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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 crisis standards 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) the state authority has declared a public health emergency. A public health emergency was declared in New Jersey on March 9, 2020 through NJ Executive Order No. 103 and continued through subsequent executive orders.

This allocation framework is grounded in ethical obligations that include the duty to care, duty to steward resources to optimize population health, equitable 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 was informed by extensive consultation with citizens, critical care medicine experts, and ethicists. New Jersey's adoption and revision of this policy was further developed by New Jersey-specific subject matter experts, best practices and data, and healthcare professionals representing geographic and professional diversity who care for demographically diverse patients. Whether or not a healthcare facility chooses to adopt the Allocation Policy is a decision to be made by each facility.

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

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: Clinicians treating patients 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.

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 life-years, 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 Assessment (SOFA) score); and 2) the likelihood of death within a few years, as outlined in Table 1, even if the patient survived their acute critical illness. 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 appropriate medical care, including palliative care, 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 as outlined in appendices describing allocation policies for neonatal patients and for pediatric patients.

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 palliative care, 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 crisis standards 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) the state 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, equitable distributive and procedural justice, and transparency.

Use of this policy is associated with state statutory and administrative law, such as P.L.2020, c.18, Department of Health Executive Directive No. 20-006, and Office of the Attorney General Law Enforcement Directive No. 2020-03.

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

- 1. Create meaningful access to ICU/critical care services for all patients. All patients who are eligible for ICU/critical care services during ordinary circumstances remain eligible for such services, and there are no exclusion criteria based on age, disability, or other factors;
- 2. Ensure that all patients receive individualized assessments by clinicians, based on the best available objective medical evidence;
- 3. Ensure that no one is denied care based on stereotypes, assessments of quality of life, perceived social worth, perceived quality of life, life-table expectancy or judgments about a person's "worth" based on the presence or absence of disabilities, mental health diagnoses, or other factors;
- 4. Ensure that discrimination based on race, age, creed, color, ethnicity, national origin, nationality or immigration status, ancestry, marital status, domestic partnership or civil union status, sex, affectional or sexual orientation, gender identity or expression, disability status, place of residence or homelessness status, socioeconomic status, justice system involvement, 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 other 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 patients in priority groups can receive critical care.

There are compelling reasons to not use exclusion criteria. Categorically excluding patients would make many think that their lives are "not worth saving," leading to justified perceptions of discrimination and fear of the health system. 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: to 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. Some priority is given to patients who do not have a very limited life expectancy, even if those patients 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 medical experts informed the principles and processes adopted in this document.⁶ New Jersey's adoption and revision of this policy was further informed by New Jersey-specific subject matter experts, best practices and data, and healthcare professionals representing geographic and professional diversity who care for demographically diverse patients.

Additional Principles

- 1. 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. During a declared public health emergency, the New Jersey Department of Health will monitor the availability and demand of scarce resources, such as ventilators and ICU beds, across the state and may take action regarding equitable distribution of such resources to facilities.
- 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.

- 4. Nothing in this policy shall abrogate the patients' autonomy to opt-out from (refuse) the use of scarce resources (e.g. through use of Practitioner Orders of Life Sustaining Treatment (POLST) or other shared decision-making tools). Patients admitted to general hospitals also retain rights enumerated in N.J.S.A. 26:2H-12.8, including rights pertaining to nondiscrimination, informed consent, facility transfer, and confidentiality.
- 5. If a patient presents to a hospital and has personal medical equipment, such as a ventilator, that equipment will not be confiscated or used for any other patient.

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 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 clinicians treating patients will not make triage decisions. Instead, each hospital will designate a critical care resources 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 officer should be appointed at each hospital facility. 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, effective communication and conflict resolution skills, and bioethics expertise where possible. To the extent possible, the lead triage officers shall adequately represent the diversity of the patient populations served by the facility.

Lead triage officers will oversee the triage process, assess all patients, assign a level of priority for each patient, communicate with treating physicians, and direct attention to the highest-priority patients. Each triage officer 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. She/he is also empowered to make decisions with the team regarding reallocation of critical care resources that have previously been allocated to patients by 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, the lead 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 lead 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 administrator who will conduct data-gathering activities, documentation and record keeping, and liaise with the hospital Command Center or bed management. The administrator 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). To the extent possible, the triage team shall include members who adequately represent the diversity of the patient populations served by the facility. The role of triage team members is to provide information to the lead triage officer and help facilitate, 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 lead 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. All documentation related to triage team decisions, communication with patients and families, appeals, and supporting documentation should be maintained in patient records and reported daily to appropriate hospital leadership and incident command. Information about the implementation of this policy may be requested from facilities by the New Jersey Department of Health in its oversight functions and to inform any future revisions of this policy.

Facilities should provide training on the allocation policy to the triage teams, hospital/system decision-makers and health care staff in advance of implementation of adopted allocation policies. To the extent possible, the training should include basic bioethics principles and implicit bias concepts.

Triage Mechanism

The lead triage officer and her/his team will use the allocation framework, outlined in Section 2 below, 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 outlined in Section 3 below. The lead 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. As the triage process is conducted, the triage team shall be mindful of the role that implicit bias may play in decision-making.

Communication of triage decisions to patients and families

Although the *authority* for triage decisions rests with the lead 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 lead triage officer should first inform the affected patient's attending physician about the triage decision. Those two physicians (the lead triage officer and the patient's attending physician) should collaboratively determine the best approach to inform the individual patient and family of the triage decision. Options for who should communicate the triage decision include: 1) solely the attending physician; 2) solely the lead triage officer; or 3) a collaborative effort between the attending physician and lead triage officer.

Regardless of the approach, special consideration should be made to ensure that communication of triage decisions is done in a competent and sensitive manner, with racially, ethnically, culturally and linguistically diverse team members available to assist in these communications if possible, and specialized assistive technology, interpretative services, or other reasonable accommodations available for patients and families who require or request it.

The best approach of the three methods outlined above for communication of triage decisions will depend on a variety of case-specific factors, including the dynamics of the individual doctorpatient-family relationship and the preferences of the attending physician. If the attending physician is comfortable with undertaking this decision, such approach is beneficial 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. However, The third (collaborative) approach may also be beneficial in certain circumstances 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 lead triage officer would explain the implications of those facts in terms of the triage decision. The lead triage officer would also emphasize that the triage decision was not made by the attending physician alone but was instead made collaboratively by both physicians after careful consideration of 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

All patients and authorized healthcare representatives who were not allocated critical care resources by the triage process must be advised of their right to appeal these decisions. It is possible that patients, families, or clinicians will challenge individual triage decisions. This appeal mechanism is grounded in principles of fairness and transparency.

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. The only permissible appeals of the initial triage decision are appeals 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 more on clinical judgment than on initial allocation decisions. Therefore, withdrawal or reallocation of critical care beds or services requires a robust process for appealing decisions. Elements of this appeals process should include the following factors:

- the individuals appealing the triage decision should explain to the lead triage officer the grounds for their appeal. Appeals based on 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 lead 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 it 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; and
- 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). A scoring system is used that 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 patients in 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, because of underlying conditions are not likely to die within 5 years are given priority over those who have such advanced conditions that they are likely to die within 5 years, even if they were to survive their 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 death is likely within a relatively short period of time 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 death likely in less than 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

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

Save life-	Prognosis for	 Death likely	 Death likely
vears	longer-term	within 5 years	within 1 year
5	survival (medical	despite	despite
	assessment of	successful	successful
	prospects for	treatment of	treatment of
	survival after	acute condition	acute condition
	hospital discharge)		

[#]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 is likely to die within a few years even if they survived to highest discharge. (2 points if death is likely predicted within five years, 4 points if death is likely within 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:

Giving heightened priority to those who are central to the health care and public health response. 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. Not only would it include those individuals who play a critical role in the chain of treating patients, directly supporting patient care and maintaining societal order. However, it would not be appropriate to prioritize frontline *physicians* and not prioritize other front-line clinicians (including and not limited to: nurses, respiratory therapists, EMTs, mental health professionals, phlebotomists, and others) and other key support personnel (e.g., maintenance staff who disinfect hospital rooms). Whether a person fits this category should be obtained from the patient, their families, or a support person at the time of admission of the patient to the hospital.

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 life-sustaining 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 life-cycle 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

With respect to children, since there is no evidence-based data on how to triage children for ventilator allocation based on the above 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 will survive even with ventilator therapy, and triage decisions should be made accordingly. Appendices 1 and 2 provide further guidance on allocation of ventilators to neonates and to pediatric patients.

<u>Pregnancy-status</u>: Pregnant patients will be assigned a priority score based on the same framework used for non-pregnant patients. If a pregnant patient is at or beyond the usual standards for fetal viability, the patient will be given a two-point reduction, giving the patient a higher priority score.

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 feature. 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 when hospitals are operating under crisis standards of care, clinicians should still make clinical judgments about the appropriateness of critical care using the same criteria they use during normal clinical practice.

<u>STEP 2:</u> Make daily determinations of how many patients in 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 to priority groups is designed to allow triage officers to create operationally clear priority groups where patients 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 patients in all other groups in the face of scarcity. Patients in the orange group have intermediate priority and should receive critical care resources. Patients in the yellow group have 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 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 substantially younger patients. In comparing ages of patients, the following

categories can serve as guidance: ages 0-17, ages 18-40, ages 41-60; ages 61-75; older than age 75. We also recommend that individuals who are vital to the acute care response (see other scoring considerations above) 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 she/he survives even with ventilator therapy, and triage decisions should be made accordingly. See Appendices 1 and 2.

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 palliative care, 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 treatment should be continued.

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 critical care resources.

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 become 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 also be made available to families.

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Appendix 1: Neonatal Ventilator Resource Allocation in Crisis Level Care

This policy applies to children less than or equal to thirty (30) days of life. For children older than thirty (30) days, refer to the Pediatric Ventilator Resource Allocation in Crisis Level Care appendix. While crisis standards of care are in effect, only current clinical needs of the Neonatal ICU will be supported and any inventory in reserve will be used for crisis needs. Neonates born outside of designated Pediatric centers during a declared crisis should be transported to appropriate Neonatal centers in accordance with non-crisis treatment pathways. After arrival at a Neonatal center, appropriate allocation of resources in accordance with this document may occur.

Absence of categorical exclusion criteria: A central feature of this neonatal appendix, like the overall 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.

It is important to note that there are some conditions that lead to immediate or near-immediate death despite aggressive therapy. Under these circumstances, clinicians do not provide critical care services (e.g., cardiac arrest unresponsive to appropriate neonatal resuscitation protocols (NRP) or pediatric advanced life support (PALS), intractable shock, etc.). 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 1: Neonatal Triage

Neonatal patients who are more likely to survive with intensive care are prioritized over patients who are less likely to survive with intensive care. Patients who do not have serious comorbid illness(es) are given priority over those who have illnesses that limit their survivability. In addition, the presence of life-limiting comorbid conditions, as determined by the primary care team, is used to characterize patients' longer-term prognosis. Guidelines for assessing these conditions are outlined below.

Existing neonatal clinical scoring systems require data that are only available *after* a patient has received medical intervention and therefore should not be used to determine prospectively which neonate would benefit from ventilator therapy. This differs from the adult clinical ventilator allocation protocol, which uses a clinical scoring system, SOFA (Sequential Organ Failure Assessment), to assess mortality risk to determine eligibility and priority for ventilator therapy. In addition, none of the existing scoring systems has been validated for triage purposes in neonates.

Until a neonatal clinical scoring system is developed and validated for triage use, physician judgment based on clinical expertise should be used to evaluate the likelihood of survival and whether a neonate is eligible for ventilator therapy. The strengths of physician clinical judgment outweigh its weaknesses. Physician clinical judgment consists of a structured decision-making process that carefully considers only specific clinical factors based on available medical evidence and not personal values or subjective judgments, such as quality of life. Although the clinical assessment does not provide a numerical score (unlike the adult protocol that provides a quantitative SOFA score), it offers an organized, rational framework to make allocation decisions in a uniform manner. Ideally, in order to make informed decisions, the attending physician and Clinical Triage Team, whose construct and function is defined in the main resource allocation document, should have experience providing care to neonates.

The attending physician's evaluation is based solely on clinical criteria, including the acute severity of a patient's current medical condition, the epidemiology of the disease causing the acute illness, and the existence and status of any severe underlying diseases or medical conditions (co-morbidities) that may hinder recovery. Mortality risk prediction is based on whether a patient could survive the acute medical episode that necessitates ventilator therapy. It is not focused on whether a patient survives in the long-term (e.g., years after the pandemic). Physicians should use all appropriate and available medical tools to conduct the most thorough examination possible in emergency circumstances. Given the potential constraints associated with a pandemic and crisis standards of care, mortality risk predictions should be based on the best clinical evidence available.

Physicians may also consider severe, end-stage chronic medical conditions when assessing mortality risk. The presence of comorbidities complicates a patient's ability to survive and may also cause the patient's acute illness (e.g., COVID-19 infection) to be more severe. However, existence of such a condition(s) should not, by itself, preclude a patient from being eligible for ventilator therapy. Instead, physicians should assess a patient's overall health to evaluate the patient's current health status. Even for a patient diagnosed with an expected fatal condition, periods of relatively good health are possible and the mere presence of a grave illness should not necessarily preclude the patient from receiving ventilator therapy. In some circumstances, a patient with a severe medical condition may require ventilator therapy because of the acute illness and not because of the chronic disease itself.

While there is a reluctance to incorporate resource utilization as a primary decision triage criterion, such as estimated duration of ventilator need as a stand-alone (primary) triage factor, accurately predicting the estimated length of time a patient may need a ventilator may be useful to identify ideal patients for this intervention so that ventilators could be utilized by as many people as possible who have a high likelihood of survival.

When assigning a color code (in the classification system described below) to a neonatal patient, the clinical triage team, as outlined in the main resource allocation document, will consider the patient's acute clinical condition as well as comorbid disease(s), which may result in immediate or near-immediate mortality even with aggressive therapy. A list of significant medical conditions, which would lead to a differentiation of the patient into the yellow category (no ventilator provided), is listed below. Patients who are not triaged to receive ventilation will receive medical care that includes intensive symptom management and psychosocial support to the patient and family. 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.

Medical Conditions that Contribute to Limitation of Life and/or to Immediate or Near-Immediate Risk of Mortality Even with Aggressive Therapy in a Neonatal Patient

- 1. Cardiac arrest not responsive to neonatal resuscitation protocols (NRP) interventions within ten (10) minutes of appropriate resuscitation efforts.
- 2. Recurrent cardiac arrest, without interval hemodynamic stability .
- 3. Irreversible age-specific hypotension unresponsive to fluid resuscitation and vasopressor therapy.
- 4. Severe brain injury with no motor response to painful stimulus, moribund.
- 5. Lethal organ dysplasia, such as agenesis of the kidneys or hypoplasia of the lungs.
- 6. < 23 weeks gestational age, based on best available dating.
- 7. < 400 grams birth weight (14 ounces).
- 8. Any other conditions resulting in immediate or near-immediate mortality even with aggressive therapy.

The primary care team would assign a color code according to the Guide below, based on clinical assessment and the criteria above:

Mortality Risk Assessment Using Physician Clinical Judgment		
Color Code and	Assessment of Mortality Risk/Organ Failure	
Level of Access		
	MODERATE risk of mortality, such as single	
Red	organ failure, associated with acute illness/injury	
	(including epidemiology of the disease, if	
Highest	known)	
	and	
Use ventilators as available	NO severe chronic comorbidity likely to worsen	
	mortality risk or duration of ventilator treatment	
	beyond that typical for the acute illness/injury	
	HIGH/UNCERTAIN risk of mortality associated	
Orange	with acute illness/injury (including epidemiology	
	of the disease, if known)	
Intermediate	and	
	Presence of MODERATE chronic comorbidity	
Use ventilators as available	likely to worsen mortality risk or duration of	
	ventilator treatment beyond that typical for the	
	acute illness/injury	
Velleur	HIGHEST risk of mortality associated with acute	
Yellow	illness/injury (including epidemiology of the	
No vertileter provided	disease, if known)	
No ventilator provided	and Broconce of SEV/ERE abronic comorbidity likely	
Use alternative forms of medical intervention	Presence of SEVERE chronic comorbidity likely to worsen mortality risk or duration of ventilator	
and/or palliative care or discharge	treatment beyond that typical for the acute	
and/or pailative care or discridige	illness/injury	
Reassess if ventilators become available	iiii 033/iiijury	

Physicians may also consider severe, end-stage chronic medical conditions when assessing mortality risk. However, the extent of functional health impairment, rather than the medical diagnosis itself, should guide decision-making when evaluating a patient's current health status. The mere existence of such a condition(s) should not, by itself, preclude a patient from being eligible for ventilator therapy. Examples of severe chronic conditions that adversely impact health functionality include, but are not limited to, Trisomy 13 and 18, anencephaly, and high thoracic meningomyelocele.

When examining chronic comorbidity, severe comorbidity is functionally defined as significant chronic impairment/deterioration of health prior to the acute illness/injury. Moderate comorbidity is functionally defined as significant chronic impairment of health with a steady health state prior to the acute illness/injury.

While the neonatal clinical ventilator allocation protocol applies to all patients in need of a ventilator, a patient may also have a comorbidity(s) that affects another organ system(s) and his/her mortality risk. Intubation for control of the airway (without lung disease) is not considered lung failure.

However, based on the cumulative impact of comorbid processes, the more severe a patient's health condition is based on the clinical factors delineated above, the less likely s/he will survive, even with ventilator therapy. Therefore, triage decisions should be made accordingly.

If there arises a situation where there are several neonatal patients in the red color code, and there are insufficient ventilators to treat all patients, the patients will be randomly chosen to receive a ventilator in accordance with the Adult and Pediatric protocols.

Considerations and Approach in Clinical Reassessment for the Provision of Critical Care Services

The considerations and approaches for neonatal patients should follow those of adult patients as outlined in the main New Jersey Department of Health Allocation of Scare Critical Care Resources During a Public Health Emergency document. Appeals will occur in alignment with the main resource allocation document.

Step 2: Clinical Reassessment

In alignment with Step 2 of the main resource allocation document, the CMO or Chair of Pediatrics, or their designee, will make daily determinations of resource management and the need for ongoing triage and clinical reassessment of ventilated patients. These determinations will be made 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). Neonatal patients will be examined for organ failure/mortality risk based on three clinical variables described below. The decision whether to continue ventilator therapy for a patient is dependent on the trend of their health data from the clinical perspective as well as consideration of daily resource management. Reassessment decisions are made based on several factors including: (1) the overall prognosis estimated by the patient's clinical parameters, which is indicative of mortality risk including the presence (or likelihood), severity, and number of acute organ failures; (2) the magnitude of improvement or deterioration of overall health, which provides additional information about the likelihood of survival with ventilator therapy; and (3) availability of critical care resources discussed above.

The clinical parameters appear below. The bold line separates the "primary" clinical variables from the "secondary" factors.

Clinical Framework (3 Variables) Used to Evaluate a Patient for Continued Ventilator Treatment		
Clinical Variable	Ranges	
Oxygenation Index (OI) ^{1, 2}	< 20 (Best)	
OR	20 – 40 (Intermediate)	
Arterial Oxygen Saturation ^{2, 3}	> 40 (Worst)	
	OR	
	> 88% (Best)	
	80 – 88% (Intermediate)	
	< 80% (Worst)	
Hypotension	Adequate circulation, with no vasoactive drugs	
	(Best) Adequate circulation, with vasoactive drugs	
	(Intermediate)	
	Hypotension, with vasoactive drugs (Worst)	
Serum Creatinine (mg/dL)	< 1 (Best);	
	1 < 3 (Intermediate);	
	> 3 (Worst)	

¹ OI = mean airway pressure (MAP) x fraction of inspired oxygen (FiO2) x 100 / partial pressure of oxygen in arterial blood (PaO2). (PaO2 may be estimated from peripheral oxygen saturation by using the oxygen dissociation curve if blood gas measurements are unavailable.)

² The absolute values of OI and arterial oxygen saturation are not easily interpretable if a patient has cyanotic congenital heart disease, but the trends may be. The site of the OI or arterial oxygen saturation measurement should be preductal if possible, otherwise, postductal is acceptable. In the newborn, preductal is the right arm.

³ If unable to obtain OI, arterial oxygen saturation may be used. Comparing current saturation to baseline saturation may be important.

Criteria for each color code at each clinical reassessment are presented below.

Clinical Reassessment Tool Ventilator Time Trials ¹		
Color Code and Assessment of Mortality Risk/Org Level of Access (Examining Six Clinical Variation		
Red Highest Use ventilators as available.	MODERATE risk of mortality and Pattern of significant improvement of overall health compared to the initial assessment	
Orange Intermediate Use ventilators as available.	HIGH / UNCERTAIN risk of mortality and No significant change or slight deterioration in overall health compared to the initial assessment	
Yellow No ventilator provided ¹ Use alternative forms of medical intervention and/or palliative care or discharge. Reassess if resources become available	HIGHEST risk of mortality and Pattern of significant deterioration (or no change ²) of overall health compared to the initial assessment	
Green	LOW risk of mortality	

Use alternative forms of medical intervention or	and
defer or discharge from protocol	No longer ventilator dependent /
Reassess as needed	Actively weaning from ventilator

1 If there is another patient in need of a ventilator, this patient would be removed from the ventilator and provided with alternate forms of medical intervention and palliative care. The Clinical Triage Team will make this decision.

2 The patient remains significantly ill.

Escalation of care and Extracorporeal Membrane Oxygenation (ECMO) considerations:

The use of ECMO (where available) will be decided on an individual basis by the Clinical Triage Officer (with input from the Attending Neonatologist and ECMO Director) based on prognosis, suspected duration of ECMO, the availability of personnel and other resources. Patients should have a high estimated likelihood of survival and a predicted ECMO course of less than 10 days as resources allow.

Appropriate clinical care of patients who cannot receive critical care:

Patients who are not eligible for critical care treatment should receive medical care including intensive symptom management and psychosocial support, which includes support of the family. 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 and multi-disciplinary support.

References

- Interim Pennsylvania; Crisis Standards of Care for Pandemic Guidelines, April 10, 2020, Version 2, Produced in cooperation with Pennsylvania Dept. of Health
- University of Pittsburgh, Department of Critical Care Medicine School of Medicine, April 15, 2020; Allocation of Scarce Critical Care Resources During a Public Health Emergency
- Ventilator Allocation Guidelines; New York State Task Force on Life and the Law, New York Department of Health, November 2015

Appendix 2: Pediatric Ventilator Allocation in Crisis Level Care

This policy is inclusive of children greater than thirty (30) days of life to the day prior to eighteen (18) years of life (up until, but not including the eighteenth (18th) birthday). For children less than thirty (30) days, please refer to the New Jersey State Neonatal Ventilator Resource Allocation in Crisis Level Care appendix.

Absence of categorical exclusion criteria: A central feature of this pediatric appendix, like the overall 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.

It is important to note that there are some conditions that lead to immediate or near-immediate death despite aggressive therapy. Under these circumstances, clinicians do not provide critical care services (e.g., cardiac arrest unresponsive to appropriate neonatal resuscitation protocols (NRP) or pediatric advanced life support (PALS), intractable shock, etc.). 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 1: Pediatric Triage

Ventilator-Dependent Chronic Care Patients

All pediatric acute care patients who need ventilator therapy, including those currently using a ventilator, are subject to the pediatric clinical protocol. Similar to the adult policy, pediatric patients using personal ventilators in chronic care facilities or at home will continue to utilize those ventilators and those ventilators will not be considered for allocation under this protocol. These patients will not be included in this policy unless they require transfer to an acute care facility and also require a more advanced ventilator, in which case, she/he is evaluated by the same criteria as all other pediatric patients who require a ventilator. Under crisis standards of care, only current clinical needs will be supported and any spare ventilator inventory in reserve will be reallocated for crisis needs.

Inclusion in Protocol

Patients must have at least one of the following inclusion criteria for consideration under the policy:

- 1) Requirement for mechanical ventilator support
 - a. Refractory hypoxemia (SpO2 <0.90 on non-rebreather mask or FiO2 > 0.85)
 - b. Respiratory acidosis (pH < 7.2)
 - c. Clinical evidence of impending respiratory failure
 - d. Inability to protect or maintain airway
- 2) Hypotension * with clinical evidence of shock**
 - a. Refractory to volume resuscitation
 - b. Requires vasopressor and/or inotropic support

*Hypotension: Systolic BP: Patients age> 10 = <90 mm Hg; Patients 1 year to 10 years old = <70 + (2 x age in years); Infants < 1 year old = <60 mmHg; Relative hypotension

** Clinical Evidence of Shock= altered level of consciousness, decreased urine output, or other evidence of end organ failure

Pediatric patients who are more likely to survive with intensive care are prioritized over patients who are less likely to survive with intensive care. Patients who do not have serious comorbid illness(es) are given priority over those who have illnesses that limit their survivability. In addition, the presence of life-limiting comorbid conditions, as determined by the primary care team, is used to characterize patients' longer-term prognosis. Guidelines for assessing these conditions are outlined below.

A majority of the most common pediatric clinical scoring systems require data that are only available *after* a patient has received medical intervention and therefore should not be used to determine prospectively which Pediatric patient would benefit from ventilator therapy. This differs from the adult clinical ventilator allocation protocol, which uses a clinical scoring system, SOFA (Sequential Organ Failure Assessment), to assess mortality risk to determine eligibility and priority for ventilator therapy. In addition, the few systems that could be used at point of triage entry, such as SOFA, have not been validated for triage purposes in children.

Physician clinical judgment consists of a structured decision-making process that carefully considers only specific clinical factors based on available medical evidence and not personal values or subjective judgments, such as quality of life. Although the clinical assessment does not provide a numerical score (unlike the adult protocol that provides a quantitative SOFA score), it offers an organized, rational framework to make allocation decisions in a uniform manner. Ideally, in order to make informed decisions, the attending physician and Clinical Triage team, whose construct and function is defined in the main document, should have experience working with critically ill children.

When assigning a color code (in the classification system described below) to a Pediatric patient, the clinical triage team, as outlined in the main resource allocation document, will consider the patient's acute clinical condition as well as comorbid disease(s), which may result in immediate or near-immediate mortality even with aggressive therapy. A list of significant medical conditions, which would lead to a differentiation of the patient into the yellow category (no ventilator provided), is listed below. Patients who are not triaged to receive ventilation will receive medical care that includes intensive symptom management and psychosocial support to the patient and family. 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.

Medical Conditions that Contribute to Limitation of Life and/or to Immediate or Near-Immediate Risk of Mortality Even with Aggressive Therapy in a Pediatric Patient

- 1. Cardiac arrest not responsive to pediatric advanced life support (PALS) interventions within twenty (20) minutes of appropriate resuscitation efforts
- 2. Recurrent cardiac arrest, without interval hemodynamic stability
- 3. Irreversible age-specific hypotension unresponsive to fluid resuscitation and vasopressor therapy
- 4. Traumatic brain injury with no motor response to painful stimulus
- 5. Burns > 91% of body surface area for children less than 2 years of age
- 6. Ranchos Los Amigos score of 4 or below (<u>https://www.neuroskills.com/education-and-resources/rancho-los-amigos-revised/</u>)
- 7. Any other conditions resulting in immediate or near-immediate mortality even with aggressive therapy

The primary care team would assign a color code according to the Guide below, based on clinical assessment and the criteria above:

Mortality Risk Assessment Using Physician Clinical Judgment		
Color Code and Level of Access	Assessment of Mortality Risk/Organ Failure	
Red	MODERATE risk of mortality, such as single organ failure, associated with acute illness/injury (including epidemiology of the disease, if	
Highest	known) and	
Use ventilators as available		

	NO severe chronic comorbidity likely to worsen mortality risk or duration of ventilator treatment beyond that typical for the acute illness/injury
Orange	HIGH/UNCERTAIN risk of mortality associated with acute illness/injury (including epidemiology of the disease, if known)
Intermediate	and
Use ventilators as available	Presence of MODERATE chronic comorbidity likely to worsen mortality risk or duration of ventilator treatment beyond that typical for the acute illness/injury
Yellow	HIGHEST risk of mortality associated with acute illness/injury (including epidemiology of the disease, if known)
No ventilator provided	and Presence of SEVERE chronic comorbidity likely
Use alternative forms of medical intervention and/or palliative care or discharge	to worsen mortality risk or duration of ventilator treatment beyond that typical for the acute illness/injury
Reassess if ventilators become available	

Considerations and Approach in Clinical Reassessment for the Provision of Critical Care Services

The considerations and approaches for pediatric patients should follow those of adult patients as outlined in the main New Jersey Department of Health Allocation of Scare Critical Care Resources During a Public Health Emergency document. Appeals will occur in alignment with the main resource allocation document.

Step 2: Clinical Reassessment

In alignment with Step 2 of the main resource allocation document, the CMO or Chair of Pediatrics, or their designee, will make daily determinations of resource management and the need for ongoing triage and clinical reassessment of ventilated patients. These determinations will be made 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). Pediatric patients will be examined for organ failure/mortality risk based on the six clinical variables described below. The decision whether to continue ventilator therapy for a patient is dependent on the trend of their health data from the clinical perspective as well as consideration of daily resource management. Reassessment decisions are made based on several factors including: (1) the overall prognosis estimated by the patient's clinical parameters, which is indicative of mortality risk including the presence (or likelihood), severity, and number of acute organ failures; (2) the magnitude of improvement or deterioration of overall health, which provides additional information about the likelihood of survival with ventilator therapy; and, (3) availability of critical care resources discussed above.

The clinical triage team evaluates the ongoing clinical measures and data trends of a patient's health condition from the clinical perspective and assigns a color code (red, orange, yellow, or green) to the patient. It is possible that a patient may exhibit better outcomes for some clinical

variables, but not for others. In this situation, the physician should place more weight on the health data trends from the Ol/arterial oxygen saturation percentages, hypotension, and Glasgow Coma Scale Score factors (see below) because these are stronger predictors of mortality risk. It should be noted that the other clinical factors (whole blood/serum lactate, serum creatinine, or serum bilirubin/scleral icterus levels), which reveal whether a patient is experiencing multiple organ failure, while useful, should *never* be the *sole* reason to justify a triage decision involving withdrawing mechanical ventilation. The latter three variables may be more useful when deciding whether a patient who is eligible for continued ventilator therapy should be placed into the red or yellow color categories.

The clinical parameters appear below. The bold line separates the "primary" clinical variables from the "secondary" factors.

Clinical Framework (Six Variables) Used to Evaluate a Patient for Continued Ventilator Treatment		
Clinical Variable	Ranges	
Oxygenation Index (OI) ^{1, 2}	< 20 (Best)	
OR	20 – 40 (Intermediate)	
Arterial Oxygen Saturation ^{2, 3}	> 40 (Worst)	
	> 88% (Best)	
	80 – 88% (Intermediate)	
	< 80% (Worst)	
Hypotension	Adequate circulation, with no vasoactive drugs	
	(Best) Adequate circulation, with vasoactive	
	drugs (Intermediate)	
	Hypotension, with vasoactive drugs (Worst)	
Glasgow Coma Scale Score4	> 8 (Best)	
(See Appendix 2 to calculate)	6 – 8 (Intermediate)	
	< 6 (Worst)	
Whole Blood/Serum Lactate (mmol/L)		
	< 3 (Best)	
Whole Blood/Serum Lactate (mmol/L) (consistently use same measurement)		
. ,	< 3 (Best) 3 – 8 (Intermediate)	
(consistently use same measurement)	< 3 (Best) 3 – 8 (Intermediate) > 8 (Worst)	
(consistently use same measurement)	 < 3 (Best) 3 - 8 (Intermediate) > 8 (Worst) < 1 year: < 0.6 (Best); 0.6 - 1.2 (Intermediate); > 1.2 	
(consistently use same measurement)	< 3 (Best) 3 – 8 (Intermediate) > 8 (Worst) < 1 year: < 0.6 (Best); 0.6 – 1.2 (Intermediate); > 1.2 (Worst)	
(consistently use same measurement)	< 3 (Best) 3 – 8 (Intermediate) > 8 (Worst) < 1 year: < 0.6 (Best); 0.6 – 1.2 (Intermediate); > 1.2 (Worst) 1 – 12 years: < 0.7 (Best); 0.7 – 2.0 (Intermediate); >	
(consistently use same measurement) Serum Creatinine (mg/dL)	 < 3 (Best) 3 - 8 (Intermediate) > 8 (Worst) < 1 year: < 0.6 (Best); 0.6 - 1.2 (Intermediate); > 1.2 (Worst) 1 - 12 years: < 0.7 (Best); 0.7 - 2.0 (Intermediate); > 2.0 (Worst) 	
(consistently use same measurement)	<pre>< 3 (Best) 3 - 8 (Intermediate) > 8 (Worst) </pre> < 1 year: < 0.6 (Best); 0.6 - 1.2 (Intermediate); > 1.2 (Worst) 1 - 12 years: < 0.7 (Best); 0.7 - 2.0 (Intermediate); > 2.0 (Worst) > 12 years: < 1.0 (Best); 1.0 - 3.0 (Intermediate); >	
(consistently use same measurement) Serum Creatinine (mg/dL) Serum Bilirubin (mg/dL) OR	 < 3 (Best) 3 - 8 (Intermediate) > 8 (Worst) < 1 year: < 0.6 (Best); 0.6 - 1.2 (Intermediate); > 1.2 (Worst) 1 - 12 years: < 0.7 (Best); 0.7 - 2.0 (Intermediate); > 2.0 (Worst) > 12 years: < 1.0 (Best); 1.0 - 3.0 (Intermediate); > 3.0 (Worst) 	
(consistently use same measurement) Serum Creatinine (mg/dL) Serum Bilirubin (mg/dL)	<pre>< 3 (Best) 3 - 8 (Intermediate) > 8 (Worst) </pre> < 1 year: < 0.6 (Best); 0.6 - 1.2 (Intermediate); > 1.2 (Worst) 1 - 12 years: < 0.7 (Best); 0.7 - 2.0 (Intermediate); > 2.0 (Worst) > 12 years: < 1.0 (Best); 1.0 - 3.0 (Intermediate); > 3.0 (Worst) < 3 (Best) 3 - 6 (Intermediate) > 6 (Worst)	
(consistently use same measurement) Serum Creatinine (mg/dL) Serum Bilirubin (mg/dL) OR	<pre>< 3 (Best) 3 - 8 (Intermediate) > 8 (Worst) </pre> < 1 year: < 0.6 (Best); 0.6 - 1.2 (Intermediate); > 1.2 (Worst) 1 - 12 years: < 0.7 (Best); 0.7 - 2.0 (Intermediate); > 2.0 (Worst) > 12 years: < 1.0 (Best); 1.0 - 3.0 (Intermediate); > 3.0 (Worst) < 3 (Best) 3 - 6 (Intermediate)	
(consistently use same measurement) Serum Creatinine (mg/dL) Serum Bilirubin (mg/dL) OR	<pre>< 3 (Best) 3 - 8 (Intermediate) > 8 (Worst) </pre> < 1 year: < 0.6 (Best); 0.6 - 1.2 (Intermediate); > 1.2 (Worst) 1 - 12 years: < 0.7 (Best); 0.7 - 2.0 (Intermediate); > 2.0 (Worst) > 12 years: < 1.0 (Best); 1.0 - 3.0 (Intermediate); > 3.0 (Worst) < 3 (Best) 3 - 6 (Intermediate) > 6 (Worst) OR No scleral icterus (Best)	
(consistently use same measurement) Serum Creatinine (mg/dL) Serum Bilirubin (mg/dL) OR	<pre>< 3 (Best) 3 - 8 (Intermediate) > 8 (Worst) </pre> < 1 year: < 0.6 (Best); 0.6 - 1.2 (Intermediate); > 1.2 (Worst) 1 - 12 years: < 0.7 (Best); 0.7 - 2.0 (Intermediate); > 2.0 (Worst) > 12 years: < 1.0 (Best); 1.0 - 3.0 (Intermediate); > 3.0 (Worst) < 3 (Best) 3 - 6 (Intermediate) > 6 (Worst) OR	

¹ OI = mean airway pressure (MAP) x fraction of inspired oxygen (FiO2) x 100 / partial pressure of oxygen in arterial blood (PaO2). (PaO2 may be estimated from peripheral oxygen saturation by using the oxygen dissociation curve if blood gas measurements are unavailable.)

² The absolute values of OI and arterial oxygen saturation are not easily interpretable if a patient has cyanotic congenital heart disease, but the trends may be. The site of the OI or arterial oxygen saturation

measurement should be preductal if possible, otherwise, postductal is acceptable. In the newborn, preductal is the right arm.

³ If unable to obtain OI, arterial oxygen saturation may be used. Comparing current saturation to baseline saturation may be important.

Clinical Reassessment Tool Ventilator Time Trials ¹		
Color Code and	Assessment of Mortality Risk/Organ Failure	
Level of Access	(Examining Six Clinical Variables)	
Red	MODERATE risk of mortality	
Highest	and	
Use ventilators as available.	Pattern of significant improvement of overall	
	health compared to the initial assessment	
Orange	HIGH / UNCERTAIN risk of mortality	
Intermediate	and	
Use ventilators as available.	No significant change or slight deterioration in	
	overall health compared to the initial assessment	
Yellow	HIGHEST risk of mortality	
No ventilator provided ¹	and	
Use alternative forms of medical intervention	Pattern of significant deterioration (or no	
and/or palliative care or discharge.	change ²) of overall health compared to the initial	
Reassess if resources become available	assessment	
Green	LOW risk of mortality	
Use alternative forms of medical intervention or and and		
defer or discharge from protocol	No longer ventilator dependent /	
Reassess as needed	Actively weaning from ventilator	

Criteria for each color code at each clinical reassessment are presented below.

¹ If there is another patient in need of a ventilator, this patient would be removed from the ventilator and provided with alternate forms of medical intervention and palliative care. The Clinical Triage Team will make this decision.

² The patient remains significantly ill.

Escalation of care and Extracorporeal Membrane Oxygenation (ECMO) considerations:

The use of ECMO (where available) will be decided on an individual basis by the Clinical Triage Officer (with input from the Attending Neonatologist and ECMO Director) based on prognosis, suspected duration of ECMO, the availability of personnel and other resources. Patients should have a high estimated likelihood of survival and a predicted ECMO course of less than 10 days as resources allow.

Appropriate clinical care of patients who cannot receive critical care:

Patients who are not eligible for critical care treatment should receive medical care including intensive symptom management and psychosocial support, which includes support of the family. 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 and multi-disciplinary support.

Criteria	Pediatric Patients	Score	Criteria Score
Best Eye Response	No eye opening	1	
(1 - 4)	Eye opens to painful stimulus	2	
	Eye opens to verbal command	3	
	Eyes open spontaneously	4	
Best Verbal Response	No verbal response	1	
(1 – 5)	Incomprehensible sounds	2	
	Inappropriate words	3	
	Confused	4	
	Oriented	5	
Best Motor Response	No motor response	1	
(1 – 6)	Extension to painful stimulus	2	
	Flexion to painful stimulus	3	
	Withdraws from painful stimulus	4	
	Localizes to painful stimulus	5	
	Obeys commands	6	
Total	Score (add three subscores, range	e from 3 to 15)	:

Additional Clinical Resources for Time Trials (Step 3) Glasgow Coma Scale

References

- Interim Pennsylvania; Crisis Standards of Care for Pandemic Guidelines, April 10, 2020, Version 2, Produced in cooperation with Pennsylvania Dept. of Health
- University of Pittsburgh, Department of Critical Care Medicine School of Medicine, April 15, 2020; Allocation of Scarce Critical Care Resources During a Public Health Emergency
- Ventilator Allocation Guidelines; New York State Task Force on Life and the Law, New York Department of Health, November 2015

Appendix 3: New Jersey Department of Health COVID-19 Professional Advisory Committee

This policy was prepared and revised over a three-month period by the New Jersey Department of Health COVID-19 Professional Advisory Committee (PAC), with input provided through meetings of the PAC Health Equity Subcommittee. Feedback was also obtained from the Medical Society of New Jersey Bioethics Committee, constituents, and legislators. The policy is adapted from a revised policy developed by the University of Pittsburgh, includes some different and additional content, and is in line with policies enacted in other jurisdictions.

NJDOH COVID-19 Professional Advisory Committee (as of summer 2020)

- Judith M. Persichilli, RN, BSN, MA, Commissioner, New Jersey Department of Health
- Eddy Bresnitz, MD, MSCE, FACP NJ DOH Medical Advisor and Professional Advisory Committee Chair; former NJDOH Deputy Commissioner and State Epidemiologist; Adjunct Professor of Epidemiology, Rutgers University School of Public Health
- Hon. Paul W. Armstrong, J.S.C. (Ret.), MA, JD, LLM, Senior Policy Fellow and Judge in Residence, Program in Health Administration, Edward J. Bloustein School of Planning and

Public Policy, Rutgers University and former Chairman of the New Jersey Bioethics Commission and the Governor's Council on AIDS.

- Cathleen Bennett, JD, MA, President and Chief Executive Officer, New Jersey Hospital Association; former NJDOH Commissioner
- Lawrence Downs, JD, Chief Executive Officer, Medical Society of New Jersey
- Margaret C. Fisher, MD, Infectious Disease Specialist, RWJBarnabas Health and Chair, Department of Pediatrics and Medical Director, The Unterberg Children's Hospital at Monmouth Medical Center, RWJBarnabas Health; Clinical Professor of Pediatrics, Rutgers University Robert Wood Johnson Medical School
- Robert C. Garrett, MHA, FACHE, Chief Executive Officer, Hackensack Meridian Health
- Brian Gragnolati, MBA, President and CEO at Atlantic Health System Immediate Past Chair, American Hospital Association
- Fred M. Jacobs, MD, JD, Executive Vice President, St. George's University, former Executive Vice President for Medical Affairs, Saint Barnabas Health Care System, former Commissioner, NJ Dept. Of Health and Senior Services
- Marc J. Levine, MD, President of Medical Society of New Jersey; President of Eastern Orthopaedic Association; Clinical Assistant Professor, Rutgers New Jersey Medical School; and Director Spine Surgery Program Robert Wood Johnson University Hospital/Hamilton
- Mary O'Dowd, MPH, Executive Director of Health Systems and Population, Rutgers Biomedical Health Sciences, Rutgers, The State University of New Jersey; former NJDOH Commissioner
- Barry H. Ostrowsky, JD, President and Chief Executive Officer, RWJBarnabas Health
- Annette Reboli, MD, Professor of Medicine and Dean, Cooper Medical School of Rowan University
- Judith E. Schmidt, MSN, DHA (c), RN, Chief Executive Office New Jersey State Nurses Association
- Marc M. Seelagy, MD, Pulmonologist, Allergy & Pulmonary Associates, P.A.; Medical Director of Critical Care Medicine, St. Francis Medical Center; and Medical Director of the Sleep Disorders Program, St. Francis Medical Center
- Michael E. Shapiro, MD, FACS, Associate Professor of Surgery, Rutgers University, New Jersey Medical School; Chair, Bioethics Committee, University Hospital
- Kevin J. Slavin, MHA, President and Chief Executive Officer, St. Joseph's Health; Chair of the Board of Trustees, New Jersey Hospital Association

Health Equity Subcommittee of the NJDOH COVID-19 PAC (as of summer 2020)

- Judith M. Persichilli, RN, BSN, MA, Commissioner, New Jersey Department of Health
- Michael E. Shapiro, MD, FACS, Associate Professor of Surgery, Rutgers University New Jersey Medical School; Chair, Bioethics Committee, University Hospital; and NJDOH PAC Health Equity Subcommittee Chair
- Fred M. Jacobs, MD, JD, Executive Vice President, St. George's University; former Executive Vice President for Medical Affairs, Saint Barnabas Health Care System; former Commissioner, NJ Dept. Of Health and Senior Services; and NJDOH PAC Health Equity Subcommittee Vice Chair
- Hon. Paul W. Armstrong, J.S.C. (Ret.), MA, JD, LLM, Senior Policy Fellow and Judge in Residence, Program in Health Administration, Edward J. Bloustein School of Planning and Public Policy, Rutgers University and former Chairman of the New Jersey Bioethics Commission and the Governor's Council on AIDS.
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- Elisa V. Bandera, MD, PhD, Professor and Chief, Cancer Epidemiology and Health Outcomes; Co-Leader, Cancer Prevention and Control, Rutgers University Cancer Institute of New Jersey; Professor of Medicine, Robert Wood Johnson Medical School
- Eddy Bresnitz, MD, MSCE, FACP, Medical Advisor and NJDOH Professional Advisory Committee Chair; former NJDOH Deputy Commissioner and State Epidemiologist; Adjunct Professor of Epidemiology, Rutgers University School of Public Health
- Damali Campbell-Oparaji, MD, Assistant Professor of Obstetrics, Gynecology and Women's Health, Division of General Obstetrics and Gynecology, Rutgers University New Jersey Medical School; President, New Jersey Medical Association
- Cynthia Y. Paige, MD, MBA, Family Physician, Summit Medical Group
- Karma Warren, MD, FAAEM, Assistant Professor of Emergency Medicine, Rutgers University, New Jersey Medical School; Chair, Community Engagement, Board Member, New Jersey Medical Association
- Patricia N. Whitley-Williams, MD, Professor of Pediatrics, Chief, Division of Allergy, Immunology and Infectious Disease, Department of Pediatrics, Associate Dean for Inclusion and Diversity, Rutgers University Robert Wood Johnson Medical School

Neonatal/Pediatric Sub-Advisory Committee

- Colin R. O'Reilly, DO, FAAP, FACOP, FCCM, Pediatric Critical Care, Pediatric Hospice and Palliative Care, and Bioethics Specialist; Assistant Vice President of Inpatient Medical Affairs, Children's Specialized Hospital
- Margaret C. Fisher, MD, Infectious Disease Specialist, RWJBarnabas Health and Chair, Department of Pediatrics and Medical Director, The Unterberg Children's Hospital at Monmouth Medical Center, RWJBarnabas Health, Clinical Professor of Pediatrics, Rutgers Robert Wood Johnson Medical School
- Patricia N. Whitley-Williams, MD, Professor of Pediatrics, Chief, Division of Allergy, Immunology and Infectious Disease, Department of Pediatrics, Associate Dean for Inclusion and Diversity, Rutgers University Robert Wood Johnson Medical School
- Michael Lamacchia, MD, Chair, Pediatrics, Attending Pediatric Infectious Diseases, St. Joseph's Children's Hospital
- Eddy Bresnitz, MD, MSCE, FACP Medical Advisor and Professional Advisory Committee Chair, former NJDOH Deputy Commissioner and State Epidemiologist, Adjunct Professor of Epidemiology, Rutgers University School of Public Health