## Subject Matter Experts Advisor Panel for the Governors Expert Emergency Epidemic Response Committee on Crisis Standards of Care Guidelines for Hospitals for the COVID-19 Pandemic

Draft Version 0.9 Date: April 4, 2020 Table of Contents

- I. General Principles and Framework
- II. Key Principles Prior to Implementation of Crisis Standards of Care
- III. Crisis Standards of Care Triage Team Structure
- IV. Crisis Standards of Care Tiered Triage Scoring System
- V. Triage Process
  - a. Types of Triage
  - b. Mechanical Ventilation
  - c. Hospital Transfers
  - d. ICU Admissions
  - e. Re-allocation of Ventilators
- VI. Personal Protective Equipment
- VII. Cardiopulmonary Resuscitation (CPR) Guidance
- VIII. Communication
  - IX. Appendix A: SOFA Score
  - X. Appendix B: Modified Charlson Comorbidity Index
  - XI. Appendix C: Alternative Crisis Standards of Care Triage Scoring Systems
- XII. Appendix D: Calculating the Crisis Standard of Care Triage Score Cutoff
- XIII. Appendix E: Committee Members
- XIV. Appendix F: References
- XV. Appendix G: Crisis Standards of Care Triage Framework for Scarce Resources
- XVI. Appendix H: Crisis Standards of Care: Emergent Triage Process
- XVII. Appendix I: Crisis Standards of Care: Prospective Triage Process
- XVIII. Appendix J: Crisis Standards of Care: Re-Allocation Triage Process

#### **I. General Principles and Framework**

This document is meant to serve as a guide and template for crisis care during the SARS-CoV-2 (COVID-19) pandemic. The Institute of Medicine defines "Crisis Standards of Care" as "a substantial change in usual healthcare operations and the level of care it is possible to deliver, which is made necessary by a pervasive (e.g., pandemic influenza) or catastrophic (e.g., earthquake, hurricane) event."<sup>1</sup> When patients must receive care that substantially deviates from the usual standard of care due to a lack of resources, a new standard of care is created, a crisis of standards of care (CSC).<sup>2</sup> Based on experiences to date from other cities and countries, there could be insufficient resources (such as intensive care unit (ICU) beds and ventilators) to provide these services to everyone in Colorado who might benefit from them.

As a state, our first aim must be to avoid such a situation. However, we must be prepared for the *extreme situation* where there are insufficient resources to care for everyone who needs them. In such a situation, the goal will be to provide the best care for the most people, and to do so in ways that sustain social cohesion, trust in the healthcare system, and our ability as a community to come together and heal in the wake of the pandemic.

All triage systems for CSC are meant for the *extreme situation* in which the number of sick individuals far exceeds the health system's resources and difficult decisions must be made as to who receives certain types of care. A triage system does not always need to decide between providing a specific service and providing no service. For the COVID-19 pandemic, a crisis could exist when fully functional critical care ventilators ("full ventilators) become a scarce resource, but less than optimal alternative forms of ventilation such as anesthesia machines, some non-invasive (NIV) machines, and disposable resuscitators ("partial ventilators") are still available.

This triage framework for CSC gives priority for critical care resources to patients with the highest likelihood of near-term survival (e.g. 1-year survival) were they to receive critical care interventions.<sup>3</sup> It also addresses the possibility of re-allocating scarce critical resources like ventilators from patients with minimal chances of survival to those with higher likelihood of survival. This triage framework has strong ethical underpinnings, including the concept that should there be a declaration of CSC from the State of Colorado, this triage guidance can be used to ensure equity between hospitals and reduce institutional variation in implementation of CSC. A few key principles guided the development of this document:

- 1. A CSC Triage System needs to be transparent, consistent, equitable, respectful, and fair to ALL individuals.
- 2. The bedside care team (e.g., physician, nurse, respiratory therapist) should NOT be involved in initial triage decisions about their own patients to enhance objectivity, avoid conflicts of interest and maintain the therapeutic relationship between bedside care teams and their patients.
- 3. A structure for triaging patients should be adopted at the highest level to reduce variation within and between institutions across the state.
- 4. At no point should factors clinically and ethically irrelevant to the triage process (e.g. race, ethnicity, ability to pay, disability status, national origin, primary language, immigration status, sexual orientation, gender identity, HIV status, religion, veteran status, "VIP" status, or criminal history) be used to make triage decisions.

- 5. Patients who are triaged such that they do not receive a given resource (e.g. do not receive a ventilator if needed) should receive optimal care within the triage framework, including expert palliative care if appropriate and available.
- 6. No single categorical exclusion criteria (e.g., patients ≥ 80 years of age or patients with a specific comorbidity) should be used outside of the triage framework. *This is a fundamental change compared to prior Colorado triage guidance*.
- 7. The triage process will be used for ALL patients who may require critical care resources, not just those who suffer from COVID-19.
- 8. The triage process will be iterative, to account for fluctuations in need for a scarce resource, resource availability, and to ensure it remains accountable and changeable as more is learned.

### **II.** Key Principles Prior to Implementation of Crisis Standards of Care

In dire circumstances where resources become limited, the Governor or a designated public health official may declare a Public Health Emergency within which CSC are authorized, sanctioning the provision of medical care at levels of quality that would otherwise be significantly less than optimal. The declaration of CSC can provide extra legal liability protection to healthcare workers. Prior to a declaration of CSC, the care of all individuals should follow practice standards that existed prior to the current pandemic. As such, prior to a declaration of CSC, decisions regarding withholding CPR or intubation and mechanical ventilation should be based on usual standards of care, including institutional policies on withholding non-beneficial care.

Under current circumstances, no CPR or intubation should take place without use of adequate personal protective equipment (PPE), as these are high-risk activities for exposure; this holds true even if donning PPE will delay the initiation of CPR.

In the period prior to CSC, **all efforts must be made to determine a patient's goals of care prior to the need for CSC**. It is critical to know whether a given patient wants to receive aggressive critical care interventions such as ICU admission or mechanical ventilation. For a patient with decision-making capacity, the individual's preferences to refuse hospitalization, life support like mechanical ventilation, and resuscitative efforts should be respected regardless of CSC. In current circumstances, ALL hospitalized patients must be asked about Advance Directives (ADs), goals of care, and strongly encouraged to appoint a proxy decision-maker (e.g. medical durable power of attorney (MDPOA)). Patients in nursing homes, skilled nursing facilities, and other long-term care settings should also be asked about ADs, and encouraged to appoint a proxy who is aware of their wishes regarding hospitalization and critical care. These actions can help prevent the healthcare system from being overwhelmed with patients who may not want critical care interventions.

#### **III.** Crisis Standards of Care Triage Team Structure

#### **Institutional CSC Triage Teams**

Each institution or healthcare system within Colorado should implement one or more CSC Triage Teams to make decisions about scarce resource allocation. Bedside providers (the Clinical Team) should not make triage decisions assuring that they maintain an effective therapeutic relationship with their patient. A CSC Triage Team can also ensure consistent and equitable decision-making during a crisis. At a minimum, a CSC Triage Team should consist of (1) an expert on ethics or palliative care, (2) an attending physician familiar with critical care (e.g. hospitalist or critical care physician), (3) a representative of nursing staff, and (4) a representative of the hospital's leadership. Members should be respected leaders within the institution capable of making difficult decisions under pressure and should be nominated by their division, departmental, or institutional leaders. A CSC Triage Team Leader should be assigned by the Chief Medical Officer of the institution. The CSC Triage Officer will be the primary person to communicate with Clinical Teams; however, decisions will be made by the entire CSC Triage Team. In certain situations, the CSC Triage Team can consult with a subject matter expert not involved in the care of the patient for further information. No one on the CSC Triage Team should have direct patient care responsibilities for any patient that is being triaged (i.e. they should not be "on service"). A CSC Triage Team and/or CSC Triage Officer should be on-call 24 hours a day and 7 days a week in rotating shifts whenever CSC for hospitals is in effect. Given the anticipated need for frequent consultations, multiple individuals should likely be assigned to the CSC Triage Team and rotate call duties.

## The CSC Triage Team will:

- 1. Assign CSC Triage Scores (see Section IV) to patients. Patients with lower CSC Triage Scores receive higher priority for scarce resources.
- 2. Determine the "CSC Triage Score Cutoff" based on the available resources for that day. CSC Triage Scores less than the triage score cutoff would receive critical care interventions such as a ventilator whereas scores that are higher may not.
- At a minimum, meet daily to review cases near the cutoff score and provide updated CSC Triage Scores for patients at high risk of decompensation/needing a ventilator (see Section IV).
- 4. Be on call 24 hours a day, 7 days a weeks for urgent evaluations of patients who are decompensating but have not yet received a CSC Triage Score (Emergent Triage).
- 5. Be the lead in any discussion about re-allocating critical care resources such as ventilators or critical care beds. The final decision for removal of ventilator support will reside with the CSC Triage Team (unless ventilation or life support is requested to be removed by the patient or proxy or is removed using institutional non-beneficial care or futility policies).
- 6. As best as possible, be blinded to potential biases that are neither clinically nor ethically relevant to triage decisions including but not limited to race, ethnicity, ability to pay, disability status, national origin, immigration status, primary language, sexual orientation, gender identity, HIV status, religion, veteran status, "VIP" status, or criminal history. Institutions should consider assigning the role of abstracting the necessary data to calculate a CSC Triage Score to persons not on the CSC Triage Team with sufficient medical knowledge to perform this task (e.g., medical students, medical librarians, or other medical professionals who cannot provide direct patient care). Alternatively, some health systems may have the ability to automate the CSC Triage Score calculation based on data from the electronic health record.

The institutional CSC Triage Team structure, membership, and team leaders should be determined prior to a declaration of CSC if timing allows. We recommend that the CSC Triage Team practice assigning CSC Triage Scores and review mock cases to determine how they would make decisions in the setting of scarce resources.

### **Regional Coordination**

A key aspect of dealing with scarce resources such as ICU beds and ventilators is regional coordination. The goal is to avoid a circumstance in which a patient presents to one hospital lacking available ventilators while a second hospital nearby has the necessary equipment and resources to care for that patient. The manner with which such a system can reallocate resources across a region or facilitate transfers between hospitals to maximize resource utilization and equity is a priority focus of the state Unified Command Center (UCC), Medical Operations Command. The EMResource system currently has information on available critical care beds and ventilators at each institution, updated daily. Institutional CSC Triage Teams must have direct and ongoing communication channels to their local/institutional Incident Command Officers/Leaders with having access to this system. Only through cooperation across multiple institutions can the best possible care be provided for the greatest number of patients.

### **IV. Crisis Standards of Care Triage Scoring System**

When a triage process for critical care resources such as ICU beds and ventilators is required, the core set of ethical principles used to determine the allocation of scarce resources must reflect concepts of fairness to ALL patients, maximizing benefit to the greatest number of patients, maximizing survivability in the near-term, and ensuring the safety of healthcare workers and first responders. The triage process will involve a multi-tiered system to determine which patients will receive scarce resources and which patients may have their resources re-allocated to other patients. A similar triage process can be adapted to ICU admissions. The first tier involves calculation of an objective CSC Triage Score. In the event of a CSC Triage Score tie between 2 or more patients in need of the same resource, the CSC Triage Team will sequentially consider tiers 2, 3 and 4. The tiered system is meant for allocation of resources. When considering reallocation of ventilators or other critical care resources, the CSC Triage Score will be reassessed and additional information may be considered including trajectory (improving, stable, worsening) and likelihood of recovery.

## Tier One: CSC Triage Score

The first tier of the triage framework is an objective scoring system based on severity of acute and chronic illness to assess likelihood of survival. No perfect scoring system exists, so the development and implementation of a triage score should be based on using the best-available clinical information at the time that a decision must be made. Institutions may refine and adapt existing standard scoring systems to attain better predictive accuracy. An institution with limited resources might use simple assessments of acute illness, such as the Sequential Organ Failure Assessment (SOFA) tool. Institutions using electronic health records with the ability to incorporate more advanced algorithms may develop, validate and then share more complex systems that provide greater predictive accuracy. The goal is to create, as much as possible, a uniform standard to reduce variation and ensure equity in triage processes between hospitals, while encouraging innovation and learning to improve triage scoring systems as the crisis evolves.

The initial CSC Triage Score is grounded in the principle of optimizing near-term health outcomes across a population. It combines a measure of severity of acute illness with a measure of chronic comorbidities that correlates with 1-year and 10-year survival. All scoring systems should incorporate measures of severity of acute illness (e.g. SOFA) and chronic illnesses associated with poorer near-term survival (e.g. modified Charlson Comorbidity Index(mCCI)).4-<sup>10</sup> The initial CSC Triage Score should combine the likelihood of surviving weeks with the

<u>likelihood of surviving months to years</u>. The initial CSC Triage Score should combine the likelihood of surviving chronic inflammatory COVID 19. An initial CSC Triage Scoring system that combines SOFA with CCI is described below:

## Example 1

Principle	Specification	Point System <sup>A</sup>				
		0	1	2	3	4
Save the	Prognosis for short-	Х	SOFA	SOFA score	SOFA	SOFA score >
most lives	term survival		score < 6	6-9	score 10-	12
	(SOFA score <sup>B</sup> )				12	
Save the	Prognosis for near-	0	1-2	3-5	6-7	<u>&gt;</u> 8
most life-	term survival					
years	(Modified Charlson					
	Comorbidity Index					
	Score <sup>C,D</sup> )					

<sup>A</sup>CSC Triage Scores range from 1-8, and persons with the lowest CSC Triage Score would be given the highest priority to receive critical care beds and services.

<sup>B</sup>SOFA = Sequential Organ Failure Assessment, see Appendix A for calculation

<sup>c</sup>See Appendix B for Modified Charlson Comorbidity Index calculation.

<sup>D</sup>AIDS defined as: Current CD4 count<200, Opportunistic infection in the last 1 month, active AIDS defining illness such as lymphoma of Kaposi's Sarcoma

The CSC Triage Score for a patient is derived as the sum of the points assigned based on the SOFA score and the points assigned based on the Charlson Comorbidity Index. <u>The CSC Triage</u> <u>Score ranges from 1-8 with lower numbers indicating higher likelihood of survival and</u> <u>prioritization of critical care resources.</u> Higher numbers indicate patients with lower likelihood of survival despite critical care interventions. We recommend use of the proposed score (combining measures acute illness with chronic illness) at a minimum. When institutions choose a specific scoring system, it should be applied universally to all patients who are triaged. Some institutions will want to augment the triage score calculations with more rapidly available data from an electronic health record. All institutions should use the best available clinical data in refining the score but the core principles and the minimum described standard should not change. Furthermore, each institution will have to decide how best to provide alternative care strategies (including early palliative care) for patients with high triage scores. An alternative scoring system based on the same ethical principles can be found in Appendix C.

# Tier Two: Pediatrics, Healthcare Workers, and First Responders as Tiebreakers

For generations society has placed a special emphasis on the survival of children as the most extreme extension of the life-cycle principle of life years saved. Pediatric patients ( $\leq$ 17 years of age) are a special consideration. Most will have a very low CSC Triage Score and therefore take priority for resources like ventilators. However, pediatric patients also have the unique ability to be transferred emergently to a pediatric hospital where some ventilators are being set aside for pediatric patients. Given the societal worth ascribed to children and the life-cycle principle, we recommend that pediatric patients be given consideration in tier 2 should there be a tie in tier 1.

Healthcare workers and first responders (EMS, firefighters, and police officers) have the potential to save other lives should they recover (multiplier effect) and they are at increased risk of exposure to a potentially lethal infection by virtue of being on the front lines of the COVID-19 response. We recommend healthcare workers and first responders with a role in the COVID-19

response receive a scarce resource over individuals not in one of these categories if all have the same initial Tier One CSC Triage Score.

## Tier Three: Special Considerations as Tiebreakers

Based on expert and community engagement, several other factors should be considered when a patient has a tie for both Tier 1 and 2 (e.g., a nurse and a firefighter, both with a CSC Triage score of 6). In no particular order these include:

- Pregnancy priority for a scarce resource may be given to a late-term pregnant patient over a non-pregnant patient.
- Life Years Saved priority for a scarce resource can be given to a patient with more life years to be saved. For example even with the same CSC Triage Score (Tier 1), some consideration may be given to a 35 year old patient over an 80 year old patient or to a patient with a life-limiting cancer diagnosis.
- Multiplier Effect priority for a scarce resource may be given to patients who are the sole caregiver to a child or elderly (not independent) family member.

Each institutional CSC Triage Team will have to decide how they wish to prioritize tier 3 considerations but consistency across cases, accurate and complete record keeping, and transparency in the decision-making process are required.

## Tier Four: Random Allocation as Tiebreaker

In the event of a tie at tiers 1, 2, and 3, we recommend the use of random allocation to decide which patient should receive a scarce resource.

For patients who are triaged not to receive a scarce resource such as a full ventilator, alternative treatment considerations including early palliative care consultation should be provided.

## **V. The Triage Process**

When a CSC is declared, some institutions may have sufficient resources to continue to provide certain critical care resources to all eligible patients. For core critical care resources like critical care beds and ventilators, each institution must determine its <u>minimum operating capacity</u> (<u>MOC</u>), which is the absolute minimum number of a resource (e.g. ventilator) needed to continue core operations. For example, some hospitals may reserve a ventilator for trauma, another for emergency C-sections and another for the transportation of patients. Hospitals may decide to use alternative ventilators for this purpose (e.g. anesthesia machines or some NIV machines). When a hospital beings to approach its MOC, the crisis triage system should be activated.

**Types of Triage:** In the setting of CSC, there are 3 time points at which triage might need to take place. For this section, we will focus on the example of ventilators, but the framework should apply to any scarce resource such as ICU beds.

1. <u>Emergent Triage</u>: Emergent triage addresses patients for whom generating a CSC Triage Score is not possible prior to a decision to administer treatment. These patients could be "found down" by emergency medical services, patients who present to the ED in extremis, out of hospital or ED cardiac arrest, severe trauma, or acute decompensation or cardiac arrest of a hospitalized patient who does not have a pre-existing CSC Triage Score (e.g., recently admitted, otherwise stable, or observation patients). For these patients healthcare workers should provide these patients with all appropriate treatment including intubation, mechanical ventilation or bag valve mask ventilation through the endotracheal tube, as examples. The CSC Triage Team should be notified immediately and provide an assessment as soon as possible. If the patient has a CSC Triage Score lower than the current triage cutoff, the critical care intervention should continue. However, if the patient has a CSC Triage Score higher than the cutoff, the CSC Triage Team will decide to discontinue mechanical ventilation, transition the patient to a partial ventilator system, or reassess existing patients for possible re-allocation (see below). In very specific situations, such as severe non-survivable brain injury, massive burns, etc. the CSC Triage Team can decide to terminate resuscitative efforts without a triage score.

- 2. <u>Prospective Triage</u>: Prospective triage involves calculating a daily CSC Triage Score for a set group of patients at the time of admission and recalculating that score on a daily basis. For resources like ventilator allocation, this would likely require calculating a CSC Triage Score for every patient in the ICU/Intermediate Care Unit (IMC) on a daily basis. Other physicians or care providers may also identify other patients at high risk of decompensation who should be assigned a daily CSC Triage Score. In such a situation, the medical team would notify the CSC Triage Team to assign the patient a CSC Triage Score. This process is prospective in nature and aims to reduce the need for emergent evaluations and prevent delays in appropriate care. If electronic health record resources allow, the CSC Triage Score should be an automated calculation on all patients in the hospitalized patients including those in the Emergency Department. See below about how this process specifically drives ventilator allocation.
- 3. <u>Re-Allocation Triage</u>: In the setting of activated CSC, patients may reach a point where they have shown a failure to improve or are progressively worsening. If a sufficient therapeutic trial has been completed or the patient shows progressive deterioration despite appropriate medical therapy and there is a need for the scarce resource (e.g., a ventilator or ICU bed), the CSC Triage Team will determine if removal/transition of that resource in favor a patient with a lower CSC Triage Score is warranted. See below for specifics related to ventilators.

#### **Ventilator Allocation (See Flowchart)**

We recommend that at a minimum the CSC Triage Team provide a CSC Triage Score for every patient in the ICU and IMC (regardless of COVID-19 status) daily based on the most recent labs and vital signs (Prospective Triage). The reason to repeat CSC Triage Scores on an ongoing basis is to account for changes in acuity of illness but also shifts in availability of resources (e.g. purchasing of new ventilators, recoveries or deaths that make ventilators newly available). If possible, the system (e.g. SOFA + mCCI) should be automated once an assessment of comorbidity status is made. Based on the available resources for that day (e.g. number of available ventilators), the CSC Triage Team must decide on a "CSC Triage Score Cutoff" above which critical care resources like intubation would not be provided. The CSC Triage Score Cutoff should be determined in collaboration with the local incident command system. It must be based on knowledge of the number of available ventilators and the anticipated need for ventilators on a given day which combines the triage scores for patients recently intubated, recoveries (extubations), deaths, and the position on the epidemic curve (i.e., accelerating phase vs recovery phase) (See Appendix D for possible calculations). Should a patient be triaged not to receive a ventilator but additional resources become available, a reassessment is should occur.

In the setting of Emergent Triage, if there is not enough time to notify the CSC Triage Team (e.g. sudden cardiac arrest outside of the ICU), then the care team should err on the side of caution and **perform all necessary interventions including intubation and manual bag valve** 

**mask ventilation with appropriate PPE protection**. As soon as the patient is stabilized, the CSC Triage Team should be notified. The CSC Triage Team should calculate a triage score for the patient based on the best available data and compare it to the CSC Triage Score Cutoff. The following outcomes are possible:

- 1. A ventilator is available and the patient's CSC Triage Score is sufficiently low such that mechanical ventilation should continue;
- 2. A ventilator is not available but the patient's CSC Triage Score is low enough that possible re-allocation of a ventilator from a patient that has failed a sufficient therapeutic trial should be considered; manual ventilation should be continued until a ventilator becomes available;
- 3. A ventilator is not available but the patient's CSC Triage Score is low enough that urgent transfer to a center with resources should be considered;
- 4. No ventilator is available and the patient's CSC Triage Score is greater than the cutoff. In such a case termination of artificial ventilation is warranted.

The CSC Triage Cutoff Score is based on the best available data at the time. If more resources become available on a given day through successful extubations or deaths, the CSC Triage Team can decide to re-calculate the cutoff score.

## **Re-Allocation of Ventilators (see Flowchart)**

If ventilator scarcity reaches the point of a declaration of CSC, consideration must be given to patients who have failed a therapeutic trial. There is no uniform definition of treatment failure as it is specific to each condition. Based on experiences around the world, the majority of patients with COVID-19 associated respiratory failure require mechanical ventilation for prolonged periods, often longer than 12 days.<sup>11,12</sup> Some patients that require longer periods of mechanical ventilation can recover, but there is clear evidence that the chances of successfully coming off a ventilator and surviving decreases the longer someone is on a ventilator.<sup>13-16</sup> If re-allocation is required, all intubated patients should receive a new CSC Triage Score. The CSC Triage Team must then decide which patients, if any, should be considered for re-allocation. Re-allocation may mean removal from the ventilator with a transition to palliative care. However, if all full ventilators have been utilized but partial ventilators (e.g. NIV ventilator or disposable resuscitators), re-allocation could mean transitioning the patient whose respiratory failure has stabilized to a partial ventilator for an additional period of possible recovery. The full ventilator should be used for patients with lower CSC Triage Scores who have a higher likelihood of survival and receiving benefit from full critical care resources. If the institution is at or below its MOC, then re-allocation of a ventilator would mean transitioning a patient who has failed treatment to palliative care.

CSC Triage Scores and the following data should be considered by the CSC Triage Team for reallocation decisions:

 Duration of mechanical ventilation. Patients with COVID-19 require extended periods of mechanical ventilation prior to improvement. Given the prolonged needs for ventilation for COVID-19 even among those who recover, we recommend that reallocation of ventilators for patients with COVID-19 only be considered after 14-21 days of mechanical ventilation. If a patient is progressively worsening despite maximal ventilator support, consideration for re-allocation can be made earlier based on the CSC Triage Team's assessment.

- 2. **Trajectory of illness.** Intubated patients who are worsening, such as those with progressive multi-system organ failure (MSOF) (shock, acute renal failure, etc), and not improving with appropriate therapy may be considered for re-allocation.
- 3. **Intensity of Resource Utilization**. Some patients on a ventilator require significantly higher levels of care than other patients receiving mechanical ventilation. For example, patients on continuous renal replacement therapy or extracorporeal membrane oxygenation (ECMO) often require a single nurse assigned to a single patient. For ECMO, even more personnel are directly assigned to a single patient. If re-allocation is required, the intensity of resource utilization combined with trajectory of illness should be considered.

These decisions will require collaboration between the CSC Triage Team and the Clinical Team. Given the potential for re-allocation of scarce resources during a pandemic, which is very different from usual critical care, the concept of a time-limited therapeutic trial should be introduced to patients/surrogates early in the course of mechanical ventilation.

If a decision is made to re-allocate (remove) a ventilator from a patient who has failed treatment, the decision must be communicated to the patient's proxy or medical durable power of attorney (MDPOA). If the proxy or MDPOA wishes to discuss with a dedicated Communication Team or a designated member of hospital administration (see Section VII), all efforts must be made to facilitate this conversation. However, given the speed with which the CSC Triage Team needs to make decisions and potentially re-allocate resources, a lengthy formalized appeals process may not be practical. The family can request a reconsideration, but, within the framework of CSC, the CSC Triage Team will retain the final decision.

## **Accountability Mechanisms**

To ensure the fairness, justice, and trustworthiness of the process for making critical and potentially controversial decisions about resource allocations, mechanisms for accountability in the process are required.

- *Transparency:* Each institution must create a process by which the CSC Triage Team can document their decision-making process for review.
- *Case-based due process mechanisms:* Decisions about triage for critical care resources are, by their very nature, urgent. The time and resource constraints envisioned in the triage process were it invoked do not allow for a lengthy appeals mechanism.
  - The only permissible "appeals" are those based on the claim that the CSC Triage Score was calculated incorrectly. These appeals will come from the Clinical Team. Appeals based on objections to the overall allocation framework will not be allowed.
  - The process of evaluating the appeal will consist of the CSC Triage Team verifying the accuracy of the triage score by re-calculating the score.
  - If an appeal results in a scoring dispute, the appeal will proceed to the hospital leadership (e.g. Chief Medical Officer) for re-scoring and rapid decision.

## **Special Considerations for Ventilators**

• <u>Ventilator Type</u> – For COVID-19 induced acute respiratory failure, the optimal and standard treatment is intubation and use of a fully functional critical care ventilator ("full ventilator"). Routine use of any alternative ventilators including NIV, anesthesia machines, and disposable respirators ("partial ventilators") due to insufficient full ventilators, will constitute care during a crisis and therefore trigger the CSC declaration.

Within the framework of the CSC Triage Scoring process, an individual with the lowest CSC Triage Score would receive the scarce resource that would otherwise be considered the usual standard of care (i.e. full ventilator). A patient with a higher CSC Triage Score may be considered for a partial ventilator or the partial ventilators could be reserved for the re-allocation process. If the institution is at or below its MOC for ventilators, early palliative care discussions should be initiated.

As of March 26, 2020 the use of a single ventilator for multiple patients has been discouraged by experts in a joint statement from the Society of Critical Care Medicine (SCCM), American Association for Respiratory Care (AARC), American Society of Anesthesiologists (ASA), Anesthesia Patient Safety Foundation (ASPF), American Association of Critical-Care Nurses (AACN), and American College of Chest Physicians (CHEST).<sup>17</sup> Prior to the implementation of CSC, we do not recommend placing multiple patients on a ventilator. Should CSC be enacted, each institution and CSC Triage Team will need to weigh the feasibility and safety of multiple patients on each ventilator. While it is functionally feasible to place more than 1 patient on a single ventilator, there are many technical, staffing, and ethical considerations. From an ethical perspective, patients placed on the same ventilator should have similar CSC Triage Scores and be at similar points in the trajectory of their illness. Multiple patients on a single ventilator involves weighing suboptimal care for 2+ patients vs optimal care for 1 patient and no critical care for others.

### Hospital Transfer CSC Triage Score

Prior to the declaration of CSC, if an individual hospital experiences significant resource shortages, the priority on their part should be transferring patients to institutions with the needed resources. Hospitals should not be required to unilaterally enact a CSC triage process without a State declaration and incident command access to information about available resources at nearby facilities.

In the setting of CSC, the CSC Triage Score can also be used to determine who should be eligible for transfer to another institution. In this situation, there will be a limited number of critical care beds and ventilators within a region, and the need within a region may exceed the regional resources. Each institution can determine an additional CSC Triage Score cut off for possible transfer to another institution. For example, if resources are very limited at Hospital A, only patients with a CSC Triage Score <3 might receive a ventilator. If other institutions near Hospital A have more resources, then the CSC Triage Team could create another cutoff where patients with a score between 3 and 5 are considered for rapid transfer. In such a situation, patients with a CSC Triage Score  $\geq 6$  would not be considered for a ventilator or transfer to another institution due to the high resource utilization and low chances of survival. Guidelines for transfer CSC Triage Score cutoffs will be institution specific and sensitive to regional availability of resources.

#### Admissions to Critical Care Units

While a similar scoring process could be used for triaging critical care admissions, additional contingency plans should be implemented. For example, some treatments usually requiring an ICU bed (such as diabetic ketoacidosis requiring an insulin infusion) may be transitioned out of the ICU (e.g. allowing insulin drips on the floor). Furthermore, the number of critical care beds and where critical care services can be provided will shift throughout the pandemic as hospitals expand their ICUs. Should critical care beds become a scarce resource, some patients may not be

eligible for ICU admission. More strict ICU admissions criteria such as refractory hypoxia requiring mechanical ventilation and/or shock may be employed. As with ventilator allocation, considerations should be made regarding acuity of illness, likelihood of near-term survival, and possible benefit from and duration of critical care services. The concept of duration of critical care services is a step beyond the guidelines for allocation of ventilators. We recommend using a similar process as the allocation of ventilators to the allocation of critical care beds led by the CSC Triage Team. This will involve having a separate CSC Triage Score cutoff for critical care admission. The CSC Triage Team will need to evaluate all patients who are acutely decompensating on the regular ward as well as the emergency department to determine which patients will receive critical care services if it becomes a limited resource. If critical care bed shortage becomes a major theme of the pandemic, further guidelines may be provided.

### V. Personal Protective Equipment

Sufficient and appropriate PPE is critical to ensuring the safety of healthcare workers and first responders. In the setting of an infectious pandemic, PPE can become a scarce resource. While health professionals have a duty to provide care even if doing so may present some risk to themselves (e.g. needle sticks), they are not obligated to do so in the face of high risk of life-threatening illness. Strict rules for different levels of PPE required for caring for patients with confirmed or suspected COVID-19 are not possible given variability in PPE availability and evolving recommendations on the optimal PPE for specific situations. However, when sufficient and appropriate PPE is not available healthcare workers may have to change their practices to ensure their own safety. For patients with confirmed or suspected COVID-19 specifically, this may first affect aerosolize-inducing procedures such as laryngoscopy, bronchoscopy, endoscopy, intubation, etc. which are high risk and require higher levels of PPE. If CSC for PPE is specifically declared, further mandates may be required. While a CSC for PPE will not change what constitutes appropriate PPE for healthcare workers, it should provide legal protections to healthcare workers in the setting of care being delayed or not provided due to appropriate PPE not being available.

## VI. Cardiopulmonary Resuscitation (CPR) Guidance

CPR presents multiple issues during the current COVID-19 pandemic. CPR can be time consuming and the provision of maximal care for one patient with poor chances of survival may negatively affect the care of other patients. Survival following in-hospital cardiac arrest is poor in usual circumstances. In COVID-19 patients, CPR has the potential to increase viral exposure to healthcare workers and utilizes a large amount of PPE. Prior to the declaration of CSC, current practice standards should be maintained. Patients who wish to receive resuscitation efforts with CPR should receive it except in accordance with institutional non-beneficial care or futility policies. Unilateral declarations to withhold CPR for all COVID-19 patients are inappropriate. There are specific issues regarding CPR that should be considered. First, adequate PPE must be available to protect healthcare workers (see Section V). After a CSC declaration, we recommend the following cardiac arrest guidelines:

1. For all patients, every effort MUST be made to understand and respect ADs prior to cardiac arrest. Cardiac arrest procedures should not be initiated if they are not wanted by the patient/surrogate.

- 2. **CPR should not be performed if adequate PPE is unavailable given the high risk of infection to healthcare workers.** In view of wide community transmission, this standard should apply to all patients, not just those known to have COVID-19.
- 3. Emergent presentations (such as to the ED in cardiac arrest) should adhere to the normal standards and indications for resuscitation if proper PPE is available.
- 4. For cardiac arrests, a restricted code team should enter the room with appropriate PPE including N95 or equivalent masks. A proposed reduced code team could consist of 2 physicians capable of airway management, 1 respiratory therapist, and 2 RNs. The recorder, pharmacist, and other chest compression rotators should wait outside of the room with the door closed and communication by phone. Based on the WHO guidelines, the most experienced airway manager should attempt intubation, which could include an anesthesiology attending on the code team.
- 5. Consideration should be given to early intubation to avoid aerosolization during chest compressions.
- 6. All code carts and airway carts should contain a HEPA/viral filter that can be attached to the bag valve mask to prevent aerosolization of viral particles when bagging through the endotracheal tube. The filter should be attached between the tube and the bag valve mask. We do not recommend a HEPA filter be placed with every bag valve mask as that could quickly deplete a limited resource.
- 7. Many COVID-19 patients with severe hypoxemia will need to be placed in a prone position. While CPR and defibrillation is technically possible in the prone position, in a crisis situation there may be insufficient resources to perform effective CPR in this population.
- 8. For patients who are already intubated, the risk of exposure to healthcare workers is reduced but not zero. A major risk of exposure would occur if the endotracheal tube is disconnected from the ventilator and attached to bag valve mask as is typically done during a code situation. Several steps can be taken to minimize this risk. A clamp can be placed on the endotracheal tube to seal it, after which the ventilator circuit is disconnected and a bag valve mask is attached with a HEPA/viral filter. Once the bag valve mask is attached, the clamp would be removed. A second option would be to use manual breaths from the ventilator (run by the RT) during CPR. A third option would be to allow normal ventilation from the ventilator but increasing the pressure trigger to prevent the delivery of spontaneous ventilations during chest compressions. For any process that uses the ventilator, careful attention must be given to prevent any disconnection in the circuit.

In summary, in the event of a declaration of CSC, ethical standards, resource availability, and likelihood of survival will affect decisions on emergent resuscitation including CPR. These standards should apply to all patients, not just COVID-19 patients.

- 1. Not performing CPR is justified if the risk to healthcare workers is too high. In the setting of the COVID-19 pandemic, this standard will likely focus on the availability of sufficient PPE. If adequate PPE is not available, healthcare workers should not perform CPR.
- 2. Not performing CPR is justified if CPR is physiologically futile and death is imminent. The CSC /Clinical Team could consider a unilateral DNR for patients with refractory shock, refractory hypoxia, or worsening multi-system organ failure despite appropriate support.

- 3. The Clinical Team/CSC Triage Team could consider an informed assent approach for DNR orders for critically ill patients based on severity of illness and premorbid status.
- 4. CPR should not be performed if there are insufficient resources such as healthcare workers, ICU beds, or ventilators.

#### **VII: Communication**

If CSC are declared, the medical team should make patients and families aware of the declaration as early as possible in the admissions process and if possible, prior to admission to an ICU. The Colorado Hospital Association has resources to answer patient and family questions about CSC. Communication between the hospital and family members of a patient in the ICU is critical. COVID-19 presents a unique challenge as the majority of patients are in isolation and not allowed any visitors. Additionally, as the volume and acuity increase over the course of the pandemic, the ICU care team may not have sufficient time to discuss triage decisions with the family. Institutions should consider forming triage communication teams, comprising care providers with expertise in communicating bad news who are not "on-service," such as palliative care, ethics, and ICU attendings who are off service. This team should be available to support the bedside team and should communicate triage related decisions to families. This communication strategy will need to be collaborative between the communication team, the CSC Triage Team and the Clinical Team, to ensure the communication team has sufficient clinical information. In institutions that do not have the resources for a separate communication team, the Clinical Team should communicate triage decisions to the patient and family.

Triage decisions may not strictly follow a clinician's or patient's preference. They are enacted only in the time of crisis. However, at all times patients and surrogates should be treated with respect and compassion regardless of CSC triage decisions. Whenever a decision that a patient will not receive a resource that is in shortage needs to be made without patient consent, assent should be sought. Refusal of assent will not change the triage decision but the opportunity to assent should be offered if time and resources allow.

Appendix A: SOFA Score<sup>4-6</sup>

SOFA Score				•		
	POINTS					
Variables	0	1	2	3	4	
Respiratory P <sub>a</sub> O <sub>2</sub> /FiO <sub>2</sub> , mmHg	>400	<u>&lt;</u> 400	<u>&lt;</u> 300	<u>&lt;</u> 200 <sup>A</sup>	<u>≤</u> 100 <sup>A</sup>	
Coagulation Platelets x 103/µL	>150	<u>&lt;</u> 150	<u>≤</u> 100	<u>&lt;</u> 50	<u>&lt;</u> 20	
Liver Bilirubin, mg/dL	<1.2	1.2-1.9	2.0-5.9	6.0-11.9	>12.0	
Cardiovascular Hypotension <sup>B</sup>	No Hypotension	MAP<70 mm Hg	Norepinephrine <0.03 Dopamine<5 OR dobutamine any dose	Dopamine <u>&lt;</u> 5 OR Epinephrine <u>&lt;</u> 0.1 OR Norepinephrine <u>&lt;</u> 0.1	Dopamine <u>&gt;15</u> OR Epinephrine >0.1 OR Norepinephrine <u>&gt;</u> 0.1	
Central Nervous System Glasgow Coma Scale	15	13-14	10-12	6-9	<6	
Renal Creatinine, mg/dL OR UOP (mL/day)	<1.2	1.2-1.9	2.0-3.4	3.5-4.9 OR UOP<500	>5 OR UOP <200	

Abbreviations: P<sub>a</sub>O<sub>2</sub> - partial pressure of oxygen in the arterioles, FiO<sub>2</sub> – fraction of inspired oxygen, MAP – mean arterial pressure, UOP – urine output

<sup>A</sup>With mechanical ventilation or other form of artificial ventilation

<sup>B</sup>On vasopressor for at least 1 hour. Doses are given as µg/kg/min

**Predicted Mortality** 

Initial SOFA Score	30-Day Mortality
0-1	0.0%
2-3	6.4%
4-5	20.2%
6-7	21.5%
8-9	33.3%
10-11	50.0%

12-14	95.2%
>14	95.2%

Variable	Score
Age	
<50	+0
50-59	+1
60-69	+2
70-79	+3
<u>&gt;</u> 80	+4
Chronic Heart Failure	+2
Dementia	+2
Chronic Pulmonary Disease	+1
Connective Tissue Disease	+1
Liver Disease <sup>A</sup>	
Mild	+2
Moderate or Severe	+4
Diabetes Mellitus with Chronic Complications	+1
Hemiplegia	+2
Renal Disease	+1
Metastatic Solid Tumor	+6
Any active malignancy including leukemia/lymphoma	+2
AIDS <sup>B</sup>	+4

## Appendix B: Modified Charlson Comorbidity Index<sup>7-9</sup>

<sup>A</sup>Severe=cirrhosis, portal hypertension, history of variceal bleeding. Moderate=cirrhosis, portal hypertension, Mild=chronic hepatitis or cirrhosis without portal hypertension

<sup>B</sup>AIDS defined as: Current CD4 count<200, Opportunistic infection in the last 1 month, active AIDS defining illness such as lymphoma of Kaposi's Sarcoma

Principle	Specification	Point System <sup>A</sup>			
		1	2	3	4
Save the most lives	Prognosis for short-term survival (SOFA score <sup>B</sup> )	SOFA score < 6	SOFA score 6- 9	SOFA score 10-12	SOFA score > 12
Save the most life- years	Prognosis for near and long-term survival (medical assessment of comorbid conditions)		Major comorbid conditions with substantial impact on long-term survival		Severely life- limiting comorbid conditions; death likely within 1 year

Appendix C: Alternative Crisis Standards of Care Triage Scoring Systems<sup>3,18</sup>

<sup>A</sup>CSC Triage Scores range from 1-8, and persons with the lowest CSC Triage Score would be given the highest priority to receive critical care beds and services.

<sup>B</sup>SOFA= Sequential Organ Failure Assessment (See Appendix A)

Examples of Major Comorbidities (decreased	Examples of Severely Life Limiting
long-term survival)	<b>Comorbidities (survival expected &lt;1 year)</b>
Moderate dementia	Severe dementia
Malignancy with <10 year survival	Cancer being treated with mostly palliative
	interventions with <1 year expected survival
NYHA Class III Heart Failure	NYHA Class IV Heart Failure + frailty
Moderately severe chronic lung disease (COPD,	Primary pulmonary hypertension with NYHA III
IPF)	or IV heart failure symptoms
ESRD with age <75	Severe chronic lung disease + evidence of frailty
	(FEV1<25%, TLC<60%, PaO2<55mmHg,
Severe multi-vessel CAD	Cirrhosis with MELD $\geq 20$ and not eligible for
	transplant
Cirrhosis with history of decompensation	ESRD with age >75

Abbreviations: NYHA – New York Heart Association, COPD – chronic obstructive pulmonary disease, IPF – idiopathic pulmonary fibrosis, ESRD – end stage renal disease, FEV1 – forced expiratory volume in the first second, TLC – total lung capacity, CAD – coronary artery disease, MELD – model for end-stage liver disease

Appendix D: An Example of Calculating the Crisis Standards of Care Triage Score Cutoff

Factors to Consider Given Information on a Specific Day

### Example 1:

Number of Critical Care Ventilators Available	3
Number of Critical Care Ventilators Expected to Become Available	2
Average CSC Triage Score of Patients at Time of Intubation in last 3 Days	4
Average Number of Patients Intubated Per Day in Last 3 days	4

In this scenario there are expected to be 5 ventilators for the day but 2 may not be available until later in the day. If the rates for intubation are stable or slightly increasing, a CSC Triage Score cutoff could be set at 5. Patients with a score of 5 and above (much sicker than those presenting in the prior 3 days) would either be triaged to a less standard ventilator or would receive a ventilator but would be rapidly re-triaged if less sick patients presented.

### Example 2:

Number of Critical Care Ventilators Available	1
Number of Critical Care Ventilators Expected to Become Available	1
Average CSC Triage Score of Patients at Time of Intubation in last 3 Days	4
Average Number of Patients Intubated Per Day in Last 3 days	4

In this scenario, only 2 ventilators are expected to become available for the day with an expected need of 4. In this scenario a CSC Triage Score cutoff of 3 or 4 could be used. Given that patients with a score of 3 are not very sick, it could prompt a discussion of re-allocation of a ventilator from a patient that has failed a therapeutic trial or consideration for transfer to an institution with more resources. It would also indicate that patients with high triage scores (e.g.  $\geq 6$ ) would not receive a ventilator.

## **Appendix E: Committee Members**

Anuj B Mehta, MD	Patrick J Gaughan, RN, BSN, MBA, MHA
Pulmonary and Critical Care Medicine	Senior Vice President, Chief Values
Assistant Professor of Medicine	Integration Officer
National Jewish Health	Centura Health
Denver Health & Hospital Authority	Centennial, CO
University of Colorado	
Stephen V. Cantrill, MD, FACEP	James K. O'Brien MD
Emergency Physician	Associate Professor
Denver Health Medical Center	Division of Pulmonary, Critical Care and Sleep
Member, Governor's Expert Emergency	Medicine
Epidemic Response Committee, CDPHE	Department of Medicine
	National Jewish Health
	Denver, CO
Aseel Dalton, RPh, LLM, PhD	Jeffrey Sankoff, MD
Visiting Scholar – Senior Research Fellow	Assistant Medical Director
Yale Interdisciplinary Center for Bioethics	Emergency Department, Denver Health
Ethics Committee	Medical Center
Denver Health & Hospital Authority	Associate Professor of Emergency Medicine
	University of Colorado School of Medicine
Thom M Dunn, PhD	Darlene Tad-y, MD, SFHM
Staff Psychologist / Ethics Committee	Vice President, Clinical Affairs, Colorado
Denver Health & Hospital Authority	Hospital Association
	Associate Professor of Medicine
	University of Colorado School of Medicine
Eric France MD MSPH	Matthew Wynia, MD, MPH, FACP
Chief Medical Officer	Professor of Medicine and Public Health
Colorado Department of Public Health &	Director, Center for Bioethics and Humanities
Environment	University of Colorado School of Medicine

## **Appendix F: References**

- 1. Committee on Guidance for Establishing Crisis Standards of Care for Use in Disaster S, Institute of M. In: *Crisis Standards of Care: A Systems Framework for Catastrophic Disaster Response*. Washington (DC): National Academies Press (US) Copyright 2012 by the National Academy of Sciences. All rights reserved.; 2012.
- Colorado Crisis Standards of Care. Colorado Department of Public Health and Environment. <u>https://www.colorado.gov/pacific/cdphe/colorado-crisis-standards-care</u>. Published 2018. Updated July 13, 2018. Accessed February 1, 2020.
- 3. White DB, Katz MH, Luce JM, Lo B. Who should receive life support during a public health emergency? Using ethical principles to improve allocation decisions. *Ann Intern Med.* 2009;150(2):132-138.
- 4. Ferreira FL, Bota DP, Bross A, Melot C, Vincent JL. Serial evaluation of the SOFA score to predict outcome in critically ill patients. *Jama*. 2001;286(14):1754-1758.
- 5. Minne L, Abu-Hanna A, de Jonge E. Evaluation of SOFA-based models for predicting mortality in the ICU: A systematic review. *Crit Care*. 2008;12(6):R161.
- 6. Vincent JL, Moreno R, Takala J, et al. The SOFA (Sepsis-related Organ Failure Assessment) score to describe organ dysfunction/failure. On behalf of the Working Group on Sepsis-Related Problems of the European Society of Intensive Care Medicine. *Intensive care medicine*. 1996;22(7):707-710.
- 7. Charlson M, Szatrowski TP, Peterson J, Gold J. Validation of a combined comorbidity index. *J Clin Epidemiol*. 1994;47(11):1245-1251.
- 8. Charlson ME, Pompei P, Ales KL, MacKenzie CR. A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. *J Chronic Dis.* 1987;40(5):373-383.
- 9. Quan H, Li B, Couris CM, et al. Updating and validating the Charlson comorbidity index and score for risk adjustment in hospital discharge abstracts using data from 6 countries. *Am J Epidemiol.* 2011;173(6):676-682.
- 10. Radovanovic D, Seifert B, Urban P, et al. Validity of Charlson Comorbidity Index in patients hospitalised with acute coronary syndrome. Insights from the nationwide AMIS Plus registry 2002-2012. *Heart*. 2014;100(4):288-294.
- 11. Bhatraju PK, Ghassemieh BJ, Nichols M, et al. Covid-19 in Critically Ill Patients in the Seattle Region Case Series. *N Engl J Med.* 2020.
- 12. ICNARC Report on COVID-19 in Critical Care. London, UK April 4, 2020.
- 13. Mehta AB, Walkey AJ, Curran-Everett D, Douglas IS. One-Year Outcomes Following Tracheostomy for Acute Respiratory Failure. *Crit Care Med.* 2019.
- 14. Ruan SY, Teng NC, Huang CT, et al. Dynamic Changes in Prognosis with Elapsed Time on Ventilators among Mechanically Ventilated Patients. *Ann Am Thorac Soc.* 2020.
- 15. Wunsch H, Guerra C, Barnato AE, Angus DC, Li G, Linde-Zwirble WT. Three-year outcomes for Medicare beneficiaries who survive intensive care. *JAMA : the journal of the American Medical Association*. 2010;303(9):849-856.
- 16. Wunsch H, Linde-Zwirble WT, Angus DC, Hartman ME, Milbrandt EB, Kahn JM. The epidemiology of mechanical ventilation use in the United States. *Critical Care Medicine*. 2010;38(10):1947-1953.
- 17. Joint Statement on Multiple Patients Per Ventilator. March 26, 2020.
- 18. White DB, Katz M, Luce J, Lo B. *Allocation of Scarce Critical Care Resources During a Public Health Emergency*. Pittsburgh, PA: University of Pittsburg; April 3, 2020.



# Appendix G





