

ETHICAL ALLOCATION OF HOSPITAL BEDS AND MECHANICAL VENTILATORS DURING THE COVID-19 EPIDEMIC

The COVID-19 pandemic is leading to scarcity of precious health care resources including hospital beds, personal protective equipment, and mechanical ventilators.

UVM Health Network is committed to fair, transparent, reasonable and wise allocation of health care resources in order to protect the people we respect and serve.

This guideline aims to clarify a pragmatic approach to the wise allocation of <u>hospital beds</u> and <u>mechanical ventilators</u> for use by frontline health care workers.

The figures and <u>appendices</u> below should enable rapid use of this document. Also, we recommend each institution develop a brief procedure appropriate to their leadership structure to enable efficient activation of the system in real time when needed.

Very brief ethical framework

Public health catastrophes such as war and pandemics can enforce difficult resource allocation decisions due to scarcity of health care resources. In such situations, the primary mandate is to maximize the number of lives saved and minimize suffering.

Utilitarian systems put in place to maximize life and reduce suffering must be fair, transparent, legal and wise. Such systems must be free of bias, free of "gaming" such as VIP's getting special treatment, transparent to enable trust, accountable, and structured to minimize individual adverse impacts as much as possible. Any infringement on personal autonomy, privacy or other rights must be proportional to the public health benefit. There is an ample literature on this subject, with one initial accessible reference on this being Christian et al "Development of a triage protocol for critical care during an influenza pandemic" *CMAJ* 2006;175(11):1377-81.

The resource allocation process, derived from the current 2007 CDC guidelines regarding a "fair process approach" must involve the following features:

- 1. Consistent application of accepted acuity/prognosis criteria in order to reduce subjective clinical decision-making, using randomization only if patients cannot be reasonably ranked
- 2. Fair treatment of cases
- 3. Impartiality and neutrality of decision-makers
- 4. Attention to respect and dignity in the treatment of all patients
- 5. Allowance of an appeals process regarding the facts that drive decision-making
- 6. Transparency about guidelines used to make decisions
- 7. Periodic review to allow adaptation of process to meet evolving realities

One key concept relevant to the development of an evidence-based approach to prioritizing care is

triage. "Triage is the process of sorting, classifying, and assigning priority to patients, especially when available medical resources are insufficient to provide care to all who need it. Triage is commonly used in situations such as natural disasters, deadly epidemics, and battlefield situations, where shortages are extreme and people die who might be saved if they had immediate access to medical care available in ordinary clinical circumstances," according to the CDC's 2011 document "Ethical Considerations for Decision Making Regarding Allocation of Mechanical Ventilators during a Severe Influenza Pandemic or Other Public Health Emergency."

Legally, the public governmental declaration of a state of emergency typically comes with relaxation of legal and regulatory oversights on clinical practice in order to allow for health care systems to adapt swiftly to the crisis. Rationing of scarce resources is one element of health care response to public health crises. Specifically, Governor Scott's March 2020 declaration of a state emergency in Vermont contains the following:

"15. Relevant rules governing medical services shall be suspended to the extent necessary to permit such personnel to provide paramedicine, transportation to destinations including hospitals and places other than hospitals or health care facilities, telemedicine to facilitate treatment of patients in place, and such other services as may be approved by the Commissioner of Health.

16. Relevant rules governing nursing services shall be suspended to the extent necessary to permit such personnel to provide medical care, including but not limited to administration of medicine, prescribing of medication, telemedicine to facilitate treatment of patients in place, and such other services as may be approved by the Secretary of State in consultation with the Commissioner of Health.

Below, we detail a system devised to meet these criteria while still being pragmatic and usable by busy frontline health care workers. The priority-setting process is designed to be reasonable, transparent, accountable, and pragmatic.

Wise allocation of hospital beds

If the supply of hospital beds becomes severely constrained from the COVID-19 pandemic, hospitals must allocate hospital beds in a fair, transparent, legal and wise fashion.

Overview

This system of hospital bed allocation should be accomplished via a combination of systematic institutional bed status levels, designated institutional triage leader decisions about bed disposition within those institutional bed status levels, and when needed a system for ethical oversight of difficult bed allocation decisions that does not ask the bedside clinician to have competing loyalties to individual patient vs. the whole population of patients. The system should have a real-time appeals approach.

Prevention of bed scarcity

To minimize the likelihood of rationing of hospital beds, UVM Health Network and collaborating hospitals are expanding treatment capacity beyond usual levels. This includes managing sicker-than-usual patients on hospital floors, expanding the number of available beds by doubling up rooms whenever possible, relaxing non-urgent infection control measures (such as private rooms for patients colonized with MRSA), developing additional sites of care in collaboration with governmental and private entities, etc.

Data-driven Incident Command oversight of hospital census

Leadership of the UVM Health Network and each hospital's incident command center will review data on bed availability across the network and at each institution every day. Data will include not only the current census status but temporal patterns in admissions and other drivers of upcoming needs e.g. expected upcoming emergency room admissions and requests for transfer between hospitals. Incident Command at each facility will set institutional bed status in collaboration with network leadership.

Institutional bed status levels

UVM Health Network hospitals already indicate whether hospital status is at its usual level (Census Level 1), above usual (Census Level 2), or beyond usual capacity (Census Level 3). At census level 3, UVM Medical Center (UVMMC) for example is closed to all but critically ill patients.

For the COVID-19 pandemic, during which we anticipate substantial demands on network and institutional capacity, each institution will use new additional census levels. This institutional status system will be set at a network level to further inter-institutional alignment. The aim of setting institutional census levels is to provide systematic guidance to the individual clinician leaders doing day-by-day triage in bed allocation, thus reducing the chances that ethically challenging resource rationing decisions will be made by a single clinician.

The new census levels are:

Census level 4 – Rationing. Network and institutional capacity unusually exceeded. Near-term expectation of running out of scarce mechanical ventilator, ICU and other clinical resources. Resource allocation system in place to enable fair and transparent allocation of resources.

Census level 5 – Disaster. Massive influx of patients exceeds network and institutional ability to address all patients' critical needs. Discharging unstable and critically ill patients to allow care for sicker critically ill patients.

The above census levels should be set in incident command at each hospital every day in collaboration with network leadership, specifically the Regional Transport System Medical Officer.

Operationalization of resource allocation system

At both census levels, the exclusion criteria in <u>Appendix A</u> will be utilized to determine if a patient is too sick to be admitted. In addition, that institution's threshold for admission will be conveyed to the Administrative Nurse Coordinator (ANC). This will allow institutional communication of threshold for admission without one person having to mediate that decision. We considered using a <u>multi-principle</u> <u>allocation system</u> such as promoted by Doug White's group at the University of Pittsburgh but ultimately were not persuaded that any one approach is superior.

Within each of the above census levels, based on institutional data regarding level of acuity of currently admitted patients, the Network Physician Coordinator (NPC) (or their designee) and either the Chief Medical Officer (CMO) (or their designee, such as the Administrative Physician Coordinator at UVMMC) will make a joint daily determination of illness severity of patients that is acceptable for admission. This will be similar to the current process for creation of thresholds for admission by triage leaders. Thresholds could include, for example, "accepting only critically ill patients that meet inclusion/exclusion criteria" or "accepting only mechanically ventilated patients ..." etc.

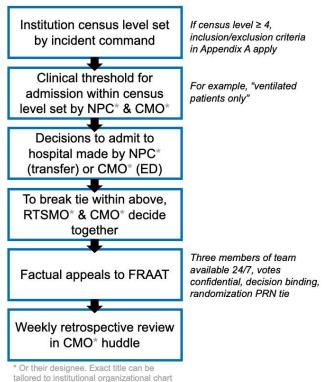
Admission triage proceeds as per usual: via the NPC when hospital transfer is considered, and via Administrative Nurse Coordinator when emergency department admission is considered. These individuals will be acting in the context of institutional census status and the day's clinical threshold for admission, as per usual, so not tasked with making individual patient disposition decisions on their own.

When transfer/admission decisions require an additional layer of judgment, such as if two patients meeting the day's admission criteria are proposed for admission on a day only one bed is available, a resource allocation decision will be made by the Regional Transport System Medical Officer (RTSMO) (or their designee) in collaboration with each facility's Chief Medical Officer (or their designee, such as the Associate Chief Medical Officer for Care Coordination and Patient Transitions [ACMO-CCPT] at UVMMC).

Prioritization decisions should be based on objective criteria as in Figure 2. Such arbitration decisions should be documented for weekly retrospective review.

Social factors like sex, race, pregnancy, job role, and wealth should not be considered in rationing decisions. It is specifically forbidden to consider disability or degree of disability in prioritization decisions. Ideally team members making such difficult determinations would be blinded to social features and consider only medical predictors of outcome.

In the event there is uncertainty or dispute about which patient to prioritize, appeal can be made to the Fair Resource Allocation Appeals Team (FRAAT). At each network hospital, FRAAT team members are



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Factors that may be considered:

- 1. Validated metrics e.g. mSOFA, CURB-65, etc.
- Prognosis and likelihood of treatment response based on risk factors relating to existent event, co-existent end-stage failure of a major organ (e.g. heart, lung, liver, or brain), and other accepted medical factors
- 3. Availability of institutional resources to address clinical needs of every patient

Factors that may NOT be considered:

- 1. Sex, gender identity, sexual orientation, race, ethnicity, national origin, religion, or pregnancy status
- Disability or degree of disability (including physical disability, developmental/cognitive disability, functional status, mental health diagnosis, chronic disease diagnosis, positive status for infectious disease(s) including HIV and HCV)
- 3. Health insurance status or ability to pay for care
- 4. Socio-economic status, profession, or other social factors

Figure 2. Factors that may and may not be considered in patient prioritization decisions.

appointed by the institution's Chief Medical Officer (CMO) (or their designee) based on wisdom, decisiveness, collegiality and clinical expertise. Appeals sent to FRAAT should provide the clinical facts that allow prioritization according to Figure 2. For each decision, three members of the FRAAT (which should be comprised of several member so there is redundant availability), including ethics, should render a final decision regarding resource allocation. Votes of individual team members will be confidential and not recorded.

In the event the FRAAT identifies patients in competition for scarce bed resources who have what the team believes is essentially equivalent need that cannot be reasonably ranked, the team should allocate beds via a simple randomization process to assure the decision is made with as little bias as possible. Randomization processes can include the <u>Google random number generator</u>, a coin flip or dice.

Reassessment. For patients who have been allocated a hospital or ICU bed, a reasonable trial of therapy should be undertaken before that patient's hospital or ICU bed becomes eligible for allocation to someone else proposed for admission. Emerging data the typical clinical course and prognosis for COVID-19 should inform such determinations. In an early series from Wuhan. China, the median hospital length of stay was 11 days (7.5 days for non-survivors and 12 for survivors) with

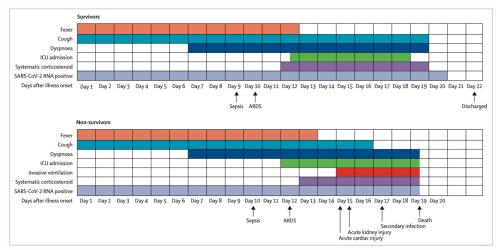


Figure 1: Clinical courses of major symptoms and outcomes and duration of viral shedding from illness onset in patients hospitalised with COVID-19 Figure shows median duration of symptoms and onset of complications and outcomes. ICU=intensive care unit. SARS-CoV-2=severe acute respiratory syndrome coronavirus 2. ARDS=acute respiratory distress syndrome. COVID-19-convairus disease 2019.

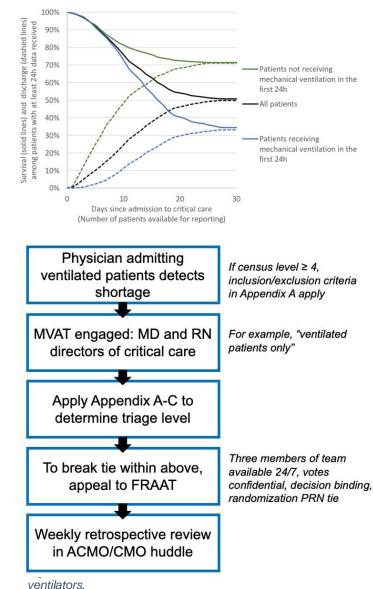
age, SOFA score and D-dimer >1 the major predictors of mortality in a multivariate model. Typical clinical courses for survivors and nonsurvivors in this series are represented below.

Investigators from a coalition of 286 ICU's in the UK have <u>published</u> some early data. In their study, overall survival among patients admitted to the ICU was 50%. Mechanically ventilated patients had 30% overall survival with a median of 6 days of intubation.

Wise allocation of mechanical ventilators

If the supply of mechanical ventilators becomes severely constrained from the COVID-19 pandemic, the hospital must make fair, transparent, legal and wise allocation of mechanical ventilators.

Our approach to scarce ventilator allocation decisions is strongly influenced by the 2015 New York state <u>ventilator allocation guidelines</u>, Biddison et al "Too Many Patients. A Framework to Guide Statewide Allocation of Scarce Mechanical Ventilation During Disasters" *Chest* 2019 and Christian et al "Development of a triage protocol for critical care during an influenza pandemic" *CMAJ* 2006;175(11):1377-81.



When patient need for mechanical ventilator support outstrips institutional mechanical ventilator availability, this UVM Health Network ventilator allocation system will be used.

Key features of UVM Health Network ventilator allocation system include a three-step system for patient mechanical ventilator assignment by an allocation team that is not at the bedside followed by time trials as well as a real-time factual appeals process

Mechanical Ventilator Allocation Team (MVAT)

When there are insufficient mechanical ventilators, the attending physician caring for a patient who requires mechanical ventilation will alert the separate non-bedside Mechanical Ventilator Assignment Team (MVAT). This team will be comprised of the director of the intensive care unit (or their designee) and the intensive care unit nursing leader (or their designee). The CMO (or their designee) for the institution can be engaged as needed for difficult decisions or process questions.

Three step system for mechanical ventilator assignment

The assessment of patient illness severity should occur in three steps: application of exclusion criteria and then systematic factual assessment of patient illness severity.

Step 1. Apply inclusion and exclusion criteria in Appendix A.

<u>Step 2.</u> Among patients who were not excluded by the criteria above, patient illness severity is judged by the SOFA score (<u>Appendix B</u>).

<u>Step 3</u>. Patient SOFA score determines patient triage code as in <u>Appendix C</u>.

Assignment of limited ventilators according to clinical priority

Following application of the triage code to the patient, mechanical ventilator is assigned accordingly. Ventilator availability is prioritized as follows:



Not a candidate for ventilator support Higher priority for ventilator support Lower priority for ventilator support Ventilator support not needed

(See <u>Appendix C</u>.)

Determination of mechanical ventilator receipt within triage codes

If there are too few mechanical ventilators for two or more patients within the same triage code, the MVAT should engage ethics for collaborative selection between patients using factual criteria outlined in Figure 2.

Social factors like sex, race, pregnancy, job role, and wealth should not be considered in rationing decisions. It is specifically forbidden to consider disability or degree of disability in prioritization decisions. Ideally team members making such difficult determinations would be blinded to social features and consider only medical predictors of outcome.

Appeals process

In the event uncertainty or disputes arise within the MVAT, appeals can be made to the Fair Resource Allocation Appeals Team (FRAAT). Members of this team will be appointed by the CMO (or their designee) based on wisdom, decisiveness, collegiality and clinical expertise. For each decision, three members of the FRAAT (which should be comprised of several member so there is redundant

availability), including ethics, should render a final decision regarding resource allocation. Votes of individual team members will be confidential and not recorded. Appeals sent to FRAAT should provide the facts regarding the patient scenario in order to allow prioritization according to the factors outlined in Figure 2. Such arbitration decisions should be documented for weekly retrospective review.

In the event the FRAAT identifies patients in competition for scarce mechanical ventilator resources who have what the team believes is essentially equivalent need that cannot be reasonably ranked, the team should allocate mechanical ventilators via a simple randomization process to assure the decision is made with as little bias as possible. Randomization processes can include the <u>Google random number</u> <u>generator</u>, a coin flip or dice.

Additional considerations regardless of the type of care being rationed

Care of patients who cannot receive the type of care being rationed. Whenever allocation decisions lead to denial of life-sustaining care, we are committed to the continued delivery of compassionate and patient-centered care including feasible treatments that can extend life and the relief of suffering. Inability to access one form of medical care does not automatically translate to inability to access other forms of care that are not in scarce supply. To communicate with patients and loved ones about unavailable medical resources, these resources from VitalTalk and supportive educational information created by the UVMMC palliative care group can help. In the event of difficult-to-manage suffering or complex goals of care discussions, palliative care consultation should be considered per institutional protocols.

Prioritization of irreplaceable workers. In extremely rare cases, the care of individuals with unusually critical and irreplaceable importance to continued functional delivery of health care can be prioritized only if prognostic evaluation suggests a high likelihood of recovery to work in the near term. An example could be critical care clinicians amid a desperate shortage of critical care clinicians that threatens the institution's ability to render life-saving care to its patients. This individual does not necessarily need to be a frontline health care worker as long as they satisfy the requirement that they contribute truly irreplaceable skills to the institution's immediate day-to-day ability to render direct life-saving clinical care AND their prognosis for near-term recovery to such work within the expected time span of the COVID-19 surge is excellent. Such decisions will be made on a case-by-case basis by an unbiased team capable to defining which individual would meet those very rare irreplaceability criteria. At UVMMC, for example, in the event those rare circumstances are invoked the decision will be made on a case-by-case basis by a team comprised of the leader of COVID-19 Incident Command, the director of human resources (at UVMMC is the Chief Administrative & Experience Officer), the patient's physician, and a representative from ethics.

Wise allocation of other forms of medical care

Other forms of medical care too could be rationed amid a disaster. For example, if too few dialysis technicians are available to address the needs of the dialysis patient population despite amelioration measures (e.g. intensified use of outpatient facilities and reduction of weekly dialysis frequency) similar prioritization of care could become necessary.

These processes must be developed by the responsible team and follow the same principles above including:

- 1. Consistent application of accepted acuity/prognosis criteria in order to reduce subjective clinical decision-making, using randomization only if patients cannot be reasonably ranked
- 2. Fair treatment of cases
- 3. Impartiality and neutrality of decision-makers
- 4. Attention to respect and dignity in the treatment of all patients
- 5. Allowance of an appeals process regarding the facts that drive decision-making
- 6. Transparency about guidelines used to make decisions

7. Periodic review to allow adaptation of process to meet evolving realities

Individual teams making rationing decisions should utilize the same type of appeals process outlined above, with as needed support from ethics. Teams making clinical program-specific resource allocation systems are welcome to use systems that parallel the ones articulated within this document, or <u>multi-principle resource allocation systems</u> such as promoted by Dr. Doug White at the University of Pittsburgh, as long as the systems they develop meet the above criteria and are used uniformly across the system distributing those resources.

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May 1, 2020

Appendix A. Inclusion and exclusion criteria.

Inclusion criteria for mechanical ventilation during rationing:

- A. Requirement for invasive ventilatory support
 - a. Refractory hypoxemia (SpO2 <90% on non-rebreather mask or FiO2>0.85)
 - b. Respiratory acidosis (pH<7.2)
 - c. Clinical evidence of impeding respiratory failure
 - d. Inability to protect or maintain airway
- B. Hypotension (SBP<90 mmg Hg or relative to needs) with clinical evidence of shock refractory to volume resuscitation requiring vasopressor or inotrope support that cannot be measured in a ward setting

Exclusion criteria for hospital bed allocation and/or mechanical ventilation during rationing:

- A. Severe trauma with poor expected outcome
- B. Severe burns with any two of the following:
 - a. >60 yrs of age
 - b. >40% of body surface area affected
 - c. Co-existent inhalational injury
- C. Unwitnessed, recurrent or unresponsive cardiac arrest
- D. Metastatic malignant disease with poor expected expected response to therapy
- E. Co-existent end-stage failure of a major organ (e.g. heart, lung, liver, or brain) with poor prior prognosis

During scarcity, while patients with varying severity levels are competing for limited health care resources, exclusion criteria for ICU admission or mechanical ventilation (but not other forms of care) include patients with "do not resuscitate" and/or "do not intubate" code status. Otherwise, advance directive and code status should not affect allocation decisions.

(Adapted from Christian et al "Development of a triage protocol for critical care during an influenza pandemic" CMAJ 2006;175(11):1377-81)

Appendix B. SOFA score calculation.

MSOFA Scoring Guidelines						
Variable	Score*					
	0	1	2	3	4	
SpO ₂ /FIO ₂ ratio** or Nasal cannula or mask 0 ₂ required to keep Sp0 ₂ >90%	SpO ₂ /FIO ₂ >400 or Room air SpO ₂ >90%	SpO ₂ /FIO ₂ 316-400 or SpO ₂ >90% at 1-3 L/min	SpO ₂ /FIO ₂ 231-315 or SpO ₂ >90% at 4-6 L/min	SpO ₂ /FIO ₂ 151-230 or SpO ₂ >90% at 7- 10 L/min	SpO ₂ /FIO ₂ <150 or SpO ₂ >90% at >10 L/min	
Bilirubin level, mg/dL (µmol/L)	< 1.2 (< 20)	1.2–1.9 (20–32)	2.0–5.9 (33–100)	6.0–11.9 (101– 203)	> 12 (> 203)	
Hypotension†	None	MABP < 70	Dop ≤ 5	Dop > 5 Epi ≤ 0.1 Norepi ≤ 0.1	Dop > 15 Epi > 0.1 Norepi > 0.1	
Glasgow Coma score	15	13–14	10–12	6–9	< 6	
Creatinine level, mg/dL	< 1.2	1.2–1.9	2.0–3.4	3.5–4.9 or urine output <500 mL in 24 hours	> 5 or urine output <200 mL in 24 hours	

Scoring criteria for the Modified Sequential Organ-Failure Assessment (SOFA) score¹

*Patients can receive a total score of 20 (5 categories with a total of 5 points for each category); any patient with a score of \geq 11 is excluded from critical care or mechanical ventilation.

** SpO₂/FIO₂ ratio: SpO₂ = Percent saturation of hemoglobin with oxygen as measured by a pulse oximeter and expressed as % (e.g., 95%); FIO₂ = Fraction of inspired oxygen; e.g., ambient air is 0.21

†MABP = mean arterial blood pressure in mm Hg (diastolic + 1/3(systolic - diastolic))

Dop= dopamine in micrograms/kg/min

Epi = epinephrine in micrograms/kg/min

Norepi = norepinephrine in micrograms/kg/min

From Vincent JL et al. The SOFA (Sepsis-related Organ Failure Assessment) score to describe organ dysfunction / failure. *Intensive Care Med.* 1996;22:707-710.

Appendix C. Triage code assignment based on SOFA score.

Triage code	Criteria	Action or priority
Blue	Exclusion criteria met or SOFA score > 11*	 Manage medically Provide palliative care as needed Discharge from critical care
Red	SOFA score ≤7 or single-organ failure	Highest priority
Yellow	SOFA score 8–11	Intermediate priority
Green	No significant organ failure	 Defer or discharge Reassess as needed

Note: SOFA = Sequential Organ-Failure Assessment.

*If an exclusion criterion is met or the SOFA score is > 11 anytime from the initial assessment to 48 hours afterward, change the triage code to Blue and proceed as indicated.

From Christian et al "Development of a triage protocol for critical care during an influenza pandemic" CMAJ 2006;175(11):1377-81