COVID-19: Crisis Standards of Care—Guidance for Health Care Systems and Providers

March 26, 2020
1:00 – 2:00 p.m. EST
How to Use WebEx Q & A

1. Open the Q&A panel
2. Select “All Panelists”
3. Type your question
4. Click “Send”
Moderator

Kayleen Klarich, Marketing and Membership Manager, the Network for Public Health Law – National Office

Areas of expertise:
- Development and execution of marketing strategies
- Management of organizational membership programs
Presenter

Dan Hanfling, MD, Vice President, Technical Staff, In-Q-Tel
- Co-Chair, National Academy of Medicine, Forum on Medical and Public Health Preparedness
- Clinical Professor, Department of Emergency Medicine, George Washington University
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- J.D., Northeastern University School of Law (MA)
- Research interests/areas of expertise:
  - Vaccinations
  - Genetics and privacy laws
  - Biotechnology
  - Health insurance consumer protections
  - Emergency public health response
  - Public health aspects of health care and health care cost reform
  - Medical use of marijuana
COVID-19: Crisis Standards of Care “The Duty to Plan”

Dan Hanfling, MD
National Academy of Medicine, Forum on Medical and Public Health Preparedness
March 26, 2020
Crisis Standards of Care

2009 Letter Report: Committee on Guidance for Establishing Crisis Standards of Care for use in Disaster Situations

Definition: “a substantial change in usual healthcare operations and the level of care it is possible to deliver which is made necessary by a pervasive or catastrophic disaster.”

- the level of care delivered is justified by specific circumstances [COVID-19 exponential spread in communities across the United States; declaration of a National Emergency]
- should be “formally declared by a state government” in recognition that crisis care operations “will be in place for a sustained period of time.”
- should “enable specific legal/regulatory powers and protections for healthcare providers in the necessary tasks of allocating and using scarce medical resources and implementing alternate care facilities” in the response.
Rationale:

- Demand (esp. ICU care) will rise beyond the capacity for providers and hospitals to deliver under usual conditions
- We must be prepared to provide guidance for how to make potentially difficult decisions, especially those regarding the allocations of limited resources
- This requires proactive, honest, transparent & accountable communications and messaging in order to ensure the trust of the American people, and the healthcare workforce

Key Messages:

Crisis standards of care were developed in order to help healthcare providers decide how to administer THE BEST POSSIBLE MEDICAL CARE when resources are limited.

As this pandemic moves across the country, we expect that standards of care will shift dynamically in communities, and in facilities, at different times.
Figure 1.
Catastrophic MCE: Triage and Response

Catastrophic MCE

Triage + 1st response

Prevailing circumstances

Receiving disease modifying treatment
Existing hospice and PC patients

The too well
The optimal for treatment
The too sick to survive
Surge Capacity Planning

‘Conventional’ Surge Capacity

‘Conventional’ Standard of Care

‘Contingency’ Surge Capacity

‘Contingency’ Standard of Care

‘Crisis’ Surge Capacity

‘Crisis’ Standard of Care

Hanfling D, Institute of Medicine, Altered Standards of Care, Regional presentations, Spring 2009.
Graph 2: Relationship between supply, demand and shift in standard of care in a sustained public health emergency.
Systems Framework for Catastrophic Disaster Response

IOM, 2012
Incident demand/resource imbalance
Risk of morbidity/mortality
The Hardest Questions Doctors May Face: Who Will Be Saved? Who Won’t?

As coronavirus infections explode in the U.S., hospitals are forced to make harrowing choices if pushed to the limits of their resources. This is already underway.

This is the coronavirus math that has experts so worried: Ventilators and hospital beds

The Toughest Triage — Allocating Ventilators in a Pandemic

Robert D. Truog, M.D., Christine Mitchell, R.N., and George Q. Daley, M.D., Ph.D.

The COVID-19 pandemic has led to severe shortages of many essential goods and services, from hand sanitizers and N-95 masks to ICU beds and ventilators. Although rationing is not unprecedented, never before has the American public been faced with the prospect of having to ration medical goods and services on this scale.
Ethical Issues: Prioritization of Insufficient Resources

- First come, first served vs. Lottery?
- Old vs. Young (Fair Innings) ?
- Prognosis: Those who will return to full health and most years to live (“Quality Life Years”)?
- Those needed for Care: Healthcare workers and other emergency responders?
- Those who keep society running (utility workers, transportation workers, etc.)?

PUBLIC ENGAGEMENT: Crucial for Community Understanding and Ethical Policies that Reflect the Communities Values and Priorities.
Basic Ethical Considerations

- Likelihood of survival and benefit from treatment are the primary considerations when allocating scarce resources.
- All lives are valued equally and without regard to disability, age, religion, race, ethnicity, sexual orientation, social statues or ability to pay.
- Age or disability alone should not be considered a clinical risk factor when allocating scarce resources.

Save the most lives possible by giving more care to people most likely to benefit.

- Complaint filed with Office of Civil Rights
- Focus on plan released by Washington DPH and Northwest Healthcare Regional Network
- Priority for people who are younger and healthier
- Asks that “OCR … issue guidance to health care providers about their obligations to not discriminate against people with disabilities within the context of delivering COVID-19 related care”
CSC – Legal Authority and Environment

- Authority to Allocate Personnel, Resources and Supplies
- Liability Protection
- Changes in HCW’s Scope of Practice
- Constitutional Issues – Due Process, Equal Protection
- And more…

Selected Legal Issues of Concern to Health Care Practitioners and Entities Responsible for Emergency Preparedness
Authority to Allocate Scarce Resources

Federal or State Emergency Declarations:

- Can shift the standard of care to emphasize the needs of the community, while still providing the best possible individual level of care.

- Can include explicit directives to implement Crisis Standards of Care developed by health care systems, and as adopted or otherwise recognized by the states.

- Triggers reliance on CSC developed or adopted by states that address timing and operational shifts during a crisis.
Liability: Standard of Care in a Declared Emergency

- Normally, the legal standard is what a reasonable health care practitioner would do under similar circumstances based in part on available resources.

- In an emergency situation, with shortages of supplies, staff, and space, the circumstances are greatly altered.

- A declaration that an emergency exists may serve to protect healthcare workers whose actions are not as likely to be found negligent in these circumstances absent willful, reckless, wanton misconduct.
Liability: Various Laws Provide Liability Protections during Catastrophic Events

Sources of Protection:
- Good Samaritan Laws
- Public Health Immunity Laws
- Federal Laws (e.g., Volunteer Protection Act)
- Malpractice Insurance
- State Emergency Public Health Statutes
- Crisis Standards of Care

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"In the absence of gross negligence or willful misconduct, any health care provider who responds to a disaster shall not be liable for any injury or wrongful death of any person arising from the delivery or withholding of health care when (i) a state or local emergency has been or is subsequently declared in response to such disaster, and (ii) the emergency and subsequent conditions caused a lack of resources, attributable to the disaster, rendering the health care provider unable to provide the level or manner of care that otherwise would have been required in the absence of the emergency and which resulted in the injury or wrongful death at issue. Va. Code Ann. § 8.01-225.02 (2008)
Changes in Scope of Practice

- To meet increased demand
- Temporary changes to practice requirements
- Waiver, revision of statutes, regulations and policies
- Overlap/common skill sets
- As done for H1N1 vaccine administration by Pharmacists and EMS Providers
Workers’ Right to Refuse Dangerous Work

- Where possible, you have asked the employer to eliminate the danger, and the employer failed to do so;
- You refused to work in "good faith." This means that you must genuinely believe that an imminent danger exists;
- A reasonable person would agree that there is a real danger of death or serious injury; and
- There isn't enough time, due to the urgency of the hazard, to get it corrected through regular enforcement channels, such as requesting an OSHA inspection.

Healthcare Facilities have a Duty to Plan and Prepare for Major Emergencies

- Potential loss of funding, licensure/accreditation, civil liability
- Tenet Health Systems/Memorial Medical Center - Settlement following Hurricane Katrina 2011
- Pham v. Texas Health Resources, Inc. Settlement 2016
- “Nina brings this case to hold Texas Health Resources responsible for what happened to her and to send a message to corporations like it that the safety of all patients and health care providers comes first. So when the next viral outbreak occurs—and it will occur—these hospitals will be prepared and those health care providers will be protected.”

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COVID-19: Data Sharing for Public Health Surveillance, Investigation and Intervention
1:00 – 2:00pm EST | April 2

COVID-19: Real-Time Guidance, Resources and Information
View resources & request assistance at networkforphl.org/covid19

HHS Topic Collection:
Crisis Standards of Care

2020 Public Health Law Conference
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