ETHICS GUIDANCE IN CRITICAL CARE OF PATIENTS DURING THE COVID-19 PUBLIC HEALTH EMERGENCY

Section 1 – Ethical Framework[1]

7/13/2020 (Version 1.1)

I. INTRODUCTION

Some predictions of the impact of COVID-19 estimate an impending increase in cases of respiratory failure of such magnitude so as to cause a significant shortage of healthcare resources, particularly "critical care resources," defined in this context to include, but are not limited to, healthcare providers, medical devices, medications, blood, dialysis, and available hospital bed space. The working group intends to succinctly present fundamental bioethical principles (respect for persons, beneficence/non-maleficence & justice) that should be taken into account in the management and allocation of healthcare resources both for COVID-19 patients as well as other patients during this state of public health emergency.[2] For purposes of this guidance, "resource allocation" means decisions to provide or not to provide a critical care resource (e.g., a hospital bed, ventilator, medication) to a patient when resources are scarce, meaning that the volume of patients in need of the resource is far greater than the amount of resource available.

II. RELEVANT ETHICAL PRINCIPLES[3]

A. Respect for Persons

Respect for persons **entails respecting the dignity of all persons and their autonomous, informed decision making**. Ordinarily in healthcare, respect for persons leads clinicians to prioritize a patient's preferences where possible. In a public health emergency, however, standard or critical care treatments may be scarce and honoring the treatment preference of every patient may not be possible. Furthermore, public health mandates may necessitate limiting patient autonomy (e.g. quarantine & isolation).

[1] This Guidance is intended solely for internal use by Emory Healthcare, Inc. during the context of the Public Health Emergency related to the coronavirus (COVID-19) and has not been subject to the review that typically would occur in a non-emergent situation. **This Guidance does not constitute the provision of medical, legal or other professional advice.** Copyright 2020, Emory University and Emory Healthcare.

[2] It is the assessment of Emory Healthcare, Inc. that the institutional response to the COVID-19 Public Health Emergency may, in the event of a surge and severe shortage of resources, reasonably interfere with the arranging for or providing of health care services or medical care to our patients.

[3] Based on the Ethical Guidelines in Pandemic Influenza & Ethical Considerations for Decision Making Regarding Allocation of Mechanical Ventilators during a Severe Influenza Pandemic or Other Public Health Emergency, Centers for Disease Control and Prevention.

These limitations should be:

1. **necessary and proportional** to the public health goal (i.e. failure to implement the limitation will lead to significant harm to the public health);
2. **the least restrictive practice** that will accomplish the public health goal; and,
3. **followed by supportive and/or compensatory measures** to those who are affected by the limitations whenever possible.

Respect for persons further entails:

- being transparent in both policy making and the implementation of those policies
- accessibly educating the public about the nature of the public health emergency and the response
- gaining informed consent for treatment
- maintaining privacy (e.g. regarding test results) unless there is a legal reason patient privacy may not be maintained
- determining patients' decision-making capacity and pursuing interventions that will restore a patient's decision-making capacity

Public health mandates do not justify treating patients without dignity or compassion.

B. Beneficence/Non-Maleficence

During this public health emergency this principle **supports acting to maximize the benefits and minimize the harms to public health** in general rather than maximizing benefits and minimizing harms to the individual patient. Doing so includes:

- increasing capacity and reducing future scarcity (e.g. by postponing elective interventions, repurposing resources and providers)
- in order to maximize benefit to the public, allocation of critical resources will be guided by two main considerations: survival to discharge and life years saved after recovery from the acute illness. These and other considerations are described further in Section 2 of this document.

C. Justice

Justice supports **the fair stewarding of resources during scarcity**. Doing so includes:

- ensuring that stewardship results in an equitable distribution of benefits and burdens
- consistency in allocation across people (treating like cases alike)
- not exacerbating existing disparities in health outcomes (e.g. decisions are not based on socio-economic, disability status, race, etc.)
- the absence of unjustified favoritism and discrimination.

D. Special Considerations for COVID-19

- Public health beneficence and non-maleficence justify prioritizing the use of Personal Protective Equipment (PPE), diagnostic testing, and vaccines when available, for exposed healthcare providers over others.
- Triage decisions should be made following a fair process. Section II of this document contains recommendations for this process.
- Since the situation is evolving, implementation of these guidelines should be based on best available scientific evidence at the time.

E. Principles That Are Not Relevant in COVID-19 Decisions

The following criteria are **not** ethical to use in the management of scarce resources during a public health emergency:

- To each according to purchasing power
- To each according to social worth
- First come, first served or considering that existing patients always take priority over new patients (Although relationally difficult, the prioritization principles may dictate that a new patient has a higher priority than an existing patient)
- Age, race, ethnicity, color, creed, national origin (including limited English proficiency), religious belief or exercise of conscience, gender, sexual orientation, gender identity or expression, disability, or socioeconomic status, when used to make discriminations that are only invidious and unrelated to factors relevant for public health or clinical decisions

III. CRITICAL CARE RESOURCES UTILIZATION AND TRIAGE, INCLUDING VENTILATOR USE

A. Critical Care Utilization/Triage in the Hospital Setting

Critical care utilization is not just an allocation/triage decision. All recommendations are premised on commitments to:

- Prevention/Preparedness
  - Increasing hospital stock of ventilators and other critical care supplies
  - Collaboration with partner institutions
  - Adaptation, threshold conservation, re-use, cross-training
  - Diversion, delay of elective utilization, and implementation of other strategies to increase supply and reduce demand for critical care resources.
- Addressing healthcare provider “duty to provide care” and other concerns

    - Engaging the community in feasible ways to share information and learn from others
    - Transparency in communication
- Decisions should be well-founded on the best available scientific evidence.
- A commitment to distributive justice and stewardship of resources is key.
- Support should be provided to healthcare providers throughout the allocation/triage process, recognizing the moral distress and emotional toll of working under conditions of scarcity in the face of catastrophic illness.
- It must be recognized that all involved in this process are working with imperfect tools for prediction and evolving clinical knowledge about a novel health threat.
- Compassionate palliative care and emotional support should be available to all critically ill patients.

B. Ethical Decision Making regarding Critical Care Resource Allocation in Conventional/Routine Usage

Routine resource allocation is characterized by:

- Minimization of adverse outcomes, including severe morbidity and death.
- Commitment to avoidance of inappropriate/unnecessary resource use.
- "First come, first served" is generally utilized to distribute ICU beds, primarily because alternative strategies generally exist for supporting patients until a bed is available.
- General practice is to continue providing treatment to patients on mechanical ventilation and other forms of support rather than reserving critical care treatment for future patients.
- Patient or surrogate consent is generally required to forego life-sustaining treatment.
    - Any decision to forego treatment considered "medically ineffective" or "medically inappropriate" would not be based strictly on limited resources.

C. Ethical Decision Making regarding Critical Care Resource Allocation in Public Health Emergency Environment

1. In General

- Scarcity is unavoidable
- Prior to allocation, preventive action – such as adaptation, threshold conservation, re-use, cross-training (as above), to increase supply and reduce demand has been exhausted.
    - It is unavoidable that not all who desire access to critical care resources will receive them. Continued recognition of the ways in which we can respect each person in our care is crucial, even when we are not able to provide a preferred treatment.

- Guidance must not be overly rigid. There must be support for clinical judgment, recognition of the challenges intrinsic to working in a rapidly evolving environment, and an attempt to avoid making marginal differences ethically determinative (e.g. treating a 49-year-old patient differently from a 50-year -old patient based purely on age).
- Resource allocation raises different ethical challenges based on alternatives that are available. The focus of much of this guidance is on allocation of critical care resources for which no or limited alternative treatment exists.

2. Proposed Ethical Framework

- Proposed ethical framework to guide identification of those most likely to benefit is based on these criteria:
    - In general, critical care resources should be allocated to those most likely to benefit. The following considerations are ethically relevant for these decisions:
    - Likelihood of recovery/survival
        - The primary consideration in most cases will be likelihood of survival to discharge. Where available, clear clinical criteria (ideally pre-determined) should be used to inform clinical assessments
            - E.g. SOFA (Sequential Organ Failure Assessment) scores and other more disease-specific prediction tools.
        - Expected years of life saved would provide a 2nd tier of guidance when needed beyond likelihood of survival to discharge
        - Other ethically relevant considerations may include:
            - Tie-breakers between patients who are of the same allocation score
                - Initially, allocation to identifiable clinical and non-clinical healthcare personnel who work in patient care areas that involve increased risk of exposure
                - Next, allocation for those that - with treatment - can be reasonably expected to live through more of the various phases of life (youth, young adult, mature adult, elder)
                - Then, as a last resort, a fairly-conducted random allocation of the resource (a lottery)
            - Differences in expected duration of critical care resource use. This may be relevant where it is likely to result in more lives saved.
    - Attention to justice/fairness throughout
        - Equity and consistency in implementation are key; patients who are similarly situated should be treated similarly. Standards will be applied equitably across populations in compliance with state and federal anti-discrimination statutes and regulations which prohibit discrimination in regard to patient age, race, ethnicity, color, creed, national origin

(including limited English proficiency), religious belief or exercise of conscience, gender, sexual orientation, gender identity or expression, disability, and socioeconomic status.
        - Processes should be rigorous and transparent.
    - Different strategies may exist for different types of resources. Some allocation strategies involve accepting gradations of suboptimal care; others involve binary decisions about critical therapies
    - Proportionality of burdens and benefits; balancing individual interests with community interests.
    - Considerations regarding allocation that are not relevant:
        - First come-first served is not a sufficient allocation framework for critical care resources in settings of severe scarcity. In addition to ignoring multiple morally relevant considerations, it puts certain groups – such as those who are less likely to be informed or those who have inadequate transportation - at a disadvantage.
        - Social value or status is not an appropriate basis for allocation of scarce resources.

- A fair and transparent process is essential and should include the following elements:
    - Establishing a triage committee:
        - This multi-disciplinary committee will provide oversight and guidance for the allocation of resources during a public health emergency. Some triage team members may be chosen from the triage committee.
        - The triage committee should incorporate, where possible, or at least have established access to, community representatives to facilitate external input on the process.
    - Establishing triage teams:
        - Allows treating physicians to serve as patient advocates.
        - The triage team should include at least three experts from multiple professional perspectives:
            - E.g. for ventilators: physician, respiratory care, critical care nurse.
                - Ethics as a member of a triage team or as a resource
            - A model for this may be multi-disciplinary “shock teams” that have been instituted to facilitate rapid decisions about treatment of cardiogenic shock.
            - Recognition that some decisions may need to be made too rapidly for a triage team to be involved.
    - Membership on the triage committee and triage teams:
        - To identify qualifications for triage experts, recommendations from the CDC Ventilator Document Workgroup include:
            - “exceptional clinical expertise, outstanding leadership ability, and effective communication skills”

        - "senior-level provider within the institution with the experience, respect, and authority to carry out the function"1
        - Record of "trustworthiness, integrity, compassion, competency in making consistent and difficult choices, and competency in clinical skills"
    - Appropriate training should be conducted where possible.
        - The Wisconsin ventilator guidance recommends "a multi-disciplinary committee to review admissions, procedures and allocation of resources so that the Committee can learn how to make such decisions without the stress and urgency that will occur in a disaster."
    - Establishment of a support mechanism for triage team members is essential for reducing moral and emotional distress.
    - Mechanism for tracking/evaluating how decisions are made.
        - A process for the daily and/or periodic review of triage decisions to ensure that 1) decision are following criteria and 2) evolving clinical evidence is assessed to determine the need for changing triage (and treatment) protocols (recommendation from the Wisconsin triage guidelines)
- Availability of compassionate palliative care is essential.

D. Availability of Compassionate Palliative Care

Patients with respiratory failure who do not receive mechanical ventilation should receive respectful and compassionate palliative care to relieve the symptoms of respiratory failure.[4] Doses of sedatives and analgesics that will cause unconsciousness are appropriate if lower doses fail to relieve symptoms.[5]

Patients or surrogates should be informed about the decision-making process due to scarcity of resources. From the CDC ventilator guidance document (2011):

- "Patients who are removed from mechanical ventilation and their families or surrogates, like patients with respiratory failure who are not placed on mechanical ventilation, should be notified this will occur, given a chance to say good-byes and complete religious rituals, and provided compassionate palliative care."
- "Withdrawing of ventilation without requiring assent of patient or surrogate continues only as long as the shortage of ICU resources continues."

[4] Rubenfeld GD (Ed). Managing Death in the ICU: The Transition from Cure to Comfort. New York: Oxford University Press; 2000.

[5] Lo B, Rubenfeld G. Palliative sedation in dying patients: "We turn to it when everything else hasn't worked." JAMA 2005; 294:1810-1816.

E. Discontinuation of Use of Critical Care Resources during a Public Health Emergency

1. Background

The discontinuation of critical care resources for patients with a poor and deteriorating clinical course is an important consideration within the triage process. It is clinically significant for the individual patient, and it affects resource availability for other patients within the hospital or health system. Deciding when and how to discontinue certain clinical interventions is a common aspect of patient care, especially in an intensive care unit. However, in a setting where critical care resource demand exceeds available supply, discontinuing resources for one patient results in that resource being available to another patient who is in need of it. In fact, this may be the primary reason to consider discontinuation in the context of a public health emergency. During ordinary care, concerns about distributive justice and resource availability are not major considerations in these decisions or in conversations with patients or their surrogates.

2. Discontinuing Critical Care Resources during a Public Health Emergency

- General considerations not specific to a public health emergency:
    - A patient's personal values and goals should be elicited as early as possible and throughout the care of a patient as the situation evolves. This can be done through conversation with the patient and may also require input from a surrogate decision maker or other sources of information such as an advance directive, past medical records, and advice from other caregivers.
    - A patient, or surrogate decision maker when the patient does not have decision making capacity, may decide that certain clinical interventions would cause disproportionate burden in light of lesser benefits. It is generally appropriate in such situations to withhold or withdraw the clinical intervention.
    - There are circumstances in which clinical interventions are medically contraindicated due to, for example, being outside established standards of care, carrying excessive clinical risk with limited expected benefit, or proving physiologically ineffective after an appropriate trial period. As noted in the AMA Code of Ethics, "Physicians are not required to offer or to provide interventions that, in their best medical judgment, cannot reasonably be expected to yield the intended clinical benefit or achieve agreed-on goals for care. Respecting patient autonomy does not mean that patients should receive specific interventions simply because they (or their surrogates) request them."[6]
    - Patients who are experiencing serious illness and especially those who are nearing the end of life should be offered Palliative Care support.

- Special considerations during a public health emergency:
    - In the context of scarcity when resources are exhausted, use of a resource by one patient results in another patient being unable to receive that resource or

[6] AMA Code of Medical Ethics Opinion 5.5 https://www.ama-assn.org/delivering-care/ethics/medically-ineffective-interventions

treatment. As described above, critical care resources must be allocated based on sound and transparent ethical criteria. The triage team will communicate with the treating physician regarding critical care resource availability in the context of the patient's allocation score. Thereafter, the triage team and/or treating physician will discuss with the patient or surrogate the option of withdrawing critical care resources from a patient with a deteriorating and poor clinical course and reallocating those resources to others with more favorable allocation scores.

- The individual assessments and allocation scoring should continue to be done for all patients after the initial allocation decision. This assessment and score can provide helpful information about the appropriateness and efficacy of a given intervention for a patient and can help the triage team and triage committee gauge how a particular patient compares to others.
- In situations of resource scarcity, these limitations should be communicated to patients and surrogate decision makers, as some patients may choose to forego or discontinue critical care resources in situations where their prognosis is poor and their use of those resources would compromise outcomes for other patients. Discussions about plans of care with a patient or their surrogate should thus include asking how preferences may or may not change during a time of scarce resources. These discussions are highly sensitive, may take various forms, and may have an important impact on patients' and surrogates' trust in clinicians. Ideally, preferences and values would be elicited prior to the initiation of any scarce critical care resources, and well in advance of any need to consider any reallocation or withdrawal decision. In eliciting patients' preferences regarding these issues, it is important to avoid undue pressure or coercion.

3. Limitations on Withdrawal of Critical Care Resources

Under ordinary circumstances, critical care resources are only withdrawn in situations in which a patient/surrogate agrees or consents to discontinuation or resources become medically contraindicated. In extraordinary circumstances in which critical care resources are exhausted, it may be **ethically** justifiable to withdraw critical care resources from patients whose condition continues to worsen in order to reallocate that resource to a patient who has a more favorable allocation score. These ethical considerations are distinct from the potential legal implications. Thus**,** in the absence of more specific state-authorized crisis standards of care or immunity protections, Emory Healthcare will continue to obtain patient/surrogate agreement or consent prior to the withdrawal of critical care resources, just as it would in routine/ordinary care circumstances. It is important to acknowledge that over the course of a patient's treatment it may be determined that a clinical intervention is medically contraindicated and therefore that the intervention should be discontinued. The treating physician is encouraged to discuss potential limits regarding the effectiveness of current interventions with the patient/surrogate and should inform the patient/surrogate why the resource has become medically contraindicated when that determination is made.