
Public Health Preparedness Laws and Policies: Where Do We Go after Pandemic 2009 H1N1 Influenza?

Jean O'Connor, Paul Jarris, Richard Vogt, and Heather Horton

The detection and spread of pandemic 2009 H1N1 influenza in the United States led to a complex and multi-faceted response by the public health system that lasted more than a year.¹ When the first domestic case of the virus was detected in California on April 15, 2009, and a second, unrelated case was identified more than 130 miles away in the same state on April 17, 2009, the unique combination of influenza virus genes in addition to its emergence and rapid spread at the end of the typical Northern Hemisphere influenza season suggested the potential for a high morbidity, high mortality event. In response, federal, state, and local public health officials conducted epidemiologic investigations with federal and state laboratory support to help to determine the scope of the H1N1 pandemic.² On April 26, the Secretary of the U.S. Department of Health and Human Services (HHS) declared a public health emergency that was renewed through June 23, 2010.³ The pandemic that ensued tested virtually every aspect of U.S. public health preparedness and response systems, from laboratory capabilities and capacities to social distancing plans.

From an epidemiologic perspective, the 2009 H1N1 outbreak occurred in two distinct waves in the spring and a second, larger one in the fall, a pattern also seen in the 1918-19 pandemic.⁴ Although 2009 H1N1 did not cause the level of widespread mortality as origi-

nally feared, compared with a typical U.S. influenza season, the virus did have a considerable impact on certain populations, such as pregnant women. 2009 H1N1 was also associated with more cases of illness and higher hospitalization rates overall and with greater rates of infection in younger age groups than older age groups.⁵ It was estimated by the Centers for Disease Control and Prevention (CDC) that 1 in 6 U.S. residents were infected with H1N1 during the pandemic.⁶

Although the complexity and duration of the 2009 H1N1 pandemic challenged epidemiologists seeking to predict and understand the two waves of infection in the population, from a public health law and policy perspective, 2009 H1N1 consisted of at least five phases of policies and policymaking by legislative bodies and public health officials at all levels of government. These policy phases were: (1) pre-event laws and policy, such as the federal Pandemic and All-Hazards Preparedness Act (PAHPA)⁷ that were developed in anticipation of a pandemic or other public health emergencies; (2) a spring phase, during which laws and policies, such as the collection of laboratory samples, social distancing efforts, and the need for funding for the response, were being developed to react to the immediate situation at hand; (3) an interim policymaking phase following the spring epidemiologic wave of infection where policy needs to respond to the second wave were being anticipated, particularly concerning vaccine availability; (4) a fall phase of policymaking responding to operational concerns, such as those related to the distribution and dispensing of vaccine and other countermeasures, and response funding; and (5) an ongoing post-event phase of policymaking responding to perceived successes and challenges of the response (see Figure 1).

Jean O'Connor, J.D., Dr.P.H., is an Adjunct Associate Professor at the Rollins School of Public Health at Emory University. **Paul Jarris, M.D., M.P.H.,** is the Executive Director of the Association of State and Territorial Health Officials. **Richard Vogt, M.D., M.P.H.,** is the Executive Director of the Tri-County Health Department in Colorado. **Heather Horton, J.D., M.H.A.,** is a Senior Attorney with the U.S. Department of Health and Human Services.

Figure 1

Selected Law and Policy Issues Associated with 2009 H1N1

	Pre-Event	Spring	Summer	Fall	Post-Event
Local	Public health emergency legal preparedness	Community mitigation; worker protection; medical countermeasures	Federal Incident Command System; healthcare surge capacity	Reaching special and vulnerable Populations; Recalls; Liability protections	Vaccine disposal; Continuity of preparedness
State	Public health emergency legal preparedness	Community mitigation; worker protection; medical countermeasures	Federal Incident Command System; healthcare surge capacity	Scope of practice; liability protections federal funding limitations; recalls	Vaccine disposal; Continuity of preparedness
Federal	Public Readiness and Emergency Preparedness Act; Emergency Use Authorizations; surveillance and laboratory infrastructure	Funding for response; Community mitigation, medical care and countermeasures; vaccine decisions	Identifying priority populations; vaccine decisions	Vaccine distribution; Funding for states; recalls	Vaccine disposal

In this article, we identify the key public health law and policy challenges and barriers associated with these five phases, highlight the policy experiences of state and local officials during the H1N1 response, and suggest opportunities to use public health preparedness policy lessons to address future policy development efforts.

Key Public Health Law and Policy Challenges Associated with the 2009 H1N1 Pandemic

Many aspects of the public health system’s response to 2009 H1N1 were successful. Core systems and capabilities were in place as a result of the federal investments made in public health preparedness. Many facets of the foundation for our national response were significantly improved over their 2003-04 levels.⁸ However, multiple factors influence the ability of communities to detect, respond to, and recover from public health events. In addition to the characteristics of the disease or condition, laws and policies influence the capability of federal, state, and local governments to detect and respond to threats to the public’s health. To identify laws and policies that played a notable role in the H1N1 response, CDC funded the Association of State and Territorial Health Officials (ASTHO)⁹ and the National Association of County and City Health Offi-

cial (NACCHO)¹⁰ to assess the policy and legal barriers to federal, state, and local public health responses.

Through a scan of existing documents, surveys of their membership, and focus groups, ASTHO and NACCHO characterized the legal and policy issues that impeded or affected the response to H1N1. NACCHO grouped its findings into the following categories: funding; communications; vaccine administration, dispensing, disposal; data collection, management, analysis; epidemiology; medical care and countermeasures; community mitigation coordination and transparency; equity and ethical issues; and other issues.¹¹ ASTHO identified similar categories: federal/state/local coordination; communications; vaccination campaign issues; surveillance, epidemiology, and laboratory services; medical care and countermeasures; workforce, capacity, and infrastructure issues; Incident Command System, Command and Control; authority; and other issues.¹² Of the findings from both organizations, the following topics, discussed below, emerged as key common themes: vaccine allocation, distribution, and dispensing issues; coordination between levels of government around the use of stockpiled material; and the need for sustainable public health response funding.

Vaccine Distribution and Dispensing

During the 2009 H1N1 pandemic, laws and policies related to the vaccine campaign presented significant challenges, especially for state and local public health responders. Laws and policy decisions influenced vaccine availability, formulation, allocation, prioritization, and guidance; ordering, delivery, and distribution; administering and dispensing; tracking, coverage, recalls, and adverse events reporting; liability; recovery, destruction and disposal. Federal policy decisions projecting the availability and timing of the vaccine and priority populations for receipt of the vaccine presented challenges for state and local health officials. Federal reimbursement policies for vaccine services created some confusion regarding who could be charged or reimbursed. State laws related to vaccination authority, or which health care professionals can vaccinate individuals within their scope of practice and in what settings, arose in numerous jurisdictions. During non-emergencies, scope of practice laws that control which health care workers can vaccinate serve important economic and public health purposes. While many states identified mechanisms to suspend those laws, the laws created challenges for other states to efficiently vaccinate large numbers of people. States that encountered these challenges should consider reviewing their laws and exploring options to suspend them through executive orders or other legal mechanism during times of an emergency response to pandemics or other public health crises.

Use of Stockpiled Materiel and Medical Countermeasures

Use and accounting for stockpiled materiel raised many policy and legal questions during 2009 H1N1. Although not easy to summarize, in brief, the policy and legal issues associated with stockpiled materiel included questions about the following:

- formulary contents;
- commercial supply chain visibility;
- use of state stockpiles;
- distribution of countermeasures other than vaccines (including anti-viral medications through local health departments);
- conflicting guidance from federal agencies on the use of personal protective equipment (e.g., N95 masks);
- extension of federal liability protections for countermeasures to state and local health departments; and
- the process by which emergency use authorizations are executed for stockpiled materiel.

Although the logistics and delivery of medical countermeasures were relatively successful during 2009 H1N1 from the perspective of delivery of materiel, the experiences of state and local health departments suggest that the enterprise surrounding the appropriate use of countermeasures during an emergency could be improved through incremental policy review and change, among other approaches. Specifically, by planning for a pandemic similar in severity to the 1918 pandemic widespread shortages of anti-virals were assumed. However, in the milder H1N1 pandemic, commercial supplies of anti-virals were sufficient, but the uninsured lacked access to those anti-virals and many public health agencies provided anti-virals to ill individuals who lacked access due to economic barriers to care.

Sustainable Public Health Response Funding

CDC receives approximately \$1.5 billion in annual appropriations to support the public health system's preparedness and emergency response needs. Approximately half of this annual appropriation is utilized to fund the procurement of materiel for the Strategic National Stockpile or retained at CDC for operations and scientific activities. The remaining half of the appropriation is awarded to 62 state, local, tribal, and territorial health departments through the Public Health Emergency Preparedness Cooperative Agreement. These funds enable baseline planning and basic public health capacities and capabilities necessary to effectively respond to state-level public health emergencies caused by all-hazards.¹³ However, the appropriation has been declining for several years, and a federal proposed budget freeze for Fiscal Year 2012 on non-security spending will impact future state and local health department preparedness activities.¹⁴ Along with decades of chronic underfunding of the public health system, the ongoing economic crisis has stressed public health responders and core public health systems.

Against this backdrop, to facilitate the response to 2009 H1N1, Congress approved a supplemental appropriation of over \$3 billion, more than \$1.35 billion of which was awarded to state, local, tribal, and territorial partners in the form of Public Health Emergency Response (PHER) grants. However, funding was awarded in four phases, each of which (1) was restricted to use for specific purposes and (2) required a separate application by the state or local government. Although PHER funds were essential to the response, the method of distributing the funding limited state and local flexibility in use of the funds and requirements for repeated applications for successive phases of grant awards diverted a strained workforce

from response to grants writing and administration and slowed the ability to implement public health protections. A sustainable, flexible national approach to funding public health emergency response is needed. As a part of that approach, notwithstanding the efforts to expedite PHER funding, a faster, and more flexible, reliable and streamlined method to ensure distribution of emergency funding from the federal government to state and local public health agencies is needed. One way to achieve distribution of funding to state and local governments would be to provide supplemental response funding through existing cooperative agreements, such as the PHEP.

Opportunities for Future Public Health Preparedness Policy Development

Public health legal preparedness — or the development, implementation, and use of laws and policies that allow public health officials to coordinate across jurisdictions, agencies, and sectors — is an essential component of preparing for bioterrorism events, infectious disease outbreaks, and public health emergencies.¹⁵ Although progress in public health legal preparedness has been made since 2001,¹⁶ it is apparent from the law and policy challenges encountered during H1N1 that no single U.S. jurisdiction — state, local, tribal, or federal — is yet fully *legally* prepared to respond to a major public health threat.

With the expiration and potential reauthorization of many provisions of PAHPA¹⁷ — enacted in 2006 to improve the nation's ability to detect, prepare for, and respond to public health emergencies — there is a potential opportunity, at least at the federal level, to address some of these challenges and enhance legal preparedness. Among other mandates, PAHPA directed HHS' Secretary to develop a National Health Security Strategy (NHSS).¹⁸ In 2010, HHS released the NHSS and a draft biennial implementation guide, intended to serve as a blueprint for developing comprehensive, national health security. The NHSS laid out 10 objectives for achieving health security, specifically noting the need for developments in law and policy as a component of many of the objectives and in the implementation documents. These findings could serve as a basis for moving forward to address some of the key law and policy challenges identified by ASTHO and NACCHO.¹⁹

Other gaps in legal preparedness could be addressed through updating state and local public health preparedness policies, education of health officials and healthcare personnel, making available additional resources to train and provide technical assistance to state and local health departments on legal issues, or through broadening local health department access

to attorneys with experience in public health matters. Regardless of how or which policy changes may be implemented to address lessons learned from 2009 H1N1, it is imperative that the public health community continue the work initiated by ASTHO and NACCHO in order to analyze and evaluate the policies associated with public health preparedness and response to inform the development of preparedness policies that better enable response.

Note

The findings and conclusions presented in this manuscript are those of the authors and do not necessarily represent the official position of CDC or HHS.

Acknowledgements

The authors wish to thank the following individuals: Amy Feuss and Stacie Kershner of CDC; Joe Foster of the HHS Office of the General Counsel; Jim Blumenstock of ASTHO; Patricia Elliot of Logan Circle Group; Subha Chandar, Michelle Chuk and Jack Hermann of NACCHO; and all the staff and membership of ASTHO and NACCHO for their important contributions to the understanding of the law and policy issues associated with the nation's response to the 2009 H1N1 influenza pandemic.

References

- Centers for Disease Control and Prevention, "The 2009 H1N1 Pandemic: Summary Highlights, April 2009–April 2010," *available at* <<http://www.cdc.gov/h1n1flu/cdcreponse.htm>> (last visited December 3, 2010) [hereinafter H1N1 Summary].
- Id.*
- U.S. Department of Health and Human Services, "H1N1 Influenza Public Health Emergency Determination Expired on June 23," *available at* <<http://www.flu.gov/news/h1n1pheexpiration.html>> (last visited October 7, 2010).
- See H1N1 Summary, *supra* note 1.
- Centers for Disease Control and Prevention, "Update: Influenza Activity – United States, August 30, 2009–March 27, 2010, and Composition of the 2010–2011 Flu Vaccine," *Morbidity and Mortality Weekly Report* 59, no. 14 (April 16, 2010): 423–430, *available at* <<http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5914a3.htm>> (last visited December 3, 2010).
- Centers for Disease Control and Prevention, *H1N1 Flu Press Conference, December 9, 2009*, Video, *available at* <<http://www.flu.gov/video/press/2009dec10.html>> (last visited December 3, 2010).
- Public Law 109-417: Pandemic and All-Hazards Preparedness Act. (120 STAT 2831; Date: 12/19/2006) [hereinafter PAHPA].
- J. Levi, S. Vinter, and L. M. Segal, *Ready or Not? Protecting the Public's Health from Diseases, Disasters, and Bioterrorism*, 3 (2009), *available at* <<http://healthyamericans.org/reports/bioterror09/>> (last visited December 3, 2010).
- Association of State and Territorial Health Officials, *Assessing Policy Barriers to Effective Public Health Response in the H1N1 Pandemic*, June 2010, *available at* <<http://www.astho.org/Display/AssetDisplay.aspx?id=4933>> (last visited December 3, 2010) [hereinafter ASTHO Report].
- National Association of County and City Health Officials. *H1N1 Policy Workshop Report*, May 4–5, 2010, *available at* <<http://www.naccho.org/topics/H1N1/upload/NACCHO-WORKSHOP-REPORT-IN-TEMPLATE-with-chart.pdf>> [hereinafter NACCHO Report].
- Id.*
- See ASTHO Report, *supra* note 9.

13. Centers for Disease Control and Prevention, Office of Public Health Preparedness and Response, "Funding Guidance and Technical Assistance to States," available at <<http://www.bt.cdc.gov/cdcpreparedness/coopagreement/index.asp>> (last visited December 3, 2010).
14. Fiscal Year 2012 Budget Guidance, *White House Office of Management and Budget Memorandum from Peter Orzag to the Heads of Departments and Agencies*, June 8, 2010, available at <http://www.whitehouse.gov/sites/default/files/omb/assets/memoranda_2010/m10-19.pdf> (last visited December 3, 2010).
15. A. D. Moulton, R. B. Gottfried, R. A. Goodman, A. M. Murphy, and R. D. Rawson, "What Is Public Health Legal Preparedness?" *Journal of Law, Medicine & Ethics* 31, no. 4 (2003): 372-383; G. W. Matthews, G. Benjamin, S. P. Mills, W. Parmet, J. J. Misrahi, *Journal of Law, Medicine & Ethics* 30, no. 3, Supp. (2002): 52-56; R. Martin, "Law as a Tool in Promoting and Protecting Public Health: Always in Our Best Interests?" *Public Health* 121 (2007): 846-853.
16. Public health preparedness: response capacity improving, but much remains to be accomplished. *GAO Testimony Statement of Janet Heinrich before the Committee on Government Reform, House of Representatives, 108th Cong.*, February 12, 2004, available at <<http://www.gao.gov/new.items/d04458t.pdf>> (last visited December 3, 2010).
17. See PAHPA, *supra* note 7.
18. U.S. Department of Health and Human Services, "National Health Security Strategy," December 2009, available at <<http://www.phe.gov/Preparedness/planning/authority/nhss/strategy/Pages/default.aspx>> (last visited December 3, 2010).
19. See National Health Security Strategy, *supra* note 18.