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# The H1N1 Influenza A Virus: A Test Case for a Global Response

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SCHOOL OF PUBLIC HEALTH and health services

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#### **About this Paper**

The threat of widespread infection from the new H1N1 influenza A virus (also known as a swine flu virus) provides the first real-time test of the global and domestic preparedness activities that have moved forward over the past few years. The World Health Organization has declared the event a "public health emergency of international concern," the first time that designation has been used under the revised International Health Regulations. A public health emergency has also been declared in the United States.

Those steps have pushed influenza plans at the local, state, national, and global levels into motion. This paper reviews the strategies, directives, and guidance documents that have been developed in recent years to meet the challenge of a long-anticipated, widespread influenza outbreak.

# For more information about the global response, contact:

Rebecca Katz, PhD, MPH Assistant Research Professor, Department of Health Policy School of Public Health and Health Services The George Washington University 2021 K Street, NW, Suite 800 Washington, DC 20006 (202) 994-4179 Email: rlkatz@gwu.edu

#### About the Rapid Health Policy Response Project

The Rapid Health Policy Response Project of the School of Public Health and Health Services at The George Washington University presents data and other background information on breaking public health stories. The goal is to educate the public, policymakers, legislators, health care providers, the media and others in order to promote informed decisionmaking.

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# The H1N1 Influenza A Virus: A Test Case for a Global Response

A new strain of an existing influenza virus has appeared, and with it an opportunity to test years of local, state, federal, and international emergency planning. The outcome is likely to have enduring health and economic consequences around the world.

The infectious agent, an H1N1 influenza A virus (also known as a swine flu virus), apparently originated in Mexico. While press reports and official accounts have varied considerably,<sup>1</sup> the Mexico Health Minister reported 727 confirmed flu cases in Mexico, and 26 deaths, as of May 4.<sup>2</sup> Also as of May 4, 286 laboratory-confirmed cases of H1N1 flu, and one death, have occurred in the United States<sup>3</sup> and WHO has confirmed disease outbreaks in 20 countries.<sup>4</sup>

At this point, the only consistent public health prevention recommendations for individuals are such standard measures as frequent hand washing with soap and cough etiquette. Any one with symptoms is urged to seek medical care.

The number of new cases, and affected nations, continues to increase. It is too early to know how far the virus will travel, how many people it will infect, or how virulent it eventually will become, but a public health emergency is at hand. An influenza pandemic, which occurs when an epidemic involves populations in multiple countries, is likely.

Against this backdrop of uncertainty, there is a hopeful development — the public health community already has a response strategy in place. The seeds for international cooperation were planted long ago (when the Pan American Health Organization was created in 1902), and planning to address public health crises has increased markedly in the past few years. Federal and state officials in the

# In Brief

- As of May 4, 286 cases of H1N1 influenza have been confirmed in the United States<sup>3</sup> and the World Health Organization has confirmed disease outbreaks in 20 countries.<sup>4</sup> While those numbers will grow, the full impact depends both on the biology of the virus and the public health response, and remains unpredictable.
- The World Health Organization has declared the flu outbreak a "public health emergency of international concern" under the International Health Regulations.<sup>7</sup> This is the first test of a new system designed to ensure a global response to a potential global health crisis.
- The U.S. government has declared a public health emergency, the first step for providing resources and support to the states, including release of stockpiled anti-viral medication.<sup>15</sup> The current response builds on years of preparation.
- The U.S. Government Accountability Office (GAO) has been monitoring the nation's influenza planning and says 10 of its 23 recommendations over the past three years have yet to be implemented.<sup>22</sup> The need to clarify leadership roles and improve support for overseas surveillance and the adequacy of state-level planning are among GAO's concerns.

United States have been preparing for this type of event. The players with key roles already know one another. "There are mechanisms for the global community to come together to mitigate the consequences of this disease," says Rebecca Katz, PhD, MPH, assistant research professor in the Department of Health Policy at The George Washington University School of Public Health and Health Services. "A lot of work has already been done to guide our approach to detection, surveillance, and response."





That work is facing its first true challenge.

# A New Virus Emerges

Outbreaks of swine influenza occur periodically and generally resemble conventional seasonal flu, causing mild symptoms in most people and sometimes life-threatening illness in susceptible populations, especially infants, the elderly, and people with compromised immune systems. However, a very different genetic mutation of the flu virus, avian in origin, was responsible for the pandemic of 1918, which killed tens of millions of people worldwide, including some 675,000 in the United States.<sup>5</sup>

The current outbreak is alarming for several reasons:

- The new strain of the H1N1 influenza A virus contains "a unique combination of gene segments that previously has not been reported among swine or human influenza viruses in the United States or elsewhere."<sup>6</sup>
- A significant portion of the population may be susceptible to the new viral strain since no one is known to have been exposed to it before. Infants and the elderly may be disproportionately vulnerable because their bodies can be overwhelmed by a very vigorous attack on their immune systems. But it is also possible that healthy young adults will prove most susceptible, as happened during the 1918 influenza.
- > The virus is effectively transmitted between humans.

The existing seasonal flu vaccine will most likely not be effective against the new virus, but two anti-viral drugs — zanamivir and oseltamivir — can help to reduce the severity of illness, if they are administered soon after exposure or within 48 hours after the symptoms first appear. A vaccine for this novel H1N1 virus is currently being developed, but will not be ready for broad use by the general public for approximately six months.

# "A Public Health Emergency of International Concern"

On April 25, following a meeting of the Emergency Committee of the World Health Organization (WHO) to assess reports of the emerging disease, the Director-General determined that the current situation constituted a "public health emergency of international concern."<sup>7</sup> It was the first time that designation has been used under the newly revised International Health Regulations.

A public health emergency of international concern is defined as "an extraordinary event which is determined to constitute a public health risk to other States through the international spread of disease and to potentially require a coordinated international response."<sup>8</sup> The declaration is guided by the World Health Organization's International Health Regulations,<sup>9</sup> which were revised in 2005 and came into force in the summer of 2007.<sup>10</sup>

*The International Health Regulations (2005):* Legally binding on WHO's 194-member countries, the current International Health Regulations define the mechanisms through which the global community comes together to mitigate the effects of a potential health crisis.<sup>8</sup>

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Under previous iterations of the International Health Regulations, nations were required to notify WHO only when cases of cholera, plague, and yellow fever occurred. There was little emphasis on responding collaboratively to prevent the spread of disease across borders. Spurred in part by the SARS epidemic of 2003 and other emerging diseases, the regulations were overhauled to move beyond disease-specific reporting. The broader approach now in effect emphasizes collective action to prevent, detect, and contain any type of public health event that might constitute a global threat.

The regulations:

- Require that all WHO member states designate an official "focal point."
  For the first time, member states are obligated to establish a 24-hour-a-day, sevenday-a-week focal point for two-way communication with WHO.
- Establish criteria for notifying WHO of possible public health emergencies. Rather than limiting reporting to a few diseases, WHO has created an instrument to help nations assess an event and determine whether to report it. In making that decision, they are guided by four questions:
  - > Is the public health impact of the event serious?
  - ➤ Is the event unusual or unexpected?
  - > Is there a significant risk of international spread?
  - > Is there a significant risk of international restriction(s) to travel and trade?

Countries are required to notify WHO within 24 hours of their assessment. In addition, they must always report the occurrence of smallpox, polio, any new subtype of human influenza, and SARS.

Obligate all participating nations to develop and strengthen their core public health capacities for surveillance and response. Under the terms of the regulations, all nations are required to assess their capacities, and to develop and implement action plans, with guidance from WHO. The timetable calls for the assessment to be completed by June 2009 and implemented by June 2012.

With the declaration of a public health emergency of international concern, there is a continuing obligation on the part of affected nations to provide detailed public health information about the spread of disease, patient outcomes, and the health measures put in place. In the United States, the Department of Health and Human Services (HHS) has taken the lead role in meeting WHO's reporting requirements through the Secretary's Operations Center.<sup>11</sup>

#### **Global Response to a Possible Influenza Pandemic**

The World Health Organization's *Pandemic Influenza Preparedness and Response Guidance Document* outlines action steps to be taken by WHO, by countries affected by a flu virus, and by those that have not yet been affected.<sup>12</sup>





The document also defines the six phases of an influenza pandemic alert. On April 29, the Director-General of WHO raised the alert level to phase 5, indicating that human-to-human transmission of an influenza virus has been confirmed in at least two countries within one WHO region.<sup>13</sup> Phase 5 "is a strong signal that a pandemic is imminent and that the time to finalize the organization, communication, and implementation of the planned mitigation measures is short."<sup>14</sup>

While the new virus is now too widely dispersed to be contained, it is still possible to mitigate its effect with heightened surveillance, early detection and treatment, and appropriate infection control in all health facilities.

### The U.S. Response

Complementing WHO's global response, federal and state actors in the United States have taken significant steps in recent years to prepare for a long-anticipated influenza pandemic, as well as any other potential public health emergency. These strategies, too, are being fully tested for the first time.

On April 26, the Acting HHS Secretary declared a public health emergency, a necessary first step for providing support to state, tribal, and local governments in the form of public health and medical services.<sup>15</sup> With a public health emergency in effect, the Centers for Disease Control and Prevention (CDC) can also make available antiviral medication from its Strategic National Stockpile. It has already done so, releasing 25 percent of the stockpile, along with personal protective equipment and respiratory protection, to promote effective responses at the state level.<sup>3</sup>

The federal government has the legal authority to take many other actions as well if it deems them necessary to limit the spread of a pandemic. These include border controls on both people and livestock, quarantines, and closing certain public transportation systems.

In addition to these authorities, the preparedness measures put in place in recent years include:

- The Security and Prosperity Partnership of North America:<sup>16</sup> As part of developing a common agenda, the leaders of the United States, Mexico, and Canada agreed in 2007 that a cooperative response to pandemic influenza is one of their top five priorities. They have put principles in place for exchanging information, coordinating their emergency actions, avoiding interference with the movement of people and goods to the maximum extent possible, advising one another of decisions that have broad impact, and striving for clear and consistent messaging to the public.
- The National Strategy for Public Health and Medical Preparedness:<sup>17</sup> This Homeland Security Presidential Directive, issued in 2007, provides the framework for protecting American health in the face of a broad array of catastrophic health events. It particularly emphasizes four areas of public health and medical preparedness: biosurveillance, countermeasure stockpiling and distribution, mass casualty care, and community resilience.



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An Interagency Task Force has been charged with implementing this directive, with HHS taking the lead on most of it.<sup>18</sup> Ambitious timelines called for most of these activities to be completed within a year following the October 2007 publication of the directive, but some of the work continues.

- The National Strategy for Pandemic Influenza was released by the White House in November 2005 and is built on three pillars — preparedness and communication; surveillance and detection; and response and containment.<sup>19</sup>
- **The HHS Pandemic Influenza Plan:**<sup>20</sup> A blueprint for preparing and responding to a pandemic influenza, this regularly updated document includes:
  - A Strategic Plan, which outlines federal plans and preparation for a coordinated public health and medical care response.
  - Public Health Guidance for State and Local Partners, which offers detailed guidance to state and local health departments in eleven key areas.
- Emergency Support Function (ESF 8) Public Health and Medical Services.<sup>21</sup> This document, a component of the National Response Framework, was first published in 2004 and updated to include lessons learned from Hurricane Katrina. The mechanism for coordinating federal assistance to states, municipalities, and tribes in the event of a public health or medical disaster or emergency, ESF 8 support includes assessing public health and medical needs, conducting surveillance, deploying medical personnel and supplies, and managing mass fatalities, among many other activities.<sup>22</sup>

Despite these substantial efforts, the United States Government Accountability Office concluded in February 2009 that some preparedness gaps remain.<sup>23</sup> Thirteen of its recommendations have been implemented, but ten are still outstanding. Among other concerns, the GAO has called for greater clarification of leadership roles and responsibilities, improved support for surveillance activities in other countries, better state-level planning, and clearer guidelines for performance monitoring.

Presciently, the GAO noted in its February report that "national priorities are shifting as a pandemic has yet to occur, and other national issues have become more immediate and pressing. Nevertheless, an influenza pandemic remains a real threat to our nation and the world."

# Linking Public Health and National Security

Historically the communities engaged in public health and in national and homeland security have operated largely independently of each other. The emerging crisis underscores the importance of closer cooperation, and evidence to date suggests this is occurring. Decision-makers in the health and security communities are working together, and their communications with the public have been skillfully executed.

For example, public health officials have demonstrated a fulsome understanding of







emergency management and incident response, while homeland security authorities have worked in tandem to convey the scientific information available to date, and to calibrate actions accordingly. Homeland Security Secretary Janet Napolitano has been a visible spokesperson on the crisis, and border agents are alert to people with signs of illness, and have been coordinating with CDC quarantine officers.

As the course of the virus unfolds, these developing relationships will be essential to prudent action. Public health and national security also intersect if pandemic influenza should result in high levels of workforce absenteeism. Critical infrastructure, including essential government services, must maintain continuity of operations, and plans are in place for this to occur.

### An Uncertain Future

The extent of the current threat remains unpredictable. This novel H1N1 influenza A virus could mutate to become less virulent and vanish without ever causing widespread illness or death, or it could pinpoint human vulnerabilities that enable it to grow more powerful.

The 1918 influenza pandemic occurred in several waves. The first wave, in April 1918, was relatively mild but a much more severe virus reemerged in a second wave in August. That pattern could occur again, with the new virus becoming more virulent at the beginning of the next traditional flu season. Public health officials are saying that the fight to control new infections will be a marathon, not a sprint.

The extensive international and national planning of the past few years provide some reassurance that a well-coordinated response will be possible. A commitment to increased global governance of shared health challenges will make it much easier for the nations of the world to coordinate unified action. At the same time, resource shortfalls and concern about national sovereignty will complicate any attempt to impose mandates.

Moreover, frameworks erected in advance of an emergency will surely need to be modified in the face of clear and present dangers. Our best hope now is that the right mechanisms have been put in place to guide an appropriate response, and that we will be nimble enough to make necessary adjustments as the facts unfold on the ground.

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# Endnotes

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