



Maintaining Civil Liberties Protections in Response to the H1N1 Flu

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On April 25, the WHO director-general convened an emergency committee and declared a “public health emergency of international concern.” The next day, the U.S. Department of Health and Human Services (HHS) issued a nationwide public health emergency declaration, allowing the federal government certain authority and flexibility in directing significant resources toward mitigation measures, including accelerated vaccine development and the stockpiling and release of antivirals. At that time, there were 20 confirmed cases of H1N1 in five states.³

By June 11, the virus had spread to 74 countries and all continents but Antarctica, and WHO raised the level of pandemic alert to “Level 6” (sustained transmission in multiple geographic regions), the highest level for a pandemic. As of September 27, approximately 340,000 confirmed laboratory cases and 4,100 deaths had been reported to WHO worldwide.⁴

On October 23, President Obama declared H1N1 a national emergency. White House officials emphasized that this was primarily a preemptive step that did not signify a worsening of the H1N1 situation. The declaration gives the secretary of HHS the authority to allow hospitals to set up temporary, offsite clinics in order to address patient overflows.

Initial overestimation of the threat

Initial reports on the H1N1 outbreak indicated that this virus might be as or more virulent than the genetically similar 1918-19 H1N1 pandemic virus, which resulted in the death of 40-100 million people worldwide and 500,000-750,000 in the U.S. alone. These early studies, which showed alarmingly high rates of hospitalization and death as compared with seasonal flu, overestimated the severity of the virus because most mild cases had gone unreported. Since then, the Centers for Disease Control and Prevention (CDC) has greatly increased surveillance efforts of the virus, and the case-fatality ratio is now thought to be much lower, and similar to that of a typical seasonal flu (CDC estimates the case-fatality rate for H1N1 to be 0.018%, more than 100 times lower than the 2% case-fatality rate associated with the 1918-19 pandemic).⁵

All current clinical data on the 2009 H1N1 influenza strain suggest that it is generally mild-moderate in severity and that the vast majority of individuals who become infected will be able to recover without medical treatment. The symptoms of the H1N1 flu are similar to seasonal flu and can include fever, chills, sore throat, cough, headache, and fatigue, but can also include vomiting and diarrhea, which are not usually seen in seasonal flus.

³ News Release: HHS Declares Public Health Emergency for Swine Flu, April 26, 2009, available at: <http://www.hhs.gov/news/press/2009pres/04/20090426a.html>

⁴ These figures are known to underestimate that actual number of cases and deaths. Approximately ¾ of the 4100 deaths were reported by the WHO Regional Office of the Americas. See World Health Organizations, Pandemic (H1N1) 2009 – update 68, available at: http://www.who.int/csr/don/2009_10_02/en/index.html

2,500 and 6,000 people died of H1N1-related causes.¹¹ These estimates are significantly higher than the numbers of reported cases.

Unpredictability. Finally, there is considerable uncertainty and unpredictability when it comes to pandemic viruses, which tend to mutate between seasons. So far, there is no evidence to indicate that the virus has mutated significantly since its resurgence in the Northern Hemisphere.¹² However, the virus is likely to continue to evolve throughout the season (though it is important to remember that could evolve in *either* direction, becoming either more serious or less so). One concern is that it could evolve away from the current vaccine or that it could become resistant to the class of anti-influenza drugs that have so far been effective against H1N1 (see below).¹³ Recent studies indicate that this may be happening.¹⁴ Some have projected a particularly harrowing scenario whereby this H1N1 strain “swaps genes” with the highly pathogenic avian H5N1 virus that has an extremely low transmission rate but a mortality rate of over 60 percent in the few human cases that have occurred.¹⁵

Vaccination and antivirals

The federal government has spent more than \$2 billion to buy at least 250 million doses of vaccine from five manufacturers and pledged to buy enough to vaccinate the entire population for free. The CDC recommended that the vaccine be made available first to five high-priority categories of individuals who are thought to be at greatest risk. These groups together comprise approximately 159 million people and include the following:

- Pregnant women
- Caregivers of infants under 6 months of age
- Everyone between 6 months and 24 years of age
- Individuals ages 25-64 with underlying conditions
- Healthcare workers and emergency personnel

Vaccination can reduce disease burden both by protecting individuals, directly, and decreasing transmission, reducing the infection risk even for those who have not been vaccinated. Flu vaccines are never 100% effective, in part because flu strains tend to evolve quickly and because the vaccine has to be developed prior to the onset (or at least

¹¹ Centers for Disease Control and Prevention, “CDC Estimates of 2009 H1N1 Influenza Cases, Hospitalizations and Deaths in the United States, April – October 17, 2009,” November 12, 2009. Available at: http://www.cdc.gov/h1n1flu/estimates_2009_h1n1.htm

¹² Statement by Thomas Frieden, CDC Commissioner, Press Conference, September 3, 2009.

¹³ Jon Cohen, “Flu Researchers Train Sights On Novel Tricks of Novel H1N1,” *Science*, Vol. 324 (15 May 2009).

¹⁴ “H1N1 Evolution Outpacing Vaccine and Host Defenses,” *Recombinomics Commentary* 13:32, November 30, 2009. Available at: http://www.recombinomics.com/News/11300901/225_Evolution.html See also: WHO, “Public health significance of virus mutation detected in Norway,” Pandemic (H1N1) Briefing Note 17, November 20, 2009. See also: Michelle Fay Cortez and Marianne Stigset, “Mutated Swine Flu Strains Block Drugs, Worsen Illness,” *Bloomberg.com*,

the peak) of the flu season if it is going to have any mitigating effect. Effectiveness tends to range from 30%-70%. Clinical trials involving 4,600 people revealed that the H1N1 vaccine is a good match to the current H1N1 virus and that one dose of the vaccine (as opposed to two) may be sufficient to stimulate a robust immune response to the virus in adults and children ages 10 and older.

Where the vaccine is not received or fails to protect, H1N1 has thus far been susceptible to one of two classes of antiviral medications that are used for the treatment of seasonal influenza. These are the neuraminidase inhibitors (oseltamivir [Tamiflu] and zanamivir [Relenza]). These drugs have been stockpiled by HHS and allocated to the states on a population basis.

Vaccine shortage

The government projected that an initial batch of approximately 40 million doses of the vaccine would be made available around the country by the middle of October, enough to

have shown that approximately one additional person out of 1,000,000 who receive a seasonal flu vaccine may be at risk.²⁰

Many have vocalized concerns about a possible relationship between vaccines and autism, but studies that have looked at this issue to date have consistently failed to show an association.²¹

2. Government Responses to H1N1

When the H1N1 flu broke, there was considerable concern in both the civil liberties and public health communities that overreactions on the part of the federal and state governments would result in serious infringements on civil liberties and panicked, less-than-effective public health strategies. Many state emergency flu preparedness plans currently on the books were modeled after the “Model State Emergency Health Powers Act” that was drafted at the request of the Bush Administration’s CDC following the anthrax letter scare in 2001. Designed to address a “worst case” scenario, the Model Act provided state officials with extensive, unchecked powers to curtail individual autonomy and privacy in the face of an emergency, including powers to surveil the public’s health and to compel vaccination, testing, treatment, isolation, and quarantine. The Model Act lacked checks and balances and privacy protections while it emphasized an ineffective, coercive approach to pandemic response rather than a public health response.²² Some states also amended their pandemic planning laws in response to the 2005 H5N1 avian flu scare, again adopting highly draconian measures that are inappropriate for the vast majority of flu situations.

Federal response

Fortunately, the Obama Administration has so far acted appropriately in response to the outbreak and has helped to establish and maintain a sense of calm throughout the country:

Unlike President Bush, who suggested that he would call in the military to quarantine large sections of the United States in the face of a pandemic, President Obama responded calmly and rationally to the outbreak by encouraging people to wash their hands and stay home when sick.

When Senator McCain and a handful of other U.S. legislators²³ suggested that closing the U.S.-Mexico border should be an option in combating the H1N1 flu strain, Obama responded appropriately that this “would be akin to closing

²⁰ CDC, “General questions and answers on Guillain-Barre syndrome,” September 14, 2009. Available at: http://www.cdc.gov/h1n1flu/vaccination/gbs_qa.htm

²¹ <http://www.cdc.gov/ncbddd/autism/research.html#vaccines>

²² See ACLU, “Q&A On the Model State Emergency health Powers Act,” online at <http://www.aclu.org/privacy/medical/14857res20020101.html>.

²³ [pr31research.html#vaccines](http://www.aclu.org/privacy/medical/14857res20020101.html#vaccines)

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appear to be moving toward a public health-oriented house bill that is devoid of these problems.

Federal government supports voluntary H1N1 vaccination

The New York emergency regulation sparked considerable concern and confusion around the country as to the federal government's H1N1 vaccination program. However, the federal government's position on this matter has been clear:

The White House, the Centers for Disease Control (CDC), the U.S. Department of Health and Human Services (HHS), and the Occupational Safety and Health Administration (OSHA) have all recommended that health care workers be among those who receive first priority for H1N1 vaccine, but that vaccination remain voluntary.

HHS Secretary Kathleen Sibelius and CDC Commissioner Tom Frieden have reiterated this position on multiple occasions.³¹

On September 28th, the federal government's website on the flu posted a notice reiterating that "the federal vaccination program for H1N1 flu is VOLUNTARY" and that, while the government will ensure that the vaccine is available to anyone who wants it, the decision to get vaccinated is up to each individual.³²

3. Looking Forward: Potential Civil Liberties Concerns

As a general rule, the flu is highly unpredictable. It is especially so in cases of a pandemic, where broad distribution of the disease around the world contributes to its

stake, there is a strong presumption protecting those rights. It is a significant thing for the government to use coercion to require individuals to be injected with a foreign biological material (on an annual basis, in the case of a seasonal flu mandate). And while side effects are generally mild, there is always the possibility – however rare – of serious adverse effects. Individuals should weigh those risks for themselves and determine whether or not to get vaccinated. Compulsory vaccination or treatment should be reserved for only the most severe situations.

Availability of less coercive measures. A well-planned and well-executed voluntary vaccination program can go a long way to achieving the public health goal of minimizing individuals' risks of disease and reducing transmission rates, especially where it is combined with efforts to encourage people to stay home when sick (e.g. ensuring reasonable sick leave and worker compensation policies in the workplace). Effective public education combined with ensuring that the flu vaccine is free and widely accessible has been shown to achieve high rates of seasonal flu vaccination in high risk populations as well as among health care workers.

Effectiveness. One of the primary reasons to initiate a mandatory vaccination program would be to attempt to eradicate the disease, but unlike smallpox or polio, influenza is not a dissa(whe)-6(nt reasnlias.001 Tw 16.4.055 -20.99Td[(com)9(b)0.0cusse

Smallpox, described by the WHO as “one of the most devastating diseases known to humanity,” is both highly communicable and highly fatal. At the time *Jacobson* was decided, repeated epidemics of smallpox had occurred for centuries around the world, killing thirty percent or more of its victims and leaving most of its survivors blind and/or disfigured.

A global effort to eradicate smallpox was underway at the time that required high vaccination rates in order to be effective. Not only is the flu far less deadly than smallpox, there is no prospect of eradicating it.

H1N1 and seasonal flu can similarly be distinguished from other diseases, such as measles, diphtheria, and polio, where vaccination has been required for school enrollment and other contexts. Seasonal flu vaccines are far more variable in their efficacy, for example, and need to be taken on an annual basis.

Shortages of medical resources

As discussed above, vaccine shortages are likely to persist. Current estimates are that the first wave of H1N1 will have peaked and be well along its decline by the time that the vaccine is made available to large segments of the general population. Current delays in vaccine production mean that if the flu were to worsen suddenly, or if the demand for the vaccine were to surge (for example, as a result of reports that the flu was becoming more severe) there could be further shortages and the need for additional rationing.

Due to the unpredictable nature of the flu, it is not possible to anticipate whether the current vaccine will be well-matched with the next wave of H1N1, or whether it might emerge as an entirely new strain. If the virus were to mutate to the point where the vaccine is no longer effective, the resulting increase in severe cases could lead to shortages of anti-viral vaccines, respirators, and hospital beds. Decisions about who should be granted priority access to care under these scenarios and who should not could lead to significant conflict.

Social distancing measures

Social distancing measures, such as school closures and voluntary home quarantines, could continue to occur this season or during a future wave of influenza. Generally these do not raise significant civil liberties concerns, although long-term school closures could cause social problems such as considerable disruption for working parents – especially single parents and those with fewer resources – who will need to stay at home to care for their children. If large numbers of individuals are required to or voluntarily stay at home under the advice of medical or public health personnel, the government may need to distribute food, medicine and other necessities.

Quarantine and isolation

At this stage, we have moved well beyond the reach of the most coercive non-pharmaceutical interventions that could be employed during a pandemic, such as quarantine and isolation. It is widely acknowledged that these measures will not be effective in containing the disease, since it is already widespread. However, if the flu mutates significantly in the direction of increased severity, panicked calls for actions, as

well as renewed calls for border closures and travel restrictions, could arise despite their lack of effectiveness.

While public health protection has traditionally been viewed as within the states' police powers, Congress also has authority under the commerce clause to impose non-pharmaceutical interventions, including isolation and quarantine, within the states.³⁹ Section 361 of the Public Health Services Act authorizes the CDC to develop regulations to apprehend, detain, and forcibly examine persons in order to prevent a disease listed by the President from entering the country or crossing state lines. In 2005, President Bush amended the list of quarantineable diseases to include "influenza caused by novel or reemergent influenza viruses that have the potential to cause a pandemic."

At the state level, the implications of a shift in the pandemic's severity for individual liberty will depend further on the state or states in which they are occurring and how that state chooses to exercise its authority. As discussed above and in the ACLU Report *Pandemic Preparedness*⁴⁰, some states have adopted highly flawed flu plans that have replaced sound public health approaches to disease prevention and mitigation with a national security approach. In Alabama, for example, the Governor or the State Board of Health may institute quarantine measures whenever they deem it necessary.⁴¹ Violation of a health or quarantine law is a criminal offense, and a police officer carrying out a quarantine order may arrest and detain without warrant anyone who attempts to interfere with these duties. In Ohio, an employer of an illegal alien with an infectious disease is

Conclusion

History has shown that too often, fear about the spread of a communicable disease has resulted in panicked responses on the part of the government and unnecessary restrictions on individual rights and autonomy. Currently, levels of public fear are not so high as to allow for such overreactions. Nevertheless, it is imperative that the nation engage now in conversation about appropriate responses to the current outbreak so that civil liberties concerns are considered part of – and not contrary to -- a public health mitigation effort. Safeguarding privacy and liberty in the face of a pandemic is crucial for maintaining public trust in public health authorities and encouraging public cooperation in efforts to mitigate disease. Coercive measures such as quarantine, travel bans, and forced vaccination and treatment clearly are not warranted for the current H1N1 flu situation, and should be imposed only in the most severe of cases and where there is a sound scientific and constitutional basis for doing so.