Ethics Guidance in Critical Care of Patients during the COVID-19 Public Health Emergency
Section 1 – Ethical Framework[1]
DRAFT 4/3/2020

I. Relevant Ethical Principles

**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

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. 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.

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] The materials are intended solely for general educational and information purposes, are made available in the context of the public health emergency related to the coronavirus (COVID-19) and have not been subject to review that typically would occur in a non-emergent situation. The materials do not constitute the provision of medical, legal or other professional advice. EMORY UNIVERSITY AND EMORY HEALTHCARE MAKE NO WARRANTIES, EXPRESS OR IMPLIED AS TO THE MATERIALS, INCLUDING, WITHOUT LIMITATION, COMPLIANCE WITH QUALITY, REGULATORY, ACCREDITATION OR STANDARDS OF CARE. EMORY EXPRESSLY DISCLAIMS ANY WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

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 significant overriding reason to disclose
- 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.

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 prioritize two main considerations: survival to discharge and life years saved. These and other considerations are described further in section II of this document

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.

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.

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)
- Race, ethnicity, religious belief, gender, sexual orientation, or IQ, when used to make discriminations that are only invidious and unrelated to factors relevant for public health or clinical decisions

II. Critical Care Resources Utilization and Triage, Including Ventilator Use

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.

Ethical decision making re ICU care/ventilator allocation in <u>Conventional/Routine Usage</u>

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.

Ethical decision making re ICU care/ventilator allocation in <u>Public Health Emergency Environment</u>

- 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 ventilation will receive it. 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).
- Allocation raises different ethical challenges based on alternatives that are available. The focus of much of this guidance is on allocation of mechanical ventilation or other fixed resources for which no alternative treatment exists.
- <u>Proposed ethical framework to guide prioritization</u> to 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 priority level
                - Priority to clinical and non-clinical healthcare personnel who work in patient care areas that involve increased risk of exposure
                - Priority 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)
        - As a last resort, a fairly-conducted random allocation of the resource (a lottery)
    - Differences in expected duration of ventilation/ICU 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.
    - 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 crisis care triage team:
        - Allows treating physicians to serve as patient advocates.
        - 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"

        - The triage team should include at least 3 experts from multiple professional perspectives:
            - E.g. for ventilators: physician, respiratory care, critical care nurse.
                - Ethics as a member of triage team or 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.
        - Appropriate training should be conducted where possible.
            - The Wisconsin ventilator guidance recommends "a multidisciplinary 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)
        - Recognition that some decisions may need to be made too rapidly for a triage team to be involved.
        - Triage committee should incorporate where possible, or at least have established access to, community representatives to facilitate external input on the process.
    - Availability of compassionate palliative care is essential.

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.[i] Doses of sedatives and analgesics that will cause unconsciousness are appropriate if lower doses fail to relieve symptoms.[ii] Although such palliative sedation has strong ethical and legal justification, health-care workers are often confused about the distinction between palliative sedation, which is intended to relieve suffering, and active euthanasia, which is intended to kill the

patient. During a public health emergency, such misunderstandings may be particularly prominent."[iii]

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."

III. Discontinuation of Critical Care Interventions in order to Reallocate Resources during a Public Health Emergency

Issue: When, if ever, is it ethically permissible to discontinue critical care interventions from a patient in order to reallocate the resource to another patient?

Background: Ordinarily the decision to forgo or withdraw clinically indicated interventions requires the explicit consent of a patient (or their surrogate/advance directive). During extraordinary times, however, where demand for healthcare resources is greater than the supply, difficult allocation decisions must be made. It is worth emphasizing that these situations offer no choice to opt-out; taking no action, for example, would essentially mean allowing the priority of first-come-first-serve to function as the distribution scheme (which is considered by many to be ethically problematic[iv]). Every allocation process has positive and negative attributes. The goal is to establish and consistently apply an allocation plan that is as good as possible in light of the particular circumstances, aligned with the mission and values of the healthcare organization, and in consideration of the community's expectations.

Key Considerations:

- **What is the clinical inclusion criteria for critical care interventions in light of the public health emergency and need to ration resources?**
    - Clinical experts, with multidisciplinary collaboration, need to decide which medical criteria are most relevant to the decision about resource allocation and set clear thresholds by which to assess individual patient cases.
- **To whom does the inclusion criteria apply?**
    - After the clinical inclusion criteria are set, the next step is to determine which patients will be evaluated for potential allocation/reallocation (e.g. only newly presenting patients or all admitted patients; or else all patients within just one hospital or within a whole system?)
    - Many resource allocation protocols agree that rationing should not be focused on a particular patient group (e.g. COVID-19 positive patients), but rather on the specific resource that is scarce (e.g. all those needing or using mechanical ventilators).
    - Ultimately, each patient who is in need of the scarce resource, or who is already receiving it, is assessed according to the new clinical inclusion criteria and either allocated the resource if indicated or else will have resources reallocated if the criteria is not met.
- **Under what circumstances could critical care interventions be discontinued for the purpose of reallocating the intervention to other patients?**
    - The decision to withhold or reallocate medical interventions from a patient is only appropriate after it is absolutely clear that there is no other way to resolve the resource scarcity, that rationing for the sake of public health is necessary, and triage protocols have been activated.
    - In order for rationing allocation to be as just as possible, all patients should be evaluated as objectively as possible according to the established clinical inclusion criteria. Those who do not meet the criteria would presumptively have it discontinued if (1) there is another patient who does meet the clinical inclusion criteria and (2) there is no other way to appropriately provide treatment for that other patient apart from reallocating the intervention.[v] [vi]
    - Continuing to provide a scarce resource to a patient who does *not* meet clinical inclusion criteria while that same intervention is withheld from other patients who *do* meet the criteria is ethically inappropriate. Acting in this way would undermine the carefully developed allocation

processes that aim to do the most good for the most people and instead sets first come, first serve as the guiding rule even when that first person does not meet clinical inclusion criteria.

- **Who decides when to discontinue critical care interventions from patients who do not meet clinical inclusion criteria?**
    - An independent review team consisting of key representatives who are not part of the patient's treating team make the decision. This team consists of allocation specialists and clinical experts just like the team who decides whether to initiate treatment.
    - Establishing an independent team apart from the bedside caregivers is done to minimize conflict of interest and maintain trust in the patient-physician relationship. This is also important to ensure that decisions are consistent over time regardless of the treating team or clinical unit.
- **How should the conversation regarding discontinuation of critical care interventions occur among providers, patients, and families?**
    - The decision to discontinue critical care treatment is difficult enough in ordinary circumstances, but the extraordinary circumstances of discontinuing it from one patient in order to reallocate it to another patient is gut-wrenching for many people. Intellectually it can be understood that someone who does not meet clinical inclusion criteria for an intervention should not receive it at the expense of other patients who do meet the criteria, but emotionally it can feel more difficult to withdraw and intervention than to withhold one. It is anticipated that these actions will cause significant moral distress among care providers, patients, and their families.
    - Ideally, patients will be made aware of the clinical inclusion criteria early upon admission; it may also be appropriate to inform them that if their condition worsens such that they no longer meet the criteria it may need to be stopped.
    - It is important to include professionals from such specialties as Palliative Care, Spiritual Health, Social Services, and Patient Advocacy in designing and supporting communication efforts.

- **Does a patient or their surrogate decision maker have recourse to appeal the decision to discontinue critical care interventions?**
    - Yes, a mechanism for additional review of the process in the event of a dispute is necessary.[vii]
    - The appeal is limited in scope to strictly evaluate whether the established process was followed appropriately. Due to the public health emergency and urgent nature of treatment decisions, the appeal process cannot evaluate disagreement with the process at large, reconsider the accuracy of clinical assessments, or provide any sort of "deeper look" into the particulars of the patient's condition. Not only would such reviews necessitate time that is unavailable, but they would also introduce a source of potential injustice in that some patients would receive more thorough consideration than others.
    - Individual appeals should then be aggregated and periodically reviewed for quality assurance and improvement.
    - It is anticipated that the appellate review team will need to be consist of members of the hospital staff due, mainly due to the urgency in which these interventions are typically needed of decision making and due to the compliance and risk hurdles that would be involved with bringing in people from outside the organization. If, however, there is a way to overcome these concerns and include community members on this team it could be a powerful way to mitigate conflict of interest and increase transparency and trust in the process.[viii]
- **Who should be made aware of these clinical inclusion criteria and the underlying rationale?**
    - Reallocation decisions are incredibly difficult, emotional, and often contentious. There may be some hesitancy to discuss these issues publicly due to fear of controversy. If reallocation becomes necessary, however, the hospital processes will quickly become public knowledge and there is a higher risk of misinformation and misunderstanding if explanations are given reactively rather than proactively.
    - The vast majority of official allocation and triage protocols throughout the United States emphasize the ethical value of transparency. The goal is for the community to be aware of the decisions that may need to be made and the underlying rationale behind them prior to them their implementation. This transparency can increase trust among the community, it ensures all parties are informed prior to the need for a decision, it helps reduce the chance of unjust discrimination by holding all parties accountable for the agreed-upon process, and it allows

provides the opportunity for public review and comment which may highlight opportunities for improvement.[ix]

Ethics Guidance Drafting Work Group members:

Kathy Kinlaw, MDiv, HEC-C; Neal Dickert, MD, PhD; Rebecca Pentz, PhD; Gerard Vong, PhD; Kevin Wack, JD, MA, MTS, HEC-C

[i] Rubenfeld GD (Ed). Managing Death in the ICU: The Transition from Cure to Comfort. New York: Oxford University Press; 2000.
[ii] Lo B, Rubenfeld G. Palliative sedation in dying patients: "We turn to it when everything else hasn't worked." JAMA 2005;294:1810-1816.
[iii] Ethical Considerations for Decision Making Regarding Allocation of Mechanical Ventilators during a Severe Influenza Pandemic of Other Public Health Emergency. Ventilator Document Workgroup, Ethics Subcommittee of the Advisory Committee to the Director, Centers for Disease Control and Prevention. 2011.
[iv] Ethical guidelines in Pandemic Influenza – Recommendations of the Ethics Subcommittee of the Advisory Committee to the Director, Centers for Disease Control and Prevention, 2007.
Excerpt, Page 7: "Some theoretical distribution criteria that would generally not be ethically supported in pandemic influenza planning include. ..first come, first served. (Superficially, this may appear to be fair but, de facto, this puts certain groups – such as those who are less likely to be informed or those who have inadequate transportation - at a disadvantage.)"
[v] NY Ventilator Allocation Guidelines: "Patients who have a medical condition on the exclusion criteria list or who no longer meet the clinical criteria for continued ventilator use receive alternative forms of medical intervention and/or palliative care. The same applies to patients who are eligible for ventilator therapy but for whom no ventilators are currently available. Alternative forms of medical intervention, such as other methods of oxygen delivery and pharmacological antivirals, should be provided to those who are not eligible or waiting for a ventilator. In addition, actively providing palliative care, especially to patients who do not or no longer qualify for ventilator therapy, decreases patient discomfort and fulfills the provider's duty to care, even when the clinician can no longer offer ventilator therapy."
[vi] Ethical Considerations for Decision Making Regarding Allocation of Mechanical Ventilators during a Severe Influenza Pandemic of Other Public Health Emergency. Ventilator Document Workgroup, Ethics Subcommittee of the Advisory Committee to the Director, Centers for Disease Control and Prevention. 2011.
Excerpt, p. 21: "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 or to provide access to patients with a better prognosis."
[vii] NY Ventilator Allocation Guidelines: "The Guidelines recognize that an ethical and clinically sound system for allocating ventilators in a pandemic includes an appeals process. After consideration of a real-time or a retrospective form of review of triage decisions, the Task Force recommends implementing a hybrid system of review – combining limited on-going individual appeals with retrospective, periodic review – which incorporates the advantageous features of both under the constraints of the pandemic. Under this system, individual appeals would be limited to

procedural/technical injustices only (e.g., when a withdrawal decision was made without considering all relevant clinical triage criteria) that could remedy a potential injustice prior to the implementation of a triage decision. Retrospectively, all cases would be reviewed periodically to verify adherence the Guidelines, and would enable evaluation of triage decisions to improve subsequent decisions."

[viii] Ethical guidelines in Pandemic Influenza, p. 3: "The public is seen as a partner with other experts, with particular attention to vulnerable or historically marginalized members of society. Clear mechanisms must be created for public involvement in planning and for feedback throughout the process."

[ix] Ethical guidelines in Pandemic Influenza, p. 3 "This commitment to clarity and openness, which is based on a deep respect for all individuals and communities involved, exists in balance with the understanding that those with the authority and responsibility of making decisions must often make decisions in a timely manner."