Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

Journal Pre-proof

Operational recommendations for scarce resource allocation in a public health crisis

Michael R. Ehmann, MD, MPH, MS, Elizabeth K. Zink, MS, RN, CCNS, CNRN, Amanda B. Levin, MD, Jose I. Suarez, MD, Harolyn ME. Belcher, MD, MHS, Elizabeth L. Daugherty Biddison, MD, MPH, Danielle J. Doberman, MD, MPH, Karen D'Souza, MHA, BSN, Derek M. Fine, MD, Brian T. Garibaldi, MD, MEHP, Eric A. Gehrie, MD, Sherita H. Golden, MD, MHS, Ayse P. Gurses, PhD, MS, MPH, Peter M. Hill, MD, MA, Mark T. Hughes, MD, MA, Jeffrey Kahn, PhD, MPH, Colleen G. Koch, MD, MS, MBA, Jason J. Marx, MD, MBA, Barry R. Meisenberg, MD, Jeffrey Natterman, JD, MA, RRT, Cynda H. Rushton, PhD, RN, Adam Sapirstein, MD, Stephen R. Selinger, MD, R Scott Stephens, MD, Eric S. Toner, MD, Yoram Unguru, MD, MS, MA, Maureen van Stone, JD, MS, Allen Kachalia, MD, JD

PII: S0012-3692(20)34804-2

DOI: https://doi.org/10.1016/j.chest.2020.09.246

Reference: CHEST 3658

To appear in: *CHEST*

Received Date: 26 August 2020

Accepted Date: 6 September 2020

Please cite this article as: Ehmann MR, Zink EK, Levin AB, Suarez JI, Belcher HM, Daugherty Biddison EL, Doberman DJ, D'Souza K, Fine DM, Garibaldi BT, Gehrie EA, Golden SH, Gurses AP, Hill PM, Hughes MT, Kahn J, Koch CG, Marx JJ, Meisenberg BR, Natterman J, Rushton CH, Sapirstein A, Selinger SR, Stephens RS, Toner ES, Unguru Y, van Stone M, Kachalia A, Operational recommendations for scarce resource allocation in a public health crisis, *CHEST* (2020), doi: https://doi.org/10.1016/j.chest.2020.09.246.

Word count: 2,995

Abstract word count: 221

References: 49

Submitted for: How I Do It

Operational recommendations for scarce resource allocation in a public health crisis

Michael R Ehmann, MD, MPH, MS*
mehmann1@jhmi.edu
Department of Emergency Medicine
Johns Hopkins University, Baltimore, MD

Elizabeth K Zink, MS, RN, CCNS, CNRN*
ezink1@jhmi.edu
Department of Neurology
Johns Hopkins University, Baltimore, MD
Department of Neuroscience Nursing
The Johns Hopkins Hospital, Baltimore, MD

Amanda B Levin, MD*
alevin32@jhmi.edu
Department of Anesthesiology and Critical Care Medicine
Johns Hopkins University, Baltimore, MD

Jose I Suarez, MD*
jsuarez5@jhmi.edu
Department of Anesthesiology and Critical Care Medicine
Department of Neurology
Department of Neurosurgery
Johns Hopkins University, Baltimore, MD

Harolyn ME Belcher, MD, MHS
belcher@kennedykrieger.org
Department of Pediatrics
Bloomberg School of Public Health
Johns Hopkins University, Baltimore, MD
Center for Diversity in Public Health Leadership Training
Kennedy Krieger Institute, Baltimore, MD

Elizabeth L Daugherty Biddison, MD, MPH
edaughe2@jhmi.edu
Department of Medicine
Johns Hopkins University, Baltimore, MD

Danielle J Doberman, MD, MPH
ddoberm1@jhmi.edu
Department of Medicine
Johns Hopkins University, Baltimore, MD

Karen D'Souza, MHA, BSN
kdsouza1@jhmi.edu
Armstrong Institute for Patient Safety and Quality
Johns Hopkins Medicine, Baltimore, MD

Derek M Fine, MD
dfine1@jhmi.edu
Department of Medicine
Johns Hopkins University, Baltimore, MD

Brian T Garibaldi, MD, MEHP
bgariba1@jhmi.edu
Department of Medicine
Department of Physiology
Johns Hopkins University, Baltimore, MD

Eric A Gehrie, MD
egehrie1@jhmi.edu
Department of Pathology
Department of Surgery
Johns Hopkins University, Baltimore, MD

Sherita H Golden, MD, MHS
sahill@jhmi.edu
Department of Medicine
Department of Epidemiology
Bloomberg School of Public Health
Johns Hopkins University, Baltimore, MD
Office of Diversity, Inclusion, and Health Equity
Armstrong Institute for Patient Safety and Quality
Johns Hopkins Medicine, Baltimore, MD

Ayse P Gurses, PhD, MS, MPH

agurses1@jhmi.edu
Department of Anesthesiology and Critical Care Medicine
Johns Hopkins University, Baltimore, MD
Armstrong Institute for Patient Safety and Quality
Johns Hopkins Medicine, Baltimore, MD

Peter M Hill, MD, MA
phill@jhmi.edu
Department of Emergency Medicine
Johns Hopkins University, Baltimore, MD

Mark T Hughes, MD, MA
mthughes@jhmi.edu
Department of Medicine
Berman Institute of Bioethics
Johns Hopkins University, Baltimore, MD

Jeffrey Kahn, PhD, MPH
jeffkahn@jhu.edu
Berman Institute of Bioethics
Johns Hopkins University, Baltimore, MD

Colleen G Koch, MD, MS, MBA
ckoch11@jhmi.edu
Department of Anesthesiology and Critical Care Medicine
Johns Hopkins University, Baltimore, MD

Jason J Marx, MD, MBA
jasonmarx@umm.edu
Department of Medicine
University of Maryland St Joseph Medical Center
University of Maryland Medical System, Towson, MD

Barry R Meisenberg, MD
bmeisenber@aahs.org
Department of Medicine
Anne Arundel Medical Center, Annapolis, MD

Jeffrey Natterman, JD, MA, RRT
jnatter1@jhmi.edu
Risk Management
The Johns Hopkins Hospital, Baltimore, MD

Cynda H Rushton, PhD, RN
crushto1@jhu.edu
Berman Institute of Bioethics
School of Nursing
Johns Hopkins University, Baltimore, MD

Adam Sapirstein, MD
asapirs1@jhmi.edu
Department of Anesthesiology and Critical Care Medicine
Johns Hopkins University, Baltimore, MD

Stephen R Selinger, MD
stephen.selinger@medstar.net
Department of Medicine
MedStar Franklin Square Medical Center, Baltimore, MD
MedStar Harbor Hospital, Baltimore, MD

R Scott Stephens, MD
rsteph13@jhmi.edu
Department of Medicine
Johns Hopkins University, Baltimore, MD

Eric S Toner, MD
etoner1@jhu.edu
Johns Hopkins Center for Health Security
Bloomberg School of Public Health,
Johns Hopkins University, Baltimore, MD

Yoram Unguru, MD, MS, MA
yunguru@lifebridgehealth.org
Berman Institute of Bioethics
Johns Hopkins University, Baltimore, MD
Division of Pediatric Hematology/Oncology
Sinai Hospital, Baltimore, MD

Maureen van Stone, JD, MS
vanstone@kennedykrieger.org
Bloomberg School of Public Health
Johns Hopkins University, Baltimore, MD
Maryland Center for Developmental Disabilities
Kennedy Krieger Institute, Baltimore, MD

Allen Kachalia, MD, JD†

kachalia@jhu.edu
Department of Medicine
Johns Hopkins University, Baltimore, MD
Armstrong Institute for Patient Safety and Quality
Johns Hopkins Medicine, Baltimore, MD

* Contributed equally to this manuscript

† Corresponding author

Correspondence to:

Allen Kachalia, MD, JD

Armstrong Institute for Patient Safety and Quality

600 N Wolfe Street CMSC 131

Baltimore, MD 21287

Telephone: 410-502-6127

E-mail: kachalia@jhu.edu

Abstract

The COVID-19 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 COVID-19 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, which determined the values and moral reference points of citizens and healthcare 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, intensive care unit 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 healthcare resources during public health catastrophes.

Introduction

The World Health Organization's declaration of a coronavirus disease 2019 (COVID-19) pandemic triggered efforts to maximize healthcare surge capacity.[1] Early experiences in China, Italy, and New York suggested that rationing of medical resources might nevertheless become necessary.[2] Domestic healthcare 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 of 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 COVID-19 pneumonia have escalating oxygen requirements during their first 48 hours of hospitalization. All are determined to require intubation and mechanical ventilation. The hospital has one available intensive care unit (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 in 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 which could engender community trust by assuring that allocation decisions were fair, consistent, legally permissible, and non-discriminatory 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 two-year (2012-2014) Maryland-wide community engagement process had been conducted to ascertain the values and moral reference points of citizens and healthcare professionals should the allocation of ventilators need to occur during a public health catastrophe.[7] The processes described herein are built upon this foundation.

Allocation schemata for mechanical ventilators, intensive care unit (ICU) resources, blood components, novel therapeutics, extracorporeal membrane oxygenation (ECMO), and renal replacement therapies were developed (see document in the online data supplement). 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 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 is comprised of 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 six weeks, tele-meetings 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]

General Principles

The SRA working group utilizes 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 short- and 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 upon 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 limit moral distress of treating clinicians, the framework requires multidisciplinary Triage Teams distinct from the patients' providers to make resource allocation decisions. Triage Team composition would be proportional to institutional size but must include at least three voting members who would adjudicate allocation decisions by a simple majority.

If patients are triaged not to receive a potentially life-saving 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.[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 would be invoked when the supply of ventilators falls to 10% at an individual hospital (See Figure E1 in the online data supplement).

Ventilators would be allocated based on a combination of short- and long-term survival likelihood. Short-term mortality is estimated by accepted tools (e.g., Sequential Organ Failure Assessment [SOFA] 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.[6] We evaluated the agreement of 11 physician raters assessing 20 patient profiles for 12 month projected life-expectancy revelaing an intra-class correlation coefficient of 0.957, 95% CI (0.921,0.981). After this calculation, patients on equal footing would be prioritized by clinical trajectory, with priority given to improving patients. If, after all triage assessments, multiple patients remain on equal footing, ventilators would be allocated by random selection (i.e., lottery).

When available, data abstractors with healthcare training and access to the electronic medical record (EMR) would manually validate the automated SOFA scores derived from the EMR and extract co-morbidities. In a resource-constrained environment, the Triage Officer would perform data validation and abstraction to present to Triage Team members for scoring. In this scenario, the Triage Officer would vote only as a “tie-breaker” 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 would be temporarily allocated a ventilator or temporized by other means to allow time for Triage Team assessment.

Absent catastrophic clinical events, patients allocated a ventilator would be given a seven-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 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 utilization (i.e., beds, equipment, staff) reaches a threshold of 95% capacity, the ICU allocation algorithm would be triggered (see Figure E2 in the online data supplement).

We created a consensus-based scoring system to allocate ICU resources to patients most needing ICU care (See Table E1 in the online data supplement). 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 would either not be allocated an ICU bed or, if currently in the ICU, be downgraded to create capacity for a higher-scoring patient. Typically, ICU triage decisions are not immediately life-or-death so there is no appeal process, although at least daily re-assessments of eligible patients would occur.

Initially, we considered assigning ICU allocation scoring system points to patients of "instrumental value," such as first responders and healthcare workers.[3] However, operational challenges, including determining who qualifies as a healthcare 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 due to the disproportionate effect a reduced blood supply might have on these specialists' patients (See Figure E3 in the online data supplement).

Each hospital, considering its typical services (i.e., trauma or obstetric centers versus 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 (TTT) is activated.

To prevent potential conflicts of interest and delays in care, transfusion triage decisions would not be left to frontline clinicians or the blood bank. In emergencies, requested blood would be released while the TTT evaluates the patient's predicted survivability (both short- and long-term) and ongoing blood needs in relation to current supply. Within 30 minutes, the TTT would make 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 (e.g., children, patients with postpartum hemorrhage, those with high likelihood of achieving hemostasis, and transfusion-dependent patients).

Novel Therapies

Multiple therapies, including hydroxychloroquine, convalescent plasma, and remdesivir have been proposed as treatments for COVID-19.[235-37] 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 high-quality 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 Emergency Use Authorization (EUA), hydroxychloroquine, if limited in availability, would have been preferentially provided to patients with conditions known to benefit from it (e.g., 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 EUA criteria to be eligible for allocation.[42]

If demand for remdesivir exceeds supply, eligible patients would be assigned to one of three tiers developed by consensus opinion. Tier one patients are early in their disease course and theorized to have significant SARS-CoV-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 would occur 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 ten-day versus five-day treatment course, and to maximize treatment for the most patients, the algorithm allocates only five-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 could likely 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 (see Figure E4 in the online data supplement).

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 could 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 seven 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 there are no mechanisms to compare disease trajectories for patients eligible for ECMO with those currently on ECMO.[45,46]

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 (see Figure E5 in the online data supplement).

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-hour instead of 24-hour blocks, considering acute peritoneal dialysis, and geographically cohorting patients 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 (Figure 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 due to 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 continually updated and improved. The proposed algorithms will need assessment during this and future public health crises.

Although validated for multiple conditions, the performance of SOFA 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.

Utilizing co-morbidities 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 prior to the pandemic was built on public engagement.[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. If, however, implementation becomes necessary, monitoring the well-being of clinicians engaged in these unprecedented allocation decisions will also be essential.

Conclusions

No universal allocation algorithm can be applied to every scarce resource, as 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 a scarce resource allocation 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 healthcare resources during this unprecedented time and during future public health catastrophes.

Acknowledgements:

Melania Bembea, MD, MPH, PhD, Glenn J R Whitman, MD, Errol L Bush, MD, and Dan L Herr, MD for reviewing the ECMO algorithm; Julia Johnson, MD for informing neonatal scoring systems; Gabor Kelen, MD and Lisa Maragakis, MD, MPH for reviewing the algorithms; Claire Levine, MS, ELS for reviewing the manuscript and providing editing comments

References

1. WHO Director-General's opening remarks at the media briefing on COVID-19. 2020; https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020. Accessed May 7, 2020.
2. Remuzzi A, Remuzzi G. COVID-19 and Italy: what next? *Lancet.* 2020;395(10231):1225-1228.
3. Emanuel EJ, Persad G, Upshur R, et al. Fair Allocation of Scarce Medical Resources in the Time of Covid-19. *N Engl J Med.* 2020.
4. Weise KB, M. Chilling' Plans: Who Gets Care as Washington State Hospitals Fill Up? *The New York Times* 2020; https://www.nytimes.com/2020/03/20/us/coronavirus-in-seattle-washington-state.html. Accessed May 7, 2020.
5. White DB, Lo B. A Framework for Rationing Ventilators and Critical Care Beds During the COVID-19 Pandemic. *JAMA.* 2020.
6. Cohen IG, Crespo AM, White DB. Potential Legal Liability for Withdrawing or Withholding Ventilators During COVID-19: Assessing the Risks and Identifying Needed Reforms. *JAMA.* 2020.
7. Daugherty Biddison EL, Faden R, Gwon HS, et al. Too Many Patients...A Framework to Guide Statewide Allocation of Scarce Mechanical Ventilation During Disasters. *Chest.* 2019;155(4):848-854.
8. Tabery J, Mackett CW, 3rd, University of Pittsburgh Medical Center Pandemic Influenza Task Force's Triage Review B. Ethics of triage in the event of an influenza pandemic. *Disaster Med Public Health Prep.* 2008;2(2):114-118.
9. Altevogt B, Stroud, C, Hanson, SL; Hanfling, D; Gostin, LO *Guidance for Establishing Crisis Standards of Care for Use in Disaster Situations – Letter Report.* Vol 2. Emergency Books 2009.
10. Christian MD. Triage. *Crit Care Clin.* 2019;35(4):575-589.
11. DeJong C, Chen AH, Lo B. An Ethical Framework for Allocating Scarce Inpatient Medications for COVID-19 in the US. *JAMA.* 2020.
12. Lin JY, Anderson-Shaw L. Rationing of resources: ethical issues in disasters and epidemic situations. *Prehosp Disaster Med.* 2009;24(3):215-221.

13. Gostin LO, Friedman EA, Wetter SA. Responding to Covid-19: How to Navigate a Public Health Emergency Legally and Ethically. *Hastings Cent Rep.* 2020;50(2):8-12.

14. Papadimos TJ, Marcolini EG, Hadian M, et al. Ethics of Outbreaks Position Statement. Part 1: Therapies, Treatment Limitations, and Duty to Treat. *Crit Care Med.* 2018;46(11):1842-1855.

15. McLane H. A disturbing medical consensus is growing. Here's what it could mean for Black patients with coronavirus. *WHYY Essay.* April 10, 2020.

16. Guelzo A. Rationing Care Is a Surrender to Death: Limiting treatment for the old or chronically ill may also violate civil-rights law. There are better ways. *The Wall Street Journal*. March 26, 2020.

17. Mello MM, Persad G, White DB. Respecting Disability Rights - Toward Improved Crisis Standards of Care. *N Engl J Med.* 2020.

18. Tobin-Tyler E. In Allocating Scarce Health Care Resources During COVID-19, Don't Forget Health Justice. *Health Affairs.* April 25, 2020.

19. Webb Hooper M, Napoles AM, Perez-Stable EJ. COVID-19 and Racial/Ethnic Disparities. *JAMA.* 2020.

20. Vergano M, Bertolini G, Giannini A, et al. Clinical ethics recommendations for the allocation of intensive care treatments in exceptional, resource-limited circumstances: the Italian perspective during the COVID-19 epidemic. *Crit Care.* 2020;24(1):165.

21. Civil Rights, HIPAA, and the Coronavirus Disease 2019 (COVID-19) 2020; https://www.hhs.gov/sites/default/files/ocr-bulletin-3-28-20.pdf. Accessed June 6, 2020.

22. Greenberg N, Docherty M, Gnanapragasam S, Wessely S. Managing mental health challenges faced by healthcare workers during covid-19 pandemic. *BMJ.* 2020;368:m1211.

23. Truog RD, Mitchell C, Daley GQ. The Toughest Triage - Allocating Ventilators in a Pandemic. *N Engl J Med.* 2020.

24. 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 Med.* 1996;22(7):707-710.

25. 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.

26. Leteurtre S, Martinot A, Duhamel A, et al. Validation of the paediatric logistic organ dysfunction (PELOD) score: prospective, observational, multicentre study. *Lancet.* 2003;362(9379):192-197.

27. Leteurtre S, Duhamel A, Salleron J, et al. PELOD-2: an update of the PEdiatric logistic organ dysfunction score. *Crit Care Med.* 2013;41(7):1761-1773.

28. Wynn JL, Polin RA. A neonatal sequential organ failure assessment score predicts mortality to late-onset sepsis in preterm very low birth weight infants. *Pediatr Res.* 2019.

29. Beltempo M, Shah PS, Ye XY, et al. SNAP-II for prediction of mortality and morbidity in extremely preterm infants. *J Matern Fetal Neonatal Med.* 2019;32(16):2694-2701.

30. Dammann O, Shah B, Naples M, et al. Interinstitutional variation in prediction of death by SNAP-II and SNAPPE-II among extremely preterm infants. *Pediatrics.* 2009;124(5):e1001-1006.

31. Moghadas SM, Shoukat A, Fitzpatrick MC, et al. Projecting hospital utilization during the COVID-19 outbreaks in the United States. *Proc Natl Acad Sci U S A.* 2020;117(16):9122-9126.

32. Shoukat A, Wells CR, Langley JM, Singer BH, Galvani AP. Projecting demand for critical care beds during COVID-19 outbreaks in Canada. *CMAJ.* 2020.

33. American Red Cross Faces Severe Blood Shortage As Coronavirus Outbreak Threatens Availability of Nation's Supply [press release]. The American Red Cross, Mar 17, 2020.

34. Gehrie EA, Frank SM, Goobie SM. Balancing Supply and Demand for Blood during the COVID-19 Pandemic. *Anesthesiology.* 2020;133(1):16-18.

35. Gautret P, Lagier JC, Parola P, et al. Clinical and microbiological effect of a combination of hydroxychloroquine and azithromycin in 80 COVID-19 patients with at least a six-day follow up: A pilot observational study. *Travel Med Infect Dis.* 2020;34:101663.

36. Shen C, Wang Z, Zhao F, et al. Treatment of 5 Critically Ill Patients With COVID-19 With Convalescent Plasma. *JAMA.* 2020.

37. Wang Y, Zhang D, Du G, et al. Remdesivir in adults with severe COVID-19: a randomised, double-blind, placebo-controlled, multicentre trial. *Lancet.* 2020;395(10236):1569-1578.

38. Hogan L. State of Maryland Executive Department Order: Preserving the Supply of Necessary Drugs. Order of the Governor of the State of Maryland No. 20-04-14-01 2020.

39. Beigel JH, Tomashek KM, Dodd LE, et al. Remdesivir for the Treatment of Covid-19 - Preliminary Report. *N Engl J Med.* 2020.

40. Working to Supply Remdesivir for COVID-19. 2020; https://www.gilead.com/purpose/advancing-global-health/covid-19/working-to-supply-remdesivir-for-covid-19. Accessed June 22, 2020.

41. Adaptive COVID-19 Treatment Trial 2 (ACTT-II). 2020; https://www.clinicaltrials.gov/ct2/show/NCT04401579. Accessed May 27, 2020.

42. Hinton D. *Emergency Use Authorization (EUA) for emergency use of remdesivir.* May 1, 2020.

43. Goldman JD, Lye DCB, Hui DS, et al. Remdesivir for 5 or 10 Days in Patients with Severe Covid-19. *N Engl J Med.* 2020.

44. RECOVERY Collaborative Group, Horby P, Lim WS, et al. Dexamethasone in Hospitalized Patients with Covid-19 - Preliminary Report. *N Engl J Med.* 2020.

45. Schmidt M, Burrell A, Roberts L, et al. Predicting survival after ECMO for refractory cardiogenic shock: the survival after veno-arterial-ECMO (SAVE)-score. *Eur Heart J.* 2015;36(33):2246-2256.

46. Schmidt M, Burrell A, Roberts L, et al. Predicting survival after ECMO for refractory cardiogenic shock: the survival after veno-arterial-ECMO (SAVE)-score. *Eur Heart J.* 2015;36(33):2246-2256.

47. Abelson RF, S; Kulish, N; Thomas K. An Overlooked, Possibly Fatal Coronavirus Crisis: A Dire Need for Kidney Dialysis. *The New York Times.* April 18, 2020.

48. Carayon P, Schoofs Hundt A, Karsh BT, et al. Work system design for patient safety: the SEIPS model. *Qual Saf Health Care.* 2006;15 Suppl 1:i50-58.

49. Galiatsatos P, Kachalia A, Belcher HME, et al. Health equity and distributive justice considerations in critical care resource allocation. *Lancet Respir Med.* 2020.

Figures and Tables

Online data supplement

Scarce Resource	Allocation Strategies and Unique Features	Secondary Review
Mechanical Ventilators	Short-term survival (prognosis scores), long-term survival (>1 year survival), pregnancy, clinical trajectory, random selection In absence of catastrophic clinical event, minimum therapeutic trial of seven 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 (Figure E2)	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 (e.g., post-partum hemorrhage)	No

ECMO	No mechanisms for comparing disease trajectories for patients eligible for ECMO with those currently on ECMO In absence of catastrophic clinical event, minimum therapeutic trial of seven 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 due to lacking evidence-based guidelines	No
Remdesivir	Random selection within consensus-based illness severity tiers	No
Hydroxychloroquine	Prioritization for evidence-supported indications	No

Table 1. Brief description of scare resource allocation algorithm

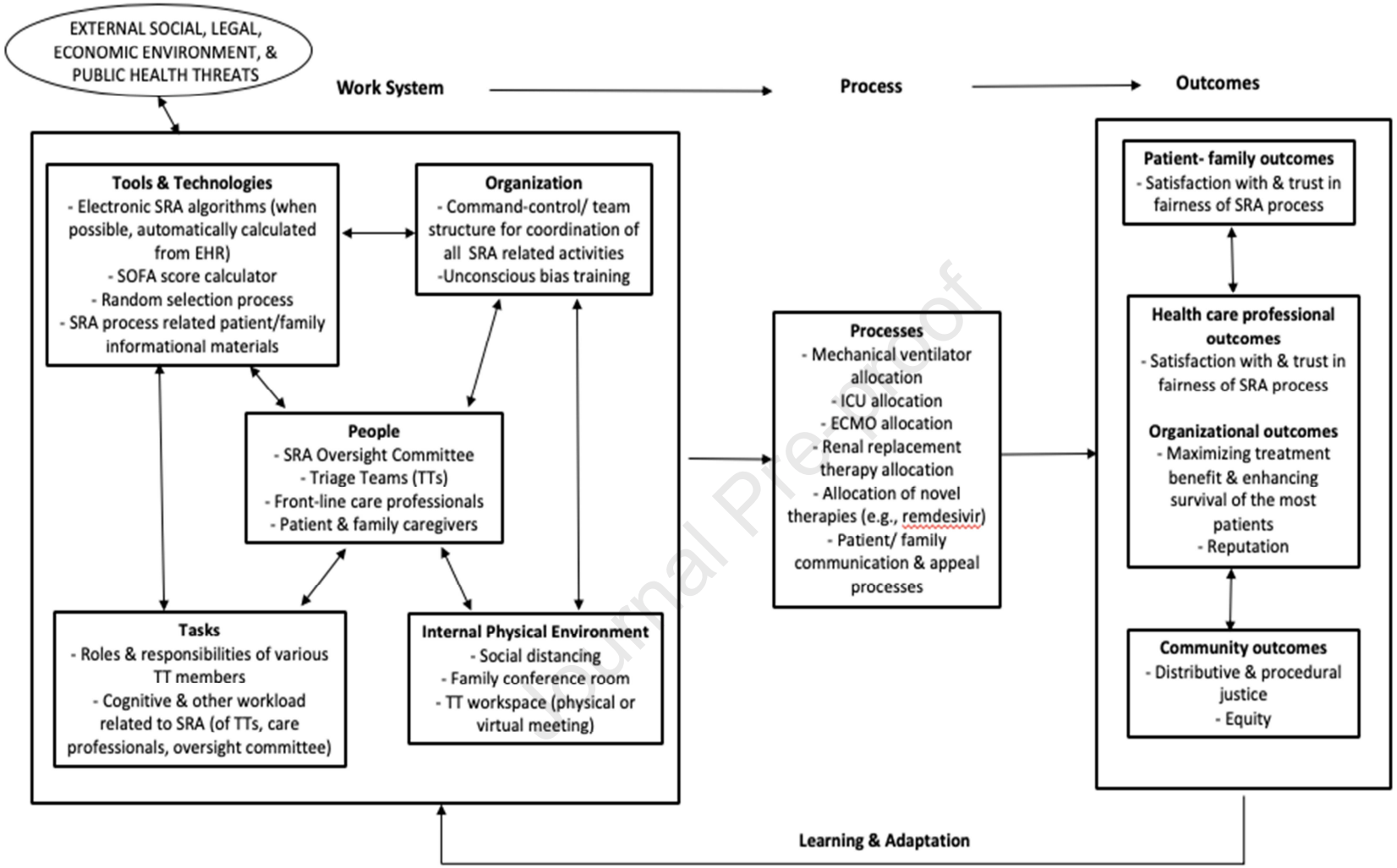

Figure 1. Systems Engineering Initiative for Patient Safety (SEIPS) Model to guide the implementation of scarce resource allocation processes