DEPARTMENT OF HEALTH

Allocation of Ventilators & Related Scarce Critical Care Resources During the COVID-19 Pandemic

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This document was collectively developed by the Minnesota COVID Ethics Collaborative (MCEC) co-led by <u>Debra DeBruin, PhD</u> from the <u>University of Minnesota, Center for Bioethics</u> and <u>Susan M. Wolf, JD</u> from the <u>University of Minnesota Consortium on Law and Values in</u> <u>Health, Environment & the Life Sciences</u>.

Introduction

Minnesota is working diligently to respond to the COVID-19 pandemic. SARS-CoV-2 is a novel virus, i.e., one to which humans do not have pre-existing immunity. It causes COVID-19, a disease that is spreading globally and can cause serious illness and death. This pandemic has overwhelmed health care systems in many countries, necessitating rationing of a variety of health care resources, including diagnostic tests, intensive care resources such as mechanical ventilators, and blood products. There are efforts underway in Minnesota to slow the spread of the illness, increase supplies of needed resources, and develop new therapies for COVID-19. Although everyone hopes that these efforts will prevent a surge of cases in which need for health resources exceeds supply, we must plan for the possibility that rationing will be necessary.

To develop ethical guidance for the allocation of scarce health resources during this public health crisis, faculty from the University of Minnesota joined with the Minnesota Department of Health (MDH), State Health Care Coordination Center (SHCCC), and Minnesota Hospital Association to convene a statewide Minnesota COVID Ethics Collaborative (MCEC). This multidisciplinary group includes members from multiple health care institutions across Minnesota and incorporates experts in ethics, law, public health, medicine, nursing, disaster planning, and spiritual care. The goal is to rapidly share expertise and support the development of sound policies and procedures to address the ethical challenges posed by the COVID-19 crisis, such as allocation of scarce medical resources in the event that need surges beyond supply. As this pandemic continues to unfold, MCEC's work will be updated based on lessons learned and emerging needs. The intent of this document is to provide a model ethics framework for the allocation of ventilators and related scarce critical care resources during the COVID-19 pandemic and to promote consistency among institutions and systems across the state of Minnesota.

MCEC's work draws upon substantial ethical guidance that had already been developed for public health emergencies in the state of Minnesota, well before the COVID-19 crisis began. This established ethical guidance was created in two projects, sponsored by and completed in partnership with MDH: the <u>Minnesota Pandemic Ethics Project</u>, and <u>Ethical Considerations for Crisis Standards of Care</u>. The development of that ethical guidance involved significant stakeholder consultation and wide community engagement. Community engagement forums

included discussion of allocation objectives, criteria for allocation, and strategies to promote equity in access and address health disparities. Using that preexisting work as a starting point, MCEC is promoting statewide collaboration to address the specifics of the COVID challenge in a way that honors the ethical commitments that Minnesota has already embraced.

In the COVID-19 pandemic, as in other public health emergencies, response must focus on the overall benefit to the population, to **try to save the most lives possible while also respecting rights and promoting fairness across our population**. This ethical framework provides guidance on how to accomplish these objectives in allocating scarce critical care resources such as ventilators. Allocation of extracorporeal membrane oxygenation (ECMO) will be managed regionally and statewide, but otherwise should generally follow this framework, although further considerations may be stated in ECMO-specific guidelines. Additional frameworks and guidelines will address allocation of other scarce resources such as diagnostics and blood.

Ethical Values Guiding COVID-19 Response

This ethical framework for COVID-19 response is grounded in the **fundamental ethical commitment** that the response to a pandemic will pursue Minnesotans' common good in ways that:

- are accountable, transparent, and worthy of trust;
- promote solidarity and mutual responsibility; and
- respond to needs respectfully, fairly, effectively, and efficiently.

To honor these fundamental value commitments, pandemic response must promote Minnesotans' common good by balancing **three ethical objectives**:

- protect the population's health by reducing mortality and serious morbidity;
- respect individuals and groups; and
- strive for fairness and protect against systematic unfairness and inequity.

What **does not** change under crisis standards of care:

- Fundamental norms of good care continue during a crisis situation. Patients should be provided the best care possible given available resources.
- Patients have a right to refuse treatment at any time, and to designate individuals who are authorized to make decisions on their behalf if they can no longer make decisions for themselves. Clinicians should encourage patients to plan ahead, and assist them if desired, by discussing the patient's care preferences and who the patient wishes to serve as their authorized decision-maker, including if the patient becomes critically ill in the COVID-19 context. In these conversations, clinicians should avoid bias and stereotypes, and refrain from pressuring patients to refuse or pursue treatment (e.g., intubation and mechanical ventilation). Clinicians should note patient preferences in their Electronic Health Record (EHR) and encourage patients to consider completing a health directive and adding that to

their EHR. The EHR should indicate how to rapidly contact the patient's authorized decisionmaker if necessary. Trained interpreters and other assistance with communication should be available for patients and authorized decision-makers, as needed.

- Patients have a right to supportive care and treatment to manage symptoms, including
 palliative care; this applies to all patients, including those who are not prioritized to receive
 specific critical care resources such as ventilators.
- Conflicts in decision making will be resolved with a transparent and consistent process that applies to all patients equally.
- Obligations to fairly and equitably distribute the burdens and benefits of the healthcare system across the community remain.

What **does** change under crisis standards of care:

- In a crisis situation the duties and obligations of the medical and public health enterprise shift from serving the interests of individuals to promoting the common interests of the community as a whole. In the COVID-19 pandemic, as in other public health emergencies, response must focus on the overall benefit to the population, to try to save the most lives possible.
- During a crisis, care may be allocated according to a different set of clinical and/or other criteria than under conventional standards of care.
- Triaging access to scarce resources means that a patient's access will depend on individualized assessment and a comparative assessment of patients who need the resource at the same time. Triage Officers and Teams will play a crucial role in allocation of scarce critical care resources.
- Access to ventilators is likely to involve time-limited trials, with periodic reassessment.
 When a patient is not improving on a ventilator after a trial period, reallocation of that resource may be considered.
- When there are not enough critical care resources for all patients, Triage Officers or Teams will have responsibility for determining who has access to scarce critical care resources such as a ventilator, not the patient's provider.
- During a crisis, the mechanisms for resolving disagreements about medical decision making may be accelerated. While patients or their authorized decision-makers have the option of requesting secondary review of a triage decision (as described below), this may also be on an accelerated timeline. Note that secondary review at the request of the patient or authorized decision-maker may not be possible when the need for ventilators and related critical care resources significantly exceeds supply.
- During a crisis, it may be necessary to restrict visitors. Creating alternative ways for patients to communicate with their loved ones, and for authorized decision-makers to participate in care decisions in a timely way should be a priority. Hospitals should also provide support for

people who need assistance with communication or other support from family, an aide, an authorized decision-maker, or staff.

 Crisis response plans should address access barriers and health disparities to avoid exacerbating health inequities.

Ethical Criteria for the Allocation of Ventilators & Related Critical Care Resources

Rationing should be avoided if possible. Efforts should be made to extend supplies and conserve resources before implementing triage or rationing; organizations should triage/ration only as a last resort. The state should also develop a statewide system that is readily available to Triage Officers and Teams to rapidly identify available resources and to allow transfer of patients to facilities with resources. The trigger for implementing triage or rationing should be clearly specified and the authority designated to declare the onset of crisis standards of care should be clear and ideally be harmonized across all institutions in a given region. Authorities designated to trigger crisis standards of care should determine when those standards are triggered at a particular threshold of scarcity. In addition, transparency demands that the **public** be informed about when such crisis standards of care have been triggered. During an extended COVID-19 response, when scarce resources will be continuously and consistently needed, allocation approaches activated under crisis standards of care should continue unless or until resources are no longer scarce. If rationing becomes necessary, the ethical commitments and objectives outlined above should inform decisions about how to ethically steward scarce critical care resources. To avoid arbitrary or unfair allocation of scarce resources, allocation criteria should be used for all patients needing access to a scarce resource, not merely COVID-19 patients.

In addition, processes should be implemented to **routinely review and revise triage/rationing decisions**. For individual patients, there may be changes in their status that would alter initial triage/rationing decisions. **Individuals who initially were deprioritized for access to resources may become prioritized**. Individuals who were granted access to resources—for example, a trial on a mechanical ventilator—may not be responding well to that resource; if the scarce resource is needed by others, it may be withdrawn and reallocated to someone at higher priority following the guidelines below. Routine retrospective review of rationing decisions should also be conducted, to ensure that this framework is applied fairly and consistently, that decisions are made without bias, and that no groups are being disproportionately impacted in a way that leads to systematic disadvantage or worsens existing inequities.

Rationing decisions should **not** consider or be based upon:

- Race, ethnicity, gender, gender identity, sexual orientation or preference, religion, citizenship or immigration status, or socioeconomic status;
- Ability to pay;

- Age as a criterion in and of itself (this does **not** limit consideration of a patient's age in clinical prognostication of likelihood to survive to hospital discharge);
- Disability status or comorbid condition(s) as a criterion in and of itself (this does **not** limit consideration of a patient's physical condition in clinical prognostication of likelihood to survive to hospital discharge);
- Predictions about baseline life expectancy beyond the current episode of care (i.e., life expectancy if the patient were not facing the current crisis), unless the patient is imminently and irreversibly dying or terminally ill with life expectancy under 6 months (e.g., eligible for admission to hospice);
- First-come, first-served;
- Judgments that some people have greater "quality of life" than others;
- Judgments that some people have greater "social value" than others.

To the extent possible, personnel responsible for making allocation decisions (Triage Officers or members of Triage Teams) should <u>not</u> be provided with patient characteristics from this list, except insofar as a characteristic listed above (for example, age) is noted to be directly relevant to determining likelihood of survival to hospital discharge. In addition, safeguards should be implemented to protect against bias (e.g., based on race, ethnicity, or disability) in decision-making. For example, Triage Officers and Teams as well as Secondary Review Teams may receive advance training on how to recognize and avoid such bias in decision-making (e.g., training regarding disability bias and anti-racism training), or institutional equity and inclusion officers may be included as members of Triage Teams and Secondary Review Teams.

Patients who are chronically ventilator dependent outside of the critical care context will not have their ventilators withdrawn in order to extend supplies. If such patients become ill and need to enter a critical care unit and be considered for access to a ventilator other than their own personal ventilator, decisions about whether to allocate a ventilator or other critical care resources to them in that context will be made by applying the criteria and process articulated in this framework.

For mechanical ventilators and related critical care resources, the following criteria *should be used* for *both decisions about initial allocation and potential reallocation*. Note that *none of these criteria categorically exclude patients (or groups of patients) from access* to resources. Rather, application of these criteria calls for an individualized assessment of each patient to determine who should have priority when not all patients can access a resource due to acute scarcity in a public health crisis.

 Clinical prognosis should ground rationing decisions. Prognosis should be understood to include both need for the resource (i.e., risk of serious morbidity or mortality if the patient were not to receive the resource), and the likelihood that the patient will benefit from access to the resource by recovery to hospital discharge. Substantial differences in prognosis are what is ethically relevant in differentiating between patients; small

differences should be viewed as morally equivalent and should not be used to allocate resources to or withhold resources from patients.

- Assessing prognosis under this framework is a rigorous process based on individualized clinical assessment incorporating well-accepted prognostic measures. Guidance for how to approach clinical prognosis has been issued by the Minnesota Department of Health (see Patient Care Strategies for Scarce Resource Situations). MDH will issue further COVID-19 guidance for patient care strategies, as needed, to aid individualized assessment. Clinicians may incorporate considerations not specifically outlined in the guidance provided by MDH, if doing so is necessary to fully assess a patient's prognosis of survival to hospital discharge (e.g., a patient presents with severe burns and COVID-19). However, the factors considered in such assessments must be fully documented in order to permit consideration by the Triage Officer or Team and Secondary Review Team.
- Prognosis should be understood narrowly in terms of likelihood of the patient surviving their current illness to hospital discharge.
- In addition to prognosis of surviving current illness to hospital discharge, allocation decisions should consider whether the patient is imminently and irreversibly dying or terminally ill with life expectancy under 6 months (e.g., eligible for admission to hospice).
- Alongside clinical prognosis, the Triage Officer or Team should consider the likely length of need for the scarce resource, when that can be reliably predicted. Patients who are reliably predicted to need a resource for a substantially greater amount of time than other patients currently needing the resource may be deprioritized to allow more patients to have access. Again, it is substantial (not small) differences that should drive decisions to allocate or withhold access to resources. If length of need cannot be reliably predicted among the candidates for consideration, it should not be used as a criterion in allocation decisions.
- For initial allocation of ventilators and related scarce critical care resources, when patients are otherwise of equal priority (i.e., there is no substantial difference in priority), considerations of fairness dictate that the Triage Officer or Team should use a random process to allocate the resource. However, if patients are otherwise of equal priority, mechanical ventilation should not be removed by this random process from patients already receiving it.
- The impact of these criteria should be closely monitored over time to ensure that this framework is applied fairly and consistently, that decisions are made without bias, and that no groups are being disproportionately impacted in a way that leads to systematic disadvantage or worsens existing inequities.

Ethical Duties to Provide Supports

The ethical commitment to provide good care to patients and to support providers creates additional duties.

- Within a health care system, there are strong ethical duties toward health care workers who serve in patient care settings that involve increased risk of COVID-19. These duties are grounded in the need to preserve their capacity to care for all of us and in a duty of reciprocity toward those facing heightened risk in service of the public. These health care workers need adequate PPE, creating both an *obligation to increase supplies and to give these workers priority to available supplies*. They should also receive some priority in access to preventives and in access to medication therapies for COVID-19 as those treatments become available.¹
- Institutions should identify a process for Ethics Support during the pandemic. The primary
 functions of Ethics Support are to facilitate application of ethical frameworks for pandemic
 response (especially given the need to respond to challenging ethical issues that will
 inevitably arise during the crisis), and to help manage moral distress of providers.
- Patients have a right to supportive care and treatment to manage symptoms, including palliative care; this applies to all patients, including those who are not prioritized to receive specific critical care resources such as ventilators, or are withdrawn from ventilators.
- Institutions should also establish resources for mental/behavioral health and spiritual care for both providers and patients/families during the pandemic. Given the distressing nature of challenges posed by the crisis, the need for such services will likely surge during the pandemic.
- Institutions should create tools for communicating to patients or their authorized decisionmakers about the grounds for allocation decisions including prognostic assessment. This framework offers some suggested scripts below as a starting point. Institutions should also assist patients with special communications needs, such as interpreters.

¹**Note:** Some MCEC participants argued that health care workers who serve in patient care settings that involve increased risk of COVID-19 should receive priority in access to ventilators and related scarce critical care resources when allocation decisions must compare patients who otherwise have equal priority. This argument is based on the duty of reciprocity noted above and the need to preserve their capacity to care for us all, especially given shortages of PPE in the COVID-19 pandemic. MCEC did not reach full consensus on this difficult issue. However, the past work sponsored by MDH and referenced on page 1 (the Minnesota Pandemic Ethics Project) concluded that key workers should have some priority in accessing preventives and medication treatments (because of the duty of reciprocity and need to preserve capacity), but not ventilators and related scarce critical care resources. The reasoning was that prioritizing key workers for ventilators could result in unfairness by systematically depriving others of access to ventilators under conditions of great scarcity. In addition, capacity to return to work in the near future after mechanical ventilation is unclear. The paragraph in text is compatible with the past ethics guidance from the Minnesota Pandemic Ethics Project.

Ethical Processes for Implementing Allocation Decision-making

This section outlines **core processes recommended** for ensuring a fair and transparent process of allocation. Individual health care systems **may need to tailor their approach** based on the size of the system and the number of personnel that can be devoted to Triage Teams and Secondary Review Teams. For example, the size and specific make-up of Triage Teams may vary by facility, depending on available staffing and the number of ventilators and other critical care resources to be allocated. It may be necessary to construct **regional Triage Teams and Secondary Review Teams** for greater Minnesota, depending on the impact of the surge in patients on the availability of qualified staff.

Trigger: The trigger for activating this framework is **impending scarcity**. As noted above, the trigger for implementing triage or rationing should be clearly specified and the authority designated to declare the onset of crisis standards of care should be clear and ideally be harmonized across all institutions in a given region. Authorities designated to trigger crisis standards of care should determine when those standards are triggered at a particular threshold of scarcity. In addition, transparency demands that the public be informed about when such crisis standards of care have been triggered. After the threshold is met, **the authority designated to do so** will declare that the trigger for this framework's **activation** has been reached. When scarcity has been sufficiently resolved, the authority will declare that this framework is **deactivated**.

Patient decision-making: A patient who is capable of decision-making is entitled to partner with their care team in making decisions guided by their values and advance directive (if any). When a patient has lost decision-making capacity, an authorized decision-maker should play that role instead, trying to decide as the patient would and following the patient's advance directive (if any). That **authorized decision-maker** should be the person appointed by the patient to play this role. If the patient has not indicated who that person should be, the clinical team should work with the patient's spouse, partner, family, or close friend. Clinicians and health care organizations should work to follow Minnesota guidance and law on surrogate decision-making. They should make sure to note in the patient's records how to reach the **authorized decision-maker** rapidly in the event an emergent triage situation arises.

Separation of roles -- triage decision-making and bedside care: Triage/rationing decisions should be made by a **Triage Officer or Team that is separate from the clinicians** providing care at the bedside. This approach to decision-making promotes the ability of bedside clinicians to advocate for their patients, thus protecting the integrity of the patient/provider relationship. It also helps to ensure that rationing decisions are made fairly, consistently, and based on objective data to allow comparisons across cases. The separation of roles does not imply that the Triage Officer or Team may not communicate with treating clinicians. For example, the treating clinicians may need to call the Triage Officer or Team's attention to an emergent case, or the Triage Officer or Team may need to consult the treating clinician to clarify factors relevant to the triage decision. In any communication between the treating clinician and Triage Officer or Team, all should be mindful that, to the extent possible, the Triage Officer or Team should <u>not</u> be provided with patient characteristics identified above as impermissible to

consider in allocation decisions. While bedside clinicians will not make rationing decisions, they will be expected to follow the directives of the Triage Officer or Team, so that resources may be ethically stewarded.

The **desirable qualities of Triage Team members** include established expertise in the management of critically ill patients, outstanding leadership ability, effective communication and conflict-resolution skills, commitment to avoiding bias and stereotypes (including those based on race, ethnicity, and disability), and training concerning equity and fairness in decision-making (e.g., training regarding disability bias and anti-racism training). The team is expected to make decisions according to this ethical framework for allocation of resources, so ethics expertise is also crucial.

Responsibilities of Triage Officer/Team:

- 1. The Triage Officer or Team will review the clinical information of:
 - a. all patients who the clinical teams have reported might require mechanical ventilation and related critical care resources in the near future;
 - b. all patients who have newly initiated mechanical ventilation;
 - c. patients whose condition has changed significantly in a way that may affect their eligibility for mechanical ventilation; and
 - d. all patients on a time-limited trial of mechanical ventilation.

Each institution should determine how the Triage Officer or Team will rapidly obtain the patient information needed for the triage decision. Options include (but are not limited to) having the bedside clinicians generate that information or having a person such as a triage nurse collect that information from the clinicians and medical record. Whatever process is implemented should incorporate the protection that to the extent possible Triage Officers or Teams should <u>not</u> be provided with patient characteristics identified above as impermissible to consider in allocation decisions.

- 2. All evaluations by the Triage Officer or Team will be based on this established allocation framework and well-accepted prognostic measures. Guidance for how to approach clinical prognosis has been issued by the Minnesota Department of Health (see <u>Patient Care</u> <u>Strategies for Scarce Resource Situations</u>). MDH will issue further COVID-19 guidance for patient care strategies, as needed, to aid individualized assessment. Note that clinicians may have incorporated considerations not specifically outlined in the guidance provided by MDH, if needed to fully assess a patient's prognosis of survival to hospital discharge (e.g., a patient presents with severe burns and COVID-19). However, the factors considered in such assessments must be fully documented to permit consideration by the Triage Officer or Team and Secondary Review Team.
- 3. The Triage Officer or Team will consider **both initial allocation and reallocation** using the criteria in the framework above.

- 4. When necessary, the Triage Officer or Team will **consider transfer** to other facilities with ventilator capacity.
- 5. The Triage Officer or Team will have responsibility to rapidly communicate all allocation decisions to the treating clinician. The allocation decision should then immediately be communicated to the patient or authorized decision-maker. The institution should establish policy clearly stating who has responsibility for communicating the decision to them. This may be the Triage Officer or Team, the treating clinician, or another team (such as Palliative Care) with the clinical and patient-specific knowledge to communicate the decision and answer questions.
- 6. When the decision of the Triage Officer or Team is communicated to **the treating clinician as well as the patient or authorized decision-maker, they will be informed of their option to request review of** the decision by the Secondary Review Team. If the clinician, patient, or authorized decision-maker is considering making a request for secondary review, they should be urged to make the request immediately (for example, within 15 minutes concerning a ventilator). In an emergent triage situation when the need for ventilators and related critical care resources exceeds supply, secondary review at the request of the patient or authorized decision-maker may not be possible.

Secondary Review Team Oversight of the Triage Officer and Teams: Institutions should also establish a **Secondary Review Team** to oversee the work of the Triage Officer or Team.

- The Secondary Review Team will be multidisciplinary and will have at least three (3) members, with relevant clinical and ethics expertise. A Triage Officer (or a member of the Triage Team) and legal counsel will be available for consultation, but will not have voting privileges. Like Triage Team members, Secondary Review Team members should have established expertise in the management of critically ill patients, outstanding leadership ability, effective communication and conflict-resolution skills, commitment to avoiding bias and stereotypes (including those based on race, ethnicity, and disability), and training concerning equity and fairness in decision-making (e.g., training regarding disability bias and anti-racism training).
- Upon request, the Secondary Review Team will consider requests for review of Triage Officer or Team recommendations, when scarce resources dictate considering withholding or withdrawing critical care treatments (such as the ventilator) from individual patients.
- Patients who do not have decisional capacity but who lack an authorized decision-maker who can participate in the decisional process, and thus have no family or close friend available to work with the clinical team, are especially vulnerable. A decision by the Triage Officer or Team that such a patient should not receive mechanical ventilation or related critical care interventions will automatically be considered for secondary review, by having an individual member of the Secondary Review Team screen the triage decision to assess whether there are grounds for secondary review.
- The Secondary Review Team will also exercise oversight by conducting routine retrospective reviews of both triage decisions and secondary reviews.

Requests for Secondary Review: For patients triaged not to receive mechanical ventilation and related interventions, they or their authorized decision-maker will be **notified of their option to request a secondary review** of the Triage Officer or Team's decision. Requests for such review will be to the Secondary Review Team. **Treating clinicians** may also request secondary review of rationing decisions. Individuals who are considering requesting such review should be informed that requests for secondary review will **only be considered based on the criteria outlined below**, to ensure that the process is both fair and manageable in the context of crisis standards of care. As noted above, in an emergent triage situation when the need for ventilators and related critical care resources exceeds supply, secondary review at the request of the patient or authorized decision-maker may not be possible.

The process for secondary review will be:

- Upon request of a secondary review by the patient, the patient's authorized decisionmaker, or treating clinician, the Triage Officer or Team immediately contacts the Secondary Review Team. The Triage Officer or Team will also immediately contact the Secondary Review Team when a patient who lacks decisional capacity and has no authorized decision-maker available is triaged to not receive mechanical ventilation or related critical care interventions.
- 2. A member of the Secondary Review Team promptly **screens the request** (or the referral of a triage decision regarding a patient lacking decisional capacity and authorized decision-maker) to make sure it raises an issue within the scope of the criteria for secondary review stated below. If it does not, then review proceeds no further.
- 3. If the review does proceed beyond the initial screening, the Secondary Review Team reviews the steps by which the Triage Officer or Team made the decision to withhold or withdraw ventilation. The review will determine if the criteria for ventilator allocation were appropriately followed. The Secondary Review Team will determine if a withdrawal or withholding decision by the Triage Officer or Team did not consider all of the relevant clinical triage criteria or misapplied the criteria.
- 4. The decision of the Secondary Review Team will be determined by a majority vote. The Secondary Review Team will respond back to the Triage Officer or Team as soon as possible, with a goal of under 30 minutes (but may take longer, depending on the complexity of the circumstances). The institution should establish policy clearly stating who has responsibility for communicating the Secondary Review Team decision to the requestor. This may be the Triage Officer or Team or another team (such as Palliative Care) with the clinical and patient-specific knowledge to communicate the decision and answer questions.

Secondary reviews will **only be considered** based upon the following **review criteria**:

- Objective information that the Triage Officer or Team's decision was based upon misinformation about allocation criteria such as the patient's prognosis; or
- Objective information that the Triage Officer or Team's decision was based upon a deviation from (1) the ethical considerations specified in this framework, or (2) objective decisionmaking.

Given the time-sensitive nature of decision-making in critical care settings, the Secondary Review Team's decision **must be considered final**.

Importance of retrospective review: The Secondary Review Team will perform retrospective review of the full set of triage decisions and cases considered for secondary review at least weekly. This is important to ensure that the triage and secondary review processes are working appropriately and in keeping with this framework. Problems discovered should be resolved immediately. The Secondary Review Team should develop a means to document retrospective reviews and problem resolution, and should have access to additional patient identifiers at this time to check that decisions are being made fairly. A significant function of retrospective review is to ensure that decisions (including initial triage decisions, clinician requests for secondary review, initial screening for secondary review, and secondary review decisions) are made without bias, including on the basis of race, ethnicity, or other characteristics identified above as impermissible to consider in decision-making. Retrospective review should also consider whether any groups are being disproportionately impacted in a way that leads to systematic disadvantage or worsens existing inequities. Data should be gathered at the state level as well as the level of health systems and institutions to assess impact and ensure fairness and equity.

Importance of documentation: All triage decisions will be documented in the patient's Electronic Health Record (EHR) **using a Triage Decision Template** developed by the institution. Similarly, all Secondary Review Team decisions will be documented in the patient's EHR using a **Secondary Review Decision Template** developed by the institution. This is important to ensure appropriate care of the patient across clinicians and shifts, to ensure transparency and accountability to the patient and family, to allow Triage and Secondary Review processes to work properly, and to enable retrospective review to spot and resolve problems. The Secondary Review Team should oversee development of these templates to ensure that they follow this ethics framework.

APPENDIX A: Communication Tool-Allocation of Resources Suggested Scripts for Patients/Families

Begin each conversation by asking the patient with decision-making capacity or their authorized decision-maker what **their understanding is of the patient's condition**.

Ask the patient or the authorized decision-maker:

- if they have been involved in any prior conversations about the use of a ventilator during the pandemic that has given rise to a resource-scarce environment; and
- what they are **most concerned about** right now.

Throughout any communication with the patient or their authorized-decision maker, it is important to give them time for the information to sink in, to ask questions, and for you to empathize with the situation. Go slowly, listen and wait for the person's response. Use teachback to make sure the patient or their decision-maker understands what has been communicated.

Part 1: PREAMBLE FOR EVERY PATIENT (OR AUTHORIZED DECISION-MAKER) REGARDLESS OF DIAGNOSIS

We are in a **national health care crisis** because of the coronavirus disease, COVID-19, outbreak. As a result, we have **more patients**, and they are sicker than what our hospitals were designed to serve. Hospitals throughout the world are being stretched beyond their capacity. Under these circumstances, our hospital has worked with other health care systems to develop a fair and equitable process to share our limited supplies and dedicate the scarcest resources to those who are more likely to benefit and recover. This unfortunately means that some treatments will not be available to everyone.

This news is difficult for us to deliver, and we understand how hard it may be for patients and their families to hear. These extremely challenging times force us to make difficult decisions. Despite the pressures on the system, we remain **committed to providing transparent, fair, respectful, and compassionate care for everyone**.

Here are the steps our hospital will follow for <u>every patient</u> if our resources get low:

- 1. We will ask patients whether they have preferences about their care. Please let us know about your preferences for your care, whether you have an advance health directive, whether you have indicated any limitations on your treatment (such as CPR or breathing machine), and whether you have chosen someone to speak for you if you are unable to speak for yourself. We also want to make sure we know how to reach that person quickly if necessary.
- 2. Every patient will be **evaluated for the likelihood of benefit** of aggressive respiratory support (meaning a breathing machine, also called a ventilator).

- 3. We will use a well-established **assessment tool** to help us make these decisions. This assessment considers the patient's condition, their likelihood to clinically improve, and for how long they are expected to need the ventilator.
- 4. A Triage Officer or Team, which is different from your regular medical team, will use this evaluation to determine what treatments and resources we can provide you. You will remain our patient and we will treat you to the best of our abilities.
- 5. If you disagree with the decision the team has made, you (or your authorized decisionmaker) can ask that the decision be reviewed by a Secondary Review Team -- a different team of people not involved in your care. [Note that in an emergent triage situation when the need for ventilators and related critical care resources exceeds supply, secondary review at the request of the patient or authorized decision-maker may not be possible.]
- 6. Members of your health care team are **available to answer any questions** you may have and to guide you through the next steps of your treatment.

Part 2: ONLY TO PATIENTS WHO ARE ELIGIBLE FOR VENTILATOR (OR THEIR AUTHORIZED DECISION-MAKER)

- 1. You may require respiratory treatment that includes a breathing machine called a ventilator. The breathing machine is used to support your breathing. We intend to provide you with this respiratory treatment as long as it is beneficial.
- 2. If the respiratory treatment does not improve your condition, it is possible that the breathing machine will be stopped to allow use by patients more likely to benefit and recover. The focus of your treatment may switch to easing your symptoms and increasing your comfort at this time.
- 3. We will keep you and your authorized decision-maker informed of your progress and the treatments that are available to you.
- 4. Members of your health care team are **available to answer any questions** you may have and to guide you through the next steps of your treatment.

Part 3: ONLY TO PATIENTS WHO ARE NOT ELIGIBLE FOR VENTILATOR (OR THEIR AUTHORIZED DECISION-MAKER)

- We wish we had different news; based on careful evaluation of your condition and using a well-accepted assessment we apply to everyone, we will manage your breathing problems by using medications and other measures. We cannot provide treatment with a breathing machine/ventilator.
- 2. We will **continue to provide other types of treatments and supportive care** for as long as you need them. Our goal is to ease your symptoms and increase your comfort.
- 3. If you wish to request a review of the decision, a separate Secondary Review Team is also available to review your plan of care. [Note that in an emergent triage situation when the

need for ventilators and related critical care resources exceeds supply, secondary review at the request of the patient or authorized decision-maker may not be possible.]

4. Members of your health care team are **available to answer any questions** you may have and to guide you through the next steps of your treatment.

Part 4: FOR PATIENTS WHOSE CONDITIONS ARE NOT IMPROVING AND ARE AT RISK OF DISCONTINUING VENTILATION (OR THEIR AUTHORIZED DECISION-MAKER)

- 1. The ventilator does not appear to be helping you. If it does not help your condition improve, the ventilator may need to be withdrawn to allow use in patients more likely to benefit and recover.
- 2. We understand that this news is very difficult to hear. We wish we were working under normal circumstances, but we are not.
- 3. Do you wish to speak with someone to help you make sense of this difficult situation?
- 4. We will keep monitoring your condition. If the breathing machine/ventilator is not helping you, we will let you (or your authorized decision-maker) know before we plan to stop providing it.
- 5. The focus of care will be to continue supportive comfort care and medical management of your shortness of breath and other symptoms, without the ventilator. We will continue to support you and your loved ones.
- 6. If you or your authorized decision-maker wish to request a review of the decision, a separate review team is also available to review your plan of care. [Note that in an emergent triage situation when the need for ventilators and related critical care resources exceeds supply, secondary review at the request of the patient or authorized decision-maker may not be possible.]
- 7. Members of the health care team are available to answer any questions you may have and to guide you through the next steps of your treatment.

Part 5: FOR PATIENTS WHO YOU EXPECT WILL PROGRESS TO DEATH (OR THEIR AUTHORIZED DECISION-MAKER)

- 1. Unfortunately, I am worried that you may die because your disease is not responding to the treatment.
- 2. As the disease progresses, we will provide supportive care and medical management of any symptoms at the end of life in accordance with your advance directive or preferences.
- 3. We **will provide support to you and your loved ones** including chaplains, palliative care specialists, and others.

- 4. Unfortunately, **we may need to limit visitors at this time**, but we will do our best to accommodate them within the limits of our current crisis.
- 5. Please **let us know about things that are important and meaningful to you** during this process.

Part 6: NEONATAL AND PEDIATRIC PATIENTS

- 1. Infants and children will be **assessed for the likelihood of benefiting from aggressive respiratory support** (or breathing machine, also called a ventilator) on a case-by-case basis.
- 2. Clinical information and well-accepted assessment tools will be used for this evaluation, and the same criteria will be applied for everyone.
- 3. A team that is separate from your child's regular medical team uses the assessment to determine whether your child will receive the limited resources and what treatments we can provide to her/him.
- 4. We will continue to provide medical care and support to your child and your family.
- 5. We have made every effort to make this decision with the best information available to us and in a fair way. **If you disagree with the decision, you may ask that the decision be reviewed** by a Secondary Review Team not involved in your child's care. [Note that in an emergent triage situation when the need for ventilators and related critical care resources exceeds supply, secondary review at the request of the patient or authorized decisionmaker may not be possible.]

[In addition to this guidance, clinicians may want to consider including suggested communication skills tips from VITALtalk: <u>https://www.vitaltalk.org/guides/covid-19-communication-skills/</u>]

REQUESTS FOR SECONDARY REVIEW OF TRIAGE OFFICER OR TEAM DECISION:

Part 7: FOR PATIENTS (OR AUTHORIZED DECISION-MAKERS) WHO REQUEST SECONDARY REVIEW

- 1. We understand you have requested secondary review of the Triage Officer or Team's decision about the breathing machine. We will notify the Secondary Review Team about the request.
- 2. The Secondary Review Team includes an experienced, multi-disciplinary team that reviews the decisions of the Triage Team throughout the hospital.
- **3.** Once their review is done, a member of the Secondary Review Team will contact the Triage Officer or Team and we will talk to you about their findings. [Note that some hospitals may designate the Triage Officer or Team or a separate unit such as the Palliative Care Team to

talk to the patient or authorized decision-maker about the Secondary Review Team's findings.]

Part 8: FOR PATIENTS FOR WHOM THE TRIAGE OFFICER OR TEAM DECISION IS CONFIRMED BY THE REVIEW (OR THEIR AUTHORIZED DECISION-MAKER)

- 1. The Secondary Review Team met and reviewed the clinical information that the Triage Officer or Team used to make the decision about stopping (or not starting) the breathing machine.
- 2. We wish we had different news; the Secondary Review Team confirmed the Triage Officer or Team's assessment and confirmed that the information used was accurate and the triage analysis was conducted appropriately.
- 3. We cannot provide treatment with a breathing machine/ventilator, but we will continue to provide other types of treatments and supportive care for as long as you (or your loved one) need them. Our goal is to ease your symptoms and increase your comfort.
- 4. Members of the healthcare team are available to answer any questions you may have and to guide you through the next steps of your treatment.

Appendix B: Communication Tool-Allocation of Resources Suggested Script for Communication to the Community

Note: Each health care system will have to consider the needs of their community. Below is a starting point for developing messaging appropriate for your system and community.

With the uncertainties surrounding the COVID-19 pandemic, we wanted to share information with you about some of the "what if?" situations that may occur during the coming weeks to months. Many efforts are ongoing and already in place to support our community and our teams as we work to minimize the spread of this illness and the burden on our healthcare system. With these interventions -- such as social distancing, cancellation of community gatherings, cancellation of non-essential medical activities, and repurposing of equipment and staff to care for patients facing serious illness -- we remain hopeful that we can provide high quality care for all in our community who need it, while keeping our vital staff safe and well.

But we also felt that it is important at this time to share with you additional work that is going on both at **[our health care system]** and at the community and state level to plan for the possibility that healthcare resource capacity may be exceeded by the needs of our community during this time. We are very fortunate at **[our institution]** and in our state to have experts in emergency preparedness, and to have strong collaboration between healthcare systems, government, and other community groups that will help us to provide the best care possible while pursuing the common good of our community.

As part of emergency preparedness, organizations in our community are developing shared tools and approaches to ensure that the same standard of care is provided everywhere in Minnesota. We are participating in the Statewide Health Care Coordination Center (SHCC), which has been established collaboratively with the Minnesota Department of Health (MDH), the eight regional health care coalitions, and a statewide working group. This center will monitor conditions and capacity of hospitals and critical care units across the state, so that any patient who requires hospitalization or critical illness care will have access to it, if available. The SHCC will also interact with local committees within hospitals to ensure that all patients and families facing serious illness have access to the same level of support and medical care throughout this time. While we are working very hard to provide our usual standard of care to all who need it, we may reach a point of crisis, where providing this level of care is no longer possible. If we reach this point, we will promise to provide care with approaches to decision making that:

- 1. Are accountable, transparent, and trustworthy;
- 2. Promote solidarity and mutual responsibility; and
- 3. Respond to patient needs respectfully, justly, effectively, and efficiently.

More specifically, if we reach a point where there is not enough staff, equipment, or facility space to provide all life-sustaining treatments that are commonly used when not in time of crisis, we will make the best of this circumstance together, and will support teams, patients,

and families regardless of outcome. We will *not* ration or limit life-sustaining treatments based on:

- race,
- ethnicity,
- gender or gender identity,
- sexual orientation or preference,
- religion,
- citizenship or immigration status,
- socioeconomic status,
- ability to pay,
- first-come first-served,
- age in and of itself (unless it is directly relevant to clinical assessment of the patient's likelihood of surviving to hospital discharge),
- disability status or preexisting illness in and of itself (unless it is directly relevant to clinical assessment of likelihood of surviving to hospital discharge), or
- perceived "quality of life,"
- Judgments that some people have greater "social value" than others.

The priority **will be** to preserve life for as many people as we can, and prioritization will be given to patients based on their chance of survival. This determination will use processes that are carefully developed by clinical and ethics teams to consider each patient's condition, that are used in a standardized way across the community without bias or prejudice, and which will be shared and transparent. We are also committed to supporting care teams, patients, and families throughout the course of illness, whether survival or death is the ultimate outcome, with palliative and pastoral care and other supports to provide comfort and minimize suffering.

We hope that circumstances will not come to this point. We encourage you to continue taking the basic steps -- social distancing, handwashing, PPE use, etc. -- that will make the biggest difference during this time. But we also are taking the approach of "hope for the best, but plan for the worst," and recognize the critical importance of being respectful, just, and valuing equally all members of our community if resources become scarce. We are in this together, and will need your help during this time. We ask for your trust that if decisions become difficult, we will use processes that are the right ones for all members of our community.

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