

Regional Planning for Extracorporeal Membrane Oxygenation Allocation During Coronavirus Disease 2019

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e-Appendix 1. Regional Planning for Extracorporeal Membrane Oxygenation Allocation During COVID-19

ECMO Allocation During a Public Health Emergency

Minnesota ECMO Consortium

Ethics Framework for Allocating ECMO

Purpose: The goal of this framework is to facilitate ethically defensible and procedurally fair clinical decisions for the allocation and use of extracorporeal membrane oxygenation (ECMO) during a crisis.

Scope: This framework is applicable to the allocation and use of ECMO. This framework applies to all patients who may need ECMO support during a crisis situation, regardless of the diagnosis.

General principles and justifications: 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 a crisis situation, decisions to allocate scarce resources must be justified by evidence of superior clinical effect and evidence of superior clinical outcomes.

Ethical obligations to promote and preserve justice and procedural fairness also remain; however, the critical justification for reallocation of scarce critical care resources is based on evidence of clinical benefit and effectiveness. Finally, it must be emphasized that obligations to individual patients remain intact, and specifically obligations to provide supportive and palliative care remain unchanged during a crisis.

Underlying assumptions: Ongoing efforts to extend/conservate resources and prevent a shortage of ECMO apparatus have been implemented and are no longer adequate. There are no other practicable interventions or strategies to prevent a shortage of ECMO apparatus.

Rationing decisions should not consider or be based upon:

- Race, ethnicity, gender, gender identity and expression, sexual orientation or preference, religion, citizenship, or socioeconomic status;
- 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);
- Ability to pay;
- Disability status 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);
- 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 not be provided with patient characteristics from this list.

ECMO allocation framework: COVID-19 Pandemic

The framework is ranked; assessment and application of item I. precedes item II., etc.

I. Allocate all available ECMO:

- A. If ECMO circuits are available, then do not ration, so as not to leave an available ECMO circuit unused when it might benefit a patient; and
- B. When the demand for ECMO exceeds or is nearly exceeding supply, ongoing communication between ECMO medical directors and program coordinators in our region will be facilitated by a robust conference call mechanism through the Regional Hospital Resource Center.
 - a. An emergency conference call involving this group will be triggered by ≥ 2 of 5 ECMO centers lacking capability to support additional patients during the course of a disaster.
- C. When the demand for ECMO exceeds supply, a regional ECMO triage consultant will assist the Regional Hospital Resource Center in allocating ECMO based on clinical criteria. That is:
 1. Relative risk for mortality, (regardless of the cause,) *and*;
 2. Relative likelihood and magnitude of clinical benefit.
 - When a patient on ECMO is improving or the time frame to improvement is reasonable given the epidemiology of the illness, this patient has priority over other eligible patients. Expected duration of the need for ECMO support may be taken into consideration.
 - Age may be taken into consideration as part of constructing prognosis and degree of clinical benefit, but not as an independent consideration distinct from prognosis and degree of clinical benefit.
 - Take into consideration best available clinical evidence regarding Covid-19 and the efficacy of ECMO to support survival, per MDH Guidance
 3. Alongside significant differences in anticipated clinical benefit derived from ECMO support, the Triage Officer or Team should consider the likely length of need for the scarce resource. Patients who are reliably predicted to need ECMO support for a substantially greater amount of time may be deprioritized to allow more patients to have access.

Consensus clinical criteria for the prioritization of ECMO by predicted survival and duration are below.

II. If the demand for ECMO exceeds the supply, then re-allocate ECMO circuits to other patients more likely to benefit clinically when:

- A. A patient has been on ECMO for a clinically agreed time-limited trial, and the patient fails to improve or declines.
 - It is permissible to re-allocate when a patient's expected duration of the need is so extreme that it precludes access by many other patients who may benefit with a shorter course.
- B. A patient has an underlying condition that makes it relatively certain that ECMO support will not significantly prolong the length of life, even if ECMO achieves its intended short-term medical goal.

- C. There is no reasonable expectation the patient will improve sufficiently to survive outside the acute care setting or the patient will not improve to allow the patient to perceive the benefits of treatment.

- III. If the demand for ECMO exceeds the supply, and multiple patients have similar medical needs, prognosis, and likelihood/magnitude of benefit, then apply a fair random procedure to allocate ECMO circuits.**

- IV. If the amount of resources required to maintain patients on ECMO related to personnel and supplies (e.g. circuit disposables, blood products) is not sustainable, then the regional ECMO triage consultant, in consultation with the ECMO medical directors' group and the Regional Hospital Resource Center, may choose to restrict or discontinue the provision of ECMO.**

Implementation and procedural considerations:

1. A triage team composed of specialist clinicians and administrators is tasked with applying this framework.
2. When a triage/rationing team is unavailable, bedside care providers may be called upon to apply the framework.
 - Generally, bedside care providers should continue to serve as advocates for their individual patients and not be called upon to ration ECMO between patients competing for this life-sustaining resource.
3. The framework is intended to be implemented without ethics consultation or expertise. This framework cannot anticipate every eventuality that may arise; as such, where unanticipated conflicts or issues arise the ethics support structure at a hospital or regional level should be consulted for guidance.
4. In following MDH recommendations, families should be counseled that ECMO is a limited resource and is considered a trial of therapy, rather than resource assignment, and may be withdrawn depending on prognosis and response to treatment.
5. A process to allow patients or care providers to appeal an allocation or re-allocation decision will be established. Appeals should be resolved by an impartial party. Appeals should be restricted only to an assessment of the validity and accuracy of a construction of the patient's prognosis and the degree and likelihood of benefit of ECMO, in following objective clinical criteria. Appeals may not be brought based upon challenges to the overall allocation framework and values.

Multidimensional Strategy to Allocate ECMO During a Public Health Emergency (5 Steps)

STEP 1: Identify the indication for ECMO on the 3x2 matrix (see Table 1 in the manuscript for full matrix with ECMO indications).

Anticipated Survival	Duration	
	Short (<5 days)	Long (≥5 days)
> 60%	A	B
30-60%	C	D
< 30%	E	F

STEP 2: Calculate SOFA score₁ (range in possible scores 0 - 24). For children, it is acceptable to substitute the pediatric SOFA score (range in possible scores is also 0 - 24).₂

STEP 3: Add up total points across all three categories using the chart below (matrix, SOFA, age) to generate the raw multidimensional strategy score

Points	1	2	3	4	5	6	7	8	9	10	11	12
Matrix	A	B				C	D				E	F
SOFA	< 6	6-8	9-11	≥ 12								
Age	< 40		41-60			61-75						

(Range of possible priority scores 3 - 22)

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STEP 4: Use raw score from multidimensional strategy to allocate ECMO to assign level of priority

ECMO Indication and Patient Prioritization Stratification	
ECMO indication and patient level of priority with code color	Priority score from multi-principle strategy tool
GREEN Highest priority	Priority score 3 - 8
YELLOW Intermediate priority (reassess as needed)	Priority score 9 - 12
RED Lowest priority (reassess as needed)	Priority score \geq 13

STEP 5: Interpret the ECMO level of priority in the context of overall hospital and intensive care unit resource availability during the entire trajectory of a disaster

	Level 1 (Conventional)	Level 2 (Intermediate)	Level 3 (Most Restrictive)	Level 4 (ECMO Not Sustainable)
ECMO capacity	< 50% of ECMO circuits are in use	50-75% of ECMO circuits are in use	> 75% of ECMO circuits are in use	All ECMO circuits are in use
	-or-	-or-	-or-	-or-
ICU capacity	< 75% of usual ICU capacity reached	75-95% ICU capacity reached	> 95% ICU capacity reached	ICU operating, or soon to be operating, using crisis standards
Change in ECMO eligibility criteria based on either ECMO or ICU capacity (above)	No change to usual ECMO eligibility criteria.	<i>In addition to Level 1:</i> * No more than 5 days of mechanical ventilation * No pre-ECMO cardiac arrest	<i>In addition to Level 2:</i> * Age < 50 years * No V-A ECMO for mechanical circulatory support only * No acute hepatic injury (ALT or AST > 1000 U/L, or total bilirubin > 12 mg/dL)	* No new ECMO may be initiated. * ECMO withdrawal (return to intensive conventional therapy and decannulation) may be required equitably distribute scarce critical care resources among a greater number of patients
*If a surge of ICU or ECMO admissions is imminent, consider pre-emptively advancing to the next level to the right (e.g., from Level 1/Conventional to Level 2/Intermediate). *It is acknowledged that every unique patient and hospital resource situation cannot be completely encapsulated by the scheme outlined here. However, exceptions should be very rare and made only with multidisciplinary input.				

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