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Operational Recommendations for Scarce October In a Public Health Crisis

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> The coronavirus disease 2019 pandemic may require rationing of various medical resources if demand exceeds supply. Theoretical frameworks for resource allocation have provided much needed ethical guidance, but hospitals still need to address objective practicalities and legal vetting to operationalize scarce resource allocation schemata. To develop operational scarce resource allocation processes for public health catastrophes, including the coronavirus disease 2019 pandemic, five health systems in Maryland formed a consortium—with diverse expertise and representation-representing more than half of all hospitals in the state. Our efforts built on a prior statewide community engagement process that determined the values and moral reference points of citizens and health-care professionals regarding the allocation of ventilators during a public health catastrophe. Through a partnership of health systems, we developed a scarce resource allocation framework informed by citizens' values and by general expert consensus. Allocation schema for mechanical ventilators, ICU resources, blood components, novel therapeutics, extracorporeal membrane oxygenation, and renal replacement therapies were developed. Creating operational algorithms for each resource posed unique challenges; each resource's varying nature and underlying data on benefit prevented any single algorithm from being universally applicable. The development of scarce resource allocation processes must be iterative, legally vetted, and tested. We offer our processes to assist other regions that may be faced with the challenge of rationing health-care resources during public health catastrophes.

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ABBREVIATIONS: COVID-19 = coronavirus disease 2019; ECMO = extracorporeal membrane oxygenation; SRA = scarce resource allocation

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The World Health Organization's declaration of a coronavirus disease 2019 (COVID-19) pandemic triggered efforts to maximize health-care surge capacity.¹ Early experiences in China, Italy, and New York suggested that rationing of medical resources nevertheless might become necessary.² Domestic health-care systems moved quickly to plan for this dire eventuality, but were faced with insufficiently detailed federal and variable state-level guidance.^{3,4}

Through a partnership among Maryland health systems, we developed a scarce resource allocation framework informed by citizens' values and by general expert consensus. No universal allocation algorithm can be applied to every scarce resource; each has unique considerations. The development of scarce resource allocation processes must be iterative, legally vetted, and tested.

Case Example

Three patients admitted with coronavirus disease 2019 (COVID-19) pneumonia have escalating oxygen requirements during the first 48 h of hospitalization. All are determined to require intubation and mechanical ventilation. The hospital has one available ICU bed and two remaining mechanical ventilators. How should these resources be allocated?

Review of Relevant Literature and Guidelines

Amidst the unprecedented circumstances of the COVID-19 pandemic, individual hospitals lacked a standardized foundation on which to develop scarce resource allocation (SRA) processes. To help fill this void, many ethical frameworks were published.^{3,5} These frameworks, well grounded in established bioethical principles, provided initial steps for building fair allocation processes, but did not address the objective practicalities and legal vetting required to operationalize SRA.

After a statewide call for collaboration, five Maryland health systems partnered to develop a consortium representing more than half of all Maryland hospitals: Johns Hopkins Medicine, Lifebridge Health, Luminis Health, MedStar Health, and University of Maryland Medical System. The goal of this partnership was to develop operational SRA processes that could engender community trust by assuring that allocation decisions were fair, consistent, legally permissible, and nondiscriminatory across all participating hospitals. Because the public bears the consequences of rationing decisions, the inclusion of public perspectives in the development of SRA frameworks is essential.⁶ Fortuitously, a 2-year (2012-2014) Maryland-wide community engagement process had been conducted to ascertain the values and moral reference points of citizens and health-care professionals should the allocation of ventilators need to occur during a public health catastrophe.⁷ The processes described herein are built on this foundation.

Allocation schemata for mechanical ventilators, ICU resources, blood components, novel therapeutics, extracorporeal membrane oxygenation (ECMO), and renal replacement therapies were developed 3 (e-Appendix 1). Creating operational algorithms for each resource posed unique challenges that were managed with imperfect solutions inherent to the trying circumstances; no single algorithm could be applied equally to all scarce resources (Table 1).

To date, none of the algorithms presented herein have required implementation. Rather, in an attempt to assist others facing the ongoing and unprecedented circumstances of the COVID-19 pandemic, we share our processes and lessons learned so that they can be applied to the current or any future public health crisis.

Working Group Formation and Health System Collaboration

Consortium partners maintained internal groups of clinical, legal, ethics, and health system leaders to address the allocation of scarce resources and to vet framework drafts. Each SRA group member had equal voice in process development. Leaders from each of the systems' working groups acted as consortium liaisons to achieve consensus.

The multidisciplinary SRA working group comprises physicians, nurses, lawyers, and scientists with expertise in anesthesiology, bioethics, critical care, cultural competency, disability law, disaster preparedness, human factors engineering, emergency medicine, health equity, health literacy, internal medicine, neonatology, nephrology, neurology, palliative medicine, pediatrics, public health, pulmonology, and transfusion medicine. For the first 6 weeks, telemeetings were held once or twice daily. The work was shared with the Maryland Hospital Association and the Maryland governor's office so that, if necessary, plans could be adopted statewide without precipitating unforeseen legal restrictions.⁶

TABLE 1	Brief Description	of Scare Resource	Allocation Algorithms
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Scarce Resource	Allocation Strategies and Unique Features	Secondary Review
Mechanical ventilators	 Short-term survival (prognosis scores), long-term survival (>1-y survival), pregnancy, clinical trajectory, random selection. In the absence of catastrophic clinical event, minimum therapeutic trial of 7 days before reallocation can be considered. 	Yes
ICU resources	Consensus-based scoring system weighted by need and urgency of need for ICU treatment and ICU monitoring; likelihood of short- term and long-term survival; pregnancy; and, for patients already in the ICU, length of time spent in the ICU and illness severity score trends (e-Appendix 1).	No
Blood components	Predicted ongoing blood need and short-term and long-term survival. Preference given to patients requiring blood transfusion with a high likelihood of survival (eg, postpartum hemorrhage).	No
ECMO	No mechanisms for comparing disease trajectories for patients eligible for ECMO with those currently receiving ECMO. In the absence of a catastrophic clinical event, minimum therapeutic trial of 7 days before reallocation can be considered.	Yes, if ECMO is being reallocated to another patient
Renal replacement therapy	Treat all patients requiring renal replacement therapy by adjusting frequency and intensity of renal replacement therapies.	No
Novel therapeutics	Support participation in clinical trials as well as expanded access and compassionate use.	No
Convalescent plasma	Random selection because of lack of evidence-based guidelines.	No
Remdesivir	Random selection within consensus-based illness severity tiers.	No
Hydroxychloroquine	Prioritization for evidence-supported indications.	No

ECMO = extracorporeal membrane oxygenation.

General Principles

The SRA working group uses ethical principles that include the duty to provide care, duty to steward resources, distributive and procedural justice, equitable and standardized practices, and transparency.^{3,4,8-19} The principles of fair chance and prognosis for both shortand long-term survival are the primary considerations for maximizing treatment benefit and enhancing survival of the most patients.

The algorithms emphasize that every patient in need of a scarce resource would be assessed by the same standardized method. Patients would not be excluded or treated differently based on their ability status, age, ethnicity, gender identity or expression, immigration status, language, national origin, race, religion, sex, sexual orientation, or ability to pay. Early framework drafts included life-cycle considerations, which can be regarded as a proxy for age; guidance from legal experts, including the governor's office, and the United States Department of Health and Human Services Office of Civil Rights highlighted the potential for such considerations to be discriminatory, so these criteria were removed.^{7,20,21} All operational algorithms focus on

first augmenting existing resources. Each algorithm identifies a threshold of remaining resource supply at which allocation processes would be implemented.

To enhance objectivity and to limit the moral distress of treating clinicians, the framework requires multidisciplinary triage teams distinct from the patients' providers to make resource allocation decisions. Triage team composition is proportional to institutional size, but must include at least three voting members who adjudicate allocation decisions by a simple majority.

If patients are triaged not to receive a potentially lifesaving medical intervention, they (or their legal representative) and their treating clinician will be notified and may request an appeal by a secondary review committee distinct from the triage team and the patients' providers (with few exceptions if time does not allow). Unconscious bias training is required for all triage team and secondary review committee members.

Consortium partners agreed that hospitals will develop and implement mechanisms to support clinicians experiencing moral distress, psychological trauma, or burnout from providing care during the unprecedented circumstances that mandate deviation from routine standards. $^{\rm 22}$

Mechanical Ventilators

COVID-19 patients requiring prolonged mechanical ventilation in China and Italy led to a shortage of ventilators.²³ The mechanical ventilator allocation algorithm is invoked when the number of available ventilators falls to 10% of total supply at an individual hospital (e-Appendix 1).

Ventilators are allocated based on a combination of short- and long-term survival likelihood. Short-term mortality is estimated by accepted tools (eg, Sequential Organ Failure Assessment and Pediatric Logistic Organ Dysfunction).²⁴⁻³⁰ Predictive tools for long-term survival are less robust; thus, any patient with a projected life expectancy of at least 12 months would be considered to have equal chance for long-term survival.⁷ We evaluated the agreement of 11 physician raters assessing 20 patient profiles for 12-month projected life expectancy, revealing an intraclass correlation coefficient of 0.957 and 95% CI of 0.921 to 0.981. After this calculation, patients on equal footing are prioritized by clinical trajectory, with priority given to improving patients. If, after all triage assessments, multiple patients remain on equal footing, ventilators are allocated by random selection (ie, lottery).

When available, data abstractors with health-care training and access to the electronic medical record manually validate the automated Sequential Organ Failure Assessment scores derived from the electronic medical record and extract comorbidities. In a resourceconstrained environment, the triage officer performs data validation and abstraction to present to triage team members for scoring. In this scenario, the triage officer votes only as a tiebreaker during allocation decisions. The number of patients requiring review determines the necessary data abstraction support and size of triage teams.

Unique to mechanical ventilator allocation, triage decisions can result in imminent death. To avoid leaving bedside clinicians with the anguishing decision of choosing between two patients before triage team assessment is possible, all patients requiring emergent intubation temporarily are allocated a ventilator or temporized by other means to allow time for triage team assessment.

Absent catastrophic clinical events, patients allocated a ventilator are given a 7-day therapeutic trial with

frequent reassessments of clinical trajectory before potential reallocation to another patient with a more favorable triage score, recognizing that patients with COVID-19 may require prolonged mechanical ventilation. Chronically ventilator-dependent patients admitted on their own ventilators would not be subject to ventilator allocation, although they could undergo other allocation decisions.

ICU Resources

The New York experience and various predictive models highlighted the likelihood for COVID-19 patient surges to exceed ICU capacity.^{31,32} If ICU resource use (ie, beds, equipment, staff) reaches a threshold of 95% capacity, the ICU allocation algorithm is triggered (e-Appendix 1).

We created a consensus-based scoring system to allocate ICU resources to patients most needing ICU care (e-Appendix 1). Factors are weighted by urgency of ICU treatment and ICU monitoring; likelihood of short-term and long-term survival; and, for patients already in the ICU, length of time spent in the ICU and illness severity score trends. Low-scoring patients either are not allocated an ICU bed or, if currently in the ICU, are downgraded to create capacity for a higher-scoring patient. Typically, ICU triage decisions are not immediately life-or-death matters, so there is no appeal process, although at least daily reassessments of eligible patients occur.

Initially, we considered assigning ICU allocation scoring system points to patients of instrumental value, such as first responders and health-care workers.³ However, operational challenges, including determining who qualifies as a health-care worker and the potential for perceived discrimination and subsequent loss of public trust, were too great, so this consideration was not included.

Blood Components

Blood scarcity became a concern early in the pandemic as social distancing measures led to widespread blood drive cancellation.^{33,34} Because transfused blood is not reusable, blood depletion within an individual hospital could be rapid. Experts in transfusion medicine, obstetrics, pediatrics, and surgery joined the SRA working group ad hoc to develop the blood allocation algorithm because of the disproportionate effect that a reduced blood supply might have on these specialists' patients (e-Appendix 1). Each hospital, considering its typical services (ie, trauma or obstetric centers vs hospitals with low procedural volumes), defines its own threshold for declaring blood scarcity. If a critical blood supply alert is triggered, clinicians whose patients traditionally require significant volumes of blood are notified and the transfusion triage team is activated.

To prevent potential conflicts of interest and delays in care, transfusion triage decisions are not left to frontline clinicians or the blood bank. In emergencies, requested blood is released while the transfusion triage team evaluates the patient's predicted survivability (both short- and long-term) and ongoing blood needs in relationship to current supply. Within 30 minutes, the transfusion triage team makes a binding decision about whether additional blood component requests will be fulfilled. Because of time limitations, this decision is not reviewable. Special consideration is given to patients with a higher likelihood of survival (eg, children, patients with postpartum hemorrhage, those with high likelihood of achieving hemostasis, and transfusiondependent patients).

Novel Therapies

Multiple therapies, including hydroxychloroquine, convalescent plasma, and remdesivir, have been proposed as treatments for COVID-19.³⁵⁻³⁷ As anecdotal experience, small studies, and lay press coverage of these therapies emerged ahead of clinical efficacy trials, a unified and transparent ethical approach to their allocation became necessary. Without highquality evidence to guide decisions, the SRA working group favored the development of, and patient participation in, clinical trials while allowing for expanded access and guideline-driven compassionate use.

Efforts were made to identify patients most likely to benefit from these therapies. For example, before withdrawal of the Food and Drug Administration Emergency Use Authorization for hydroxychloroquine, if limited in availability, it would have been provided preferentially to patients with conditions known to benefit from it (eg, systemic lupus erythematosus).³⁸ Conversely, without evidence-based guidelines to identify COVID-19 patients most likely to benefit from convalescent plasma, random selection was determined to be the fairest allocation process.

Remdesivir demonstrated benefit in patients with COVID-19 before its manufacture was scaled to meet

demand.^{39,40} Ongoing trials remain an option for receiving remdesivir.⁴¹ Patients unable to obtain remdesivir via a clinical trial or expanded access protocol must meet Food and Drug Administration Emergency Use Authorization criteria to be eligible for allocation.⁴² If demand for remdesivir exceeds supply, eligible patients are assigned to one of three tiers developed by consensus opinion. Tier one patients are early in their disease course and theorized to have significant severe acute respiratory syndrome coronavirus 2 viremia most likely to benefit from therapy. Tier three patients have the most advanced COVID-19 disease and are considered least likely to benefit. To ensure fair chance for all eligible patients, allocation within each tier occurs via random selection. Pregnant patients unable to receive remdesivir via an expanded access protocol receive priority for allocation within their assigned tier. Without evidence of superiority from a 10-day vs 5-day treatment course, and to maximize treatment for the most patients, the algorithm allocates only 5-day courses.43

Dexamethasone, another potential therapy with evidence demonstrating a mortality benefit for patients with COVID-19, was not thought to be a limited resource. Therefore, the SRA working group has not yet addressed its allocation.⁴⁴

ECMO

ECMO is a scarce resource even under normal conditions. Recognizing that demand during the pandemic likely could exceed capacity despite a lack of evidence that ECMO benefits patients with COVID-19, the SRA working group engaged ECMO specialists for developing an ECMO allocation algorithm (e-Appendix 1). An ECMO capacity management team defined hospital ECMO capacity based on available equipment and staff. The ECMO triage algorithm is activated when only two additional patients can be accommodated. One ECMO circuit is reserved at all times for a pediatric patient. During ECMO scarcity, barring catastrophic clinical events, a patient placed on ECMO is given a minimum therapeutic trial of 7 days before reallocation is considered. A secondary review can be requested for reallocation decisions that would remove a patient from ECMO support. Unique considerations for ECMO allocation include that established ECMO mortality prediction scores may not apply to patients with COVID-19 and that no mechanisms exist to compare disease trajectories for patients eligible for ECMO with those currently receiving ECMO.45,46

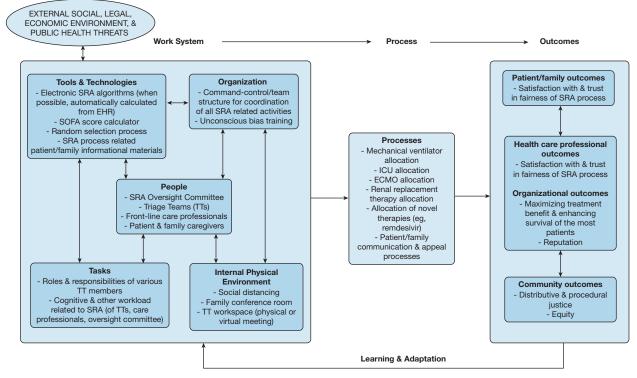


Figure 1 – Systems Engineering Initiative for Patient Safety model to guide the implementation of scarce resource allocation processes.⁴⁸ ECMO = extracorporeal membrane oxygenation; SOFA = Sequential Organ Failure Assessment; SRA = scarce resource allocation; TT = triage team.

Renal Replacement Therapy

The New York experience made clear that the incidence of COVID-19-related acute kidney injury had the potential to overwhelm existing dialysis resources.⁴⁷ The renal replacement therapy algorithm calls for aggressive conservation of equipment, supplies, and personnel (e-Appendix 1). Unique to renal replacement is the ability to conserve resources or to provide less or different dialysis to enhance survival of more patients. For example, providing continuous dialysis in 12-h blocks instead of 24-h blocks, considering acute peritoneal dialysis, and classifying patients by geographic cohort for simultaneous dialysis could stretch scarce resources, including dialysis personnel. A dialysis triage team coordinates conservation efforts.

Implementation Process Development

To lessen the cognitive burden of triage team members, we applied the Systems Engineering Initiative for Patient Safety framework to structure process implementation (Fig 1).⁴⁸ A human factors engineer provided expertise with process mapping, work system design, team science, and proactive risk assessment. Experts in Lean Six Sigma methodology consulted on issues of efficiency and process redundancies. The health informatics team

developed automated short-term survival scores, created data entry and reporting methods for the rapid collection of patient data, and masked patient information to reduce bias. Clinical members of the SRA working group vetted processes for usability and clinical relevancy through simulation.

Educational materials, including talking points for clinicians and handouts for patients, were developed to alert patients and families of the potential for SRA because of resource constraints and to communicate clearly and consistently about specific allocation decisions. Individuals with disabilities and the SRA working group's health equity and disability experts reviewed all patient handouts for health literacy and readability. Materials were translated into the five languages most commonly encountered across the health systems.

Limitations and Future Actions

As the COVID-19 pandemic evolves and more information becomes available, these processes will be updated and improved continually. The proposed algorithms will need assessment during this and future public health crises. Although validated for multiple conditions, the performance of Sequential Organ Failure Assessment and other short-term mortality prediction tools for patients with COVID-19 has not been evaluated. Ongoing comprehensive evaluation of patients treated for COVID-19 within our systems may allow generation of improved predictive models to replace population-based scoring tools.

Using comorbidities to estimate long-term survival risks reinforces systemic disparities in health outcomes. However, in keeping with the findings of the statewide community engagement process, only patients with severe, advanced, and unrecoverable chronic illness resulting in a life expectancy of 12 months or fewer would be considered less eligible for ventilator allocation.⁷ If implementation becomes necessary, the SRA working group will monitor for unintended consequences, including association of sociodemographic factors and resource allocation, to improve the algorithm. If, despite our efforts to ensure equity, review of aggregate data reveals disparate care, then the algorithms should be modified. Addition of a health equity adjustment factor has been proposed to facilitate equity in access to scarce resources.⁴⁹

Transparency and inclusion of public perspectives in the development of allocation frameworks are essential. The foundational Maryland ventilator allocation framework was built on public engagement before the COVID-19 pandemic.⁷ The SRA working group recognizes that constant iteration is necessary and welcomes feedback to invite modifications.

Finally, our SRA working group hopes that current public health and hospital capacity efforts in response to the COVID-19 pandemic will prevent the need to implement these processes. However, if implementation becomes necessary, monitoring the well-being of clinicians engaged in these unprecedented allocation decisions also will be essential.

Conclusions

No universal allocation algorithm can be applied to every scarce resource, because each has unique considerations. In our experience, the rapid pace of new data acquisition continues to require frequent adjustments to these algorithms. The development of SRA processes must be iterative, legally vetted, and tested. Through a partnership of health systems in Maryland, we were able to develop an SRA framework informed by citizens' values and consistent with the general consensus of experts. We hope that this framework can serve as a guide for other regions that may be faced with the challenge of rationing health-care resources during this unprecedented time and during future public health catastrophes.

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Additional information: The e-Appendix can be found in the Supplemental Materials section of the online article.

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