Regional Planning for Extracorporeal Membrane Oxygenation Allocation During COVID-19

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Abbreviation List

ARDS, acute respiratory distress syndrome; COVID-19, coronavirus disease 2019; E-CPR, extracorporeal cardiopulmonary resuscitation; ECLS, extracorporeal life support; ECMO, extracorporeal membrane oxygenation; ICU, intensive care unit; SAT, science advisory team.

Abstract

Health systems confronting the 2019 novel coronavirus (COVID-19) pandemic must plan for surges in ICU demand and equitably distribute resources to maximize benefit for critically ill patients and the public during periods of resource scarcity. For example, morbidity and mortality could be mitigated by a proactive regional plan for the triage of mechanical ventilators. Extracorporeal membrane oxygenation (ECMO), a resource-intensive and potentially life-saving modality in severe respiratory failure, has generally not been included in proactive disaster preparedness until recently. This article explores underlying assumptions and triage principles that could guide the integration of ECMO resources into existing disaster planning. Drawing from a collaborative framework developed by one United States metropolitan area with multiple adult and pediatric extracorporeal life support centers, this article aims to inform decision-making around ECMO use during a pandemic such as COVID-19. It also addresses the ethical and practical aspects of not continuing to offer ECMO during a disaster.

The 2019 novel coronavirus (COVID-19) pandemic has placed unprecedented pressure on intensive care units (ICUs) in Asia and Europe to provide scalable respiratory critical care in hospitals already near their capacity.[1] Preparations at U.S. hospitals for surges in ICU demand are well underway, with an overall goal of equitably distributing resources to maximize benefit during a period of resource scarcity. Existing critical care guidelines address crisis decision-making and the inevitable demand for ICU beds, ventilators, and medications.[2-4] To avoid *ad hoc* decision-making during a pandemic, guidelines emphasize the proactive development of operational plans and clinical recommendations for specific shortages.[5,6] This is especially important for triage decisions about high intensity medical interventions such as extracorporeal life support which includes extracorporeal membrane oxygenation (ECMO).

ECMO can be a life-saving therapy for select patients with influenza- or coronavirus-associated pneumonia leading to severe acute respiratory distress syndrome (ARDS).[7,8] Stimulated by improvements in ECMO safety and transportability, the volume of adult ECMO cases and ECMO-capable centers has increased dramatically in the wake of the 2009 influenza A (H1N1) pandemic.[9] Furthermore, the World Health Organization's interim clinical guidance for COVID-19 suggests that, in regions with access to ECMO expertise, patients with refractory hypoxemia despite lung protective ventilation strategies be considered for referral to an ECMO center.[10] ECMO is resource intensive compared to conventional critical care, its availability is inconsistent, and regional coordination is often lacking.[11,12] These challenges only amplify the vulnerability of ECMO to resource saturation during a pandemic, yet guidelines have neglected the thoughtful allocation of ECMO resources as compared with other modalities for artificial support.

The Minnesota Department of Health Science Advisory Team (SAT) is an advisory body to the state health commissioner. It includes clinical, policy, ethics, and public health members who develop guidelines for clinical resource allocation during crises. The SAT has developed regional response plans for various scenarios.[13] These plans combine subject matter expertise from the SAT with policy and operational support from the local healthcare coalition, a disaster planning and response group representing hospitals, public health, emergency medical services, and emergency management. Key principles assure that:

- Clinical decision support tools are available in advance, and can be adapted to the incident,
- All participating hospitals have awareness of the situation via a coordination/consultation mechanism,
- Specialty resources are directed to those most likely to benefit,
- Expert clinicians are involved in the decision-making process.

Due to the significant potential for resource saturation during a viral pandemic, a similar regional construct was desired for ECMO.

Of the five ECMO centers in Minnesota (population 5.5 million), four are in the Minneapolis/St Paul metropolitan area (population 3.5 million). At peak capacity, these centers could theoretically support 40 ECMO patients simultaneously. Sustainability depends on available personnel, supplies, and ICU space. Several referring hospitals can initiate ECMO but cannot provide ongoing management.

Our group identified six core assumptions that inform ECMO decision-making in crises:

1. ECMO is a limited resource subject to saturation.
2. Some indications for ECMO are better characterized than others, allowing predictions about duration of support and patient outcome. For example, ECMO patients with influenza A pneumonia and ARDS in 2009 received ECMO and mechanical ventilation for an average of 10 and 25 days, respectively, with acceptable outcomes.[7] Although several centers in the U.S. and abroad have experience with ECMO for patients infected with COVID-19, outcome data is not widely available.
3. For other causes of refractory cardiopulmonary failure, the role of ECMO and optimal management are still evolving. This raises several medical and ethical questions regarding resource distribution during crises.

4. ECMO requires a substantial investment of resources. It may be necessary to limit ECMO support to patients more likely to survive. These decisions—likely made at the clinician or hospital level—ought to be based on a framework determined in advance with input from subject experts, ethics committees, health systems, and the community.
5. When demand for ECMO is high and prioritization by indication is necessary, preference should be given to conditions with historically better outcomes and shorter expected duration of support.
6. Epidemics may require further prioritization or novel strategies. A process must be in place to integrate public health and clinical expertise to address incident-specific challenges.

Operationalizing these concepts requires communication and consensus-building. Beginning in 2019, we leveraged an existing ECMO workgroup that includes two designees from each regional ECMO center—generally the ECMO medical director and program coordinator—who understand staffing, equipment, and ICU capacity at their institution. Members of this ECMO consortium have maintained regular communication around pandemic preparedness through semi-annual meetings. Contact between centers has necessarily kept pace with the rapid spread of COVID-19 infection in our community; we hold biweekly virtual meetings with more frequent operational updates as necessary. We have collaborated on tabletop exercises to simulate just-in-time triage of patients and ECMO equipment. Recently, the ECMO consortium developed an online surveillance tool which displays center-specific and aggregate census data for actual ICU, ventilator, and ECMO capacity at the four ECMO centers in our metro area. This allows ECMO clinicians and the larger healthcare coalition to maintain situational awareness as well as hold each other accountable should scarce resource allocation become necessary in our region during the dynamic trajectory of the COVID-19 pandemic.

In our concept, when an ECMO center lacks resources to initiate or manage ECMO, or anticipates lacking these resources shortly, other centers will be contacted. If two or more regional centers are unable to assist, the requesting center will use an existing regional on-call disaster response coordinator to trigger an immediate conference call among regional ECMO directors. If, during a prolonged incident, demand has outstripped regional resources, the group will plan for incident-specific prognosis, equipment shortages, and evaluate the feasibility of continuing to provide ECMO. The COVID-19 pandemic may require a centralized triage team, with rotating ECMO clinician support, to evaluate transfer requests in real time from referring hospitals in our region using a toll-free number provided by the healthcare coalition.

A surge in demand may trigger resource conservation measures, such as the discontinuation of extracorporeal cardiopulmonary resuscitation (E-CPR) programs for patients suffering refractory out-of-hospital cardiac arrest, deferring elective procedures likely to require post-operative ECMO (e.g. congenital heart disease repair), and an earlier return to high-intensity mechanical ventilation for patients already on veno-venous ECMO support.

Our workgroup agreed upon a framework for ECMO decision-making in times of resource constraint (Table 1 and e-Appendix). The timing of deployment of this ECMO allocation framework will need to be flexible, incident-specific, and synchronized with the larger regional healthcare response, and likely will coincide with the appointment of an ECMO triage officer or team to advise the regional incident command system. Table 1 groups the most common indications for ECMO into three tiers based on expected outcome, with cut points at 30% and 60% approximate survival. These tiers are further divided into short or long expected duration of ECMO support, using a consensus cut point of five days. When determining a patient's eligibility and priority for ECMO during a public health emergency, the regional ECMO triage team—or in its absence, ECMO clinicians at the hospital level—will assess the prognosis by ECMO indication, critical illness severity, the anticipated duration of use, and patient age. (See the e-Appendix for our rationale and five-step method for ECMO allocation). Our consortium adapted this priority scoring system from a construct by D.B. White and colleagues describing the allocation of scarce critical care resources such as ventilators.[14,15] It is consistent with priorities for ECMO use in a consensus guideline concerning COVID-19.[16] There is ethical and practical value to a consensusdriven, common regional framework of decision support during the COVID-19 response, without discouraging clinicians from considering their local context or patient factors.

ECMO should be considered a trial of support rather than an indefinite resource assignment. In our approach, patients and family members will be counseled that ECMO is a highly specialized resource that may be withdrawn depending on response to therapy. Patients may receive other available support modalities as appropriate if they are ineligible for ECMO.

One of the strengths of this framework is that the triage decision-making matrix is based on survival data, and as such the position of any given indication for ECMO in the matrix may be adjusted over time (Table 1). There is currently insufficient data to accurately predict survival of COVID-19 patients supported with ECMO. Once a sufficient quantity and quality of data are available it may be determined that more, or fewer, patients with COVID-19 should be offered this technology.

An important limitation of our ECMO allocation framework is that it does not evaluate the relative benefit of ECMO support as compared with conventional support, which is a fundamentally different concept from the short-term prognosis associated with a certain indication for ECMO. For example, a patient with status asthmaticus and severe hypercarbic respiratory failure (a Tier I indication with short anticipated duration of ECMO support per Table 1) has a favorable prognosis with ECMO support, but their prognosis has historically been favorable with mechanical ventilation as well, so in certain cases the relative benefit of ECMO over conventional support may be small. Many ECMO indications listed in Table 1 lack robust comparative effectiveness data, therefore this prognostic framework should be viewed as a starting point for resource allocation. Especially during the healthcare resource constraints of a global pandemic such as COVID-19, thoughtful patient selection remains vital to maximizing the relative benefit of ECMO for individual patients. An objective prioritization scheme employed by an impartial ECMO triage officer should complement, rather than replace, nuanced clinical judgement by a group of experienced clinicians at the bedside.

Proactive ECMO resource allocation has several advantages for existing medical disaster preparedness systems during the COVID-19 pandemic. ECMO centers can leverage response mechanisms maintained by regional healthcare coalitions to manage interfacility alerts, notification, and coordination. This allows smooth integration into the incident management system. By including ECMO resources, operational leaders will have a more comprehensive accounting of finite ICU assets. A proactive approach to these events ensures that potentially difficult allocation decisions are as equitable and transparent as possible for the sickest patients.

ECMO has benefitted patients with severe respiratory failure who likely would have died without it.[17] The likelihood of difficult decisions around ECMO allocation during the COVID-19 response is real and pressing. The evidence base for ECMO in this pandemic is still evolving, but each step forward strengthens our collective efforts as stewards of finite resources. We encourage other health systems to partner with local disaster management experts to refine our framework and adopt a process for ECMO coordination. Continued integration of these plans into a unified critical care approach to surge capacity will maximize benefit for vulnerable patients with COVID-19 infection during periods of resource scarcity.

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References

1. Remuzzi A, Remuzzi G. COVID-19 and Italy: what next? *Lancet*. In press. https://doi.org/10.1016/S0140-6736(20)30627-9.
2. Hanfling, D., Altevogt, B.M., Viswanathan, K., and Gostin, L.O, eds. *Crisis Standards of Care: A Systems Framework for Catastrophic Disaster Response.* Institute of Medicine, Washington, DC: National Academies Press; 2012.
3. Sprung CL, Zimmerman JL, Christian MD, et al. Recommendations for intensive care unit and hospital preparations for an influenza epidemic or mass disaster: summary report of the European Society of Intensive Care Medicine's Task Force for intensive care unit triage during an influenza epidemic or mass disaster. *Intensive Care Med.* 2010;36:428-443.
4. Einav S, Hick JL, Hanfling D, et al. Surge capacity logistics. Care of the critically ill and injured during pandemics and disasters: CHEST consensus statement. *Chest* 2014;146(4_Suppl):e17S-e43S.
5. Hick JL, Einav S, Hanfling D, et al. Surge capacity principles. Care of the critically ill and injured during pandemics and disasters: CHEST consensus statement. *Chest.* 2014;146(4_Suppl):e1S-e16S.
6. Christian MD, Sprung CL, King MA, et al. Triage. Care of the critically ill and injured during pandemics and disasters: CHEST consensus statement. *Chest.* 2014;146(4_Suppl):e61S-e74S.
7. Combes A, Pellegrino V. Extracorporeal membrane oxygenation for 2009 influenza A (H1N1)-associated acute respiratory distress syndrome. *Semin Respir Crit Care Med.* 2011;32:188-194.
8. Alshahrani MS, Sindi A, Alshamsi F, et al. Extracorporeal membrane oxygenation for severe Middle East respiratory syndrome coronavirus. *Ann Intensive Care*. 2018;8(1): https://doi.org/10.1186/s13613-017-0350-x.

9. Extracorporeal Life Support Organization. ECLS Registry Report: International Summary, January 2020; https://www.elso.org/Registry/Statistics/InternationalSummary.aspx. Accessed March 14, 2020.

10. World Health Organization. Clinical management of severe acute respiratory infection when novel coronavirus (2019-nCoV) infection is suspected—interim guidance. Published January 28, 2020. Accessed March 14, 2020. https://www.who.int/publications-detail/clinical-management-of-severe-acute-respiratory-infection-when-novel-coronavirus-(ncov)-infection-is-suspected.

11. Peek GJ, Mugford M, Tiruvoipati R, et al. Efficacy and economic assessment of conventional ventilatory support versus extracorporeal membrane oxygenation for severe adult respiratory failure (CESAR): a multicentre randomised controlled trial. *Lancet.* 2009;374:1351-1363.

12. Wallace DJ, Angus DC, Seymour CW, et al. Geographic access to high capability severe acute respiratory failure centers in the United States. *PLoS One.* 2014;9:e94057.

13. Minnesota Department of Health. Patient care strategies for scarce resource situations, December 2013; https://www.health.state.mn.us/communities/ep/surge/crisis/standards.pdf. Accessed May 1, 2019.

14. White DB, Lo B. A framework for rationing ventilators and critical care beds during the Covid-19 pandemic. *JAMA.* In press. https://doi:10.1001/jama.2020.5046.

15. University of Pittsburgh Department of Critical Care Medicine. A model hospital policy for allocating scarce critical care resources; https://ccm.pitt.edu/?q=content/model-hospital-policy-allocating-scarce-critical-care-resources-available-online-now. Accessed April 4, 2020.

16. Extracorporeal Life Support Organization. ECMO for Covid-19 patients with severe cardiopulmonary failure. https://www.elso.org/Portals/0/Files/pdf/ECMO%20for%20COVID%2019%20Guidance%20Document.Final%2003.24.2020.pdf. Accessed April 4, 2020.

17. Combes A, Hajage D, Capellier G, et al. Extracorporeal membrane oxygenation for severe acute respiratory distress syndrome. *New England Journal of Medicine* 2018;378:1965-1975.

Table 1. Framework for prioritizing common ECMO indications during a disaster, by predicted survival and duration of support

Tier (Predicted survival)	Short Duration ECMO Anticipated (≤5 days)	Long Duration ECMO Anticipated (>5 days)
Tier 1 (>60%)	Acute hypercarbic respiratory failure due to status asthmaticus Cardiac arrest or cardiogenic shock due to severe accidental hypothermia (i.e. extracorporeal rewarming) Pediatric pre- and post-cardiotomy cardiogenic shock Neonatal meconium aspiration syndrome	Acute respiratory failure due to infection (especially influenza or coronavirus) with single-organ failure Acute respiratory failure due to trauma (drowning, pulmonary contusion, etc.) with single-organ failure Pediatric myocarditis Other neonatal indications (including sepsis, congenital diaphragmatic hernia, and persistent pulmonary hypertension of the newborn)
Tier 2 (30-60%)	Poisoning-induced cardiogenic shock Massive pulmonary embolism	Acute respiratory failure from any cause with multi-organ failure (including kidney injury requiring dialysis or hypotension requiring vasopressor support) Pediatric/neonatal cardiac arrest from a cardiac etiology
Tier 3 (<30%)	Adult post-cardiotomy cardiogenic shock Out-of-hospital, refractory cardiac arrest with favorable prognostic features (i.e. extracorporeal cardiopulmonary resuscitation [E-CPR]) Cardiac arrest with non-shockable rhythm or unfavorable prognostic features (including most adults with in-hospital cardiac arrest)	Bridge to lung transplantation for irreversible respiratory failure Acute respiratory failure and severe immunocompromise (e.g. stem cell transplant <240 days post-transplant) Cardiovascular collapse refractory to vasopressors in the setting of multi-organ failure of any cause (e.g. septic shock)