

COMMENTARY

Strengthening the International Health Regulations: lessons from the H1N1 pandemic

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The International Health Regulations (2005) [IHR(2005)] represent a potentially revolutionary change in global health governance. The use of the regulations by the World Health Organization (WHO) to respond to the outbreak of pandemic influenza A 2009-H1N1 highlights the importance of the regulations to protecting global health security. As the 2009-H1N1 pandemic illustrated, the IHR(2005) have provided a more robust framework for responding to public health emergencies of international concern (PHEICs), through requiring reporting of serious disease events, strengthening how countries and WHO communicate concerning health threats, empowering the WHO Director-General to declare the existence of PHEICs and to issue temporary recommendations for responding to them, and requiring countries not to implement measures that unnecessarily restrict trade and travel or infringe on human rights. However, limitations to the effectiveness of the IHR(2005) revealed in the 2009-H1N1 pandemic include continuing inadequacies in surveillance and response capacities within some countries, violations of IHR(2005) rules and a potentially narrowing scope of application only to influenza-like pandemic events. These limitations could undermine the IHR(2005)'s potential to contribute to national and global efforts to detect and mitigate future public health emergencies. Support for the IHR(2005) should be broadened and deepened to improve their utility as a tool to strengthen global health security.

Keywords Health policy, legislation, international health policy, World Health Organization, public health emergencies

Introduction

Following the SARS outbreak in 2003 and concerns about an influenza pandemic in 2004–05 after avian influenza A (H5N1) emerged, the World Health Organization (WHO) adopted in May 2005 the revised International Health Regulations [IHR(2005)] (WHO 2005). The revised regulations were the product of a decade-long revision process within WHO that substantially changed this international legal regime by expanding its scope of application, the obligations of States Parties and WHO's powers to respond to public health emergencies. The IHR(2005) figured prominently in the WHO's response to the influenza A (H1N1) outbreak (Fidler

2009; Katz 2009). For the first time since the IHR(2005) entered into force in June 2007, WHO utilized the regulations to create an Emergency Committee to advise the WHO Director-General, declare a public health emergency of international concern and issue temporary recommendations on increasing surveillance and on the need to avoid unnecessary trade, travel and human rights restrictions.

The use of the IHR(2005) during the 2009-H1N1 influenza outbreak has raised questions about whether the regulations functioned as intended. Initial analysis suggests that the IHR(2005) worked well in the 2009-H1N1 outbreak (Fidler 2009; Katz 2009). This event, however, also revealed concerns about the realization of the regulations' full potential. These

concerns include narrow interpretations of the WHO Director-General's power to declare a public health emergency of international concern, the lack of coordinated and adequately funded global support for IHR(2005) implementation by developing countries, the relationship between the IHR(2005) and WHO's pandemic influenza alert system and the ability of countries to violate the IHR(2005)'s rules on measures affecting trade, travel and human rights with relative impunity.

The power to declare a public health emergency of international concern

One of the IHR(2005)'s innovations is the concept of a 'public health emergency of international concern' (PHEIC). Rather than requiring States Parties only to report cases of specific diseases, the regulations mandate reporting of any natural or manmade disease event—biological, chemical or radiological—that may constitute a PHEIC. The IHR(2005) contain a decision instrument that guides States Parties through the process of determining whether they must report a disease event to WHO (Fidler 2003; Baker and Fidler 2006). The regulations deem any case of human influenza caused by a new virus subtype as a potential PHEIC that must be reported to WHO, which therefore requires that States Parties report cases of novel influenza viruses, such as 2009-H1N1, to WHO. Under the IHR(2005), the WHO Director-General is empowered to analyse information received from States Parties and non-governmental sources in order to determine, with the advice of an Emergency Committee, whether a disease event actually constitutes a PHEIC, as Director-General Margaret Chan did in the case of the 2009-H1N1 threat.

The PHEIC declaration in the 2009-H1N1 outbreak revealed the significance of this aspect of the IHR(2005). Such a declaration requires the WHO Director-General to issue temporary recommendations on how countries should respond to the PHEIC. The PHEIC declaration for the 2009-H1N1 outbreak did not prove controversial; in fact, the controversy generated by WHO's pandemic influenza alert system largely overshadowed the PHEIC declaration (Fidler 2009). Nevertheless, the first PHEIC declaration raises some questions about this power.

The first-ever PHEIC declaration draws attention to other significant disease events that the WHO Director-General has not considered PHEICs under the approach adopted in the IHR(2005), perhaps providing insight into the scope of the PHEIC-declaration power. Serious public health events, including the emergence and spread of XDR-TB (Calain and Fidler 2007; Wilson *et al.* 2007), significant cholera outbreaks and the export of melamine-contaminated food (Bell 2008), did not lead to the convening of the Emergency Committee or a PHEIC declaration by the WHO Director-General. In considering whether the XDR-TB problem warranted PHEIC treatment, the Global Task Force on TB stated that 'the IHR Emergency Committee and temporary recommendations are really intended for outbreaks of acute disease, rather than the "acute-on-chronic" situation of MDR-TB and XDR-TB' (Global Task Force on XDR-TB 2006). Similar reasoning might explain the lack of PHEIC attention given to the melamine problem, but nothing in the IHR(2005) textually supports this reasoning. Further, it

does not explain the non-use of a PHEIC declaration with respect to the rapid spread of acute outbreaks of cholera, especially given the IHR(2005)'s identification of cholera as a pathogen of international concern [Annex 2 of the IHR(2005)].

This admittedly brief experience with the IHR(2005) suggests that WHO practice might limit PHEIC declarations to a very small number of infectious diseases with characteristics resembling novel human influenza viruses or SARS. This narrow scope reflects a conservative approach to the political and epidemiological discretion the IHR(2005) provide the Director-General in determining the existence of a PHEIC. Too much caution might, however, prevent the IHR(2005) from being used more strategically to draw attention to serious public health harms that require international action and assistance.

Preparing for a public health emergency: surveillance and response capacities

The IHR(2005) require States Parties to develop and maintain minimum core capacities, to conduct surveillance and to respond to public health threats from the local to the national levels [Annex 1 of the IHR(2005)]. States Parties had to assess their capabilities in these realms by 2009 and must be compliant with these obligations by 2012 (with the option for time extensions). The 2009-H1N1 outbreak revealed continuing problems with surveillance and response capacities in many countries, and these problems connect to growing concern that many States Parties will not be able to comply with their minimum core capacity requirements by the deadline, even with allowed extensions (Calain 2007a,b).

For example, the response to the 2009-H1N1 influenza outbreak underscores the importance of countries developing real-time, comprehensive clinical surveillance in order to rapidly identify outbreaks that might occur. The lack of readily available, high-quality surveillance in Mexico may have contributed to delays in identifying the outbreak and mischaracterization of the virus's severity. The inability to estimate accurately a proper denominator for the number of affected individuals in Mexico resulted in a grossly inflated mortality rate associated with 2009-H1N1 (Garske *et al.* 2009). As a result, recognition of the strain's novelty, its sustained human-to-human transmission and its virulence was delayed, which made interventions recommended in WHO's influenza pandemic preparedness plan (e.g. ground-level containment, social distancing and distribution of anti-virals) more difficult. The WHO pandemic influenza strategy hinges on the ability of countries to detect, at the earliest stages, the emergence of a novel pathogen with efficient human-to-human transmission (Ferguson *et al.* 2005; Longini *et al.* 2005).

However, complying with the IHR(2005)'s surveillance and response capacity obligations generates challenges and tensions, especially for developing and least-developed countries. First, as the 2009-H1N1 outbreak illustrated, many developing and least-developed countries are far from being able to comply with the IHR(2005)'s minimum core capacity mandates, and no coordinated, adequately funded global health initiative is underway to deliver assistance to such countries to implement

the IHR(2005). Support for implementation of the IHR(2005) is often voiced, as illustrated by the creation of a WHO collaborating centre on IHR(2005) implementation at the US Centers for Disease Control and Prevention¹ and by the inclusion of IHR(2005) implementation support in the new US National Health Security Strategy (US Department of Health and Human Services 2009). However, to date, these and other expressions of support for IHR(2005) implementation have not coalesced into coordinated, funded global action.

Second, some view the minimum core capacity mandates as potentially distorting national public health priorities by requiring developing countries to expend resources for potential PHEICs, which are of great concern to wealthier nations, at a time when resources for public health emergencies of local concern are scarce and diminishing (Lancet 2004; Calain 2007a). The controversy over the sharing of avian influenza H5N1 samples and benefits derived from research on such samples (e.g. vaccines), including the rejection of the applicability of the IHR(2005), reflects a developing-country sense of the inequity in the way the current system operates (Garrett and Fidler 2007; Fidler 2008). Similarly, problems experienced with creating more developing-country access to vaccine for 2009-H1N1 revealed the IHR(2005)'s lack of relevance to addressing questions of equity and fairness in access to disease-response technologies (Fidler 2010).

Relationship between the IHR(2005) and the WHO pandemic alert system

The IHR(2005)'s role in the global handling of the 2009-H1N1 outbreak was obscured by the controversies that erupted over the application of WHO's influenza pandemic alert system, through which the WHO Director-General can determine various alert phases in order to stimulate governments to prepare for or respond to a pandemic. The management of the 2009-H1N1 outbreak by WHO created confusion about the relationship between the IHR(2005) and the influenza pandemic alert system. Legally speaking, the IHR(2005) contain no provisions that mention, let alone authorize, anything connected with the influenza pandemic alert system. The argument that the decision to raise the alert levels constitutes a temporary recommendation under the IHR(2005) is not persuasive for two reasons. First, the WHO Director-General only sought the Emergency Committee's advice two out of the three times she raised the pandemic alert levels. The IHR(2005) require Emergency Committee input before the Director-General issues any temporary recommendations. Second, WHO never included the country-level actions contained within the alert system's levels in listing the temporary recommendations made under the IHR(2005). Thus, what happened in the 2009-H1N1 context raises questions about the explicit legal propriety of using the IHR(2005)'s Emergency Committee to advise on raising pandemic influenza alert levels.

Potential violations of the IHR(2005)

The 2009-H1N1 outbreak also produced behaviour by some countries that raised questions about their compliance with the

IHR(2005). The IHR(2005)'s purpose 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' (article 2). In addition, 'States Parties shall treat travelers with respect for their dignity, human rights and fundamental freedoms and minimize any discomfort or distress associated with such measures' (article 32). States Parties applying measures that are more restrictive of trade and intrusive for travellers than recommendations issued by WHO must provide WHO with the public health rationale and scientific evidence justifying such measures (article 43) (von Tigerstrom 2005).

Examples of potential violations of these obligations arose during the 2009-H1N1 outbreak. Despite WHO's determination that travel advisories and restrictions were not necessary, many countries used such measures in responding to the outbreak. Other countries implemented restrictions on pork products exported by countries affected by 2009-H1N1 cases even though WHO and the World Animal Health Organization (OIE) repeatedly stated that such restrictions were not justified. Controversies also arose from the isolation or quarantine of individuals and groups arriving from, or associated with, 2009-H1N1-affected countries—policies that were also inconsistent with WHO recommendations (Gostin 2009). In one case, WHO requested a country's public health rationale and scientific justification for its actions, in accordance with the IHR(2005).

For the most part, the countries engaging in actions that potentially violated the IHR(2005) did so without suffering serious consequences. Like most international agreements, the IHR(2005) do not contain a mandatory dispute settlement process or enforcement mechanism. The larger concern with these potential violations is that they occurred during an outbreak of a comparatively mild virus, creating the possibility of more widespread violations if a more dangerous virus emerges and spreads. More unnecessary trade, travel and human rights restrictions could undermine incentives States Parties have to comply with their obligations to report public health events that may constitute PHEICs. Under this scenario, the IHR(2005) are at risk of unravelling through systematic violations, in much the same way as earlier versions of the regulations did. However, it is important to recognize that in the absence of the IHR(2005), it is possible that these restrictions would have been more widespread.

Strategies for supporting the IHR(2005)

The problems identified above should not detract from the importance of the IHR(2005). The use of the IHR(2005) during the 2009-H1N1 outbreak revealed the revised regulations as a considerable improvement over the previous governance approaches, particularly in the flow of information between countries and WHO. The issues identified in this article indicate, however, that WHO and the States Parties face challenges in strengthening implementation of and compliance with the IHR(2005) (Box 1).

In terms of the WHO Director-General's power to declare a PHEIC, consideration should be given to making more robust

Box 1 Key points**Improvements in the response to 2009-H1N1 resulting from the coming into force of the IHR(2005)**

- Clear reporting requirements for countries.
- Identification of national focal points for communication with WHO.
- Integration of information received from States Parties and non-governmental sources.
- Use of the Director-General's power to declare a PHEIC.
- Issuance of temporary recommendations concerning the management of the pandemic.
- Monitoring responses for unnecessary trade, travel and human rights restrictions.

Areas where the IHR(2005) should be supported

- Technical and financial support to developing and least-developed countries to assist them in meeting surveillance and response capacity requirements of IHR(2005).
- Consideration of using the power to declare PHEICs for a broader range of global health threats.
- Development of mechanisms to improve compliance with the IHR(2005) and WHO recommendations issued thereunder.

use of the IHR(2005) for public health threats. PHEIC declarations could prove useful in other contexts by drawing attention and assistance to efforts to prevent the spread of serious transboundary public health harms. The WHO Director-General could also make use of the power to issue standing recommendations under the IHR(2005) as part of strategies to improve how countries deal with different types of serious international public health danger.

The relationship between the IHR(2005) and the WHO pandemic alert system should be clarified so that questions about, or challenges to, the use of the Emergency Committee established under the regulations do not create political and legal complications in the midst of a potential emergency. The efficiency of using the Emergency Committee for advising the Director-General on declaring a PHEIC, issuing temporary recommendations and raising pandemic phase levels is obvious, but the lack of legal authority for the Emergency Committee to provide advice on pandemic phase levels should be addressed, perhaps through a resolution of the World Health Assembly or a formal amendment to the regulations.

In terms of reducing potential violations of the IHR(2005)'s rules on trade and travel measures, amending the IHR(2005) to include an enforcement mechanism or penalties for violations would not be possible politically. The Director-General could, however, implement more strongly the requirement in the IHR(2005) mandating that States Parties provide the public health rationale and scientific evidence justifying trade and travel restrictions not conforming to WHO recommendations. Such action could include asking the Review Committee established under the IHR(2005) to provide its views on the

justifications for trade and travel restrictions that do not conform to WHO recommendations. In addition, States Parties could make expedited use of the good offices of the Director-General for resolving disputes raised by restrictive trade and travel measures. Finally, WHO, OIE and the World Trade Organization could explore strategies to reduce trade reactions to PHEICs and other public health threats that are not supported by public health principles or scientific evidence, perhaps through formation of a cooperative mechanism to respond in real time to alleged violations of trade and health rules during international public health events.

Perhaps the most pressing need for new strategic action concerns the danger that many States Parties, especially developing and least-developed countries, will not be in compliance with their minimum core obligations on surveillance and response capacities by the deadlines established in the IHR(2005). Key to progress on these obligations is technical assistance and financial resources from developed countries, the availability of which would be linked to measurable improvements in the minimum core surveillance and response capacities mandated by the regulations. Creation and operation of assistance mechanisms could be supported and coordinated by WHO and powerful global health partners, such as the World Bank, the Group of 20 and philanthropic organizations (e.g. Gates and Rockefeller Foundations).

The 2009-H1N1 outbreak highlighted the potential the revolutionary change in international law the IHR(2005) represent, but it also revealed problems that require immediate attention. Stronger global health security will require strategic advances in the implementation of, and compliance with, the IHR(2005). Without such advances, the problems seen during the 2009-H1N1 outbreak may multiply exponentially if the world community faces a more dangerous influenza virus or some other virulent microbial surprise.

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Endnote

- ¹ Statement by Under Secretary Tauscher on Biological Weapons, 9 December, 2009, at <http://www.america.gov/st/texttrans-english/2009/December/20091210142708xjsnommis0.2277948.html>.

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