Emergency Preparedness: Crisis Standard of Care

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I have no relevant financial relationships with commercial interests to disclose.
Crisis Standard of Care

1. What are they?
2. When and why might we need them?
3. How are they different from normal standards of care?
4. Who has the authority/responsibility to develop them?
5. What are the ethical and legal issues?
What Are Crisis Standards of Care

A substantial change in the usual health care operations and the level of care it is possible to deliver... justified by specific circumstances and... formally declared by a state government in recognition that crisis operations will be in effect for a sustained period.

(Even the most prepared community can find itself without adequate medical resources.)
**What Are Crisis Standards of Care?**

Guidelines that the state could implement in a extreme public heath emergency...

*to help healthcare providers make decisions about the use and allocation of scarce medical resources*

*when even the best preparedness plans are not enough to meet the demand for care*
When Might We Need Crisis Standards of Care?

**Extreme Crisis**
- Hurricane, Pandemic, Earthquake, Bioterrorism

**Scarce Medical Resources**
- Blood, Ventilators, Drugs, Vaccines
How Are Crisis Standards Different?

Crisis Standards

- Goal: Save as many lives as possible/Community Focus

Normal Standards

- Goal: Maximize individual patient care/Individual Focus
Where Do Crisis Standards Fit In?
Possible Strategies to Maximize Care: Examples of CSC

**Space**
- Use non-clinical space for inpatient beds (hallways, conference rooms, tents)
- Restrict operating rooms to urgent cases

**Supplies**
- Sterilize and re-use single-use equipment/disposable equipment
- Prioritize drugs/vaccines/ventilators to patients at high risk and most likely to benefit
- Prioritize comfort care for patients who will die
Possible Strategies to Maximize Care: Examples of CSC

**Staff**
- Expanded “scopes of practice”, e.g. nurses provide care that physicians would usually provide
- Prioritize vaccines and treatment to healthcare providers to enable them to provide patient care
Basic Operational Principles of Crisis Standards of Care

*CSC guidelines will*—

- Permit flexibility for provider discretion where, in the good-faith judgment of the provider, circumstances warrant exception
- Be scalable to the changing and unpredictable needs and resource availability of disasters
- Emphasize early conservation, adaptation and substitution strategies aimed at lowering the risk of having to resort to more extreme re-allocation measures
Basic Clinical Principles of Crisis Standards of Care

- CSC guidelines should anticipate and reflect reasonable and prudent practice under the circumstances of the particular disaster.

- CSC are temporary and proportionate to the circumstances – the goal is to return to normal care as soon as possible.

- CSC guidelines should be clinically sound, based upon the best available information.
Ethical Issues: When there are insufficient resources… how should we decide who gets what?

• First come, first served?
• Lottery?
• Favor certain groups?
  • The old?
  • The young? (“Fair Innings”)
  • Those who will return to full health and most years to live? (“Quality Life Years”)
  • Healthcare workers and other emergency responders?
  • Workers who keep society running (utility workers, transportation workers, etc.)
• Save the most lives possible by giving more care to people most likely to benefit?
Basic Clinical Principles of Crisis Standards of Care

- 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
Why Do We Need Crisis Standards of Care?

1. So patients and their families know that they will receive fair access to the best possible care under the circumstances

2. So critical resources are conserved and distributed efficiently to those who need them and will benefit the most

3. To promote transparent decision-making and public trust in the fairness and equity of the system
Why Do We Need Crisis Standards of Care?

4. To protect those who might otherwise face barriers to accessing care
5. To prevent hoarding and overuse by those with more access
6. To help providers make decisions and protect them from unfair lawsuits
Authority: Federal or State?

- Federal and State Authority
  - To declare emergencies and take actions to protect public health including waiver of statutory and regulatory licensure, certification, reimbursement related requirements
  - Order adherence to CSC in public health emergencies

- National CSC?
  - Increased consistency?
  - If CSC are controversial, and need to reflect community values, is it more advisable for states to develop them?

- For CSC, so far Federal guidelines – “how to” for states “to do”
Authority: State

- Guidance – Leave it to health care practitioners and systems: No state mandate to use CSC.

- Mandate: Does state have requisite authority to mandate implementation of crisis standards?
  - Flexibility in statutory authority to impose standards during public health emergency
  - Authority to issue orders to health care providers and facilities, including imposition of uniform CSC
  - Authority to waive statutory and regulatory requirements for facilities and scope of practice for providers

- Require (through regulation, grant conditions or persuasion) appropriate infrastructure at health care facilities and systems for implementation of standards.
CSC Public Engagement: *Process and Goals*

A series of **Stakeholder** and **General Public** forums designed to:

1. Elicit community values and priorities concerning the allocation of scarce medical resources during disasters and pandemics

2. Test alignment of CSC principles and goals with these values and priorities

3. Reach out to and engage members of diverse communities—particularly those who face barriers to access—in the process

4. Inform the CSC guidelines prior to adoption
Liability: The Concern

- Civil liability – medical malpractice can be a concern for physicians in disaster situations whether they are (1) providing care in resource limited situations or (2) following CSC guidance for the ethical and efficient allocation of scarce medical resources.

- Is liability protection important for providers in disaster situations?
  - **No**: No evidence that liability protection is key to or necessary for provider response. (Rothstein, M.A. *Currents in Contemporary Ethics: Malpractice Immunity for Volunteer Physicians in Public Health Emergencies: Adding Insult to Injury*. J. Law Med. Ethics, Mar 2010; 38: 149 - 153.)

  - **Yes**: 2006 APHA survey: How important is liability protection in deciding whether to volunteer in an emergency? 69.4% essential or important; 25% somewhat important.
Liability: Perception v. Reality

- Past experience -- very few malpractice cases arising out of disaster care
- Criminal prosecutions extremely rare
- Civil and state/federal funding and certification/licensure sanctions for health care facility failure to plan
- Currently - patchwork of liability protections for health care providers depending on:
  - If compensated or not (volunteer)?
  - If compensated, who does provider work for? Federal, state, private?
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

Pham v. Texas Health Resources, Inc.  
Complaint filed March 2, 2015
“Nina brings this case to hold Texas Health Resources accountable 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.”
Liability: 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

Sources of Protection
Liability: Impact of CSC

• Issue: If providers follow CSC in a disaster situation and change the focus from individual care “to the max”, to maximization of lives saved, are providers protected from liability?

• CSC could function in the same way that accepted medical standards for the provision of care in specific specialties and procedures currently do. Standards inform malpractice decisions the way acknowledged standards for other medical care and procedures do.
Questions and Discussion

Appreciation for work on CSC and attribution for various slides/portions of slides to:

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- Priscilla Fox, JD - Massachusetts Department of Public Health
- Barbara Fain, JD, MPH - consultant to MDPH and IOM Committee