

Sound Science and the New International Health Regulations

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The new International Health Regulations (IHR) entered into effect in June 2007. In order to ensure cooperation and avoid disputes between WHO member states, the new IHR have “sound science” clauses. Yet history suggests that during public health emergencies of international concern, actors may seek to leverage scientific uncertainty according to their political interests. This paper argues that further deliberation about how to establish a robust, transparent and rapid dispute resolution procedure is needed.

SARS and avian influenza, two high profile emerging diseases, have wreaked considerable havoc around the world in recent years. Humans, animals, economies and our sense of health security have been victims of these outbreaks. Alarmed by the rapidity with which these two diseases have spread around the world, much investment has been placed into better understanding the factors that might drive the spread of infectious disease, whether increased trade and travel, climate change, intensive agriculture, migration, or so on.¹ Furthermore, international health and political communities have placed an increased emphasis on strengthening global health governance. Thus infectious diseases have been added to the agendas of high-level political meetings such as last year’s G8 summit in St. Petersburg, Russia. Meanwhile, SARS provided the final momentum needed for the World Health Assembly to adopt the revised International Health Regulations (IHR) after roughly ten years of consultation, deliberation and negotiation.²

By now the significance and innovation of the new IHR have been well documented. Some argue these regulations, which entered into effect in June 2007, are “unprecedented in the history of the relationship between international law and public health.”³ Amongst other developments, the new IHR vastly expand the range and nature of disease events that fall under its scope; incorporate human rights principles⁴; mandate WHO member states to “develop, strengthen and maintain” surveillance capacities (Article 5.1); enable WHO to take into account reports of disease outbreaks from non-state sources (Article 9); and grant the WHO Director-General (DG) the power to determine whether an event “constitutes a public health emergency of international concern” (Article 12).

There are high stakes involved in declaring public health emergencies of international concern (PHEICs). Doing so mandates WHO to issue both temporary and standing (but non-binding) recommendations for implementations to be adopted by the affected WHO member state as well as other WHO member states (Articles 15-18). Additionally, any such declaration could have immediate economic ramifications for the country in which the disease event is occurring, either through declines in tourism, decreased demand for exports or, worse, trade embargoes. To prevent any of this from happening unjustifiably, the new IHR does have safeguards. To ensure that WHO declarations of PHEICs are made with proper deliberation,

Article 12.4 requires that the WHO Director-General takes into account data from the member state, advice from an Emergency Committee and the logic of a decision instrument (Annex II). More importantly, Article 12.4 also states that declarations must be as far as possible based upon scientific principles while incorporating all available scientific evidence and considering assessments of the risks to: human health, the international spread of disease and interference with international traffic.

Similarly, although the new IHR enable member states to implement their own protective measures which “achieve the same or greater level of health protection than WHO recommendations” (Article 43.1.a), these measures must be supported by scientific principles and available scientific evidence while also taking any specific WHO guidance into account (Article 43.2). It has been noted that these scientific requirements parallel similar requirements in WTO agreements, notably the SPS Agreement.⁵ This is clearly intentional. Avoiding conflict with other binding international law was an important concern raised by WHO member states during the IHR revision process.⁶ Furthermore, a high degree of transparency and consistency is clearly required to ensure the cooperation of all WHO member states. As one member of the IHR revision team has argued, “if outside response regarding traffic and trade is not restrained by a solid, internationally accepted, risk assessment, global surveillance will never work.”⁷

Thus the new IHR broaden the scope of infectious disease governance while also placing a greater emphasis on linking preventative measures with available scientific evidence. Yet will this be enough to avoid disagreements between WHO member states or between WHO and its member states?

This would seem improbable, and not simply because dispute settlement under the new IHR is “essentially voluntary.”⁸ One of the underappreciated insights from the SARS outbreak of 2003 is that during a pandemic, science and politics are difficult to disentangle. Recalling the dispute between the Canadian government and WHO over WHO advisories against travel to Toronto, one lesson must be that when a country is faced with significant economic consequences, resistance is as likely as cooperation, even if the new IHR make covering up disease events less desirable. In 2003, the Canadians lobbied (politically and scientifically) to have the travel advisory removed. For example, as Ontario’s Chief Medical Officer suggested that WHO’s scientific arguments were not “convincing,”⁹ another Canadian official suggested that the WHO advisory was “guided by political concerns rather than facts.”¹⁰ Following a closed door meeting between WHO and Canadian officials, the resolution of this dispute appeared to many to be a scientific/political compromise, with the WHO reversing its advisory but only after the Canadians agreed to increase airport screening, a WHO recommendation that Canada had previously thought too burdensome.¹¹

It is important to remember that PHEICs are often situations of high scientific uncertainty. Unknown information might include the incubation period, the attack rate, the case fatality rate, the mode of transmission and even the causative agent. Thus how risk assessments are conducted and what member states perceive to be valid scientific evidence or appropriate preventative measures can be expected to vary significantly. Moreover, if the WTO SPS Agreement’s “sound science” provisions have been influential on the new IHR, then it should not escape health policy-makers that there have been numerous high-profile WTO disputes over the interpretation and

application of science-based risk assessments, such as trans-Atlantic disagreements over the regulation of genetically modified organisms.¹²

Disputes of this nature reinforce a large body of research that draws attention to the substantial impacts that political, regulatory and cultural contexts can have on how scientific evidence is perceived and acted upon.¹³ Although it is tempting to view the new IHR as emblematic of a new era in which health has a greater role in global politics and diplomacy,¹⁴ the converse, that global politics and diplomacy now have a greater role in health, may also be true. That the new IHR are predicated on sound science should be viewed of not as an end-point but as an important starting point for further and needed discussions about how to establish transparent, robust and rapid dispute resolution processes during public health emergencies of international concern.

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¹ D. A. King et al., "Infectious Diseases: Preparing for the Future," *Science* 313, no. 5792 (8 September 2006): 1392-1393.

² World Health Assembly, *Revision of the International Health Regulations*, WHA 58.3, May 23, 2005.

³ David Fidler and Lawrence O Gostin, "The New International Health Regulations: A Historic Development for International Law and Public Health," *Journal of Law, Medicine & Ethics* 34, no. 1 (Spring 2006): 93.

⁴ David Fidler, "From International Sanitary Conventions to Global Health Security: The New International Health Regulations," *Chinese Journal of International Law* 4 (2005): 325-392.

⁵ Fidler and Gostin, "the New International Health Regulations"; Fidler, "From International Sanitary Conventions to Global Health Security."

⁶ Fidler and Gostin, "the New International Health Regulations"; Fidler, "From International Sanitary Conventions to Global Health Security."

⁷ Johan Giesecke, "Prevention, not panic – epidemics and trade sanctions," *Lancet* 356, no. 9229 (August 12, 2000): 589.

⁸ Fidler and Gostin, "The New International Health Regulations."

⁹ André Picard and Caroline Alphonso, "Canadians ratchet up criticism of travel advisory," *The Globe and Mail*, April 25, 2003.

¹⁰ "SARS Scare in Toronto," *The New York Times*, April 25, 2003.

¹¹ Clifford Krauss, "The SARS Epidemic: Canada; Advice to put off trips to Toronto is lifted by WHO," *The New York Times*, April 30, 2003.

¹² World Trade Organization, *European Communities – Measures affecting the approval and marketing of Biotech Products: Report of the Pandel*, WT/DS291/R, WT/DS292/R, WT/DS293/R, September 29, 2006.

¹³ Sheila Jasanoff, *Designs on Nature: Science and democracy in Europe and the*

United States (Princeton: Princeton University Press, 2005).

¹⁴ Richard Horton, "Health as an instrument of foreign policy," *Lancet* 369, no. 9564 (March 10-March 16, 2007): 806-807.