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# Practical, Ethical, and Legal Challenges Underlying Crisis Standards of Care

*James G. Hodge, Jr., Dan Hanfling, and Tia P. Powell*

## Introduction

Public health emergencies invariably entail difficult decisions among medical and emergency first responders about how to allocate essential, scarce resources (e.g., medicines, supplies, personnel). To the extent that these critical choices can profoundly impact community and individual health outcomes, achieving consistency in how these decisions are executed is valuable.<sup>1</sup> Since the terrorist attacks on September 11, 2001, however, public and private sector allocation plans and decisions have followed uncertain paths. Lacking empirical evidence and national input, various entities and actors have proffered multifarious approaches on how best to allocate scarce resources to protect the public's health.<sup>2</sup> Though beneficial in some jurisdictions, these approaches fail to clarify how the type and amount of care delivered in major emergencies might be curtailed. This is due, in part, to a lack of meaningful guidance on shifting standards of care in major emergencies.

In March 2012, the Institute of Medicine (IOM) released additional guidance to assist facilities and practitioners to address scarce resource allocation through the development of "crisis standards of care" (CSC) in catastrophes.<sup>3</sup> IOM's report elucidates the meaning and implementation of a CSC framework

based on extensive input and available research. As discussed below, it further recognizes that the identification and resolution of complex practical, ethical, and legal challenges underlying real-time implementation of CSC are indispensable to protecting the public's health. These challenges, discussed in part in the IOM report, are described further below.

## Implementing a Catastrophic Response Framework

Catastrophic events may include loss of governmental operations, disruption of critical infrastructure, and concomitant threats to communal health.<sup>4</sup> Use of an improvised nuclear device, urban dissemination of drug resistant anthrax, emergence of a pandemic and highly pathogenic influenza strain, or occurrence of a natural disaster may all lead to such conditions in the United States. Each event requires well-coordinated, pre-planned responses to save lives and mitigate morbidity as much as possible.

In 2009, the Department of Health and Human Services, Assistant Secretary for Preparedness and Response requested IOM to closely consider the medical, public health, ethical, and legal aspects of these emergencies. During the throes of the 2009/2010 H1N1 pandemic, IOM assembled a special committee to rapidly promulgate initial guidance to establish standards of care in crises. Expanding on the notion that surge capacity in response to a large-scale event flexes across a continuum — ranging from *conventional* to *contingency* to *crisis* responses<sup>5</sup> — the committee abandoned prior terminology focused on "altered standards of care."<sup>6</sup> Instead, it referred to "crisis standards of care" as a "substantial change in usual healthcare operations and the level of care it is possible to deliver resulting from a pervasive or cata-

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**James G. Hodge, Jr., J.D., LL.M.**, is the Lincoln Professor of Health Law and Ethics at the Sandra Day O'Connor College of Law at Arizona State University. **Dan Hanfling, M.D.**, is the Special Advisor of Emergency Preparedness and Response at Inova Health System and a Clinical Professor in the Department of Emergency Medicine at George Washington University. **Tia P. Powell, M.D.**, is the Director of the Montefiore-Einstein Center for Bioethics and a Professor of Clinical Epidemiology and Clinical Psychiatry at Albert Einstein College of Medicine.

strophic disaster.”<sup>7</sup> These standards shift based on existing conditions during medical surge responses (and thus do not represent a single standard). Consideration of such events highlights the interdependency of public and private emergency responders. Delivery of effective disaster medical care cannot be

IOM’s initial guidance on the scope of CSC was beneficial, but actors needed more to clarify and implement a CSC framework nationally. In 2012, the committee elaborated on the development of CSC within a systems framework for catastrophic disaster response. As per Figure 1, this framework highlights key ele-

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achieved without strong public health architecture, coordinated efforts by emergency managers, and out-of-hospital care by emergency medical and ambulatory care providers as well as private health care practitioners.

ments, including ethical and legal guidance, to assure a comprehensive, cohesive approach in response to catastrophic events.

Core steps include meaningful provider and community engagement to adjust the delivery of care grounded on fair and equitable principles. Health care providers and public health practitioners must coordinate the allocation and delivery of scarce medical resources based on clinical processes and decisions developed through broad-based consensus. This requires a fundamental priority shift from routine, patient-centric health care services to providing the best care possible to the largest numbers of victims of catastrophes.<sup>8</sup> Protecting the health of the public is paramount. Coextensively, front line providers must be free to make difficult life and death decisions without the threat of *post hoc* “second-guessing” to allow them to focus on saving lives and reducing suffering.

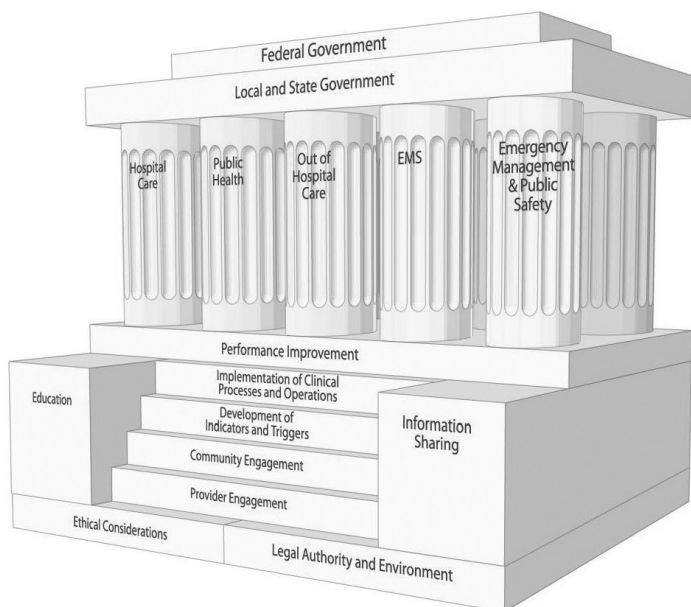


Figure 1

### A Systems Approach to Catastrophic Disaster Response

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### Ethical Challenges Underlying Implementation

In its 2012 report, IOM issued a single ethics recommendation, aimed largely at health care workers (HCWs): *Adhere to ethical and professional norms in crisis standards of care*. Translating this all-encompassing recommendation into practical actions during emergencies requires additional ethical norms. IOM offers three substantive principles (fairness, duty to care, and duty to

steward resources) as well as four ethical process principles (transparency, consistency, proportionality, and accountability).

Moving from abstract principles and norms to the concrete world of health care delivery presents translational challenges. Allocation of scarce resources should be fair, but when does a specific policy meet the conditions of being fair? Several principles emerge. First, different participants must agree that the allocation system treats them fairly. Second, fair allocation does not mean that all are treated equally. Rather, patients of a similar class must be treated alike. Treatment is to be based upon objective and consistent criteria, such as prognosis. Some differences (e.g., race, ethnicity, and religion) are excluded from fair allocation decisions. Whether factors like age and job description should be considered in allocation schemes is less clear. For instance, discussions about whether HCWs and other first responders should have enhanced access to scarce medical resources are contentious and dependent on the goals of enhanced access, types of treatment, and desires to enhance access for other groups.

Goals for enhanced access in emergencies may include (1) incentivizing work attendance, (2) rewarding risks at work, or (3) returning staff to work. Obstacles may inhibit attaining of these goals. Some survey data suggest that HCWs fear reporting to work during infectious disease outbreaks.<sup>9</sup> Enhanced access to preventive measures might alleviate their concerns. Facilities have a reciprocal duty to protect and care for HCWs who take on risks when treating others, an ethical obligation that exists independently of incentives to encourage attendance. Of course, HCWs are not the only ones who encounter risks. Conversely, some health workers may actually have little front line exposure or risk.

The type of treatment also matters in the ethical weight of arguments for enhanced care for HCWs. Allocation of life-saving treatments like ventilators generates considerable controversy; enhanced distribution of preventive measures like flu vaccines appears more acceptable. If the aim is to keep HCWs in the field, vaccines are more likely to be effective than ventilators. A HCW needing ventilator support because of severe respiratory illness stemming from pandemic influenza is unlikely to return to work during the pandemic. In contrast, access to an effective vaccine may prevent illness and keep HCWs active.

Greater access for one group means less access for others in this zero sum game. Contentious decisions about which groups come before others may differ among communities. Of note, a CDC workgroup in 2010 addressed the needs of children in public health disasters.<sup>10</sup> Among its recommendations is that chil-

dren should have enhanced access to critical care, including adult ICU beds. Compelling arguments underlie this recommendation. Although children face a higher level of risk in many disasters, there are fewer ICU beds per capita for them. Children have less immunity and are more likely to fall ill from pandemic influenza than adults, and yet are more likely to survive critical illness. Finally, many communities prioritize children when resources are scarce. This may lead to a reduction of ICU beds for adults generally, especially if HCWs also are prioritized.

In sum, saying that allocation systems should be fair is easier than actually constructing such systems. Implementation of ethically sound policies requires careful efforts at the community level and a rigorous assessment of the ethicality of policy decisions.

### The Role of Law and Crisis Standards of Care

A slate of core legal concerns in implementing CSC cuts across public and private sectors involved in coordinating and providing emergency care during disasters, as summarized in Table 1.

Addressing these (and other) questions is complicated by changing legal dynamics during crises. Federal, state, tribal, and select local governments are empowered to declare states of emergency, disaster, or public health emergency. Critical emergency legal powers may include:

- authorizing expedited public health powers to acquire and allocate scarce resources;
- waiving existing laws impeding public health responses;
- enabling cross-state licensure of HCWs and volunteers;
- expanding or contracting HCWs' scope of practice; and
- immunizing specific actors and entities from liability for ordinary acts of negligence.

However, each of these powers may be dependent on the type and duration of governmental declarations,<sup>12</sup> which, in turn, may advance or impede implementation of CSC depending on real-time "legal triage" efforts to identify and overcome legal barriers.<sup>13</sup> Legal conflicts inherent in balancing individual and communal interests invariably arise, including the oft-debated liability risks of HCWs and entities.<sup>14</sup> On one side, practitioners and entities raise liability as a major concern during emergencies when implementation of CSC necessitates difficult allocation decisions because of limited resources.<sup>15</sup> High-profile cases involving health care practitioners<sup>16</sup> and hospitals<sup>17</sup> following

Table I

**Select Legal Issues Related to Implementing CSC<sup>11</sup>**

<b>Subject</b>	<b>Legal Issues</b>
Organization of Personnel	<ul style="list-style-type: none"> <li>• How are employees, independent contractors, and volunteers legally distinguished for the purpose of coordinating services and benefits?</li> <li>• Do existing labor contracts or union requirements affect the ability of the entity and its personnel to respond to an emergency?</li> <li>• Have appropriate contractual or other mechanisms been executed to facilitate the delivery of services by employed or volunteer personnel, ensure worker safety, or make available workers' compensation or other benefits?</li> </ul>
Access to Treatment	<ul style="list-style-type: none"> <li>• Has the entity assessed its strategy for conducting medical triage under legal requirements for treating existing and forthcoming patients?</li> <li>• Is the entity prepared to screen and potentially divert excess numbers of patients during an emergency consistent with the Emergency Medical Treatment and Active Labor Act (EMTALA), absent its waiver?</li> <li>• Do health care personnel who are designated to treat existing and forthcoming patients pose any risks to patients either through (1) exposure to infectious or other conditions or (2) the use of personal protective equipment that may impede the delivery of medical services?</li> </ul>
Coordination of Health Services	<ul style="list-style-type: none"> <li>• Are health care personnel aware of the legal effects of a shift to crisis standards of care and changes relating to scopes of practice during a declared emergency?</li> <li>• Are health care personnel knowledgeable about conditions related to FDA's issuance of emergency use authorizations, including accompanying mandatory emergency use information for patients and providers?</li> <li>• Are adequate mechanisms in place to ensure compliance with surveillance, reporting, testing, screening, partner notification, quarantine, isolation, or other public health mandates?</li> <li>• Are legal issues concerning the use of volunteer health professionals during an emergency addressed via the entity's emergency plan?</li> </ul>
Patients' Interests	<ul style="list-style-type: none"> <li>• Can patients with physical or mental disabilities be accommodated during the emergency consistent with disability protection laws?</li> <li>• Do patients have adequate access to available medical countermeasures to ensure their health and safety?</li> <li>• Are there appropriate measures to ascertain patients' informed consent?</li> <li>• Barring waiver, are the entity and its personnel prepared to respect patients' health information privacy rights?</li> <li>• Is the entity prepared to evacuate at-risk patients in response to an emergency?</li> </ul>
Allocation of Resources	<ul style="list-style-type: none"> <li>• Is the process for allocating scarce resources fair, reasonable, nondiscriminatory, and credibly based on protecting the public's health?</li> <li>• Are federal, state, or local policies regarding resource allocation followed?</li> <li>• Can government appropriate existing resources (with just compensation) for communal purposes during an emergency?</li> </ul>
Liability	<ul style="list-style-type: none"> <li>• When may the entity and its personnel be liable for their actions in treating patients via CSC?</li> <li>• What legal protections from liability for entities, their health care personnel, independent contractors, or volunteers (including insurance coverage) apply?</li> <li>• May entities and their personnel face potential liability for failure to adequately plan or train for emergencies?</li> </ul>
Reimbursement	<ul style="list-style-type: none"> <li>• Are there established reimbursement protocols for treating patients?</li> <li>• Are private health insurers or other payors legally required to reimburse for care delivered to patients in furtherance of the public's health?</li> <li>• Are entities organized to seek federal and state reimbursement through the Centers for Medicare &amp; Medicaid Services, the Federal Emergency Management Agency, or other sources for care delivered in off-site facilities operated by the entity?</li> <li>• Have federal/state authorities accelerated, altered, or waived Medicare/Medicaid requirements for reimbursement?</li> </ul>
Interjurisdictional Cooperation	<ul style="list-style-type: none"> <li>• Has the entity executed memoranda of understanding (MOUs), mutual-aid agreements (MAAs), or other agreements to facilitate interjurisdictional coordination of emergency health services?</li> <li>• Are these agreements consistent with governmental requirements?</li> <li>• Is the entity's all-hazards emergency plan integrated with community-level emergency planning and objectives?</li> <li>• Have state or local governments on international borders addressed specific concerns through lawful agreements?</li> </ul>

Hurricane Katrina have contributed to liability concerns among many HCWs. In response, governments have established policy norms, passing an array of statutory and regulatory liability protections<sup>18</sup> (e.g., the federal Public Readiness and Emergency Preparedness [PREP] Act<sup>19</sup>). These protections collectively immunize practitioners, volunteers, and some entities from negligence claims resulting from actions during declared emergencies.<sup>20</sup>

Conversely, some suggest that emergency liability

liability for ordinary negligence compromises these decisions.

Patients adversely affected through negligence are not without recourse. Some may be entitled to emergency compensation funds. Those affected by willful, wanton, or criminal acts by HCWs can seek legal remedies since virtually no emergency liability protections insulate HCWs or volunteers from these acts. In addition, liability protections for health care entities are more limited than those for practitioners or volunteers.<sup>24</sup>

IOM's guidance on CSC presents a cohesive methodology designed to improve planning and preparedness efforts. Still, as noted in the IOM report and discussed above, practical, ethical, and legal challenges in implementing CSC in emergencies may lead to variances among public and private actors and entities. Addressing these challenges in advance of and during real-time crises is essential to prevent excess morbidity and mortality when the stakes are at their highest.

protections for HCWs and volunteers are ill-advised and unnecessary because (1) liability claims do not proliferate following emergencies, (2) changing standards of care sufficiently resolve any claims that do arise, and (3) adversely affected patients or their families should not be denied access to courts to contest acts of medical negligence.<sup>21</sup> Policymakers, however, have largely rejected each of these points. It is not entirely known how many liability claims actually arise following emergencies (i.e., many may not be filed in court; others may be negated because of existing immunities). What is known is that when HCWs perceive a significant threat of liability, they may fail to respond in kind with allocation plans that refocus resource decision-making away from individual patient outcomes toward protecting the public's health. Anecdotal accounts of HCW's unwillingness or failure to participate in emergency responses due to fear of liability are backed up by specific empirical data.<sup>22</sup>

Relying on shifts in medical standards of care during emergencies to fully insulate providers from negligence claims ignores the distinctions between medical and legal standards of care. Just because the medical standard of care may change in emergencies does not always mean the legal standard follows suit.<sup>23</sup> During the implementation of CSC, HCWs must make tough decisions about who receives and who is denied specific services or medicines. Some patients may be negatively impacted in the interests of protecting the public's health. Exposing HCWs to

## Conclusion

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## References

1. Government Accountability Office, *Emergency Preparedness: States Are Planning for Medical Surge, but Could Benefit from Shared Guidance for Allocating Scarce Medical Resources*, 2008, GAO-08 668, available at <<http://www.gao.gov/new.items/d08668.pdf>> (last visited January 9, 2013).
2. Institute of Medicine, *Crisis Standards of Care: A Systems Framework for Catastrophic Disaster Response* (2012).
3. *Id.*
4. E. L. Quarantelli, University of Delaware Disaster Research Center, "Emergencies, Disaster and Catastrophes Are Different Phenomena," Preliminary Paper no. 304, available at <<http://dspace.udel.edu:8080/dspace/bitstream/handle/19716/674/PP304.pdf?sequence=1>> (last visited January 9, 2013).
5. J. L. Hick, J. A. Barbera, and G. D. Kelen, "Refining Surge Capacity: Conventional, Contingency, and Crisis Capacity," *Disaster Medicine and Public Health Preparedness* 3, Supp. 2 (2009): S59-S67.

6. Agency for Healthcare Research and Quality, "Altered Standards of Care in Mass Casualty Events: Bioterrorism and Other Public Health Emergencies," Publication no. 05-0043 (2005).
7. Institute of Medicine, Committee on Guidance for Establishing Standards of Care for Use in Disaster Situations, *Guidance for Establishing Crisis Standards of Care for Use in Disaster Situations: A Letter Report* (September 24, 2009).
8. See Institute of Medicine, *supra* note 2.
9. C. B. Irvin, L. Cindrich, et al., "Survey of Hospital Healthcare Personnel Response During a Potential Avian Influenza Pandemic: Will They Come to Work?" *Prehospital and Disaster Medicine* 23, no. 4 (2008): 328-335.
10. A. H. Antommaria, T. Powell, et al., "Ethical Issues in Pediatric Emergency Mass Critical Care," *Pediatric Critical Care Medicine* 12, Supp. 6 (2011): S163-S168.
11. See Institute of Medicine, *supra* note 2.
12. J. G. Hodge, Jr., "Legal Triage During Public Health Emergencies and Disasters," *Administrative Law Review* 58, no. 3 (2006): 627-644.
13. J. G. Hodge, Jr. and E. D. Anderson, "Principles and Practice of Legal Triage During Public Health Emergencies," *New York University Annual Survey of American Law* 64, no. 2 (2008): 249-291.
14. See Institute of Medicine, *supra* note 2.
15. M. Carpenter, J. G. Hodge, Jr., and R. Pepe, "Deploying and Using Volunteer Health Practitioners in Response to Emergencies: Proposed Uniform State Legislation Provides Liability Protections and Workers' Compensation Coverage," *American Journal of Disaster Medicine* 3, no. 4 (2008): 17-23.
16. A. Nossiter and S. Dewan, "Patient Deaths in New Orleans Bring Arrests," *New York Times*, July 19, 2006, available at <<http://www.nytimes.com/2006/07/19/us/19patients.html?pagewanted=all>> (last visited January 9, 2013).
17. J. G. Hodge, Jr. and E. F. Brown, "Assessing Liability for Health Care Entities That Insufficiently Prepare for Catastrophic Emergencies," *JAMA* 306, no. 3 (2011): 308-309.
18. S. Hoffman, R. A. Goodman, and D. D. Stier, "Law, Liability, and Public Health Emergencies," *Disaster Medicine and Public Health Preparedness* 3, no. 2 (2009): 117-125.
19. 42 U.S.C. § 247d-6d.
20. S. Hoffman, "Responders' Responsibility: Liability and Immunity in Public Health Emergencies," *Georgetown Law Journal* 96, (2008): 1913.
21. G. J. Annas, "Standard of Care - In Sickness and in Health and in Emergencies," *New England Journal of Medicine* 362 (2010): 2126.
22. See Institute of Medicine, *supra* note 2.
23. J. G. Hodge, Jr. and B. Courtney, "Assessing the Legal Standard of Care in Public Health Emergencies," *JAMA* 303, no. 4 (2010): 361-362.
24. Department of Health and Human Services, *Emergency System for Advance Registration of Volunteer Health Professionals (ESAR-VHP): Legal and Regulatory Issues* (2009).