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**Rapid Expert Consultation on Crisis Standards of Care for the
COVID-19 Pandemic (March 28, 2020)**

March 28, 2020

ADM Brett Giroir, M.D.
Assistant Secretary for Health
200 Independence Avenue, SW
Washington, DC 20201

Robert Kadlec, M.D.
Assistant Secretary for Preparedness and Response
200 Independence Avenue, SW
Washington, DC 20201

Dear ADM Giroir and Dr. Kadlec:

Attached please find a rapid expert consultation that was prepared by the co-conveners of the Crisis Standards of Care working group, John Hick and Dan Hanfling, with input from others listed in the attachment, and conducted under the auspices of the National Academies of Sciences, Engineering, and Medicine's Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats.

Building on the previous decade of National Academies reports, the aim of this rapid expert consultation is to articulate the guiding principles, key elements, and core messages that undergird Crisis Standards of Care decision making at all levels. It does not, and in our opinion should not, attempt to dictate exactly what choice should be made under exactly what circumstance, as that depends on the specific circumstances of the case at hand, and these must be left to the judgment of the professional, institutional, community, and civic leaders who are best situated to understand the local reality.

In my opinion, one of the most important components of the rapid expert consultation is the core principle derived from earlier reports, namely, that Crisis Standards of Care compel thinking in terms of what is best for an entire group of patients, on the principle of saving the most lives (or achieving the best outcome for the group of patients) rather than focusing only on an individual patient under your care. When equipment, staffing, and material are sufficient, focusing only on what is best for each individual patient is tantamount to the best outcome for the collection of patients because the group outcome is simply the sum of the individual outcomes. Under conditions that compel Crisis Standards of Care, this identity of outcomes for the individual and

group breaks down, and the decision makers cannot avoid the hard choices before them. We hope these principles, elements, and messages can assist in discussing and making these difficult, heart-rending decisions.

Respectfully,
Harvey V. Fineberg, M.D., Ph.D.
Chair
Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

This rapid expert consultation responds to your March 25 request to provide a rationale for the implementation of crisis standards of care (CSC) in response to the COVID-19 outbreak. Also discussed are the broad principles and core elements of CSC planning and implementation. This discussion builds on a 10-year foundation of three seminal reports on CSC issued in 2009, 2012, and 2013 by the Institute of Medicine (IOM), which are described in Appendix A at the end of this document.

This document is meant to provide principles and guidance. It is neither appropriate nor feasible for us to detail actual choices and preferences that apply to specific situations, each of which depends on the exigencies of the epidemic relative to locally available facilities, equipment, personnel, and other needed resources. Rather, this document describes the basis upon which to carry out such decision making whenever it has to happen.

Catastrophic emergencies are by their very nature disruptive and life altering. They can have far-reaching societal impacts, even challenging fundamental assumptions about how we live and what we take for granted. Nowhere is this more evident than when medical facilities cannot deliver the usual level of care to all those who need medical attention. This is the current and likely future reality for many institutions caring for the growing numbers of patients with SARS-CoV-2 infection.

Crisis Standards of Care Definition, Guiding Principles, and Key Elements of Planning

Crisis standards of care are applied when a pervasive or catastrophic disaster make it impossible to meet usual health care standards.

GUIDING PRINCIPLES

- Health care planning must do everything possible never to need CSC.
- CSC have the joint goals of extending the availability of key resources and minimizing the impact of shortages on clinical care.
- CSC strive to save the most lives possible, recognizing that some individual patients will die, who would survive under usual care.
- Implementation of CSC will require facility-specific decisions regarding the allocation of limited resources, including how patients will be triaged to receive life-saving care.

KEY ELEMENTS OF CSC PLANNING

Ethical Grounding

- During a catastrophic crisis, it is vitally important to uphold the core ethical principles of fairness, duty to care, duty to steward resources, transparency in decision making, consistency, proportionality, and accountability.
- When resource scarcity reaches catastrophic levels, clinicians are ethically justified—and, indeed, are ethically obligated—to use the available resources to sustain life and well-being to the greatest extent possible.

Engagement, Education, and Communication

- CSC planning must involve both providers and the public in order to ensure the legitimacy of the process and the standards.
- These CSC planning processes must be proactive, honest, transparent, and accountable regarding the state of the U.S. health care system as COVID-19 cases increase, in order to warrant the public's trust.
- Senior leadership must prepare health care workers for the possible need for CSC and support them as they face the decisions that violate usual care standards.

Legal Considerations

- Health care workers who must make difficult decisions implementing CSC must have adequate guidance and legal protections.
- Under disaster conditions, adherence to core constitutional principles remains a constant, but other statutory or regulatory provisions can be altered as necessary in real time.

Indicators, Triggers, and Responsibility *(Examples of hospital indicators, triggers, and tactics for transitions along the continuum of care are outlined in Appendix A.)*

- Institutions must be alert to indicators that signal a shift to CSC levels of care.
- Observation of those indicators should trigger plans for initiating the contingency or crisis care standards.

Evidence-Based Clinical Operations

- Decisions made at the bedside should be evidence-based.
- Current predictive scoring systems of patient outcomes have unclear value in the COVID-19 context.
- Evidence-based care guidelines may emerge over the course of the pandemic, and with them, CSC guidelines should also evolve, if feasible.

Shifting to CSC is the only ethically tenable approach to shortages of health care resources. Ultimately, this shift represents not a rejection of ethical principles but their embodiment.

THE CONTINUUM OF CARE

Standards of care fall along a continuum of three levels, reflecting the incremental surge in demand relative to available health care resources:

- *Conventional care* is everyday health care services.
- *Contingency care* arises when demand for medical staff, equipment, or pharmaceuticals begins to exceed supply. Contingency care seeks functionally equivalent care, recognizing that some adjustments to usual care are necessary.
- *Crisis care* occurs when resources are so depleted that functionally equivalent care is no longer possible.

Appendix A provides examples of the kinds of shortages that can trigger CSC.

THE GOAL OF CSC PLANNING

The transition from conventional to contingency to crisis care comes with a concomitant increase in morbidity and mortality. Thus, it is crucial that planning ensure that CSC is never needed, proactively moving resources ahead of when they are needed. When the system is at risk of becoming overwhelmed, the goal then becomes to conserve, substitute, adapt, and reuse, so that, only in the most extreme of circumstances, are CSC needed.

THE KEY ELEMENTS OF CSC PLANNING

Here, we elaborate briefly on the five key elements of CSC planning:

- A strong ethical grounding;
- Integrated, continuing community and provider engagement, education, and communication;
- Assurances regarding legal authority and environment;
- Clear indicators, triggers, and lines of responsibility; and
- Evidence-based clinical processes and operations.

Ethical Grounding. During a crisis, it is vitally important to adhere to core ethical principles: fairness, the duty to care, the duty to steward resources, transparency in decision making, consistency, proportionality, and accountability. Medical decisions informed by these ethical principles may allow for actions that would be unacceptable under ordinary circumstances, such as not providing some patients with resources when other patients would derive greater benefit from them. When resource scarcity reaches catastrophic levels, clinicians are ethically justified—and indeed are ethically obligated—to use the available resources to sustain life and well-being to the greatest extent possible.

Engagement, Education, and Communication. Both providers and the public must be engaged in CSC planning both to ensure the legitimacy of the process and the resulting standards and to achieve the best possible result. Both the public and health care providers must understand these difficult choices and be engaged in developing the criteria for making them. Those criteria must then be clear enough that practitioners can apply them when making decisions at the bedside, especially when the stewarding of scarce resources means withholding or withdrawing critical care services. Those criteria must reflect the values, wishes, and interests of all patients, especially the most vulnerable.

In the current pandemic, public trust is essential. To this end, health care leaders must be proactive, honest, transparent, and accountable when communicating the state of their institutions and the system as a whole. Given the resources available at the start of the crisis and expected during the immediate period, demand for health care services, especially in critical care, will soon outstrip health care providers' ability to deliver usual care in many communities, as has already occurred in several metropolitan areas. Reports on extreme conditions elsewhere may not prepare the public for the shift to CSC in their own hometowns. Health care and political leaders have a duty to forewarn the public about what is coming, and the implications of CSC.

Senior leaders must also provide material and moral support to health care workers, who will bear the physical, health, and psychological burdens of working under CSC conditions. Providing that support will require careful, consistent messaging; ongoing two-way communication; and attention to the needs created by grueling, stressful work.

Legal Considerations. The law must inform CSC and create incentives for protecting the public's health and respecting individual rights. Extreme scarcity can necessitate difficult life-and-death decisions. Health care workers who will have to make them must have adequate guidance and legal protections. They must be able to follow the rule of law, even under disaster conditions.

At the same time, health care workers must be continually and clearly informed about all relevant changes in statutory or regulatory provisions. These legal issues may affect (1) the organization of key personnel, (2) fair access to treatment, (3) coordination of services within and across health systems, (4) assurance of patients' interests, (5) allocation of scarce resources, (6) protection of health care workers and volunteers from unwarranted liability claims, (7) reimbursement of costs incurred when protecting the public's health, and (8) interjurisdictional cooperation and coordination.

Indicators, Triggers, and Responsibility. Communities must be alert to indicators that signal a shift in the level of care that can be delivered. Under pandemic conditions, changes can occur rapidly. Being as prepared as possible requires situational awareness, open lines of practical and risk communication, and clear lines of authority and responsibility. Appendix A provides examples of such signals.

Evidence-Based Clinical Operations (Making Clinical Decisions Under Crisis Conditions). Bedside decisions should be evidence-based, drawing on clinical research and experience as

consistently and transparently as possible. These should evolve as evidence accrues. For the current situation, existing prospective tools are insufficient for decision making. For example, Sequential Organ Failure Assessment (SOFA) scores have proven to be poor predictors of individual patients' survival, particularly for those with primary respiratory failure. Hence, at their current state of development, these scores are not suitable for excluding patients with respiratory failure from SARS-CoV-2 from receiving critical care. Similar reservations apply to other currently available decision support tools, although their value may improve as experience accumulates with patients having SARS-CoV-2 infection. Even in the face of imperfect data, decision making will be needed at multiple levels. Governments and institutions should consider these criteria proactively, and disseminate them publicly and transparently. This will permit public input and enable better response to evolving science and local circumstances. A useful summary of ethical guidelines and list of resources has been compiled by The Hastings Center.¹

It is important to separate triage at each level of care from care provided at the bedside. This enables caregivers to better fulfill their ethical obligations to individual patients, while other decision-making processes ensure care provides the greatest good for the greatest number. Governments at all levels, institutions, and frontline caregivers should recognize that these decisions are difficult and inherently involve ethical concerns. Ongoing peer and psychological support for those involved will be essential for them to continue their work.

THE BOTTOM LINE

Despite efforts to forestall the spread of SARS-CoV-2 to date, it appears that the COVID-19 outbreak will continue expanding across the United States. We can, therefore, anticipate that a growing number of hospitals will face medical needs that outpace the existing supply of ventilators, protective equipment, and other essentials, as well as the rate that enhanced supply can be produced, acquired, and put into place. These circumstances will require a shift to CSC.

Preparing for CSC means taking all feasible measures—including reuse, substitution, conservation, and administrative controls—to prevent or delay the need for CSC as long as possible. These measures must be taken at all levels of government, the health care system, and society. There is also an imminent need to prepare for difficult decisions about allocating limited resources, triaging patients to receive life-saving care, and minimizing the negative impacts of delivering care under crisis conditions. These preparations and the decisions that arise from them should be transparent and shared with the public. We hope the principles and elements of CSC planning outlined here will help decision makers at all levels.

Preparations for CSC include trustworthy communication with all stakeholders. Both the content and the process of those communications must convey the messages in the box below, which summarize the principles in the three seminal IOM reports on CSC. Failure to communicate regarding the shift to CSC will diminish public trust in health care providers and systems, as well as in government leadership. Without clear, consistent, candid communication, lost faith in institutions could become one more victim of COVID-19.

¹ Berlinger et al. 2020. Ethical framework for health care institutions & guidelines for institutional ethics services responding to the coronavirus pandemic: Managing uncertainty, safeguarding communities, guiding practice. The Hastings Center. <https://www.thehastingscenter.org/ethicalframeworkcovid19>.

Key Messages and Principles

The following key messages and principles drawn from the three seminal Institute of Medicine (IOM) reports, described in Appendix A, can serve as a starting point for introducing the commitments of those responsible for the shift to CSC in response to COVID-19:

- **We, the health care community, are doing everything possible to prevent and avoid crisis conditions and maintain conventional standards of care.** We are partners with the rest of society in slowing the spread of disease to decrease the number of people who may need critical care at the same time.
- **We recognize that the principal goal of implementing CSC is to maximize benefits to society, which includes saving as many lives—patients, health care workers, and front-line first responders—as possible.** CSC decisions allocate scarce treatment resources to those patients who are most likely to benefit, consistent with community values as articulated by bodies convened for this purpose (see Appendix A). Applying this overarching principle requires wise stewardship of medical resources, so that health care workers can help as many patients as possible. They need government, business, and health care systems to increase the supply and timely delivery of needed resources.
- **We are committed to creating CSC strategies that are fair, equitable, and responsive in order to maximize the safety of providers and patients.** Fairness is of paramount importance in the allocation of scarce life-saving medical resources.
- **We will communicate CSC in clear, consistent terms, through channels relevant to diverse stakeholder audiences.** We will speak with one voice to convey governmental commitment to a deliberate, thoughtful process on making these decisions of grave importance. We will draw on relevant research and community experience.
- **We anticipate that conditions will change as the pandemic spreads nationally, leading to dynamic shifts in standards of care, across communities and facilities.** We will apply the best available science to forecast those needs, address them equitably, and communicate the rationale for our actions.
- **We will consider patient and family preferences insofar as possible, within the constraint of allocating resources with the goal of saving the most patient and provider lives.** We will respect patients' dignity and preserve their comfort in all instances.
- **We will prepare adequately for the emotional impacts of CSC on health care workers, patients, their loved ones, and the public as a whole.** We will address the behavioral health needs of health care workers, patients, and their families, knowing the distress that CSC decisions will bring. We will explain these decisions and demonstrate empathy with the distress and losses.

Respectfully,
John Hick, M.D.
Member
Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

Dan Hanfling, M.D.
Co-Chair
2009, 2012, and 2013 Institute of Medicine Crisis Standards of Care committees

APPENDIX A

Foundational Work of the Institute of Medicine

A decade ago, during the period between the first and second waves of the H1N1 pandemic, the Institute of Medicine (IOM) convened a committee to address the following fundamental questions related to crisis standards of care (CSC):

- Who should receive care when not all who need it can be attended to?
- How should decisions be made about who gets access to care?
- Should the standard of care change to reflect the care that can be delivered under such circumstances?

The answers to these core questions formed the basis for the recommendations in the IOM's 2009 Letter Report.² One of those recommendations was to “enable specific legal/regulatory powers and protections for health care providers in the necessary tasks of allocating and using scarce medical resources and implementing alternate care facilities” in the response to such events. The Letter Report also emphasized that CSC should be “formally declared by a state government” in recognition that crisis care operations “will be in place for a sustained period of time.”

Building on this work, the IOM in 2012 issued a report³ articulating a systems framework for catastrophic disaster planning and response, highlighting specific steps that key stakeholders—hospitals and health systems, public health and public safety agencies, emergency medical services, and providers of outpatient medical services—would need to take to prepare for health care delivery under crisis conditions. The third report, published in 2013,⁴ focused on the development of a toolkit identifying the indicators, triggers, and tactics needed to transition from conventional care to CSC.

² Institute of Medicine. 2009. *Guidance for Establishing Crisis Standards of Care for Use in Disaster Situations: A Letter Report*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/12749>.

³ Institute of Medicine. 2012. *Crisis Standards of Care: A Systems Framework for Catastrophic Disaster Response: Volume 1: Introduction and CSC Framework*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/13351>.

⁴ Institute of Medicine. 2013. *Crisis Standards of Care: A Toolkit for Indicators and Triggers*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/18338>.

These reports are as timely and relevant today as they were the day they were released. The conditions under which CSC must be considered as a possibility clearly exist today, given the rapid spread of COVID-19 in communities across the United States and the resulting declarations of a public health emergency by U.S. Department of Health and Human Services Secretary Azar; a national emergency by President Trump; and emergency declarations by every U.S. state and territory, as well as hundreds of municipalities.⁵

All decision makers engaged in the response to the COVID-19 outbreak will be challenged to answer crucial, complex questions reflecting the ethical, legal, clinical, political, and societal dimensions of this crisis. They will need to make difficult decisions about the allocation of resources, decisions with life-and-death consequences. The CSC framework, expressed in the recommendations and guidance of the IOM reports constitute the foundation for this rapid expert consultation and can guide our nation's response.

APPENDIX B

Authors and Reviewers of This Rapid Expert Consultation

This rapid expert consultation was prepared by Dan Hanfling, In-Q-Tel, and John Hick, Hennepin County Medical Center, as the co-conveners of the CSC working group under the auspices of the National Academies' Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats. The working group for this document included the following individuals: Donald Berwick, Institute for Healthcare Improvement; Richard Besser, Robert Wood Johnson Foundation; Carlos del Rio, Emory Vaccine Center; James Hodge, Arizona State University; Kent Kester, Sanofi Pasteur; Jennifer Nuzzo, Johns Hopkins Bloomberg School of Public Health; Tara O'Toole, In-Q-Tel; Richard Serino, Harvard T.H. Chan School of Public Health; Beth Weaver, RESOLVE; and Matthew Wynia, University of Colorado Center for Bioethics and Humanities.

Harvey Fineberg, chair of the Standing Committee, approved this document. The following individuals served as reviewers: Baruch Fischhoff, Carnegie Mellon University; Bernard Lo, The Greenwall Foundation; Nicole Lurie, Coalition for Epidemic Preparedness Innovations and Harvard University; and Monica Schoch-Spana, Johns Hopkins Bloomberg School of Public Health. Ellen Wright Clayton, Vanderbilt University Medical University, and Susan Curry, University of Iowa, served as arbiters of this review on behalf of the National Academies' Report Review Committee and their Health and Medicine Division.

⁵ Descriptions of the emergency, disaster, and public health emergency categories can be found at <https://www.networkforphl.org/resources/emergency-legal-preparedness-covid19>.