

Allocation of Scarce Critical Resources under Crisis Standards of Care

University of California Critical Care Bioethics Working Group

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The UC Bioethics Working Group developed these guidelines carefully but expeditiously in the spring of 2020, given concerns for the potentially severe shortage of ventilators and other resources. We anticipate revising these guidelines over time based on public input, supply chain changes, population health outcomes and other aspects of the pandemic as it evolves. We are committed to maintaining a working document that reflects the principles and sensitivities of the people of California.

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Table of Contents

Executive Summary	6
I. Background	8
A. Purpose	8
B. Guiding Ethical Principles	8
C. Equality and the Application of Ethical Principles to Triage	10
II. Resource Allocation Principles and Application	11
A. Thresholds: When to Enact Crisis Standards and Implement Triage Allocation Plans	13
B. Triage and Prioritization: How to Implement Triage Allocation Plans	14
i. General Considerations	14
ii. Triage Officers and Teams	14
iii. Triage Review Committee	15
iv. Resource Availability and Allocation Priority	15
v. Communication of Triage Decisions to Patients and their Surrogates	16
vi. Appeals and Automatic Review	16
vii. Continual Reassessment of Crisis Conditions, Thresholds, and the Results of Allocation Policies	17
C. Special Patient Populations	18
i. Catastrophically ill patients not expected to survive	18
ii. Patients receiving solid organ transplants	18
iii. Immediate post-operative care of complex surgical patients	19
iv. Participants in clinical research studies	19
D. Supportive Care	20
i. Extending Palliative Care	20
ii. Iterative Clarification of Goals of Care	21
iii. Psychosocial Support	21
1. Patients and families	21
2. Health care workers	22
E. Ensuring Trustworthiness	22
i. Public Engagement and Transparency	22
Individual institutions	22
2. University of California Governance	24
ii. Alignment among UCs, CDHP, and the Public	25

III. Triage Decision Protocol Algorithm	25
A. Initial Triage Allocation Assessment	30
i. Patients Presenting to the Emergency Department	32
ii. Patients Presenting from the Hospital Ward	32
iii. Patients Already in Intensive Care Units at the Time of Crisis Declaration	32
B. Re-triage Allocation Assessments	32
C. Tiebreakers	34
D. Triage Code Status Orders	35
IV. Supply Chain and De-escalation of Crisis	36
V. Conclusions	37
Appendix 1: Review of Prior Research and Reports	38
Appendix 2: Evaluation of SOFA, Frailty scoring	44
Appendix 3: Ethical Controversies in Triage	48
Appendix 4: Worksheet for Examining Priority for Critical Workers	62
Appendix 5: Ventilation and Mortality Considerations with COVID-19 Patients	64
Appendix 6: Sample Guidelines for ECMO/ECLS Indications and Contraindications in Adult COVID-1 Patients	19 65
Appendix 7: Broader Community: Regional Coordination and Collaborating with Departments of Publ Health	lic 67
Appendix 8: Clinical Decision Support Tools for Triage Allocation	68
References	77
References for Assessment of Critical Care Survival Schema	80



Executive Summary

Introduction: The COVID-19 global pandemic has obligated hospitals worldwide to consider scenarios in which the demand for critical resources could outstrip the supply. This report, based upon the collaborative work of individuals representing the six medical campuses of the University of California, aims to articulate guidelines for the triage of critically ill patients in the event that essential resources, such as ventilators, become scarce. In such extreme scenarios, sound ethical principles represent the backbone of an allocation scheme predicated on saving the most lives while respecting human equality.

Respect for the moral equality and inherent dignity of each person—regardless of age, disability status, or other extraneous factors—requires that all individuals (including prisoners and undocumented persons) be included and evaluated in the same triage pool of individuals requiring treatment in acute care settings. Consistent with the central goal of saving as many lives as possible, triage decisions will be based on *medically relevant prognostic factors for surviving the acute critical illness*, rather than on quality of life, life-years, or social value considerations, which may be biased. Individuals already on ventilators in chronic care settings will not be triaged unless they present in acute care settings, and personal home ventilators belonging to patients will not be re-allocated to other patients.

This report applies to the situation when standard practice is replaced by Crisis Standards of Care and includes detailed sections on the following: resource allocation principles and application, the triage decision protocol algorithm, considerations for pushing the supply chain, and a number of essential supplemental resources and references.

Resource Allocation Principles and Application: Crisis Standards of Care (CSC) are applied when a health system is so overwhelmed by a public health event that critically ill individuals, who would normally receive any reasonable therapy, may receive limited treatment or non-traditional provision of care if system surge capacity is exceeded. Essential to CSC are the duty to plan and steward scarce resources while maintaining transparency, fairness and consistency. This includes developing a system of triage. All critically ill patients, not only those suffering from a specific public health emergency, are included in triage planning. In order to be prepared, activation of a triage plan should begin just prior to the point when a system exceeds surge capacity. This will allow for implementation of triage to go into effect at the time CSC is activated.

Each hospital should appoint a cohort of rotating Triage Officers who will implement triage decisions in key utilization areas (emergency departments and intensive care units). Triage Officers should be physicians with established expertise in the management of critically ill patients. The Triage Officer should be part of a Team, consisting of at least one other licensed health care professional and at least one administrative staff member who will conduct data-gathering activities. Triage officers and Teams are supported by a Triage Review Committee, which serves to adjudicate appeals and review all assessments that may trigger the reallocation of a potentially life-sustaining treatment. The Committee should make reasonable efforts to be representative of the community served by the hospital.

When a patient is being evaluated for possible admission or transfer to the ICU, the Triage Officer/Team will assign an allocation score, according to the detailed algorithm in Part III of this report.

This score will determine a patient's initial triage category to receive critical care services. The Triage Officer/Team and attending physician should collaborate to determine how best to communicate the results to the patient, family, or surrogate. Social work, spiritual care, and palliative care services should be available to assist patients and families in this process. The need for ongoing utilization of a crisis triage protocol should be continuously evaluated, and triage should be suspended immediately once critical resources are no longer scarce.

A Triage Decision Protocol Algorithm has been configured based upon the need for critical care, likelihood of benefitting from critical care and determination of an allocation score. This allocation score is based upon the Sequential Organ Failure Assessment tool (SOFA) and co-morbidities associated with low likelihood of short-term survival from a critical illness. Patients are then assigned to triage categories based on a multi-principle scoring scheme. Allocation of resources will then be based upon these groupings and resources currently available at the facility. Reassessment of individuals' allocation scores and available resources is iterative.

Supportive care and palliative care are integral to a system operating under CSC. Palliative care services may be stretched beyond their capacities during a crisis and challenged to provide direct comfort to families. Hospital leadership should plan to expand palliative care services in anticipation of CSC, and consider training allied health professionals to augment the work of traditional palliative care practitioners and those on the front lines providing psychological support.

Operating under CSC requires our health systems to ensure proper communication and transparency with the public and coordination with state and local public health officials. Crisis standards and this triage allocation algorithm should be communicated in a manner whereby all people have access to relevant information, with qualified interpreters as necessary. Respecting requests for religious accommodation and respecting the needs of persons with disabilities are essential for fairness, equity, and broad communication.

Pushing the Supply Chain and Final Points: UC Health must plan appropriately for allocation of scarce resources. A parallel process is also essential: continuation of aggressive measures to acquire needed equipment such as ventilators. These efforts include sharing information on inventories across the UC system in order to reallocate resources, exploring alternatives to single use invasive ventilation by gathering data on the utility and safety of non-invasive ventilation, and investigating the efficacy and safety of splitting ventilators between two patients.

This report reflects a concerted effort by our working group to create a just triage plan to save the most lives under CSC conditions. We are guided by principles of justice, a duty to plan, and a duty to steward scarce resources. We are confident that we will overcome this pandemic in solidarity with our community of Californians, and we maintain our commitment at the University of California to serve our patients with the highest standards of care.



I. Background

A. Purpose

The purpose of this report is to provide guidance about a triage management scheme for the allocation of scarce resources and to articulate its ethical underpinnings. The COVID-19 pandemic may lead to a crisis state during which demand exceeds the supply of resources of individual hospitals within the University of California system. Essential to emergency preparedness is the development of a just strategy for allocation of scarce resources in the event that hospitals exceed their surge capacity. Those resources may include ventilators, dialysis/continuous renal replacement equipment, extracorporeal membrane oxygenation (ECMO) devices, and personnel.

The goal during the COVID-19 pandemic, as in other pandemics, is to save the most lives. To that end, the guidelines developed in this report focus on assessing the likelihood of short-term survival benefit from mechanical ventilation in particular, although the principles and triage team structure can be applied to other scarce resources. This report outlines the guiding ethical principles, the structure of the triage team, an assessment instrument for resource allocation, and critical elements to support the triage framework. This process of triage and resource allocation must be fair and transparent, applied evenly and equitably across all people in need of scarce resources.

B. Guiding Ethical Principles

Public health emergencies may require difficult decisions in situations of extreme time pressure, limited resources, clinician strain, and broader social upheaval. It is vital that these decisions be guided by widely accepted and publicly endorsed ethical principles.

One of the most familiar frameworks for biomedical ethics centers around a few key principles.¹ Here we lay out those principles as well as some of their most important implications for public health crises:

- 1. <u>Beneficence and Non-Maleficence</u>.²³⁴ There is a duty to promote health and avoid harm. This general principle has several important corollaries:
 - a. <u>Duty to Care</u>. ^{5 6} Healthcare workers have a duty to care for patients in their charge, and patients should not be abandoned. Healthcare organizations have a reciprocal duty to support and protect healthcare workers, for example with adequate PPE.
 - b <u>Duty to Promote the Public Good</u>.³⁴ There is also a broader duty to promote the common good of the population as a whole, which includes the duty to save the greatest number of lives possible during a pandemic.³⁴
 - c. <u>Duty to Plan</u>:⁵⁷ There is a duty to plan for public health crises, including a duty to enact plans that prevent or mitigate resource shortages.
 - d. <u>Duty to Steward Scarce Resources</u>.⁵⁷ Once shortages occur, there is a duty to carefully steward scarce resources in order to save as many lives as possible.

- 2. <u>Respect for Persons</u>.²³⁴⁸ There is a duty to recognize and respect the inherent dignity and worth of each human being, as well as their moral equality. This general principle implies, among other things:
 - a. <u>Respect for Individual Rights and Freedoms</u>.⁴ Individuals have inherent rights and freedoms that must be respected, although it might be necessary to curtail some individual liberties during a public health crisis.
 - b. <u>Respect for Autonomy</u>. There is a duty to respect the decisions of autonomous individuals and to enable people to make reasoned and informed choices, whenever doing so is feasible during a public health crisis.
- 3. <u>Justice</u>. There is a duty to enact only those policies that are just. Justice has many aspects:
 - a. <u>Fairness and Consistency</u>. ^{2 3 5 6 8} Policies must be applied consistently across people and time, and any differences in treatment must be based on medically relevant differences among individuals. Decision makers must be neutral and strive to eliminate bias.
 - b. <u>Proportionality</u>.⁵ Crisis planning policies and restrictions must be appropriately limited in time and scale according to the scope and severity of the crisis.²
 - c. <u>Protection for Populations with Special Needs or Vulnerabilities</u>. Plans and decisions should take into account the special needs or vulnerabilities of certain populations.⁴
 - d. <u>Avoid Exacerbating Existing Disparities</u>.²³⁸ Decisions should not exacerbate existing disparities in health outcomes or access to healthcare.
 - e. <u>Duty to Collect Information</u>.²³⁸⁹ There is a duty to collect the full range of relevant facts before making decisions and to revisit decisions as new information emerges.
 - f. <u>Transparency</u>. ^{2 3 8} The public has a right to know what decisions were made, who made them, and the reasoning behind them.
 - g. <u>Public Involvement</u>.⁵ When feasible, input should be sought from people who stand to benefit from or be harmed by policies. When public participation is not feasible, responsible parties should seek to understand the perspectives of those affected by their decisions, including underrepresented or vulnerable communities.

In a severe crisis, these principles may be in tension, either with each other or with themselves. For instance, the obligation to provide a needed resource to the extremely ill may conflict with the need to promote the common good by giving those same resources to people who are more likely to survive. In such situations medical institutions must shift from their traditional focus on individual patients to a focus on populations, the common good, and the protection of civil society – that is, a shift to crisis standards of care.³ ¹⁰ As the National Academy of Medicine (formerly, Institute of Medicine) wrote, "Ultimately, this shift represents not a rejection of ethical principles but their embodiment." ¹⁰

There is no single formula for resolving every moral conflict, but following in the footsteps of various federal and state institutions, we will generally balance the competing needs in this way:

We seek to achieve the greatest medical benefit for the greatest number of patients, but only in ways that show proper respect for the intrinsic worth of each person, for the moral equality of all people, and for the requirements of justice.²⁸

Later sections of this document detail the rationale undergirding this general framework, its origin in the policies of state and local government, and the reasons for the specific policies endorsed in this document.

C. Equality and the Application of Ethical Principles to Triage

The previous section explained that the primary ethical guideline during a pandemic is to do the greatest medical good for the greatest number of people, but that this principle is constrained by the requirement to show proper respect for the moral equality of all people. Here we explain some of the important ways in which triage protocols must respect equality and human dignity. Appendix 3 discusses these in more detail, as well as additional ethical issues related to triage protocols.

<u>Equality the Default.</u> Triage protocols give priority to individuals who are most likely to survive. In making triage decisions, clinicians and other members of the Triage Team must therefore look at all factors that are relevant to prognosis for survival. The requirement to respect moral equality entails a strong presumption that other factors should not be used to triage patients. Any deviations from this rule (for example, priority for critical workers) must be shown to ultimately respect the moral equality of all people.

<u>The Goal of Objectivity.</u> In situations where the need for critical resources exceeds availability, allocation decisions should be determined by the difference that a resource would make on overall predicted survival of the acute episode, rather than on a first-come, first-served basis. In addition, triage protocols should be implemented using widely applied objective medical criteria, or expert opinion if such criteria are not available.²

<u>Prisoners and Undocumented Immigrants</u>. Reports from some public forums indicate that some citizens believe that prisoners and undocumented immigrants should be de-prioritized during triage, but this is not permissible.

<u>Application of Triage Protocols to All Who Need Scarce Resources.</u> When resources become scarce, some people who need those resources will be suffering from conditions related to the pandemic and others will be suffering from unrelated conditions. In such situations, triage protocols should be applied to all who need the scarce resource, not just those suffering from conditions related to the pandemic.

<u>Reallocation.</u> In a triage situation, there could be a patient who is already using a resource—e.g., a ventilator—and another patient who needs the same resource. If the second patient is more likely to survive on the ventilator than the first patient, the question arises of whether the resource should be reallocated to the second. Equality requires that reallocation be considered, and reallocation is permitted whenever indicated by the triage protocol, subject to (a) any legal constraints, and (b) the

additional protection of an automatic appeals review by the review committee in such cases, as described below.

<u>Disability and Return to Previous State of Health</u>. Some triage protocols make allocation decisions based not only on overall predicted acute-episode survival but also on quality of life after treatment. Such protocols are sometimes viewed with suspicion by individuals with disabilities, who fear that they are seen as having lower quality of life than non-disabled individuals and therefore that they will be assigned lower triage priority in virtue of their disabilities. To ensure non-discrimination against individuals with disabilities, triage protocols must either not score individuals based on their quality of life after treatment, or assess at most how far treatment will return the patient to *their own baseline* quality of life.

General Recommendation to Protect and Provide for Vulnerable Populations. Hospitals should take deliberate, active steps to ensure that vulnerable or marginalized populations receive equal access to scarce resources. These might include, among other things, (1) reaching out to organizations and services designed to serve groups with special needs or groups that are particularly vulnerable or disadvantaged; (2) ensuring access for those with disabilities, limited English language skills, and other groups with functional needs; (3) mitigating or eliminating, as far as possible, the sense of distrust that some historically disadvantaged people might feel toward the medical system in general or a triage system in particular; and (4) being prepared to participate in regional or statewide plans designed to ensure that the same resources are available and in use at similarly situated facilities—a step that helps mitigate or eliminate disparities of access and distribution among facilities. Allocation decisions should aim to align with national standards when feasible.

As noted earlier, these and other ethical issues related to triage are discussed at greater length in Appendix 3.

II. Resource Allocation Principles and Application

In a pandemic crisis, in spite of our best efforts to expand surge capacity, the number of patients needing care could exceed the resources available to treat them. In light of this, we need to proactively plan for a worst-case scenario, even as we make all efforts to maximize our resources. Some key points about those plans are listed below, and details are provided in the sections that follow. It is critical to keep in mind that any plan will be imperfect and will need to be adjusted as the crisis progresses.

<u>Crisis Standards of Care.</u> In the event we face a critical shortage of life sustaining therapies including ventilators, dialysis/CRRT, ECMO, ICU beds or personnel, we will need to transition to crisis standards of care (CSC). CSC are used when health care systems are so overwhelmed by a public health event that it is impossible to provide the normal, or standard, level of care to all patients. Critically ill individuals who normally would receive "any reasonable therapy," even therapies of unlikely benefit during a non-crisis situation, may receive limited treatment and non-traditional provision of care when hospitals exceed their surge capacity and adopt CSC. This is necessary to maximize the number of lives saved during a pervasive or catastrophic public health event such as a pandemic, even though it may increase the risk to the individual patient of a worse outcome.^{7 13}

CSC involve a plan for triage and allocation of scarce resources, and that plan is detailed in the sections that follow.

Scope of Crisis Standards. As detailed below, any triage system will need to include <u>all</u> patients in acute care settings, including non-COVID-19 patients. This applies to individual hospitals, but ideally it would also mean that all hospitals in a region would coordinate with the local or regional government (e.g., county public health officials) about when to activate CSC. The means of regional communication should be set up in advance. Coordinating with other hospitals in the region maximizes resources within the community and increases equity of care.

<u>Preparation</u>. The sections that follow detail the preparatory steps hospitals should undertake. Among other things, the hospital (and region, if appropriate) should preselect the Triage Officer(s) and Teams. The Triage Team should be appointed in such a way that the participants are never providing clinical care to triaged patients at the same time. Sub-specialties to be represented may include but are not limited to: Pulmonary Critical Care, Surgical Critical Care, Neurocritical Care, Burns, Trauma, and Cardiac Critical Care. Triage Officers should be available through the command center 24/7 for consultation on new patients. Emergent unexpected presentations requiring rapid decision making should follow the predetermined triage criteria set forth below. We recommend starting the process of triage scoring prior to exhausting resources so that when CSC are enacted, preparation for triage has already been completed.

<u>Communication</u>. As detailed below, it is imperative to communicate early with the community about the potential need for rationing of resources. The institution's communication officer should reach out to the media to help inform the region (resources for this are available in the attached Toolkit). Once the region has converted to CSC, patients and families—both those already admitted and those presenting for treatment—should be immediately informed of a region's conversion to CSC, including the use of triage. They should likewise be informed when clinical decisions are being made based on these standards.

<u>Fairness and Consistency.</u> Any process of tertiary triage and rationing must be fair and transparent applied evenly across all patients. Specific steps are detailed in the sections below. Among other requirements, there can be no perception of disparity that would erode trust in the system.¹¹ ¹² Tertiary triage will occur for patients already in the hospital in addition to those who are arriving to the emergency department. Triage criteria and specific limits of resources should be known to providers; a briefing is recommended at least daily during CSC. Frequent reassessment of prior triaging should occur regularly and with any significant changes in resources, for example loss or gain of staff, or an unexpected delivery of ventilators.



A. Thresholds: When to Enact Crisis Standards and Implement Triage Allocation Plans

During a pandemic or other public health crisis, frequent reports to the regional authority from each facility on the number of ventilators available and the number of patients potentially requiring mechanical ventilation within 24 hours will be necessary. Triage and allocation will be implemented if a hospital or region is confronted with a severe shortage of life sustaining treatments where all preventive and preparatory measures have been exhausted, including access to needed resources at other hospitals. Defined threshold triggers, which may vary according to local resources and circumstances, will be used to identify the need to start triage.

When infrastructure allows for this, the decision to initiate crisis triage should be made by an identified regional authority with situational awareness of regional health care demands and resources. ¹⁴ Specific levels of regional coordination will vary according to regional circumstances and institutions. Acknowledging this variation, it may also be appropriate for a designated hospital administrator to make the decision that a threshold has been reached and therefore crisis triage is in effect. Individual healthcare providers will not make individual decisions at the bedside to adopt CSC. ¹⁵

The National Academy of Medicine offers the following "Continuum of Care" framework for delineating thresholds for contingency standards and CSC: standards of care fall along a continuum of three levels, reflecting the incremental surge in demand relative to available healthcare resources:

- 1. Conventional care is everyday healthcare services.
- 2. <u>Contingency care</u> arises when demand for medical staff, equipment, or pharmaceuticals begins to exceed supply. Contingency care seeks functionally equivalent care, recognizing that some adjustments to usual care are necessary.
- 3. <u>Crisis care</u> occurs when resources are so depleted that functionally equivalent care is no longer possible. 16

Activation of triage plans should begin prior to the demand for critical care services exceeding resources. At 20% surge capacity (i.e., 20% over standard hospital capacity) standard of care can still be met; however, for most institutions to maintain standard care at 100% surge capacity, resources will need to be conserved, reused and/or substituted. Beyond 100% surge capacity standard treatment will likely change to crisis standards of care (CSC) due to limited resources such as ventilators. Hence, 80-90% surge capacity represents the threshold for activation of the triage plan in preparation for the need to allocate limited resources. It is important to reiterate that the transition to a CSC should be declared within a region by local health authorities. However, in some circumstances a hospital administrator may need to declare an internal CSC.

The goal is to start the process of triaging patients prior to resources being completely depleted. Ventilators and the staff required to operate them are likely to be a critical resource on which triage allocation will be based. This is based on knowledge of the current COVID-19 crisis and evidence from global experience with this disease. Patients fighting COVID-19 may need a ventilator for 21 days or longer.

Availability and demand for life saving resources must be assessed frequently during the triage process. This is required to identify changes in patient status and to allow reallocation of critical resources. Reassessment includes individuals who were previously deemed non-survivable or those who were not provided critical resources, based on improvement in their condition and/or improvement in available resources. Real-time information is important to allow constant feedback and reevaluation of crisis or contingency conditions.

B. Triage and Prioritization: How to Implement Triage Allocation Plans

i. General Considerations

The implementation of triage allocation plans will involve the following general considerations, described in more detail in the sections that follow:

- Triage allocation plans should only be invoked when the institution's operational mode converts to a CSC, as determined by institutional leadership and/or regional health authorities.
- All crisis allocation decisions should be made by a third-party Triage Officer or Triage Team.
 This will enable the attending physician and supporting clinicians to maintain the duty to care for the individual patient, with the standard goals of prolonging life and alleviating suffering, within the resource constraints imposed by the crisis.
- Triage decisions should be made solely on the basis of the uniform application of clear allocation criteria, detailed in Part III below. In general, any considerations other than those captured by the allocation criteria should not impact triage decisions.
- The results of triage decisions should be communicated to the patient and/or family, who should have an opportunity to understand the basis for the decision. Clinicians should document the disclosure and discussion with the patient/family in the medical record.
- Disagreements about the triage allocation decision should be adjudicated by a limited appeals process, described below.

ii. Triage Officers and Teams

The following can serve as models for <u>Triage Officer</u> and <u>Triage Team</u> composition, which can be adapted to local hospital circumstances as necessary. Triage Team establishment should be reviewed by the individual institution's Diversity and Inclusion Division or Officer.

Each hospital should appoint a cohort of rotating Triage Officers who will implement triage decisions in key utilization areas (e.g., emergency department, ICUs). Triage Officers should be physicians ideally with established expertise in the management of critically ill patients (such as Intensivists and Emergency Medicine physicians). They should possess strong leadership skills, and effective communication and conflict resolution skills. Ideally, senior faculty should be prioritized. Prior experience in emergency management training is also ideal. Triage Officers will oversee the triage process, assessing all patients who are candidates for the critical resource, assigning a level of priority for each, communicating with treating physicians, and allocating or re-allocating critical care resources to the highest-priority patients as described in the algorithm below. Hospitals might consider a process whereby Triage Officers are nominated by the chairs/directors of the clinical departments or divisions that provide care to critically ill patients, and approved by the Chief Medical Officer and the individual(s) responsible for emergency management.

Where personnel resources permit, the Triage Officer should be part of a team, consisting of at least one other licensed health care professional (e.g., nurse and/or respiratory care practitioner) with acute care (e.g., critical care or emergency medicine) experience, and at least one administrative staff member who will conduct data-gathering activities, documentation and record keeping, and assist liaising with a hospital Command Center and patient placement/bed control. 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). Health systems are encouraged to work with their local health information technology offices to create tools to facilitate data collection and capture (e.g., tabulation of items used to calculate triage allocation scores) in the permanent medical record, as well as reporting these items to facilitate triage allocation decisions. Triage Team members provide information to the Triage Officer and help facilitate and support the triage decision-making process. A representative from hospital administration and/or hospital incident command center should be linked to the Triage Team, in order to supervise maintenance of accurate records of triage scores and to serve as a liaison with hospital leadership.

A roster of approved Triage Officers and team members should be maintained that is large enough to ensure around-the-clock availability, on short notice, with sufficient rest periods between shifts. Shifts should last no longer than 13 hours (to enable 30 minutes of overlap and handoffs on each end). Team decisions and supporting documentation should be recorded in the patient's medical record and reported daily to appropriate hospital leadership and the command center.

iii. Triage Review Committee

In addition to the Triage teams, institutions should develop a <u>Triage Review Committee</u> to serve four functions: (1) adjudication of any appeals of the initial triage decisions, (2) review of any allocation assessment that triggers the *reallocation* of a potentially life sustaining treatment, (3) review of any allocation assessment concerning an unrepresented patient, and (4) ongoing oversight and review of triage processes, crisis conditions, and need for modification.

The Triage Review Committee should ideally include representation from: Triage Officers and Teams, the Chief Medical Officer/Chief Nursing Officer, Bioethics, Legal Affairs, Diversity and Inclusion, Critical Care, and Palliative Care. In addition, the Triage Review Committee should have representation consistent with the patient population being served. Institutions could consider including on the Triage Review Committee a lay community member that is not a member of the hospital's staff.

iv. Resource Availability and Allocation Priority

When determining a patient's initial allocation of a scarce resource, such as a ventilator, the following steps should be undertaken:

Assess current availability of resources. Resource allocation decisions in times of scarcity require an accurate, complete, and real-time working knowledge of available resources. As COVID-19 disease may result in severe respiratory failure due to ARDS, all relevant resources (e.g., ventilators, ICU rooms, medication, etc.) should be accounted for across an institution or region, twice daily in ideal circumstances, and no less than once per day.

Calculate allocation score and assign to triage category. When a patient is being evaluated for possible admission or transfer to the ICU, the Triage Officer/Team will assign an allocation score, according to the detailed algorithm in Part III below. This score will determine a patient's initial prioritization category to receive critical care services. When an unstable patient, who has not yet been triaged by the Triage Officer/Team, presents to critical care providers, immediate stabilization should proceed per usual standards of care. This may include ventilatory support, endotracheal intubation, and positive pressure ventilation, until the Triage Officer/Team is able to assess the patient and determine his or her allocation score.

With the exception of patients (or their surrogates) who elect to defer or decline particular interventions, there are no categorical exclusions to triage pool participation and triage assessment. Patients who either elect to defer or decline interventions or are not allocated critical care services will receive the most appropriate next level of available medical care, which always will include appropriate symptom management and palliative measures when indicated.

Determination of which allocation levels will receive services. The Triage Officer/Team, in consultation with the hospital incident command center or other appropriate administrators, will determine which allocation level(s) will receive limited resources, based on currently available resources. Individuals within the same category should be triaged by the methods described below.

v. Communication of Triage Decisions to Patients and their Surrogates

The Triage Officer/Team and attending physician should collaborate to determine how best to communicate the results to the patient, family, or surrogate. The optimal method of communication may vary depending on an attending physician's relationship with the affected person(s), the workload of the treatment team or triage team, and other factors. Social work, spiritual care, and palliative care services should be available to assist patients and families in this process.

A written, plain language explanation of the triage and appeals process should be provided to the patient and/or surrogate(s). Decisions should also be verbally explained clearly with supporting medical information in the patient or surrogate's native language, using medical interpreters as necessary. These patient and/or surrogate(s) communications should include:

- An explanation of how the triage decision was made and the limited appeals process
- An explanation of the medical facts supporting this decision in plain language
- An explanation of what could happen to the patient without critical care support
- The options available for ongoing treatment, including palliative care services
- An offer of referral for support services, including social work and spiritual care

vi. Appeals and Automatic Review

An appeals process of triage decisions is necessary to ensure fairness and equity. However, real-time appeals of triage decisions should be permissible only to ensure that the triage policy was followed appropriately (that is, to ensure the triage score was calculated correctly). Appeals contesting the allocation framework itself should not be considered. All appeals should be made to the Triage Officer/Team by the attending physician of record or other licensed health care worker (e.g., registered

nurse, respiratory care practitioner, clinical social worker) involved in the care of the patient in consultation with the attending physician. In deciding whether to request an appeal, the Attending Physician should take into account concerns voiced by the patient, family members, or other members of the clinical team.

Every allocation decision (including initial assessment and reassessment) for an unrepresented patient (i.e. an individual who lacks decisional capacity and for whom there is no appropriate surrogate) should <u>automatically</u> be reviewed by the Triage Committee prior to assignment to an allocation level. Similarly, every case where a ventilator or other scare resource is to be reallocated should <u>automatically</u> be reviewed by the Triage Committee prior to reallocation.

For any appeal or automatic review, the Triage Review Committee will independently evaluate for catastrophic conditions and re-calculate the score, based on a review of all relevant information. All appeals and reviews should be resolved expeditiously (ideally within 30 minutes of the request). Results of the review should be communicated to the attending physician, who should collaborate with the Review Committee members to determine how best to communicate the results to the health care team member requesting the review. Social work and spiritual care should be available to assist in communicating decisions to patients and families.

vii. Continual Reassessment of Crisis Conditions, Thresholds, and the Results of Allocation Policies

The need for ongoing utilization of a crisis triage protocol should be continuously evaluated, and triage should be suspended immediately once critical resources are no longer scarce. Institutions should consult with local health authorities regarding these decisions, which should be made in conjunction with hospital or health system leadership.

In addition, because widespread acute care triage would be novel, if this policy is implemented and triage teams perform allocation decision making over a prolonged time period, the institution should take steps to develop and deploy, in a timely way, a method of tracking the implementation of this policy, defining and describing quality performance of Triage Teams, and longitudinally analyzing their performance. This is likely to require allocating a quality analyst or individual with equivalent capabilities, to be overseen by appropriate institutional authorities, to process the data emerging from local triage team activities, so that it can be regularly reported to institutional authorities for the purposes of oversight. Data collection should include data on morbidity and mortality outcomes to assess trends by demographic factors such as gender, race and ethnicity, geographic location, or socioeconomic status.

At the conclusion of an emergency triggering crisis standards of care and implementation of the triage protocol, a formal report describing the institution's experience, patient outcomes, community response, and lessons learned should be developed and shared with providers, institutional leaders and governing authorities, patients, and the public. Feedback from these stakeholders should be utilized to evaluate and update, as appropriate, all aspects of the triage framework.



C. Special Patient Populations

i. Catastrophically ill patients not expected to survive

Certain new acute medical conditions may be so catastrophic or profound that the patient is at a very high (~90+%) risk of death in the acute setting. In non-crisis circumstances, some patients in these categories might survive with extensive and aggressive intervention, although it is not possible to predict which specific patient will do so. Existing illness or injury severity scoring systems were not specifically designed for triage situations that would involve prioritizing patients for care; however, in a crisis situation it is reasonable to employ them to prioritize allocation of dramatically limited critical care resources because they are better suited than alternative methods for an emergency clinical triage protocol. Such clinical scoring systems allow for real time decision making that avoids allocating scarce resources to those extremely unlikely to benefit. They are objective, reproducible, and provide transparency regarding severity evaluation by providing a validated assessment of those least likely to survive in the short term, even with aggressive treatment.

Patients who have a catastrophic condition but who receive intubation prior to initial evaluation (for example, pre-hospital intubation during cardiac arrest, urgent intubation in the emergency department prior to imaging diagnosis of severe stroke or traumatic brain injury) will be re-evaluated within 1 hour after hospital arrival in order to determine whether or not critical care resources should be continued based on their prioritization. As detailed further in the triage algorithm (below, Part III), all patients including these are considered eligible for critical care resource allocation during crisis. Patients with an acute catastrophic condition will be included in the Blue category (lowest priority for critical care resources due to extremely high risk of death).

ii. Patients receiving solid organ transplants

Prioritization of patients after or listed for transplant of heart, lung or liver include special considerations.

Overall, transplant patients have a high degree of clinical instability with a disproportionate probability of good outcome, including long term outcome if they are transplanted. The working group debated this extensively, and the degree of uncertainty around the timing of a transplanted organ made it difficult to justify adjustments for patients who are listed but who have not yet received an offer for organ transplantation.

For those who have an active offer under consideration by the transplant team, where the patient is the primary recipient, it is reasonable to suspend triage decisions temporarily until the final decision on an organ offer is made (i.e., the procurement team has decided not to accept the organ or the patient receives a transplant). Patients whose offer is declined by the transplant team should re-enter the triage pool in the same position they were in previously. Should another new offer be received, the process would repeat.

For those who have been transplanted, their critical care needs in the immediate post-transplant period largely arise from the need for supportive care for successful engraftment of the donated organ. The time to achieve this varies by organ, but can be on the order of several days. Because of their excellent prognosis post-transplant with successful engraftment, this working group proposes allowing a

temporary suspension of triage rules for post-transplant patients, as detailed in the allocation algorithm in Part III below. Additionally, patients who are experiencing delayed graft function or graft failure within the first 90 days post-transplant should be treated as if they do not have end-stage organ failure when assessing their triage allocation score.

iii. Immediate post-operative care of complex surgical patients

Patients who undergo complex surgical procedures may have postoperative critical care needs that are largely due to the nature of the procedure and portend an otherwise excellent recovery prospect (e.g., cardiac procedure requiring temporary pacemaker insertion or transient circulatory support, staged abdominal surgery where the abdomen is left open). Because of this, we propose to make allowances for a temporary exemption for patients undergoing complex or staged surgical procedures that extend until a predefined period from the final operative procedure.

iv. Participants in clinical research studies

A fundamental principle of clinical research is the position of therapeutic equipoise—a state of uncertainty regarding the benefits and risks of the investigational intervention. Under conditions of equipoise, the potential benefit of an investigational intervention or drug should be thought of as equal to either usual care or placebo. As such, it is impossible to determine whether a study product will benefit an individual participant *a priori*; thus, an investigational study participant should not necessarily be prioritized over usual care for any individual patient.

Patients who participate in clinical research studies may also be critically ill. This illness could be due to the underlying medical condition for which the patient is enrolled in research (e.g., progression of disease in a patient with advanced end-organ disease or malignancy) or due to an agent being studied in the research study (e.g., efficacy or toxicity from a novel antiviral therapy used to treat an ailment such as COVID-19; efficacy or toxicity from a novel antineoplastic agent used to treat an underlying cancer). In any case, during a time of scarce critical care resources under a declaration of crisis standards of care, the resources needed to provide support for a critically ill research participant may be limited.

The principle of reciprocity for patients participating in studies related to the pandemic that caused the public health crisis might suggest the following: patients who are undergoing research that may ameliorate the crisis have assumed risks to themselves by participating in a trial; thus, it could be argued that these study participants could reasonably be afforded priority access to critical care resources. Additionally, the principle of the multiplier effect (see Appendix 3 for detailed discussion) might suggest that it would be reasonable to prioritize those who serve to test an intervention that could save lives and lead to a more rapid resolution of the public health crisis. Reallocating the provision of life-sustaining critical care resources away from study participants under the triage allocation decision process could also bias study results in the estimation of mortality outcomes.

However, there are important countervailing considerations, including concerns regarding undue *inducements* to participate in such research. Informed consent to participate in research by a participant or their surrogate is a central canon of human subject research ethics. Should participation in clinical research result in triage prioritization for life-sustaining treatment, this could unduly influence

or induce a decision to participate in a study with unknown risks. Furthermore, the crisis may aggravate the *vulnerable status* of participants experiencing significant economic duress due to a pandemic or disaster situation. Such individuals may be unduly influenced to participate in research due to provision of payment for care by the study sponsor(s).

Furthermore, in response to the reciprocity argument above, we point out that the principle of informed consent also implies that a patient or their surrogate has been made aware of and accepted the risk of potential adverse effects of treatment, including the potential that these adverse effects might not be mitigated by medical care, potentially resulting in morbidity or death. Taken together, there is significant concern with prioritizing research study participants, both in terms of disproportionate advantages for critical care resources and in terms of excessive inducements to consent. ¹⁷

This workgroup weighed these potential pros and cons of using clinical research participation status in triage allocation decisions and determined that, in light of the above considerations, participants in clinical research studies should not be afforded special consideration for critical care triage allocation decisions during a declaration of crisis standards of care.

D. Supportive Care

i. Extending Palliative Care

As the scope of the pandemic grows, and institutions are forced to change their operational mode to crisis standards of care, the demand for primary and specialist palliative care will sharply increase. All of the public-facing documents that deal with the problem of responding to a pandemic emphasize the important role for palliative care in assisting with symptom management, decision-support, and emotional and spiritual support for patients and families.

Each UC health system has a program in specialist palliative care, though there is wide variation in the size and composition of programs across the UC systems. Similarly, most large non-academic health systems also have specialist palliative care providers, but overall access to palliative care is inadequate in many parts of the State. All medical practitioners are encouraged to embrace and practice "primary palliative care," particularly with the recognition that specialist palliative care practitioners are few in relation to need. The large number of hospital admissions and severity of disease in the COVID-19 pandemic will exacerbate this shortage.

In addition to challenges related to volume and personnel resources, the circumstances of COVID-19 will substantially alter the typical ways in which palliative care providers are able to support patients (e.g. being with patients, facilitating family meetings, providing decision support to patients and surrogates). Strategies for infection control, and for preservation of limited PPE, for example, will force hospital leaders and clinicians to devise creative and flexible approaches to ensuring the highest possible quality of care for the many patients who will die during the pandemic.

As early as possible, hospital leaders and palliative care teams should devise plans to accommodate the surge in demand for palliative care services and the adaptations that will be required to deliver those services, given the unique constraints posed by the circumstances of the pandemic. Such

strategies should take into account local on-the-ground strengths and resources, as well as leveraging partnerships with allied experts such as social workers, chaplains, pharmacists, and others to extend services as much as possible.

ii. Iterative Clarification of Goals of Care

To the extent possible, realistic goals of care should be established at the time of admission and reassessed with any significant change in clinical status. At a minimum, chart documentation should include identification of a health care proxy or surrogate medical decision-maker, contact information for this designated individual and alternate if available, identification of existing advance care planning documentation, and acquisition of copies for the chart. Completed POLST forms should be reviewed and included in the medical record. For patients at risk for escalation of care, such as older adults, those with significant cardiac or pulmonary comorbidities, and individuals with compromised immune systems, clarification of goals will be particularly important.

Since these guidelines recommend the reassessment of ventilator allocation decisions every 72 hours, communication with patients and families should emphasize the concept of a "time-limited trial," with clear markers of improvement that are assessed and used to inform the unfolding conversation about achievable goals. Conversely, interval events that further compromise outcomes should serve as opportunities for urgent reassessment of care goals and code status. Anticipated outcomes should be clearly articulated to the patient and families and anticipatory guidance be provided that aligns with care goals, or as necessary, resource allocation.

iii. Psychosocial Support

1. Patients and families

For critically ill and dying patients, contact with families and loved ones is often a vitally important component of care. Final conversations can promote acceptance of the severity of illness and provide a sense of closure and completion of relationships. The nature of medical care during the COVID-19 pandemic, however, upends all the normal modes of providing psychosocial support to seriously ill patients and their loved ones. Policies on infection control and visitor restriction, while necessary in this crisis, are likely to result in significant emotional distress for patients and families, strained decision-making for surrogates, and challenges with grief for the bereaved.

It is imperative and urgent that administrators, IT professionals, clinical leaders in social services, mental health, chaplaincy, palliative care, and other disciplines partner in devising novel, creative ways to maintain supportive communication and contact with patients and families, despite the limitations required for the pandemic response. In particular, for patients who are likely to die because of an unfavorable allocation score, skilled psychosocial support should be provided to convey continued care and concern for the patient and their loved ones. This communication may be provided in anticipation of, during, and following admission. Local or institutional grief support resources should be explored and, as available, provided to families and loved ones.

Frontline clinicians facing difficult communication tasks may benefit from COVID-specific conversation guides developed by palliative care experts.^{18 19 20} (See accompanying Toolbox for examples of resources for patients, families, and healthcare workers.)

2. Health care workers

Not only patients and families, but health care workers too, are likely to face significant moral distress and emotional fatigue in the dire circumstances of the pandemic. Many will need support above and beyond their routine strategies for emotional and physical self-care. Health system leaders should partner with local mental health experts (e.g. departments of psychiatry or clinical psychology, departments of social work, etc.) and existing internal support resources (e.g. employee assistance programs) to devise strategies to respond to and support health care workers in distress. (See accompanying Toolkit for examples.)

E. Ensuring Trustworthiness

i. Public Engagement and Transparency

The guiding principles in Part I stress that institutions must be transparent and engage with the public. Ideally, pandemic planning would take place well in advance, with strong public input. In the middle of a crisis, the most robust forms of public input might not be possible, but the values of transparency and public engagement still imply at least three concrete requirements. Institutional leaders must: use publicly-informed documents or guidance to shape the policies they develop, provide open and honest channels of communication with the public during the crisis, and seek meaningful public engagement to the extent possible, including after-the-fact review and revision of pandemic policies.

Regarding the use of publicly informed guidance, this document's policies and guiding principles were formulated using publicly informed policies, as detailed in Appendix 3. We include some further discussion of public communications and engagement in the sections below.

1. Individual institutions

Individual institutions must provide open and honest channels of communication with the public during a crisis. Since each UC Hospital and clinic serves a unique local population, communications must be tailored to meet the particular needs of local communities, including those populations that may be most vulnerable during a pandemic due to poverty, disability, access to healthcare, language or cultural differences, and other factors.

As part of those communications, each hospital should prepare patient education and staff education materials geared toward addressing the patient care and medical decision-making questions that may arise during the pandemic and during a period of scarce resources. (See Toolbox for examples.) As the Institute of Medicine wrote, "Transparency regarding limited resources forms a critical part of communication even before, but certainly during, a patient's hospital admission. Clinicians and facilities need to inform patients and families of the time-limited nature of trials of ventilator therapy and other

scarce resources." Patient education materials should include language translations for the various populations in the local catchment area.

Communications should also extend beyond each hospital and into the community, with the goal of communicating information about the pandemic crisis and triage plans. These public education efforts should be made also in relevant non-English languages, and should be coordinated with state and local public health officials ⁵ When relevant, institutions should make use of alternative communication channels (e.g., social media) in addition to the typical media sources.

During public communications, the type of information, specificity, and details should be tailored to the concerns and educational level of the target population. Messaging should include efforts to inform and provide resources to assist those populations with special needs, e.g., the elderly, impoverished or homeless individuals, those with physical disabilities, pregnant persons, children, those with mental illness or cognitive disability, those with pre-existing medical conditions or bedridden individuals, individuals with drug or alcohol use disorders, and those who are socially isolated and may have limited access to information.

In particular, UC Health entities should not overlook their obligations under federal civil rights laws to help ensure all segments of the community are served by:

- Providing effective communication with individuals who are deaf, hard of hearing, blind, and visually impaired through the use of qualified interpreters, picture boards, and other means;
- Providing meaningful access to programs and information to individuals with limited English proficiency through the use of qualified interpreters and through other means;
- Making emergency messaging available in plain language and in languages prevalent in the
 affected area(s) and in multiple formats, such as audio, large print, and captioning, and ensuring
 that websites providing emergency-related information are accessible;
- Addressing the needs of individuals with disabilities, including individuals with mobility impairments, individuals who use assistive devices or durable medical equipment, and individuals with immunosuppressed conditions including HIV/AIDS in emergency planning;
- Respecting requests for religious accommodations in treatment and access to clergy or faith practices as practicable.²¹

In addition, UC Health entities should consider adopting, as circumstances and resources allow, the following practices to help ensure all segments of the community are served:

- Making use of multiple outlets and resources for messaging to reach individuals with disabilities, individuals with limited English proficiency, and members of diverse faith communities; and
- Stocking facilities with items that will help people to maintain independence, such as hearing aid batteries, canes, and walkers²¹

As one part of the overall goal of fostering meaningful public engagement during the crisis, each hospital's Triage Team should be attentive to concerns expressed by patients and families both prior to and during the implementation period of the pandemic triage decision framework. Each hospital should have some mechanism in place to seek ongoing feedback from the local community impacted by this

triage policy. Results of these efforts should be shared both with local hospital leadership and with the UC Health Critical Care Bioethics Workgroup on a routine basis.

2. University of California Governance

In its role of overseeing one of the largest and most influential healthcare systems and research enterprises in California, the University's governance structure has a key role to play in educating Californians who may be impacted by these unanticipated changes and by the implementation of crisis standards of care policies. Constructive and transparent communication will require ongoing engagement and collaboration with the media, healthcare advocacy groups, other healthcare institutions in California and nationally, and other key stakeholders. These efforts should also include direct engagement with the community impacted by crisis standard of care policies.

Ensuring trustworthiness will require open and honest communication regarding the realities of resource limitations, the impact of the COVID-19 pandemic on the healthcare system, and its ability to provide the usual level of care that members of our community otherwise expect.⁵ University leaders and UC Health are also responsible for communicating the reasoning behind decisions to implement these crisis standards of care in pandemic emergencies.

When communicating with the public about that reasoning, University leaders and UC Health may draw on guidelines by the California Department of Public Health for healthcare surge during emergencies.⁴ These guidelines emphasize that "during a healthcare surge, the delivery of care will shift from individual-based to population based outcomes" and therefore, institutions will have to "consider a departure from the individual patient-based outcomes that physicians have been long conditioned to uphold in favor of an approach that saves the most lives."

Public communications should make it clear that, as the National Academy of Medicine (Institute of Medicine) report states, "crisis standards justify limiting access to scarce treatments, but neither the law nor ethics support the intentional hastening of death, even in a crisis." In this regard, communications can emphasize and clarify that this policy does not endorse the practice of euthanasia, and that physician assisted suicide for terminally ill patients (as permitted under California's End of Life Options Act) is entirely distinct from the allocation of scarce resources under crisis standards of care. Contrary to some mistaken characterizations in the media, triage decisions under crisis conditions do not amount to physicians "choosing who lives and who dies"; rather, the crucial triage decision is who will medically benefit most from allocation of scarce critical resources. In the process of triage allocation, no patient is abandoned or left without access to palliative or supportive care.

It is important that these communications begin early. The CDPH guidelines note, "Moving to a population-based set of treatment protocols represents a radical departure from patient-based decision making. It is essential that efforts be made well in advance of a healthcare surge to generate public understanding and acceptance for the change." This is sound advice. Californians have no historical reference point for the current Covid-19 pandemic: our State and the UC Health system have never in living memory encountered an analogous pandemic on this scale, nor have we encountered a natural disaster with the capacity to strain our statewide healthcare system to this extent.

University leaders should also seek community input into policies as the situation unfolds, seeking out dialogue with formal authorities, citizens at-large, and local opinion leaders.²² All parties should come away from this process understanding why crisis standards are necessary and how these standards will be applied within a community context.⁵ Establishing public trust will require open and honest communication regarding the realities of resource limitations, the impact of the COVID-19 pandemic on the healthcare system, and our ability to provide the usual level of care that members of our community otherwise expect.⁵

ii. Alignment among UCs, CDHP, and the Public

To uphold the principles of fairness and consistency, patients at different hospitals in the same affected area should not receive vastly different levels of care. Thus, each UC hospital and UC Health as a whole needs to coordinate planning, communication, and real-time pandemic response with local county public health agencies and the statewide California Department of Public Health's (CDPH) crisis triage plans.

Coordination is particularly important in order to maintain fairness for vulnerable populations. The IOM report notes that, "Consistent policies may also help eliminate unfair local efforts to discriminate against vulnerable groups on the basis of factors such as race or disability," and furthermore, "building trust is particularly important in more vulnerable populations, including those with preexisting health inequities and those with unique needs related to race, ethnicity, culture, immigration, limited English proficiency, and lower socioeconomic status."⁵

At the same time, efforts to keep policies consistent across institutions or geographic regions should not unduly limit the ability of institutions to adjust their response to the particular needs of the local community. While consistently employing the same pandemic triage decision framework, each UC institution should have sufficient ability to tailor its general response to this pandemic according to circumstances on the ground, taking sufficient account of its unique patient population and particular local circumstances. For individual institutions, "flexibility is necessary [in accord with local circumstances], but [this] requires careful deliberation and documentation where local practices do not follow common guidance."⁵

In summary, public engagement and communication should include efforts to solicit input from the local communities most impacted by decisions, while at the same time coordinating this with the interests of communities across the entire state. Transparency, clear communication, and accountability before, during, and following this pandemic are essential for building and maintaining the public's trust.⁵

III. Triage Decision Protocol Algorithm

This resource allocation schema (Figure 1) is developed to prioritize critical care services by using a ranking system to estimate the likelihood of survival of critical illness with ICU interventions. Crisis situations necessitate that critical care management shift from the practice of early transfer to intensive care units for signs of early decompensation to one of allocating critical care to the patients who have already decompensated and require life-sustaining treatment. If a patient is assessed as meeting criteria for the consideration of ICU care (see Table 1 for inclusion criteria), they will enter the triage

decision pool and assessment should proceed as described below. Goals of care are considered in all cases, as described in Part II above, and no patient who expresses that they would refuse critical care interventions should be placed in an ICU.

Critical care during crisis needs to be allocated first to patients most likely to survive their acute critical illness, in order to maximize the number of lives saved. As such, the next step would be to assess for an immediate catastrophic illness or injury that portends low likelihood of short-term survival (Table 2). These patients are not categorically excluded from critical care, but instead categorized at the lowest level, such that they could potentially still receive ICU care were sufficient resources available, but because of their extremely high risk of death, should be the last patients to receive critical care resources in a crisis situation of shortage.

Additionally, in service of the goal to maximize the number of lives saved in the acute care setting, the remaining patients will be evaluated using an aggregate, multi-modal scoring system that accounts for acute illness severity using the Sequential Organ Failure Assessment system score (SOFA)²³, with additional consideration for severe life-limiting comorbidities expected to affect near-term survival and moderately severe chronic comorbidities that can influence acute care outcomes (Table 3). Where available, primary data has been evaluated (see References for Assessment of Critical Care Survival Schema appendix), and where no or limited data are available, expert consensus from UC specialty physicians has been sought. Scoring systems when available are used, but for several conditions such as severe malignancy or severe baseline neurological impairment their presence should be assessed as major or severe.

For medical comorbidities and chronic conditions that limit short-term survival, this workgroup recommends the use of the list in Table 3; though as the crisis evolves, the criteria should be revisited and adapted to meet local needs. Clinical groups at the institution should define these severe conditions prospectively and not change them ad hoc from patient to patient. Any time the clinical criteria are modified, all patients assigned allocation scores should be reevaluated. Because comorbidities that limit survival exist across all major organ systems (e.g. cardiac, pulmonary, neurological, oncologic/hematologic, gastrointestinal/hepatology, etc.), none is excluded from comorbidity assessment due to special considerations (such as age or organ transplant status).

Figure 1: Resource allocation diagram by allocation score criteria

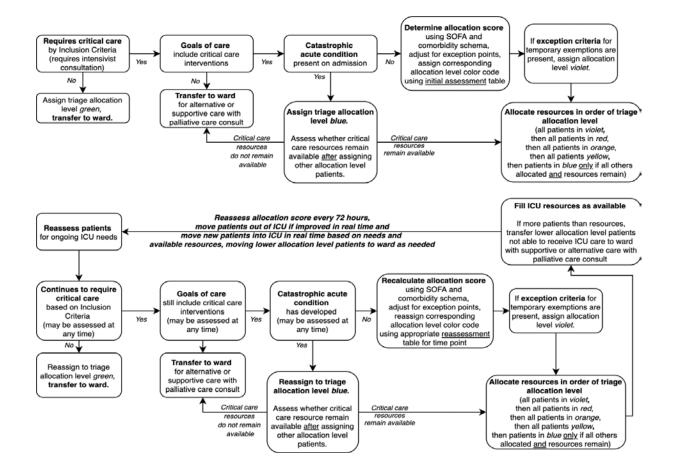


Table 1: Inclusion criteria for consideration of critical care

Patient has an acute medical condition that would potentially benefit from critical care		
Requires invasive mechanical ventilation	 Refractory hypoxemia (SpO2<90% on non-rebreather mask at flow of ≥15 LPM) Respiratory acidosis with pH < 7.20 on arterial blood gas Clinical evidence of respiratory failure Inability to protect airway 	
Requires vasoactive support for hypotension or unstable rhythm	 Systolic blood pressure < 90 mmHg with clinical evidence of shock (end-organ failure) refractory to volume resuscitation Unstable bradyarrhythmia refractory to electrolyte replacement Unstable tachyarrhythmia requiring vasoactive drip or cardioversion Requires mechanical circulatory support 	
Requires extracorporeal life support	Above criteria, plus assessment of acceptability by ECMO team	
Requires intensive neurologic monitoring or intervention	 Acute neurologic condition (e.g. intracranial/intraventricular hemorrhage, subarachnoid bleed with unsecured aneurysm, traumatic brain injury, or ischemic stroke with mass effect or acute hydrocephalus, severe CNS infection) with Glasgow Coma Scale < 13 Status epilepticus refractory to initial antiepileptic therapy Spinal cord injury at or above C5 with ASIA-A and B criteria²⁴ 	
Requires intensive interventions for trauma or major surgical condition	 Trauma causing significant instability or neurologic insult Post-operative condition with significant instability or requiring close critical care observation Post-operative from endovascular or thrombolytic management of high-risk (e.g., ST-elevation) myocardial infarction, stroke, or thromboembolic disease for first 24 hours post-event 	

Table 2: Catastrophic medical conditions with low likelihood of short-term survival present at presentation

procentation		
Refractory cardiac arrest	 Any unwitnessed out of hospital cardiac arrest without ROSC prior to arrival Any witnessed cardiac arrest with inability to obtain ROSC after 60 minutes from onset without a shockable rhythm present 	
Hypoxic-ischemic brain injury after cardiac arrest	Coma (inability to respond to verbal commands) after ROSC from cardiac arrest with non- shockable rhythm without confounding drugs, toxins, or metabolic derangements	
Severe burns	American Burn Association expected mortality ≥90% (Table 17 in Appendix 8)	
Severe trauma	Trauma Injury Severity Score predicting ≥90% mortality (Table 15 in Appendix 8)	
Severe neurological injury (rule out confounders to clinical assessment such as sedation, transient seizure, or treatable hydrocephalus)	 Non-traumatic intracerebral hemorrhage with max-ICH Score ≥ 9 (Table 20 in Appendix 8) Aneurysmal subarachnoid hemorrhage with HAIR Score = 8 (Table 21 in Appendix 8) Traumatic brain injury with ≥ 90% predicted death on IMPACT score²⁵ Coma in ischemic stroke with brainstem infarction due to basilar artery occlusion which is non-revascularized or without clinical improvement after revascularization. 	

N.B.: ROSC=return of spontaneous circulation, ICH=intracerebral hemorrhage; GCS=Glasgow Coma Scale

Table 3: Medical comorbidities and chronic conditions that limit short-term survival.

Major comorbidities that are associated with increased risk of short-term mortality from critical illness	Severely life-limiting comorbidities associated with high mortality even in absence of critical illness (survival typically ≤ 1 year), and which are correlated with significantly increased risk of short-term mortality from critical illness
 Pre-existing neurological condition (dementia, stroke, other neurodegenerative disease) with baseline modified Rankin Score ≥ 4 ACC/AHA Stage C heart failure, NYHA Class II-IV Severe, inoperable multi-vessel coronary artery disease or valvular disease WHO Class 3 pulmonary hypertension (symptomatic with minimal exertion, asymptomatic only at rest) Moderately severe chronic lung disease (e.g., COPD, IPF) but not requiring chronic oxygen or ventilation End stage renal disease on dialysis Cirrhosis with MELD <20 and history of prior decompensation 	 Minimally conscious or unresponsive wakeful state from prior neurological injury ACC/AHA Stage D heart failure WHO Class 4 pulmonary hypertension Severe chronic lung disease with FEV₁ < 20% predicted, FVC < 35% predicted, or in absence of PFTs, chronic home O₂ at rest or mechanical ventilation Cirrhosis with MELD score ≥20 Metastatic cancer with expected survival ≤1 year despite treatment Refractory hematologic malignancy (resistant or progressive despite conventional initial therapy) Terminal illness with Clinical Frailty Scale Score ≥8

N.B.: In the absence of appropriate expertise (which can include triage officer, backup officer, primary team, or rapid consultation) to evaluate, the patient is NOT docked for major comorbidities. Points for the items included in this table may be added to a patient at any time if they are discovered after admission to the ICU and reprioritization may be done as necessary.

It should be noted that these conditions appear on these lists only because they help predict short-term survival in critical illness: the fact that someone will, for example, have less than 5 year expected survival is <u>not alone a reason</u> to add triage points unless that fact correlates with short-term mortality. Moreover, among the conditions that correlate with reduced short-term survival, more priority points are assigned to those severely life-limiting comorbidities than to major comorbidities, since the former have a greater influence on short-term mortality than the latter, such that even in absence of critical illness they shorten survival.

Table 4: Multi-principle strategy to allocate critical care resources during crisis

Principle	Specification	Allocation Point System			
		1	2	3	4
Current Overall Clinical Status	Prognosis for acute survival (SOFA or MSOFA ²⁶ score)	SOFA score < 6 <u>or</u> MSOFA <6	SOFA score 6-9 <u>or</u> MSOFA 6-8	SOFA score 10-12 <u>or</u> MSOFA 9-11	SOFA score > 12 <u>or</u> MSOFA>11
Co-occuring conditions that moderate mortality	Co-occurring conditions that influence acute survival		Major comorbid condition(s)		Severely life-limiting condition(s)
Deductions see Ta	ble 5 below.				

Table 5: Special considerations for triage allocation: exemptions and point adjustments

Group	Initial Triage	First reevaluation	Second reevaluation	Reevaluations thereafter
Critical worker (see Appendix 3 for definition)	Exempt for 72 hours, then initial triage at that time as usual, start triage clock at time 0 and deduct 4 points	Deduct 4 allocation points	Deduct 2 allocation points	Deduct 2 allocation points
Pregnant person (If estimated gestational age ≥24 weeks; if intrauterine fetal demise or delivery, then triage as usual)	Triage as usual, deduct 4 points	Triage as usual, deduct 4 points	Triage as usual, deduct 4 points	Triage as usual, deduct 4 points
Pre-transplant, active organ offer	Exempt only during time offer being evaluated, start triage clock at time of pause	Triage as usual	Triage as usual	Triage as usual
Post-operative, complex non- transplant surgery	Exempt for 120 hours, then initial triage at that time as usual, start triage clock at time 0	Triage as usual	Triage as usual	Triage as usual
Post-operative, transplant surgery	Exempt for 240 hours, then initial triage at that time as usual, start triage clock at time 0	Triage as usual, treat as if severe life- limiting comorbidity is resolved regardless of graft function for 90 days	Triage as usual, treat as if severe life- limiting comorbidity is resolved regardless of graft function for 90 days	Triage as usual, treat as if severe life- limiting comorbidity is resolved regardless of graft function for 90 days

A. Initial Triage Allocation Assessment

During a crisis declaration, an initial triage assessment shall occur at the time each new patient is determined to potentially need critical care. Patients will be assessed by a consulting critical care physician to determine whether they meet the requirements for critical care (Table 1). Those not meeting the inclusion needs for ICU care are assigned triage category **green** and are not currently ill enough to require critical care. They should be reassessed as needed if their clinical status deteriorates.

The Triage Team will review each case referred for critical care for catastrophic illnesses and injuries with consultation from the appropriate specialists when needed (Table 2). Those deemed to meet these catastrophic criteria are assigned triage category **blue** and only allocated to critical care during crisis if there are still resources after every patient in the other triage levels (**red, orange, yellow, violet**) are allocated.

The Triage Team will then assign an initial allocation score based on the points system outlined in Table 4 by calculating SOFA scores (Table 10) and adding additional chronic illness points (Table 3)

and making any pertinent adjustments to the score for special considerations (Table 5). Patients in triage level **violet** are temporarily exempt (e.g., active transplant organ offer) from triage prioritization and will enter the schema once their temporary exception lapses. Patients who have a catastrophic condition that would assign them to category blue should not be superseded by exceptions and moved to the violet category.

A summary of the delineations of these triage categories for initial triage is found in Table 6. Patients shall be categorized for entry by assigning all of the patients in the top triage category (**red**) and if all patients are assigned at that level and resources remain, assigning all of the patients in the next triage category (**orange**), and then the lowest triage category (**yellow**).

Within triage categories, patients should be treated equally, since the discriminative ability of single point changes of SOFA score on predicting survival between patients is limited. Individual triage allocation points, therefore, should not be used to make a rank list for order of allocation of critical care, even within categories. Should resources be limited to the point where all patients in a particular triage category are not able to receive critical care, tiebreakers shall be used to determine which of the patients receive critical care. The method to determine how to allocate in ties is described further below.

Table 6: Initially assigning patients to triage categories using multi-principle scoring

Triage Categories	Assessment of Mortality Risk/Organ Failure
Red Highest priority for critical care services, higher likelihood of survival. Use life-saving resources as available.	Allocation Score 1-3
Orange Intermediate priority for critical care services, intermediate likelihood of survival. Use life-saving resources as available.	Allocation Score 4-6
Yellow Lower priority for critical care services, higher risk of death. Use life-saving resources as available.	Allocation Score 7-8
Green Critical care not currently needed due to clinical stability. Use alternative forms of medical intervention or defer or discharge. Reassess as needed.	No significant organ failure AND/OR No requirement for life- saving interventions
Blue Lowest priority for critical care services due to extremely high risk of death. Use alternative forms of medical intervention and/or palliative care or discharge. Reassess as resources become available.	Acute catastrophic condition (Criteria from Table 2)
Violet Temporary exemption from triage allocation scoring. Continue to use critical care resources until exemption lapses.	See criteria in Table 5



i. Patients Presenting to the Emergency Department

The working group recommends that whenever feasible, without compromising patient safety, emergency department physicians delay the initiation of critical care services (e.g., intubation) until an assessment is made by a critical care physician for inclusion criteria and by the Triage Team for assessment of catastrophic conditions and prioritization by calculating allocation scores. However, in patients too unstable to defer initiation, the working group recognizes that intervention should not be delayed. Patients who come to the hospital already receiving critical care interventions upon arrival to the emergency department (e.g., intubations in the field) should continue to receive those interventions until the Triage Team can evaluate their candidacy and triage category. It is likely not feasible for the Triage Team to coordinate with EMS to prevent these interventions from being given prior to arriving at the hospital.

ii. Patients Presenting from the Hospital Ward

Similar to the recommendation to defer initiation of critical care in the emergency department until a triage assessment is made, this working group recommends that patients on the hospital wards be delayed for initiation of critical care services until this evaluation is completed whenever feasible and without compromising patient safety. However, in situations where critical care cannot safely be delayed while this determination is made (e.g., code blue), critical care should be initiated immediately, and a triage assessment should be made as soon as possible about whether to continue critical care, ideally within an hour of initiation of critical care.

iii. Patients Already in Intensive Care Units at the Time of Crisis Declaration

All patients already admitted to intensive care unit beds shall have their initial triage category calculated, with the baseline time of entry as the time a crisis declaration was made. Any patient determined not to require critical care on the strict inclusion criteria (Table 1) shall be assigned to **green** and transferred to the ward, to be reassessed for critical care at any time should their condition deteriorate in the future. Those meeting any catastrophic condition criteria (Table 2) shall be assigned to **blue**, and critical care resources shall no longer be allocated unless all patients in other triage categories are assigned and additional resources remain. The remaining eligible patients shall be ranked by their triage category and beds assigned equally for preexisting ICU patients and those requiring entry de novo from the emergency department or ward.

B. Re-triage Allocation Assessments

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. The trial duration should be modified as appropriate if subsequent data emerge that suggest the trial duration should be longer or shorter. Centers should also adjust the reevaluation time window to their individual needs (e.g., if the 72-hour readjustments recommended here are not adequate to keep pace with the inflow of new patients, consider reducing to every 48 hour reassessments). For the initial duration of trials, this working group recommends reassessment every 72 hours.

According to the protocol recommended here, the triage category will be reassessed every 72 hours from the initial assessment and new categories assigned for changes in clinical status. Change in triage category to level **blue** should be made at any time if there is a catastrophic complication (Table 2) that would preclude critical care and need not wait until 72h reassessments. Additionally, patients should be assessed daily by the intensivist for their need for ongoing critical care and changed to level **green** if they no longer require intensive care.

The first 72-hour reassessment follows the schema in Table 7. Triage categories are assigned more strictly than at initial presentation, and any patient with significant clinical worsening determined by SOFA score would be categorized lower. The 144-hour assessment and each assessment thereafter follow the schema in Table 8, and the criteria for significant worsening are tighter.

Table 7: Multi-principle triage category first re-assessment (Hour 72)

Triage Categories	Assessment of Mortality Risk/Organ Failure		
Red Highest priority for critical care services, higher likelihood of survival. Use life-saving resources as available.	Allocation Score 1-3		
Orange Intermediate priority for critical care services, intermediate likelihood of survival. Use life-saving resources as available.	Allocation Score 4-6		
Yellow Lower priority for critical care services, higher risk of death. Use life-saving resources as available.	Allocation Score 7-8 OR Increase in allocation score of ≥ 3 points from increase in SOFA from any initial score¹		
Green Critical care not currently needed due to clinical stability. Use alternative forms of medical intervention or defer or discharge. Reassess as needed.	No longer ventilator dependent or actively weaning from ventilator AND/OR No longer in need of circulatory support/drips		
Blue Lowest priority for critical care services due to extremely high risk of death. Use alternative forms of medical intervention and/or palliative care or discharge. Reassess when resources become available.	Acute catastrophic condition (Table 2)*		
Violet Temporary exemption from triage allocation scoring. Continue to use critical care resources until exemption lapses.	See criteria in Table 5		
* If a patient develops a catastrophic condition (Table 2) before first reassessment, re-triage to blue			

Table 8: Multi-principle triage category re-assessment (Hour 144, then each 72h thereafter)

Triage Categories	Assessment of Mortality Risk/Organ Failure
Red Highest priority for critical care services, higher likelihood of survival. Use life-saving resources as available.	Allocation Score 1-3
Orange Intermediate priority for critical care services, intermediate likelihood of survival. Use life-saving resources as available.	Allocation Score 4-6
Yellow Lower priority for critical care services, higher risk of death. Use life-saving resources as available.	Allocation Score 7-8 OR Increase in allocation score ≥2 points from increase in SOFA since previous assessment¹
Green Critical care not currently needed due to clinical stability. Use alternative forms of medical intervention or defer or discharge. Reassess as needed.	No longer ventilator dependent or actively weaning from ventilator AND/OR No longer in need of circulatory support/drips
Blue Lowest priority for critical care services due to extremely high risk of death. Use alternative forms of medical intervention and/or palliative care or discharge. Reassess when resources become available.	Acute catastrophic condition (Table 2)*
Violet Temporary exemption from triage allocation scoring. Continue to use critical care resources until exemption lapses.	See criteria in Table 5
¹ Despite low or moderate previous score, patient has worsened significantly	

C. Tiebreakers

In the case of fewer critical resources available within a tier than beds available, tiebreakers should be implemented to determine the next allocated patients. This working group considered age, using the life-cycle principle, which is not based on social utility, but rather the justification that individuals should be afforded equal opportunity to pass through the stages of life from childhood, young adulthood, middle, then old age. There is public health precedent for such a determination in the allocation of influenza vaccines, and other studies of ethics and aging support it as well²⁷. However, after extensive discussion of this methodology, the working group believed that ethical problems as well as potential conflict with existing statutes precluded its use. Therefore, for individuals within the same triage

² If a patient develops a catastrophic condition (Table 2) before reassessment, re-triage to blue

category, if there are fewer resources than needed to allocate every patient within that triage level, allocation should proceed by random lottery. Likewise, determining discontinuation of ventilators from patients within the same triage category should proceed by random lottery.

D. Triage Code Status Orders

Under crisis standards of care, decisions about who should receive critical care resources are guided by a population health approach to save the most number of lives. This necessitates prioritizing the allocation of scarce resources to those most likely to survive critical illness. Physicians cannot, in good conscience, offer medical interventions (including CPR) that they judge to be of no benefit, or to be disproportionately harmful, to patients. Furthermore, the law does not require physicians to do so, even if patients or their surrogates request such medically non-beneficial or harmful interventions.

This working group recognizes that triage allocation decisions may conflict with the previously stated goals and wishes of patients or their health care surrogates, who may have expressed preferences for aggressive treatment measures, including intensive care and cardiopulmonary resuscitation in the event of cardiac or respiratory arrest. For purposes of these triage guidelines, an arrest is defined as loss of spontaneous circulation that requires chest compressions, defibrillation, or emergency electrical pacing, <u>and/or</u> respiratory failure requiring intubation and mechanical ventilation if life is to be prolonged. Resuscitative efforts are defined as the performance of chest compressions, invasive mechanical ventilation, defibrillation, or electrically assisted cardiac pacing.

Under a declaration of crisis standards of care, it would be medically inappropriate and medically ineffective to provide resuscitative efforts to those who are not currently eligible to receive critical care resources following a cardiac or respiratory arrest. Resuscitative efforts are clinically indicated only if supportive critical care, such as a ventilator, is available after the patient is stabilized from the arrest. If there are no ventilators or other available critical care resources available to be allocated to a patient following resuscitation efforts, then attempting resuscitation is medically non-beneficial (medically futile) in that it is extremely unlikely to achieve the desired outcome of prolonging life. Attempting resuscitation in these circumstances does not benefit a patient who cannot be supported through critical illness and in fact may contribute to and prolong suffering for the patient.

As such, for any patient whose triage priority level is lower than the threshold for ICU admission for critical care resources such as ventilatory support, which is almost always required following resuscitation, we recommend that a code status order be entered by the triage officer indicating: (1) that specified critical care resources are not available for the patient at the present time, and (2) that as such, no resuscitative efforts should be made if the patient experiences cardiac or respiratory arrest. This order would not preclude the use of elective or emergent electric cardioversion for patients who are not pulseless with unstable arrhythmias, which should still be assessed to receive defibrillation as deemed appropriate by the treating physician(s). This order should remain in place unless and until sufficient resources become available for the patient to receive critical care. If and when resources become available for the patient, goals of care shall be addressed with the patient and/or their duly-designated health care surrogates. This goals of care conversation should be done prior to reversion of code status to Full Code and transfer to the intensive care unit for provision of critical care to ensure that such a transfer is still aligned with their desired outcomes.



IV. Supply Chain and De-escalation of Crisis

UC Health must plan appropriately for the deployment of crisis standards of care and allocation of scarce resources in the event that hospitals exceed their surge capacity; however, we must also emphasize that such a scenario represents an intolerable situation that demands diligent efforts to swiftly resolve. Situations of ventilator or other critical resource scarcity should not be allowed to continue a single hour longer than absolutely necessary.

Therefore, implementation of a triage system of scarce resource allocation must exist in parallel with continual efforts to push the supply chain of those resources. This is a critical component of a duty to steward scarce resources and the duty to care for every patient. UC Health should consider applying the following steps to augment the inventory of critical care ventilators at our hospitals and across the University of California system:

- 1. Development of a system to share resources across the UC medical campuses: Information sharing regarding inventory of unused resources can facilitate a system by which a campus with a scarcity can temporarily acquire ventilators from campuses in surplus. This scenario is feasible given the geography of the state and the potential for COVID-19 cases to surge at different times across California. Planning should include UC hospital incident command systems' participation in regional medical operations centers, which can promote the use of shared regional resources such as ventilator pools or caches.
- 2. Re-purposing operating room ventilators, using improvised ventilators or other resources for Critical Care usage: Adaptations may be necessary based upon the severity of disease and the type of operating room or other alternate ventilation techniques available.
- 3. Early utilization of non-invasive ventilation and other techniques: Although there is significant fluidity in the treatment of COVID-19, early data demonstrates a benefit from the use of high flow nasal cannula, awake self-proning and non-invasive ventilation in an attempt to avoid the need for invasive ventilation. Given these potential benefits, hospitals should consider acquiring additional non-invasive equipment. It is critical to review these non-invasive techniques and equipment to optimize utilization and to properly protect health care providers from aerosolization. BiPAP and CPAP machines should both be considered along with the appropriate personal protective equipment.
- 4. Patients who are not allocated specific resources (such as a ventilator) should be considered for mitigating care (for example, intubation and supplemental oxygen without a ventilator) if this could meet a care need such as airway protection.
- 5. Allocating one ventilator to two patients: Data on outcomes from this practice are scarce. Private companies and Schools of Engineering (including some within the University of California system) are in the process of developing connectors and splitters in order to create this accommodation. It is too early for this report to make a strong recommendation on the clinical application of this technique.
- 6. Philanthropy: The University of California and its individual campuses have already engaged in conversations with the private sector, regionally, nationally and internationally to acquire ventilators and potentially manufacture ventilators. These efforts should be redoubled if we approach situations of scarcity.

These and other steps can potentially improve time to de-escalation of the triage process by improving the availability of ventilators or other scarce resources. Patterns of infection of COVID-19 across the world increasingly provide us with a lens as to what we may expect regarding safe timing of deescalation. As of the publication of this report, we suggest that triage assessment should continue until 30% of ventilators are not in use, with continual reassessment and a readiness to reenact triage until a clear pattern emerges that the institution and region no longer require implementation of crisis standards of care and the infrastructure for disaster preparedness can be relaxed.

V. Conclusions

The thresholds and recommendations outlined in this resource allocation algorithm for prioritization for triage should be evaluated by the UC Office of the President on a regular basis as the crisis situation evolves. Additional data regarding prognostication of outcomes in a particular disease state may become relevant as the crisis unfolds. For example, this working group does not currently recommend the use of COVID-19-specific decision tools, as the data that underpins them is not robust and the triage pool will contain both COVID-19 cases and patients with other acute conditions. But over time, specific disease state clinical markers or comorbidities might emerge as useful in prognosticating COVID-19-specific outcomes and the proportion of such cases in the ICU will likely increase. If this becomes the case, the decision protocol in Part III may be updated and revised accordingly. (Note that updates to this triage algorithm will be made at the level of UCOP, not by individual hospitals.)

In accord with the principle of transparency, this report is intended to be a public document, subject to public feedback, critique, and revision as necessary in order to more fully align with the needs and interests of all Californians.

Appendix 1: Review of Prior Research and Reports

As part of our public role, UC Health hospitals may face extremely challenging ethical questions during the Covid-19 pandemic that do not arise during everyday operations. For instance, they might have to decide how to allocate scarce resources to some patients and not others. Because our hospitals' decisions are part of a *public* effort, they should be governed by the choices and values of the citizenry, just as all public policies should be. This view is echoed in the writings of previous government institutional efforts to prepare for the possibility of influenza pandemics (such as the H1N1 epidemic of 2009.

To our knowledge, California has not conducted any surveys of the ethical values that Californians would like to bring to bear on triage and other pandemic-related issues. Likewise, federal institutions such as the CDC and VA endorse the *principle* of surveying the public, but have not conducted those surveys. In light of this, we conclude that the best sources of ethical guidance—the ones that best reflect the values of the public—include ethical guidelines put forward by the CDC, Veterans Health Administration, and California Department of Public Health. Although the CDC, VA, and California guidelines are not informed by direct surveys of the public, they are at least created by institutions indirectly responsible to the citizenry. In addition, we looked for insights from state guidelines from Maryland, Minnesota, and New York, as described below. While these guidelines come from states other than California, they have the advantage that they were based on deliberation with the general public.

A. Prior Public Engagement Projects on Flu pandemic Algorithms

Many important decisions faced by a society might best be made by decision makers in partnership with the public. Public deliberation projects involve a sponsor that convenes a group of people, ideally a representative cross-section of the public. Participants are informed about an issue or issues, and then they are asked to deliberate and debate the issues in order to bring to light their values after listening fully to the perspective of others. Content is reported to decision makers in order to assist them in understanding public perspective.²⁸ There are methodological criticisms to public engagement projects like these and concern over their applicability to larger policy questions. First, the best way to approximate public will is by engagement with a random sample of citizens, which was in general not performed in any public engagement project listed below. In addition the context is contrived with participants given a fixed series of principles, a priori defined, or a document to review, thus with associated biases. Finally, the information and training given to participants may also be biased toward one viewpoint or another.

Some groups have used deliberative methods to enlist community participation in decisions concerning allocation of scarce resources in hypothesized pandemic scenarios in the hope that qualitative and quantitative analysis of these representative bodies might inform policy. In 2005 the CDC and IOM along with other public institutions sponsored the Public Engagement Project on Pandemic Influenza (PEPPI). Roughly 250 citizens from Georgia, Massachusetts, Nebraska, and Oregon participated with 50 stakeholders in a deliberative process concerning the early allocation of limited supply of vaccine in the early days of an influenza pandemic. Participants were asked how such vaccines should be

allocated. By and large citizens articulated "assuring functioning of society" as a primary goal with "reducing individual deaths and hospitalizations due to influenza" as a secondary goal.²⁹

In 2006 the New York State Department of Health commissioned the Task Force on Life and the Law to "consider ethical and clinical issues in the allocation of ventilators in an influenza pandemic". This task force produced a draft guideline in 2007,30 structured predominantly on guidelines from the Ontario Health Plan for Influenza Pandemic. They adopted a triage criteria which excludes patients based upon severe chronic organ failure, catastrophic injury, and SOFA score. To solicit comments, these guidelines were published in the New York Times, on the State Register, and on the Department of Health website. Four community meetings of about 25-50 participants each were held in 2008 to discuss the guidelines, as were 3 additional meetings with healthcare providers. A third party vendor, under the guidance of the Task Force, also executed an extensive community engagement project in 2011 along 13 counties in New York, although further information concerning the results of these experiences is not shared in their documents. Draft Guidelines were presented for comment at professional forums including: "Confronting the Ethics of Pandemic Planning: The Summit of the States," (2008), the Institute of Medicine Workshop on "Altered Standards of Care in A Mass Casualty Event" (2009), the American Medical Association's "Third National Congress on Health System Readiness" (2009), the Public Health Preparedness Summit (2011), and the American Society for Bioethics and Humanities Annual Meeting (2011 and 2012). They were published in a peer reviewed journal.31 These projects resulted in the following changes to their final guideline. First, the guidelines stressed the need for triage officers and the triage infrastructure are to be hospital specific. Second they recommended that chronic care facilities not be included in the acute care of severely ill patients. Although there was a narrowing of the exclusion criteria to eliminate severe end organ failure, the format of triage and conclusions concerning age and care providers were essentially unchanged.7

Starting initially as a pilot project, 32 and finalizing in a community engagement forum 33 researchers at Johns Hopkins used similar deliberative methods to engage 324 participants in the Baltimore area concerning allocation of mechanical ventilators in time of scarcity. They were given a representative disaster scenario and expertise on key characteristics of mechanical ventilation. They were asked to deliberate on allocation of mechanical ventilators when needs exceed supply, and whether providers should ever be allowed to remove one person from mechanical ventilation who needs it in order to benefit another. They were given a list of six ethical principles upon which to deliberate. The group was diverse in ethnicity and religious background, about 25% were health care workers. The group stressed the need for transparency, and in general were open to the idea of using a combination of ethical principles in triage decisions. They expressed concerns of bias in decision making and patient abandonment. The group valued mostly the principles of survival of current illness and living longer. followed by the principle of value to others. In general first come first served, life stages and lottery decisions were less valued. While there was not unanimity, a majority (63.1%) favored the idea that removal of a ventilator from one patient might be acceptable. Based upon this experience this project recommended a triage protocol that weighed predominantly principles of early survival with early exclusion of non-survivable presentations to health care providers, and acute illness severity with a severity of illness tool. It also placed primary importance on long term survival via comorbidity evaluation. In the case of tiebreakers life stage and eventually lottery would be employed. This approach has found its way into triage policy from the State of Maryland⁹ as well in part in guidelines from the University of Pittsburgh.¹⁴



B. Review of IOM and Other State-specific Principles

There is an extensive literature on the ethics of pandemic management and triage. When choosing which literature to use as sources or comparisons, we must seek documents that have the stamp of public authority, which includes policies based on the views of the public and/or policies created by institutions that are responsible to the public. This method is endorsed in the writings of U.S. Government institutions, including the Centers for Disease Control and the Veterans Administration.²³⁸ It is also endorsed by the National Academy of Medicine, whose recommendations were made in response to a request from the U.S. Department of Health and Human Services.⁵

Several sources fulfill these criteria to varying degrees:

- Some are federal or California documents created by government organizations that are responsible to all U.S. citizens or to Californians in particular. These include reports by the Veterans Health Administration (VHA), the Centers for Disease Control (CDC), and the California Department of Public Health (CDPH).
- Some are guidelines from states other than California, though ones that have the advantage that they were based on at least some deliberation with or input from that state's public. These include state guidelines from Maryland, Minnesota, and New York.
- Finally, there are reports from the Institute of Medicine (IOM), now known as the National Academy of Medicine. Although the IOM is not a government body, its reports were generated at the request of the Department of Health and Human Services and have been widely influential.

General Comparison of These Sources

The documents listed above make remarkably uniform recommendations about the principles to be used during pandemic management. Differences between them are often small matters of phrasing. When a principle is absent from a document, often it is implicit in the way the document reasons about policy. Table 9 below compares only the principles which are explicitly stated. Definitions of the principles follow the table:



Table 9: Comparison of Principles Explicitly Stated

	VHA	CDC	CDPH	MD	MN	NY	IOM
Save the Greatest Number/Pop. Health	Yes	Yes	Yes	Yes	Yes	Yes	
Respect Persons/Individual Rights	Yes	Yes	Yes		Yes		
Protect Populations with Special Needs			Yes		Yes	Yes	
Fairness/Consistency	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Avoid Exacerbating Disparities		Yes			Yes	Yes	
Duty to Care	Yes		Yes	Yes	Yes	Yes	Yes
Duty to Steward Resources	Yes	Yes	Yes		Yes	Yes	Yes
Duty to Collect Information	Yes	Yes		Yes	Yes		
Transparency/Public Involvement	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Proportionality	Yes				Yes		Yes
Accountability	Yes				Yes		Yes



Principles:

Duty to save the greatest number of lives/promote population health: Providers should save the greatest number of lives possible⁴ and focus on benefits to the population as a whole.³

Duty to Respect Individual Rights: Healthcare organizations should respect the rights of patients,⁴ as well as the autonomy and intrinsic worth of persons.³

Protect populations with special needs: Healthcare organizations should take into account the special needs of various groups.⁴

Avoid exacerbating existing disparities: Responses to a pandemic should not exacerbate existing disparities in health outcomes.³

Duty to collect information: Decisions should be based on the best available evidence, and decision-makers should conduct research to improve the quality of information.³ Policies should be changed in light of new information ⁹

Fairness/Consistency: The protocols could be viewed as fair by all parties.⁵ Any differences in treatment must be based on appropriate differences between individuals.⁶ Decision makers should be impartial and neutral.³ Like groups must be treated alike.⁵ The public may feel that scarce resources have not been allocated fairly if patients at different hospitals in the same affected area receive vastly different levels of care.⁶

Duty to Care: providers should provide medical treatment to the specific patients under their care, and patients should not be abandoned.⁵ Health care institutions have a reciprocal duty to support healthcare workers,⁶ including the provision of adequate personal protective equipment. Duties to care may extend outside healthcare workers' professional roles, e.g., when healthcare workers must care for their children.⁶

Duty to Steward Resources/Plan: Healthcare institutions and workers must steward scarce resources in order to advance the goal of saving the most lives.⁵ Plans for a crisis should be in place before the crisis occurs.⁷

Transparency/Public Involvement: the public should be allowed to provide input into ethically-laden decisions about pandemic management, and the values driving policy should be explicitly communicated to the public.⁵ Transparency also implies candor in communication about disasters.⁵

Proportionality: Policies and restrictions must be appropriately limited in time and scale according to the scope and severity of the crisis.⁵

Accountability: Individuals in the healthcare system at all levels must accept and act upon appropriate responsibilities.⁵



How These Sources Prioritize Principles

The documents listed above make remarkably uniform recommendations about the principles to be used during a pandemic. All of them prioritize population health and focus on saving the greatest number of lives possible, although always with some caveats or restrictions. The VHA gives the most explicit defense of not merely maximizing lives saved. They first state their position:

Decision-making in pandemic influenza planning and response must be based on achieving the greatest good for the greatest number...within constraints of respect for human dignity and fairness....²

They note that this echoes a recommendation from the CDC:

We have concluded that a classic utilitarian approach to defining priorities, 'the greatest good for the greatest number,' is not a morally adequate platform for pandemic influenza planning. We recommend an approach to ethical justification, that, like utilitarianism, evaluates the rightness or wrongness of actions or policies primarily by their consequences, but, we further recommend that planning should take into account other checks ('side constraints') grounded in the ethical principles of respect for persons, non-maleficence, and justice.⁸

The VHA then highlights a case intended to show why the goal of maximizing lives saved must be constrained by the requirements of fairness and human dignity:

This guidance is based on the fundamental assumption that decision-making in pandemic influenza planning and response must be based on achieving the greatest good for the greatest number (the principle of utility) within constraints of fairness and human dignity.... Although a strictly utilitarian approach to pandemic planning and response might justify concentrating health care resources (staff, beds, supplies, and drugs) on saving those lives that have a high likelihood of being saved, an approach that balances utility, fairness and human dignity, as advocated in this guidance, requires that steps are also taken to provide for those who are not expected to survive.²



Appendix 2: Evaluation of SOFA, Frailty scoring

Table 10 - Sequential Organ Failure Assessment Tool³⁴

Organ System	0	1	2	3	4		
P _a O ₂ /FiO ₂ on arterial blood gas	≥400	300-399	200-299	100-199	<100		
(or SpO ₂ /FiO ₂ when ABG not available) ¹	(≥512)	(357-511)	(214-356)	(89-213)	(<89)		
Platelet count (10³/μL)-	≥150	100-149	50-99	20-49	<20		
Bilirubin (mg/dL)	<1.2	1.2-1.9	2.0-5.9	6.0-11.9	≥12		
Hypotension (vasopressor doses in mcg/kg/min)	None	MAP < 70 mmHg	Dopamine < 5	Dopamine 6-15 or Epinephrine <0.1 or Norepinephrine < 0.1	Dopamine > 15 or Epinephrine ≥ 0.1 or Norepinephrine > 0.1		
Glasgow Coma Scale Score	15	13-14	10-12	6-9	<6		
Creatinine (mg/dL) or (Urine output (mL/24h))	<1.2	1.2-1.9	2.0-3.4	3.5-4.9 (<500)	>5 (<200)		
^{1.} For patients on low-flow oxygen systems, use estimated FiO ₂ from Table 13 below.							

Table 11 - Modified Sequential Organ Failure Assessment Tool

Organ System	0	1	2	3	4
S _p O ₂ /FiO ₂ on arterial blood gas	>400	316-400	236-315	151-235	≤150
Liver	No scleral icterus or jaundice			Scleral icterus or jaundice	≥12
Hypotension (vasopressor doses in mcg/kg/min)	None	MAP < 70 mmHg	Dopamine ≤ 5 or Dobutamine any dose	Dopamine 6-15 or Epinephrine <0.1 or Norepinephrine < 0.1	Dopamine > 15 or Epinephrine ≥ 0.1 or Norepinephrine > 0.1
Glasgow Coma Scale Score	15	13-14	10-12	6-9	>6
Creatinine (mg/dL)	<1.2	1.2-1.9	2.0-3.4	3.5-4.9	>5

 $^{^{\}hbox{\scriptsize 1.}}$ For patients on low-flow oxygen systems, use estimated FiO $_{2}$ from Table 10.

Table 12 - Estimation of FiO2 for patients on low-flow oxygen systems³⁶

Flow (L/min)	Mean FiO₂					
	Mouth Closed	Mouth Open				
Nasal Cannula						
1	0.24	0.28				
2	0.30	0.38				
3	0.35	0.43				
4	0.40	0.50				
5	0.45	0.56				
6	0.48	0.60				
Face Mask						
7	0.51	0.64				
8	0.50	0.66				
9	0.56	0.71				
10	0.59	0.73				
11	0.60	0.75				
12	0.62	0.76				
13	0.64	0.77				
14	0.68	0.79				
15	0.70	0.81				

N.B., If mouth closure at time of evaluation unknown, use left column for mouth closed.

Conclusions:

- 1. SOFA-based models evaluated on their prognostic performance fell under 5 categories:
 - a. Single SOFA scores at fixed times
 - b. Sequential SOFA measurements
 - c. Individual SOFA components
 - d. Combination of SOFA with over covariates
 - e. SOFA patterns automatically discovered from the data
- 2. For predicting mortality, SOFA-based models at admission seem to be competitive with severity of illness models limited to the first 24 hours of admission, and models based on sequential SOFA scores have comparable performance with other IOF (individual organ failure) scores.

3. The combination of SOFA-based models with admission-based models results in superior prognostic performance than either model alone.

Figure 2: Frailty Index³⁷

Fatigue: "How much of the time during the past 4 weeks did you feel tired?" 1 = All of the time, 2 = Most of the time, 3 = Some of the time, 4 = A little of the time, 5 = None of the time. Responses of "1" or "2" are scored as 1 and all others as 0. Baseline prevalence = 20.1%.

Resistance: "By yourself and not using aids, do you have any difficulty walking up 10 steps without resting?" 1 = Yes, 0 = No. Baseline prevalence = 25.5%.

Ambulation: By yourself and not using aids, do you have any difficulty walking several hundred yards?" 1 = Yes, 0 = No. Baseline prevalence = 27.7%.

Illnesse: For 11 illnesses, participants are asked, "Did a doctor ever tell you that you have [illness]?" 1 = Yes, 0 = No. The total illnesses (0-11) are recoded as 0-4=0 and 5-11=1. The illnesses include hypertension, diabetes, cancer (other than a minor skin cancer), chronic lung disease, heart attack, congestive heart failure, angina, asthma, arthritis, stroke, and kidney disease. Baseline prevalence = 2.1%.

Loss of weight: "How much do you weigh with your clothes on but without shoes? [current weight]" "One year ago in (MO, YR), how much did you weigh without your shoes and with your clothes on? [weight 1 year ago]" Percent weight change is computed as: [[weight 1 year ago - current weight]/weight 1 year ago]] * 100. Percent change > 5 (representing a 5% loss of weight) is scored as 1 and < 5 as 0. Baseline prevalence = 21.0%.

Conclusions:

- 1. The Frailty Index is among the most popular frailty definitions and predictive of mortality.
- 2. The mortality risk according to the Frailty Index has never been quantified with meta-analysis in the literature.
- 3. All meta-analyses suggested that the frailty measured by the Frailty Index is a significant predictor of short term mortality.

Appendix 3: Ethical Controversies in Triage

This appendix discusses the general ethical framework from section 1 as well as some of its implications. Its sections include:

- Choice of Guiding Principles
- Public Engagement Projects on Flu Pandemic Choices
- Specific Ethical Issues Related to Triage
 - Equality the default
 - o General Recommendation to Protect and Provide for Vulnerable Populations
 - Prisoners and Undocumented Immigrants
 - Disability and Return to Previous State of Health
 - Application of Triage Protocols to All Who Need Scare Resources
 - o Reallocation of Scarce Resources
 - Triage Protocols and Pre-Existing Health Inequities
 - Triage Priority Based on Age
 - The Multiplier Effect and Pregnancy
 - Priority to Health Care Workers, First Responders, and Other "Critical Workers"

Choice of Guiding Principles

Hospitals in America have both a private and public role. Part of the time they operate in the free market, contracting with individual consumers and insurance companies. However, they are also expected to play public roles. For example, EMTALA requires Medicare-participating hospitals to provide emergency care to all patients, regardless of their insurance status or ability to pay, thus making hospitals part of a public safety net for health care.

During a severe pandemic or other crisis, the public role of hospitals increases. Hospitals move from being largely private institutions to being essential players in a public health effort whose aim is to preserve as many lives as possible and help maintain the functioning of civil society.

As part of this public role, hospitals during a pandemic could face vexed ethical questions that do not arise during everyday operations. For instance, they might have to decide how to allocate scarce resources to some patients and not others. Because the hospital's decisions are part of a public effort, they should be governed by the choices and values of the citizenry, just as all public policies should be. This view is echoed in the writings of U.S. Government institutions, including the Centers for Disease Control and the Veterans Administration. It is also endorsed by the National Academy of Medicine, whose recommendations were made in response to a request from the U.S. Department of Health and Human Services.

To our knowledge, neither the Federal Government nor California has conducted any surveys of the ethical values that the public would like to bring to bear on triage and other pandemic-related issues. Likewise, federal institutions such as the CDC endorse the principle of surveying the public, but have not conducted those surveys. In light of this, the next-best sources are those that are either created by a government institution indirectly responsible to the citizenry and/or based at least partly on public input.

Documents which meet these requirements to varying degrees include:

- Ethical guidelines put forward by the CDC, Veterans Health Administration, and California
 Department of Public Health. These are not informed by direct surveys of the public, they are at
 least created by institutions indirectly responsible to the citizenry.
- State guidelines from Maryland, Minnesota, and New York. While these guidelines come from states other than California, they have the advantage that they were based on deliberation with the general public.
- Reports from the Institute of Medicine (now the National Academy of Medicine). The Institute of
 Medicine is not a government body, but its reports were generated at the request of the
 Department of Health and Human Services and have been widely influential.

Fortunately, there is no need to adjudicate the precise merits of these documents or others, since all are in broad agreement about the ethics of crisis and pandemic management. The ethical guidelines presented in the opening section of this document represent a distillation of the recommendations in these federal and state guidelines. They reflect the best possible attempt to represent the values of the citizenry in our decisions.

Public Engagement Projects on Flu Pandemic Choices

As noted above, many of the most important decisions about pandemic management should be made by decision makers in partnership with the public. Given the importance of public input, we here review some of the existing literature on public engagement projects regarding flu pandemic choices. The projects have important limitations, but the limited information collected during the projects accords with the general principles outlined in this document.

Public deliberation projects involve a sponsor that convenes a group of people, ideally a representative cross-section of the public. Participants are informed about an issue or issues, and then they are asked to deliberate and debate the issues in order to bring to light their values after listening fully to the perspective of others. Content is reported to decision makers in order to assist them in understanding public perspective (Siegel et al, American Medical Association Journal of Ethics. 2013. 15(1): 56-64). There are methodological criticisms of public engagement projects like these and concern over their applicability to larger policy questions. First, the best way to approximate public will is by engagement with a random sample of citizens, which was in general not performed in any public engagement project listed below. In addition, the context is contrived with participants given a fixed series of principles, a priori defined, or a document to review, thus with associated biases. Finally, the information and training given to participants may also be biased toward one viewpoint or another.

Some groups have used deliberative methods to enlist community participation in decisions concerning allocation of scarce resources in hypothesized pandemic scenarios, with the hope that qualitative and quantitative analysis of these representative bodies might inform policy. In 2005 the CDC and IOM along with other public institutions sponsored the Public Engagement Project on Pandemic Influenza (PEPPI). Roughly 250 citizens from Georgia, Massachusetts, Nebraska, and Oregon participated with 50 stakeholders in a deliberative process concerning the early allocation of limited supply of vaccine in the early days of an influenza pandemic. Participants were asked how such vaccines should be

allocated. By and large citizens articulated "assuring functioning of society" as a primary goal with "reducing individual deaths and hospitalizations due to influenza" as a secondary goal.²⁹

In 2006 the New York State Department of Health commissioned the Task Force on Life and the Law to "consider ethical and clinical issues in the allocation of ventilators in an influenza pandemic". This task force produced a draft guideline in 2007, Allocation of Ventilators in an Influenza Pandemic: Planning Document: Draft for Public Comment³⁰ structured predominantly on guidelines from the Ontario Health Plan for Influenza Pandemic. They adopted triage criteria which exclude patients based upon severe chronic organ failure, catastrophic injury, and SOFA score. To solicit comments, these guidelines were published in the New York Times, on the State Register, and on the Department of Health website. Four community meetings of about 25-50 participants each were held in 2008 to discuss the guidelines, as were 3 additional meetings with healthcare providers. A third-party vendor, under the guidance of the Task Force, also executed an extensive community engagement project in 2011 along 13 counties in New York, although further information concerning the results of these experiences is not shared in their documents.

Draft Guidelines were presented for comment at professional forums including: "Confronting the Ethics of Pandemic Planning: The Summit of the States," (2008), the Institute of Medicine Workshop on "Altered Standards of Care in A Mass Casualty Event" (2009), the American Medical Association's "Third National Congress on Health System Readiness" (2009), the Public Health Preparedness Summit (2011), and the American Society for Bioethics and Humanities Annual Meeting (2011 and 2012). They were published in a peer reviewed journal.³¹ These projects resulted in the following changes to their final guidelines. First, the guidelines stressed the need for triage officers and the triage infrastructure to be hospital specific. Second, they recommended that chronic care facilities not be included in the acute care of severely ill patients. Although there was a narrowing of the exclusion criteria to eliminate severe end organ failure, the format of triage and conclusions concerning age and care providers were essentially unchanged.⁷

Starting initially as a pilot project (Daugherty Biddson et al. Annals ATS.2014.11(5). 777-783) and finalizing in a community engagement forum (Daugherty Biddson et al. Chest.2018.187-195) researchers at Johns Hopkins used similar deliberative methods to engage 324 participants in the Baltimore area concerning allocation of mechanical ventilators in time of scarcity. They were given a representative disaster scenario and expertise on key characteristics of mechanical ventilation. They were asked to deliberate on allocation of mechanical ventilators when needs exceed supply, and whether providers should ever be allowed to remove one person from mechanical ventilation who needs it in order to benefit another. They were given a list of six ethical principles upon which to deliberate. The group was diverse in ethnicity and religious background, about 25% were health care workers. The group stressed the need for transparency, and in general were open to the idea of using a combination of ethical principles in triage decisions. They expressed concerns of bias in decision making and patient abandonment. The group valued mostly the principles of survival of current illness and living longer, followed by the principle of value to others. In general, first come first served, life stages, and lottery decisions were less valued. While there was not unanimity, a majority (63.1%) favored the idea that removal of a ventilator from one patient might be acceptable.

Based upon this experience, this project recommended a triage protocol that weighed predominantly principles of early survival with early exclusion of non-survivable presentations to health care providers,

and acute illness severity with a severity of illness tool. It also placed primary importance on long term survival via comorbidity evaluation. In the case of tiebreakers, life stage and eventually lottery would be employed. This has found its way into triage policy from the State of Maryland⁹ as well in part in guidelines from the University of Pittsburgh¹⁴.

Specific Ethical Issues Related to Triage

Some of the most vexed ethical issues in pandemic and crisis planning concern the formulation of triage protocols. Here we comment on some of the most prominent issues. In each case we try to bring to bear the views of the public on each of the contested issues, either through direct examination of public documents or through the application of the values expressed in those documents.

<u>General Recommendation to Protect and Provide for Vulnerable Populations</u>. One of our core ethical principles is the protection of vulnerable populations, and all the public documents we surveyed all direct hospitals to take deliberate, *active* steps to ensure that vulnerable or marginalized populations receive equal access to scarce resources.³⁴⁷ These might include, among other things, these steps:

- Hospitals can reach out to organizations and services designed to serve groups with special needs⁴ or groups who are particularly vulnerable or disadvantaged.³⁸ Such groups might include "social service agencies, home care providers, community health centers, community organizations, faith-based communities that serve low income people and other populations with health disparities as well as those with access and functional needs."³⁸ Those groups can call attention to access barriers and other sources of potentially unequal treatment.
- Facilities should ensure access for those with disabilities, limited English language skills, and other groups with functional needs.³⁸
- The Maryland guidelines note that placing too great a priority on the criterion of long term survival may further disadvantage people who are already disadvantaged, since poorer people and people of color are more likely than other groups in society to have serious health problems.⁹ This issue is discussed further below.
- Facilities should mitigate or eliminate, as far as possible, the sense of distrust that some
 historically disadvantaged people might feel toward the medical system in general or a triage
 system in particular.⁷
- The New York guidelines note that hospitals should be prepared to participate in regional plans
 designed to ensure that the same resources are available and in use at similarly situated
 facilities (i.e., all facilities in one area affected by the pandemic) to reduce inequalities of access
 and distribution among facilities. (New York 2017, pp. 32/33).

<u>Prisoners and Undocumented Immigrants</u>. Notes on Maryland public forums indicate that some citizens believe that prisoners and undocumented immigrants should be de-prioritized during triage. However, all public documents we surveyed reject such de-prioritization. Some do so in explicit discussions of prisoners and/or undocumented immigrants, or in statements of general principles that are incompatible with de-prioritization. Others public documents reject it implicitly, by not including de-prioritization in their triage protocols. On the basis of the public consensus, we conclude that prisoners and undocumented immigrants should not be de-prioritized.

<u>Disability and Return to Previous State of Health.</u> Some triage protocols make allocation decisions based not only on overall predicted survival but also quality of life after treatment. Such protocols are sometimes viewed with suspicion by individuals with disabilities. Standard health measurement scales such as QALY and DALY scales generally give a lower rating to the quality of life of individuals with disabilities than to those without. The concern is that individuals with disabilities will therefore be assigned lower triage priority in virtue of their disabilities. For instance, if a non-disabled patient and a blind patient could both be saved by allocating them a ventilator, standard QALY scoring would tell you that the non-disabled patient will have a better "quality of life" after recovery, simply because they are not blind.

The public documents we surveyed offer this guidance:

- The California guidelines label "change in quality of life" an "appropriate criterion for resource allocation" and add that "The benefit of the population of patients during a healthcare surge will be maximized if treatment is provided to patients who will have the greatest improvement in quality of life. Change in quality of life can be defined by comparing functional status with treatment to functional status without treatment."
- The CDC offers no concrete guidance, merely surveying different triage options.
- The Maryland guidelines do not discuss the issue explicitly but the Maryland protocol does not score individuals based on quality of life.⁹
- The Minnesota guidelines say that rationing should not be based on "judgments that some people have greater quality of life than others."³⁸
- New York also concludes that "factors that reflect quality of life judgments rather than estimates of mortality should be eliminated from the triage process." They also reject policies about withdrawing care from chronically ventilator-dependent patients that would de facto prioritize non-disabled individuals over individuals with disabilities.
- The VHA guidelines do not directly address the issue but their triage protocol does not include quality of life assessments.

The consensus of these documents is not to triage based on expected quality of life after treatment. The only possible exception is California's general remarks about "change in quality of life." However, that remark is ambiguous between (a) triaging patients based on their expected quality of life after treatment, as scored on some health measurement scale such as a QALY scale, and (b) triaging patients based on how far the treatment returns them to their own baseline quality of life.

On the basis of our assessment of these documents, we conclude that triage protocols should either not assess patients based on expected quality of life after treatment or, to ensure non-discrimination against individuals with disabilities, assess at most how treatment will return the patient to their own baseline quality of life.

Application of Triage Protocols to All Who Need Scare Resources. When resources become scarce, some people who need those resources will be suffering from conditions related to the pandemic and others will not. For instance, during a ventilator shortage caused by an influenza pandemic, some might need a ventilator because they are suffering from influenza, but others will need a ventilator for other reasons—they suffer severe COPD exacerbation, require ventilation under general anesthesia, and so on. In such situations, the consensus of all public documents is that triage protocols should be applied to all who need the scarce resource, not just those suffering from conditions related to the pandemic.

<u>Reallocation</u>. In a triage situation, there could be a patient who is already using a resource—e.g., a ventilator—and another patient needs the same resource. It is also possible that the second patient is more likely to survive on the ventilator than the first patient. In such situations and ones like them, the question arises of whether you should reallocate the resource to the second patient. The documents surveyed offer this guidance:

- The VHA document clearly states that scarce resources may be withdrawn from one patient when doing so 'optimizes scarce resources', though they caution about legal concerns over withdrawal of treatment.²
- The CDC asks hospitals and states to "address the issue," and then clearly writes in a way that, at the very least, does not disallow withdrawal—e.g., "Policies for withdrawal of patients from ventilators need to be the least restrictive possible..."
- The CDPH guidelines state that during surge and crisis situations, "certain lifesaving efforts may have to be discontinued" and elsewhere that "a healthcare provider may determine that...care being provided to an individual will be discontinued or withdrawn..." In addition, the California guidelines discuss the New York guidelines as "an example of standards that might be implemented during a catastrophic emergency," and as explained below, the New York guidelines allow withdrawal and reallocation.4
- Maryland notes that participants in public forums "expressed concern" over withdrawal of a ventilator and reallocation to another patient, and that professionals expressed concern about the legal ramifications of withdrawal, as well as the emotional, psychological, and moral distress of withdrawal. In the end Maryland sanctions withdrawal so long as is done "with caution" and allows a limited appeals process. There is extensive discussion of whether withdrawal is legal under Maryland law, indicating that withdrawal is not legally unproblematic.⁹
- Minnesota speaks of withdrawal in general as something that might happen when implementing crisis standards of care and has one specific reference to the possibility of reallocation using Minnesota guidelines.³⁸
- The New York guidelines allow withdrawal and reallocation.⁷

On the basis of the consensus in these documents, we conclude that reallocation is permitted whenever indicated by the triage protocol, subject to (a) any legal constraints, and (b) any additional protections a Triage Committee may wish to put in place regarding reallocation—e.g., special appeals procedures.

<u>Triage Protocols and Pre-Existing Health Inequities</u>. Triage protocols often triage patients based at least partly on their chance of survival *simpliciter* or longer-term survival. Some population sub-groups in the United States (e.g., racial and ethnic minorities) disproportionately suffer from health conditions which will reduce their chances of survival during a pandemic—e.g., when a patient with pre-existing COPD becomes infected with CoVid-19. Some would argue that these pre-existing health disparities are the result of social injustices and therefore that it is problematic to de-prioritize such individuals during triage.

The Maryland guidelines take up this issue and state:

"Although important, placing too great a priority on the criterion of long term survival may, in certain circumstances, further disadvantage people who are already disadvantaged; poor people and people of color are more likely than other groups in society to have multiple and serious co-morbidities because of poorer access to medical care and because of the direct debilitating effects of poverty on health."

Likewise, the New York guidelines comment that:

"It is not appropriate for a triage officer/committee to compare patients within the same [triage priority] category. ...[among other problems], such comparisons may intensify inherent biases in the health care system and the disproportionate and disparate provision of care for already disadvantaged populations."

The documents we surveyed draw these conclusions:

- The VA guidelines do not attempt to correct for the problem that populations with greater rates of health problems will be disproportionately de-prioritized in most triage protocols.
- The CDC guidelines do not address this problem specifically, though they do discuss the making of distinctions within a triage category: "steps should be taken to ensure that all patients reaching the highest priority group have equitable access to the pool of ventilators. This assures that allocation does not exacerbate pre-existing inequalities in access to health care or disproportionately impact vulnerable populations."3
- After describing the problem in the quote above, the Maryland guidelines state that: "Because of concerns about compounding injustices associated with systematic disadvantage and the arbitrariness of co-morbidities, unlike other algorithms that have been proposed for ICU triage in a disaster, the scoring system to be used here does not distinguish between one and multiple co-morbidities or between mild and moderate co-morbidities. Patients whose co-morbidities are so serious that they are expected to live no more than 12 months even with successful ICU treatment are assigned a score of 3."9
- The Minnesota and CDPH guidelines do not address this issue directly, although there
 are many places where they generally indicate a need to protect vulnerable and
 disadvantaged populations.
- The New York guidelines offer the solution quoted above—a restriction against comparing patients within the same triage category.

The recommendations from these public documents are not entirely consistent. In light of this, our working group examined the issue ourselves, attempting to bring to bear our guiding principles. This situation creates a tension between our goal of not exacerbating pre-existing inequities and the goal of maximizing the number of lives saved. In the end the committee agreed on two things. First, we adopted a protocol that comports with the Maryland system, which does not distinguish between one and multiple co-morbidities. Second, we concluded that we should not attempt to further prioritize

anyone on the basis of any potential pre-existing health inequalities, with each member endorsing that conclusion for some or all of the following reasons:

- The working group had no public mandate for taking its own judgments on controversial public issues about justice and injustice in healthcare generally, and then implementing them during a public health crisis.
- Even if the working group decided to make such judgments, any attempt to correct for pre-existing health inequities would have to say *how much* correction is required, which would in turn even more controversial and pragmatically impossible value judgments about the type and degree of the injustices in our society. The working group felt it was not possible for it to do this, and that in addition, as above, it had no public mandate for rendering judgments on such complicated and contentious public issues.
- Many public documents stress that the most important goal during a public health crisis should be maximizing the number of lives saved.

In addition, the committee felt that it should be known that this issue revealed to us that a satisfying choice is not always available in extraordinary circumstances, and that during a public health crisis, sometimes a choice is inevitably tragic, involving substantial moral costs no matter what.

Triage Priority Based on Age. Young people will often receive *de facto* priority in a triage protocol because those protocols always place a heavy weight on likelihood of survival, and young people are in general more likely to recover from illness than older ones. However, a separate ethical issue is whether we should, in addition, give independent weight to youth, prioritizing it to some extent regardless of its effect on survival. (Often the rationale for doing so is that young people have longer expected lifespans, so preserving the lives of younger people saves more "life years.") A case will make the issue clearer. If a 20-year-old has a 20% chance of survival with a ventilator, but a 55-year-old has a 50% chance of survival, who should be given the ventilator? If one cares only about lives saved, one favors the 55-year-old. If one places intrinsic weight on youth, then (based on average lifespan), one might favor the 20-year-old. The average male lifespan in America is 75, and (.20 x 55) is greater than (.5 x 20).

The Working Group recognizes the importance of this issue and began initial deliberations about it. In the midst of those deliberations we were advised that priority based on age was likely to constitute illegal age discrimination. For that reason, age is not a factor in triage in our protocol.

Priority to Health Care Workers, First Responders, and Other "Critical Workers". Most major documents about triage discuss the possibility of giving priority to police officers, firefighters, some healthcare workers, and other individuals who are essential to fighting the pandemic and maintaining the functioning of civil society. This is one of the most difficult issues for any triage working group to confront, because many of the members of that group are likely to be healthcare workers who could benefit from priority assignment. In light of this, the working group took strict steps to ensure that it was not imposing its own views on this issue but rather attempting to comply with the recommendations of state and federal governments, as recorded in public documents.



Those documents discuss three possible justifications for giving triage priority to critical workers:

- 1. Reciprocity. A public health emergency demands sacrifices from all citizens, but not all suffer the same risks. Some argue that because some critical workers take more risks in the name of the public good, those critical workers are owed some level of priority in triage in return.
- 2. The Multiplier Effect. Because certain individuals are involved in saving the lives of others, an argument can be made that when you save that individual, you potentially save others as well. For instance, some might make the case that when you save a tailor, you save just him, but that when you save an ICU doctor, you are not only saving her but at least have the possibility of saving the others she will go on to help when she returns to the workforce.
- 3. Incentivizing the Work Force. Some express concern that during a pandemic, especially a protracted one, an increasing number of critical workers will refuse to perform duties that put them at risk, either by leaving their positions, taking paid or unpaid leave, or refusing to undertake certain risky tasks. One way to mitigate this phenomenon might be to give some level of priority to critical workers. (Note that this is essentially a variant of the multiplier effect: the claim is that by offering priority, we incentivize job performance which in turn allows critical workers to continue saving others.)

It is important note that these rationales are different from those based on "social value":

4. Social Value. Judgments of social value assess individuals based on how they contribute to society. For example, some people might think an entrepreneur is more important to society than an unemployed artist, that a teacher is more valuable to society than a cashier, and so on. We reject the use of any judgments of social value during triage.

With respect to reciprocity, the public documents we consulted say these things:

- The California Public Health guidelines say nothing about reciprocity in general and do
 not contain a specific triage protocol. They do discuss the New York guidelines as "an
 example of standards that might be implemented during a catastrophic emergency," and
 as noted below, the New York guidelines reject priority for critical workers.⁴
- The CDC reports are unclear. They only note that reciprocity arguments are sometimes given by others, saying that "...some may argue that the ethical principle of reciprocity may provide ethical justification for giving priority to those who put themselves at risk during a severe pandemic (i.e., health care providers and emergency responders), especially prior to the availability of a vaccine."
- The Maryland guidelines examined priority for critical workers but only on the basis of a multiplier effect, not reciprocity.9
- The Minnesota guidelines endorse reciprocity in general, saying "fairness requires society to protect those who take on risk on behalf of the public" (Minnesota 2020, p. 23), but then principally discuss personal protective gear and training rather than priority

for treatment. Their protocol ultimately gives some level of priority to critical workers, but the principal rationale seems to be the multiplier effect.³⁸

- The New York ventilator guidelines consider priority for critical workers but only on grounds of work incentives.⁷
- The VHA guidelines consider priority to critical workers but only on grounds of a multiplier effect.²

These documents suggest that even if reciprocity is given some weight during the design of protocols, it should not be the principal factor. Instead, the multiplier effect should be the principal basis, if any, for giving priority to critical workers.

There are two questions to ask about the multiplier effect, one factual and the other moral. The factual question is whether saving certain individuals does, in fact, lead to saving other lives as well. Here it is important to note that the question is not whether saving any *particular* health care worker, police officer, or firefighter (etc.) will lead to others being saved. (Probably not—any one individual, in any profession, is usually dispensable or replaceable.) Instead, the question is whether a *general policy* of prioritizing some individuals will, over time, have a multiplier effect. We can lose any one or another ICU physician, but if we lose too many in the aggregate during a pandemic, more people will die.

We know of no research that attempts to measure multiplier effects during actual pandemics, although the VHA does quote troubling projections about possible shortages of health care workers during a crisis and does give priority to them for preventative measures such as vaccines.² We must therefore fall back on our best estimates and educated guesses, and in our estimation, it is plausible that, in some dire situations, priority to certain groups of people would, over time, have a multiplier effect.

Even if a multiplier effect exists, there is a moral question of whether its existence is *morally* relevant and should lead to priority access to scarce resources. The documents we relied upon render these conclusions:

- The VA triage criteria give no priority to critical workers because they believe it is a less justifiable a criterion than the others they selected, though they did view priority to critical workers as a "reasonable" criterion for allocation.² They also noted that priority to critical workers has these potential drawbacks: (a) it may violate equity and/or degrade public trust if perceived to apply too broadly, (b) it might be too difficult to define who is a "critical" worker, and (c) it would be problematic to allocate resources to critical workers who are too ill to serve in their role, even if they recover.
- The CDC reports are unclear. As noted above, they appear in some ways sympathetic to priority for critical workers, though they caution about misuse—e.g., when a healthcare worker is given higher priority for a ventilator, but is so sick that she is unlikely to recover quickly enough to help others during this pandemic.³
- The California Public Health guidelines say nothing about this issue in general and do not contain a specific triage protocol. They do discuss the New York guidelines as "an example of standards that might be implemented during a catastrophic emergency," and as noted below, the New York guidelines reject priority for critical workers.⁴

- The Maryland guidelines examined priority for critical workers during public surveys but do not include that priority in their protocol.⁹
- The Minnesota guidelines endorse priority for critical workers, placing them on a separate triage track.³⁸
- The New York ventilator guidelines consider and reject priority for critical workers. Their concerns echo the CDC's: (a) critical workers on a ventilator are unlikely to return to their crucial occupations quickly, (b) it is difficult to determine who is a critical worker, and (c) some of the people they surveyed objected to the appearance of favoritism.

The evidence from these public documents is not consistent. However, it is notable that none of the documents which explicitly discussed the priority issue objected to priority for critical workers in principle. Instead, they raised various practical problems for putting that principle into practice. In light of this, this working group concludes that priority could potentially be given to critical workers so long as it can be done in a way that avoids or substantially mitigates the practical difficulties. Specifically, any proposal for priority critical workers would have to meet these standards:

- A. The definition of "critical worker" must be clear, naming very specific job categories or circumscribing a class of individuals with enough specificity that they can be identified by those charged with employing the triage protocol.
- B. There must be a plausible argument that *each* category of critical worker included in the definition would have a multiplier effect.
- C. The definition of critical worker must not be overly broad, so that vast numbers of individuals are on the priority track and an objectionably small number of resources would be left for the general public. Concretely, the proposal should not have the implication that, for example, most ICU beds would be allocated only to critical workers, leaving almost none for the general public.
- D. There must be a plausible argument that giving priority access to the specific resources in the proposal (e.g., ventilators, ICU beds) would allow the critical workers to return to work guickly enough to have a multiplier effect.
- E. The proposal, if made public, must not be one that would evoke widespread accusations of favoritism and degrade people's trust in the medical system.

In Appendix 4, we have an included a flowchart that can help hospitals determine whether their proposed policy on critical workers meets these conditions. We employed this chart ourselves, doing our best to (a) describe a class of critical workers who would plausibly have a multiplier effect, without (b) having that definition run afoul of the pragmatic problems described by some of the public documents. Although not perfect, we believe the following is a reasonable combination of ethical and pragmatic demands:

When critical workers are prioritized, it should be done as described in the protocol above.
 However, critical workers will not be prioritized if it seems highly unlikely the treatment will allow them to live and return to work during the next year.

- Critical workers are:
 - EMTs
 - Police Officers
 - Firefighters
 - Critical healthcare workers, as defined below
 - Other individuals who, over time, might be revealed to have a multiplier effect roughly equivalent to the individuals above, given the specific way the pandemic unfolds.

And a "critical healthcare worker" will be defined as:

• any health care worker who (a) has been disproportionately exposed to COVID-19 through the workplace, and who works in a field that is (b) necessary for the control of the pandemic, and where in addition (c) prioritizing workers in that field is reasonably viewed as a necessary step to maintain adequate medical staffing in that field during the pandemic. Early data out of the National Health Institute in Italy has found that 1 in 10 people infected by COVID-19 are health care workers. Attempts are currently being made across the United States to understand the proportion affected by community spread, close contacts, or work-related exposures.

This definition requires some interpretation by anyone employing it. This has the advantage that it may be interpreted in light of the particular circumstances faced by each hospital. However, those interpreting the definition must pay special attention to restriction (C) above -- the definition of critical worker must not expand so far that vast numbers of individuals are on the priority track and an objectionably small number of resources would be left for the general public. The general public cannot benefit from a 'multiplier effect' if most scarce resources are going to critical workers. It is worth noting that, on the surface, this definition might seem to restrict the class of critical healthcare workers to those who deserve reciprocity rather than those who produce a multiplier effect, since it partly focuses on those who have taken risks in the service of the public good. However, that was not the rationale for circumscribing the class of critical healthcare workers in this way. Instead, the definition constitutes a compromise between identifying all healthcare workers who could realistically produce a multiplier effect while at the same time meeting the restrictions outlined above, especially restrictions C and E.

We note that the working group examined two other definitions that we considered reasonable. One would restrict the class of critical healthcare workers to those suffering from COVID-19, which could conceivably enhance public acceptance of the policy, as well as narrow the class of critical healthcare workers, should the group identified in our original definition prove unworkably large:

A critical healthcare worker is any health care worker who (a) has been
disproportionately exposed to COVID-19 through the workplace, (b) who is suffering
from COVID-19, or (when diagnosis is not yet available) who is reasonably suspected of
suffering from it, and who works in a field that is (c) necessary for the control of the
pandemic, and where in addition (d) prioritizing workers in that field is reasonably viewed
as a necessary step to maintain adequate medical staffing in that field during the
pandemic.

A third definition is similar to the previous one, but contains terms that are more concrete and perhaps easier to employ in practice. It could be used if our original definition proves too vague to work in practice:

A critical healthcare worker is someone who meets these conditions: (a) they have been
disproportionately exposed to COVID-19 through the workplace, and (b) they are
infected with COVID-19 or, when testing is not feasible, are reasonably suspected of
having COVID-19, and (c) they participate in direct care for COVID-19 patients as part of
their job.

<u>The Multiplier Effect and Pregnancy</u>. Pregnant persons might be seen to offer a multiplier effect, since some would argue that if we can save them and the fetus they are carrying, we are saving two lives instead of one. The documents we surveyed offer these opinions on this issue:

- The Maryland guidelines offer some priority for pregnant persons in their third trimester, so long as the mother's and fetus's prognosis for survival is not poor.[26]
- The New York guidelines state that pregnant persons should not receive special access to ventilator treatment and are instead subject to the usual adult triage procedure, though they note that pregnant persons might be prioritized for vaccines and other preventive measures.⁷
- Although there is no explicit discussion of pregnancy, the VA, CDC, and Minnesota guidelines give no priority to pregnant persons.
- The California guidelines say nothing about this issue in general and do not contain a specific triage protocol. They do discuss the New York guidelines as "an example of standards that might be implemented during a catastrophic emergency," and as noted above, the New York guidelines reject priority for pregnant persons except in the case of preventive measures.⁴

The evidence from these public documents is not entirely consistent. The majority of public documents give no priority to pregnant persons, but the Working Group also noted that multiple public sources did give *in principle* endorsement to the multiplier effect (explained above) as a basis for priority, and many people would regard the saving of pregnant persons, during at least some stages of pregnancy, as creating a multiplier effect.

In light of this, our working group examined the issue ourselves, attempting to bring to bear our guiding principles. This was perhaps the most vexed issue we discussed, and the Working Group noted that any group should takes steps to avoid imposing its own views on the significance of fetal life, since we recognize both the sharp divisions in society about this issue, as well as the disagreements among philosophical and bioethical experts. In the end, we sought the advice of medical experts on the critical care of pregnant persons, and they advised us that giving priority to pregnant persons before week 24 of pregnancy was unlikely to produce a multiplier effect, since any person at that stage of pregnancy who need the kinds of scarce resources discussed in this document were extremely unlikely to carry a fetus to term. The group therefore elected to give priority to pregnant persons only at week 24 and

after. In addition, because the rationale for giving priority to a pregnant person is the multiplier effect, no priority will be given to such persons once they have delivered.

Special Considerations for Transplant Patients. Transplant patients are selected for likelihood of survival using structured, detailed methods and receive considerable attention to prepare them for a life-saving procedure. Hospitals that house transplant programs are specially resourced and trained for these complex procedures and this expertise should be employed when available. Post-transplant patients received an organ that represents a potentially saved life. Patients who are awaiting transplant have a theoretical prognosis that is better than their underlying organ failure would confer because of the chance for full organ function with transplant—particularly for heart, liver, and lung transplantation. However, these factors must be balanced against the prognosis of a patient with acute illness without chronic organ failure. Furthermore, just allocation of resources may prioritize patients with new acute illness over patients with or slated for organ transplants because organ transplant patients have already consumed considerable health care resources, and many other patients in need might have limited access to transplant. We resolved these questions in favor of some considerations (see Part II for details) for patients who have an available organ for transplant, or who are immediately post-transplant) but not for patients awaiting transplant with no immediately available organ.



Appendix 4: Worksheet for Examining Priority for Critical Workers

This is a flowchart designed to tell us whether a **proposal for priority to critical workers** can address the major objections found in public documents

Step 1: Formulate your proposal so that it can be examined.

- A proposal must give priority to several categories of critical workers. Give a precise
 definition of each category that is included in your proposal—e.g., "ICU Nurse," "1st-year medical
 student," "palliative care doctor," "home health care aide," "police officer," "researcher on
 COVID-19 who is not a provider," etc. Try to avoid vague categories like "healthcare worker" or
 "critical worker."
 - If you cannot define each of these categories precisely, then the proposal fails—start over. (To see if you have a precise definition, use this test: suppose you picked a random healthcare worker out of the hospital, could you say whether they fall into any particular category or not? If not, your categories are probably too vague.)
- A proposal must also tell us how much priority to give to critical workers. Define this level of
 priority with precision—e.g., "subtract 1 point from the triage scale," "separate track for critical
 workers," "tie-breaker with a triage category," etc. If you cannot define the level of priority with
 precision, then the proposal fails—start over.
- For reasons that will become clear, a proposal can only be evaluated against a projection of how severe the pandemic is likely to become. Drawing on CDC reports and other things, take your best educated guess about the likely severity as well as the possible range of possible variants.

Step 2: Determine whether the proposal has multiplier effects.

- Taking each category of critical workers in your proposal one-by-one, estimate as best you can what would happen if **that category** of critical workers were given the level of priority you want to assign to them.
- Also estimate what would happen if those same workers were not given priority, as best you can.
 - NOTE: Even if critical workers are not given priority, many will live and return to their jobs. You are trying to imagine the marginal difference between what will happen with and without priority.
- For each category of critical worker in your proposal, is it plausible that giving priority to those workers has a multiplier effect—i.e., saving those critical workers allows additional people to be saved as well?
 - o If no, then the proposal fails—start over.



Step 3: Determine whether the proposal is overly broad.

- New York objected that some definitions of "critical worker" are so broad that massive numbers
 of people will be "critical workers," effectively putting vast number of people on a priority track
 and leaving an objectionably small number of resources for the general public.
- Does your definition have this problem? (E.g., if we enacted your proposal, would most of the ICU now be filled with critical workers?)
 - o If yes, then the proposal fails—start over.

Step 4: Determine whether the proposal offers priority to the wrong things.

- Some public documents object that giving priority to certain kinds of treatment—e.g.,
 ventilators—cannot have a multiplier effect, since critical workers who need vents are unlikely to recover well enough to produce a multiplier effect
- Using your best educated guesses about the extent and nature of the pandemic, ask of each
 resource that you are prioritizing: are critical workers receiving priority to those specific
 resources unlikely to be able to return to work quickly enough to have a multiplier effect?
 - o If yes, then the proposal fails—start over.

Step 5: Determine public response.

- Ask yourself: if this proposal were made public on the front page of the Los Angeles Times and San Francisco Chronicle, would it evoke widespread accusations of favoritism and degrade people's trust in the medical system?
 - o If yes, then the proposal fails—start over.

If you have reached this step, then the proposal has overcome all the major objections in public documents. It is a **candidate** for adoption.

• If multiple proposals pass, then one must be picked using other criteria—presumably including which one is likely to produce the greatest multiplier effect.



Appendix 5: Ventilation and Mortality Considerations with COVID-19 Patients

Endotracheal intubation and mechanical ventilation are used to treat respiratory failure—often categorized as hypoxemic or hypercapnic respiratory failure, or a combination of the two. The procedures may also be undertaken to ensure airway protection in the absence of significant pulmonary disease, such as with severe, acute neurologic or metabolic processes. With the exception of elective surgeries, endotracheal intubation is generally performed as an emergent or urgent procedure to prevent the life-threatening complications of hypoxemia and acidemia.

Based on the published data, approximately 15-20% of patients hospitalized for COVID-19 disease will meet the definition of severe or critical disease—as defined by the 2019 American Thoracic Society guidelines on community acquired pneumonia. [Wu Z, et al. Characteristics of and Important Lessons from the Coronavirus Disease 2019 (COVID-19) Outbreak in China Summary of a Report of 72 314 Cases from the Chinese Center for Disease Control and Prevention. JAMA. Feb 24 2020.] Upwards of 16% of all hospitalized patients with COVID-19 may require ICU admission. [Grasselli, et al. Critical Care Utilization for the COVID-19 Outbreak in Lombardy, Italy. JAMA. 2020.] Respiratory failure is a common occurrence with severe COVID-19 disease with 39% of those patients requiring mechanical ventilation, including 14% requiring invasive mechanical ventilation. [Guan W, et al. Clinical Characteristics of Coronavirus Disease in 2019 in China. NEJM. 2020] Severity of disease, ICU utilization rates, and the use of mechanical ventilation may be influenced by several factors including, healthcare delivery systems, and the age distribution and prevalence of comorbid conditions in affected patient populations.

Data regarding survival and other outcome measures for patients with severe COVID-19 disease, particularly those who require mechanical ventilation, is limited. A small (and ongoing) cohort of critically ill patients from Washington state (n=21) reveals a mortality rate of 50%, thus far. However, 8 of those patients are still mechanically ventilated with a mean follow up of only 7.5 days. 2 patients (10%) have thus far survived to discharge from the ICU.[Arentz, M, et al. Characteristics and Outcomes of 21 Critically Ill Patients With COVID-19 in Washington State. JAMA. February 24, 2020.] Patients and their advocates should be counseled on our most up to date understanding of potential outcomes associated with disease severity and potential interventions.

Appendix 6: Sample Guidelines for ECMO/ECLS Indications and Contraindications in Adult COVID-19 Patients

Background:

A subset of COVID-19 patients present with severe pneumonia and can rapidly develop ARDS. ECMO/ECLS is an invasive and resource-intensive therapy that has been used successfully in the treatment of ARDS in previous influenza virus epidemics, suggesting that it may have the potential to benefit select patients with COVID-19. However, there is limited clinical experience in using ECMO/ECLS for ARDS in the setting of COVID-19, and details about the natural course of the infection, late complications and chances of pulmonary recovery remain unknown. Additionally, resources for the administration of ECMO/ECLS may become limited in the setting of this pandemic, and risk of COVID-19 exposure to healthcare personnel administering ECMO is substantial.

The use of ECMO/ECLS can be considered in carefully selected patients as outlined below.

Indications:

The primary indication for ECMO/ECLS in COVID-19 will be acute respiratory failure requiring VV-ECMO. A subset of patients have developed concurrent cardiomyopathy resulting in cardiogenic shock. Because the latter group of patients have thus far had poor outcomes, evaluation for VA-ECMO will be extremely selective.

- 1. VV ECMO: Acute respiratory failure
 - a. Severe hypoxemia PaO₂/FiO₂ <100 for >6 hours despite optimal care
 - i. Lung protective ventilation P_{plat} <30 cmH₂O and VT <6 ml/kg PBW
 - ii. Higher PEEP attempted (unless contraindicated)
 - iii. Persistent hypoxemia despite use of <u>BOTH</u> of the following adjunctive therapies:
 - 1. neuromuscular blocking agents
 - 2. prone positioning

AND/OR:

- b. Severe CO- $_2$ retention/ hypercapnia with refractory acidosis (pH <7.25) despite optimal lung protective ventilation P_{plat} <30 cmH $_2$ O and VT <6 ml/kg PBW for >6 hours.
- 2. VA ECMO: Heart failure / cardiogenic shock
 - a. Heart failure / Cardiogenic shock refractory to conventional medical management:
 - i. SBP <85, MAP<55, CI <1.8 on \geq 2 of the following:
 - 1. Dopamine > 15 mcg/kg/min
 - 2. Dobutamine > 15mcg/kg/min
 - 3. Epinephrine > 0.05 mcg/kg/min
 - 4. Norepinephrine > 0.3 mcg/kg/min
 - 5. Vasopressin > 2 u/h

AND:

b. Signs of systemic hypoperfusion



- i. Worsening metabolic acidosis
- ii. Rising lactate
- iii. New onset of organ dysfunction:
 - 1. Oliguric/anuric renal failure
 - 2. Acute liver failure

Contraindications:

Patients with any of the contraindications noted below have a higher risk of poor outcome but may be deemed acceptable ECMO/ECLS candidates in rare, carefully evaluated cases. See general guidelines for resource allocation if a scarcity of ECMO equipment and providers exists.

- Age > 60
- Severe neurologic injury
- Ongoing or recent cardiac arrest
- Aortic dissection, severe peripheral vascular disease, severe aortic insufficiency (in cases of VA-ECMO)
- CNS or other major hemorrhage
- Mechanical ventilation >7days
- Underlying pulmonary disease requiring chronic use of O2
- Immunodeficiency
- History of ESRD on chronic hemodialysis
- Advanced liver disease
- Advanced shock with multiorgan failure

Appendix 7: Broader Community: Regional Coordination and Collaborating with Departments of Public Health

There are a number of reasons for individual institutions, or a set of academic medical centers, to be concerned about the approaches across the community to allocation of scarce resources in the setting of a pandemic crisis. First, states (ref NY, MD and the many others) or other broad regions may enact allocation strategies that may direct or guide the policies of individual facilities. Second, crisis allocation mechanisms will often propose to suspend institutional policy due process rules and maybe contradict state or local law. For instance, in California clinicians must facilitate transfer to another provider willing to provide a refused treatment. What is the significance of this rule in the setting of no available beds? Is it suspended by virtue of infeasibility? Similarly Medicare appeal processes will be violated by most crisis allocation mechanisms. Additionally, many institutions have due process provisions within hospital policies that will need to be suspended in the crisis standards of care. Whether these rules are enacted by a regional set of institutions or across a state has implications for the legal risks and willingness of institutions and providers to adhere to triage policies. Thirdly, the principle of justice demands that similar cases be treated similarly. If a patient at one facility is subjected to triage rules while another at a nearby institution is not, this is not only unjust, but will promote hospital shopping and may cause wasteful transfers. Lastly, if a common set of allocation criteria exist across institutions, these are easier for the public to digest and this will facilitate public understanding of the rules, leading to greater transparency.

In California, individual hospitals began working on developing pandemic policies soon after it became clear that COVID-19 was spreading beyond China. Many institutions had prior policies from the H1N1 epidemic and experience with Ebola. Much early policy work adopted schemas from the IOM principles and statewide model policies such as New York. In several regions institutions worked together to try to build similar policies. For example, in southern California, more than fifty institutions participated in SCBCC meetings reviewing principles and individual institutions' policies. Most of these facilities focused on multi-principle prioritization system from University of Pittsburgh. During this period, there was interest in working with state and local departments of public health. Policy generation appeared to develop more quickly at the individual institutional level than at the state level in California.

Appendix 8: Clinical Decision Support Tools for Triage Allocation

Table 13: Glasgow Coma Scale

Criteria	Description	Score
Best Eye Response (1-4)	No eye opening	1
	Eye opens to painful stimulus	2
	Eye opens to verbal command	3
	Eye opens spontaneously	4
Best Verbal Response (1-5)	None	1
	Incomprehensible sounds	2
	Inappropriate words	3
	Confused	4
	Oriented	5
Best Motor Response (1-6)	No motor response	1
	Extension to painful stimulus	2
	Flexion to painful stimulus	3
	Withdraws from painful stimulus	4
	Localized to painful stimulus	5
	Obeys commands	6

Table 14: Trauma Score System (Boyd et al., 1987)

Parameter	Points
Respiratory rate	
10-24	4
25-35	3
>35	2
0-9	1
Respiratory effort	
Normal	1
Shallow, retractive	0
Systolic Blood Pressure	
>90	4
70-90	3
50-69	2
<50	1
No carotid pulse	0
Capillary refill	
Normal	2
Delayed	1
Absent	0
Glasgow Coma Scale	
14-15	6
11-13	5
8-10	4
5-7	3
3-4	1

Table 15: Trauma Injury Severity Score Survival Probabilities (Boyd et al., 1987, Domingues et al., 2018)

Trauma Score	Probability of Survival
16	99%
15	98%
14	95%
13	91%
12	83%
11	71%
10	55%
9	37%
8	22%
7	12%
6	7%
5	4%
4	2%
3	1%
2	0%
1	0%

Table 16: Hunt-Hess Scale for Intracranial Hemorrhage

Criterion	Grade
Asymptomatic, mild headache, slight nuchal rigidity	1
Moderate to severe headache, nuchal rigidity, no neurologic deficit other than cranial nerve palsy	2
Drowsiness or confusion, mild focal neurologic deficit	3
Stupor, moderate to severe hemiparesis	4
Coma, decerebrate posturing	5

Table 17: American Burn Association mortality estimates (Taylor et al., 2014)

Age	Burn Size (% total body surface area)									
(yrs)	0- 10%	11- 20%	21- 30%	31- 40%	41- 50%	51-60%	61-70%	71-80%	81-90%	91%+
5.0 - 19.9	Out- patient	Very high	Very high	High	High	High	Medium	Medium	Medium	Low
20.0 - 29.9	Out- patient	Very high	Very high	High	High	Medium	Medium	Medium	Low	Low
30.0 - 39.0	Out- patient	Very high	Very high	High	Medium	Medium	Medium	Medium	Low	Low
40.0 - 40.9	Out- patient	Very high	Very high	Medium	Medium	Medium	Medium	Low	Low	Low
50.0 - 59.9	Out- patient	Very high	Very high	Medium	Medium	Medium	Low	Low	Low/ Expectant	Low/ Expectant
60.0 - 60.9	Very high	Very high	Medium	Medium	Low	Low	Low	Low/ Expectant	Low/ Expectant	Low/ Expectant
70.0 +	Very high	Medium	Medium	Low	Low	Low/ Expectant	Expectant	Expectant	Expectant	Expectant

Outpatient: Survival and good outcome expected, without requiring initial admission.

Very high: Survival and good outcome expected with limited/short-term initial admission and resource allocation (straightforward resuscitation, length of stay < 14 - 21 days, 1 - 2 surgical procedures).

High: Survival and good outcome expected (survival $\geq 90\%$) with aggressive and comprehensive resource allocation, including aggressive fluid resuscitation, admission $\geq 14-21$ days, multiple surgeries, prolonged rehabilitation.

Medium: Survival 50 - 90% and/or aggressive care and comprehensive resource allocation required, including aggressive resuscitation, initial admission > 14 - 21 days, multiple surgeries and prolonged rehabilitation.

Low: Survival < 50% even with long-term aggressive treatment and resource allocation.

Expectant: Predicted survival < 10% even with unlimited aggressive treatment.

Table 18: Modified Rankin Scale (Wilson et al., 2002)

Modified Rankin Scale ³	Structured Interview for the Modified Rankin Scale
5=Severe disability: bedridden, incontinent, and requiring constant nursing care and attention.	5=Severe disability; someone needs to be available at all times; care may be provided by either a trainer or an untrained caregiver. Question: Does the person require constant care?
4=Moderately severe disability: unable to walk without assistance, and unable to attend to own bodily needs without assistance.	4=Moderately severe disability; need for assistance with some basic ADL, but not requiring constant care. Question: Is assistance essential for eating, using the toilet, daily hygiene, or walking?
3=Moderate disability; requiring some help, but able to walk without assistance.	3=Moderate disability; need for assistance with some instrumental ADL but not basic ADL. Question: Is assistance essential for preparing a simple meal, doing household chores, looking after money, shopping, or traveling locally?
2=Slight disability; unable to carry out all previous activities but able to look after own affairs without assistance.	2=Slight disability; limitations in participation in usual social roles, but independent for ADL. Questions: Has there been a change in the person's ability to work or look after others if these were roles before stroke? Has there been a change in the person's ability to participate in previous social and leisure activities? Has the person had problems with relationships or become isolated?
1=No significant disability despite symptoms; able to carry out all usual duties and activities.	1=No significant disability; symptoms present but not other limitations. Question: Does the person have difficulty reading or writing, difficulty speaking or finding the right word, problems with balance or coordination, visual problems, numbness (face, arms, legs, hands, feet), loss of movement (face, arms, legs, hands, feet), difficulty with swallowing, or other symptom resulting from stroke?
0=No symptoms at all.	0=No symptoms at all; no limitations and no symptoms.

Table 19: Clinical Frailty Scale (McDowell, Xi, Lindsay, & Tuokko, 2004; Rockwood et al., 2005)

Score	Description
1 – Very Fit	People who are robust, active, energetic, and motivated. These people commonly exercise regularly. They are among the fittest for their age.
2 – Well	People who have no active disease symptoms but are less fit than category 1. Often, they exercise, or are very active occasionally
3 – Managing well	Medical problems are well controlled, but not regularly active beyond routine walking
4 – Vulnerable	Not dependent on others for daily help, but symptoms limit activities. Common complaints include being slowed up and/or tired during the day
5 – Mildly frail	More evident slowing; need help in high-order IADLs. Impairs shopping and walking outside the home, meal preparation, and housework.
6 – Moderately frail	Need help with all outside activities and keeping house. Often have problems with stairs, need help with bathing, may need minimal assistance with dressing.
7 – Severely frail	Completely dependent for personal care, from whatever cause (physical or cognitive). Even so, they seem stable and not at high risk of dying within 6 months.
8 – Very severely frail	Completely dependent for personal care, approaching end of life. Typically, they could not recover even from a minor illness
9 – Terminally III	Approaching the end of life. This applies also to those with a life expectancy of < 6 months who are not otherwise evidently frail.

N.B on scoring frailty in dementia:

Degree of frailty corresponds to degree of dementia.

Mild: Forgetting details of recent event, but remembering the event itself, repeating same question/story, social withdrawal

Moderate: recent memory is very impaired, even though they seemingly can remember their past life events well. Can do personal care with prompting.

Severe: Cannot do personal care without help.

Table 20. Determination of the max-ICH Score

Component	Points
NIH Stroke Scale score	
0-6	0
7-13	1
14-20	2 3
<u>≥</u> 21	3
Age (years)	
< 69	0
7 0-74	1
75-79	2 3
<u><</u> 80	3
Intraventricular hemorrhage	
No	0
Yes	1
Oral Anticoagulation	
No	0
Yes	1
Lobar ICH volume, cm ³	
< 30	0
<u>≥</u> 30	1
Nonlobar ICH volume, cm ³	
< 10	0
> 10	1
Total max-ICH score	0-10

Abbreviations: ICH=intracerebral hemorrhage; NIHSS=NIH Stroke Scale. All components indicate measures on initial examination or initial CT/MRI. Lobar ICH was defined as ICH originating at the cortex and cortical–subcortical junction. Nonlobar ICH included deep, cerebellar, and brainstem origin. Deep ICH location was defined as ICH exclusively involving basal ganglia, thalamus, internal capsule, and deep periventricular white matter. ICH encompassing both deep and lobar location should be scored according to the location that ICH most likely originated from. Thus, more than 1 point referring to ICH volume can only be reached by the rare event of 2 distinct ICH (1 large lobar and 1 large nonlobar ICH).

Reference:

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Table 21. Determination of the subarachnoid hemorrhage (HAIR) score

Component	Points
Hunt-Hess Scale score	
5	4
4	1
1-3	0
Age (years)	
<u>≥</u> 80	2
60-80	1
< 60	0
Intraventricular hemorrhage	
Yes	1
No	0
Re-bleed within 24 hours	
Yes	1
No	0
Total HAIR score	0-8

Reference:

Lee VH, Ouyang B, John S, et al. Risk stratification for the in-hospital mortality in subarachnoid hemorrhage: the HAIR score. Neurocrit Care 2014;21:14-9.



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