Revisiting Legal Foundations of Crisis Standards of Care

Public Health and the Law

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About This Column

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In 2009 the novel influenza strain H1N1 (a.k.a. swine flu) raged across the globe presenting unknown risks to populations.[1] Initial public concerns were heightened by early reports of potential untimely casualties and long-term morbidity. Fortunately these fears did not fully materialize. Yet, the oft-repeated specter of rapid global migration of viral, infectious diseases like H1N1, West Nile,[2] Ebola,[3] Zika,[4] and COVID have cumulatively generated crises mentalities among health care workers (HCWs) and within health care systems. Substantial national and regional preparedness activities since 9/11 exposed additional vulnerabilities to public health catastrophes. High on the list of concerns was a recognized lack of affirmative, consistent standards of care to employ in emergencies.[5] In a true crisis, HCWs and entities would essentially have to "wing it" in regards to allocating scarce resources and providing critical treatment. In response, the Department of Health and Human Services, Assistant Secretary for Preparedness and Response (ASPR) requested the Institute of Medicine (now part of the National Academies of Science, Engineering and Medicine (NASEM)) to promulgate initial guidance on standards of care to use in public health crises.[6]

As a member of the original NASEM committee, our essential goal was not to espouse definitive standards of care for HCWs to deploy. Rather, we sought to provide guiding principles and templates for public and private sectors to consider in planning for large scale, emergency events.[7] The committee dispatched prior terminology focused on "altered standards of care."[8] A new term, "crisis standard of care" (CSC), was framed and defined generally as a "substantial change in usual health-care operations and the level of care …resulting from a pervasive or catastrophic disaster."[9]

Since its inception, most states and many localities are generating an array of CSC plans with federal or other financial support.[10] American hospitals and other providers implement CSC following natural disasters, emerging infectious diseases, and mass casualty events (MCEs).[11] Consequently, they face a slate of legal and policy issues (e.g., emergency declarations, access, allocations, liability risks/protections, authority, licensure, scope of practice, reimbursements, disabled/special needs populations) chronicled previously by NASEM's committee.[12] Absent resolution (often in real-time), these issues can stymie CSC implementation when time is of the essence. Lives may be lost and injuries suffered unnecessarily due solely to law or policy barriers during crises like COVID.

On November 21-22, 2019, NASEM convened a workshop in Washington, DC in light of the 10th anniversary of its original CSC report.[13] Participants assessed the successes of CSC implementation as well as manifold challenges in law, ethics, and policy. From these discussions emerged two overriding, compelling law/policy questions: (1) what is the appropriate legal "trigger" justifying a shift to CSC?; and (2) what evidence lawfully substantiates critical medical and public health choices made in crises? These pivotal questions, discussed below, lie at the core of future implementation of defen-

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sible, consistent standards of care in public health emergencies (PHEs).

Legal Triggers to Shift to Crisis Standards of Care

An original premise of the NASEM committee in 2009, which it elaborated further in a second report in 2012,[14] focused on the genesis of a public health crisis. Diverse crises present varying threats to the community's health.[15] As 2019 workshop participants noted, crisis means different things to HCWs depending on the context and setting.[16] For large health systems or entities in metropolitan areas, a crisis might arise from a MCE like an explosive detonation (e.g., Boston Marathon bombing 2013) or active shooter tragedy (e.g., Las Vegas concert (2018)). Dozens, hundreds, or thousands of persons may be immediately imperiled by such acts, testing the surge capacity of even well-staffed and equipped hospitals. In smaller jurisdictions, HCWs may perceive a crisis following a surge of patients from a vehicular collision on a nearby highway.

In either scenario, the actual crisis arises from the same cause: an immediate lack of resources (e.g., doctors, nurses, volunteers,[17] beds, meds, supplies) available to assure patient medical outcomes normally achievable in non-crises. By this measure, the scarcity of resources defines the crisis, not the event itself. The primary dilemma, however, is that neither scarcity of resources nor tangible events alone may provide sufficient "cover" for implementing medical care or public health services outside the norm of routine practices. Something more is needed legally to trigger CSC implementation.

In 2009, NASEM's committee explored the issue of legal triggers to justify implementation of CSC in response to "pervasive or catastrophic disaster[s]," whether natural or manmade.[18] Government-declared emergencies emerged as a default trigger, and for good reason. Federal, state, tribal, and many local governments may declare states of emergency, disaster, or PHE, each of which authorizes a bevy of powers that can help facilitate CSC responses. Emergency declarations may expedite the acquisition or allocation of scarce resources, waive existing legal barriers, allow medical licensure reciprocity, expand scopes of practice, insulate specific actors and entities from liability and raise immediate public awareness.[19]

However, relying on emergency declarations as a consistent spark for CSC implementation is problematic. Issuance of such declarations is unreliable. Even when emergency legal powers are clearly needed, government leaders may be resistant to declare them.[20] Historically, the same event (e.g., H1N1, Zika) implicating similar threats to the public's health may warrant a PHE in one state, but not another. Inconsistencies are further exacerbated by dissimilarities related to the use, duration, scope, and breadth of emergency authorities across jurisdictions.[21]

What constitutes a PHE is, at best, a moving, politicized target. Crafting and implementing real-time crisis standards interjurisdictionally is hard when the legal activations on which their execution lies are indeterminate. Consequently, CSC implementation requires sophisticated "legal triage" efforts[22] designed to identify and overcome perceived or actual legal barriers irrespective of the status of legal declarations.[23] For some jurisdictions that have planned and trained well ahead, this path may be clear; for others, the road ahead is pocked with legal mines that may delay or obscure CSC implementation.

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Evidence Base Substantiating Tough Allocation Choices

Even when the legal trigger for CSC implementation is clear, such as a limited-duration emergency declaration in the aftermath of a major natural disaster (e.g., Hurricanes Harvey and Maria (2017)) substantiating the bases for critical allocations of medical or public health services may not be. One of the panels at NASEM's 2019 workshop examined repercussions stemming from questionable premises supporting CSC. Take, for example, a medically-determined assessment by HCWs to withdraw an elderly person from a ventilator during a PHE to mobilize its use for other priority patients. This is no hypothetical. It happened during emergency response efforts to the catastrophic earthquake in Haiti in 2010 according to panelist, Sheri Fink, M.D., Ph.D.[24] Such decisions alone raise thorny ethical and legal quandaries, but what if the actual bases for implementing CSC decisions lacked justification? That is, what if allocation decisions made pursuant to CSC guidance could not be shown currently or later to ameliorate health outcomes? The ethicality of crisis decisions over who wins or loses is clearly at stake. What about the legality?

A decade ago NASEM's 2009 committee recognized that CSC was not static; the standards must fluctuate based on existing conditions.[25]

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Implementing CSC is not about singularly pre-determining the precise outlay of limited resources. Rather, it entails a process of making defensible decisions motivated by the interests of patients and the public's health amidst catastrophe. In such environments, emergency services involve the real-time provision of care based on the best available medical and public health evidence subject to change as conditions warrant.[26] So long as public and private sector responses to crises follow sufficient process and are guided by reliable medical/public health findings, they may be legally validated despite negative impacts for select patients or subpopulations. Even in times of routine medical care delivery, HCWs are not guarantors of patient health outcomes. They are only liable for failing to meet prevailing standards of care.[27] In crises, it is exceedingly difficult for HCWs to withhold laudable treatment of any patient,[28] much less to make such decisions under the threat of future liability.[29] As a result, explicit liability protections for HCWs regarding acts of ordinary negligence in crises are merited.[30]

Still, what if the very foundation for making critical choices in crisis was later demonstrated through observation or research to lack efficacy? If the goal all along was to avoid "winging it," can government justify widespread CSC planning, preparedness, and response activities if proof of efficacy is missing? Acknowledging a paucity of strong, empirical evidence sustaining or debunking prior or existing CSC protocols or implementation, NASEM panelists and commenters resounded the committee's prior and current calls for more research.[31]

Absent demonstrated validation of a lack of efficacy, however, CSC response activities are legally practical. Imagine the alternatives flowing from a lack of CSC planning. Left to "ad hoc" judgements among public health or medical personnel, CSC implementation could be based on little more than guesswork applied unevenly across patients and populations. Winners and losers in the battle over limited resources might come down to who you know, how much you can pay, or how much sympathy a patient or family can generate. None of these factors justifies emergency medical care in crises. CSC planning and preparedness activities may not be perfect, but they are lawful in helping to assure more relevant factors tied to the best available evidence are deployed.

A decade of theory, planning, and execution of CSC has produced profound improvements among public and private sectors facing real-time decisions in how best to allocate scarce resources when the risks of morbidity and mortality are at their zenith. Careful, measured implementation of CSC in the decade ahead mandates (1) greater clarity on appropriate legal triggers and pathways to effectuating legal triage; and (2) increased assessments of the bases for making tough decisions when health care resources dwindle. If there is a better approach to divvying out resources in true crises, the public deserves to know it. Yet, protecting the public's health in major emergencies means some decisions may have to be made without complete data. In this way, CSC mimics calculated risks that arise in the delivery of individual medical care, but at an even greater level of urgency and population impact.

Note

Although the author served on the aforementioned CSC committee and participated at the 2019 workshop, any opinions, findings, conclusions or recommendations expressed in this publication are his own and do not represent the policy or position of IOM.

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