

State of New Jersey Office of the Attorney General Department of Law and Public Safety

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GURBIR S. GREWAL Attorney General

ATTORNEY GENERAL LAW ENFORCEMENT DIRECTIVE NO. 2020-03

- TO: All County Prosecutors Director, Division of Criminal Justice
- **FROM**: Gurbir S. Grewal, Attorney General
- **DATE:** April 11, 2020

SUBJECT: Directive Regarding Non-Prosecution of Healthcare Facilities and Professionals Adhering to Triage Protocols During COVID-19 Pandemic

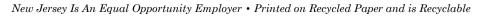
Healthcare providers across the country may soon confront a question with extraordinary moral weight and serious legal implications: how should they allocate scarce medical resources among patients in their care? The coronavirus disease 2019 (COVID-19) pandemic is pushing healthcare systems towards the limits of their capacity, and healthcare providers may be forced to decide how to withdraw or withhold certain types of treatment, including mechanical ventilation, from some patients and provide them to others.

In March 2020, the New Jersey Department of Health (DOH) convened a panel of medical experts to advise the State on the difficult ethical questions that New Jersey may face during this pandemic. Those efforts resulted in DOH's publication on April 11, 2020, of *Allocation of Critical Care Resources During a Public Health Emergency*, a model policy for health care facilities that may confront those difficult questions. DOH's model policy is based on the Model Hospital Policy for Allocating Scarce Critical Care Resources published by Douglas B. White, MD, MAS, of the University of Pittsburgh Department of Critical Care Medicine.

As healthcare professionals and facilities weigh the many implications of resourceallocation decisions, some have asked whether they will face civil or criminal liability for their triage judgments made during the COVID-19 pandemic. The question of civil liability was addressed in DOH's Executive Directive 2020-006 (Apr. 11, 2020), which provides:

A health care facility that adopts the Department of Health's model policy *Allocation of Critical Care Resources During a Public*







PHILIP D. MURPHY Governor

SHEILA Y. OLIVER Lt. Governor *Health Emergency*, as well as the health care facility's agents, officers, employees, servants, representatives and volunteers, shall not be civilly liable for any damages arising from an injury to a patient caused by any act or omission pursuant to, and consistent with, such policy. Such immunity supplements any other immunities and defenses that may apply.

However, the Executive Directive did not address criminal liability for triage decisions, nor did Executive Order No. 112 (2020), which provides another source of immunity from civil liability. *See* Executive Order No. 112 (2020), at ¶¶ 7–9 (stating that the Executive Order's immunity provisions "shall not extend to acts or omissions that constitute a crime, actual fraud, actual malice, gross negligence or willful misconduct"). As legal scholars have noted, a clinician who removes a ventilator from a patient—knowing that the patient will or might die as a result—could conceivably face criminal homicide charges, and the risk of such prosecution, however remote, could deter professionals from making medically appropriate decisions in the midst of a public health emergency. *See* I. Glenn Cohen, et al., *Potential Legal Liability for Withdrawing or Withholding Ventilators During COVID-19: Assessing the Risks and Identifying Needed Reforms*, JAMA (Apr. 1, 2020), available at https://jamanetwork.com/journals/jama/fullarticle/2764239. This Directive is designed to address those concerns and provide a clear framework for medical providers seeking guidance during peak COVID-19 hospital admissions.

Therefore, pursuant to the authority granted to me under the New Jersey Constitution and the Criminal Justice Act of 1970, N.J.S.A. 52:17B-97 to -117, I hereby DIRECT all law enforcement and prosecuting agencies operating under the authority of the laws of the State of New Jersey to implement and comply with the following policies, procedures, standards, and practices.

- 1. No prosecuting agency in New Jersey shall bring a criminal prosecution against any health care facility that adopts the Department of Health's model policy *Allocation of Critical Care Resources During a Public Health Emergency*, or against any of the health care facility's agents, officers, employees, servants, representatives or volunteers, arising from an injury to a patient caused by any act or omission pursuant to, and consistent with, such policy.
- 2. No prosecuting agency in New Jersey shall bring a criminal prosecution against any healthcare provider, including but not limited to a doctor, nurse, or hospital, for any act or omission in contravention of such an allocation policy without the approval of the Attorney General.

This Directive shall take effect immediately.

Gurbir S. Grewal Attorney General

ATTEST:

Veronica Allende Director, Division of Criminal Justice Dated: April 11, 2020



State of New Jersey DEPARTMENT OF HEALTH PO BOX 360 TRENTON, N.J. 08625-0360 www.nj.gov/health

PHILIP D. MURPHY Governor SHEILA Y. OLIVER Lt. Governor

JUDITH M. PERSICHILLI, RN, BSN, MA Commissioner

EXECUTIVE DIRECTIVE NO. 20-006

WHEREAS, Coronavirus disease 2019 ("COVID-19") is a contagious and, at times fatal, respiratory disease caused by the SARS-CoV-2 virus; and

WHEREAS, COVID-19 is responsible for the 2019 coronavirus outbreak which has now spread to the United States of America, including but not limited to the State of New Jersey; and

WHEREAS, the spread of COVID-19 within New Jersey constitutes an imminent public health hazard that threatens and presently endangers the health, safety and welfare of the residents of the State; and

WHEREAS, on March 9, 2020, New Jersey Governor Philip D. Murphy issued Executive Order No. 103 ("EO 103") proclaiming that a public health emergency and that a state of emergency exists in the State of New Jersey; and

WHEREAS, EO 103 recognizes that it is necessary and appropriate to take action against this public health hazard to protect and maintain, as well as, restore the health, safety and welfare of New Jersey residents and visitors pursuant to N.J.S.A. 26:13-1, et seq. and N.J.S.A. App. A:9-33, et seq., among other legal authorities; and

WHEREAS, as of April 11, 2020, there were at least 58,151 positive cases of COVID-19 in New Jersey and at least 2,183 of those cases having resulted in death; and

WHEREAS, of the infected persons hospitalized, many will require ventilators and other scarce resources; and

WHEREAS, based upon currently available information and estimates, the number of infected persons requiring ventilators and other medical equipment will likely exceed the number of available ventilators and other medical equipment available; and

WHEREAS, Douglas B. White, MD, MAS, of the University of Pittsburgh Department of Critical Care Medicine has published a Model Hospital Policy for Allocating Scarce Critical Care Resources (the "Pittsburgh Model Policy"); and

WHEREAS, the New Jersey Department of Health published *Allocation of Critical Care Resources During a Public Health Emergency* on April 11, 2020, which is adapted from the Pittsburgh Model Policy; and

WHEREAS, it is in the public interest to implement measures that accomplish the goal of ensuring that all health care facilities that may face a shortage of ventilators or other scarce resources adopt and adhere to medically ethical and appropriate guidelines for the allocation of ventilators, ICU/critical care beds, and critical care staff, and develop a structure to effectuate those guidelines; and

WHEREAS, Executive Order No. 112 (2020) confers immunity on healthcare providers for certain acts or omissions in the course of providing services in support of the State's COVID-19 response, but such immunity may not provide adequate protection from liability for acts or omissions pursuant to, and consistent with, a facility's resource-allocation policy; and

WHEREAS, the New Jersey Emergency Health Powers Act, specifically N.J.S.A. 26:13-11, authorizes the Commissioner of the New Jersey Department of Health to issue orders to

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control, restrict and regulate by allocation the use of medical supplies necessary to protect the public health, safety and welfare of the people of the State; and

NOW THEREFORE, I, Judith Persichilli, Commissioner of the New Jersey Department of Health, by virtue of the powers vested in me by the New Jersey Emergency Health Powers Act, N.J.S.A. 26:13-1, et seq., as well as the authority conferred on me by Executive Order No. 103, do hereby declare and order as follows:

- 1. All health care facilities in New Jersey that possess mechanical ventilators for the care of all patients requiring use of such ventilators must determine whether to adopt a written policy to govern the allocation of mechanical ventilators during the public health emergency arising from COVID-19. Such a policy may, in addition, govern the allocation of other scarce medical resources.
- 2. A health care facility that adopts the Department of Health's model policy Allocation of Critical Care Resources During a Public Health Emergency, as well as the health care facility's agents, officers, employees, servants, representatives and volunteers, shall not be civilly liable for any damages arising from an injury to a patient caused by any act or omission pursuant to, and consistent with, such policy. Such immunity supplements any other immunities and defenses that may apply.

This Directive shall take effect immediately. The provisions of this Directive shall remain in force and effect for the duration of the Public Health Emergency originally declared in EO 103 pursuant to the New Jersey Emergency Health Powers Act, N.J.S.A. 26:13-1 et seq., unless modified, supplemented and/or rescinded, but the immunity conferred by Paragraph 2 of this Directive shall continue in perpetuity.

Judith Persichilli, R.N., B.S.N., M.A.

Commissioner

4/11/ 2030 Date



State of New Jersey DEPARTMENT OF HEALTH PO BOX 360 TRENTON, N.J. 08625-0360

www.nj.gov/health

PHILIP D. MURPHY Governor

SHEILA Y. OLIVER Lt. Governor JUDITH M. PERSICHILLI, RN, BSN, MA Commissioner

April 11, 2020

Allocation of Critical Care Resources During a Public Health Emergency (Adapted from the University of Pittsburgh Model Policy*)

Executive Summary

Introduction: The purpose of this document is to provide guidance for the triage of critically ill patients in the event that a public health emergency creates demand for critical care resources that outstrips the supply. These triage recommendations will be enacted by a hospital only if: 1) the hospital is operating under a crisis standard of care; 2) critical care capacity is, or will shortly be, overwhelmed despite taking all appropriate steps to increase the surge capacity to care for critically ill patients; and 3) a regional authority has declared a public health emergency. This allocation framework is grounded in ethical obligations that include the duty to care, duty to steward resources to optimize population health, distributive and procedural justice, and transparency. It is consistent with existing recommendations for how to allocate scarce critical care resources during a public health emergency, and has been informed by extensive consultation with citizens, critical care medicine experts, and ethicists.

This document describes 1) the creation of triage teams to ensure consistent decision making; 2) allocation criteria for initial allocation of critical care resources; and 3) reassessment criteria to determine whether ongoing provision of critical care resources are justified for individual patients.

Section 1. Creation of triage teams: Patients' treating clinicians will not make triage decisions. Instead, each hospital will designate an acute care triage team, consisting of a physician supported by a nurse and administrator, who will apply the allocation framework described in this document. The physician and nurse preferably should have past experience in caring for patients in a critical care unit (including, but not limited to, an ICU, CCU, PACU, SICU, ED). The separation of the triage role from the clinical role is intended to promote objectivity, avoid conflicts of commitments, and minimize moral distress. The triage team will also be involved in patient or family appeals of triage decisions, and in collaborating with the attending physician to disclose triage decisions to patients and families. Facilities should provide training to the triage teams and hospital/system decision-makers and health care staff in advance of implementation of adopted allocation policies.

*<u>https://ccm.pitt.edu/?q=content/model-hospital-policy-allocating-scarce-critical-care-resources-available-online-now</u>

Section 2. Allocation criteria for Intensive Care Unit/Critical Care admission: This allocation framework is based primarily on two considerations: 1) saving lives; and 2) saving lifeyears, both within the context of ensuring meaningful access for all patients and individualized patient assessments based on objective medical knowledge. All patients who meet usual medical indications for intensive care unit (ICU)/critical care beds and services will be assigned a priority score using a 1-8 scale (lower scores indicate higher likelihood of benefit from critical care), derived from 1) patients' likelihood of surviving to hospital discharge, assessed with an objective and validated measure of acute physiology (e.g., the Sequential Organ Failure Score (SOFA) score); and 2) the presence of a severely limited life expectancy even if the patient survived the acute critical illness (**Table 1**). This raw priority score may be converted to three color-coded priority groups (e.g., high, intermediate, and low priority) if needed to facilitate streamlined implementation in individual hospitals. All patients will be eligible to receive critical care beds and services regardless of their priority score, but available critical care resources will be allocated according to priority score, such that the availability of these services will determine how many patients will receive critical care. Patients who are triaged to not receive ICU/critical care beds or services will be offered medical care including intensive symptom management and psychosocial support.

Note that the SOFA scoring system is not appropriate for use in children or neonates. Because there is no evidence-based data on how to triage children specifically for ventilator allocation based on these clinical factors, a triage officer/team must use best clinical judgment.

Section 3. Reassessment for ongoing provision of critical care/ventilation: The triage team will conduct periodic reassessments of all patients receiving ICU/critical care services during times of crisis (i.e., not merely those initially triaged under the crisis standards). The timing of reassessments should be based on evolving understanding of typical disease trajectories and of the severity of the crisis. A multidimensional, individualized assessment should be used to quantify changes in patients' conditions, such as recalculation of severity of illness scores, appraisal of new complications, and treating clinicians' input. Patients showing improvement will continue to receive ICU/critical care services until the next assessment. Patients showing substantial clinical deterioration that portends a very low chance for survival will have critical care discontinued. These patients will receive medical care including intensive symptom management and psychosocial support. Where available, specialist palliative care teams will provide additional support and consultation.

Introduction & Ethical Considerations

The purpose of this document is to provide guidance for the triage of critically ill patients in the event that a public health emergency creates demand for critical care resources (e.g., ventilators, critical care beds) that outstrips the supply. These triage recommendations will be enacted by a hospital only if: 1) the hospital is operating under a crisis standard of care; 2) critical care capacity is, or will shortly be, overwhelmed despite taking all appropriate steps to increase the surge capacity to care for critically ill patients; and 3) a regional authority has declared a public health emergency. This allocation framework is grounded in ethical obligations that include the duty to care, duty to steward resources to optimize population health, distributive and procedural justice, and transparency.

Ethical goals of the allocation framework: Consistent with accepted standards during public health emergencies, a goal of the allocation framework is to achieve benefit for populations of patients, often expressed as doing the greatest good for the greatest number.^{1,2} It should be noted that this goal is different from the traditional focus of medical ethics, which is centered on promoting the wellbeing of individual patients.³ In addition, the framework is designed to: achieve the following:

- 1. create meaningful access for all patients. All patients who are eligible for ICU/critical care services during ordinary circumstances remain eligible, and there are no exclusion criteria based on age, disabilities, or other factors;
- 2. ensure that all patients receive individualized assessments by clinicians, based on the best available objective medical evidence;
- ensure that no one is denied care based on stereotypes, assessments of quality of life, or judgments about a person's "worth" based on the presence or absence of disabilities or other factors;
- 4. ensure that discrimination based on race, creed, color, national origin, nationality, ancestry, marital status, domestic partnership or civil union status, sex, affectional or sexual orientation, gender identity or expression, disability, place of residence, socio-economic or insurance status is explicitly avoided; and, to the extent possible, those making allocation decisions should be unaware of these patient characteristics.

No use of categorical exclusion criteria: The allocation framework described in this document differs in two important ways from other allocation frameworks. First, it does not categorically exclude any patients who, in usual circumstances, would be eligible for critical care resources. Instead, all patients are treated as eligible to receive critical care resources and are prioritized based on potential to benefit from those resources; the availability of critical care resources determines how many priority groups can receive critical care. There are compelling reasons to not use exclusion criteria. Categorically excluding patients will make many think that their lives are "not worth saving," leading to justified perceptions of discrimination. Moreover, categorical exclusions are too rigid to be used in a dynamic crisis, when critical care resources shortages will likely surge and decline episodically during the public health emergency. In addition, such exclusions violate a fundamental principle of public health ethics: use the means that are least restrictive to individual liberty to accomplish the public health goal. Categorical exclusions are not necessary because less restrictive approaches are feasible, such as allowing all patients to be eligible and giving priority to those most likely to benefit.

Second, the allocation framework goes beyond simply attempting to maximize the number of patients who survive to hospital discharge, because this is a thin conception of doing the greatest good for the greatest number.⁴ Instead, within the context of keeping all patients eligible, the allocation framework also attempts to increase overall survival by giving some priority to patients who do not have a very limited life expectancy even if they survived the acute critical illness. There is precedent for using this criterion in allocation of scarce medical resources; U.S. rules to allocate lungs for transplantation incorporate patients' expected duration of survival after transplantation, not simply whether transplantation will avert impending death.⁵ Extensive consultation with citizens, ethicists, and critical care medicine experts informed the principles and processes adopted in this document.⁶

Additional Principles

- No institution should have to resort to limiting access to critical care resources, including ventilators, while neighboring, or regional institutions still have capacity. Implementing an allocation plan should be a last resort. Either resources or patients, should be moved from one hospital to another to ensure this is the case, regardless of patient's insurance status, or pre-existing contracts between hospitals/systems and insurers.
- 2. Any allocation system should be equitable (fair) and serve to maximize lives and lifeyears saved (utility). However, considerations of quality-adjusted life years (QALYs) is not appropriate, and could lead to subjective, discriminatory decisions, particularly related to those with disabilities.
- 3. Facilities should provide training to hospital/system decision-makers and health care staff in advance of implementation of adopted allocation policies. Services to attend to provider moral distress should be strengthened.

This document describes 1) the creation of triage teams to ensure consistent decision making; 2) allocation criteria for initial allocation of critical care resources; and 3) reassessment criteria to determine whether ongoing provision of scarce critical care resources are justified for individual patients.

Section 1. Creation of triage teams

The purpose of this section is to provide guidance to create a local triage team at each hospital whose responsibility is to implement the allocation framework described in Sections 2 and 3. It is important to emphasize that patients' treating physicians will not make triage decisions. Instead, each hospital will designate an acute care triage team, consisting of <u>at least one</u> physician supported by <u>at least one</u> nurse and <u>at least one</u> administrator, who will apply the allocation framework described in this document. These decisions are grounded in public health ethics, not clinical ethics, and therefore a triage team with expertise in the allocation framework should make allocation decisions. The separation of the triage role from the clinical role is intended to enhance objectivity, avoid conflicts of commitments, and minimize moral distress.

Lead Triage Officers

A group of triage officers should be appointed. Preferable qualities of triage officers include being a physician with established expertise in the management of critically ill patients (e.g. past experience in caring for patients in a critical care unit including, but not limited to, an ICU, CCU, PACU, SICU, ED), strong leadership ability, and effective communication and conflict resolution skills. This individual will oversee the triage process, assess all patients, assign a level of priority for each, communicate with treating physicians, and direct attention to the highest-priority patients. S/he is expected to make decisions with the team according to the allocation framework described below, which is designed to benefit the greatest number of patients, even though these decisions may not necessarily be best for some individual patients. To optimize effective functioning in a crisis, the triage officer should ideally be well-prepared and trained in advance by means of disaster drills or exercises. The triage officer has the responsibility and authority to apply the principles and processes of this document to make decisions about which patients will receive the highest priority for receiving critical care. S/he is also empowered to make decisions with the team regarding reallocation of critical care resources that have previously been allocated to patients, again using the principles and processes in this document. In making these decisions, the triage officer and team should not use principles or beliefs that are not included in this document.

So that the burden is fairly distributed, triage officers and team members will be nominated by the chairs/directors of the clinical departments that provide care to critically ill patients. The Chief Medical Officer and the individual responsible for emergency management should approve all nominees. A roster of approved triage officers and team members should be maintained that is large enough to ensure that they will be available on short notice at all times, and that they will have sufficient rest periods between shifts.

Triage Team

In addition to the triage officer, the triage team should also consist of a nurse preferably with past experience in caring for patients in a critical care unit including, but not limited to, an ICU, CCU, PACU, SICU, ED) (even if no longer clinically active), and one administrative staff member who will conduct data-gathering activities, documentation and record keeping, and assistance liaising with a hospital Command Center or bed management. The staff member must be provided with appropriate computer and IT support to maintain updated databases of patient priority levels and scarce resource usage (total numbers, location, and type). The role of triage team members is to provide information to the triage officer and to help facilitate and support and document the decision-making process. A representative from hospital administration should also be linked to the team, in order to supervise maintenance of accurate records of triage scores and to serve as a liaison with hospital leadership.

The triage officer and team members should function in shifts lasting no longer than 13 hours (to enable 30 minutes of overlap and handoffs on each end). Therefore, there should be two shifts per day to fully staff the triage function. Team decisions and supporting documentation should be reported daily to appropriate hospital leadership and incident command.

Facilities should provide training to the triage teams and hospital/system decision-makers and health care staff in advance of implementation of adopted allocation policies.

Triage Mechanism

The triage officer and her/his team will use the allocation framework, detailed in Section 2, to determine priority scores of all patients eligible to receive the scarce critical care resource. For patients already being supported by the scarce resource, the evaluation will include

reassessment to evaluate for clinical improvement or worsening at pre-specified intervals, as detailed in Section 3. The triage officer will review the comprehensive list of priority scores for all patients and will communicate with the clinical teams immediately after a decision is made regarding allocation or reallocation of a critical care resource.

Communication of triage decisions to patients and families

Although the authority for triage decisions rests with the triage officer and his/her team, there are several potential strategies to *disclose* triage decisions to patients and families. Communicating triage decisions to patients and/or their next of kin is a required component of a fair allocation process that provides respect for persons.⁷ The triage officer should first inform the affected patient's attending physician about the triage decision. Those two physicians should collaboratively determine the best approach to inform the individual patient and family. Options for who should communicate the decision include: 1) solely the attending physician; 2) solely the triage officer: or 3) a collaborative effort between the attending physician and triage officer. The best approach will depend on a variety of case-specific factors, including the dynamics of the individual doctor-patient-family relationship and the preferences of the attending physician. If the attending physician is comfortable with undertaking the disclosure, this approach is useful because the communication regarding triage will bridge naturally to a conveyance of prognosis, which is a responsibility of bedside physicians, and because it may limit the number of clinicians exposed to a circulating pathogen. The third (collaborative) approach is useful because it may lessen moral distress for individual clinicians and may augment trust in the process, but these benefits must be balanced against the risk of greater clinician exposure. Under this approach, the attending physician would first explain the severity of the patient's condition in an emotionally supportive way, and then the triage officer would explain the implications of those facts in terms of the triage decision. The triage officer would also emphasize that the triage decision was not made by the attending physician but is instead one that arose from the extraordinary emergency circumstances, and reflects a public health decision. Regardless of who communicates the decision, it may useful to explain the medical factors that informed the decision, as well as the factors that were not relevant (e.g., race, ethnicity, gender, insurance status, perceptions of social worth, immigration status, among others). If resources permit, palliative care clinicians or social workers should be present or available to provide ongoing emotional support to the patient and family.

Appeals process for individual triage decisions

It is possible that patients, families, or clinicians will challenge individual triage decisions. Procedural fairness requires the availability of an appeals mechanism to resolve such disputes. On practical grounds, different appeals mechanisms are needed for the initial decision to allocate a scarce resource among individuals, none of whom are currently using the resource, and the decision whether to withdraw a scarce resource from a patient who is not clearly benefiting from that resource. This is because initial triage decisions for patients awaiting the critical care resource will likely be made in highly time-pressured circumstances. Therefore, an appeal will need to be adjudicated in real time to be operationally feasible. For the initial triage decision, the only permissible appeals are those based on a claim that an error was made by the triage team in the calculation of the priority score or use/non-use of a tiebreaker (as detailed in Section 2). The process of evaluating the appeal should include the triage team verifying the accuracy of the priority score calculation by recalculating it. The treating clinician or triage officer should be prepared to explain the calculation to the patient or family on request.

Decisions to <u>withdraw</u> a scarce resource such as mechanical ventilation from a patient who is already receiving it may cause heightened moral concern. Furthermore, such decisions depend on more clinical judgment than initial allocation decisions. Therefore, there should be a more

robust process for appealing decisions to withdraw or reallocate critical care beds or services. Elements of this appeals process should include:

- The individuals appealing the triage decision should explain to the triage officer the grounds for their appeal. Appeals based in an objection to the overall allocation framework should not be granted.
- The triage team should explain the grounds for the triage decision that was made.
- Appeals based in considerations other than disagreement with the allocation framework should immediately be brought to a Triage Review Committee that is independent of the triage officer/team and of the patient's care team (see below for recommended composition of this body).
- The appeals process must be expedited so that the appeals process does not harm patients who are in the queue for scarce critical care resources currently being used by the patient who is the subject of the appeal.
- The decision of the Triage Review Committee or subcommittee for a given hospital/system will be final.
- Periodically, the Triage Review Committee should retrospectively evaluate whether the review process is consistent with effective, fair, and timely application of the allocation framework.

The Triage Review Committee should be made up of at least three individuals, recruited from the following groups or offices: Chief Medical Officer or designee, Chief Nursing Officer or other Nursing leadership, Legal Counsel, a hospital Ethics Committee or Consult Service, members of an institution's ethics faculty, and/or an off-duty triage officer. Three committee members are needed for a quorum to render a decision, using a simple majority vote. The process can happen by telephone or in person, and the outcome will be promptly communicated to whomever brought the appeal.

Section 2. Allocation process for ICU/CRITICAL CARE admission

The purpose of this section is to describe the allocation framework that should be used to make initial triage decisions for patients who present with illnesses that typically require critical care resources (i.e., illnesses that cannot be managed on a hospital ward in that hospital). The scoring system applies to all patients presenting with critical illness, not merely those with the disease or disorders that have caused the public health emergency. For example, in the setting of a severe pandemic, those patients with respiratory failure from illnesses <u>not</u> caused by the pandemic illness will also be subject to the allocation framework. This process involves two steps, detailed below:

- 1. Calculating each patient's priority score based on the multi-principle allocation framework;
- 2. Determining each day how many priority groups will receive access to critical care interventions.

First responders and bedside clinicians should perform the immediate stabilization of any patient in need of critical care, as they would under normal circumstances. Along with stabilization, temporary ventilatory support may be offered to allow the triage officer to assess the patient for critical resource allocation. Every effort should be made to complete the initial

triage assessment within 90 minutes of the recognition of the likely need for critical care resources.

<u>STEP 1:</u> Calculate each patient's priority score using the multi-principle allocation framework.

This allocation framework is based primarily on two considerations: 1) saving lives; and 2) saving life-years, both within the context of ensuring meaningful access for all patients and individualized patient assessments based on objective medical knowledge. Patients who are more likely to survive with intensive/critical care are prioritized over patients who are less likely to survive with intensive care/critical care. Patients who do not have a severely limited life expectancy are given priority over those who have such advanced conditions that they have a very limited life expectancy even if they survive the acute critical illness.

As summarized in **Table 1**, the Sequential Organ Failure Assessment (SOFA) score (or an alternate, validated, objective measure of probability of survival to hospital discharge) is used to determine patients' prognoses for hospital survival. The presence of conditions in such an advanced state that life expectancy is very limited is used to characterize patients' longer-term prognosis. Based on consultation with experts in disability rights and physical medicine and rehabilitation, we have intentionally not included a list of example conditions associated with life expectancy <1 year and <5 years. The rationale for this is that such lists run the risk of being applied as blanket judgments, rather than in the context of individualized assessments by clinicians, based on the best available objective medical evidence.

Principle	Specification	Point System*			
		1	2	3	4
Save lives	Prognosis for short-term survival (SOFA score [#])	SOFA score < 6	SOFA score 6-8	SOFA score 9-11	SOFA score ≥12
Save life- years	Prognosis for longer-term survival (medical assessment of prospects for survival after hospital discharge)		Life expectancy < 5 years despite successful treatment of acute condition		Death likely within 1 year despite successful treatment of acute condition

Table 1. Multi-principle Strategy to Allocate Critical Care During a Public HealthEmergency

[#]SOFA= Sequential Organ Failure Assessment; note that another measure of acute physiology that predicts in-hospital mortality, such as LAPS2 score, could be used in place of SOFA, but should similarly be divided into 4 ranges.

*Scores range from 1-8, and persons with the lowest score would be given the highest priority to receive critical care beds and services.

Points are assigned according to the patient's SOFA score (range from 1 to 4 points) plus the determination that a patient has a severely limited life expectancy even if they survived to

highest discharge. (2 points if life expectancy predicted to be less than five years, 4 points for life expectancy less than one year (**Table 1**)). These points are then added together to produce a total priority score, which ranges from 1 to 8. Lower scores indicate higher likelihood of benefiting from critical care, and priority will be given to those with lower scores.

Other scoring considerations:

<u>Giving heightened priority to those who are central to the health care and public health</u> <u>response</u>. Individuals who perform tasks that are vital to the response, including those whose work directly supports the provision of acute care to others, should be given heightened priority. The specifics of how to operationalize this consideration will depend on the exact nature of the heath care and public health emergency. Options include subtracting points from the priority score for these individuals or using it as a tiebreaker criterion (see below). This category should be broadly construed to include those individuals who play a critical role in the chain of treating patients and maintaining societal order. However, it would not be appropriate to prioritize frontline *physicians* and not prioritize other front-line clinicians (e.g., nurses and respiratory therapists) and other key personnel (e.g., maintenance staff that disinfects hospital rooms).

Giving heightened priority to those who have had the least chance to live through life's stages: We suggest that life-cycle considerations should be used as a tiebreaker if there are not enough resources to provide to all patients within a priority group, with priority going to younger patients. We recommend the following categories: age 0-17, age 18-40, age 41-60; age 61-75; older than age 75. The ethical justification for incorporating the life-cycle principle is that it is a valuable goal to give individuals equal opportunity to pass through the stages of life—childhood, young adulthood, middle age, and old age.⁸ The justification for this principle does not rely on considerations of one's intrinsic worth or social utility. Rather, younger individuals receive priority because they have had the least opportunity to live through life's stages. Evidence suggests that, when individuals are asked to consider situations of absolute scarcity of lifesustaining resources, most believe younger patients should be prioritized over older ones.⁹ Public engagement about allocation of critical care resources during an emergency also supported the use of the lifecycle principle for allocation decisions.⁶ Harris summarizes the moral argument in favor of life-cycle–based allocation as follows: "It is always a misfortune to die . . . it is both a misfortune and a tragedy [for life] to be cut off prematurely."¹⁰

Because there is no evidence-based data on how to triage children for ventilator allocation based on these clinical factors, a triage officer/team must use best clinical judgment. However, the basic principle is that the more severe a patient's health condition is based on these clinical factors, the less likely s/he survives even with ventilator therapy, and triage decisions should be made accordingly.

Absence of categorical exclusion criteria: A central feature of this allocation framework is that it does not use categorical exclusion criteria to bar individuals from access to critical care services during a public health emergency. There are several ethical justifications for this. First, the use of rigid categorical exclusions would be a major departure from traditional medical ethics and raise fundamental questions of fairness. Second, such restrictive measures are not necessary to accomplish public health goals during a pandemic or disaster; it is equally feasible to assign all patients a priority score and allow the availability of resources to determine how many patients can receive the scarce resource. Third, categorical exclusion criteria may be interpreted by the public to mean that some groups are "not worth saving," leading to perceptions of unfairness and distrust. In a public health emergency, public trust will be essential to ensure cooperation with restrictive public health measures. Thus, an allocation system should make clear that all individuals are "worth saving" by keeping all patients who

would receive critical care during routine clinical circumstances eligible, and by allowing the availability of beds and services to determine how many eligible patients receive them. It is important to note that there are some conditions that lead to immediate or near-immediate death despite aggressive therapy such that during routine clinical circumstances clinicians do not provide critical care services (e.g., cardiac arrest unresponsive to appropriate ACLS, massive intracranial bleeds, intractable shock). During a public health emergency, clinicians should still make clinical judgments about the appropriateness of critical care using the same criteria they use during normal clinical practice.

STEP 2: Make daily determinations of how many priority groups can receive scarce critical care resources. Hospital leaders and triage officers should make determinations twice daily, or more frequently if needed, about what priority scores will result in access to critical care services. These determinations should be based on real-time knowledge of the degree of scarcity of the critical care resources, as well as information about the predicted volume of new cases that will be presenting for care over the near-term (several days). For example, if there is clear evidence that there is imminent shortage of critical care resources (i.e., few ventilators available and large numbers of new patients daily), only patients with the highest priority (lowest scores, e.g., 1-3) should receive scarce critical care resources. As scarcity subsides, patients with progressively lower priority (higher scores) should have access to critical care interventions. There are at least two reasonable approaches to group patients: 1) according to their raw score on the 1-8 multi-principle allocation score; and 2) by creating 3 priority categories based on patients' raw priority scores (e.g., high priority, intermediate priority, and low priority). Using the full 1-8 scale avoids creating arbitrary cut-points on what is a continuous scale and allows all the information to be used from the priority score. Using priority categories is consistent with standard practices in disaster medicine and avoids allowing marginal differences in scores on an allocation framework that has not been extensively tested to be the determinative factor in allocation decisions. Both approaches are reasonable. The best choice depends on institutional preferences and comfort with different ways to operationalize triage protocols on the front lines of clinical care.

Instructions on how to assign patients to color-coded priority groups. For those institutions that prefer to create broader, color-coded priority groups, this section provides instructions on how to do so. Once a patient's priority score is calculated using the multi-principle scoring system described in Table 1, each patient should be assigned to a color-coded triage priority group, which should be noted clearly on their chart/EHR (Table 2). This color-coded assignment of priority groups is designed to allow triage officers to create operationally clear priority groups to receive critical care resources, according to their score on the multi-principle allocation framework. For example, individuals in the red group have the best chance to benefit from critical care interventions and should therefore receive priority over all other groups in the face of scarcity. The orange group has intermediate priority and should receive critical care resources. The yellow group has lowest priority and should receive critical care resources if there are available resources after all patients in the red and orange groups have been allocated critical care resources.

Use Raw Score from Multi-principle Scoring System to Assign Priority Category				
Level of Priority and Code Color	Priority score from Multi-principle Scoring System			
RED Highest priority	Priority score 1-3			
ORANGE Intermediate priority (reassess as needed)	Priority score 4-5			
YELLOW Lowest priority (reassess as needed)	Priority score 6-8			

Table 2. Assigning Patients to Color-Coded Priority Groups

Resolving "ties" in priority scores/categories between patients. In the event that there are 'ties' in priority scores/categories between patients and not enough critical care resources for all patients with the lowest scores, life-cycle considerations should be used as the first tiebreaker, with priority going to younger patients. We recommend the following categories: age 0-17, age 18-40, age 41-60; age 61-75; older than age 75. We also recommend that individuals who are vital to the acute care response be given priority, which could be operationalized in the form of a tiebreaker or subtracting points from the score.

If there are still ties after applying priority based on life-cycle considerations and consideration of healthcare workers, and if the hospital used the 3 -priority category approach described above (e.g., high, intermediate, and low priority), the raw score on the patient prioritization score should be used as a tiebreaker, with priority going to the patient with the lower raw score.

If there are still ties after these two tiebreakers are applied, a lottery (i.e., random allocation) should be used to break the tie.

It is important to reiterate that all patients will be *eligible* to receive critical care beds and services regardless of their priority score. The availability of critical care resources will determine how many eligible patients will receive critical care.

Again, because there are no evidence-based data on how to triage children for ventilator allocation based on SOFA scoring, a triage officer/team must use best clinical judgment. However, the basic principle is that the more severe a patient's health condition is based on these clinical factors, the less likely s/he survives even with ventilator therapy, and triage decisions should be made accordingly.

Appropriate clinical care of patients who cannot receive critical care. Patients who are not triaged to receive critical care/ventilation will receive medical care that includes intensive symptom management and psychosocial support. They should be reassessed daily to

determine if changes in resource availability or their clinical status warrant provision of critical care services. Where available, specialist palliative care teams will be available for consultation. Where palliative care specialists are not available, the treating clinical teams should provide primary palliative care.

Section 3. Reassessment for ongoing provision of critical care

The purpose of this section is to describe the process the triage team should use to conduct reassessments on patients who are receiving critical care services, in order to determine whether s/he continues with the treatment.

Ethical goal of reassessments of patients who are receiving critical care services. The ethical justification for such reassessment is that, in a public health emergency when there are not enough critical care resources for all, the goal of maximizing population outcomes would be jeopardized if patients who were determined to be unlikely to survive were allowed indefinite use of scarce critical care services. In addition, periodic reassessments lessen the chance that arbitrary considerations, such as when an individual develops critical illness, unduly affect patients' access to treatment.

Approach to reassessment

All patients who are allocated critical care services will be allowed a therapeutic trial of a duration to be determined by the clinical characteristics of the disease. The decision about trial duration will ideally be made as early in the public health emergency as possible, when data becomes available about the natural history of the disease. Trial duration will also need to be tailored for other non-pandemic diseases and patient contexts, given the concern that patients with certain disabilities may need longer trials to determine benefit. The trial duration should be modified as appropriate if subsequent data emerge about the clinical course of the pandemic illness.

The triage team will conduct periodic reassessments of patients receiving critical care/ventilation. A multidimensional assessment should be used to quantify changes in patients' conditions, such as recalculation of severity of illness scores, appraisal of new complications, and treating clinicians' input. Patients showing improvement will continue with critical care/ventilation until the next assessment. If there are patients in the queue for critical care services, then patients who upon reassessment show substantial clinical deterioration as evidenced by worsening SOFA scores or overall clinical judgment should have critical care withdrawn, including discontinuation of mechanical ventilation, after this decision is disclosed the patient and/or family. Although patients should generally be given the full duration of a trial, if patients experience a precipitous decline (e.g., refractory shock and DIC) or a highly morbid complication (e.g., massive stroke) which portends a very poor prognosis, the triage team may make a decision before the completion of the specified trial length that the patient is no longer eligible for critical care treatment

Appropriate clinical care of patients who cannot receive critical care.

Patients who are no longer eligible for critical care treatment should receive medical care including intensive symptom management and psychosocial support. Where available, specialist palliative care teams will be available for consultation. Access to and resources for palliative care should be strengthened in order to provide support and conduct effective patient and family centered conversations. Where palliative care specialists are not available, the

treating clinical teams should provide primary palliative care. Bereavement support services should be made available to families.

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