

The Revised International Health Regulations: A Framework for Global Pandemic Response

Rebecca Katz and Julie Fischer

The 2009 H1N1 influenza outbreak tested the revised International Health Regulations [IHR (2005)] robustly for the first time. The IHR (2005) contributed to swift international notification, allowing nations to implement their pandemic preparedness plans while Mexico voluntarily adopted stringent social distancing measures to limit further disease spread – factors that probably delayed sustained human-to-human transmission outside the Americas. While the outbreak revealed unprecedented efficiency in international communications and cooperation, it also revealed weaknesses at every level of government. The response raises questions regarding the extent to which the IHR (2005) can serve as a framework for global pandemic response and the balance between global governance of disease control measures and national sovereignty.

INTRODUCTION

On April 25, 2009, the Director General of the World Health Organization (WHO) declared the novel H1N1 influenza virus outbreak unfolding in North America a public health emergency of international concern. The notification, communications, and international collaboration leading up to this declaration all took place within the framework of the Revised International Health Regulations [IHR (2005)]. The 2009 H1N1 pandemic marked the first use of the IHR (2005) to address a global public health emergency and was for the most part successfully. This experience, however, raises larger questions about how the IHR (2005) and the associated powers conferred on WHO contribute to and operationalize the concept of global governance of disease. As much as the H1N1 experience demonstrated the power of the IHR (2005), it also highlighted the shortcomings, particularly reliance on uneven national capacities and limited responses to states that exceeded evidence-based public health, trade, and travel recommendations. This paper explains the role of the IHR (2005) in responding to the H1N1 pandemic, discusses the successes and weaknesses of the regulations in ‘governing’ the global response to the outbreak, and outlines options for strengthening the IHR (2005) as a tool for pandemic preparedness and response within the broader context of global health governance mechanisms.

INTERNATIONAL HEALTH REGULATIONS

The global community has long recognized the need for international collaboration and governance to contain the spread of infectious diseases. In the 1800’s, international agreements and discussion focused on a select subset of diseases (primarily cholera, and later plague and yellow fever) and quarantine regulations necessary to prevent the shipping trade from transporting these diseases across international borders.¹ The discussions and negotiations were codified into the First International Sanitary

Convention of 1892, later to become the International Sanitary Regulations.² Through many revisions, the structure of these agreements remained fairly static until after World War II, with the establishment of the World Health Organization (WHO). In 1951, WHO adopted the existing conventions and related agreements as the International Sanitary Regulations, which became binding on WHO member states. In 1969, the regulations were revised and renamed the International Health Regulations.³

The International Health Regulations of 1969 [IHR (1969)], with only minor changes over the course of several decades, were intended to “strengthen the use of epidemiological principles as applied internationally, to detect, reduce or eliminate the sources from which infection spreads, to improve sanitation in and around ports and airports, to prevent the dissemination of vectors and, in general, to encourage epidemiological activities on the national level so that there is little risk of outside infection establishing itself.”⁴ The regulations themselves, however, focused tightly on the control of a short list of diseases. While the agreement encouraged epidemiologic activities, the only obligations lay in the capacity to report specific diseases such as cholera to WHO, and maintain minimal public health capabilities at ports and borders. Over time, compliance with the regulations diminished, in part because countries saw limited national benefits from the disease reporting requirements; the global surveillance system under the IHR (1969) gradually faded in relevance and effectiveness.⁵

By the 1990’s, consensus emerged amongst the global health community that the threat of emerging (e.g. Ebola virus) and re-emerging (e.g. dengue) infectious diseases was increasing. Accelerated globalization facilitated the rapid spread of these diseases. The existing regulations contained no answer, either in disease surveillance or response, to the growing international HIV/AIDS crisis. The tools available to govern the international response to cross-border outbreaks had clearly become inadequate. This recognition resulted in a resolution at the 1995 World Health Assembly to revise the International Health Regulations to better address contemporary realities and aid in global governance of disease reporting and responses.⁶ Despite this, years passed with very little progress towards revising the IHR.⁷

The emergence of the SARS virus in 2003 changed the political mood. The experience of trying to ascertain information about an emerging disease event and coordinate a worldwide response to contain and mitigate an international outbreak provided the impetus to create an instrument to govern the next global public health emergency. Intergovernmental working groups were formed, text was negotiated, and on 23 May 2005, the World Health Assembly adopted the Revised International Health Regulations, known as IHR (2005).⁸ These revised regulations are binding on 194 State Parties, including all WHO Member States.

The stated purpose of IHR (2005) is 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.”⁹ The regulations themselves, with 10 parts and 9 annexes, have several key provisions worth noting. First and foremost, the scope of the IHR (2005) expands beyond a specific disease list to include any event that would constitute a public health emergency of international concern (PHEIC). Second, the regulations emphasize the importance of global communications and cooperation for early detection and mitigation of potential PHEICs. This includes obligations for

each nation to develop the means to detect, report, and respond to public health emergencies. To that end, the regulations require that every Member State establish a National IHR Focal Point for communication to and from WHO (both headquarters and the regional offices), and meet core capacities for disease surveillance and response, as defined by Annex 1 of the IHR (2005). Using these mechanisms, nations must notify WHO within 24 hours of a national assessment of any event that may constitute a public health risk to other States requiring a coordinated international response. In exchange, WHO will coordinate communications across nations, provide technical assistance to responding nations, and work with international scientific experts to develop recommendations for mitigating the consequences of the event.

The revised IHR (2005) retained directions about the importance of responding to public health emergencies in ways that minimize the impact on travel and trade, and at the same time respect individual human rights. The IHR (2005) greatly expanded WHO's authorities in global governance, allowing WHO to use external sources of information to identify possible PHEICs, to make inquiries of national authorities based on unofficial information sources, and to set forth recommendations even in the absence of cooperation or agreement from affected Member States [see Table 1 for a comparison of the IHR (2005) and previous regimes].

Table 1: Evolution of the International Health Regulations, 1951 to the Present

IHR Component	1951-2007	2007-present
Scope	Cholera, Plague, Yellow Fever and Smallpox* (removed after eradication); Control at Borders	Public Health Emergency of International Concern; Detection and Containment at Source
Communication	Countries fax reports to WHO	IHR National Focal Points (NFP) and WHO's secure website
Notification	Report to WHO within 24 hours	Report to WHO within 24 hours. 72 hours to respond to follow up requests
Coordinated Response	No mechanism for coordinating international response to contain disease	Assistance in response/recommended measures
Authority	WHO not able to initiate an inquiry: dependence on official country notifications	WHO can initiate requests for information based on unofficial sources. Can ask for additional information
National Capacity	Provide disease inspection and control at ports of entry	Provide disease inspection and controls at ports of entry Meet minimum core capacity for detection, reporting and assessment

Response Capabilities	Pre-determined public health controls at points of entry	Flexible, evidence-based responses adapted to nature of threat
------------------------------	--	--

IHR (2005) entered into force during the summer of 2007 (June 15th for most nations, later in the summer for the United States and India), although WHO Member States agreed to commence voluntary implementation in May 2006 should conditions be considered relevant to the risk posed by avian and pandemic influenza.¹⁰ Nations began an assessment of their core capacities that ended in June 2009, and have until 2012 to achieve full compliance. As of July 2009, 99 percent of all Members States had designated a National Focal Point, available for communications with designated WHO IHR Contact Points 24 hours a day, 7 days a week. Eighty-six percent of the National Focal Points (NFP) had accessed the IHR Event Information Site (a secure website hosted by WHO that posts information regarding public health events and recommendations).¹¹ While countries worked on their national assessments, designated NFPs, and submitted reports of potential PHEICs to WHO, the IHR (2005) were not truly tested until spring 2009.

H1N1 AND THE IHR (2005)

While the novel swine influenza A (H1N1) triple reassortant virus may have been circulating for several years, it emerged as the cause of an epidemic and eventually a pandemic starting in March 2009 in Mexico.¹² Mexican governmental and nongovernmental disease surveillance systems began to detect an unexpectedly large number of acute respiratory infections. On April 11, Mexico began discussions with the Pan American Health Organization (PAHO, the WHO regional office for the Americas) about what appeared to be an unusually intense and prolonged influenza season. The events that followed represent the first use of the IHR (2005) to coordinate detection, reporting, mitigation, and communications activities in support of the global response to a public health emergency.

The specific actions and timeline of events in the detection and reporting of H1N1 influenza under the IHR (2005) have been detailed elsewhere.¹³ It is essential to note that the IHRs were used exactly as spelled out in the text of the agreement. At the time of initial notification, PAHO used its explicit authority under the IHR (2005) to reach out to Mexico, launching consultations about the evolving epidemic. IHR NFPs in Mexico and the US, where H1N1 appeared next, notified relevant WHO regional offices per protocol outlined in IHR (2005) to alert the global community to a potential PHEIC. As outlined by the regulations, the Director General of WHO consulted with both the US and Mexico, and formally declared the emergence of H1N1 to be a Public Health Emergency of International Concern. An Emergency Committee convened by the Director General per Article 49 of IHR (2005) approved the PHEIC determination and provided initial recommendations for addressing the situation.

The IHR (2005) provided not only the template for the initial notification and eventual determination of a public health emergency, but a structure for coordinated response activities. On April 25th, the day H1N1 was declared a PHEIC, WHO deployed

personnel to Mexico to assist in response efforts. The Emergency Committee issued temporary recommendations that no travel or trade restrictions be imposed. WHO, working with the International Civil Aviation Organization and the International Air Transport Association, produced detailed guidance for the case management of H1N1 influenza in air transport. These recommendations outlined evidence-based measures that Member States could take under IHR (2005) obligations to prevent public health risks from spreading, avoid unnecessary interference with international traffic and trade, and apply health measures to international travelers.¹⁴ WHO coordinated the worldwide distribution of diagnostic kits, the shipment of antivirals to affected countries, and the sharing of virus isolates and sequences with the international community. WHO also coordinated vaccine pledges by both Member States and manufacturers of approximately 200 million doses for distribution to 95 less-developed nations.¹⁵

As the IHR (2005) obligated all nations to report cases of H1N1 influenza to WHO, Member States scaled up their influenza surveillance efforts. Affected nations began to update their case estimates regularly.¹⁶ The establishment of IHR NFPs enabled WHO to engage in an unprecedented level of communications with all Member States. This served to coordinate response efforts and ensure that nations received up-to-date information regarding virus spread, pathogenesis, and transmissibility, as well as containment strategies. The IHR (2005) thus served as a guiding framework for the coordinated response to the pandemic, not only during the early days but also as the pandemic passed through the southern hemisphere starting in May 2009, and during the resurgence over the northern hemisphere's fall and winter.

IHE (2005) as a Framework for National Responses to H1N1

The strengths and weaknesses of the IHR (2005) are exemplified in national responses to the 2009 H1N1 influenza pandemic. By stepping forward, Mexico sacrificed its own interests for the greater good of global public health. First, Mexico worked with its regional WHO office to make proper notifications regarding the emergence of a novel influenza strain. Although some criticized Mexico for not detecting the virus quickly enough, its federal government reported transparently and rapidly once the nature of the outbreak became clear, and reached out to neighboring countries for laboratory diagnostic support.¹⁷ After notification, the country heeded recommendations from WHO and the global community and imposed drastic measures to contain further spread of the virus. These included massive social distancing measures to discourage crowding, including school closings, canceled attendance at sporting events, and encouragement to avoid religious ceremonies, as well as house isolation of cases.¹⁸ In early May, Mexican authorities suspended non-essential government and business activities over a long holiday weekend, costing Mexico City alone an estimated \$57 million per day.¹⁹ Early estimates pegged losses to the Mexican economy due to influenza at 0.3 to 0.5 percent of gross domestic product (GDP) for 2009. As tourism slumped at home, Mexican citizens traveling abroad became subjects of discrimination.²⁰

The US and Canada also responded transparently and generously to the emerging pandemic. Both countries complied with IHR (2005) obligations for notification, provision of disease-related information, and ongoing communications. Both also

provided technical assistance and resources to help the global community mitigate the consequences of the pandemic. The US and Canada freely shared viral samples, provided diagnostic kits that were shipped around the world, and when it became available, both countries donated H1N1 influenza vaccines to WHO for global distribution.²¹

The unfolding H1N1 influenza epidemic also highlighted weaknesses in the IHR (2005) framework. The revised IHR clearly outline the process by which WHO distills expert advice into technical guidance for Member States. This includes highlighting evidence-based responses that national authorities can employ to limit disease introductions at ports and borders. This did not stop some countries from making unilateral decisions that were neither scientifically sound nor consistent with WHO guidance, and dismissed IHR (2005) principles obligating countries to respect human rights and cause minimal disruption to the international flow of people and goods.

- ❖ In late April, Egyptian authorities ordered the slaughter of all pigs in the country, an estimated 250,000 pigs in all. At the time, there had not been a single case of H1N1 influenza in the country, nor any reported outbreaks in pigs worldwide. Many felt the move stemmed from political and religious pressures rather than scientific reasoning.²² (The Coptic Christian minority are the only consumers of pork in the country.)
- ❖ Twenty countries banned the importation of pork and pork products from Mexico, Canada and the US.²³ Bans occurred in spite of a joint statement by WHO, the United Nations Food and Agriculture Organization (FAO), the World Organization for Animal Health (OIE) and the World Trade Organization (WTO) that pork and pork products were not a source for H1N1 influenza infections.²⁴
- ❖ On April 28, Indonesia's Health Minister declared that H1N1 influenza was genetically engineered and intentionally released by the US to promote its pharmaceutical industry, in contradiction of all available scientific evidence.²⁵
- ❖ Many of the East and Southeast Asian countries that bore the brunt of the 2003 SARS epidemic reacted extremely strongly, and not always rationally, to the spread of H1N1 influenza. For example, China and Singapore quarantined some travelers based on nationality (particularly Mexicans, Canadians and Americans), regardless of potential exposure to the H1N1 virus. Others were quarantined if they had recently been in Mexico.²⁶ There was no evidence in many of these cases that individuals had been exposed to the virus. WHO even requested that China provide a public health justification for its actions under the IHR (2005).²⁷
- ❖ Similarly, several of the nations most affected by SARS in the Asia-Pacific region employed thermal scanners to screen travelers for fever at airports in response to the 2009 H1N1 influenza pandemic.²⁸ Scientific evidence suggests that thermal screening has only limited utility in controlling an influenza pandemic.²⁹ WHO and the IHR Emergency Committee recommended very early in the outbreak against entry and exit screening, as they felt it would unreasonably hinder trade and travel without reducing the spread of the virus.³⁰
- ❖ Early in the outbreak, several countries suspended flights to North America, even though WHO and the IHR Emergency Committee declared that these were not sound decisions for containing the virus.³¹

Many nations eventually converged toward WHO and Emergency Committee recommendations and global standards for addressing the pandemic. However, these early actions by nations outside the governance structure of the IHR, or in spite of the IHR (2005), serve as a vivid reminder that nations are sovereign entities that can and will make their own decisions in response to a public health threat, regardless of global health governance structures.

IHR (2005), H1N1 and Pandemic Planning

Renewed outbreaks of H5N1 avian influenza that spread inexorably from Southeast Asia in 2004-5 throughout Asia, and eventually to Africa and Europe, coincided with adoption of the revised IHR. A global health community still galvanized by SARS began to develop local, national and international pandemic plans. These plans varied depending on the level of government and national capacities, but in general they addressed pharmaceutical and non-pharmaceutical interventions, continuity of operations, medical and public health surge capacity, and plans for containment, mitigation and resilience. The IHR (2005) do not specifically mandate creation of pandemic preparedness plans. However, many of the plans reference the IHR (2005), particularly as they pertain to international coordination during a pandemic.³² The IHR (2005) do require that Member States “establish, operate and maintain a national public health emergency response plan.....to respond to events that may constitute a public health emergency of international concern” [IHR (2005) Annex 1, 6g]. Given that the H1N1 pandemic was declared a PHEIC, having a national pandemic influenza response plan became an IHR (2005) obligation – although, technically, only after the crisis began.

WHO published a pandemic plan in 1999, two years after the first major outbreak of H5N1 avian influenza in Hong Kong. It was updated in 2005 and again in 2009, in part to better reflect the entry into force of the IHR (2005). The 2009 version included contributions from 135 scientists from 48 countries; its April 2009 publication interestingly coincided with the emerging H1N1 influenza outbreak.³³ The April 2009 version of the WHO pandemic plan references the obligations under the IHR (2005) to report cases of influenza caused by a new subtype [described in IHR (2005) Annex 2]. The plan outlined obligations of Member States to engage in ongoing influenza surveillance, respond to WHO requests for information, provide for international travelers, and obtain information from aircraft, ships, and other vehicles. The revised plan also maintained a multi-phase pandemic alert system based on the extent and geographical distribution of human-to-human transmission, intended to help national authorities plan and implement their own responses to a potential pandemic.³⁴

The IHR Emergency Committee, convened by the Director General of WHO to evaluate and provide recommendations regarding the declaration of a PHEIC, has continued to meet regularly through at least February 2010 to provide ongoing guidance on the H1N1 influenza pandemic. At the fourth meeting of the IHR Emergency Committee on June 11, 2009, the WHO Director General raised the pandemic alert level to Phase 6, a full pandemic, declaring that the H1N1 outbreak met the established criteria of community-level outbreaks in at least two WHO regions.³⁵ The sequential declarations of the PHEIC and the pandemic triggered the activation of national pandemic response plans. As discussed, these plans did not necessarily stem from the

IHR (2005) mandates, but did align with the IHR legal framework for international cooperation in response to the virus.

IHR (2005) and Global Health Governance in Operation

Although forerunner regimes to the IHR (2005) imposed international reporting obligations upon states, disease control ultimately relied on public health responses within national borders. In essence, this paradigm assumed that the best defense is a good offense, for those capable of mounting one. Little expectation existed that outbreaks could be controlled at the source, or that actors beyond the major state powers would play a significant role in limiting international disease spread.

In the past two decades, the health and development catastrophe of HIV/AIDS catalyzed a transformation in development assistance for health. Global health assistance more than tripled between 1990 and 2007, reaching US\$21.8 billion. Private sources accounted for more than 26 percent of this aid, led by the Bill and Melinda Gates Foundation. Non-governmental organizations (NGOs) play an increasingly significant role in implementing global health initiatives in the field. Annual overseas expenditures on health programs by US-based NGOs alone exceeded an estimated US\$5 billion in 2007.³⁶ In 2006, foreign ministers from several middle-income nations joined their counterparts from France and Norway in calling for a stronger strategic focus on global health security within the context of foreign policy, implicitly emphasizing the importance of emerging economies in implementing the IHR (2005) and other health agreements.³⁷

The plurality of public and private sector stakeholders, each driven by distinct national or institutional motivations, has spurred demands from many quarters for a more coherent approach to global health governance. Governance refers to the decision-making process that societies, communities, or organizations use to identify and set specific goals, and the processes for putting those decisions into action. Proponents of stronger global health governance often focus on the lack of “architecture” under which state and non-state actors could harmonize their policy goals and program activities. Ultimately, many of these lamentations about the lack of governance reflect frustrations with the failures of States to build sustainable local public health capacities, and to use these as a platform for interaction with global health activities.³⁸

The IHR (2005) encompass the strongest existing tool for global health governance, integrating stakeholders beyond the major state powers more fully into the global disease detection and response framework. However, their success still depends heavily on national capacities and cooperation, and they cover only a portion of global health activities. State Parties conceded some previously sacrosanct points of sovereignty under the IHR (2005) with the expectation that greater transparency and accountability might insulate increasingly interdependent economies against the costs of public health crises. Decision makers in high-income nations have focused on the utilitarian benefits of cooperation, framing the IHR (2005) among other communicable disease surveillance and control programs as global public goods.³⁹

Many questions about how the IHR (2005) obligations would be operationalized during a PHEIC came into focus during the 2009 H1N1 influenza pandemic. The first obvious success of the new regulations lies in information sharing. The IHR (2005) provided a functional framework for communications and the dissemination of

informed guidance to coordinate responses throughout the 2009 pandemic. The designation of IHR National and WHO Focal Points constitutes one of the most straightforward requirements within the revised IHR, for which WHO has promulgated extensive legal and policy tools.⁴⁰ Access to contact information for NFP not only facilitated communications with WHO, but allowed country representatives to communicate directly with each other – a capability that seems obvious, but proved more problematic in the past.

In contrast, operationalizing the revised regulations for disease control at ports and borders [IHR (2005) Part IV, Articles 19-22] proved less conclusive. Actions taken by many countries during the 2009 H1N1 pandemic ignored the innovation contained in the IHR (2005)—the ability of WHO to recommend evidence-based measures—compared to historical regimes. The IHR (2005) allow countries to focus capacity-building on “designated ports of entry” and give national authorities latitude in identifying “practicable” responses, a concession to the wide range in resources among states. The first robust test of the IHR (2005) as a tool to coordinate disease control at ports of entry revealed more about sovereignty than capabilities.

Because Mexico and the US reported the initial outbreak transparently, the pandemic did not test the ability of the regulations to govern a more fundamentally recalcitrant sovereign state. However, the 2009 pandemic highlighted the greatest operational challenge in the IHR (2005): building the national and sub-national public health capacities necessary for countries to detect and respond to public health events wherever they occur. Although the IHR (2005) addressed the need for developed nations to assist resource-constrained countries in building capacities, the slow evolution of guidance to understand what core capacity actually means left many donors and implementing nations puzzled about funding targets and metrics. Low- and middle-income nations have been obligated to meet IHR core capacity requirements in disease surveillance, reporting and response without a standing commitment of financial resources. While the IHR (2005) emphasize the responsibilities of all states to build public health infrastructure in the name of mutual protection, the underlying global health security paradigm can be perceived alternatively as an enormous obligation for developing nations assumed primarily to protect the populations of developed nations – and consequently, a requirement that might elicit backlash against full implementation.⁴¹

WHO and Global Governance under the IHR (2005)

The legally binding mandate that State Parties meet minimum core capacity requirements for disease detection, assessment, reporting, and response constitutes the heart of the revised regulations. These activities build on WHO’s core competencies as the primary instrument of global health governance: setting priorities and establishing norms to help national authorities prepare for public health crises.

The legacies of WHO’s global malaria and smallpox eradication campaigns of the 1950s and 1960s highlight significant institutional challenges in managing large global health initiatives that remain a concern. The former foundered amid top-down management structures with little ownership at the country level and overreliance on technological interventions. Not only did the effort fall short of intentions, but it left such a sour taste that WHO almost declined to support the subsequent smallpox

eradication campaign – an effort prosecuted successfully and at a much lower cost due to integration into existing national public health infrastructures.⁴²

The IHR (2005) conferred dramatically expanded powers and obligations on WHO. First, the IHR (2005) allow WHO new authority to collect information on potential public health crises from unofficial sources, from NGOs to the Global Outbreak and Alert and Response Network, and to pose questions about events directly to Member States. This provides a disease surveillance tool not available during the SARS outbreak that might very well have provided much more timely insights into China's regional epidemic prior to cross-border spread. At the same time, the stewardship of confidential information—and the capability to act on it through the declaration of PHEICs and information sharing with other States and the public—demands new types of responsible management.⁴³

WHO implements its research and capacity-building agenda through its six relatively autonomous regional offices, which provide a distinctive capacity to accommodate local priorities and facilitate cooperation among neighboring states. In addition, the 145 WHO country offices, covering 159 Member States, provide robust channels to communicate with local governmental and non-governmental health actors.⁴⁴ Nonetheless, WHO's core staff remains small and its routine budget extremely tight for existing mandates, let alone to develop new crisis response capacities. WHO relies on technical experts from highly resourced nations to provide assistance to partner states during public health emergencies.

From its inception, WHO has effectively provided technical support to help nations build their public health capacities, and disseminated information necessary to allow evidence-based decision-making at the national level. Experts convened by WHO help shape guidance, norms, and standards. Although WHO serves as the center of global health governance, its traditional strengths lie in crafting the global health agenda rather than managing or overseeing implementation of specific programs.

PRESSURES ON GLOBAL GOVERNANCE FOR H1N1

In the immediate wake of the SARS outbreak, sudden fear of the consequences of a single nation's failure to report an emerging infection—whether due to lack of will or capacity—overcame many of the concerns about sovereignty that had previously stalled the IHR revision process. During the negotiations of the IHR (2005), the global community and developed nations in particular were perfectly comfortable with granting WHO more authority and power to govern global disease detection and response capabilities. The emergence of the first PHEIC in North America challenged the prevailing assumption that the next public health emergency would come from a nation with limited resources and public health capabilities. High and upper-middle income countries endured the economic implications of reporting an emerging disease, as well as WHO's perceived interference with political judgments and national sovereignty.

Responses by high-level European organizations reflected the changing mood after WHO's authorities under the IHR (2005) dovetailed with its pandemic alert system, and H1N1 influenza proved less lethal than strains modeled in planning scenarios. On April 30, 2009, the Council of the European Union adopted conclusions regarding H1N1 influenza, calling for continued cooperation at the EU and international

levels and “(w)elcom[ing] the rapid action taken by the Member States in the framework of the WHO’s IHR.”⁴⁵ Months later, the unrelated Council of Europe (an independent treaty-based organization with 47 member states) convened the first of a planned series of public hearings to investigate whether the pharmaceutical industry influenced WHO’s decision to declare a pandemic in June 2009 in order to profit from the response. Experts called by the Council questioned whether WHO should hold authority to declare a pandemic, given the economic consequences (approximately \$18 billion) of the 2009 decision.⁴⁶ In response, Keiji Fukuda of WHO refuted accusations of influence by the pharmaceutical industry as unfounded. He asserted that the decision to declare a pandemic stemmed from scientifically sound evidence, and stated that the IHR “provide the world with an orderly, rules-based framework for detecting, assessing, reporting, declaring and responding to public health emergencies of international concern. They also provide the world with a system of checks and balances to ensure that no one, including the WHO Director-General, has unfettered power when making decisions.”⁴⁷

These ongoing arguments reveal the tensions in maintaining state support for a regime deliberately designed to value expert assessments over national interests. Apart from the contentiousness of the pandemic declaration, concerns arose about the role of the expert committee in validating public health measures. Not only did WHO turn to the IHR Emergency Committee for advice on transmission patterns and health risks, but for views on the pandemic declaration itself. Some have argued that the IHR Emergency Committee’s mandate never authorized such a role, and that the committee should restrict its advice to technical rather than procedural matters.⁴⁸ The WHO Pandemic Plan specifically cites the role of the IHR Emergency Committee in developing temporary recommendations and advising the Director General if the event is declared a PHEIC (as it was), but does not explicitly discuss the role of the committee in advising on pandemic phases, an issue that clearly needs to be re-examined in the post-pandemic period.⁴⁹

This first test of the system took place under unanticipated circumstances: although the H1N1 outbreak clearly met the definition of widespread transmission established as a threshold for declaring a pandemic, the disease itself turned out to be unexpectedly moderate. The move from pandemic alert level 4 to 5 led to immediate economic consequences, particularly for travel and trade-dependent industries. Many national decision makers strongly pressured WHO to consider illness severity in moving past level 5, fearing that economic impacts of the declaration would be disproportionate to the actual disease threat.⁵⁰ As stated by Margaret Chan, Director General of the WHO, “(t)he reality check by the new H1N1 virus caused a disconnect or a mismatch between the expectations and the reality....The reaction would span from complacency to some kind of suspicion [depending on whether the pandemic touched their lives or not].”⁵¹

IHR (2005) and Pandemic Preparedness

Although the IHR (2005) do not explicitly address pandemic preparedness, their implementation during the 2009 H1N1 influenza pandemic makes it perfectly clear that the IHR play a part in crisis response and in preparedness for the next pandemic. In order to meet the mandated core capacities under the revised regulations, WHO outlined seven work areas. Those with the most functional relevance for pandemic

preparedness focus on strengthening: national disease prevention, surveillance, control and response systems; public health security in travel and transport; WHO global alert and response systems; and capabilities to manage specific risks (such as novel influenza strains).⁵²

The H1N1 influenza outbreak also highlighted the major weakness of the IHR (2005) as a tool for pandemic response: disease detection capabilities vary widely among Member States, and the global disease surveillance network is as strong as its weakest link. Mexico, an emerging economy in the midst of economic and demographic transitions, has steadily improved its health indicators over the last two decades. Nonetheless, its ratio of skilled laboratory workers to the population is less than one-fourth of US levels.⁵³ In March 2009, only Mexico's national reference laboratory had the capacity to conduct the confirmatory tests necessary to diagnose a novel influenza strain. Even after the US and Canada supplied technical assistance and additional equipment and supplies to establish diagnostic capacity for H1N1 influenza in late April, delays in training personnel resulted in a backlog of 1,000 specimens during the peak of the outbreak. Three weeks elapsed between the initial recognition of unusual patterns of influenza-like illnesses and diagnostic confirmation (although Mexico acted promptly through the IHR mechanisms at that point).⁵⁴ The ongoing epidemic revealed critical gaps in other regions. By mid-August 2009, South Africa had reported more than 3,000 cases and several deaths. No other sub-Saharan African nation had reported more than 85 cases, and many had reported no more than one.⁵⁵ This almost certainly represents a lack of disease detection and reporting capacities, rather than effective control of the expanding pandemic in these countries.

Differences in disease detection and response capacities outweigh concerns about information sharing and sovereignty in terms of obstacles that could derail successful IHR (2005) implementation. The IHR (2005) mandates are intended to smooth the disparities in public health capacities among low- and middle-income countries that slow disease detection and response. However, many of the obstacles will not be easily overcome, even with more concrete guidance and sufficient resources.

MOVING FORWARD: ENFORCEMENT AND SUPPORT FOR THE IHR (2005)

In testing the IHR (2005) robustly for the first time, the 2009 H1N1 influenza events highlighted obstacles to governing pandemics.

Lack of Enforcement Mechanisms

While all Member States are legally obligated to follow the IHR (2005), there is no formal penalty for failure to notify WHO of a potential PHEIC, or for failure to achieve core capacities for surveillance, reporting and response. WHO has no power to force nations to comply with IHR (2005) obligations. The absence of adjudication mechanisms can be seen as a compromise that made sovereignty concessions in the IHR revision process politically palatable, at a price.

To date, cooperation with the regulations depends on international trust, and the understanding that populations and threats to populations are interconnected. National leaders who take timely action secure assistance from the international community to speed the response to public health events, and boost political legitimacy at home and abroad. Adherence has also been grounded in the idea that nations can no longer

control the flow of information, and public health emergencies will become apparent regardless of whether national officials report. Leaders who fail to report a public health emergency promptly face potentially embarrassing and costly travel and trade restrictions if WHO reveals information about the event, as well as collective finger-pointing of communities focused on poor domestic health governance.

Mexican authorities acted as quickly as possible in reporting H1N1, demonstrated good faith, and secured global assistance. By cooperating with WHO and the rest of the global community, Mexico's political leaders garnered legitimacy at home and international respect for being good global citizens. However, the lack of formal enforcement means that nations may not report potential PHEICs. This decision may be based on a political calculation, an economic assessment, or a general lack of competence to make the determination.

Although outside of the IHR (2005), the long-running controversy over Indonesia's refusal to share H5N1 influenza specimens through the WHO Global Influenza Surveillance Network (GISN) illustrates the lack of health governance answers to a nation that refuses to engage. Indonesia has cited the Convention on Biological Diversity as precedent for "viral sovereignty," exploiting the patchwork of treaties that directly and indirectly govern global influenza responses ostensibly to leverage access to influenza vaccines. However, even a 2007 World Health Assembly resolution specifically addressing equity in virus and vaccine sharing failed to break the stalemate. The IHR (2005) mandate sharing of information – whether this includes biological materials remains legally ambiguous.⁵⁶

In the same way, the IHR lack formal mechanisms to respond to non-evidence based actions at ports and borders. However, other mechanisms do exist to address complaints about actions such as restrictions on trade or travel. Although travelers subjected to isolation or quarantine without respect to IHR protections have little formal recourse outside of regular diplomatic or legal channels, WTO provides a forum to evaluate actions such as unwarranted bans on pork imports clearly implemented in violation of WHO recommendations under the IHR (2005).

Weak Links in the Global Disease Surveillance Network

The IHR (2005) establish a worldwide baseline for disease detection and control capabilities. Many countries will struggle to achieve compliance by 2012. Low and middle-income nations in Asia, Africa, and Latin America suffer critical shortages of skilled health workers, including laboratory and public health workers that are rarely the focus of global health workforce strategies.⁵⁷ Substantial technical assistance will be needed to identify the human and material resources needed on the local, national, regional, and global levels, followed by financial commitments to develop those resources in a sustainable manner.

Expert consensus on the types of disease surveillance and public health activities that constitute IHR (2005) core capacity requirements evolved quickly. These provided nations with a necessary broad framework for assessing current capabilities. However, specific technical guidance has trickled out much more slowly. Many countries embarked on assessment, planning, and capacity-building in the absence of detailed guidance only released by WHO in spring 2010.

Dependence on State Capacities and Willing Coordination

In the end, there may be 194 legitimate mechanisms for implementing the IHR (2005). However, as in every area of public health, there will be shared standards for minimal competence. There has been little time, few resources, and no established forum for sharing information on IHR capacities tested by real events. Donor and recipient nations look to WHO to disseminate strong, evidence-based guidance to refine capacity-building and pandemic preparedness plans. This, in turn, requires that all State Parties share lessons learned from events such as the 2009 H1N1 influenza pandemic transparently.

In the last decade, public health actors have shifted from a platform of international to global health, with a focus on human security at the core of assistance and operations. However, global health does not operate in a post-Westphalian environment. Although the IHR (2005) mandate global information sharing and coordination, all public health actions still originate in the community, requiring government capacities at local, state and national levels. The 2009 H1N1 influenza outbreak reaffirmed that we have not yet reached a point, nor is it necessarily the objective to reach a point, that the international community can supplant local public health infrastructure for pandemic preparedness and response and beyond.

Next Steps

The IHR (2005) secured political support during adoption as a mechanism to respond to emerging infections, but they could provide the framework to build broader capacities with local relevance (and thus local buy-in and sustainability). For example, the IHR provide an impetus to strengthen health information systems, which can and should be put to routine use in collecting information on local and national public health priorities. Specific laboratory tests may be unique to emerging infections, but trained laboratory personnel, systems for specimen collection and transportation, and quality assurance and control systems should apply to all national public health efforts. The IHR (2005) thus present the international community with an organizing principle for strengthening laboratory and public health capacities fundamental to health systems.

Many countries have focused initially on reporting and implications for sovereignty, without looking forward to the next step: building response capacities. Even in developed nations like the US, standards for public health preparedness at the subnational level have developed through a complicated process. The IHR (2005) offer a forum for the development of international communities of practice around concepts of resiliency.

The IHR (2005) are not the framework for all global health governance or capacity-building, but address a subset of health systems strengthening and coordination challenges. Historically, donors and partner nations have adopted “vertical” strategies focused on specific diseases or conditions. Strategies that attempt to strengthen IHR (2005)-mandated core capacities without considering broader national health sector strategies risk creating IHR “silos,” and reinforcing redundancies in countries already strained by scarce resources and inadequate health workforces. Many national health authorities already answer to dozens of international mandates and

fundings; an IHR (2005) implementation process not rooted in meeting local and global needs risks becoming yet another burden unlikely to be sustained.

Rebecca Katz is an Assistant Professor of Health Policy and Emergency Medicine at School of Public Health and Health Services, George Washington University.

Julie Fischer leads the Stimson Center Global Health Security Program.

¹ Norman Howard-Jones, "The scientific background of the International Sanitary Conferences, 1851-1938," *WHO Chronicle* 11 (November 1974): 495-508; V. Hubert, "The Unification of the Globe by Disease? The International Sanitary Conferences on Cholera, 1851-1894," *The Historical Journal* 49, no. 2 (2006): 453-476.

² David P. Fidler, "The Globalization of Public Health: The First 100 Years of International Health Diplomacy," *Bulletin of the World Health Organization* 79, no. 9 (2001): 842-9; Hugh S. Cumming, "The International Sanitary Conference," *American Journal of Public Health* 16, no. 10 (October 2006): 975-980.

³ David P. Fidler, *International Law and Infectious Diseases*, Chapter 3, "International Health Regulations." (Oxford: Clarendon Press, 1999).

⁴ World Health Organization, *International Health Regulations (1969)*, 3rd ed. (Geneva: WHO, 1983), 5.

⁵ David P. Fidler, "The Future of the World Health Organization: What Role for International Law?" *Vand J Transnat'l L.*, 31 (1998): 1079; D. Bishop, "Lessons from SARS: Why the WHO Must Provide Greater Economic Incentives for Countries to Comply with International Health Regulations," *Georgetown Journal of International Law* 36 (2005): 1173; L. Gostin, "International Infectious Disease Law," *JAMA* 291, no. 21 (June 2004): 2623-2627; J. Blum, "Global Health and Wellness: A Response to International Health Threats: Law as Development: Reshaping the Global Legal Structures of Public Health," *Mich St. J. Int'l L.*(2004): 207; E. Stein, "International Integration and Democracy: No Love at First Sight," *American Journal of International Law* 95 (2001): 489.

⁶ World Health Assembly, *Revision and Updating of the International Health Regulations*, WHA48.7, May 12, 1995.

⁷ Some progress did occur. In 2001, the World Health Assembly adopted a resolution on global health security, and in 2002, they again called for the need to revised the IHR. World Health Assembly Resolution, *Global Health Security: Epidemic Alert and Response*, WHA54.14, May 2001; World Health Assembly Resolution, *Global Public Health Response to Natural Occurrence, Accidental Release or Deliberate Use of Biological and Chemical Agents or Radionuclear Material that Affect Health*. WHA.55.16, May 2002.

⁸ World Health Assembly. *Revision of the International Health Regulations (2005)*, WHA58.3, May 23, 2005.

⁹ *Ibid.*

¹⁰ World Health Assembly. *Application of the International Health Regulations (2005)*. WHA59.2, May 2006.

¹¹ Bruce J. Plotkin, "Influenza A (H1N1): Lessons Learned and Preparedness for the Future; IHR – Global Public Health Framework for an Interdependent World" (paper presented in Cancun Quintana Roo, Mexico, July 1-3, 2009). Available at:

<http://www.insp.mx/encuentroh1n1/ponencias/Plotkin.pdf>

¹² Laurie Garrett, "The Path of a Pandemic," *Newsweek*, May 2, 2009. Available at:

www.newsweek.com/id/195692/output/print; "Update: Novel Influenza A (H1N1) Virus Infections-Worldwide, May 6, 2009," *MMWR* 58, no. 17 (May 8, 2009): 453-458.

¹³ Rebecca Katz, "Use of the Revised International Health Regulations During Influenza A (H1N1) Epidemic, 2009," *Emerging Infectious Diseases* 15, no. 5 (August 2009): 1165-1170.

¹⁴ World Health Organization, *WHO Technical Advice for Case Management of Influenza A (H1N1) in Air Transport, Developed in Cooperation with The International Civil Aviation Organization and The International Air Transport Association* (Geneva: WHO, May 13, 2009).

¹⁵ World Health Organization, *Production and Availability of Pandemic (H1N1) 2009 Vaccines* (Geneva: WHO, October 30, 2009). Available at:

http://www.who.int/csr/disease/swineflu/frequently_asked_questions/vaccine_preparedness/production_availability/en/index.html

¹⁶ For example, Taiwan, by April 28th, had increased surveillance activities to monitor H1N1 24 hours a day. SY Huang, "International Disease Surveillance Mechanism for 2009 Pandemic Influenza A (H1N1) in Taiwan," *Taiwan Epidemiology Bulletin* 25, no. 10 (October 25, 2009): 708-726.

¹⁷ S. Goforth, "H1N1: Trend and Lessons," *Foreign Policy Blogs Network*, May 25, 2009. Available at:

<http://mexico.foreignpolicyblogs.com/2009/05/25/h1n1-trends-lessons/>

¹⁸ The World Bank, *Influenza A: Questions and Answers*. Available at:

<http://web.worldbank.org/WBSITE/EXTERNAL/NEWS/0,,print:Y~isCURL:Y~contentMDK:22160388~pagePK:64257043~piPK:437376~theSitePK:4607,00.html>

¹⁹ William B. Cassidy, "Mexico to Shut Down Business to Fight Swine Flu," *The Journal of Commerce Online*, April 30, 2009. Available at:

<http://www.joc.com/node/411099>, March 2010; Julie Watson and Lisa J. Adams, "Swine flu an epidemic of losses for Mexico economy," *Associated Press*, April 30, 2009. Available at:

<http://abcnews.go.com/US/wireStory?id=7465917>, March 2010.

²⁰ Lawrence Gostin, "Influenza A (H1N1) and Pandemic Preparedness Under the Rule of International Law," *JAMA* 301, no. 22 (June 2009): 2376-2378; PBS Newshour, *Mexico's Tourism in the Wake of H1N1* May 6, 2009. Available at:

http://www.pbs.org/newshour/globalhealth/0506_tourism_slideshow/index.html?type=flash

²¹ UPI, *Canada Donating Excess H1N1 Vaccine* UPI.com, January 28, 2010. Available at:

http://www.upi.com/Top_News/International/2010/01/28/Canada-donating-excess-H1N1-vaccine/UPI-11221264706200/; N. Lurie, "Statement on Safeguarding Our Nation: HHS Response to the

H1N1 Outbreak," Committee on Homeland Security, October 27, 2009. Available at:

<http://www.hhs.gov/asl/testify/2009/10/t20091027a.html>

²² ABC News, *Egypt Orders Pig Cull*, April 30, 2009. Available at:

<http://www.abc.net.au/news/stories/2009/04/30/2556545.htm?section=justin%20Egypt%20orders%20pig%20cull>.

²³ Gostin, "Influenza A (H1N1) and Pandemic Preparedness Under the Rule of International Law";

Jonathan Lynn, "Swine Flu Alert Prompts Pork Import Bans," Reuters, April 27, 2009. Available at:

<http://www.reuters.com/article/latestCrisis/idUSN27533817>, March 2010.

²⁴ *Joint FAO/WHO/OIE/WTO Statement on Influenza A (H1N1) and the Safety of Pork*, May 2, 2009.

Available at:

http://www.who.int/mediacentre/news/statements/2009/h1n1_20090502/en/index.html

²⁵ Garrett, "The Path of a Pandemic."

²⁶ Katz, "Use of the Revised International Health Regulations During Influenza A (H1N1) Epidemic, 2009."

²⁷ D. Fidler, "H1N1 After Action Review: Learning from the Unexpected, the Success and the Fear," *Future Microbiology* 4, no. 7 (2009): 767-769.

²⁸ Xinhua, *8 Influenza A/H1N1 Cases Confirmed in Asia-Pacific Region*, www.chinaview.cn, May 4, 2009.

Available at:

http://news.xinhuanet.com/english/2009-05/04/content_11312995.htm; Gostin, "Influenza A (H1N1) and Pandemic Preparedness Under the Rule of International Law."

²⁹ D. Bitar, A. Goubar, and J.C. Desenclos, "International Travels and Fever Screening During Epidemics: A Literature Review on the Effectiveness and Potential Use of Non-Contact Infrared Thermometers."

Eurosurveillance 14, no. 6 (2009): 19115-10. Available at:

<http://www.eurosurveillance.org/ViewArticle.aspx?ArticleId=19115>, March 2010.

³⁰ World Health Organization, *No Rationale for Travel Restrictions* (Geneva: WHO, May 1, 2009).

Available at:

http://www.who.int/csr/disease/swineflu/guidance/public_health/travel_advice/en/index.html

³¹ Gostin, "Influenza A (H1N1) and Pandemic Preparedness Under the Rule of International Law."

- ³² For example, see India's pandemic plan, *Management of H1N1 Pandemic*. Available at: <http://ndma.gov.in/ndma/assistance/PandemicFlu.pdf>
- ³³ World Health Organization, *Statement by Dr. Keiji Fukuda on Behalf of the WHO at the Council of Europe Hearing on Pandemic (H1N1) 2009*, January 26, 2010. Available at: http://www.who.int/csr/disease/swineflu/coe_hearing/en/index.html
- ³⁴ World Health Organization, *Pandemic Influenza Preparedness and Response* (Geneva: WHO, April 2009). Available at: <http://www.who.int/csr/disease/influenza/PIPGuidance09.pdf>
- ³⁵ BJ Plotkin, "Influenza A (H1N1): Lessons Learned."
- ³⁶ Nirmala Ravishankar., "Financing of Global Health: Tracking Development Assistance for Health from 1990 to 2007," *Lancet* 373 (2009): 2113–24.
- ³⁷ Ministers of Foreign Affairs of Brazil, France, Indonesia, Norway, Senegal, South Africa, and Thailand, "Oslo Ministerial Declaration—Global Health: A Pressing Foreign Policy Issue of Our Time," *Lancet* 369 (2007):1373–8.
- ³⁸ D.P. Fidler, "Architecture Amidst Anarchy: Global Health's Quest for Governance," *Global Health Governance* 1 (2007):1-17.
- ³⁹ Richard D. Smith and Landis MacKellar, "Global Public Goods and the Global Health Agenda: Problems, Priorities and Potential," *Globalization and Health* 3 (2007): 9-16.
- ⁴⁰ World Health Organization, *International Health Regulations (2005): Toolkit for Implementation in National Legislation – The National IHR Focal Point* (World Health Organization: Geneva, January 2009).
- ⁴¹ Sarah Davies, "Securitizing Infectious Disease," *International Affairs* 84, no. 2 (2008): 295.
- ⁴² Frank Fenner, D. A. Henderson, Isao Arita, Zedenek Jezek, Ivan Ladnyi. *Smallpox and its Eradication*. (WHO: Geneva, 1988). Available at: <http://whqlibdoc.who.int/smallpox/9241561106.pdf>; D.A. Henderson, *Smallpox: The Death of a Disease* (New York: Prometheus Books, 2009).
- ⁴³ David P. Fidler, "From International Sanitary Conventions to Global Health Security: the New International Health Regulations," *Chinese Journal of International Law* 4 (2005): 325-392.
- ⁴⁴ World Health Organization, "WHO Country Offices." Available at: http://www.who.int/countryfocus/country_offices/en/
- ⁴⁵ *EU Council Conclusions on Influenza A/H1N1 infection*, April 30, 2009. Available at: www.europa-eu-un.org/home/pritn.asp?1=1&lg=5
- ⁴⁶ R. Watson, "Council of Europe Launches Investigation into H1N1 Pandemic," *BMJ* 340 (2010); c641.
- ⁴⁷ World Health Organization, *Statement by Dr. Keiji Fukuda*
- ⁴⁸ Fidler, "H1N1 After Action Review."
- ⁴⁹ World Health Organization, *Pandemic Influenza Preparedness and Response* (Geneva: WHO, April 2009) Section 3.2.1. Available at: <http://www.who.int/csr/disease/influenza/PIPGuidance09.pdf>
- ⁵⁰ Laurie Garrett, "The Global Response to the Swine Influenza," *Council on Foreign Relations*, May 8, 2009. Available at: www.cfr.org/publication/19299/global_response_to_the_swine_influenza.html
- ⁵¹ H. Branswell, "H1N1 Pandemic Poses Big Communications Challenge for Global Health Agency: Chan," *Metro*, December 28, 2009. Available at: www.metronews.ca/articleprtn/408025?language=en
- ⁵² World Health Organization, *International Health Regulations (2005): Areas of Work for Implementation*. (Geneva, WHO, June 2007).
- ⁵³ World Health Organization Statistical Information System, March 2010. Available at: <http://www.who.int/whosis/en/>
- ⁵⁴ Jon Cohen, "Exclusive: Interview with Head of Mexico's Top Swine Flu Lab," *ScienceNOW*, May 1, 2009. Available at: <http://news.sciencemag.org/sciencenow/2009/05/01-01.html>; "Outbreak of Swine-Origin Influenza A (H1N1) Virus Infection --- Mexico, March--April 2009," *MMWR* 58, no. 17 (May 8, 2009): 467-470. Available at: <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5817a5.htm>, March 2010.

⁵⁵ WHO African Region, *Pandemic (H1N1) 2009 African Region Situation Updates*, August 26, 2009, Available at:

<http://www.afro.who.int/ddc/influenzaa/updates/index.html>.

⁵⁶ David P. Fidler, "Influenza Virus Samples, International Law, and Global Health Diplomacy," *Emerg Infect Dis* 14, no. 1 (2008):88-94.

⁵⁷ World Health Organization, *World Health Report 2006: Working Together for Health* (Geneva: WHO, 2006).