
Five Legal Preparedness Challenges for Responding to Future Public Health Emergencies

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Since the anthrax attacks of 2001 and the severe acute respiratory syndrome (SARS) outbreak of 2003, significant efforts have been made to develop and revise a range of legal tools designed to strengthen public health emergency responses.¹ The 2009 H1N1 pandemic provided an unprecedented opportunity to implement and exercise many of these mechanisms. At the global level, the World Health Organization (WHO) declared a public health emergency of international concern (PHEIC) pursuant to the revised International Health Regulations [IHR (2005)], and many governments declared national or regional emergencies.² At the U.S. federal level, the Secretary of Health and Human Services (HHS) made public health emergency and Public Readiness and Emergency Preparedness (PREP) Act declarations. In addition, the Food and Drug Administration (FDA) issued Emergency Use Authorizations (EUAs) (to allow the emergency use of certain antiviral medications, diagnostic tests, and respirators during the pandemic), and President Obama declared a National Emergency (to authorize the use of temporary waivers or modifications of certain federal requirements related to health care facility responses).³ Select state and local governments also declared emergencies.⁴

Collectively, these actions changed the legal playing field and facilitated pandemic responses. However, legal preparedness challenges remain an obstacle to improving readiness for future public health threats. This article provides a brief summary of five U.S. legal preparedness topics that warrant additional consideration: (1) EUA implementation at the local level; (2) expansion of health care practitioner scopes of prac-

tice; (3) evidence base for non-pharmaceutical interventions; (4) crisis care liability protections for health care practitioners; and (5) liability associated with failing to adequately plan for disasters.

Emergency Use Authorization (EUA) Implementation

The Project BioShield Act established the emergency use authority in 2004. Under specific conditions, this legislation permits the emergency use of drugs, devices, or biological products that have not yet been approved, cleared, or licensed, or the unapproved use of products that have been approved, cleared, or licensed.⁵ The EUA process requires several steps, including a determination of an emergency by the Secretary of the Department of Homeland Security, Secretary of the Department of Defense, or Secretary of HHS and a declaration by the HHS Secretary of an emergency justifying an EUA. After ensuring certain criteria are met, the FDA Commissioner may then issue an EUA.⁶

During the H1N1 pandemic, multiple EUAs were issued for antiviral medications, diagnostic tests, and respirators.⁷ These authorizations gave public health and medical practitioners additional, important tools to mitigate H1N1-related morbidity and mortality. Despite being a critical response instrument, local challenges surfaced, including interpretation and timing of issuance of EUAs. For example, some health departments have noted that they do not have advance access to EUA content and conditions because EUAs are issued at the time of the emergency. Such issues raise logistical challenges and are concerning for sudden-onset events that would require immediate dispensing of medical countermeasures to a large population (e.g., an anthrax attack in a major city).⁸ Confusion also remains about whether state and local

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countermeasure caches, which have been created to protect first responders and health care workers prior to the arrival of Strategic National Stockpile medications, would be covered through EUAs.⁹ Resolving these and other operational concerns prior to the next public health emergency could facilitate and improve efficiency of local and state responses involving the use of countermeasures.¹⁰

Scope of Practice Expansions

Scopes of practice set forth the services that licensed health professionals may perform. Due to the fact that such standards are defined by state practice acts, they may vary across jurisdictions. During catastrophic health emergencies, patient volume surges and health care staffing shortages are likely. Therefore, emergency planning efforts acknowledge the option for states to temporarily allow certain categories of health care providers (e.g., nurses, paramedics) to perform patient care duties outside their normal scope of practice to increase the cadre of responders.¹¹ For example, a nurse might be authorized temporarily to perform certain tasks during an emergency that, under normal conditions, only a physician would be certified to conduct.

While state governments have limited experience in expanding practitioner scopes of practice during emergencies, some expanded scopes of practice during the H1N1 pandemic. Expansions were largely limited to increasing the number of practitioners available to administer pandemic vaccine, but approaches, requirements, and limitations varied by state.¹² It is unclear how scope of practice expansions would be implemented beyond vaccination for other types and levels of patient care. No unified and consistent approach for temporarily expanding practitioner scopes of practice exists. Whether professional societies that normally oppose expansions for routine care during normal times would support them during emergencies is uncertain.¹³ Expanding scopes of practice is an innovative approach for maximizing limited health care staffing resources to meet patient needs in catastrophic emergencies. Further exploration into the acceptability and feasibility of effectively implementing these strategies — and with some level of consistency to minimize public and practitioner confusion — is needed.

Evidence Base for Non-Pharmaceutical Interventions

National, state, local, and tribal governments have broad powers to respond to a wide range of public health threats. Many of these powers have been updated and expanded in recent years to reflect modern realities.¹⁴ Among such authorities is the ability

to implement non-pharmaceutical interventions to limit the spread of disease through social distancing (e.g., isolation, quarantine, school closures, public event cancellations). During the recent H1N1 outbreak, public health leaders used a variety of these tools. However, certain interventions such as quarantine and school closures were used inconsistently. In the U.S., for example, school closure laws and policies were applied unevenly, at times within the same state or local jurisdiction.

It is understandably tempting for political leadership and other officials to want to “do something” immediately in response to an emergency, but the ability to act does not always justify the resulting actions or decisions. While generally accepted as effective measures for controlling disease transmission, limited, and at times conflicting, evidence exists about the effectiveness of many non-pharmaceutical interventions.¹⁵ Social distancing approaches, which may have been useful historically, could have unintended consequences, including discrimination; loss of employment, income, educational time, and school meals; and recongregation (e.g., during school closures, students might reconvene at central community locations, such as shopping malls; during H1N1, group protests occurred after the cancellation of sporting events). For these reasons, such powers should be used judiciously. Additional research is needed to further assess the optimum timing of implementation of these tools, as well as which interventions most effectively control or stop the spread of disease with the least socio-economic impact.

Crisis Care Liability Protections

The capability of the nation’s health care system to respond to health emergencies has improved significantly since 2001, but the country remains underprepared for a catastrophic health event.¹⁶ During these events, dramatic changes in the provision of health care and allocation of medical resources will be required. This has recently been referred to by the Institute of Medicine as “crisis standards of care.” Due to severe shortages in health care staff, supplies, and space, the overall focus of care will necessarily shift to those allocations that provide the greatest good for the greatest number. Despite the existence of national guidance, most states are still in the early stages of planning for such crises.¹⁷

While volunteer health care responders generally have broad liability protections during emergency responses, questions remain about how best to protect non-volunteer health care practitioners from unreasonable liability for their actions in crisis care scenarios. In addition, the question remains whether such

liability protections are needed to encourage response participation.¹⁸ The U.S. lacks comprehensive liability protections for practitioners in times of crisis, and state-level protections vary. Various legal proposals have been floated to address the existing patchwork of liability protections. These include providing immunity to all responders (whether paid or volunteer, or responding as a state actor or under a private entity) and deeming health care responders state employees so that they can be covered under state tort claims acts.

At a minimum, states, health officials, practitioner communities, and health care facilities should collaboratively develop — with input from the public — comprehensive, properly vetted, and acceptable crisis care plans, guidelines, and clinical protocols for providing health care during resource-scarce, catastrophic health emergencies. This includes clear processes and roles for decision making during an event. Such planning will help to strengthen health system preparedness and deter ad hoc responses and decisions that could result in patient harm. It will also resolve real or perceived inequities in health care allocations and provide a basis for establishing the standard of care during catastrophic emergencies.

Liability for Failing to Adequately Plan for Emergencies

While relatively rare, lawsuits related to response actions taken during health disasters have emerged. In the wake of Hurricane Katrina, criminal charges (which were later dropped) and wrongful death claims were brought against a physician and two nurses at Memorial Medical Center for allegedly hastening the deaths of several patients.¹⁹ After the SARS experience in 2003, a number of cases included allegations that the province of Ontario was negligent in its response to the outbreak by failing to issue adequate warnings to nurses about SARS or ceasing inter-hospital patient transfers.²⁰ A relatively recent development in disaster-related liability is the legal theory of failing to adequately plan for emergencies.²¹ For example, following Hurricane Katrina, the family of a ventilator-dependent patient who passed away during the disaster at Pendleton Methodist Hospital (which lost power) alleged that the patient's death resulted from the hospital's failure to have an adequate evacuation plan and a sufficient emergency electrical power system.²²

The *Pendleton* case, which ultimately ended in a settlement in 2010, raises interesting questions about how far the duty of hospitals, health systems, and their administrators to plan and prepare for emergencies extends.²³ Through statutes, policies, and standards for accreditation, health facilities must already under-

take certain disaster planning efforts.²⁴ Because many hospitals have received federal funding since 2002 to strengthen disaster preparedness, expectations of the role of hospitals in responses have risen. Assessing how much preparedness was necessary for effectively responding to a specific type and scale of emergency might be easily evaluated in hindsight when a disaster ends. With some exceptions, though, it is extraordinarily difficult to gauge and predict *before* disaster strikes the specific extent to which a hospital should prepare. As federal, state, and local laws, policies, and protocols, as well as professional organization guidance and standards, for health care system disaster preparedness further develop, preparedness expectations of health facilities will likely increase. Therefore, defining the extent of reasonable levels of health facility preparedness for various types of emergencies, while also fairly balancing the financial costs of attaining such preparedness, requires further evaluation.

Conclusion

These five challenges in emergency legal preparedness necessitate additional attention. Of course, other legal preparedness issues remain (including many related to these challenges) and may be equally important. Examples of these potential concerns include the following: (1) addressing inconsistencies in legal authorities and implementation of legal response tools during emergencies across and within states; (2) assessing the extent to which health facilities must comply with language access requirements for individuals with limited English proficiency; and (3) conducting rapid, after-action research on the use, impact, and effectiveness of legal response tools.²⁵ In addition, major disease threats will increasingly require enhanced international collaboration. Therefore, at the global level, it will be necessary to address health governance and capacity challenges, primarily those related to the revised International Health Regulations. New legal response concerns will develop with the emergence of novel disease and other public health threats. Because law is at the foundation of many emergency response efforts, addressing these and other legal preparedness challenges at all levels of government and within the health care system before the next major disaster arises is critical for strengthening our collective readiness to respond to public health emergencies.

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