
Global Public Health Legal Responses to H1N1

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Introduction

Pandemics challenge the law and often highlight its strengths or expose its limits. The novel strain of influenza A (H1N1) virus that emerged in the spring of 2009 and rapidly spread around the globe was no exception. The H1N1 pandemic prompted the first significant application of a number of international legal and policy mechanisms that have been developed in the last decade to respond to this kind of event. Furthermore, it presented a considerable test for public health systems at all levels, from global to local.

Although initial predictions forecasting high morbidity and mortality from this virus overestimated its eventual impact, the human toll of the pandemic was nevertheless significant. The World Health Organization (WHO) reported approximately 1.5 million people were infected worldwide in 214 countries, resulting in over 25,000 confirmed deaths, but the actual health impact of the outbreak was certainly much higher.¹

Several explanations may be offered, in hindsight, to explain the lower-than-expected morbidity and mortality rates. The rates might represent a momentous success for public health, validating the strategies — including legal strategies — employed to stem the spread of the disease. The result might also be attributed to epidemiological fortuity, since this strain of influenza A (H1N1) virus proved less virulent than initially feared. Public health systems would not likely have functioned or responded as well had the strain

been more deadly. Alternatively, some have described the public health response as an overreaction, questioning the designation of this outbreak as a pandemic and arguing that public health efforts may have been motivated by bad faith decisions or conflicts of interest within public health systems and institutions.²

Our analysis suggests that the 2009 influenza A (H1N1) virus prompted a number of legal responses that were integral to the resulting public health outcomes. Legal frameworks supported a complex global response, requiring the combined efforts of governments, inter-governmental and non-profit institutions, and private entities. The application of these frameworks demanded international cooperation among these actors on activities including disease surveillance and sharing of information and resources. In addition, laws impacted access to pharmaceutical countermeasures such as vaccines and antiviral medication. Governments also employed public health powers to institute a variety of non-pharmaceutical countermeasures in an attempt to control the spread of the virus, including quarantine, school closures, and other social distancing measures.

Three key examples of global public health legal responses to the H1N1 pandemic are illustrated below: (1) the role of Mexico as a first responder; (2) the first conceptual and operational test of the revised International Health Regulations (IHR (2005)); and (3) the legal and policy complications raised by virus-sharing agreements between countries.

Legal Responses to the Influenza Outbreak in Mexico

In Spring 2009, Mexico experienced outbreaks of influenza-like illness (ILI). On April 12, 2009, Mexico confirmed an outbreak of ILI occurred in La Gloria in

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the state of Veracruz and reported this outbreak to the WHO. Later in April, outbreaks of severe pneumonia in Distrito Federal (Mexico City) and San Luis Potosi precipitated increased surveillance throughout the country.³ By the end of April, the U.S. Centers for Disease Control and Prevention reported seven confirmed human cases of influenza A (H1N1) in the United States, with mild ILI symptoms.⁴ Experts agreed that, in its early stages, the outbreak of influenza A (H1N1) virus in Mexico and the United States marked the beginning of a worldwide pandemic.⁵ The high fatality rate of the novel influenza A (H1N1) infection among younger, previously healthy people was particularly disturbing.⁶

Mexico reacted quickly and aggressively in its surveillance and social distancing measures in response to the H1N1 threat. Government officials cooperated immediately with the WHO, the Pan American Health Organization, and neighboring countries in reporting and analyzing the flu outbreak. On April 17, 2009, in response to the increase in reports of respiratory illness, the Mexican General Directorate of Epidemiology issued a national epidemiologic alert to all influenza-monitoring units and hospitals asking that they test and report all cases of severe respiratory illness. Health officials conducted epidemiological studies to assess the threat and to obtain information on the disease and its dissemination.⁷

Between March and the end of May 2009, Mexican public health surveillance efforts helped identify sev-

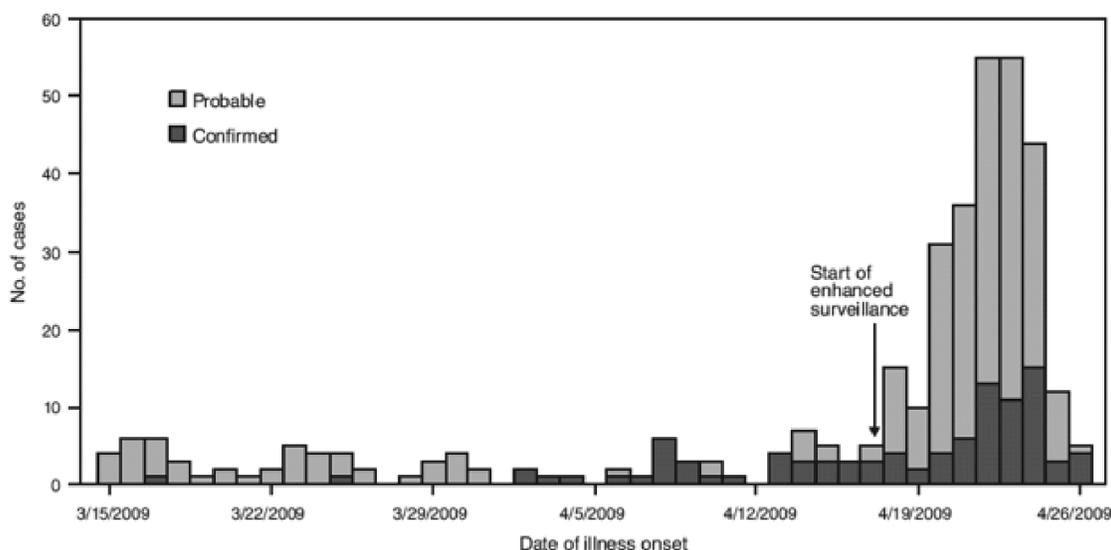
eral cases of acute respiratory illness, most of which were confirmed to be the novel influenza A (H1N1) virus infection. As of April 26, ninety-seven patients with laboratory-confirmed infections had died.⁸ See Figure 1, below.

On April 24, the Council for General Hygiene, in consultation with Mexican President Felipe Calderon, ordered, among other measures, that all schools and large public gatherings, such as soccer games in Mexico City and surrounding areas, be closed or suspended for about ten days. By May, Mexican authorities reported that the outbreak had likely peaked in late April. WHO publically acknowledged that Mexico had been cooperative and forthright in addressing the influenza A (H1N1) outbreak.⁹

Public health surveillance and enforcement are crucial public health strategies. The Mexican government used both effectively following the emergency of the novel influenza A (H1N1) virus. Some evidence traces the initial outbreak to a major industrial pig farm near the town of La Gloria.¹⁰ The farm is operated by Granjas Carroll de México, a Mexican corporation partially owned by the U.S. corporation, Smithfield. The Mexican government has rejected the claim that the original infection came from this farm, despite the known ability of the influenza A (H1N1) virus to jump from humans to swine and vice versa.¹¹ However, at least one man has brought a wrongful death action against Smithfield for the death of his pregnant wife from influenza A (H1N1).¹² Given the possible role of indus-

Figure 1

Number of Confirmed (N = 97) and Probable (N = 260) Cases of Influenza A (H1N1) Virus Infection by Date of Illness Onset – Mexico, March 15–April 26, 2009



Source: Centers for Disease Control and Prevention, "Outbreak of Swine-Origin Influenza A [H1N1] Virus Infection – Mexico, March–April 2009," *MMWR Morbidity and Mortality Weekly Report* 58 (Dispatch) (April 30, 2009): 1-3, at 1.

trial pig farming in generating the virus, public health officials should also examine the impact of industrial farming techniques on the cultivation and spread of influenza viruses.

The International Health Regulations

The 2009 H1N1 pandemic was the first true test of the IHR (2005), an international instrument legally binding on all WHO Member States. The purpose of the 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...public health risks, and which avoid unnecessary interference with international traffic and trade.”¹³ The regulations entered into force in 2007, following efforts to update the IHR (1969) due to increased global travel and trade and the risk of emerging health threats, such as severe acute respiratory syndrome (SARS) in 2003.

The IHR (2005), which greatly expanded WHO’s authority to respond to international health emergencies, are not limited to specific diseases or modes of transmission. These regulations obligate Member States to develop core disease surveillance and response capacities, establish a National IHR Focal Point (NFP), notify WHO of events that may constitute a public health emergency of international concern (PHEIC), and ensure health measures are based on scientific principles and available evidence. They also authorize the WHO Director-General to convene an Emergency Committee, make a PHEIC determination, and issue temporary recommendations.¹⁴

Based on initial information from Mexican and U.S. health authorities about the influenza A (H1N1) outbreak, WHO Director-General Margaret Chan convened an Emergency Committee to assess the situation, announcing on April 25, 2009 the first-ever PHEIC.¹⁵ On June 11, 2009, WHO raised the global pandemic alert to level 6, the highest possible rating.¹⁶

WHO’s declaration of a PHEIC led to various global, national, and local responses aimed at mitigating the pandemic’s health and societal impact. Though not implemented uniformly, these actions included deployment of WHO personnel, declarations of national and local emergencies, activation of pandemic response plans, implementation of community mitigation measures (e.g., quarantine, border controls, school closures), distribution of antiviral medications, and development of the influenza A (H1N1) vaccine. Some interventions (e.g., restricting travel, culling pigs) meant to control the spread of the virus resulted in unintended socio-economic repercussions. Mexico, for example, suffered severe economic consequences stemming in part from travel and trade advi-

sories issued by other countries, often against WHO guidance.¹⁷

The global response to the H1N1 pandemic was a significant improvement compared to the response during the 2003 SARS epidemic. This improvement was largely due to WHO’s expanded powers and the strengthened framework for responding to international public health threats under the IHR (2005). Although some countries acted unilaterally to protect national interests, most Member States successfully complied with the regulations.¹⁸ This compliance facilitated timely notification, cooperation, and communication between Member States and WHO, which likely helped mitigate the pandemic’s impact.

The response also highlighted challenges in global public health governance. As the regulations continue to guide responses to new disease threats, ensuring transparency in decision making, enforcing compliance, balancing global public health goals with national sovereignty, and strengthening national response and disease surveillance capacities should be further assessed.¹⁹ An external review of WHO’s response by the IHR Review Committee is currently underway to evaluate many of these concerns.²⁰

Sharing Virus Samples between Countries

WHO’s Global Influenza Surveillance Network (GISN)²¹ worked as intended during the 2009 H1N1 pandemic, with Member States using GISN to share flu strains internationally to speed vaccine development. The fact that all nations shared their flu strains during the pandemic is notable. At one point, however, it was unclear whether Indonesia — with the support of other developing nations — would withhold its strains, absent a commitment from developed countries to share with poorer nations the pandemic vaccine developed from strains gathered through GISN.

Indonesia had refused to share influenza strains with WHO in 2007 after learning that novel H5N1 influenza strains it had volunteered to GISN in 2005 were used by a private manufacturer to produce and patent a high-priced vaccine that the Indonesian government could not afford to purchase in sufficient quantity to protect its citizenry. Only after WHO Member States agreed to open negotiations focused on developing standards for “benefits sharing” among those participating in GISN did Indonesia resume sharing its flu strains with the world community.²²

At the time of the 2009 H1N1 pandemic, WHO negotiations over “benefits sharing” were at a stalemate. Developing countries like Indonesia insist that nations with the financial means to pre-purchase global supplies of pandemic vaccines must share those vaccines with developing nations as a *quid pro quo* for

their participation in GISN; meanwhile, developed nations, like the United States, resist such a mandate. Amidst ongoing disagreements, public health officials were relieved when Indonesia agreed to share its H1N1 strains with WHO.²³

The 2009 H1N1 pandemic experience will affect substantially the next round of “benefits sharing” negotiations by strengthening the position of developing nations. First, the pandemic confirmed the inequity of voluntary vaccine sharing between developed and developing nations. Certainly, the primary responsibility of developed countries is to protect their own citizens. Moreover, the delay in providing excess vaccine to developing nations may have been exacerbated by vaccine production problems as well as by WHO’s demand that nations hold WHO harmless for any injuries that might result from donated vaccine. Nonetheless, there is evidence that wealthy nations delayed honoring their promises to donate vaccine until after they had secured certain supply for themselves and the strain proved less virulent than had been feared.²⁴ Second, it highlights the developed world’s increasing dependence on poorer nations to participate in influenza surveillance. As evidence, since the pandemic, both the United States and the United Nations have called for redoubled global influenza surveillance efforts among humans and animals, especially in developing nations.²⁵

Conclusion

Pandemics fray social norms and test legal rules among countries. The global response to the 2009 H1N1 pandemic involved the marshalling and sharing of resources and information, the testing and application of new legal infrastructures, and the identification of deficiencies in these tools. It applied new technologies in areas such as vaccine production, information sharing, and epidemiological tracking. It spurred the future development of even newer and more advanced technologies, which may have future legal implications. Finally, it reiterated what has become an important consideration in pandemic planning and response: that a truly effective response requires complex governance efforts supported by law. These efforts must occur on all levels, from global to local, and by all actors, whether governmental, international, non-governmental, or private.

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