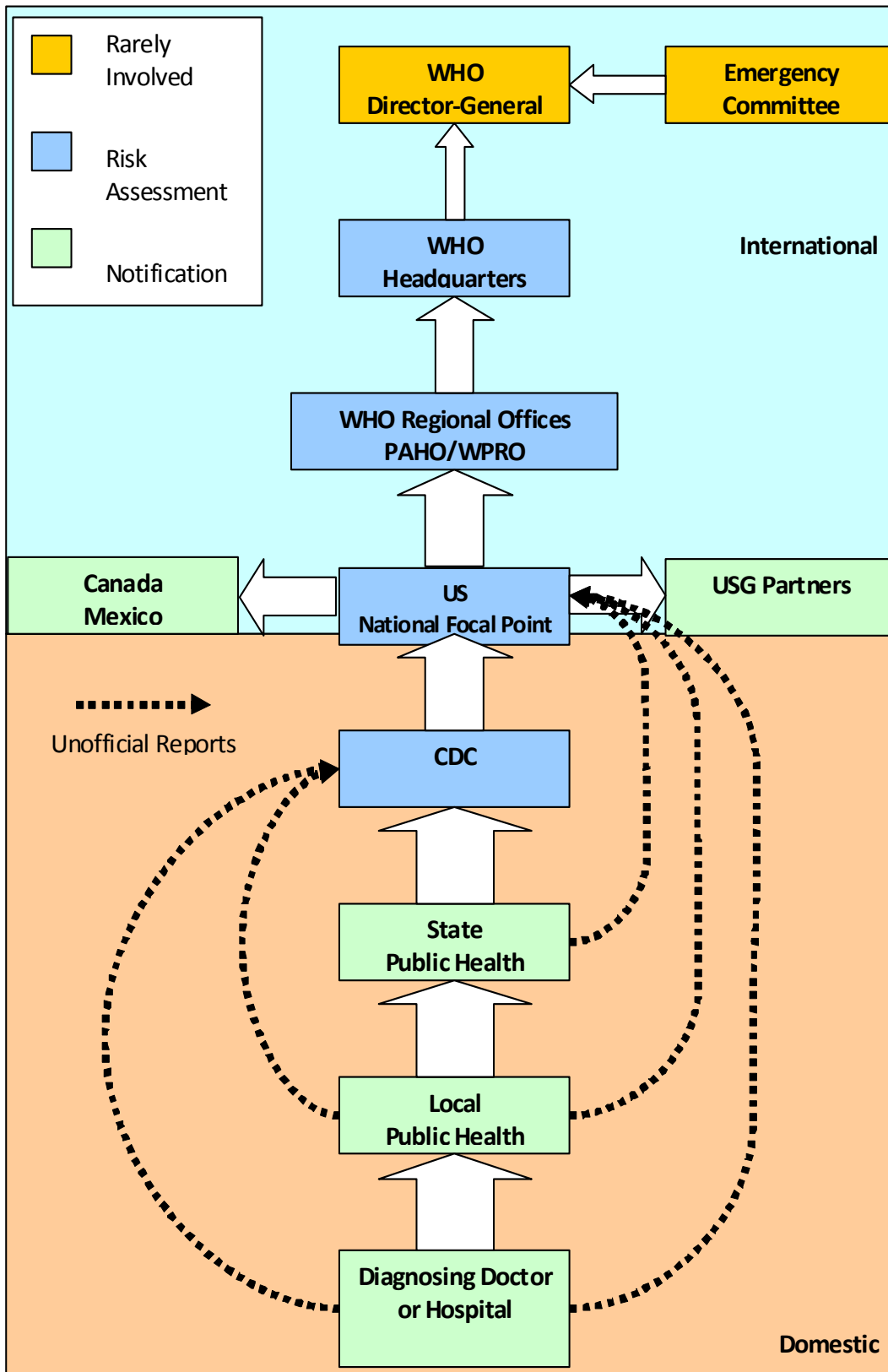
*denotes lead agencies in domestic implementation

HHS also supports implementation through its operating divisions, including CDC. Implementation involves local, state, and Federal actors, as well as multisectoral cooperation.

Effective detection of and response to a public health emergency often involves not only the public health sector, but agencies that address food and agriculture, commerce, transportation, homeland security, and environmental protection. At the state level, the engagement of these diverse stakeholders on IHR (2005) implementation varies widely.

The demands on operational capabilities and communications outside the health sector are important to understand, because state and local authorities will likely detect and respond first to any public health emergency. In the US, the states almost exclusively regulate and carry out public health activities.⁵⁹ CDC coordinates public health surveillance at the federal level but depends on voluntary notification by the states of an outbreak or potential threat.⁶⁰ Once knowledge of an event reaches the US national focal point (the HHS Secretary's Operations Center), HHS/ASPR officials assess the event and decide whether to convene a consultation group to evaluate options, relying on CDC's epidemiologic expertise.⁶¹ Based on their recommendations, and with the consent of senior leadership, the US National Focal Point notifies WHO (the Geneva headquarters and the two regional offices serving the US), Mexico and Canada (as outlined in the Security and Prosperity Partnership of North America), and other US government agencies' emergency operations centers of a potential PHEIC. State and federal agencies must work together to notify public and private stakeholders where the event originated. The following map illustrates the flow of communication among partners involved in detecting and reporting a potential PHEIC in the US:

Figure 4: Mapping US Disease Detection and Notification Channels under the IHR (2005)



US disease detection and response capabilities rely heavily on state and local public health capacities. Federal decision makers have increasingly recognized the need to detect and respond to public health emergencies effectively in the context of national security, justifying more consistent funding for public health surveillance and response. Prompted by the 2001 anthrax assaults, Congress increased annual funding for civilian biodefense from a baseline of about \$633 million to about \$6 billion by FY2009. This includes funding to build public health and laboratory capacities at the local, state, and Federal levels, in addition to resources for biodefense research and development. Awards to build state and local preparedness and response capabilities totaled more than \$7.6 billion from FY2001 through FY 2010, plus about \$39 million more to enhance real-time disease reporting through the US Laboratory Response Network.⁶² The recent Health Care Reform law created a small program to help state, local, and tribal health departments increase epidemiology and laboratory capacity.⁶³

These programs have provided a new level of resources to build domestic capabilities for disease detection, assessment, reporting, and response, contributing to US compliance with the IHR (2005) requirements. However, most discussions of IHR (2005) implementation within the US have taken place at the federal level. States and communities are thus effectively building US capacities consistent with the IHR (2005), often with little or no awareness that the regulations have relevance to them. For example, a survey of state epidemiologists in all 50 states and the District of Columbia conducted by the Council of State and Territorial Epidemiologists in early 2009 reported that more than 90% used some form of risk assessment algorithm to determine whether CDC should be notified of unusual or unexpected events. More than 90% of jurisdictions also categorized the four immediately notifiable IHR (2005) infections as reportable diseases, and could identify a specific point of contact for reporting zoonotic and other infectious disease outbreaks. However, plans for communicating with CDC and with other stakeholders at the state level in a timely way varied widely, and not all states included unusual or unexpected events as reportable diseases. Although 90% used risk assessments algorithms in deciding whether to contact CDC, only half of respondents used them to initiate formal investigations of public health emergencies. This translates not only to possible delays, but a missed opportunity to use the type of decision-making tool promoted by the IHR (2005) as a national template, facilitating more harmonized state disease detection, assessment, and reporting.⁶⁴ Communications between the state and Federal levels, particularly among non-health sectors, remains a serious challenge.⁶⁵ The problem is even more complex at the local level. Despite perennial challenges in interagency and cross-sector coordination, the US is generally assumed to be well within the requirements for IHR (2005) compliance.

Global implementation – the US as partner

The outlook is less rosy in other regions. The IHR (2005) framework implicitly assumes that countries will build their core capacities for public health surveillance on the foundations of functional health systems. Many weak states fall short of this prerequisite, and a larger number of low and middle income states face solvable but serious gaps.

WHO collects national self-assessments each year to help countries track their progress toward IHR (2005) implementation. These data are not publicly available, and only a handful of IHR gap assessments and implementation strategies have been published in the peer-reviewed literature. The limited data available paints a mixed picture. The majority of middle-income countries in Asia, Latin America, and Eastern Europe can now point to gains in health indicators (such as life expectancies at birth that exceed 65 years and low infant mortality rates), a result of investments in basic public infrastructures and essential health services since the 1970s. These countries generally have adequate clinical, laboratory, and public health capabilities for routine disease surveillance. They may not have developed seamless public health responses – particularly when it comes to the real-time/all-hazards/event-based detection systems demanded by the revised IHR – but they routinely detect and respond to health events. Most of these countries still have unfinished agendas for rapid response and surge capacity, and face challenges in integrating animal and human health systems to predict and prevent zoonotic disease outbreaks. This will require continued mobilization of resources, depending in turn on sustained political commitment *between* crises.

In contrast, many low- and low-middle income nations still carry heavy infectious disease burdens and high maternal and child mortality. Despite new emphasis on health systems strengthening as a targeted outcome of health assistance, many global health initiatives have focused on detecting and responding to one disease at a time. Public health leaders in these nations must balance many competing priorities and coordinate numerous stakeholders, including efforts funded by outside donors. They must tackle these demands despite shortfalls in the skilled health workforce (including epidemiologists and laboratory technicians) that may take decades to amend. Fragmented supply and information management systems and resource constraints mean that laboratories below the national level may lack appropriate reagents and protocols to identify the causes of disease, and to pass samples and results on to the right people in a timely way. In this context, IHR (2005) implementation is only one more demand among many. Countries that still struggle to collect and report accurate data on high-priority endemic diseases will require substantial technical and financial assistance to sustain public health systems robust enough to detect emerging crises and respond in real time.

As noted previously, the high-level focus that allows countries to adapt the IHR (2005) requirements flexibly to local conditions also precludes easy adoption of assistance strategies by donors who may appreciate the objectives of the regulations, but see no obvious milestones or metrics.

The global disease detection and response network is only as strong as the weakest link. US government funding for global health more than doubled between fiscal years 2004 and 2008, reaching an annual total of more than \$9.6 billion. Spending on HIV/AIDS, mostly through the commitment to the President's Emergency Plan for AIDS Relief (PEPFAR), drove two-thirds of this increase. Ensuring that every country possesses the capacity to detect and respond to a public health event before it spills across borders would protect US vital interests at home and abroad, as outlined in the 2009 *National Strategy for Countering Biological Threats*. Thus, the IHR (2005) framework resonates with US global health and biological security priorities. In

FY2008, the US dedicated about 1% of health assistance to building capacity for the response to avian and pandemic influenza, deemed the highest priority emerging infectious disease threats during this period.⁶⁶

Article 44 of the revised IHR encourage states to share technical cooperation and assistance, logistical support, and financial resources through bilateral and multilateral channels in order to develop, strengthen and maintain public health capacities.⁶⁷ As the largest bilateral donor of health assistance, US leadership and responsibilities in this area are preeminent.

Many US government agencies now include the IHR (2005) in developing their disease surveillance and response capacity-building strategies. However, a formal government-wide strategy for IHR (2005) implementation assistance had not yet been released at the time of this report. An interagency working group, reporting to the National Security Staff at the White House, is in the process of developing a whole-of-government strategy to support global IHR (2005) implementation, building on individual agency activities detailed below.

- ***The Biological Weapons Convention (BWC).*** An August 2009 meeting of experts in Geneva under the BWC intersessional process focused on building disease surveillance capacity. Statements submitted by US government technical experts during this meeting stressed *opportunities* to use Article X of the BWC and the IHR (2005) as parallel platforms for enhancing disease surveillance capacities.⁶⁸ Formal remarks delivered by Under Secretary of State Ellen Tauscher to the subsequent meeting of BWC State Parties in December 2009 emphasized the US commitment to supporting such efforts under Article X (which explicitly includes disease surveillance capacity building as an area of assistance).⁶⁹
- ***The Global Health Initiative (GHI).*** In May 2009, President Obama announced a 6-year, \$63 billion strategy to develop a comprehensive US global health engagement strategy.⁷⁰ The strategy features cross-cutting core principles (such as a woman- and girl-centered approach and country ownership)⁷¹ in addition to nine global health targets that encompass broad categories as well as specific diseases.⁷² Health systems strengthening constitutes both a core principle *and* a target area under the implementation plan released in 2010. However, despite the essential role of public health surveillance in building health systems and rational public health interventions, the GHI plan includes no mention at all of the IHR (2005) as a matter for technical consideration or health assistance.⁷³
- ***National Strategy for Countering Biological Threats.*** The Obama Administration released its *National Strategy for Countering Biological Threats* in November 2009. The strategy expanded upon previous incarnations by creating a comprehensive approach to protect against naturally, accidentally, or deliberately released biological threats. The first objective of this Strategy—“Promote global health security”—addressed the need to assist other nations in building disease detection and response capacities as outlined in the IHR (2005).⁷⁴ This objective calls for the US to partner with other countries and

regions to build up sustainable and transparent animal and human disease detection and reporting capabilities. The Strategy also references the IHR (2005) and the BWC in its final call to “(t)ransform the international dialogue on biological threats” with a focus on promoting discussion among countries to address emerging biological threats.⁷⁵

- **National Security Strategy.** The Obama Administration released its *National Security Strategy* in May 2010. The strategy highlighted the links between disease and national security and committed US leadership to building disease surveillance and response capabilities at home and abroad.⁷⁶ Although the strategy does not explicitly cite the IHR (2005), it strongly emphasized the importance of disease containment principles wholly aligned with the regulations:

“The threat of contagious disease transcends political boundaries, and the ability to prevent, quickly detect and contain outbreaks with pandemic potential has never been so important. An epidemic that begins in a single community can quickly evolve into a multinational health crisis that causes millions to suffer, as well as spark major disruptions to travel and trade. Addressing these transnational risks requires advance preparation, extensive collaboration with the global community and the development of a resilient population at home.”⁷⁷

- **National Health Security Strategy.** The Administration released this strategy in December 2009 to help “galvanize efforts to minimize the health consequences associated with significant health incidents,” including infectious disease outbreaks, and biological and other attacks.⁷⁸ The Strategy notes the H1N1 influenza outbreak and the fact that diseases and other threats spread rapidly over geographic borders. While mostly a domestic strategy, the document does refer to the importance of capacity strengthening abroad. Further, in Appendix A: Capabilities for National Health Security, the IHR (2005) are mentioned directly, stating the US should coordinate with international partners and:

“Work with relevant domestic and foreign officials and agencies to obtain and share information needed for situational awareness and response to a health incident; provide timely notification to the World Health Organization (WHO) and other countries/agencies as appropriate of any Public Health Emergency of International Concern, in compliance with the International Health Regulations (IHR) 2008 [sic]; provide technical assistance to other countries and agencies to help them strengthen their core public health capacities and capabilities and thereby fulfill their obligations under IHR 2008.”⁷⁹

Table 3: US Government Agency Engagement in IHR (2005)-Related Work

US Government Agency		Engagement in Building Global Disease Surveillance Capacity
Department of Agriculture (USDA)		<ul style="list-style-type: none"> The Animal and Plant Health Inspection Service (APHIS) is heavily engaged in animal health issues, including those that can affect humans, and works closely with international organizations and bilateral partners to build research and surveillance capacities. APHIS has been very engaged in avian influenza preparedness and response. The Agricultural Research Service (ARS) is USDA's chief research organization and conducts research worldwide to ensure safe food and other agricultural products.
Department of Defense (DOD)		<ul style="list-style-type: none"> Three Navy and two Army overseas laboratories contribute to disease surveillance capacity building by training local personnel and enhancing national diagnostic and research capacities. The Global Emerging Infections Surveillance and Response System, part of the US Armed Forces Health Surveillance Center, integrates the existing overseas research laboratories and aspects of the Military Health System by facilitating information-sharing and supporting disease surveillance, research, and capacity-building programs systemwide. Since October 2009, the Defense Threat Reduction Agency (DTRA) has dramatically scaled up its involvement in building surveillance capacities for naturally occurring as well as deliberately released emerging infections through the newly renamed Cooperative Biological Engagement Program.
Department of Energy (DOE)		Programs within the DOE National Laboratories support disease surveillance capacity through technical and policy research and training, including studies to better understand data, characterize host-pathogen interactions, and deploy field identification systems.
	HHS Secretary's Operations Center	The HHS Secretary's Operations Center serves as the US IHR National Focal Point.
Department of Health and Human Services (HHS)	Office of the Assistant Secretary for Preparedness and Response (ASPR)	<ul style="list-style-type: none"> The Division of International Health Security in the HHS/ASPR Office of Policy and Planning provides technical assistance to international partners and coordinates cross-border efforts to build IHR core capacities to strengthen public health preparedness and response at home and abroad. HHS/ASPR also leads US domestic implementation by promoting awareness of the IHR among state and local stakeholders and coordinating the interagency process of reviewing, assessing, and notifying potential PHEICs.
	Office of Global Health Affairs (OGHA)	OGHA supports the US in international negotiations on disease detection and response capacity-building, specimen-sharing, and other global health diplomacy issues.
	Centers for Disease Control and Prevention (CDC)	<ul style="list-style-type: none"> The new Center for Global Health encompasses the Division of Global Disease Detection and Emergency Response (DGDDER), with regional centers in Thailand, Kenya, Guatemala, China, Egypt, Kazakhstan (and start-ups in India and South Africa) and a health

Stimson Center
Global Health Security Program

		<p>security division. The GDD centers operate as partnerships between CDC and host nation health ministries to detect and respond to public health threats. The GDD centers bring US and regional experts together for outbreak response and to build sustainable capacities for emerging infectious disease detection and response, laboratory quality and safety, pandemic influenza preparedness, research, and health communications. The centers also function as members of the WHO Global Outbreak Alert Response Network during emergencies.</p> <ul style="list-style-type: none"> • In 2009, WHO designated GDD a Collaborating Center for Implementation of IHR National Surveillance and Response Capacity. This designation explicitly recognizes GDD as technical resource to support partner nation capacity-building under the IHR framework (although it includes no budget support). • The Center for Global Health includes the Field Epidemiology (and Laboratory) Training Program, modeled on CDC’s Epidemic Intelligence Service. CDC has helped establish 33 programs that have produced more than 1500 graduates in applied epidemiology since 1980. • CDC conducts short-term training programs in disease detection and response with international partners, and assists directly in international outbreak investigations at the request of host nations.
	<p>Food and Drug Administration (FDA)</p>	<p>FDA works internationally to support food safety regimens and early identification of pathogens in food sources, including through building partner nation regulatory capacities.</p>
	<p>National Institutes of Health (NIH)</p>	<p>NIH institutes and centers support research through contracts and grants to scientists around the world. The National Institute of Allergy and Infectious Diseases carries out this mission with a focus on infectious diseases. The John E. Fogarty International Center for Advanced Study in the Health Sciences specifically supports basic scientific research into pathogens of local, regional, and global importance and advanced training in the biomedical and behavioral sciences.</p>
	<p>US Agency for International Development (USAID)</p>	<p>The Emerging Pandemic Threats program has focused on the human-animal health interface, particularly at the community level, with programs to support wildlife pathogen detection, early prediction of disease, outbreak response capacity, and risk reduction. USAID has also supported avian and pandemic influenza preparedness and control efforts in developing countries.</p>
	<p>Department of State (DOS)</p>	<ul style="list-style-type: none"> • The Biosecurity Engagement Program (BEP) focuses on capacity-building for disease detection and control, as well as pathogen security. • The Office of International Health and Biodefense in the Bureau of Oceans, International Environment and Scientific Affairs (OES/IHB) plays a key role in international negotiations on global health issues, including those relevant to IHR (2005) implementation. • Bureaus and offices directed by the Under Secretary for Arms Control and International Security Affairs have facilitated a dialogue among stakeholders to explore how cooperative capacity building

	for disease detection and response under IHR (2005) could support implementation of the Biological and Toxin Weapons Convention, UN Security Resolution 1540, and other nonproliferation efforts.
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These different missions help explain why the US has taken so long to develop one coherent strategy for IHR (2005) global implementation, and for setting priorities for assistance. For example, USAID's focus on emerging pandemic threats means it focuses on geographic regions considered high risk for the emergence of zoonotic diseases, such as Central Africa and parts of Asia. The CDC Division of Global Disease Detection and Emergency Response, which does have an international mandate to support IHR (2005) implementation, considers trends in diseases of public health significance and host country commitment when identifying partner nations, leaning toward those with existing relationships with CDC, other US agencies, and international partners. The overseas military labs and other DOD engagements have engaged in capacity-building and collaborative research, including work on diagnostics and therapies important to partner nations, driven by force health protection, security assistance, and cooperative threat reduction objectives. The various State Department programs that engage in global disease detection and response capacity-building also focus on geopolitical significance in identifying partner nations – not necessarily using the same criteria. To make things more complicated, the quadruplicate US agency strategies for promoting public health surveillance and response capacity-building under the IHR (2005) have not been aligned in any way with the parallel strategies to strengthen health systems through the Global Health Initiative. The key to success for any of these programs must begin with finding the common thread among these divergent strategies and selecting several countries to be exploring what it means for the US to support core capacity building. This in turn will serve as a template and demonstration not only for IHR, but for health systems strengthening writ large.

THE FIRST REAL TEST: H1N1 AND IHR (2005)

The 2009 H1N1 influenza A virus pandemic was the first event declared a PHEIC by the WHO Director-General under the revised IHR (2005). In mid March of 2009, Mexican health officials detected an unusually large number of influenza-like illness cases.⁸⁰ On April 11, Mexican authorities opened a discussion with officials from the Pan American Health Organization (PAHO), the regional office of WHO, and after a few days of discussions formally notified PAHO of a PHEIC.⁸¹ On April 18, the US National Focal Point notified PAHO that two cases of novel influenza had been detected in southern California.⁸² The WHO Director General convened the IHR Emergency Committee, and with its advice declared H1N1 influenza a PHEIC on April 25, activating WHO's pandemic influenza plan and issuing temporary recommendations under the IHR (2005).⁸³

The timely alert of the H1N1 outbreak to the WHO allowed other countries to put their pandemic plans into action and prepare at the community level, allowing for faster reaction. Most agree the overall response under the revised IHR was efficient, especially in comparison to responses during the SARS outbreak. The creation of NFPs enabled real-time communication and facilitated information sharing and notification.

Although the spread and cumulative death toll of SARS paled in comparison to that of H1N1 (Table 4), the SARS outbreak galvanized an utterly different public response. We can only speculate as to why SARS galvanized the international community's acceptance of an unprecedented new regulatory framework to strengthen disease detection and control, while the H1N1 influenza outbreak elicited backlash against WHO amid unfounded accusations of a "fake pandemic." SARS was a novel and poorly understood pathogen with no known chemoprophylaxis or treatment that emerged in the tumultuous period following the September 11, 2001 terrorist attacks and anthrax assaults in the US.⁸⁴ The general familiarity with "the flu" as compared to the mysterious and poorly understood SARS might help explain widespread complacency about the health risks, even during early phases of the outbreak.⁸⁵ The public health and emergency response communities had used worst-case scenarios based on the 1918 "Spanish flu" pandemic to sensitize the public and decision makers to the urgency of preparedness efforts. After early confusion resolved into a less drastic picture, relief gave way to reports that frequently used the term "mild" to characterize H1N1 infection. In contrast, sensationalized media portrayals of the SARS epidemic amplified household fears.⁸⁶ Early WHO global reports on SARS provided the first case definitions based on clinical signs and symptoms and recommended isolation and barrier nursing of suspected cases.⁸⁷ In 2009, the countries most likely to respond aggressively to the H1N1 influenza A pandemic included those that had suffered most keenly from SARS. In North America, agitation about access to vaccines early in the epidemic was soon replaced with relative indifference as perceptions of the risks of infection failed to match public apprehensions of the very term "pandemic."

Table 4: Comparison of SARS and H1N1 Outbreak and Response

	SARS	H1N1 Pandemic
Dates of Outbreak	Nov. 2002-July 2003 ⁸⁸	April 2009-August 2010 ⁸⁹
Cases	8,096 ⁹⁰	~200 million ⁹¹
Deaths	774 ⁹²	18,172 ⁹³
Case Fatality Ratio	9.6% ⁹⁴	0.15%-0.25% ⁹⁵
Countries Affected	29 ⁹⁶ (95% of cases in 12 countries of Western Pacific, also in Europe and North America) ⁹⁷	214 ⁹⁸
First Probable Case	Nov. 16, 2002 in Southern Chinese Province of Guangdong ⁹⁹	March 11, 2009 in Mexico City ¹⁰⁰
First Death(s)	Nov. 2002-Feb. 2003 5 deaths reported in China ¹⁰¹	April 12, 2009 in Oaxaca, Mexico, one death reported ¹⁰²
WHO First Notified	Feb. 11, 2003: 300 cases and 5 deaths reported by Chinese MOH ¹⁰³	April 11, 2009: NFP reports unusually intense and prolonged influenza-like illness activity to PAHO under the IHR (2005) ¹⁰⁴
International Propagation	Feb. 21, 2003: Traced to a hotel in Hong Kong, where several people contract SARS from doctor, spread SARS to Europe, North America, other Asian countries ¹⁰⁵	<ul style="list-style-type: none"> • April 18, 2009: US reports 2 cases of H1N1 • April 26, 2003: Canada announces 1 case of H1N1¹⁰⁶
WHO Response	Global alerts issued March 12 and March 15, 2003. Second alert includes travel advisory and case definition ¹⁰⁷	PHEIC declared April 25, 2009 (followed by the immediate release of guidance and coordination of delivery of antivirals for affected regions)

A few carrots, no sticks

The events leading to WHO declaration of a PHEIC early in the H1N1 influenza pandemic and the level of communications among countries as the pandemic unfolded demonstrated the effectiveness (and importance) of the revised regulations. The regulations facilitated communications among WHO and its member states during a crisis, as intended.¹⁰⁸ The coordinated response, particularly between the US, Mexico and Canada, helped mitigate early spread of the virus.¹⁰⁹ Countries with confirmed cases shared samples of the virus with the international community for purposes of risk assessment, analysis, and for vaccine development.¹¹⁰

While this “first run” of the regulations should be viewed as a success, there are lessons to be learned and instances where there was clear non-compliance with the IHR (2005). For example, the intent and spirit of the regulations is to impose minimum interference with travel and trade. However, absent any recommendation from WHO, certain countries recommended against travel to North America and some even quarantined North American citizens regardless of exposure to the H1N1 influenza virus.¹¹¹ Several countries banned pork imports from North America, despite authoritative reports that no links had been found between eating properly

cooked pork and contracting H1N1 influenza.¹¹² These actions clearly demonstrate a primary weakness of the IHR (2005) – the lack of mechanisms to compel compliance. In the end, there is no enforcement mechanism if states take actions based on their own short-term interests rather than global public goods, or even their own long-term benefits.

The H1N1 pandemic also illustrated the importance of preparedness and local core capacity building. Luckily, Mexico and the United States, the first countries with known cases of the virus, had communications and response systems in place to act relatively quickly. Even so, bottlenecks in laboratory testing delayed the initial confirmation of a novel influenza strain in Mexico – a delay that might have been disastrous in the case of a more virulent strain. WHO's *Report of the Review Committee on the Functioning of the International Health Regulations (2005) and on Pandemic Influenza A (H1N1) 2009* concluded that despite success in this instance, "the core national and local capacities called for in the IHR are not yet fully operational and are not now on a path to timely implementation worldwide."¹¹³ The goal of the IHR (2005) is to ensure no matter where in the world such an outbreak occurs, nations will be capable of detecting and responding to public health crises quickly. At this point, this is certainly not the case.

What is at Stake?

At a time when many countries have begun to invest in strong health systems at home and abroad, the IHR (2005) provide a template for building integrated disease surveillance and response capacities sensitive to local and global health security priorities. However, current US policy places IHR (2005) primarily under the aegis of biological security, separate from discussions related to global disease detection and response taking place under the Global Health Initiative. Capacity building to identify and respond appropriately to disease -- from understanding the real burden to ensuring that those at risk have access to appropriate care, done cost effectively and in a timely way -- requires a shared set of capabilities in the clinic, the laboratory, and in the field. Too often, the difficulty in integrating these issues into policies that cut across agencies and sectors results in good ideas being locked into programmatic silos.

The Global Health Initiative provides a critical opportunity to coordinate and integrate efforts. This can only happen with leadership from the top to overcome very real logistical challenges. Doing so, however, will ensure the US makes the best use of health assistance resources and that partner nations are presented with a unified vision of USG assistance efforts. The IHR (2005) provide a unique opportunity for the US to work within the larger Global Health Initiative to assist in building systems that address not only emerging infections, but also epidemic-prone diseases, and endemic diseases such as HIV, tuberculosis, and malaria simultaneously.

Building the necessary capacities will require sustained commitment from national leaders inside and beyond the health sector, as well as consistent funding over the long-term. Resources to assist low and middle-income nations in IHR (2005) implementation have not been forthcoming to the required extent, in part because the demands and costs of implementation remain poorly understood. Donors must understand how best to assist nations

in building national and international systems capable of rapidly detecting any public health threat. As the US and the global health community move forward, such information will be essential to a comprehensive strategy for building public health capacities, and international security, for the future.

About Us

The Stimson Center's Global Health Security Program explores the growing demands on the world's public health infrastructure, from policies intended to contain transnational disease threats to a new focus on the economic benefits of promoting health in the world's poorest nations, and the changing roles for health issues in defense and diplomacy. The Global Health Security Program leads an ongoing project to help countries identify their needs to reach the necessary capacities for IHR compliance and to build the case for support. Using a framework for assessing the infrastructure, human resources, tools and processes required to achieve country compliance and "real world" budget data, the team is building a model to better understand the costs of IHR (2005) implementation.

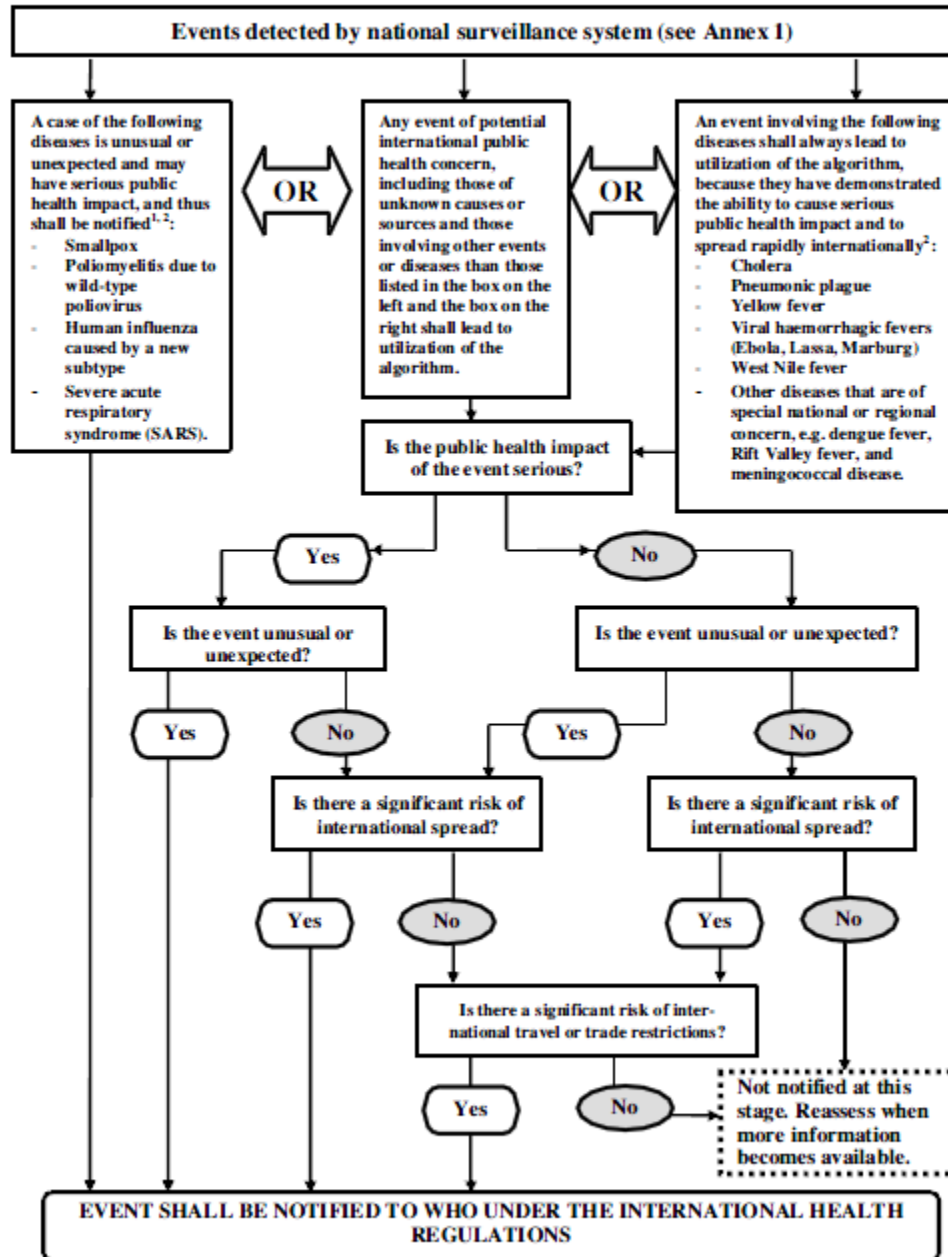
For more information, please contact:

Dr. Julie Fischer
Senior Associate
Stimson Global Health Security Program
1111 19th Street NW, Washington DC 20036
jfischer@stimson.org
202-478-3419

Dr. Rebecca Katz
Assistant Professor of Health Policy and Emergency Medicine
The George Washington University
2021 K Street, NW Suite 800, Washington, DC 20006
rlkatz@gwu.edu
202-994-4179

APPENDIX 1
(From the International Health Regulations 2005)

ANNEX 2
**DECISION INSTRUMENT FOR THE ASSESSMENT AND NOTIFICATION
OF EVENTS THAT MAY CONSTITUTE A PUBLIC HEALTH EMERGENCY
OF INTERNATIONAL CONCERN**



¹ As per WHO case definitions.

² The disease list shall be used only for the purposes of these Regulations.

APPENDIX 2
Core Capacity Competencies

Core Capacity	Component	Country Level Indicator
National legislation, policy, & financing	National legislation and policy	Laws, regulations, administrative requirements, policies, or other government instruments in place are sufficient for implementation of obligations under IHR.
	Financing	Funding is available and accessible for implementing IHR (including developing core capacities).
Coordination and NFP communications	IHR coordination, communication and advocacy	A mechanism is established for the coordination of relevant sectors in the implementation of IHR.
		IHR NFP functions and operations are in place as defined by the IHR (2005).
Surveillance	Indicator based, or routine, surveillance (also referred to as structured surveillance, routine surveillance, and surveillance for defined conditions)	Indicator based, routine, surveillance includes the early warning function for the early detection of public health events.
	Event based surveillance is established	Event based surveillance is established.
	Surveillance overview of information on IHR related hazards (situation awareness)	A coordinated mechanism is in place for collecting and integrating information from sectors relevant to IHR
Response	Rapid response capacity	Public health emergency response mechanisms are established
	Case management	Case management procedures are established for IHR relevant hazards.
	Infection control	Infection prevention and control (IPC) is established at national and hospital levels.
	Disinfection, decontamination, and vector control	A program for disinfection, decontamination, and vector control is established.
Preparedness	Public health emergency preparedness and response	Multi-hazard National Public Health Emergency Preparedness and Response Plan is developed.
	Risk and resource management for IHR preparedness	Public health risks and resources are mapped.
Risk Communication	Policy and procedures for public communications	Mechanisms for effective risk communication during a public health emergency are established.
Human Resources	Human resource capacity	Human resources are available to implement IHR core capacity requirements.
Laboratories	Laboratory diagnostic and confirmation capacity	Laboratory services are available and accessible to test for priority health threats.
		Influenza surveillance is established.
	Specimen collection and transport	System for collection, packaging and transport of clinical specimens
	Laboratory biosafety and biosecurity	Laboratory biosafety/biosecurity practices are in place.
Point of Entry	Laboratory based surveillance	Laboratory data management and reporting is established.
	Surveillance at PoE	Effective surveillance is established at PoE.
	Response at PoE	Effective response at PoE established

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