

## ETHICS GUIDELINES FOR CRISIS STANDARDS OF CARE IN PUBLIC HEALTH EMERGENCIES

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### 1. Preamble

Public health emergencies can pose extraordinary if not unprecedeted challenges for health care systems, institutions and practitioners. Many of these challenges are shaped by shortages of people, equipment, medication and/or appropriate treatment venues. When systems, institutions or clinicians lack adequate resources, it is both unrealistic and inappropriate to expect or require them to conduct operations or practice their professions according to non-emergency standards. For this reason, many states have adopted “crisis standards of care” policies, guidelines or laws to govern such altered standards.

This document incorporates or is shaped by; and is prepared in awareness of

- Evolving national crisis care standards
- Guidance by the U.S. Food and Drug Administration and Centers for Disease Control and Prevention
- Communication with critical care physicians and ethics experts from around the country

### 2. History

The State of Florida has some experience in crisis standards of care. In response to the 2009 H1N1 influenza emergency,<sup>1</sup> the Florida Department of Health in 2010 established a Pandemic Influenza Technical Advisory Committee and commissioned “Pandemic Influenza: Triage and Scarce Resource Allocation Guidelines,” which was completed in 2011.<sup>2</sup> The Committee’s draft was not formally approved or adopted. Its “Introduction” reads, in part,

In the event of a pandemic influenza or other public health emergency, the demand for healthcare resources and services will dramatically increase. Out of

<sup>1</sup> [http://www.floridahealth.gov/diseases-and-conditions/disease-reporting-and-management/disease-reporting-and-surveillance/data-and-publications/\\_documents/2009-section5.pdf](http://www.floridahealth.gov/diseases-and-conditions/disease-reporting-and-management/disease-reporting-and-surveillance/data-and-publications/_documents/2009-section5.pdf)

<sup>2</sup> [http://www.floridahealth.gov/programs-and-services/emergency-preparedness-and-response/healthcare-system-preparedness/\\_documents/acs-guide.pdf](http://www.floridahealth.gov/programs-and-services/emergency-preparedness-and-response/healthcare-system-preparedness/_documents/acs-guide.pdf)

necessity, scarce resources and patient care will have to be allocated so as to generally “do the greatest good for the greatest number”. Towards this end, the Florida Department of Health has prepared this guidance document to assist public and private medical and healthcare entities statewide in dealing with such events.\* The Department’s responsibilities in such events include: 1) development and coordination of a State Pandemic Influenza Response Plan and other health/medical emergency response annexes included in the State Comprehensive Emergency Management plan, 2) epidemiology surveillance/situational awareness, and investigation, 3) implementation of Governor and Surgeon General directives, including, but not limited to, executive order(s), emergency declaration, or a declaration of public health emergency, 4) coordination of resource requests through Emergency Support Function (ESF) 8 at the State Emergency Operations Center (SEOC), 5) provision of guidance for healthcare facilities in a pandemic, and 6) issuance of patient triage and care recommendations.

Moreover, under “Basic Premises,” it notes,

Ethical goals informing the department’s recommendation to allocate resources include: reducing harms and promoting benefits; respecting equal liberty and human rights; ensuring that the burdens imposed by allocation are shared fairly and do not fall disproportionately on some of Florida’s residents. Public officials and healthcare workers should be professional and accountable, and their decision-making process should be open and transparent, culturally sensitive, and sustain public trust. The department recommends focusing on the treatment that would most likely be lifesaving and on those whose functional outcome would most likely improve with treatment. The ethical rationale for this recommendation is that it most likely secures the goals of public health emergency preparedness, including allocating resources, and minimizes the burdens that might result if decisions were made unfairly... In scarcity, efforts should focus on treatments most likely to be lifesaving and on patients most likely to improve with treatment. Decisions should minimize the burdens on others.

The Advisory Committee did not encounter any public opposition to its Guidelines. Then as now, there was broad state and national consensus on

- The need for such guidelines
- The medical science justifying altered care standards
- The ethical foundations of such standards

The 2011 Guidelines for altered care standards included extensive empirical evidence and featured uncontroversial statements of core public health values. Then as now,

Florida's academic, medical and nursing communities enjoy significant expertise and experience on ethical and other issues arising in public health emergencies.<sup>3</sup>

### **3. Scope and Adoption/Activation**

These guidelines apply to adult and pediatric patients, including those diagnosed with or strongly suspected of having contagious and life-threatening maladies. In the current context this means COVID-19. The document's principles, values and guidance can be applied to other, similar public health emergencies. These Guidelines are activated by order by [the Governor or Surgeon General / county health department director / institutional leadership] which order will also specify their duration. After such a declaration, the institution may accelerate or delay implementation of various provisions, as circumstances warrant.

### **4. Principles and Values**

The following are uncontroversial and widely accepted principles and values to guide medical and institutional decisions during a public health emergency.

1. Clinicians have fundamental, uncontroversial and overarching duties to treat patients, including those with contagious maladies. This is known as the “duty to treat.” Such a duty both assumes and implies that clinicians have the resources necessary to provide the intended treatment, and that treatment is expected to be effective. That is, one cannot be said to have a duty if one is unable to carry out the duty.
2. It follows that physicians, nurses and other health professionals have no duty to offer or provide treatments which they have determined, based on the best available evidence and within a reasonable degree of medical probability, will not benefit patients, are not effective or are contrary to standard clinical judgment.
3. In normal circumstances, it is reasonable to evaluate, treat and admit patients, and provide them with equipment and other resources on a “first-come, first-served” basis. In a public health emergency, however, that approach risks wasting resources, using resources ineffectively or depriving patients who might benefit from appropriate attention and resources.
4. All patients deserve the highest-quality care possible in the circumstances. However, offering or delivering interventions believed to be ineffective does not contribute to high-quality care.
5. As with all clinical judgments, the judgment that an intervention is non-beneficial or futile need not be infallible. These decisions are always left to appropriately trained clinicians – as they must also be under these guidelines. The standard for

<sup>3</sup> The Florida Bioethics Network (FBN, <https://fbn.miami.edu>), for instance, is a 30-year-old professional organization, the leaders and members of which have expertise in ethical issues related to public health, clinical practice and biomedical research. FBN institutional members (including state and private academic medical centers, hospitals, nursing homes and hospices) have long collaborated with the Departments of Health, Children and Families and Elder Affairs; and the U.S. Centers for Disease Control and Prevention. One Florida institution, the University of Miami, is home to a World Health Organization Collaborating Center in Ethics and Global Health Policy, the only such in the United States.

decision making given in Florida Statutes is “a reasonable degree of medical probability.”<sup>4</sup>

6. Palliative care is always appropriate, and should be made available as available and as widely as possible, especially for patients for whom crisis standards of care are adopted.

#### 4.1 Institute of Medicine (IOM) and Centers for Disease Control (CDC)

##### 4.1.1 IOM

The IOM in 2009 defined “crisis standards of care” as

A substantial change in usual healthcare operations and 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 is formally declared by a state government, in recognition that crisis operations will be in effect for a sustained period. The formal declaration that crisis standards of care are in operation enables 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.<sup>5</sup>

Moreover, the IOM emphasized “the need for states to develop and implement consistent crisis standards of care protocols both within the state and through work with neighboring states, in collaboration with their partners in the public and private sectors.”<sup>6</sup> Such standards should be driven by ethical norms and process elements.<sup>7</sup> Norms or values include the following:

- **Fairness.** This requires that all patients be treated equally based on their diagnosis and prognosis and not their social standing, socioeconomic class, ability to pay, etc. People with mental or physical disabilities, non-citizens, prisoners or religious minorities, for instance, may not be discriminated against.
- **Professional duty to care:** As above, this is the duty one acquires by virtue of having specialized knowledge or skills.

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<sup>4</sup> FS 765.101(4) ([http://www.leg.state.fl.us/Statutes/index.cfm?App\\_mode=Display\\_Statute&URL=0700-0799/0765/0765.html](http://www.leg.state.fl.us/Statutes/index.cfm?App_mode=Display_Statute&URL=0700-0799/0765/0765.html)) uses this standard to identify (in)effectiveness of a treatment, i.e., “end-stage condition” is defined as “an irreversible condition that is caused by injury, disease, or illness which has resulted in progressively severe and permanent deterioration, and which, to a reasonable degree of medical probability, treatment of the condition would be ineffective.” That probability concept is sometimes known as the “standard of medical reasonableness.”

<sup>5</sup> IOM (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, p. 18.

<sup>6</sup> Ibid., p. 4.

<sup>7</sup> Ibid., pp. 18ff. Similar norms are identified by the Society of Critical Care Medicine (“Critical Care Resource Allocation Recommendations,” draft, forthcoming).

- **Professional duty to steward resources:** Professionals enjoy great power and standing, and with this comes the responsibility to ensure that resources are used wisely and not squandered.

Ethical process elements are needed to foster and sustain clinician confidence and public trust, and include these:

- **Transparency:** Civil society requires that public health and resource-allocation decisions, as well as policies governing the behavior of professionals, be subject to public scrutiny. Community engagement is a component of transparency.
- **Consistency:** To promote fairness, similarly situated individuals and groups must be treated similarly. Consistency helps prevent discrimination against vulnerable groups.
- **Proportionality:** Measures adopted to manage emergencies should not be more restrictive or onerous than necessary. Any rationing plan, for instance, should not be more severe than needed. To be sure, there can be uncertainty about what will be needed in the near- and long-term future.
- **Accountability:** This means that individuals must be able to explain to and educate colleagues and communities about the reasons for policy and other decisions. There is an important role for state and institutional leadership in this regard. Accountability “puts a face” on institutional responsibility, and builds public and trust.

These norms and values themselves are not rules; some of them might in certain circumstances conflict with others. What is required throughout emergency planning and operations is ongoing self-scrutiny to ensure that values are honored to the extent possible, and that review of the decisions and processes is ongoing and competently conducted. A review mechanism is described below.

#### 4.1.2 CDC

The Centers for Disease Control and Prevention’s Ethics Subcommittee of the Advisory Committee to the Director saw the need, also in 2011, to identify “ethical standards and principles relevant to allocation of ventilators during a severe pandemic or other public health emergency ...”<sup>8</sup> The group made clear that

A public health emergency creates a need to transition from individual patient-focused clinical care to a population-oriented public health approach intended to provide the best possible outcomes for a large cohort of critical care patients. The trigger for the transition from usual critical care procedures to emergency mass critical care should occur when there is a substantial extreme mismatch between

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<sup>8</sup> <https://www.cdc.gov/os/integrity/phethics/ESdocuments.htm>. A Florida university was represented on this committee.

patient need and available resources, that is, when the numbers of critically ill patients surpass the capability of traditional critical care capacity.<sup>9</sup>

In such a case, there is a need to make difficult decisions related to resource allocation: “In order to use scarce resources most efficiently, in some clinical situations where there is a severe shortage of life-saving medical resources, priority is given to those who are *most likely to recover* after receiving them.”<sup>10</sup> Moreover,

To achieve the public health goal of minimizing the number of preventable deaths during a severe pandemic emergency, states and hospitals need to address the issue of removing from ventilators patients with respiratory failure whose prognosis has significantly worsened in order to provide access to patients with a better prognosis. During a declared public health emergency, decisions about allocation of scarce resources must be made in accordance with transparent, accountable, and fair public health directives. Policies for withdrawal of patients from ventilators need to be the least restrictive possible – i.e., withdrawing of ventilation without requiring assent of patient or surrogate continues only as long as the shortage of ICU resources continues.<sup>11</sup>

## 5. Implementation

The following stances are uncontroversial and widely accepted. To articulate them is to signal the importance of shared goals and to make clear to institutions and clinicians that they enjoy and should count on the support of the people in their communities.

1. The duty to treat neither entails that all possible treatments are appropriate nor requires that they be attempted. Certain interventions – mechanical ventilation, extracorporeal membrane oxygenation (ECMO) and cardiopulmonary resuscitation (CPR) being key examples – might be non-beneficial or futile and therefore ethically may be withheld or withdrawn.
2. The overarching goal of these guidelines is to ensure institutional readiness to deliver the best care possible in the context of a public health emergency. There might arise circumstances in which it is medically contraindicated, physically impossible, or not beneficial to a patient to provide certain kinds of diagnostic or therapeutic interventions. These guidelines apply to circumstances in which such impediments require flexibility and clinical judgment in determining the appropriate level of patient care.
3. That a clinician might be at risk of infection is in itself not an over-riding consideration. However, if a clinician contracts a serious malady in the course of providing futile care and is therefore quarantined or sickened (and hence unable to treat other patients), such nonbeneficial intervention undermines the

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<sup>9</sup> Ibid., p. 7.

<sup>10</sup> Ibid., p. 9; original emphasis.

<sup>11</sup> Ibid., p. 21.

institutional mission and deprives other patients of treatment – *without any counterbalancing benefit to the initial patient.*

4. These guidelines are intended in part to support attending physicians, front-line nurses and other healthcare providers during a public health emergency. They do not require or forbid any specific intervention. They do require a decision based on clinical judgment, the best-available evidence and accessible resources in individual cases. This parallels non-emergency triage standards, such as organ transplantation in which a patient may receive an organ (i) if the patient is a candidate, i.e., it is believed the new organ will work; (ii) an appropriate organ is available to transplant. It would be irresponsible to transplant an organ with a low probability of a successful outcome.
5. Although informed and autonomous *refusals* of treatment by patients or legally authorized representatives should be honored, their *requests* do not enjoy the same status. That is, some patients and family members make requests that are inappropriate, are contrary to sound medical judgment, violate medical standards, are dangerous or increase risk. Whether any request should be honored must be assessed or filtered by standard medical judgment. The making of a request does not in itself impose a duty on a clinician.<sup>12</sup>
6. An alteration in standards of care must be carefully reviewed. **Table 1** gives some examples of care standards which might be temporarily altered depending on the severity of the malady and on the magnitude or scope of the emergency it has produced. A review process is recommended below.

<b>Medical or Hospital Standard</b>	<b>Alternative</b>
Direct or face-to-face clinician-patient interaction	Telehealth interaction
Mechanical ventilation with a particular device	Ventilation with another kind of device, e.g., use of a transport ventilator when the standard is an intensive-care ventilator. In cases of device shortages, triage might be necessary to allocate available tools.
One ventilator for each patient	Use of ventilator to support more than one patient
Each patient in a bed in a standard hospital room	Patients in beds placed in other venues
Critically ill patients in critical care units	Critical care patients in other units refitted to extent possible
Cardio-pulmonary resuscitation	No CPR
Extracorporeal membrane oxygenation	No ECMO

<sup>12</sup> Compare in this regard requests for (i) antibiotics for viral infections, (ii) narcotics with no correspondingly appropriate pain symptoms or (iii) treatments, interventions or surgeries for which there is inadequate evidentiary support. Authorities and experts agree it is inappropriate to comply with such illicit requests.

First-come, first-served access to treatment and resources	Triage standard of saving as many lives as possible
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**TABLE 1: Standards and Alternatives**

It is important to note that some standards have become such not based on evidence but on other considerations. This is especially the case with CPR, which is often attempted with the knowledge that it will not benefit the patient. In an emergency, at the least, clinicians must be able to forgo non-beneficial interventions. There is no ethical or legal basis<sup>13</sup> for requiring licensed clinicians to undertake procedures they believe will not work.

## 6. Triage, Rationing and Crisis Standards of Care

The first breathing machines were negative-pressure respirators invented in the 19<sup>th</sup> Century. They found widest use in the first half of the 20<sup>th</sup> Century as “iron lungs” for polio patients. The first positive-pressure ventilators evolved from the 1950s and shaped modern critical care medicine and hospitals’ special critical- or intensive-care units. These machines push air into lungs for patients who cannot breathe, or breathe enough. Intended as “bridge” treatments to sustain life until underlying maladies are cured or mitigated, the goal is eventually to wean patients from the machines. Some patients cannot be weaned. Some patients develop ventilator-acquired pneumonia and other complications.

Patients with respiratory disorders often require ventilator support. Reputable assessments and calculations project that there will not be enough ventilators to meet patient needs in the current Coronavirus pandemic. Therefore, not every patient who needs a ventilator will get a ventilator. Failure to plan for this at the institutional and governmental levels invites disorder, permits arbitrariness, risks bias and increases the likelihood that patients who would have survived with ventilator support will die because patients likely to die were using the machines.

With a rationing plan to address this, preventable deaths will be reduced; without such a plan, preventable deaths will occur anyway, along with those that were not preventable. Put differently, institutions need to guide their clinicians’ decisions about which patients

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<sup>13</sup> FS 765, which addresses advance directives, includes the following: “765.205 Responsibility of the surrogate... [Surrogates must] “provide written consent using an appropriate form whenever consent is required, including a physician’s order not to resuscitate.” This is interpreted by some as requiring surrogate concurrence with the withholding of CPR and perhaps other interventions in a public health emergency. Legislative intent under 765, about advance directives, was not and, indeed, could not possibly have been to require ineffective treatments during mass-casualty events or to forbid triage decisions that are based on a “reasonable degree of medical probability.” Indeed, 765.202 seems to contradict 765.101(4) and undermines that standard.

should receive ventilator support to reduce the number of deaths that would otherwise result. This is a form of triage: save those who can be saved; efforts to save those who cannot be saved are futile.

Triage entails difficult decisions. Clinicians are not used to it; they are accustomed to trying to save many patients with poor prognoses; and few if any have training in triage principles. They face great moral distress. They should be supported in fostering and acting with moral courage. To decrease clinicians' moral distress, institutions should adopt protocols with thoughtful and uncontroversial ethical foundations. This can help ensure that difficult decisions are as consistent as possible across providers.

Evidence-based plans driven by widely accepted ethical principles constitute the best if not the only way to save as many patients as possible and support those making the difficult decisions needed to accomplish this.

## **6.1 Guidelines for Institutional Processes**

Institutions should institute triage protocols. These protocols should incorporate the following elements.

### **6.1.1 Triage Evidence Support Teams**

Healthcare institutions should establish teams to meet regularly in person and/or electronically and as needed to evaluate the latest crisis information and to direct responses to that information. There is no standard composition of such teams, but there is an evolving consensus that institutions should consider the following members:

- Chief medical officer or designee
- Chief nursing officer or designee
- A critical care expert
- An ethics expert
- A member of the clergy

Institutions with pediatric practices should ensure pediatricians are included.

These teams must be able to act quickly, as emergency situations can evolve quickly. Teams should be on call 24/7, and should establish on-call rotations. A chair may be designated.

The teams will direct decision making regarding the various and challenging criteria to be used for resource allocation and reallocation. They should have access to such expertise as the institution or its neighbors can provide. Decisions are likely to address criteria for identifying or defining "key personnel," "elective procedure," "acceptable risk" and so on. This is will be a fluid process, as the concepts "key," "elective" and "acceptable" might evolve as the situation changes.

Triage teams will

- Shape and direct development of crisis standards policies or guidelines, and their activation and use
- Create and use a list or spreadsheet with salient patient information and ventilator status; the list will be maintained by critical-care unit physicians and nurses
- Try to ensure appropriate principles, values and norms are incorporated in those documents and in their application
- Oversee the review process described below
- Direct public engagement and communication
- Constitute and signal institute accountability for crisis care management

### **6.1.2 Review Process**

Triage, rationing and emergency resource allocation decisions should be fair, unbiased, proportional and as effective as possible. One way to accomplish this is with an ongoing review process. Triage Evidence Support Teams have two primary review functions, although more can be identified as needed.

The first is to support clinicians in decisions related to resuscitation, ventilator allocation and blood, dialysis and medication use. Time permitting, i.e., not in an unexpected emergency, physicians, nurses and others should try to seek advice and second opinions when applying an alternate care standard. Such support is generally not required. It is recommended if a clinician wants guidance.

The second is to develop and provide an ongoing review mechanism to track institutional decision making, ensure an evidence-based and ethically optimized application of crisis standard guidelines and revise those guidelines – including this one – as needed. The Triage Evidence Support Team will review both the cases submitted for bedside or on-the-spot review, as just above; and review all cases after triage decisions are made (whether reviewed at the time or not). This process should be ongoing and iterative, that is, should include regular reviews of triage decisions to inform any needed revision to guidelines and future bedside case reviews.

Results of these overviews should be communicated to critical-care team members and others, as appropriate; and team members should be encouraged to comment on the reviews. This sliding-scale process ensures an ongoing cycle to solicit, receive and act on information as situations evolve. It is a day-to-day process, and should help institutions both make of-the-moment decisions and, as importantly, anticipate future challenges.

### 6.1.3 Role of Institutional Ethics Committees

The Joint Commission, the American Society for Bioethics and the Humanities and the Florida Bioethics Network all call for, at the very least, an ethics process to guide and advise clinicians, patients and families, administrators and others when they face a decision shaped by ethical issues, tensions or conflicts. Ethics committees are widely agreed to have three functions: education, case consultations and policy creation and review. All three functions will be needed in a public health emergency or mass casualty event.

Most generally, ethics committees should

- Help prepare and review crisis standards of care policies, guidelines and procedures
- Be available for case consultations that arise in the application of such guidance documents
- Inform leadership about ethical issues arising in all other matters arising during an emergency

The Florida Bioethics Network has published *Guidelines for Ethics Committees*, which provide comprehensive advice about their composition, structure, functions and operations.

## 7. Ventilator Allocation and Re-allocation Guidelines

This section provides a Resource Triage Protocol. It calls for decisions to be based on the best available evidence regarding patients' conditions and prognoses, available resources and anticipated resource needs and ethical values (as given above). This evidence and these values entail that:

- Triage decisions should be determined by expected incremental increase in short-term and long-term survival. Patients most likely to survive to discharge and to live longest in the community after discharge are given priority.
- Triage decisions may take into account patients' anticipated quality of life and the resources required to achieve incremental survival. Patients who are expected to survive with minimal quality of life or who will require a disproportionate amount of resources to survive are given lower priority.
- If patients have similar expected incremental increases in survival, priority should be given to the younger patients based on the principle that people should have the opportunity to live as much of the normal human life cycle as possible.<sup>14</sup>

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<sup>14</sup> These three statements, not in any particular order, are elaborated below. They are adapted from a policy developed by the Center for Medical Ethics & Health Policy at Baylor College of Medicine.

Even as different institutions might adopt somewhat different technical criteria for crisis management, it is essential that all institutions adopt a crisis protocol of some kind.

## 7.1 Resource Triage Protocol

1. Triggers for ventilator triage
  - a. Fewer than 20 ventilators on stand-by, or
  - b. Predicted time to reach capacity <72 hours
2. Activation of Ventilator triage
  - a. On call Triage Evidence Support Team is notified by critical care leadership.
  - b. MD designated by the Chief Medical Officer is assigned the ventilator triage pager. Clinician must be free from clinical duties during period of triage service.
  - c. The availability of a ventilator (due to death or terminal extubation of a ventilated patient) is communicated immediately (at any hour) to the team chair. The chair then contacts other team members. The next eligible patient is selected according to process outlined below.
3. Mortality risk assessment and triage
  - a. Principles
    - i. Allocation is independent of reason for mechanical ventilation (influenza vs. COVID vs. CHF exacerbation vs intra-abdominal sepsis are all weighted equally)
    - ii. No priority for social status, demographic characteristics or “value to society”<sup>15</sup>
    - iii. Priority is maximizing survival to hospital discharge
    - iv. Defined triage system balances saving the most lives and the most life-years
  - b. A triage system will be implemented to stratify patients for resource utilization
    - i. Short term prognosis will be scored by SOFA scores or, for pediatric patients, modified SOFA scores, PELOD-2 criteria<sup>16</sup> or other appropriate indexes.

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<sup>15</sup> Some have proposed that healthcare workers be given priority. Justifications for this approach include “payback” for placing themselves at risk and avoiding healthcare worker elopement during the crisis. Arguments against healthcare worker priority include loss of public trust in such a system and the fact that ventilator priority does not enable healthcare workers to return to work soon enough to help in the crisis (this differs from justification for vaccine priority). Finally, it is very difficult to define “healthcare worker.” Does it include all MDs and RNs, or only those on front lines of pandemic response? Which other professionals should benefit?

<sup>16</sup> Leteurtre S, Duhamel A, Salleron J, Grandbastien B, Lacroix J, Leclerc F, Groupe Francophone de Réanimation et d’Urgences Pédiatriques (GFRUP). PELOD-2: an update of the PEdiatric logistic organ dysfunction score. *Critical Care Medicine* 2013;41(7),1761-1773.

- ii. Long term prognosis will be scored by comorbidities and, if necessary, age<sup>17</sup>
- iii. Scores for both short- and long-term prognosis will be added to obtain a final score
- iv. Ties are adjudicated using age
- c. Scoring via Sequential Organ Failure Assessment (SOFA) scores.<sup>18</sup>
  - 1. 1 point: SOFA <6
  - 2. 2 points: SOFA 6 - 8
  - 3. 3 points: SOFA 9 - 11
  - 4. 4 points: SOFA ≥12
- d. Scoring via comorbidities
  - i. Comorbidities (e.g., CVD, DM, chronic respiratory disease, HTN, cancer) have been found to influence COVID-19 survival rates.
  - ii. Patients will be scored based on comorbidities
  - iii. 1 point added for “mild” disease found to affect COVID-19 survival, for instance
    - 1. Diabetes
    - 2. Coronary artery disease
    - 3. Hypertension
  - iv. 2 points added for major comorbidities, for instance
    - 1. Moderate Alzheimer’s disease or dementia
    - 2. Malignancy <10 year survival
    - 3. NY Heart Association class III
    - 4. Moderate lung disease (COPD/ILD)
    - 5. End-stage renal disease
    - 6. Severe (inoperable) CAD
  - v. 4 points added for severe, life-limiting comorbidities
    - 1. Severe Alzheimers’ disease or dementia
    - 2. Metastatic/stage IV cancer
    - 3. NY Heart Association stage IV
    - 4. Severe chronic lung disease (FEV1 < 25%, TLC < 60%, room air PaO<sub>2</sub> <55mmHg)

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<sup>17</sup> Other possible variables for secondary triage include first-come, first-served, and a lottery. Both of these present significant ethical challenges. The former might disproportionately disfavor lower socio-economic status and those who have difficulty accessing medical care. A lottery system will be difficult to put in effect (place all patient names in a hat every time a vent becomes available?). Moreover, both options undermine the goal of triage by allowing the allocation of a scarce resource to someone who will not benefit at the expense of another who would. However, if all other criteria outlined here are the same – that is, for instance, if two clinically indistinguishable patients need a ventilator – then a lottery might be permissible.

<sup>18</sup> Raith EP et al. JAMA 2017;317:290-300. Other guidelines utilize only Red, Yellow, Blue and Green, with the cutoff for Blue as >11. Due to the severe nature of this illness and the anecdotal reports of improvement after prolonged and severe illness, this proposal creates an additional triage category and elevates the score for the exclusionary Blue category.

5. Cirrhosis with MELD > 20
  6. Traumatic brain injury with GCS best motor response = 1
  7. Severe burns where predicted survival <10%
  8. Cardiac arrest categories:
    - a. Unwitnessed arrest
    - b. Recurrent arrest
    - c. Trauma-related arrest
  9. Severe immunocompromised states, e.g., AIDS, refractory neutropenia due to chemotherapy or hematologic malignancy
  10. Any other conditions resulting in immediate or near-immediate mortality even with aggressive therapy
  - vi. Scores then dictate priority of ventilator usage by Priority Categories
    1. Priority Group 1: Scores 1 – 3
    2. Priority Group 2: Scores 4 – 5
    3. Priority Group 3: Scores 6 – 8
    4. Priority Group NA: no significant organ failure or no requirement for critical care resources
  - vii. Within priority groups, patients are further stratified based on age; in this and only this unlikely case, lower age is prioritized
4. SOFA score assignments and periodic reassessments
    - a. On admission and daily, all patients are assigned a SOFA score by a designated member of the treatment team.
    - b. The tracking spreadsheet is updated daily by 8 a.m. and posted.
    - c. When more than one patient requires a single, available ventilator, the triage team chair assigns the ventilator to the patient requiring intubation based on ranking within priority scores.
    - d. Teams are expected to update SOFA scores and need for ventilation by 8 a.m. daily. At that time, the Triage Evidence Review Team will review all scores to determine if any intubated patients have achieved scores  $\geq 12$ .
  5. If the SOFA score equals or exceeds 12 at any point during the course of a patient's treatment with mechanical ventilation, the triage team shall make an assessment, including any likelihood of recuperation/recovery and, if appropriate, instruct the treatment team to consult palliative care and withdraw mechanical ventilation within 8 hours.<sup>19</sup>

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<sup>19</sup> Limiting extubation to patients with such a poor prognosis departs from recommendations of other protocols that suggest extubating patients with mortality predictions of 50%. In this protocol, limiting extubation to mortality scores  $>80\%$  strikes a balance between continuing to care for sick, intubated patients while recognizing that there are others with a better chance of survival. This threshold can be revised as conditions change and warrant.

6. In a crisis situation, a decision to withdraw support might need to be based on a SOFA score lower than 12.
7. Reevaluation of clinical status of all intubated patients if ventilator triage is required
  - a. Ventilators currently in use on patients with high mortality are better used in times of crisis on patients with a higher likelihood of surviving.
  - b. All currently ventilated patients in Priority Group 3 will be evaluated for extubation with Triage Evidence Support Team.
8. Ongoing clinical evaluation of ventilated patients for prognosis
  - a. A lengthy intubation both monopolizes a ventilator and portends a worse outcome. Analysis of a patient's medical course at intervals of 48 and 120 hours after intubation will provide prognostic information to guide ventilator usage.
  - b. Ventilated patients at 48 and 120 hours after intubation will be evaluated for prognosis, and a decision on continuing mechanical ventilation will be made by the Triage Evidence Support Team.
  - c. For all ventilated patients
    - i. Parameters at 48 hours will serve as the baseline for clinical evaluation.
    - ii. Comparison of same parameters at 120 hours will determine if clinical progress has been achieved, stagnated or deteriorated.
    - iii. Patients with clear clinical deterioration based on comparison of 48- and 120-hour parameters will be removed from the ventilator if the Triage Evidence Support Team agrees. Removal may come earlier than 120 hours if clinical status is worsening; this decision will require the attending ICU physician to make a judgment based on clinical trajectory.
    - iv. Patients with stagnant or improved clinical progress will be re-evaluated daily using same criteria to determine clinical course.
    - v. Parameters for evaluation:
      1. All patients with ARDS (Berlin criteria) regardless of COVID-19 status
        - a. P/F ratio using same FiO<sub>2</sub>, PEEP and positioning (prone/supine) at 48 and 120 hours (necessitates coordination of arterial blood gas analysis)
        - b. SOFA scores will be used as secondary analysis to further stratify prognosis in patients experiencing additional complications, such as shock.
      2. All patients without ARDS (Berlin Criteria)
        - a. SOFA scores at 48 hours will be compared to scores at 120 hours.

3. The clinical judgement of the attending ICU physician must also be considered in weighing decisions on terminal extubation.
9. Provision of ECMO
  - a. ECMO is a highly resource-intensive intervention.
  - b. There is a limited number of ECMO perfusion specialists; one is always required at the bedside of each patient, i.e., 24 hours a day.
  - c. Given severe limitations in resources (hardware, expendables, staffing and additional critical care resources associated with ECMO use), ECMO should be used sparingly or not at all during periods of “ventilator triage” activation.
  - d. ECMO will not be offered during the stipulated crisis period addressed by these guidelines. Appeals may be considered by the institution’s Triage Evidence Support Teams and will be decided based on outcome probability (e.g. SOFA or, in pediatrics, PELOD-2 etc.; data available from the Extracorporeal Life Support Organization registry).
10. Communication and consultation
  - a. When the ventilator triage protocol is activated, all patients on mechanical ventilation and their families, as well as all subsequently admitted patients, will be informed about the triage protocol and will be provided a copy of these guidelines.
  - b. All patients admitted during periods of triage activation, or their legally authorized representative, if available, should be informed that changes in clinical status might entail withdrawal of mechanical ventilation.
  - c. Any withdrawal from mechanical ventilation should be accompanied by a palliative care consultation.
11. Appeal process: A patient or family may appeal the decision to withdraw a patient from a ventilator. Such an appeal should be communicated to the Triage Evidence Review Team; the unit’s ethicist will respond as soon as possible, review the decision and confer with other team members. The full team will then render a decision. This review is to be limited to ensuring the protocol was properly administered, i.e., in the decision to extubate; and determine there was no discernable deviation from the ethical principles, norms and processes identified above.
12. Other interventions, including but not limited to endotracheal intubation, hemodialysis, radiologic imaging and surgery, should be assessed and decided by similar criteria. These criteria may be modified as necessary and appropriate.
13. This crisis protocol promotes the needs of the community over the preferences of individuals. This will cause moral distress in those clinicians who, despite agreeing with this stance during a public health emergency, are still aware of the effect it will have on individual patients’ lives. Doing the right thing for public health can pose difficult challenges for the traditional clinician-patient relationship. The purpose of this document is to maximize efficient use of a

limited resource and to provide treating clinicians with a moral justification for life-saving actions in extraordinary circumstances. After the crisis, all institutions should evaluate their use of these guidelines to learn and adopt principles to improve future crisis preparedness and response.

## **8. Cardiopulmonary Resuscitation**

The determination whether to attempt to resuscitate a patient whose heart has stopped or malfunctioned is guided by similar values and norms. In this case, however, the step-wise detail required for ventilator allocation is not required.

1. Patients will receive such evaluation, medication and support as determined necessary for their treatment.
2. When possible and time permitting – that is, not in an emergency – any adoption of an altered standard of care may be reviewed in advance by the Triage Evidence Support Team. Advance or pre-emptory review is permissible. All decisions to limit an intervention will be reviewed after the case by the institution's Triage Evidence Support Team.
3. In cases in which the attending or other responsible physician makes the clinical judgment that CPR would be ineffective, clinicians need not commence CPR. A do-not-resuscitate order (DNR) may then be entered in the patient's medical record. Such a decision should be based on the likelihood of CPR's failure and/or increased harm to the patient. In case the intervention increases risk of death or disease to caregivers, this may be taken into account only in addition to the treatment's futility and insofar as it will have a detrimental effect on the institution's ability to continue care for that patient or for other patients.
4. In the event that the institution has implemented its Resource Triage Protocol, it may also be appropriate not to offer CPR for certain patients with or without COVID-19, on the grounds that if the patient had a cardiac arrest and return of spontaneous circulation were achieved, the patient would not receive a high enough priority for subsequent critical care. These patients would likely fall into the category of "severe life-limiting comorbidity," as above.
5. In public health emergencies declared by appropriate authorities, as above, such a medical determination does not require the concurrence of the patient or surrogates. Communication with the patient or surrogates is always appropriate, if possible, and reasons for forgoing any treatment should be explained. If there is not time to do this before a treatment is not provided, such an explanation should be attempted afterward.
6. Other interventions, including but not limited to endotracheal intubation, hemodialysis, radiologic imaging and surgery should be assessed and decided by similar criteria, including the availability of necessary equipment.
7. In case of disagreement (between or among team members; team and family; family members) about a clinical judgment, second opinions are strongly encouraged. The institution's Ethics Committee will often be able to provide insight on ethical issues and offer mediation or other support.

## **9. Blood, Dialysis, Drugs**

As a general consideration, decisions regarding use and allocation of other scarce resources may be managed similarly, that is, in accord with the principles and standards articulated so far. These include but are not limited to

- Blood and blood products
- Hemodialysis
- Medications, e.g., antibiotics, vasopressors/inotropes, etc.

In case of questions related to allocation of such things, questions should be put to the Triage Evidence Support Team, which will provide guidance and, as needed, detailed instructions.

## **10. Other considerations**

- A decision to forgo any treatment shall be documented in the patient's medical record.
- Appropriate pain management shall be provided in all cases.
- Care teams must support to the extent possible approved research during emergencies.
- The institution's Ethics Committee(s) shall be available at all times for consultations. It is understood that, as per professional standards, ethics committees do not dictate or direct patient care. All patient care decisions rest on the authority of the attending or other physicians, as available and appropriate.