

The Pandemic and All-Hazards Preparedness Act

Improving Public Health Emergency Response

James G. Hodge, Jr, JD, LLM

Lawrence O. Gostin, JD

Jon S. Vernick, JD, MPH

PUBLIC HEALTH EMERGENCY PREPAREDNESS AND RESPONSE have been defining goals in the United States since the terrorist and anthrax attacks in the fall of 2001. The objective of emergency preparedness is to improve the nation's ability to detect and respond to an array of public health emergencies including bioterrorism, emerging infectious diseases, and natural disasters. Despite progress toward this goal, the public is skeptical about the government's capabilities, fueled by the perceived lack of leadership and accountability following Hurricane Katrina.¹ On December 19, 2006, President George W. Bush signed the Pandemic and All-Hazards Preparedness Act (PAHPA), which is intended to improve the organization, direction, and utility of preparedness efforts.² PAHPA centralizes federal responsibilities, requires state-based accountability, proposes new national surveillance methods, addresses surge capacity, and facilitates the development of vaccines and other scarce resources.² This act, however, raises important issues regarding federalism, evidence-based practice, privacy, volunteerism, and technological innovation.

Federalism: Balancing Interjurisdictional Responsibilities

Building on the Public Health Service Act,³ PAHPA seeks to ensure that national authorities are organized and well-equipped to respond to a catastrophic event. The act aspires to answer the question of "who is in charge" by squarely placing the Department of Health and Human Services (DHHS) as the lead agency for "federal public health and medical response[s] to public health emergencies covered by the National Response Plan,"² which otherwise vests most emergency management functions in the Department of Homeland Security.⁴ This represents a significant shift of federal authority for the public health components of emergency responses.

National public health emergencies also involve interjurisdictional coordination at all levels of government. Traditional principles of federalism, modern public health practice, and a need for frontline preparedness require tribal (eg, American Indian), state, and local entities to be ready for emer-

gency responses. Existing guidance from the White House⁵ and DHHS⁶ encourages these subnational entities to detect, prepare for, and respond to public health emergencies. PAHPA acknowledges that interjurisdictional coordination is pivotal during emergencies, but does not specify how federal entities should align with tribal, state, and local governments. Instead, DHHS is generally instructed to work with states and localities to fulfill the act's objectives. Further specification is lacking, perhaps in deference to state public health preparedness plans required by the act. As experienced during Hurricane Katrina, however, these plans have limits. They do not have the same force of law as statutes, lack consistency across levels of government, and ultimately broke down when tested. Until issues of uncertainty and lack of coordination are resolved legislatively, these dilemmas could arise in future disasters.

State and Local Public Health Preparedness: Evidence-Based Policies

Despite generalities on the need to coordinate national and local emergency responses, PAHPA's expansive provisions actually may allow federal authorities to usurp traditional subnational public health activities. PAHPA mandates state and local governments, and other eligible entities (eg, hospitals, laboratories, universities), to create and implement plans to enhance public health preparedness and security, consistent with "measurable evidence-based benchmarks and objective standards" developed by DHHS.² These benchmarks will include standards on how to integrate public and private sector efforts, develop public health security capabilities, meet surge capacity, protect at-risk individuals, and ensure continuity of operations.² The intent is to provide incentives to recipient jurisdictions to meet DHHS' national standards of preparedness.

The Institute of Medicine⁷ and many health experts recommend evidence-based public health policies. As with medical care, public health officials should be required to demonstrate the cost-effectiveness of interventions. PAHPA's use of benchmarks is supported by Congress' constitutional power to hold states accountable as a condition of award-

Author Affiliations: Center for Law & the Public's Health at Georgetown and Johns Hopkins Universities, Washington, DC, and Baltimore, Md (Messrs Hodge, Gostin, and Vernick); and O'Neill Institute for National and Global Health Law, Washington, DC (Mr Gostin).

Corresponding Author: James G. Hodge, Jr, JD, LLM, Center for Law & the Public's Health, Johns Hopkins Bloomberg School of Public Health, 624 N Broadway, Hampton House Room 588, Baltimore, MD 21205 (jhodge@jhsph.edu).

ing emergency preparedness grants.⁸ However, what should these benchmarks require, how will they be used to judge jurisdictions, and how should failures to meet these standards be addressed? Congress did not prescribe criteria for how states should be judged for noncompliance. States or localities that fail to meet the DHHS benchmarks (however determined) may be denied federal funds on an escalating scale. Denied funds may be redistributed to other jurisdictions. Although consistent with constitutional norms, these fiscal sanctions may effectively deny funds to jurisdictions that need them most and potentially exacerbate preparedness disparities nationally.

Electronic Surveillance: Protection of Privacy

To enhance surveillance and rapid response, PAHPA requires DHHS to establish a national electronic network to collect and analyze public health data from governmental and private sector entities.² By generating standardized data formats for existing state and local surveillance systems, DHHS seeks to maximize the compatibility and usefulness of real-time information to assess situational awareness capabilities.

Creating a national electronic public health data network for federal and subnational public health authorities should significantly improve surveillance for many health hazards. National efforts to collect public health data are not novel, although public health reporting practices in the United States are traditionally performed at the state and local levels.⁹ The Centers for Disease Control and Prevention already acquires emergency health data through its BioSense program¹⁰ and has access to vast state-based public health systems. In 2006, Congress debated, but failed to pass, the National Reportable Conditions Act,¹¹ which would have authorized the Department of Homeland Security (not DHHS) to directly operate a national health surveillance system to protect national security.

Government certainly needs to acquire, use, and disclose accurate, meaningful health data to detect or respond to public health emergencies.⁸ Nevertheless, the federal government's collection of identifiable, often sensitive health information can invade personal privacy.⁹ PAHPA affords federal officials too much discretion to accumulate and share personal health information without adequate safeguards. There are other federal rules designed to protect privacy,⁹ notably regulations issued by DHHS pursuant to the Health Insurance Portability and Accountability Act (HIPAA).¹² The HIPAA Privacy Rule, however, effectively excludes public health data collections from its protections.¹³ Other privacy laws merely provide a patchwork of protections for national public health data.⁹

Health information privacy concerns should be addressed in advance through new DHHS regulations that include (1) defined limits as to the types and amounts of identifiable data acquired; (2) innovative guidance on permissible governmental uses of these data for public health purposes before, during, and after emergencies; (3) provisions to pre-

vent disclosure of data for non-public health purposes without informed consent; and (4) meaningful safeguards to prevent unauthorized access.

Enhancing Volunteer Health Care Personnel to Meet Surge Capacity

Meeting "surge capacity" during catastrophic events is a priority at every level of government and within the private sector. Surge capacity often refers to garnering critical supplies such as vaccines, pharmaceuticals, and medical equipment. Ensuring an adequate number of well-trained health care professionals to meet patient demands is equally important. PAHPA authorizes DHHS to oversee all federal health personnel during a public health emergency, including volunteers requested for federal service through the Emergency System for Advance Registration of Volunteer Health Professionals (ESAR-VHP) and Medical Reserve Corps (MRC).² These programs were created originally with federal funds to organize volunteer health personnel under state and local control.¹⁴ PAHPA transfers some control of these systems to the federal government. DHHS can now link ESAR-VHP and MRC systems into a single, national verification system, identify volunteers within these systems, and effectively recruit the volunteers for federal emergency response efforts (even if these volunteers may have been counted on by state or local governments).

National coordination of interstate volunteer health professionals during emergencies presupposes that the legal environment supports their deployment. Qualified, registered health care professionals who volunteer to assist for humanitarian purposes deserve protection from liability.¹⁵ During Hurricane Katrina, thousands of interstate and intrastate volunteer health personnel faced potential legal liability or other risks for their actions depending on the nature of their deployment, their existing employment, and varying laws.¹⁵ Whether real or perceived, the specter of liability hindered the deployment or minimized the utility of skilled volunteers.

Following Hurricane Katrina, medical and other organizations called for national legislative reforms to facilitate the use of emergency volunteer health personnel.⁵ Congress unsuccessfully introduced several bills to reduce the liability exposure of volunteers.^{16,17} The National Conference of Commissioners on Uniform State Laws is preparing an act to provide automatic licensure reciprocity and other protections for volunteers at the state level,¹⁸ which may include strong liability protections. Another possibility is to expand the scope of "Good Samaritan" laws, which immunize uncompensated volunteers acting in good faith in specific emergency settings.¹⁹

PAHPA is largely silent on these issues. Although the act encourages the emergency waiver of medical licensing requirements for out-of-state volunteer health professionals,² it does not reduce the liability exposure or otherwise protect health care volunteers or the entities that send or host them. Nor does it guarantee appointment of an emer-

gency volunteer as a federal employee through which the volunteer may be protected from liability as are members of the federal Commissioned Corps.² PAHPA represents a missed opportunity to expand existing federal liability protections of the Volunteer Protection Act of 1997²⁰ (that immunizes uncompensated volunteers of governmental entities or nonprofit organizations) and other laws to all registered volunteer health personnel. These laws motivate qualified volunteers to serve without fear of civil recourse for their noncriminal actions; encourage entities to send, accept, and use volunteers; and ultimately help to protect the public's health during emergencies.²¹

Rapid Development of Vaccines and Pharmaceuticals

PAHPA promises new initiatives for the rapid development of biological interventions (eg, vaccines, drugs) for highly pathogenic influenza or other health hazards. The act establishes a new Biomedical Advanced Research and Development Authority (BARDA) within DHHS.² BARDA is charged with accelerating the development of new products by fostering collaboration, supporting research, encouraging innovation, and offering technical guidance among governmental and private sector entities. PAHPA authorizes the appropriation of more than \$1 billion through the Biodefense Medical Countermeasure Development Fund,² although Congress has not fully appropriated these resources to date.

By coordinating national efforts and removing some regulatory restraints, BARDA may support a slate of countermeasures for biological, chemical, radiological, or nuclear threats. Yet, this idealistic goal is threatened by practical market-based realities. PAHPA does not ensure adequate economic incentives to stimulate maximum private sector participation. Even with some federal funding, pharmaceutical companies may be unwilling to take the associated financial risks without greater assurance of a reliable market for their products. Companies are concerned about potential liability. PAHPA does not address potential solutions to these problems such as advanced market commitments for vaccines or pharmaceuticals, investment incentives, or limited liability assurances.²²

Seeking Fairness in Allocating Limited Resources

The need for ethically fair allocation of scarce resources during emergencies has been debated internationally.²³ The World Health Organization,²⁴ many of its member nations, and numerous public and private sector entities have called for guiding principles. Ethical models for resource allocation have been (and are continuing to be) proposed.²³ During emergencies, DHHS will be responsible for distributing scarce medical countermeasures. But PAHPA offers little guidance about how these resources should or would be allocated. Instead, Congress generally directs DHHS to consider at-risk populations and loosely refers to DHHS' au-

thority to address "rapid distribution and administration of medical countermeasures" in the National Health Security Strategy submitted to Congress every 4 years.²

Lacking congressional direction, allocation planning prior to an emergency or in real time is the default. Ethical allocation of vaccines is discussed in DHHS' pandemic influenza plan, which prioritizes who will receive scarce vaccine supplies, beginning with those essential to their manufacture.⁶ Although these guidelines are helpful, DHHS has not fully considered how to allocate resources for non-pharmacologic measures (eg, ventilators, hospital beds, quarantine facilities), nonfederal supplies, or during other types of emergencies.

Conclusions

National public health emergencies present immense challenges. Preparedness is multifaceted, with public and private sectors having essential yet sometimes poorly defined roles. Public health responses are politically controversial because there is so much at stake. Response efforts affect the lives, health, and safety of potentially tens of thousands of individuals. Against this backdrop are urgent calls for greater governmental accountability, organization, and capacity.

PAHPA streamlines federal public health responses, holds states accountable for their performance, creates a national surveillance structure, facilitates volunteerism, and encourages the rapid development of medical countermeasures. However, it also does not resolve complex, long-standing issues of interjurisdictional coordination, privacy, liability, private sector incentives, and distributive justice—all of which are critical to improve public health emergency preparedness.

Financial Disclosures: None reported.

Disclaimer: The US Department of Homeland Security supports the Center for Law & the Public's Health, and the Alfred P. Sloan Foundation supports Georgetown University Law Center, but this article does not necessarily represent the views of these funders.

REFERENCES

1. Trust for America's Health. New poll finds dramatic rise in public concern about biological and chemical terrorism [press release]. February 2, 2007. <http://healthyamericans.org/newsroom/releases/release020207.pdf>. Accessed February 9, 2007.
2. Pandemic and All-Hazards Preparedness Act, Pub L No. 109-417, §101 *et seq* (2006).
3. Public Health Service Act, 42 USC §201 *et seq* (2006).
4. National Response Plan. <http://www.dhs.gov/xlibrary/assets/NRPbaseplan.pdf>. Accessed March 5, 2007.
5. The White House. *The Federal Response to Hurricane Katrina: Lessons Learned*. Vol 58, 2006. <http://www.whitehouse.gov/reports/katrina-lessons-learned/>. Accessed March 5, 2007.
6. US Department of Health and Human Services Web site. HHS pandemic influenza plan. <http://www.hhs.gov/pandemicflu/plan/pdf/HHSPandemicInfluenzaPlan.pdf>. Accessed March 5, 2007.
7. Institute of Medicine. *The Future of the Public's Health in the 21st Century*. Washington, DC: National Academy Press; 2002.
8. Gostin LO. *Public Health Law: Power, Duty, Restraint*. 2nd ed. Berkeley, Calif and New York, NY: University of California Press and Milbank Memorial Fund. In press.
9. Hodge JG. Health information privacy and public health. *J Law Med Ethics*. 2004;31:663-671.
10. US Centers for Disease Control and Prevention Web site. BioSense. <http://www.cdc.gov/biosense/index.htm>. Accessed March 17, 2007.

11. National Reportable Conditions Act, S. 3898 (2006).
12. Health Insurance Portability and Accountability Act, Pub L No. 104-191, 110 Stat 1936 (1996).
13. Public welfare: security and privacy, 45 CFR §164.512(a)(b) (2004).
14. Health Resources and Services Agency. *Emergency System for Advance Registration of Volunteer Health Professionals (ESAR-VHP): Legal and Regulatory Issues*. Washington, DC: Dept of Health and Human Services; 2006.
15. Hodge JG. Legal issues concerning volunteer health professionals and the hurricane-related emergencies in the Gulf Coast region. *Public Health Rep*. 2006;121:205-207.
16. Hurricane Katrina Emergency Health Workforce Act of 2005, S. 1638 (2005).
17. GIVE Act of 2005, S. 1747 (2005).
18. National Conference of Commissioners on Uniform State Laws. *Uniform Emergency Volunteer Health Practitioners Act*. 2007. <http://www.uevha.org/DesktopDefault.aspx?tabindex=1&tabid=55>. Accessed March 5, 2007.
19. Public/Private Legal Preparedness Initiative at the University of North Carolina School of Public Health Web site. <http://nciph.sph.unc.edu/law/>. Accessed March 17, 2007.
20. Volunteer Protection Act of 1997, 42 USC §14503 (2000).
21. Hodge JG, Gable LA, Calves S. Volunteer health professionals and emergencies: assessing and transforming the legal environment. *Biosecure Bioterror*. 2005;3:216-223.
22. Gostin LO. Medical countermeasures for pandemic influenza: ethics and the law. *JAMA*. 2006;295:554-556.
23. Thompson AK, Faith K, Gibson JL, Upshur REG. Pandemic influenza preparedness: an ethical framework to guide decision-making. *BMC Med Ethics*. 2006;7:1-12.
24. World Health Organization Department of Communicable Disease. *WHO Global Influenza Preparedness Plan*. Geneva, Switzerland: World Health Organization; 2005.

EDITORIALS

Editorials represent the opinions of the authors and *JAMA* and not those of the American Medical Association.

Lack of Benefit From Nitric Oxide Synthase Inhibition in Patients With Cardiogenic Shock Looking for the Reasons

Gjin Ndrepepa, MD

Albert Schömig, MD

Adnan Kastrati, MD

CARDIOGENIC SHOCK COMPLICATING ACUTE MYOCARDIAL infarction (AMI) is one of the most serious and challenging conditions in cardiovascular medicine, with up to two thirds of patients dying within a few weeks.^{1,2} According to data from a national registry of nearly 300 000 patients with ST-segment elevation AMI, the overall incidence of cardiogenic shock (diagnosed at both presentation and after admission) was 8.6%.³

Even though the incidence of cardiogenic shock has remained stable over the time,^{2,4} mortality rates among patients with cardiogenic shock have decreased over the last decade. Some of the major factors contributing to this decline are early revascularization with percutaneous coronary intervention or coronary artery bypass graft surgery^{1,5} and interventions that increase cardiac output, including inotropic agents and supportive mechanical devices such as intra-aortic balloon counterpulsation and left ventricular assist devices.⁶ Babaev et al³ reported that percutaneous coronary intervention rates in patients with cardiogenic shock increased from 27.4% in 1995 to 54.4% in 2004 and that this increase was associated with a reduction in overall in-hospital mortality rates from 60.3% to 47.9% during that time.

See also p 1657.

Even with application of these therapies, mortality rates remain unacceptably high. Additional and novel therapeutic interventions are badly needed. One possible new approach stems from recent work demonstrating important pathophysiological roles of inflammatory cytokines, the complement system, and increased levels of nitric oxide due to enhanced expression of inducible nitric oxide synthase (NOS).⁷ These intriguing findings led to the Tilarginine Acetate Injection in a Randomized International Study in Unstable MI Patients With Cardiogenic Shock (TRIUMPH) trial, reported in this issue of *JAMA*.⁸

The TRIUMPH trial was a randomized, multicenter, double-blind, placebo-controlled trial of patients with refractory cardiogenic shock despite successful coronary revascularization. Patients were randomized to receive the non-specific NOS inhibitor tilarginine (L-N^G-monomethylarginine [L-NMMA]), 1-mg/kg bolus plus 1-mg/kg per hour 5-hour infusion, or matching placebo. Although the investigators planned to enroll 658 patients, the study was terminated prematurely after enrollment of 398 patients based on a pre-specified analysis of futility. Despite a significant increase in systolic blood pressure at 2 hours among patients in the tilarginine group vs the placebo group (12 vs 7 mm Hg; *P* = .001), there were no differences in the primary end point of 30-day mortality or in secondary outcomes of shock reso-

Author Affiliations: Deutsches Herzzentrum, Technische Universität, Munich, Germany.

Corresponding Author: Adnan Kastrati, MD, Deutsches Herzzentrum, Lazarettstrasse 36, 80636 Munich, Germany (kastrati@dhm.mhn.de).