

## CRISIS STANDARDS OF CARE

### POLICY

Decision-making during extreme conditions shifts ethical standards to a utilitarian framework in which the clinical goal is the greatest good for the greatest number of individuals. As a result, optimal services that may be available at other times may not be available. It will be necessary to do what is sufficient given the specific conditions at the time. The organization of care under extreme conditions will be in the Incident Command Structure with collaboration with others whose expertise and authority may have an impact on the professional, such as legal interpretations of jurisdiction's emergency regulations.

### PURPOSE

In a large scale emergency, healthcare may be compromised, at least in the short term, to deliver services consistent with established Standards of Care. Therefore, it is necessary to identify, plan, and prepare for making necessary adjustments in current health and medical care standards to ensure that the care provided in response to a mass casualty event results in as many lives saved as possible.

### ETHICAL PRINCIPLES

When crisis standards of care prevail, as when ordinary standards are in effect, healthcare practitioners must adhere to ethical norms. Conditions of overwhelming scarcity limit autonomous choices for both patients and practitioners regarding the allocation of scarce healthcare resources, but do not permit actions that violate ethical norms. Health care professionals are always obligated to provide the best care they reasonably can under given circumstances. For purposes of developing recommendations for situations when healthcare resources are overwhelmed, the committee defines the level of health and medical care capable of being delivered during a catastrophic event as *crisis standards of care* (see definition).

Professionals may ask which choices and standards might properly shift during a disaster, and when core ethical values draw a bright line that separates behaviors that are acceptable from those that are unacceptable. The following are key elements of Crisis Standards of Care protocols and associated components.

#### Protection of the Public from Harm

A foundational principle of public health ethics is the obligation to protect the public from serious harm. This principle requires that citizens comply with imposed restrictions in order to ensure public wellbeing or safety. To protect the public from harm, hospitals may be required to restrict public access to service areas (e.g. restricted visiting hours), to limit availability of some services (e.g. elective surgeries), or to impose infectious control practices (e.g. masks or quarantine).

*When making decisions designed to protect the public from harm, decision makers should:*

- Weigh the medical and moral imperative for compliance
- Ensure stakeholders are made aware of the medical and moral reasons for public health measures
- Ensure stakeholders are aware of the benefits of compliance & the consequences of non-compliance
- Establish mechanisms to review these decisions as the public health situation changes and to address stakeholders concerns or complaints

### Stewardship

In our society, both institutions and individuals will be entrusted with governance over scarce resources, such as vaccines, antivirals, ventilators, hospital beds and even health care workers. During a pandemic influenza outbreak, difficult decisions about how to allocate material and human resources will have to be made, and there will be collateral damage as a result of these allocation decisions. Those entrusted with governance roles should be guided by the notion of stewardship. Inherent in stewardship are the notions of trust, ethical behaviour, and good decision-making.

*Decision makers have a responsibility to:*

- Avoid and/or reduce collateral damage that may result from resource allocation decisions
- Maximize benefits when allocating resources
- Protect and develop resources where possible
- Consider good outcomes (i.e. benefits to the public good) and equity (i.e., fair distribution of benefits & burdens)

### Trust

Trust is an essential component in the relationships between clinician and patient, between staff and the organization, between the public and health care providers, and between organizations within a health system. In a public health crisis, stakeholders may perceive public health measures as a betrayal of trust (e.g. when access to needed care is denied) or as abandonment at a time of greatest need. Decision-makers will be confronted with the challenge of maintaining stakeholders' trust while at the same time stemming an influenza pandemic through various control measures. It takes time to build trust.

*Decision-makers should:*

- Take steps to build trust with stakeholders before the crisis hits not while it is in full swing
- Ensure decision making processes are ethical and transparent to those affected stakeholders

### Equity

The principle of equity holds that, all things being equal, all patients have an equal claim to receive needed health care. During influenza pandemic, however, tough decisions will need to be made about which health services to maintain and which to defer because of extraordinary circumstances. Measures taken to contain the spread of a deadly disease will inevitably cause considerable collateral damage. In an influenza pandemic, this will extend beyond the cessation of elective surgeries and may limit the provision of emergent or necessary services.

*Decision-makers must strive to:*

- Preserve as much equity as possible between the interests of patients [afflicted with the influenza] and those who need urgent treatment for other diseases
- Ensure procedural fairness in decision-making

### Solidarity

SARS heightened the global awareness of the interdependence of health systems and the need for solidarity across systemic and institutional boundaries in stemming a serious contagious disease. An influenza pandemic will not only require global solidarity, it will require a vision of solidarity within and between health care institutions.

*Solidarity requires:*

- Good, open and honest communication
- Open collaboration, in a spirit of common purpose, within and between health care institutions
- Sharing public health information
- Coordinating health care delivery, transfer of patients, and deployment of human and material resources

Reciprocity

Reciprocity requires that society supports those who face a disproportionate burden in protecting the public good and takes steps to minimize their impact as far as possible. In an influenza pandemic, measures to protect the public good are likely to impose a disproportionate burden on health care workers, patients, and their families. Health care workers may face expanded duties, increased workplace risks, physical and emotional stress, isolation from peers and family, and in some cases, infection leading to hospitalization or even death. Similarly, quarantined individuals or families of ill patients may experience significant social, economic, and emotional burdens.

*Decision-makers and institutions are responsible for:*

- Easing the burdens of health care workers, patients, and patient's families in their hospitals and in coordination with other health care organizations
- Ensuring the safety of their workers, especially when redeploying staff in areas beyond the usual scope of practice

Proportionality

Proportionality requires that restrictions to individual liberty and measures taken to protect the public from harm should not exceed what is necessary to address the actual level of risk to, or critical need of, the community.

*Decision makers should:*

- Use least restrictive or coercive measures in limiting or restricting liberties or entitlements
- Use more coercive measures only in circumstances where less restrictive measures have failed to achieve appropriate public health ends.

Duty to Provide Care

The duty to provide care and to respond to suffering is inherent to all health care professionals' codes of ethics. In an influenza pandemic, demands on health care providers and the institutions in which they work will overwhelm resources. Health care providers will have to weigh demands from their professional role with other competing obligations to their own health, to family and friends. Health care workers will face significant challenges related to resource allocation, scope of practice, professional liability, and workplace conditions.

*Decision makers should:*

- Work collaboratively with stakeholders and professional colleges in advance of a mass casualty incident to establish practice guidelines
- Work collaboratively to develop fair and accountable processes to resolve disputes
- Provide supports to ease this moral burden of those with the duty to care

- Inform essential staff that employees may perform duties outside their routine responsibilities or scopes of practice
- Develop means through which institutions will handle appeals or complaints, especially with regards to work exemptions, or the vaccination/prophylaxis of staff

### Individual Liberty

Individual liberty is a value enshrined in health care practice under the principle of respect for autonomy. Under usual circumstances, health care providers balance respect for individual autonomy with a duty to protect individual patients from harm. In a public health crisis, however, restrictions to individual liberty may be necessary to protect the public from serious harm. Patients, staff, and members of the public may all be affected by such restrictions.

*Restrictions to individual liberty should:*

- Be proportional to the risk of public harm
- Be necessary and relevant to protecting the public good
- Employ the least restrictive means necessary to achieve public health goals
- Be applied without discrimination

### Privacy

Individuals have a right to privacy in health care. In a public health crisis, it may be necessary to override this right to protect the public from serious harm. A proportionate response to the need for private information requires that it be released only if there are no less intrusive means to protect public health.

*Decision makers should:*

- Disclose only private information that is relevant to achieve legitimate and necessary public health goals
- Release private information only if there are no less intrusive means to protect public health
- Determine whether the good that is intended is significant enough to justify the potential harm that can come from suspending privacy rights, (e.g. the harm from stigmatization of individuals or particular communities)
- Provide public education to correct misconceptions about disease transmission and to offset misattribution of blame to particular communities

### **DEFINITIONS:**

**Crisis standards of care** is a substantial change in usual healthcare operations and in the level of care it is possible to deliver, which is made necessary by a pervasive (e.g., pandemic influenza) or catastrophic (e.g., earthquake, hurricane) disaster. This change in the level of care delivered is justified by specific circumstances and can be formally declared by a health care facility based on the current situation and available data, in recognition that crisis operations will be in effect for a sustained period. The health care facility should use its surge capacity, increase staffing, obtain additional resources, implement MOU's with other entities, and contact Public Health for assistance. A formal declared state of emergency from the Governor that crisis standards of care are in operation will 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 facility operations.

**Legal standards of care** may be defined as the care and skill that a healthcare practitioner must exercise in particular circumstances based on what a reasonable and prudent practitioner would do in similar circumstances. During declared states of emergency, however, the legal environment changes. Emergency declarations trigger an array of non-traditional powers that are designed to facilitate response efforts through public and private sectors. Emergency laws may (1) provide government with sufficient flexibility to respond; (2) mobilize central commands and infrastructures; (3) encourage response efforts by limiting liability; (4) authorize interstate recognition of healthcare licenses and certifications; (5) allocate healthcare personnel and resources; and (6) help to change medical standards of care and scope of practice. The extent of legal powers during emergencies, however, depends on the type of emergency declared. The federal government, every state, many territories, and some local governments may declare either general states of “emergency” or “disaster” in response to crises that affect the public’s health. Such declarations largely authorize emergency management agencies and others to use general legal powers to coordinate emergency responses. An array of state and federal liability protections exist for providers—particularly volunteers and government entities and officials acting in their official duties—who act in good faith and without willful misconduct, gross negligence, or recklessness

**Medical standards of care** describe the type and level of medical care required by professional norms, professional requirements, and institutional objectives. Medical standards of care vary (1) among types of medical facilities such as hospitals, clinics, and alternate care facilities, and (2) based on prevailing circumstances, including during emergencies.

**Memorandum of Understanding (MOU)** is a formalized relationship with mutual recognition of services available for collaboration in the event of a disaster.

**Scope of practice** refers to the extent of a licensed or certified professional’s ability to provide health services pursuant to their competence and license, certification, privileges, or other lawful authority to practice.

## **PROCEDURES:**

### **Section 1 - Patient Management**

1. Needs of current patients and the resources they require will be a part of the overall resource allocation.
2. Usual scope of practice standards may not apply.
3. Equipment and supplies will be rationed and used in ways consistent with achieving the ultimate goal of saving the most lives.
4. Current documentation standards may be impossible to maintain.
5. Providers may need to make treatment decisions based solely on clinical judgment.
6. Determine minimal level of care required.
7. Elective procedures that may result in the use of a ventilator should be postponed.
8. Increase space capacity.
  - a. Rapid discharge of ED and other patients who can continue their care at home safely.
  - b. Cancellation of elective surgeries and procedures with reassignment of surgical staff members and space.
  - c. Identify a “Bed Czar” to monitor the bed and resource statuses.

- d. Expansion of critical care capacity by placing select ventilated patients on monitored beds in non-critical care areas.
  - e. Conversion of single rooms to double rooms or double rooms to triple rooms if possible.
  - f. Use of beds and cots in non-patient care areas for non-critical patient care.
9. All available means of “surge capacity” must be created.
- a. Plan for staff shortages.
    - Implement call system for additional staff members.
    - Provide day care or pet care services as possible.
    - Changes in staff scheduling as necessary (e.g., duration of shifts, staffing ratios, changes in staff assignments).
    - Reassignment of qualified administrative nursing staff members to clinical roles.
    - Use non-hospital staff members such as family members for basic patient care.
  - b. Stockpile and conserve personal protective equipment.

## **Section 2 - Emergency Department**

1. Triage efforts will focus on maximizing the number of lives saved.
2. Triage decisions will consider the allocation of all available resources across the spectrum of care.
3. Utilize alternative triage sites for minor symptoms or potentially infectious patients.

## **Section 3 –Ventilator Use**

1. A triage review team, consisting of clinical and non-clinical personnel (e.g., pastoral care, ethics, risk management, legal, patient relations, etc.), will make appropriate triage decisions for ventilator use.
2. The SOFA (Sequential Organ Failure Assessment) score for adults or PRISM (Pediatric Risk of Mortality) score will be used to categorize patients requiring ventilators.
3. Patients currently on ventilators when the Crisis Standards are implemented will be assessed to determine if they meet the criteria for continued use.
4. Candidates for extubation will include patients with the greatest probability of mortality.
5. Exclusion criteria will focus on current organ function, rather than on specific disease entities. If one of the exclusion criteria is present, the patient will be referred for supportive and/or palliative care and will not be considered a candidate for ventilator support.
  - a. Exclusion Criteria for Ventilator Access
    - Cardiac arrest: unwitnessed arrest, recurrent arrest, arrest unresponsive to standard measures, trauma-related arrest
    - Incurable malignancy with poor prognosis
    - Severe burns: body surface area >40%, severe inhalation injury
    - End-stage organ failure:
      1. Cardiac: Heart Associated III or IV
      2. Pulmonary: severe chronic lung disease with Forced Expiratory Volume <25%
      3. Hepatic: Model of End-stage Liver Disease score >20
      4. Neurologic: severe, irreversible neurologic event or condition with high expected mortality
    - Patient or patients designee declines ventilator
6. Implementing SOFA or PRISM scores for critical care triage:
  - a. A SOFA or PRISM score should be calculated each day for all patients requiring access to

critical care resources with each patient classified into red (highest priority), yellow (intermediate priority), and blue or green (low priority).

- b. If a patient's status is green, the patient should be transferred out of critical care.
- c. If a patient's status is blue based on the presence of exclusion criteria at any time during the hospital stay, the patient should be transferred out of the critical care area. A "Do Not Resuscitate" order (DNR) should be documented, and appropriate palliative and supportive care should be provided.
- d. In the absence of "exclusion criteria", decisions to institute or continue invasive or non-invasive ventilator support should be made at initial triage, then at appropriate intervals as determined by the triage review team (e.g., at 12 hours, 48 hours, 120 hours, and daily thereafter). This assessment process will determine the likelihood of survivability with ventilatory support.
- e. If decisions must be made to remove patients from a ventilator to provide resources for other patients, the following guidelines are recommended:
  - A new patient classified as yellow (intermediate priority) who meets critical care admission criteria should not have priority over a current critical care patient classified as yellow or red (high priority).
  - A new patient classified as red who meets critical care admission criteria should not have priority over a current critical care patient classified as red.
  - A new patient classified as red who meets critical care admission criteria should not have priority over a current critical care patient classified as yellow during the first 5 days (120 hours) of critical care hospitalization.
  - A patient classified as red who meets critical care admission criteria may have priority over a current critical care patient classified as yellow after 5 days (120 hours) of critical care hospitalization.

#### **Section 4 –Palliative Care**

1. The goals of palliative care are relief from suffering, treatment from pain, psychological and spiritual care, and a support system to help the patient, the family, and caregivers.
2. Clinicians should provide documentation of the rationale and decision process.

#### **Section 5 – Supplies and Equipment**

1. Supplies must be rationed in the way consistent of achieving the ultimate goal of saving the highest number of patients.
2. Disposable supplies may need to be re-used during severe shortages.
3. If laboratory and radiology resources are exhausted, treatment decisions may need to be made based solely on physical exam, history, and clinical judgment
4. MOU's with governmental and private entities should be implemented to maintain resources.

#### **Section 6 - Clear communication with the public is essential before, during, and after the event.**

1. Spokespersons at all levels—local, state, regional, and federal—should coordinate their messages.
2. Patients and families should be informed of the crisis standards of care process

#### **Section 7—Enable Hospital Decompression**

1. Establish alternative care sites in conjunction with other healthcare entities and the Division of Public Health.

2. Request resources from private transport companies, Emergency Medical Services, and Public Health to decompress the hospital as needed
3. Transfer patients to and from facilities as needed based on hospital resources.

### **Section 8 - Appendices**

1. Delaware Public Health and Medical Advisory Group Prioritization of Ethical Values
2. Critical Care Triage Guidelines
3. Ventilator Allocation Flowchart
3. SOFA Score
4. PRISM Score

### **REFERENCES**