VENTILATOR ALLOCATION GUIDELINES

University of Rochester
Coronavirus Ethics Response Group

University of Rochester
Rochester, NY
May 2020

CORONAVIRUS ETHICS RESPONSE GROUP
MEMBERSHIP LISTING
MAY 2020

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PREFACE

In 2015, the New York State Task Force on Life & the Law released updated Ventilator Allocation Guidelines (2015 NY State Guidelines) to aid health care workers and institutions "in the ethical allocation of ventilators during an influenza pandemic." The updated guidelines include separate chapters on adult, pediatric, and neonatal allocations. In March 2020, when the first cases of the Pandemic known as COVID-19 (Coronavirus Infectious Disease 2019) presented in New York State, the University of Rochester Medical Center and its affiliates formed a Coronavirus Ethics Response Group (CERG). The goal of the CERG was to develop an operational Triage Protocol (Protocol) for the allocation of ventilators during Covid-19 should any one of the hospitals in the URMC system have more patients in need of mechanical ventilation than ventilators in that hospital.

Several features of this effort are noteworthy, most importantly the interprofessional and interdisciplinary nature of this endeavor, the inclusion of community representation in the process, and the regional collaboration. The 2015 NY State Guidelines incorporated public input; the CERG furthered this commitment to community engagement by including community members in the development and implementation of the Protocol. Community participation is vital to the success of public health measures. CERG collaboration with the Rochester Regional Health (RRH) ethics committee additionally demonstrates a commitment to a community-wide approach to resource allocation decisions.

Priorities, as we began this endeavor, were to design a system with the ability to rapidly perform triage assessments for a large number of patients competing for ventilators, with minimal opportunity for the introduction of bias by the triage team. Furthermore, this task had to be completed swiftly, as our ICU Director stated, "I might need to use it next Wednesday."

Two additional features are significant. First, the CERG developed this Protocol in response to a novel virus that was overwhelming resources in New York City, in anticipation that upstate New York would soon face the same crisis. Second, unlike the 2015 NY State Guidelines, CERG developed the University of Rochester Ventilator Allocation Protocol to be operational. If COVID-19 causes a ventilator shortage in upstate New York, the URMC Chief Medical Officer or his designee can invoke this Protocol to protect bedside clinicians from making public health decisions.

This Protocol provides an ethical response to ventilator allocation shortage specific to the COVID-19 Pandemic. CERG will continue to work on guidance on resource allocation shortages in the event of a different epidemic or pandemic. We welcome feedback from clinicians and the public as we evaluate our work.

ACKNOWLEDGEMENTS

To date, the COVID-19 Pandemic has resulted in the illness of millions and the death of hundreds of thousands of people. It is the greatest public health disaster of our generation and has turned our attention from individual health to a focus on public health. Responding to the Pandemic required the response of our community. Over one hundred individuals participated in the development and preparation for the potential implementation of the Ventilator Allocation Guidelines. Remarkably, this effort led to the ability to activate the adult triage protocol within two weeks of the first CERG meeting. While we thank all of those individuals, we especially acknowledge the assistance from the following departments and individuals.

First, the Department of Surgery provided the administrative talents of Pam Urban and Jodi Barker, who organized our efforts and supported the production of this document.

We acknowledge the previous work of Anthony Pietropaoli MD, who led the team of Will Bossard, Justin Foster, and Christine Groth in the development of the ICU automated SOFA scoring program. The Clinical and Translational Science Institute provided a critical partnership: the leadership of Jeanne Holden-Wiltse and Anthony Corbett led to the development and implementation of the BLIS COVID-19 database system that incorporated the automated SOFA scores, facilitated regular assessment of ventilated patients, and provided the randomization process.

The 2015 NY Ventilator Allocation Guidelines document does not include instructions on how it should be implemented in the COVID -19 Pandemic. Chin-Lin Ching MD, Richard Dees PhD, and Jessica Shand MD analyzed the available clinical data repeatedly, applying different evaluation and assessment intervals to modify the 2015 NY Guidelines to the current Pandemic. David Kaufman, MD connected CERG with ICU directors across Western New York to collaborate and share data.

John Cullen, PhD documented triage processes. Dr. Cullen and Mitchell Wharton, PhD led the training of triage teams. Triage team members participated in training and provided twice-a-day reassessments of ventilated patients to work out technical and logistical details and to capture the data for analysis. Adrienne Morgan, PhD and the Reverend Lawrence Hargrave engaged community members in the development of our process and as members of triage teams. The Institute of Innovative Education, under the direction of Sarah Peyre Ed.D. and Colin Mackenzie, adapted space for the Ventilator Allocation Command and Training Center within days of our request.

Marianne Chiafery, DNP, our expert in Moral Distress, recognized the potential impacts of ventilator decisions on health care workers. She and Beth Goldenberg, NP developed support structures. Bernie Sussman, MD, Tom Carroll, MD, and Rob Horowitz, MD understood the difficult communications in situations where patients were denied ventilators, or removed from ventilators, especially in a time when hospital visitors were strictly limited and developed internal communication strategies.

Carl D'Angio, MD and Jessica Shand, MD led the development of the neonatal and pediatric guidelines. Their leadership and dedication to neonatal and pediatric patient care framed much of the discussion about how to best integrate neonates and pediatric patients into the Protocol. Natalie Whaley, MD, Eva Pressman, MD, and Jill Cholette, MD contributed to the deliberations about pregnant women and pediatric patients.

Lauren Bruckner, MD assumed command of the Protocol Assurance Committee and the development of multi-faceted appeals processes. Her clinical and informatics skills helped us better understand the types of triage appeals problems we might face, as well as potential solutions.

Margaret Somerset, Esq, Elizabeth Talia, Esq., Laura Wilson, Esq, Justin Weis, MD, Patrick Hopkins, DNP, Timothy Dean, MDiv, and Debra Roberts, MD contributed to discussions and documentation. Their engagement, clarity of thought, and attention to detail greatly improved the deliberative process.

An ethical response to a public health crisis requires attention to justice and equity across health systems. Chris Reynolds, MD invited us to join ethics committee discussions in the Rochester Regional Health System and he participated in the CERG meetings. This infusion of new input to our ethics committees resulted in deeper and broader discussions. Our goal is to have similar responses to ventilator allocation throughout the region.

The CERG hopes the region does not experience a ventilator shortage, but thanks to the support of the URMC and the hard work of so many individuals, we believe this Protocol ensures that the University of Rochester Medical community is appropriately prepared for an overwhelming surge during the COVID-19 Pandemic, and is better prepared to respond to future possible pandemics.

Sincerely,

Richard A. Demme MD, FACP

Margie Hodges Shaw, JD, PhD, HEC-C

INDEX OF TERMS AND ABBREVIATIONS

2015 New York State Guidelines	New York State Task Force on Life & the Law 2015 Ventilator Allocation Guidelines
ACT	Advanced Communication Training
Affiliate Hospitals	Highland Hospital, FF Thompson Hospital, St. James Hospital, Noyes Memorial Hospital, Jones Memorial Hospital
ABA	American Burn Association
APP	Advanced Practice Provider
ARDS	Acute Respiratory Distress Syndrome
BLIS	BioLab Information System
CCT	COVID Communications Team
CERG	Coronavirus Ethics Response Group
CMO	Chief Medical Officer
COVID-19	Coronavirus Infectious Disease 2019
CPAP	Continuous Positive Airway Pressure
DNI	Do not intubate
EAP	Employee Assistance Program
ECMO	Extracorporeal Membrane Oxygenation
ED	Emergency Department
eMRN	Electronic Medical Record Number
FFT	FF Thompson Hospital
HH	Highland Hospital
ICU	Intensive Care Unit
MRN	Medical Record Number
NRP	Neonatal Resuscitation Program
NYS	New York State
PAC	Protocol Assurance Committee
PALS	Pediatric Advanced Life Support
PAQ	Protocol Assurance Queries
P-OFS	Pediatric Organ Failure Score
RRH	Rochester Regional Health
SJH	St. James Hospital
SMH	Strong Memorial Hospital
SOFA	Sequential Organ Failure Assessment
UR	University of Rochester
URMC	University of Rochester Medical Center
V-A	Venous-Arterial
VAP	Ventilator Allocation Protocol
VIP	Very Important Person
V-V	Venous-Venous

COLOR CODING SUMMARY FOR ADULT AND PEDIATRIC/NEONATAL PATIENTS

COLOR CODE VENT PRIORITY	ADULT PATIENTS	PEDIATRIC AND NEONATAL PATIENTS
Brown	DNI, Advance directive, no ventilator allocated	DNI, advance directive, no ventilator allocated
Green	No ventilator needed, or healthy enough for extubation	No ventilator needed, or healthy enough for extubation
RED: FIRST PRIORITY	SOFA 1-7: An adult patient who is intubated for airway protection without organ failure is designated as RED. Once assigned a ventilator, RED patients keep the ventilator as long as they remain RED.	P-OFS of <2: A pediatric patient or neonatal patients with single organ failure, with or without mild insufficiency of organ systems. Once assigned a ventilator, RED patients keep the ventilator as long as they remain RED.
YELLOW: SECOND PRIORITY	SOFA 8-11: YELLOW patients are allowed a fair trial of intubation, until the first assessment at 120 hours. Once assigned a ventilator, they keep it until the next assessment. But after each assessment, any patient designated YELLOW can be displaced by a new RED patient during the first 12 hours after their assessment. After that point, they will remain on the ventilator until their next formal assessment.	P-OFS 2-2.5: Pediatric patients or neonatal patients with 2-organ system failure, or single organ system failure with insufficiency or 2 or more other organs. YELLOW patients are allowed a fair trial of intubation, until the first assessment at 120 hours. Once assigned a ventilator, they keep it until the next assessment. But after each assessment, any patient designated YELLOW can be displaced by a new RED patient during the first 12 hours after their assessment. After that point, they will remain on the ventilator until their next formal assessment.
BLUE: THIRD PRIORITY	SOFA 12-24: BLUE patients may receive ventilators if they are available. However, they are always subject to reallocation. Any new RED or YELLOW patient needing a ventilator takes priority.	P-OFS≥3: Pediatric patients or neonatal patients with multi-organ system failure and poor prognosis who do not meet exclusion criteria. BLUE patients may receive ventilators if they are available. However, they are always subject to reallocation. Any new RED or YELLOW patient needing a ventilator takes priority.
Purple	MEETS EXCLUSION CRITERIA	MEETS EXCLUSION CRITERIA

TABLE OF CONTENTS

TABLES AND APPENDICES

Executive Summary

Introduction

This guideline was written by a multidisciplinary and interprofessional committee of the University of Rochester Medical Center and its 5 regional affiliates (URMC and Affiliates) to provide two things during a Coronavirus Infectious Disease Pandemic known as COVID-19: (1) an operational triage Protocol for the allocation of ventilators during a surge of patients which risks overwhelming the respiratory resources of all of the hospitals in the region; and (2) a summary of the method by which the Protocol was crafted with a description of each of the supportive committees identified as necessary for the successful implementation of this Protocol.

This Protocol is intended to preserve the clinician/patient relationship; treating clinicians will not serve on triage teams. The duty of treating clinicians is to focus on improving the health of all patients in their care.

Background

Global pandemics and novel viruses present especially difficult challenges to hospital systems when they are faced with managing large numbers of patients who require more resources than are available at the local level. URMC and Affiliates recognized this risk in March 2020 when the first cases of COVID-19 presented in New York State. As the virus began to spread through the United States in early 2020, New York State quickly became one of the epicenters. While Federal and New York State governments, as well as public health departments, continue to diligently work to respond to this crisis, to date there has been no cure, no vaccine, and no herd immunity. Consequently, COVID-19 remains a high risk to the populations of Upstate New York, including Rochester and the Finger Lakes - all regions served by URMC and Affiliates.

To address the risk that these surges could overwhelm the resources, URMC and Affiliates formed a Coronavirus Ethics Response Group (CERG). The goal of the CERG was to develop an operational Protocol for the allocation of ventilators during Covid-19 should any one of the hospitals in the University of Rochester (UR) system have more patients in need of mechanical ventilation than ventilators in that hospital.

Strong Memorial Hospital, Highland Hospital, and FF Thompson Hospital share the same electronic medical record, so patients from these larger facilities can be listed in one place for assessment for ventilators. Our initial plan was to transfer patients who were sick with COVID-19 at the smaller Affiliate Hospitals to Strong Memorial Hospital. Therefore, the same ventilator allocation protocol could be employed for all of the patients in the UR system.

The CERG collaborated closely with representatives of Rochester Regional Health (RRH) to ensure as much continuity as possible in the two resource allocation protocols. In an attempt to avoid disparate treatment of patients in the region, representatives of each system participated in the ethics committee deliberations regarding resource allocation protocols. In addition, CERG worked closely with Critical Care physicians across the State to develop an allocation protocol grounded in the available clinical evidence.

Recognizing the growing evidence that use of the Sequential Organ Failure Assessment (SOFA) adversely impacts disadvantaged and minority populations, the CERG considered alternative scoring systems from the one recommended by the 2015 New York State Department of Health Ventilator Allocation Guidelines (2015 NY State Guidelines) and consulted with the Community Engagement Committee. The Community Engagement Committee members valued a foundational feature of the Protocol, that triage decisions were blinded to patient information, and discouraged amendments that had potential to introduce individual biases into the process. At the recommendation of the Community Engagement Committee, CERG kept identifying patient information out of triage decisions and reaffirmed support of early targeted education

and interventions to ensure equity in access to assessment, care, testing, and appropriate treatment; transparency in policies and procedures; a commitment to data analysis; and continued collaboration with community stakeholders regarding ventilator allocation protocols. Members of the Community Engagement Committee collaborated with community leaders to expand upon existing outreach in these areas.

Triage Protocol Principles

Principles of public health ethics, specific to conditions of scarcity of essential medical resources, guided development of the Protocol. These principles include equality of persons, ethical resource allocation, duty to care, duty to steward resources, duty to plan, procedural justice, distributive justice, and transparency. This Protocol applies these principles in an effort to maximize lives saved in this COVID-19 public health emergency. The Protocol will be invoked at the direction of the URMC Chief Medical Officer (CMO) or his designee at each of the URMC hospitals based upon the likelihood of insufficient ventilators to treat patients in need of a ventilator. Once the Protocol in invoked, it applies to all patients in need of ventilatory assistance, not just patients being treated for COVID-19.

The core operational principles of the Protocol were derived from the 2015 NY State Guidelines. There are, however, several aspects of the 2015 NY State Guidelines which were not clinically compatible with the COVID-19 epidemic. Consequently, the CERG worked diligently to mold the 2015 New York State Guidelines into a functional Protocol that correlated to the clinical characteristics of patients with COVID-19 in order to give any patient who was allocated a ventilator the best opportunity for a successful trial of mechanical ventilation.

Importantly, the chapters in 2015 NY State Guidelines were developed through the work of independent committees. Efforts to operationalize a consistent ventilator allocation protocol uncovered complexities. For example, the 2015 NY State Guidelines concluded that "when probability of mortality among the pool of patients have been found equivalent… then young age (i.e., 17 years old and younger) may be utilized as a tie-breaker to select a patient for ventilator therapy." The protocol also states: "Pregnant women do not receive special access to ventilator treatment and are subject to the adult clinical ventilator allocation protocol." CERG deliberated on the implications of these recommendations under various clinical circumstances in order to develop a consistent approach to ventilator allocation in the event of fetal viability.

There are 5 basic steps within the Protocol: 1) patients are screened for exclusion criteria – either by reason of an advance directive declining mechanical ventilation or because of medical conditions indicating a very short life expectancy; 2) patients are assessed for risk of mortality using SOFA for adult patients and P-OFS (Pediatric Organ Failure Score) for neonatal and pediatric patients; 3) each patient is assigned a color code designating their level of priority in the allocation of a ventilator; 4) patients eligible for ventilator support are given a trial of intubation to provide an opportunity for improvement of their health status; and 5) patients on a ventilator are reassessed at predetermined intervals to determine whether they will continue with a trial of ventilation based upon whether their SOFA or P-OFS scores have met specific criteria.

Committee Structure

The CERG is an interprofessional and interdisciplinary committee comprised of representatives from medical and nursing specialties (pulmonary, critical care, palliative care, nephrology, psychiatry, pediatrics, and neonatology), bioethics, chaplaincy, URMC and Affiliates' legal counsel, Boards of Directors, leadership in Diversity and Inclusion, the Clinical and Translational Science Institute, and the greater Rochester community. Developing an operational protocol required development of a committee structure to address both ethical and logistical issues. This document details the substantial committee work necessary for the development and operationalization of this Protocol.

Operationalizing this Protocol was only possible through the support and collaboration of informaticists, programmer/analysts, statisticians, bioethicists, data scientists, and clinicians.

Recognizing the importance of community engagement in resource allocation decisions, the CERG created an Advisory Board and a Community Engagement Committee. Members of the Community Engagement Committees serve as members of the CERG, members of the Advisory Board, and members of triage teams.

Introduction and Committee Structure

(see Appendix 1 for Committee membership listings)

Introduction

The emergence of COVID-19 infection represents a public health emergency of the gravest dimensions. The United States, and New York State in particular, have become the epicenter of this global pandemic. Federal and New York State governments, as well as public health departments, are diligently working to respond to this crisis. Disease trends and estimates demonstrate rapid escalation of COVID-19 cases throughout New York State, including the Rochester and Finger Lakes region.

As required by the New York State Department of Health, URMC and Affiliates initiated plans to expand capacity to meet demands of the COVID-19 Pandemic. These plans include specific actions to address the possibility of insufficient mechanical ventilators to meet the needs of patients in respiratory failure when demands are at their peak.

To prepare for the expected surge in patients needing critical care and ventilator assistance, URMC and Affiliates formed a Coronavirus Ethics Response Group (CERG). The CERG is comprised of representatives from medical and nursing specialties (pulmonary, critical care, palliative care, nephrology, psychiatry, pediatrics, and neonatology), bioethics, chaplaincy, URMC and Affiliates' legal counsel, Boards of Directors, leadership in Diversity and Inclusion, the Clinical and Translational Science Institute, and the greater Rochester community. The CERG's primary task is to prepare a Triage Protocol for all patients requiring ventilators (Protocol). This Protocol, as approved by URMC Senior Leadership, is intended to determine ventilator allocation if a shortage arises. In deliberations, the CERG considered existing recommendations regarding ventilator allocation in a scarce resource setting and emerging literature on crises standard of care in the context of COVID 19. This Protocol is modeled on the New York State Ventilator Allocation Guidelines of the New York State Task Force on Life and the Law, New York State Department of Health, November 2015 (2015 NY Guidelines). The goal of the Protocol is to maximize the survival of patients during their acute medical episode.

The Protocol is not limited to patients with a positive COVID-19 diagnosis. It will apply to all ventilated patients, regardless of diagnosis, hospitalized within the URMC and Affiliates system. The Protocol may be invoked at the direction of the URMC Chief Medical Officer (CMO) or his designee at any of the URMC affiliated hospitals when any location drops below 25% of their available ventilator pool. If Strong Memorial or a regional hospital (Highland Hospital, F.F. Thompson Hospital, Nicholas Noyes, Jones Memorial Hospital and/or St. James Hospital) crosses this threshold, the CMO at that facility should contact the URMC CMO or designee to convene discussion with clinical and hospital administrative leadership regarding options of available resource redistribution or mitigation strategies within the system.

There is much unknown about the nature of COVID-19 infection. The CERG relied on available clinical data to develop the Protocol (**see Triage Development Team Section under Committee Structure**). The CERG will continue to evaluate the data during the Pandemic to ensure the Protocol maximizes lives saved, and will amend the Protocol as necessary, in consultation with representatives of the CERG Advisory Board, and subject to the approval of the URMC CMO.

The COVID-19 Pandemic presents distinctive ethical challenges. In usual circumstances, medical decisions are centered on individual patients and guided by respect for their values and autonomous choices. In a public health emergency, urgent medical priorities may require balancing the well-being of each patient and the public interest. The Protocol discussed below has been guided by principles of public health ethics specific to conditions of scarcity of essential medical resources. These principles include equality of

persons, ethical resource allocation, duty to care, duty to steward resources, duty to plan, procedural justice, distributive justice, and transparency. In keeping with the 2015 New York State Guidelines, the Protocol applies these principles in an effort to maximize lives saved in this COVID-19 public health emergency. A critical reason for development and use of such a protocol is the protection of the provider patient relationship. The burden of life and death decisions should not fall to individual care providers; such decisions are antithetical to the moral obligations of health professionals. Patients must be able to trust health care providers to attend to their health. Use of this Protocol removes any individual's conscious or unconscious biases from the decision-making process. To expedite the development of the Protocol the CERG created a committee structure.

External Document Review Committee

The External Document Review Committee summarized the protocols in use in other hospital systems (including outside of the State of New York). This process was designed to help the CERG identify any ethical or clinical considerations that may have been overlooked. The group was able to obtain the draft COVID-19 triage protocols from a small numbers of university hospital systems (University of Pennsylvania, University of North Carolina, University of Wisconsin, New York Presbyterian), as well as general guidelines issued by the Swiss Medical Association and the UK National Health Service. In addition, they reviewed the existing academic literature on COVID-19 triage. They summarized the recommendations in these documents and presented them for discussion to the Advisory Board. Of particular note was that most guidelines included advanced age as a non-clinical reason to either exclude patients from resources (Wisc., Swiss) or break ties between patients who have similar clinical prognosis (Penn, UNC). The use of age (outside of clinical indication) to allocate resources was rejected by the NYS Guidelines, and the Advisory Board re-affirmed that age would not be included as a non-clinical criterion. Additionally, early data from Chicago and other cities indicated that elderly and minority patients were those most likely to die of COVID-19. A decrease in access to ventilators for the elderly might lead to greater loss of life, and restrict from ventilators those most in need.

The External Document Review Committee also identified proposals to alleviate the disproportionate impact of COVID-19 on marginalized communities. The group presented one such proposal: the use of the Area Deprivation Index (a measure of disadvantage by census block, typically used to allocate public health resources) as a tiebreaker amongst patients who are equally likely to benefit from ventilator access. The proposal was discussed with the Community Engagement Committee, and also the CERG. The CERG decided against the proposal on the grounds that (i) the index had not been validated for use in individual clinical decision-making, (ii) the use of census blocks was too coarse-grained to effectively target resources towards the most disadvantaged, and (iii) support amongst the leaders of marginalized communities was low.

Community Engagement Committee

The Community Engagement Committee included diverse community members who share a mission to address fairness, equity, and potential bias in the dissemination of guidelines and procedures if hospitals experience a shortage of ventilators. Membership consists of community leaders who represent critical diversity in terms of race, ethnicity, religion, sexual identity, refugee and documentation status, and ability. Committee members: 1) contribute to informed decision-making during and after the crisis; 2) ensure transparency during and after the COVID-19 crisis; 3) recognize that social and economic determinants of health will disproportionately affect people from marginalized populations; 4) identify strategies to mitigate disproportionate effects of the Protocol; 5) commit to continuing the conversation after the crisis; and 6) respect diversity, equity, and inclusion throughout the process.

Recognizing the use of SOFA scores disproportionately impacts historically disadvantaged populations, the CERG, on the counsel of the Community Engagement Committee, recommended early targeted education and interventions to ensure equity in access to assessment, care, testing, and appropriate treatment; transparency in policies and procedures; a commitment to data analysis; and continued collaboration with community stakeholders regarding ventilator allocation protocols.

Internal Communications Committee

Communicating with patients and their families about COVID-19 infection, their specific medical circumstances and treatment options, clarifying values and preferences, and establishing patient-concordant plans of care require both sensitivity and sophisticated communication skills. These discussions will be complicated by clinical uncertainty of a new disease process, and the potential both for large numbers of extremely ill patients and triage decisions in the event of ventilator scarcity. If we must implement the Protocol we will have the difficult responsibility of discussing decisions to withhold or withdraw ventilators from patients who are too sick to receive one or have failed to improve with an adequate time trial of ventilator support. The Internal Communications Committee (ICC) recognizes the following initiatives to address challenges of effective and supportive communication about COVID-19 treatment decisions including the possible use of the Protocol.

ACT: Enriching clinician communication about COVID-19 and potential ventilator limits -- The leadership of URMC's Advanced Communication Training (ACT) modified their communication enrichment program to address COVID-19-specific challenges. This program is being rapidly disseminated by Zoom to clinicians who will engage in conversations about these challenges. The curriculum considers four scenarios, two of which involve discussions about ventilator allocation limits: 1) proactive outpatient advance care planning in case of serious COVID-19 illness; 2) treatment planning for a seriously ill patient suspected of COVID-19 infection, and the potential for ventilator limits; 3) discussion with a patient denied a desired ventilator; and 4) withdrawal of a ventilator from a patient who wishes to retain it. As of mid-May 2020 this program has reached nearly 800 clinicians. All URMC clinicians have also been directed to the ACT website which contains a downloadable ACT-COVID-19 pocket card and a wealth of other COVID-19 resources. https://act-ur.com/acts-program-covid-19-updates/

Palliative Care support – Our ICU, ED and Hospitalist teams routinely engage in frank discussions with patients and families about serious illness, prognosis and treatment options. Although these primary teams manage most patient care independently, the Palliative Care team is always available to assist them with complicated symptom management, goals of care clarification, and to support primary teams strained by surging numbers of COVID-19 cases. The Palliative Care team is prepared to contribute as needed for optimal patient, family, and clinical team care support. This may include, for example, joint Palliative Care/Hospitalist or Palliative Care/ICU 'lightning rounds' to address and anticipate the unique challenges presented by COVID-19.

COVID Communications Team – If the ventilator allocation Protocol is invoked, family notification of allocation/reallocation decisions will be managed by the COVID Communications Team (CCT). The COVID Communications Team is comprised of physicians and APPs selected for both communication excellence and medical knowledge.

When implementation of the ventilator allocation Protocol is imminent, or has occurred, the CCT will schedule two clinicians on call at all times. When the Triage Team indicates the need for ventilator reallocation, the critical care team will contact the on-call CCT clinician to review the case. This will consist of focused information exchange, to include patient name, medical record number, outline of medical situation and course, surrogate contact information, prognosis, available treatment options and their likely outcomes. The CCT clinician will phone the surrogate contact and identify as, e.g., "Dr. Joe Smith, from the COVID Communications Team of SMH." They will frankly and compassionately discuss the relevant background information and ventilator allocation decision, including the objectivity, uniformity and universality of the Protocol. They will facilitate consideration of medical treatment options informed by the attending team's prognostic impressions, and patient/family values. These options may include pure symptom-focused care during what is expected to be the patient's dying minutes, hours, or days; or potentially additional disease-directed treatments, for example, for those who want "everything possible to stay alive longer." In all cases, the provision of symptom-relieving care will be emphasized. After concluding, the CCT clinician will contact the clinically responsible team to report the outcome of the

discussion with surrogates, and then document the relevant details in the patient's medical record. This will end the COVID Communication Team's involvement in the patient case. Entry of relevant medical orders will be the responsibility of the critical care team.

Moral Distress and Staff Support Committee

During a pandemic there is great potential for health care workers to suffer moral distress, defined as "a psychological response to morally challenging situations such as those of moral constraint, moral conflict, or both (Foure, 2012). There are many potential sources of distress. Some examples are: the process of removing or refusing ventilator treatment to critically ill people, the tension of personal safety versus professional obligation to care for the sick, the necessity of altering usual health care practices that focus on a concern for the individual patient to the goal of maximizing the public good, and inability to interact with the patient and family in the usual ways due to physical distancing restrictions.

Emotional responses to moral distress may include anger, anxiety, grief, frustration, guilt, suicidal thoughts and a desire to conscientiously object to participation in patient care. Physical symptoms include inability to sleep, tension headaches and muscle pain, nightmares and distancing or removing oneself from the source of distress.

Staff who experience an ethically troubling patient care situation may have difficulty processing the event. Debriefing provides an opportunity for staff to talk about and work through emotions and feelings of moral distress. Literature and work in the field of debriefing supports its positive effects on care providers.

In the event that the URMC Chief Medical Officer implements the Protocol, it is recommended that a formal, planned system of staff support to address morally distressing events be implemented. Planned debriefings will be held twice a day after change of shift (7:45 am and 7:45 pm) and will be available on an as-needed basis 24 hours/7 days per week. Immediate requests for a debriefing meeting can be accessed by paging the clinical ethicist on call.

The Moral Distress and Staff Support Committee created structures to support faculty and staff as part of the planning process for a potential resource allocation shortage and in anticipation of implementation of the Protocol. Members of the committee are required to have a solid educational background in clinical health care ethics, ethical deliberation and argument, as well as ability to facilitate small group discussions about clinical ethics topics. A multi-faceted approach was developed and included:

1. Planned meetings upon request with staff in a group setting or individually to talk about ethically troubling situations.
2. Weekly meetings with service leaders from Critical Care Nursing to share perceptions of staff morale, needs for support, and what type of support is needed.
3. Weekly meetings with other support service leaders from Employee Assistance Program, the Chaplaincy Services, and Behavioral Mental Health Services to share perceptions and resources so that the care delivery to staff is suited to the need.
4. Anticipating needs of staff based on surge impact on hospital operation;: a team member will participate in daily administrative reports about supplies, staffing, and patient census.
5. Creation and implementation of a moral distress email for staff to have easy access to the team to ask questions or request a meeting, moral_distress@urmc.rochester.edu.
6. Working with other critical support services, such as the Director of Respiratory Therapy and the Director of Environment Services to ascertain support needs.
7. Maintaining and continuing to develop a source file of helpful resources, including scripts for difficult conversations during Pandemic, to share with staff as indicated.
8. Weekly meetings with ethics representatives from the Affiliate Hospitals to share ideas to best support staff and each other.
9. Monitoring the CERG team members for indications for team moral distress and arrange for debriefings and process evaluation as indicated.

10. Deploying a moral distress debriefing team, for clinical teams responsible for extubating adult, neonatal, and pediatric patients. Teams will consist of ethicists, trained facilitators, adult and/or pediatric palliative care team members, adult and/or pediatric chaplaincy, and staff from the Employee Assistance Program to provide individual and team support. (***Appendix 2: Moral Distress and Staff Response Rapid Response and Debriefing Process)***
11. The Moral Distress and Staff Support Committee members will not be active in making patient triage decisions. It would be difficult to objectively facilitate a unit ethics debriefing if the Moral Distress Committee member had been a participant in patient triage decisions.

Protocol Development Committee

The overall goal of the Protocol Development Committee was to adapt the 2015 NY State Guidelines into a ventilator allocation protocol that could be clinically implemented during the COVID-19 Pandemic, upholding the principle of saving the most lives. Challenges to this goal included how best to adapt clinical scoring systems into ventilator priorities to minimize bias, the logistics of providing that data to ventilator triage teams for final decision-making, and critical differences between influenza- the disease for which the NYS Guidelines were designed to address- and COVID-19. To overcome these challenges, the Protocol Development Team developed three processes in parallel:

1) A method for extracting SOFA scores from the electronic medical record in real-time and exporting them, in a de-identified manner, to the ventilator triage teams.
2) An algorithm for ventilator triage teams to assign ventilator priority categories based on SOFA scores.
3) Real-time analysis of SOFA scores and ventilator priority assignments for all ventilated patients in the URMC health system to determine feasibility and accuracy of the algorithm.

The 2015 NYS Guidelines recommend use of the SOFA to assess prognosis of patients requiring mechanical ventilation when placing patients into high (RED color code), intermediate (YELLOW color code), and low (BLUE color code) priority for ventilator allocation. Critical to this process is the re-evaluation of SOFA scores at prescribed time intervals in order to re-evaluate which patients will be most likely to survive with continued ventilator support. Unfortunately, analysis of available national and international COVID-19 outcome data indicated that while the time intervals for clinical reassessment recommended by the NYS Guidelines may have been predictive for influenza (reassessment after the first 48 hours, then every 3 days afterward) they did not take into account the longer average time-on-ventilator required for COVID-19 patients, nor the early organ failure trajectory of the disease. In particular, the first reassessment time point for ventilated patients needed to be appropriately long enough to allow for improvement of high-priority COVID-19 positive patients, but not so long that allocation became a first-come-first-serve scenario.

Working with Critical Care physicians from Albany, Syracuse and Buffalo, the original consensus was to move the first reassessment point from 48 hours to 72 hours. To test this algorithm, the Protocol Development Committee applied it to COVID-19 positive ventilated patients at our institution prior to the necessity of ventilator allocation. The results were devastating. Most patients who require mechanical ventilation were actively decompensating and developing multi-organ system failure shortly after intubation. By applying the algorithm at 72 hours and following the NYS guidelines for SOFA score-based reassessment, almost all of the COVID-19 positive patients were downgraded to the low ventilator priority category (BLUE), meaning that each would risk losing their ventilator in reallocation. This would violate the guiding ethical principle of saving the most lives.

Through detailed analysis of all clinical data available on mechanically ventilated patients across URMC, the Protocol Development Committee determined that moving the first reassessment point to 120 hours placed more COVID-positive patients in the intermediate priority (YELLOW) category with relatively less risk of losing their ventilators. Real time data analysis also allowed the Protocol Development Team to uncover a significant disadvantage that occurred in COVID-19 patients when comparing SOFA scores at the time of intubation and the time of first assessment to render allocation priority. For COVID-19 patients,

SOFA scores at intubation were highly inaccurate at predicting prognosis on a ventilator; patients almost always decompensated before improving. The final algorithm re-scores patients at 120 hours (essentially resetting their T0 SOFA scores), then reassesses their priority according to the rubric in the NYS guidelines (SOFA 1-7 = RED/high priority, SOFA 8-11 = YELLOW/ intermediate priority, SOFA > 12 = BLUE/low priority) every 48 hours. Based on COVID-19 patient data analysis, "improvement" – which was not well-defined in the NYS Guidelines -- is defined as one SOFA point.

In summary, the ability of the Protocol Development Team -- through real-time automated reporting of SOFA scores and analysis of available clinical data on ventilated COVID-19 patients -- allowed for critical modifications to the 2015 NYS Guidelines to account for the unique physiology of COVID-19 patients while upholding the guiding principle of saving the most lives. The ongoing work of the Protocol Development Team applies the current algorithm to study survival patterns in allocation priority subgroups and time-on-ventilator to inform future pandemic planning.

Translational Data and Informatics Team

The goal of the Translational Data and Informatics Team (TDIT) is to design, implement and maintain the data systems that allow the Protocol Assurance Committee, Triage Teams, and Protocol Development Committee to design, implement, monitor and assess the Protocol. The TDIT includes informaticists, data scientists and programmer/analysts, and works closely with the bioethicists and physicians involved with the CERG committees. We were fortunate, that a previous URMC Quality Assurance ICU project had resulted in the development of an automated SOFA scoring system for hospitalized patients based on lab results and other clinical information through the electronic record. This system allowed for review of each patient's previous and current SOFA scores. The automation of this system allowed for the assessment of SOFA scores of numerous patients in rapid fashion, and limited potential inter-rater variability and the introduction of bias. The TDIT merged this existing program with a new database that allowed triage teams to input priority assessments and perform randomizations. The TDIT designed, implemented, and maintains the Biolab Information Server (BLIS) COVID-19 Database. The TDIT continues to work with the eRecord team to assure timely data flow from the clinical Electronic Medical Records.

The TDIT's work is not simply technical data support. It also provides design work flows for protocol implementation, algorithms for minimizing bias, ensures de-identification of data, designs and implements visualizations and data tables to ensure the highest level of decision support for the triage teams, and identifies and correct inconsistencies at all levels. The TDIT also implements privacy and data security strategies that support the ethical guidelines in the Protocol.

Triage Committee/Triage Teams

The Triage Committee will include a Triage Committee Chair; Vice Chair; and members comprised of actively practicing and retired medical professionals, including physicians, nurses, respiratory therapists, physician assistants, nurse practitioners, bioethicists, philosophers and community members recommended by the CERG. Treating clinicians will not serve on triage teams. In general, triage team members should include medical personnel who are not expected to be clinically busy during a respiratory illness pandemic, such as ophthalmologists, dentists, and surgeons who are not performing elective surgeries. If the Protocol is invoked, a call schedule will be put in place such that seven teams of six members, led by a Triage Officer, will serve in rotating and staggered shifts of 8 hours. Staggered shifts are designed to ensure continuity of the process and communication among teams. Each Triage Team will be led by a Triage Officer. The duties of the Triage Committee members are to implement the Protocol if invoked. Under the direction of the Triage Officer, the Triage Teams 1) apply the triage algorithm to ventilated patients up for reassessment every twelve hours, with at least two triage team members verifying each assessment; 2) use the BLIS COVID-19 database to randomize all patients currently in a category permitting ventilator reallocation for purposes of the lottery; 3) respond to clinical requests for a ventilator; 4) apply the algorithm to determine whether to reallocate a ventilator, and if so which ventilator; 5) notify Attendings of patients whose ventilator is reallocated through the randomized process; 6) notify Attendings of ventilator availability; 7)

maintain all Triage Protocol records; and 8) collaborate with the Protocol Assurance Committee as needed. Triage Committee members and team members will not access the Medical Record of ventilated patients. The Vice Chair will take on any duties of the Chair if the Chair cannot act.

In acknowledgment of both the moral burden on members of this committee and the critical function of the team, a Triage Committee member may resign at any time upon verbal or written notice to the Triage Committee Chair. A Triage Committee member may also be temporarily or permanently removed at any time by the Triage Committee Chair for a conflict of interest or for misconduct. Misconduct may include, but not be limited to, a failure to fulfill the duties of the position, a failure to disclose a conflict of interest, or a disclosure to a member of the public or the media, without permission of the URMC CMO, of the activities of the Committee. A Triage Committee member will immediately disclose any actual or potential conflicts of interest that may arise to the Chair or Vice-Chair. The Chair or Vice-Chair will determine if temporary or permanent removal is necessary. A member will be temporarily removed from the Committee if medically indicated.

The on-call triage team will meet in a secure location at a Ventilator Allocation Command Center that has been identified by the Institute of Innovative Education (IIE), and has been supplied with three computers with access to the BLIS COVID-19 database. Printers are available to print the randomized lottery results every 12 hours, to identify patients of lower priority at risk of losing a ventilator to a patient of higher priority. A phone "hotline" number has been assigned, with six wireless Voice-Over-Internet Protocol (IP) phones that ring in a "round robin" pattern, to handle requests from multiple providers for ventilators for their patients. A fax machine will be used to submit ventilator re-allocation information forms to medical records. This Command Center setting has been and will be used to train triage team members on how to complete ventilator priority assessments, and how to perform the list randomizations. Two beds will be available in the Command Center, as well as a refrigerator and microwave oven***. (see Appendix 9)***

Protocol Assurance Committee

The goal of the Protocol Assurance Committee (PAC) is to ensure data validity, consistent methodology, and implementation fidelity for the Protocol. Checks and balances will be incorporated into the plan to promote confidence that data are correct and processes reliable. The PAC will also work with the CERG and/or relevant sub teams to identify and correct workflow concerns, as they relate to data assurance and Protocol processes.

Issues to review may include, but are not limited to: 1) confirming that patient demographics are fully blinded to Triage Teams; 2) validating that the SOFA scores are calculated accurately; 3) verifying that the color coding process is being conducted as intended and that ventilators are being allocated in accordance with the Protocol (i.e., recognition of variances); and 4) working with CERG to support problem solving in workflow concerns.

The PAC will NOT function to adjudicate requests for Protocol exceptions or to impart clinical judgements. While the Protocol is being utilized, the PAC will regularly audit a random sampling of cases to confirm the function of the process as described above. If the PAC identifies any concerns or errors in the function of the Protocol, the PAC will report the concerns or errors to the CERG Advisory Board immediately. The PAC will also work to resolve any concerns with Protocol processes, raised by the members of the Triage Teams, CERG Advisory Board, or UR Medicine Senior Leadership Group. Finally, after the Protocol is no longer being utilized, the PAC will summarize and present its findings to the CERG Advisory Board for review and for future considerations.

Protocol Assurance Queries (PAQ): A real-time validation process has been created in case a clinician expresses concern about the validity of the SOFA/P-OFS calculation, and/or the color-coding algorithm for their patient for whom a ventilator is being requested or re-allocated. Such a query will prompt the PAQ Team to conduct a Medical Record review, manual calculation of the SOFA/P-OFS score, and re-assessment of the color-coding assignment to ensure there were no system calculation and/or data flow errors.

- If the Protocol is invoked, a call schedule will be put in place such that at least one member of the PAQ Team is available 24/7.
- A PAQ may be initiated by the Triage Team during communication with a clinician whose patient needs a ventilator or whose ventilator needs to be re-allocated.
- The goal is to have the PAQ review completed, and the results communicated back to the Triage Team, within 30 minutes of the request.
- If a mistake that results in a different ventilator allocation decision is identified, then corrective action will be immediately taken regarding the patient in question.
- Identification of such errors will also prompt a thorough review by the Protocol Assurance and Data Flow Committees to determine if systemic corrective actions are needed.

Protocol Disagreements: Once invoked, the Protocol ***must*** be applied in practice ***without exception*** or else risk undermining the entire Protocol. Therefore, a Protocol disagreement cannot be used to delay or override a ventilator allocation decision. However, the CERG recognizes the moral distress placed on clinicians asked to implement ventilator allocation decisions. Thus, a Protocol disagreement will prompt a request for immediate leadership intervention to support the clinician/clinical team and to ensure the ventilator allocation decision is carried out expeditiously. Protocol disagreements include concerns expressed about the Protocol itself, how the Protocol is being applied in practice, and/or any request for leadership adjudication regarding a ventilator allocation decision.

- The Triage Team will contact the CMO (or their designee) of the hospital where the clinician with a Protocol disagreement is located.
- The CMO at each hospital will decide how to operationalize requests for leadership intervention originating from their hospital.

Coronavirus Ethics Response Advisory Board

The Coronavirus Ethics Response Advisory Board (Board) will include broad representation. The Board will meet regularly with the CERG. The responsibility of the Advisory Board members is to respectfully engage in deliberations, offer advice, and make recommendations as part of the development of a ventilator allocation Protocol. The Advisory Board members shall address concerns of the CERG, Community Engagement Committee, Protocol Assurance Committee, Moral Distress and Staff Support Committee, Document Review Committee, and Internal Communications Committee. As needed, the Board will assist in amending this Protocol during the Pandemic. After the Pandemic, the Board will review and evaluate ethical issues considered during the Pandemic, including but not limited to how the Protocol functioned from an ethics perspective as well as findings of the PAC. The Board may prepare a report of its findings and any recommendations for future similar protocols, and public health initiatives.

Adult Triage Protocol

The Adult Protocol contains five steps: 1) patients are screened for exclusion criteria – either by reason of an advance directive declining mechanical ventilation or because of medical conditions indicating a very short life expectancy; 2) patients are assessed for risk of mortality using SOFA scoring; 3) each patient is assigned a color code designating their level of priority in the allocation of a ventilator; 4) patients eligible for ventilator support are given a fair trial of intubation to provide an opportunity for improvement of their health status; and 5) patients on a ventilator are reassessed at predetermined intervals to determine whether they will continue with a trial of ventilation based upon whether their SOFA scores have met specific improvement criteria.

Advance Directives

The New York State Clinical Ventilator Allocation Guidelines are based on a public health ethics framework which includes a duty to steward resources. During the COVID-19 Pandemic, human resources, laboratory resources, and ventilator resources are all at risk for being stretched to their limits. In the event that there are insufficient ventilators to treat all patients who need them, the ethical standard of distributive justice requires that scarce resources not be allocated to a patient who has declared a preference not to receive those resources.

It will be important to identify, as early as possible (before or during a hospital admission) which patients have chosen not to be allocated a full complement of medical resources. During this Pandemic it will be imperative to know a patient's advance directives with regard to mechanical ventilation. An advance directive to forego mechanical ventilation should not be construed as a decision to forego other treatments or resources that may be in limited supply. When possible, advance care directives should be reaffirmed by the patient. Decisions regarding alternative medical treatment, including palliative care, should be discussed with the patient or surrogate to ascertain their preferences in the context of the COVID-19 Pandemic and the patient's specific medical circumstances.

Exclusion Criteria

1. Once activated, the Protocol begins with the clinical determination of which patients require, or will soon require, ventilator support, and if so, whether those patients meet Exclusion Criteria **(TABLES A, B and C).**
2. The primary clinical team will make every effort, as medical circumstances allow, to rule out Exclusion Criteria during the initial triage assessment.
3. If necessary, and if resources allow, patients may be temporarily intubated during the initial triage assessment.
4. The initial triage assessment may take place in the emergency department (ED), on the medical floor, or in the ICU.
5. If any Exclusion Criteria is present, the patient will not be placed in the pool of patients who will be pre-screened for ventilator allocation. Instead, patients with Exclusion Criteria will receive aggressive symptom management, alternative forms of medical intervention, and/or palliative care.

TABLE A – Exclusion Criteria for Ventilator Support in Adult Patients

1.	Executed Advance Directive, DNI order, MOLST or witnessed verbal declaration expressly rejecting intubation or mechanical ventilation
2.	Unwitnessed cardiac arrest
3.	Recurrent cardiac arrest without hemodynamic stability
4.	Cardiac arrest unresponsive to standard interventions and measures
5.	Trauma related arrest
6.	Irreversible age-specific hypotension unresponsive to fluid resuscitation and vasopressor therapy
7.	Traumatic brain injury with no motor response to painful stimulus
8.	Severe burns where the expectation of survival is less than 10% even with unlimited aggressive therapy
9.	Any other condition(s) resulting in immediate or near-immediate mortality even with aggressive therapy

TABLE B – Glascow Coma Scale Score Criteria for Determining Traumatic Brain Injury

BEST MOTOR RESPONSE (1 to 6)	
No Motor Response to Painful Stimulus	1
Extension to Painful Stimulus	2
Flexion to Painful Stimulus	3
Withdraws from Painful Stimulus	4
Localizes to Painful Stimulus	5
Obeys Commands	6

TABLE C – ABA Triage Decision Table for Burn Victims based on Anticipated Outcomes Compared with Resource Allocation

Age (yrs)	Burn Size (% total body surface area)									
	0-10%	11-20%	21-30%	31-40%	41-50%	51-60%	61-70%	71-80%	81-90%	91%+
5.0 - 19.9	Out-patient	Very high	Very high	High	High	High	Medium	Medium	Medium	Low
20.0 - 29.9	Out-patient	Very high	Very high	High	High	Medium	Medium	Medium	Low	Low
30.0 - 39.0	Out-patient	Very high	Very high	High	Medium	Medium	Medium	Medium	Low	Low
40.0 - 40.9	Out-patient	Very high	Very high	Medium	Medium	Medium	Medium	Low	Low	Low
50.0 - 59.9	Out-patient	Very high	Very high	Medium	Medium	Medium	Low	Low	**Low/ Expectant**	**Low/ Expectant**
60.0 - 60.9	Very high	Very high	Medium	Medium	Low	Low	Low	**Low/ Expectant**	**Low/ Expectant**	**Low/ Expectant**
70.0 +	Very high	Medium	Medium	Low	Low	**Low/ Expectant**	**Expectant**	**Expectant**	**Expectant**	**Expectant**

Outpatient: Survival and good outcome expected, without requiring initial admission.
Very high: Survival and good outcome expected with limited/short-term initial admission and resource allocation (straightforward resuscitation, length of stay < 14 – 21 days, 1 – 2 surgical procedures).
High: Survival and good outcome expected (survival ≥ 90%) with aggressive and comprehensive resource allocation, including aggressive fluid resuscitation, admission ≥ 14 – 21 days, multiple surgeries, prolonged rehabilitation.
Medium: Survival 50 – 90% and/or aggressive care and comprehensive resource allocation required, including aggressive resuscitation, initial admission ≥ 14 – 21 days, multiple surgeries and prolonged rehabilitation.
Low: Survival < 50% even with long-term aggressive treatment and resource allocation.
Expectant: Predicted survival ≤ 10% even with unlimited aggressive treatment.

Initial Triage Assessment and Mortality Risk Assessment Using Sequential Organ Failure Assessment (SOFA) Scores

1. If no Exclusion Criteria are present, the patient will be assigned a triage score derived from the patient's likelihood of surviving to hospital discharge as assessed with a SOFA score (**TABLE D**).
2. The critical care team will order that clinical data be collected, at least daily, to assess six of the patient's key organ systems - lungs, liver, brain, kidneys, blood clotting, and blood pressure - that constitute a SOFA score.
3. Every patient who has been identified as likely to require mechanical ventilation, or who is actively receiving mechanical ventilation for any medical condition, will have SOFA scores calculated at least daily and reported in their e-Record.
4. Whenever possible, surrogates will be told in advance that the Protocol requires all intubations to be a time trial.
5. If, at any time, a patient who is either awaiting the allocation of a ventilator, or who is receiving mechanical ventilation, develops Exclusion Criteria (**TABLE A**), this patient will be removed from the pool of patients whose SOFA scores continue to be calculated at least daily. Under such circumstances, the Critical Care Team shall discontinue mechanical ventilation if this patient is receiving mechanical ventilation and support the patient with other appropriate medical treatment, comfort care and/or palliative care.

TABLE D – Sequential Organ Failure Assessment Scoring Scale

Variable	0	1	2	3	4	Score (0-4)
PaO_2/FiO_2 mmHg	> 400	< 400	< 300	< 200	< 100	
Platelets, x $10^3/\mu L$ (x $10^6/L$)	> 150 (> 150)	< 150 (< 150)	< 100 (< 100)	< 50 (< 50)	< 20 (< 20)	
Bilirubin, mg/dL (µmol/L)	< 1.2 (< 20)	1.2 - 1.9 (20 - 32)	2.0 - 5.9 (33 - 100)	6.0 - 11.9 (101 - 203)	> 12 (> 203)	
Hypotension	None	MABP < 70 mmHg	Dop < 5	Dop 6 - 15 or Epi < 0.1 or Norepi < 0.1	Dop > 15 or Epi > 0.1 or Norepi > 0.1	
Glasgow Coma Scale Score (see next page to calculate)	15	13 - 14	10 - 12	6 - 9	< 6	
Creatinine, mg/dL (µmol/L)	< 1.2 (< 106)	1.2 - 1.9 (106 - 168)	2.0 - 3.4 (169 - 300)	3.5 - 4.9 (301 - 433)	> 5 (> 434)	
				TOTAL (0 - 24):		

Color Coding Using Sequential Organ Failure Assessment (SOFA) Scores, and Priority to Be Allocated a Ventilator on Admission

1. At the time of a patient's initial SOFA score calculation, the patient shall be assigned a color code by the URMC BLIS COVID-19 Database (**TABLE E**)
   i. BROWN: patients who have refused intubation or the use of a ventilator in an advanced directive
   ii. GREEN: SOFA =0 (patients who either do not require mechanical ventilation at this time, or who have sufficiently improved with mechanical ventilation to warrant extubation).
   iii. RED: SOFA =1-7 (patients who have the highest level of access to ventilator therapy because they are most likely to recover with treatment and have the lowest risk of mortality)
   iv. YELLOW: SOFA =8-11 (patients who have an intermediate level of access to ventilator therapy because their likelihood of survival is intermediate and/or uncertain and they have a medium risk of mortality).
   v. BLUE: SOFA =12-24 (patients who have the lowest access to ventilator therapy because they have the highest risk of mortality).
   vi. PURPLE: patients who are not eligible for ventilator allocation due to exclusion criteria
2. The initial color codes assigned by the URMC BLIS COVID-19 Database to the patients shall be their "Admission" color code.
3. The Admission color code shall be used to determine the initial level of priority to be given patients awaiting the allocation of a ventilator.
4. RED color-coded patients receive the 1st priority for the allocation of ventilators.
5. YELLOW color-coded patients receive the 2nd priority for the allocation of ventilators and are only allocated a ventilator if there are no RED color-coded patients awaiting a ventilator.
6. BLUE color-coded patients receive the 3rd priority for the allocation of ventilators and are only allocated a ventilator if there are no RED color-coded patients or YELLOW color-coded patients awaiting allocation of a ventilator.

TABLE E – URMC and Affiliates Ventilator Priority Color Codes

Color Code Vent Priority	Initial Assessment SOFA SCORE #1	Reassessment #1 120 hours/5 days SOFA SCORE #2	Reassessment #2 168hours/7 days SOFA SCORE #3	Reassessment #3 216 hours/9 days SOFA SCORE #4
	DNR/DNI, ADVANCE DIRECTIVE, NO VENTILATOR ALLOCATED			
No Vent needed	***NO VENTILATOR ALLOCATED, or healthy enough for extubation.*** • **No organ insufficiency**			
RED: FIRST PRIORITY See Note 1	• **Initial SOFA 1-7 or SINGLE ORGAN FAILURE** • Some organ insufficiency • If ventilator allocated, must be given a reasonable trial of intubation.	• SOFA 0-7, remains Red • SOFA 8-11 becomes Yellow • SOFA 12-24 becomes Blue	• If significant improvement (≥1 SOFA points), remains RED. • If no significant improvement and SOFA ≤ 7 then downgraded *to* YELLOW, loses ventilator if RED IS waiting • If worsens and SOFA≥ 8 , then downgraded to BLUE, loses ventilator if RED or YELLOW waiting. • See Note 4	• If significant improvement (≥1 SOFA points), remains RED. • If no significant improvement and SOFA ≤ 7 then downgraded *to* YELLOW, loses ventilator if RED IS waiting • If worsens and SOFA≥ 8 , then downgraded to BLUE, loses ventilator if RED or YELLOW waiting. • See Note 4
YELLOW: SECOND PRIORITY See Note 2	• **Initial SOFA 8-11** • Severe organ insufficiency • Ventilator allocated if there are BLUE on ventilator (See Note 5) • If ventilator allocated, must be given a reasonable trial of intubation.	• SOFA 0-7, becomes Red • SOFA 8-11 remains Yellow • SOFA 12-24 becomes Blue	• If significant improvement (≥1 SOFA points), upgraded to RED and keeps ventilator. • If no improvement or worsens, downgraded to BLUE, loses ventilator if RED or YELLOW waiting.	• If significant improvement (≥ 1 SOFA points), upgraded to RED and keeps ventilator. • If no improvement or worsens, downgraded to BLUE, loses ventilator if RED or YELLOW waiting.
BLUE: THIRD PRIORITY See Note 3	• **Initial SOFA 12-24** • Multi-organ failure • Ventilator allocated ***ONLY if no RED or YELLOW waiting***. • If ventilator allocated, may be up for reallocation at any point.	• SOFA 0-7, becomes Red • SOFA 8-11 becomes Yellow • SOFA 12-24 remains Blue	• If significant improvement to SOFA 0-7, upgraded to RED and keeps ventilator • If improved to SOFA 8-11, upgraded to YELLOW and keeps ventilator if no RED waiting. • If no improvement, remains BLUE and loses ventilator if RED or YELLOW waiting	• If significant improvement to SOFA 0-7, upgraded to RED and keeps ventilator • If improved to SOFA 8-11, upgraded to YELLOW and keeps ventilator if no RED waiting. • If no improvement, remains BLUE and loses ventilator if RED or YELLOW waiting
MEETS EXCLUSION CRITERIA	***NO VENTILATOR ALLOCATED*** *unless* ***NO*** *blue, yellow, or red patients waiting* *Exclusion Criteria: 1. Unwitnessed cardiac arrest; 2. Recurrent cardiac arrest without hemodynamic stability; 3. Cardiac arrest unresponsive to standard interventions and measures; 4. Trauma related arrest; 5. Irreversible age-specific hypotension unresponsive to fluid resuscitation and vasopressor therapy; 6. Traumatic brain injury with no motor response to painful stimulus; 7. Severe burns where the expectation of survival is less than 10% even with unlimited aggressive therapy; 8. Any other conditions resulting in immediate or near-immediate mortality even with aggressive therapy*			

- ***General principle:*** At each reassessment point, if no sufficient improvement, downgraded in color
- Whenever a group of people is eligible either to receive a ventilator or to be removed from a ventilator, a random process will be used to determine who should either receive or be removed.

Color Code Vent Priority	Initial Assessment SOFA SCORE #1
	DNR/DNI, ADVANCE DIRECTIVE, NO VENTILATOR ALLOCATED
NO VENT NEEDED	***NO VENTILATOR ALLOCATED, or healthy enough for extubation.*** • **No organ insufficiency**
RED: FIRST PRIORITY A patient who is intubated for airway protection without organ failure is designated as RED. Once assigned a ventilator, RED patients keep the ventilator as long as they remain RED.	• **Initial SOFA 1-7 or SINGLE ORGAN FAILURE** • Some organ insufficiency • If ventilator allocated, must be given a reasonable trial of intubation.
YELLOW: SECOND PRIORITY YELLOW patients are allowed a **fair trial of intubation**, until the first assessment at 120 hours. Once assigned a ventilator, they keep it until the next assessment. But after each assessment, any patient designated YELLOW can be displaced by a new RED patient during the first 12 hours after their assessment. After that point, they will remain on the ventilator until their next formal assessment.	• **Initial SOFA 8-11** • Severe organ insufficiency • Ventilator allocated if there are BLUE on ventilator (See Note 5) • If ventilator allocated, must be given a reasonable trial of intubation.
BLUE: THIRD PRIORITY BLUE patients may receive ventilators if they are available. However, they are always subject to reallocation. Any new RED or YELLOW patient needing a ventilator takes priority.	• **Initial SOFA 12-24** • Multi-organ failure • Ventilator allocated ***ONLY if no RED or YELLOW waiting***. • If ventilator allocated, may be up for reallocation at any point
MEETS EXCLUSION CRITERIA	***NO VENTILATOR ALLOCATED*** *unless* ***NO*** *blue, yellow, or red patients waiting* *Exclusion Criteria: 1. Unwitnessed cardiac arrest; 2. Recurrent cardiac arrest without hemodynamic stability; 3. Cardiac arrest unresponsive to standard interventions and measures; 4. Trauma related arrest; 5. Irreversible age-specific hypotension unresponsive to fluid resuscitation and vasopressor therapy; 6. Traumatic brain injury with no motor response to painful stimulus; 7. Severe burns where the expectation of survival is less than 10% even with unlimited aggressive therapy; 8. Any other conditions resulting in immediate or near-immediate mortality even with aggressive therapy*

- ***General principle:*** At each reassessment point, if not sufficient improvement, downgraded in color
- Whenever a group of people is eligible either to receive a ventilator or to be removed from a ventilator, a **random process** will be used to determine designation.

TABLE E (continued)

Color Code Vent Priority	REASSESSMENT #1: 120 hours (5 days) SOFA SCORE #2
	DNR/DNI, ADVANCE DIRECTIVE, NO VENTILATOR ALLOCATED
NO VENT NEEDED	*NO VENTILATOR ALLOCATED, or healthy enough for extubation.* • **No organ insufficiency**
RED: FIRST PRIORITY A patient who is intubated for airway protection without organ failure is designated as RED. Once assigned a ventilator, RED patients keep the ventilator as long as they remain RED.	• SOFA 0-7, REMAINS Red • SOFA 8-11 BECOMES Yellow • SOFA 12-24 BECOMES Blue
YELLOW: **SECOND PRIORITY** **YELLOW** patients are allowed a **fair trial of intubation**, until the first assessment at 120 hours. Once assigned a ventilator, they keep it until the next assessment. But after each assessment, any patient designated YELLOW can be displaced by a new RED patient during the first 12 hours after their assessment. After that point, they will remain on the ventilator until their next formal assessment.	• SOFA 0-7, BECOMES Red • SOFA 8-11 REMAINS Yellow • SOFA 12-24 BECOMES Blue
BLUE: **THIRD PRIORITY** BLUE patients may receive ventilators if they are available. However, they are always subject to reallocation. Any new RED or YELLOW patient needing a ventilator takes priority.	• SOFA 0-7, BECOMES Red • SOFA 8-11 BECOMES Yellow • SOFA 12-24 REMAINS Blue
MEETS EXCLUSION CRITERIA	***NO VENTILATOR ALLOCATED*** *unless **NO** blue, yellow, or red patients waiting* *Exclusion Criteria: 1. Unwitnessed cardiac arrest; 2. Recurrent cardiac arrest without hemodynamic stability; 3. Cardiac arrest unresponsive to standard interventions and measures; 4. Trauma related arrest; 5. Irreversible age-specific hypotension unresponsive to fluid resuscitation and vasopressor therapy; 6. Traumatic brain injury with no motor response to painful stimulus; 7. Severe burns where the expectation of survival is less than 10% even with unlimited aggressive therapy; 8. Any other conditions resulting in immediate or near-immediate mortality even with aggressive therapy*

- ***General principle:*** At each reassessment point, if not sufficient improvement, downgraded in color
- Whenever a group of people is eligible either to receive a ventilator or to be removed from a ventilator, a **random process** will be used to determine designation.

Color Code Vent Priority	REASSESSMENT # 2, 3, 4, and beyond (every 2 days) SOFA SCORE
	DNR/DNI, ADVANCE DIRECTIVE, NO VENTILATOR ALLOCATED
NO VENT NEEDED	*NO VENTILATOR ALLOCATED, or healthy enough for extubation.* • **No organ insufficiency**
RED: FIRST PRIORITY A patient who is intubated for airway protection without organ failure is designated as RED. Once assigned a ventilator, RED patients keep the ventilator as long as they remain RED.	• If significant improvement (≥1 SOFA points), remains RED. • If no significant improvement and SOFA ≤ 7 then downgraded *to* YELLOW, loses ventilator if RED IS waiting • If worsens and SOFA≥ 8 , then downgraded to BLUE, loses ventilator if RED or YELLOW waiting. • See Note 4
YELLOW: **SECOND PRIORITY** **YELLOW** patients are allowed a **fair trial of intubation**, until the first assessment at 120 hours. Once assigned a ventilator, they keep it until the next assessment. But after each assessment, any patient designated YELLOW can be displaced by a new RED patient during the first 12 hours after their assessment. After that point, they will remain on the ventilator until their next formal assessment.	• If significant improvement (≥1 SOFA points), upgraded to RED and keeps ventilator. • If no improvement or worsens, downgraded to BLUE, loses ventilator if RED or YELLOW waiting.
BLUE: **THIRD PRIORITY** BLUE patients may receive ventilators if they are available. However, they are always subject to reallocation. Any new RED or YELLOW patient needing a ventilator takes priority.	• If significant improvement to SOFA 0-7, upgraded to RED and keeps ventilator • If improved to SOFA 8-11, upgraded to YELLOW and keeps ventilator if no RED waiting. • If no improvement or worsens, remains BLUE and loses ventilator if RED or YELLOW waiting
MEETS EXCLUSION CRITERIA	***NO VENTILATOR ALLOCATED*** *unless **NO** blue, yellow, or red patients waiting* *Exclusion Criteria: 1. Unwitnessed cardiac arrest; 2. Recurrent cardiac arrest without hemodynamic stability; 3. Cardiac arrest unresponsive to standard interventions and measures; 4. Trauma related arrest; 5. Irreversible age-specific hypotension unresponsive to fluid resuscitation and vasopressor therapy; 6. Traumatic brain injury with no motor response to painful stimulus; 7. Severe burns where the expectation of survival is less than 10% even with unlimited aggressive therapy; 8. Any other conditions resulting in immediate or near-immediate mortality even with aggressive therapy*

- ***General principle:*** At each reassessment point, if not sufficient improvement, downgraded in color
- Whenever a group of people is eligible either to receive a ventilator or to be removed from a ventilator, a **random process** will be used to determine designation.

TABLE E (continued)

Notes

1. A patient who is intubated for airway protection without organ failure is designated as RED. Once assigned a ventilator, RED patients keep the ventilator as long as they remain RED.
2. YELLOW patients are allowed a fair trial of intubation, until the first assessment at 120 hours. Once assigned a ventilator, they keep it until the next assessment. But after each assessment, any patient designated YELLOW can be displaced by a new RED patient during the first 12 hours after their assessment. After that point, they will remain on the ventilator until their next formal assessment.
3. BLUE patients may receive ventilators if they are available. However, they are always subject to reallocation. Any new RED or YELLOW patient needing a ventilator takes priority.
4. Some patients may advance to SOFA = 0, but still require ventilation. Once patients have reached SOFA=0, they may remain on the ventilator through the next assessment cycle to see if they can be weaned. If they can still not be weaned after two cycles at SOFA = 0, then they are downgraded to YELLOW.
5. YELLOW patients who require a ventilator cannot take a ventilator from another YELLOW patient on a ventilator. If there are no BLUE patients and only YELLOW and RED patients on a ventilator, the patient waiting for a ventilator cannot be allocated one, and will need to be supported until either a new ventilator becomes available or the next assessment point.

Time Trials

1. When an Admission RED color-coded patient is allocated a ventilator, they are entitled to a trial of ventilation for the entire Initial Interval of 5 days to determine if mechanical ventilation will improve their health.
2. When an Admission YELLOW color-coded patient is allocated a ventilator, they are entitled to a trial of ventilation for the entire Initial Interval of 5 days to determine if mechanical ventilation will improve their health.
3. When an Admission Interval BLUE color-coded patient is allocated a ventilator, they are subject to reallocation if any new RED or YELLOW patient needs a ventilator.

First Interval of Reassessment – (Ventilator Day 5)

1. At Ventilator Day 5, all ventilated patients are reassessed and assigned a "Initial Interval" color code.
2. Once reassessed, RED color-coded patients keep the ventilator as long as they remain RED.
3. Once reassessed, YELLOW patients can be displaced by a new RED patient during the first 12 hours after reassessment. After that point, YELLOW color-coded patients keep the ventilator until their next reassessment.
4. Once reassessed, BLUE color-coded patients can be displaced by a new RED or YELLOW patient.

Intervals of Reassessment – (Ventilator Day 7, 9, 11, 13, etc.)

1. A RED color-coded patient stays RED if their SOFA score shows significant improvement by a decrease of 1 or more points.
2. If the SOFA score of a RED color-coded patient has remained the same or increased numerically and their SOFA is less than or equal to 7, their color code is downgraded to YELLOW.
3. If the SOFA score of a RED color-coded patient has remained the same or increased numerically and their SOFA greater than or equal to 8, their color code is downgraded to BLUE.
4. If the SOFA score of a RED color-coded patient is zero and the patient continues to require ventilation, the patient may remain on the ventilator through the next assessment cycle to see if they can be weaned. If they cannot be weaned after two cycles at SOFA=0, then they are downgraded to YELLOW.
5. If the SOFA score of a YELLOW color-coded patient has decreased numerically, their color code is upgraded to RED.
6. If the SOFA score of a YELLOW color-coded patient has remained the same or increased, their color code is downgraded to BLUE.
7. If the SOFA score of a BLUE color-coded patient has decreased numerically to a SOFA between 0-7, their color code is upgraded to RED.
8. If the SOFA score of a BLUE color-coded patient has decreased numerically to a SOFA between 8-11, their color code is upgraded to YELLOW.

9. If the SOFA score of a BLUE color-coded patient does not change, has decreased numerically to a SOFA greater than or equal to 12, or increased numerically, their color code remains BLUE.

Measurements of Improvement

To demonstrate significant improvement, at Reassessment Intervals after the first Interval of Reassessment, patients must improve their SOFA score as described in the FLOW diagram in **TABLE F**.

Lottery

When all ventilators are in use and new patients arrive at the hospital, the Protocol determines whether to reallocate a ventilator from a ventilated patient to support a new patient who needs a ventilator to survive. This decision is based on the best evidence available and the goal is to save the most lives, meaning patients who are improving retain their ventilator and patients who are not improving risk having their ventilator reallocated to a patient with a better likelihood of survival. The reallocation occurs through a lottery system, providing patients who have an equivalent chance of short-term survival an equal chance of reallocation. Every twelve hours, the Triage Teams use the BLIS COVID-19 data base to randomize the ventilated patients according to their current mortality risk assessment:

Red Color-Coded Patients

RED color-coded patients are not subject to the lottery.

Yellow Color-Coded Patients

If there are no BLUE color-coded patients and a new RED patient needs a ventilator, the patients who are colored coded YELLOW enter a lottery to determine which patient will have their ventilator reallocated. YELLOW color-coded patients are in the lottery for a 12-hour period.

Blue Color-Coded Patients

BLUE color-coded patients enter a lottery when a new RED or YELLOW patient needs a ventilator and there are no ventilators available. The system records SOFA scores every 30 minutes. Before reallocation of a ventilator of a BLUE color-coded patient, the Triage Team will compare the most recent SOFA score with the last SOFA score used for assessment. If the SOFA score has decreased, indicating the patient improvement, the Triage Team will move to the next patient on the list for purposes of this reallocation decision. This results in a reallocation priority of BLUE color-coded patients who are not improving.

Pregnant Patients

Given the preference for pediatric and neonatal patients, the adult protocol preferences pregnant women with a viable fetus. Pregnant women at 24-28 weeks will not enter the lottery regardless of color code status. Since pregnant patients at 24-28 weeks would be offered a C-section if they were randomized for removal from a ventilator and the neonatal protocol preferences neonatal patients for a ventilator over any adult, it is an efficient use of resources to maintain pregnant patients on ventilators between weeks 24 and 28 of gestation (i.e. the period where ventilators would be automatically allocated to the neonate delivered by C-section), since the ventilator would support both the potential patient and the pregnant patient rather than being allocated to one.

Moreover, while the pregnant patient is at risk of having their ventilator removed post week 28 of gestation (when the neonate would likely thrive without ventilator support), the pregnant patient is not being used merely as an instrument to bring the fetus to the point of viability without need of ventilation. Instead, pregnant patients between 24-28 weeks benefit by being allocated additional chances to improve that they would not have otherwise received.

If a pregnant woman delivers a child after 28 weeks gestation, but remains on a ventilator, she will be reassessed for ventilator priority again 48 hours after delivery.

Trials of Extubation
Some patients may advance to a SOFA = 0 but still require ventilation. Once patients have reached a SOFA= 0, they remain on the ventilator through the next assessment cycle to provide time to wean from ventilator support. If a patient is unable to be weaned after two cycles at SOFA = 0, then they are downgraded to YELLOW.

Appeals of Triage Decisions

A. If time and medical urgency permit, decisions by a Triage Team may be appealed by the critical care clinical team on the grounds that the patient's SOFA score was calculated incorrectly, that the color-coding for the patient was incorrectly assigned, or that the selection for extubation by randomization was incorrectly performed.

B. Membership of the Triage Appeals Committee will include representation from the Triage Team, the Protocol Assurance Committee, and the URMC Chief Medical Officer (CMO) or his designee.

C. The Triage Appeals Committee will respond to appeals requesting validation of the data used to calculate the color code. Two members of the Appeals Committee, who are not members of the Triage Committee, will review the patient's clinical data to confirm the accuracy of the SOFA score and review the color-coding assigned the patient at each Interval of Reassessment to make sure that the patient was not incorrectly color-coded or identified for downgrading or a randomized lottery for reassignment of a ventilator.

D. The Appeals Committee will respond to appeals regarding process integrity. Two members of the Appeals Committee, who were not involved in the initial color-coding of the patient, will review the Protocol process to ensure appropriate application and appropriate assignment of color code.

E. During the review of clinical data by the Triage Appeals Committee, the critical care team will continue to provide the patient airway management and ventilatory assistance (either mechanical or manual), as the critical care team is able.

F. Immediately upon completing a review, the PAC or the Triage Appeals Committee shall notify the critical care team and the Triage Committee of its decision and any appropriate changes in SOFA scoring, color coding, or decisions on ventilator assistance will be implemented.

G. Considerations such as perceived social status, employment status, age, race, ethnicity, gender, gender identity, sexual orientation, religion, immigration status, ability to pay, putative "VIP" status, disabilities, or veterans' status will not be a basis for appeal of any decision of the Triage Committee.

Termination of the Protocol
If this Protocol is invoked, it will be terminated as determined by the URMC CMO.

Neonatal and Pediatric Triage Protocol

Ventilator Allocation Guidelines
The 2015 New York State guidelines for ventilator allocation, based on the pathophysiology of epidemic influenza, envisioned a significant burden of respiratory failure due to influenza among all age groups. Because the SOFA scoring system, even with adjustment for age, has limited accuracy and applicability in children due to differences in physiology, the NYS guidelines include separate decision-making recommendations for determining allocation of ventilators needed by children, and newborns. The allocation decisions for each group were based on a similar, color-codes decision-making flows, but took into account the individual physiologies and measures of illness severity of each group. The New York State Guidelines concluded that when the pool of patients eligible for ventilator therapy included "*both*

adults and children" and the "available clinical data suggest that the probability of mortality among the pool of patients have found to be equivalent… then young age may be utilized as a tie breaker to select a patient for ventilator therapy."

The CERG extensively deliberated potential approaches to pediatric and neonatal ventilator allocation, taking physiologic, moral, ethical, and societal precedent into account, including a review of the limited existing protocols that address the inclusion or exclusion of pediatric patients. The CERG decided to remain broadly faithful to the NYS 2015 guidelines; adopted the widely-clinically-agreed-upon NYS Guideline Exclusion criteria for determining initial eligibility for a ventilator; and adapted the untested, but easily understood NYS Guideline criteria for organ failure both for initial ventilator assignment and movement among severity (color) groups at the time of sequential re-evaluation. The authors of the New York State 2015 guidelines reviewed multiple potential pediatric and neonatal disease severity scoring systems and rejected each on the basis of lack of evidence of prognostic accuracy. The authors instead developed their own, also untested, criteria for movement among groups. The URMC and Affiliates Protocol utilizes different untested criteria, the Pediatric Organ Failure Score (P-OFS), for movement among groups.

The Neonatal and Pediatric Protocol contains the same five steps as the Adult Protocol: 1) patients are screened for exclusion criteria – either by reason of an advance directive declining mechanical ventilation or because of medical conditions indicating a very short life expectancy; 2) patients are assessed for risk of mortality using P-OFS scoring; 3) each patient is assigned a color code designating their level of priority in the allocation of a ventilator; 4) patients eligible for ventilator support are given a fair trial of intubation to provide an opportunity for improvement of their health status; and 5) patients on a ventilator are reassessed at predetermined intervals to determine whether they will continue with a trial of ventilation based upon whether their P-OFS scores have met specific criteria.

The neonatal and pediatric patients are given preference by being moved into a poorer prognosis group only if they worsened (as opposed to adults, who would be downgraded for failure to improve). This preference, different from the preference in the NYS Guidelines, recognizes both the physiology and the disease outcomes among infants and children. Neonatal and pediatric patients who are randomized into the reallocation pool do not receive an additional preference. The neonatal and pediatric Protocol includes mitigation strategies to minimize the draw on shared resources.

The rationale for this approach largely rests on the significant differences between influenza and COVID-19 respiratory illness relevant to the discussion of ventilator allocation among children and newborns. Primary among these is that severe influenza disproportionately affects the very young and the very old, while COVID-19-related respiratory failure appears relatively uncommon among infants and children. As a result, children and neonates with COVID-19 are not likely to compete significantly for ventilators with others within their age groups. A global allocation of ventilators among all age groups would thus specifically disadvantage neonates and children with non-COVID-19 childhood diseases in order to provide ventilator support to adults with COVID-19-related respiratory failure. This would represent a shift of ventilators from one age group to another, a situation different from that envisioned in the NYS 2015 guidelines, where influenza disease was expected to be more evenly distributed among age groups.

This Protocol comports with the NYS Guidelines in emphasizing physician judgement. Although clinical impression is potentially fraught with bias, it has, at least among neonates, been associated with a high predictive value for death or subsequent neurodevelopmental impairment (although the outcome was heavily driven by subsequent impairment). This Protocol specifically takes into account the clinical observation that children are far more likely to survive their "acute illness" (one of the pillars of the NYS evaluations for ventilator assignment), even if the course of that illness is prolonged.

Advance Directives

During this Pandemic it will be imperative to know any decisions made in advance with regard to mechanical ventilation. A decision to forego mechanical ventilation should not be construed as a decision

to forego other treatments or resources that may be in limited supply. Decisions regarding alternative medical treatment, including palliative care, should be discussed with the patient's surrogate to ascertain their preferences in the context of the COVID-19 Pandemic and the patient's specific medical circumstances.

Exclusion Criteria

Neonatal and pediatric patients will be evaluated according to the New York State 2015 Guidelines for exclusion criteria from being allocated a ventilator. The guidelines, with specific local variations noted, are listed below.

TABLE F

NYS 2015 Guidelines List of Exclusion Criteria for Pediatric Patients Medical Conditions that Result in Immediate or Near-Immediate Mortality Even with Aggressive Therapy

- Cardiac arrest not responsive to pediatric advanced life support (PALS) interventions within 20 minutes of appropriate resuscitation efforts
- Recurrent cardiac arrest, without interval hemodynamic stability
- Irreversible age-specific hypotension unresponsive to fluid resuscitation and vasopressor therapy
- Traumatic brain injury with no motor response to painful stimulus (i.e., best motor response = 1) (See Appendix 1)
- Burns > 91% of body surface area for children less than 2 years of age
- Any other conditions resulting in immediate or near-immediate mortality even with aggressive therapy[1]*

[1]This "catch all" phrase encompasses other possibilities because the list above is merely a guide and does not list every medical condition that would result in immediate or near-immediate mortality.

*Examples of conditions drawn from local experience include "last ditch" ventilation in the terminal stages of disease (such as cancer) or severe conditions, such as hypoxic-ischemic encephalopathy with herniation, where the is minimal opportunity for long term survival. In addition, each Division or service within the Children's Hospital will discuss and put into place criteria for exclusion with their patient population.

TABLE G

NYS 2015 Guidelines List of Exclusion Criteria for Neonatal Patients Medical Conditions that Result in Immediate or Near-Immediate Mortality Even with Aggressive Therapy

- Cardiac arrest not responsive to neonatal resuscitation (NRP) interventions within 10 minutes of appropriate resuscitation efforts
- Recurrent cardiac arrest, without interval hemodynamic stability
- Irreversible age-specific hypotension unresponsive to fluid resuscitation and vasopressor therapy
- Severe brain injury with no motor response to painful stimulus, moribund
- Lethal organ dysplasia, such as agenesis of the kidneys or hypoplasia of the lungs
- < 23 weeks gestational age, based on first trimester dating
- < 400 grams birth weight (14 ounces)
- Any other conditions resulting in immediate or near-immediate mortality even with aggressive therapy[1]*

[1]This "catch all" phrase encompasses other possibilities because the list above is merely a guide and does not list every medical condition that would result in immediate or near-immediate mortality.

*Examples of conditions, drawn from local experience and a joint statement from the neonatal community in Buffalo, New York include:

1. Anencephaly
2. Trisomy 13
3. Trisomy 18
4. Triploidy, Tetraploidy
5. Skeletal dysplasia resulting in severe restrictive lung disease
6. Genetic syndromes known to be incompatible with life
7. Complex congenital anomalies incompatible with life (e.g. tracheal agenesis)
8. Inoperable congenital heart disease
9. Renal agenesis-oligohydramnios sequence

Of these, only Trisomies 13 and 18 have even a small chance of survival beyond the immediate neonatal period. In Trisomy 13, the likelihood is small enough that withholding ventilator support is reasonable. Although survival beyond the neonatal period in Trisomy 18 is possible, apnea requiring mechanical ventilation indicates inadequate respiratory drive for long-term, ventilator-free survival. This list is not exhaustive. This protocol excludes neonates under 24 weeks' gestation. Other disorders without likelihood of survival beyond the neonatal survival would also be included.

In all cases of withholding ventilation, appropriate comfort care would be instituted. In all these cases, the decision to withhold ventilation would be made, according to the NYS 2015 criteria, by the clinical team, and communicated to the family by the clinical team. Since these infants and children would not be offered mechanical ventilation, they would never enter the allocation pool.

Color-Coding Using Pediatric Organ Failure Scores (P-OFS), and Priority to Be Allocated a Ventilator on Admission

If no exclusion criteria are present, the pediatric and neonatal patients will be assigned a triage score derived from the patient's likelihood of surviving to hospital discharge as assessed with a P-OFS score, according to their degree of organ dysfunction. Patients would be assigned a ventilator, as available, according to their severity (color) category. Severity would be assigned by number of organ systems with significant dysfunction. The NYS 2015 Guidelines for initial categorization of illness provide little physiological guidance regarding disease severity, so the criteria for initial categorization are identical to the reassessment criteria in the Guidelines (Step 3 of Pediatric Protocol, pg. 138 or Step 3 of Neonatal Protocol, pg. 189, see below), described in detail in Intervals of Reassessment, below. This assessment would include any infant or child already mechanically ventilated on the day that the Ventilator Allocation Protocol was invoked. Failure of any individual organ will be defined as meeting the "worst" category, as defined in the NYS 2015 Ventilator Allocation Protocol (Step 3 of Pediatric Protocol, pg. 138 or Step 3 of Neonatal Protocol, pg. 189, see below). For Pediatric patients, in keeping with the recommendations in the NYS 2015 Guidelines, at least two (2) of the criteria for organ failure must be oxygenation, hypotension or GCS (above the heavy black line in Table H). For Neonatal patients, at least two (2) of the criteria must be oxygenation or blood pressure (above the heavy black line in Table J). The single worst score for each organ for each day would be used. Missing values (which were likely not collected because the child was too healthy to ascertain them) would be given a score of 0.

1. At the time of a patient's initial P-OFS score calculation, the patient shall be assigned a color code:

   a. BROWN: DNI, Advance directive, no ventilator allocated.

   b. GREEN: P-OFS =0 (patients who either do not require mechanical ventilation at this time, or who have sufficiently improved with mechanical ventilation to warrant extubation).

   c. RED: P-OFS <2 (patients who have the highest level of access to ventilator therapy because they are most likely to recover with treatment and have the lowest risk of mortality)

d. YELLOW: P-OFS 2-2.5 (patients who have an intermediate level of access to ventilator therapy because their likelihood of survival is intermediate and/or uncertain and they have a medium risk of mortality).

e. BLUE: P-OFS $\geq$3 (patients who have the lowest access to ventilator therapy because they have the highest risk of mortality).

f. PURPLE: Meets exclusion criteria

2. The initial color codes assigned to the patients shall be their "Admission" color code.

3. The Admission color code shall be used to determine the initial level of priority to be given patients awaiting the allocation of a ventilator.

4. RED color-coded patients receive the 1st priority for the allocation of ventilators.

5. YELLOW color-coded patients receive the 2nd priority for the allocation of ventilators and are only allocated a ventilator if there are no RED color-coded patients awaiting a ventilator.

6. BLUE color-coded patients receive the 3rd priority for the allocation of ventilators and are only allocated a ventilator if there are no RED color coded patients or YELLOW color coded patients awaiting allocation of a ventilator.

Time Trials

1. When an Admission RED color-coded patient is allocated a ventilator, they are entitled to a trial of ventilation for the entire Initial Interval of 5 days to determine if mechanical ventilation will improve their health.
2. When an Admission YELLOW color-coded patient is allocated a ventilator, they are entitled to a trial of ventilation for the entire Initial Interval of 5 days to determine if mechanical ventilation will improve their health.
3. When an Admission Interval BLUE color-coded patient is allocated a ventilator, they are subject to reallocation if any new RED or YELLOW patient needs a ventilator.

First Interval of Reassessment – (Ventilator Day 5)

1. At Ventilator Day 5, all ventilated patients are reassessed and assigned a "Initial Interval" color code.
2. Once reassessed, RED color-coded patients keep the ventilator as long as they remain RED.
3. Once reassessed, YELLOW patients can be displaced by a new RED patient during the first 12 hours after reassessment. After that point, YELLOW color-coded patients keep the ventilator until their next reassessment.
4. Once reassessed, BLUE color-coded patients can be displaced by a new RED or YELLOW patient.

Intervals of Reassessment – (Ventilator Day 7, 9, 11, 13, etc.)

1. A RED color-coded patient stays RED if their P-OFS score remains the same.
2. If the P-OFS score of a RED color-coded patient has increased numerically to 2-2.5, their color code is downgraded to YELLOW.
3. If the P-OFS score of a RED color-coded patient has increased numerically to $\geq$3, their color code is downgraded to BLUE.
4. If the P-OFS score of a YELLOW color-coded patient has decreased numerically to <2, their color code is upgraded to RED.
5. A YELLOW color-coded patient stays YELLOW if their P-OFS score remains the same.
6. If the P-OFS score of a YELLOW color-coded patient has increased to 3, their color code is downgraded to BLUE.
7. If the P-OFS score of a BLUE color-coded patient has decreased numerically to <2, their color code is upgraded to RED.
8. If the P-OFS score of a BLUE color-coded patient has decreased numerically to 2-2.5, their color code is upgraded to YELLOW.

9. If the P-OFS score of a BLUE color-coded patient does not change or increases their color code, but does not meet exclusion criteria, remains BLUE.

Assignment of neonates and pediatric patients to the Yellow or Blue categories results in an automatic consultation with the Neonatal or Pediatric Critical Care attending physician, in accordance with the NYS 2015 Guidelines' recommendation for attending physician input on pediatric and neonatal cases. The purpose of the consultation would be to confirm that there were no unique pediatric, physiologic circumstances (e.g., congenital heart disease with a complete mixing lesion) that explained all or a portion of the organ failure score and to appropriately assess the patient's likely short-term survivability.

Lottery

When all ventilators are in use and new patients arrive at the hospital, the Protocol determines whether to reallocate a ventilator from a ventilated patient to support a new patient who needs a ventilator to survive. This decision is based on the best evidence available and the goal is to save the most lives, meaning patients who are improving retain their ventilator and patients who are not improving risk having their ventilator reallocated to a patient with a better likelihood of survival. The reallocation occurs through a lottery system, providing patients who have an equivalent chance of short-term survival an equal chance of reallocation. Every twelve hours, the Triage Teams use the BLIS COVID data base to randomize the ventilated patients according to their current mortality risk assessment:

<u>Red Color-Coded Patients</u>
RED color-coded patients are not subject to the lottery.

<u>Yellow Color-Coded Patients</u>
If there are no BLUE color-coded patients and a new RED patient needs a ventilator, the patients who are colored coded YELLOW enter a lottery to determine which patient will have their ventilator reallocated. YELLOW color-coded patients are in the lottery for a 12-hour period.

<u>Blue Color-Coded Patients</u>
BLUE color-coded patients enter a lottery when a new RED or YELLOW patient needs a ventilator and there are no ventilators available.

TABLE H
Pediatric Reassessment Criteria (2015 NYS Guidelines, p. 138)

Step 3: Time Trials – Clinical Framework (Six Variables) Used to Evaluate a Patient for Continued Ventilator Treatment	
Clinical Variable	**Ranges**
Oxygenation Index (OI)[1, 2] **OR** **Arterial Oxygen Saturation**[2, 3]	**< 20** (Best) **20 – 40** (Intermediate) **> 40** (Worst) **OR** **> 88%** (Best) **80 – 88%** (Intermediate) **< 80%** (Worst)
Hypotension	**Adequate circulation, with no vasoactive drugs** (Best) **Adequate circulation, with vasoactive drugs** (Intermediate) **Hypotension, with vasoactive drugs** (Worst)
Glasgow Coma Scale Score[4] **(See Appendix 2 to calculate)**	**> 8** (Best) **6 – 8** (Intermediate) **< 6** (Worst)
Whole Blood/Serum Lactate (mmol/L) (consistently use same measurement)	**< 3** (Best) **3 – 8** (Intermediate) **> 8** (Worst)
Serum Creatinine (mg/dL)	**< 1 year:** < 0.6 (Best); 0.6 – 1.2 (Intermediate); > 1.2 (Worst) **1 – 12 years:** < 0.7 (Best); 0.7 – 2.0 (Intermediate); > 2.0 (Worst) **> 12 years:** < 1.0 (Best); 1.0 – 3.0 (Intermediate); > 3.0 (Worst)
Serum Bilirubin (mg/dL) **OR** **Scleral icterus**[5]	**< 3** (Best) **3 – 6** (Intermediate) **> 6** (Worst) **OR** **No scleral icterus** (Best) **Scleral icterus** (Intermediate) **Clinical jaundice** (Worst)

[1] OI = mean airway pressure (MAP) x fraction of inspired oxygen (FiO_2) x 100 / partial pressure of oxygen in arterial blood (PaO_2). (PaO_2 may be estimated from peripheral oxygen saturation by using the oxygen dissociation curve if blood gas measurements are unavailable.)

[2] The absolute values of OI and arterial oxygen saturation are not easily interpretable if a patient has cyanotic congenital heart disease, but the trends may be.

[3] If unable to obtain OI, arterial oxygen saturation may be used. Comparing current saturation to baseline saturation may be important.

[4] If a patient is deeply sedated and/or paralyzed, a clinical evaluation using Glasgow Coma Scale Score is not valid.

[5] If serum bilirubin values cannot be obtained, a physical examination may be performed for signs of scleral icterus. (Exclude neonates with physiological jaundice.)

TABLE I

Pediatric Organ Failure Score (P-OFS) for CHILDREN <18, EXCLUDING NEONATES, adapted from Reassessment Criteria, 2015 NYS Guidelines.

P-OFS Pediatric Patients

MAJOR CRITERIA

Clinical Value PULMONARY	Range	Status	Points
Oxygenation Index	<20	Best	0
	20-40	Intermediate	0
	>40	Worst	1
OR			
Arterial O2 Sat	>88%	Best	0
	80-88%	Intermediate	0
	<80%	Worst	1

Clinical Value CARDIOVASC	Range	Status	Points
Hypotension	Adequate, with no vasoactive drugs	Best	0
	Adequate, with vasoactive drugs	Intermediate	0
	Hypotension, with vasoactive drugs	Worst*	1
**Clinically validate PERFUSION STATUS*			

Clinical Value NEUROLOGIC	Range	Status	Points
Glasgow Coma Scale	>8	Best	0
	6-8	Intermediate	0
	<6	Worst	1

MINOR CRITERIA

Clinical Value LACTATE	Range	Status	Points
Whole Blood Lactate	<3	Best	0
	3-8	Intermediate	0
	>8	Worst	1/2

Clinical Value BILIRUBIN/LIVER	Range	Status	Points
Total Bilirubin With ≥ 50% DIRECT	<3	Best	0
	3-6	Intermediate	0
	>6 Tbili *and* >3 DBili	Worst	1/2

Clinical Value CREATININE/RENAL	Range (Age)	Status	Points
Serum Creatinine	< 0.6 (< 1 y) <0.7 (1-12 y) <1.0 (>12 y)	Best	0
	0.6-1.2 (< 1 y) 0.7-2.0 (1-12 y) 1.0-3.0 (>12 y)	Intermediate	0
	> 1.2 (< 1 y) > 2.0 (1-12 y) > 3.0 (> 12 y)	Worst	1/2

Ventilator Priority	P-OFS Score
RED	< 2
YELLOW	2 - 2.5 At least 1 major criteria
BLUE	≥ 3 At least 2 major criteria

TABLE J

Neonatal Re-evaluation Criteria (NYS 2015 Ventilator Allocation Guidelines, pg. 189)

Step 3: Time Trials – Clinical Framework (Three Variables) Used to Evaluate a Patient for Continued Ventilator Treatment	
Clinical Variable	**Ranges**
Oxygenation Index (OI)[1, 2] **OR** **Arterial Oxygen Saturation**[2, 3]	**< 20** (Best) **20 – 40** (Intermediate) **> 40** (Worst) OR **> 88%** (Best) **80 – 88%** (Intermediate) **< 80%** (Worst)
Hypotension	**Adequate circulation, with no vasoactive drugs** (Best) **Adequate circulation, with vasoactive drugs** (Intermediate) **Hypotension, with vasoactive drugs** (Worst)
Serum Creatinine (mg/dL)	**< 1** (Best) **1 < 3** (Intermediate) **> 3** (Worst)

[1] OI = mean airway pressure (MAP) x fraction of inspired oxygen (FiO_2) x 100 / partial pressure of oxygen in arterial blood (PaO_2). (PaO_2 may be estimated from peripheral oxygen saturation by using the oxygen dissociation curve if blood gas measurements are unavailable.)

[2] The absolute values of OI and arterial oxygen saturation are not easily interpretable if a patient has cyanotic congenital heart disease, but the trends may be. The site of the OI or arterial oxygen saturation measurement should be preductal if possible, otherwise, postductal is acceptable. In the newborn, pre-ductal is the right arm.

[3] If unable to obtain OI, arterial oxygen saturation may be used. Comparing current saturation to baseline saturation may be important.

TABLE K

Pediatric Organ Failure Score (P-OFS) for NEONATES, adapted from Neonatal Reassessment Criteria, 2015 NYS Guidelines.

Neonatal/NICU Patients

MAJOR CRITERIA (only)

Clinical Value PULMONARY	Range	Status	Points
Oxygenation Index	<20	Best	0
	20-40	Intermediate	0
	>40	Worst	1
OR			
Arterial O2 Sat	>88%	Best	0
	80-88%	Intermediate	0
	<80%	Worst	1

Clinical Value CARDIOVASC	Range	Status	Points
Hypotension	Adequate, with no vasoactive drugs	Best	0
	Adequate, with vasoactive drugs	Intermediate	0
	Hypotension, with vasoactive drugs	Worst*	1
**Clinically validate PERFUSION STATUS*			

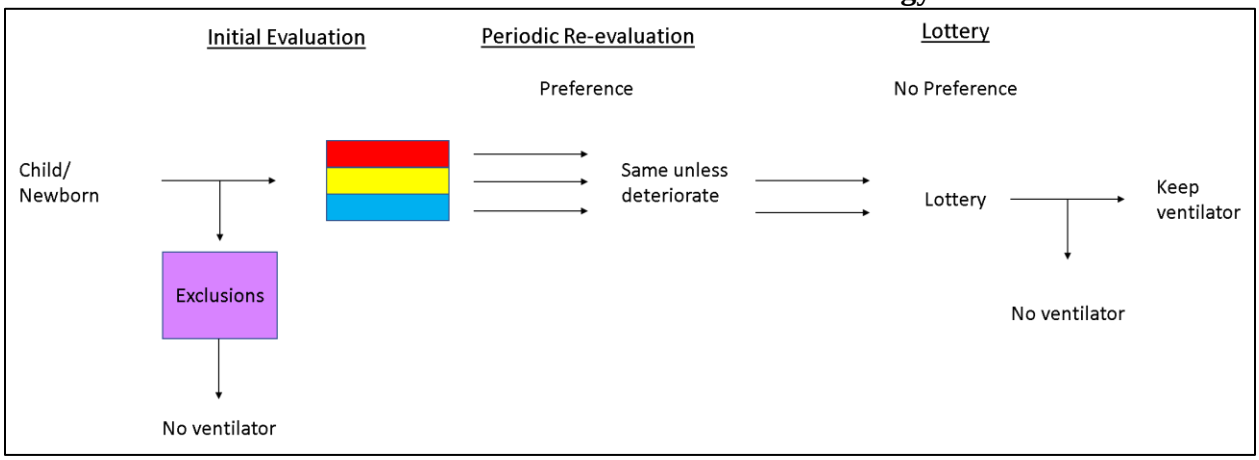
Clinical Value CREATININE/RENAL	Range	Status	Points
Serum Creatinine	<1	Best	0
	1 <3	Intermediate	0
	≥ 3	Worst	1

Ventilator Priority	P-OFS Score
RED	< 2
YELLOW	2 – 2.5 At least 1 major criteria
BLUE	= 3 At least 2 major criteria

TABLE L: SUMMARY OF SCORING

COLOR CODE Ventilator Priority	ASSESSMENT (at time of ventilator request, 5 days, then q48 hours) P-OFS=Pediatric Organ Failure Score (for pediatrics and neonates)
BROWN	*ADVANCE DIRECTIVE, NO VENTILATOR ALLOCATED*
GREEN: NO VENT NEEDED	No ventilator needed or healthy enough for extubation
RED: FIRST PRIORITY	• P-OFS < 2 • If ventilator allocated, must be given a reasonable trial of intubation • Remains RED unless significant worsening that downgrades to YELLOW or BLUE
YELLOW: SECOND PRIORITY	• P-OFS ≥ 2 • Receives ventilator only if no RED patients • If ventilator allocated, must be given a reasonable trial of intubation • Remains YELLOW unless significant improvement that upgrades to RED or significant worsening that downgrades to BLUE
BLUE: THIRD PRIORITY	• P-OFS ≥ 3 • Receives ventilator **only if no RED or YELLOW waiting** • If ventilator allocated, may be up for reallocation at any point
PURPLE: MEETS EXCLUSION CRITERIA	Receives trial of intubation only if no RED, YELLOW, or BLUE patients waiting

TABLE M
Schematic of Neonatal/Pediatric Ventilator Allocation Strategy



Appeals of Triage Decisions

A. If time and medical urgency permit, decisions by a Triage Team may be appealed by the critical care clinical team on the grounds that the patient's P-OFS score was calculated incorrectly, that the color-coding for the patient was incorrectly assigned, or that the selection for extubation by randomization was incorrectly performed.

B. Membership of the Triage Appeals Committee will include representation from the Triage Team, the Protocol Assurance Committee, and the Chief Clinical Officer of the Golisano Children's Hospital or his designee.

C. The Triage Appeals Committee will respond to appeals requesting validation of the data used to calculate the color code. Two members of the Appeals Committee, who are not members of the Triage Committee, will review the patient's clinical data to confirm the accuracy of the P-OFS score and review the color-coding assigned the patient at each Interval of Reassessment to make sure that the patient was not incorrectly color-coded or identified for downgrading or a randomized lottery for reassignment of a ventilator.

D. The Appeals Committee will respond to appeals regarding process integrity. Two members of the Appeals Committee, who were not involved in the initial color-coding of the patient, will review the Protocol process to ensure appropriate application and appropriate assignment of color code.

E. During the review of clinical data by the Triage Appeals Committee, the critical care team will continue to provide the patient airway management and ventilatory assistance (either mechanical or manual), as the critical care team is able.

F. Immediately upon completing a review, the PAC or the Triage Appeals Committee shall notify the critical care team and the Triage Committee of its decision and any appropriate changes in P-OFS scoring, color coding, or decisions on ventilator assistance will be implemented.

G. Considerations such as perceived social status, employment status, age, race, ethnicity, gender, gender identity, sexual orientation, religion, immigration status, ability to pay, putative "VIP" status, disabilities, or veterans' status will not be a basis for appeal of any decision of the Triage Committee.

Consequences and Mitigation
This Protocol allows children to continue ventilator support provided they do not deteriorate to the point of multi-organ failure. As a result, this decision has significant consequences. The clearest of these is that allowing prolonged ventilation of children who remained stable would prevent their ventilators from being reallocated. In the case of ventilator shortage, this approach could thus lead to fewer lives saved.

Several methods will be employed to minimize the impact of giving preference to children for continuing mechanical ventilation.

1. Clinical teams will discuss withdrawal of ventilator support with the families of children who do not meet exclusion or organ failure criteria, but have a relatively low likelihood of survival to hospital discharge for other reasons.
2. Ventilator sparing management (e.g. hand ventilation during administration of surfactant via transient intubation, aggressive use of bubble CPAP among infants).
3. No ventilators will be held in reserve for pediatric patients. Ventilators for children would be obtained using the same "just-in-time" system to be used to move ventilators among adults.

Termination of the Protocol
If this Protocol is invoked, it will be terminated as determined by the URMC CMO.

APPENDIX 1

COMMITTEE MEMBERSHIP

EXTERNAL DOCUMENT REVIEW COMMITTE	
Jonathan Herington, Lead	Timothy Quill
Timothy Dean	
COMMUNITY ENGAGEMENT COMMITTEE	
Adrienne Morgan, Co-Lead	Lawrence Hargrave, Co-Lead
Linda Chaudron	Nancy Rice
Davin Searls	Tressa Newton
John Cullen	Linda Clark
Candice Lucas	Keith Patterson
Shirley Thompson	Kit Miller
INTERNAL COMMUNICATIONS COMMITTEE	
Bernard Sussman, Lead	Robert Horowitz
Tom Carroll	
MORAL DISTRESS AND STAFF SUPPORT COMMITTEE	
Marianne Chiafery, Lead	Natalie Whaley
Beth Goldenberg	OJ Sahler
Jenna Gonillo	
PROTOCOL DEVELOPMENT COMMITTEE	
Chin-Lin Ching, Lead	Richard Dees
Jessica Shand	
TRANSLATIONAL DATA AND INFORMATICS COMMITTEE	
Jeanne Holden-Wiltse, Lead	Jack Chang
Anthony Corbett	Justin Foster
Gregg Nicandri	
TRIAGE COMMITTEE/TRIAGE TEAMS*	
Richard Demme, Chair	Margie Hodges Shaw, Vice-Chair
John Cullen, Triage Officer	Mitchell Wharton, Triage Officer
Adrienne Morgan, Triage Officer	
**Triage team members shall remain anonymous*	
PROTOCOL ASSURANCE COMMITTEE	
Lauren Bruckner, Lead	Irena Pesis-Katz
Mary Carey	Nancy Rice
Sally Norton	Jaclyn Wilmarth
Andriana Ongoiba	
ECMO TEAM	
Leway Chen, Lead	Lisa Owen
Karin Chase	Sunil Prasad
Joseph Delehanty	Karen Smith
Anna Lambert	

CORONAVIRUS ETHICS RESPONSE ADVISORY BOARD		
Marc Ambrosi	Lawrence Hargrave	Sally Norton
Lauren Bruckner	Scott Hartman	Timothy Quill
Thomas Caprio	Jon Herington	Sarah Rehler
Mary Carey	Robert Horowitz	Nancy Rice
Leway Chen	Anna Lambert	Hazel Robertshaw
John Cullen	Candice Lucas	Martin Zand

APPENDIX 2

Moral Distress and Staff Support Rapid Response and Debriefing Process

Overview

During a pandemic there is great potential for health care workers to suffer moral distress, defined as "a psychological response to morally challenging situations such as those of moral constraint, moral conflict, or both (Foure, 2012). There are many potential sources of distress. Some examples are: the process of removing or refusing ventilator treatment to critically ill people; the tension of personal safety versus professional obligation to care for the sick; the necessity of altering usual health care practices that focus on a concern for the individual patient to the goal of maximizing the public good; and the inability to interact with the patient and family in the usual ways due to physical distancing restrictions.

Emotional responses to moral distress may include anger, anxiety, grief, frustration, guilt, suicidal thoughts and a desire to conscientiously object to participation in patient care. Physical symptoms include inability to sleep, tension headaches and muscle pain, nightmares and distancing or removing oneself from the source of distress.

Staff who experience an ethically troubling patient care situation may have difficulty processing the event. Debriefing provides an opportunity for staff to talk about and work through emotions and feelings of moral distress. Literature and work in the field of debriefing supports its positive effects on care providers.

In the event that the URMC Chief Medical Officer implements the Protocol for ventilator and resource allocation, it is recommended that a formal, planned system of staff support to address morally distressing events be implemented. Planned debriefings will be held twice a day after change of shift (7:45 am and 7:45 pm) and will be available on an as-needed basis 24 hours/7 days per week. Immediate requests for a debriefing meeting can be accessed by paging the clinical ethicist on call at 5-2222.

The planned debriefings will be held at a hospital site large enough to accommodate physical distancing requirements and will have ZOOM access to facilitate the participation of staff who are offsite. Given the complex and varying nature of the potential concerns that staff may bring to the discussion, 3 types of professional facilitators are needed at each session: practical advice for personal needs (EAP), mental health check (Behavioral Mental Health professional) and ethics/spiritual support (ethicist, moral distress team members, chaplaincy). The Wellness Partners may also be able to provide assistance with manning this program. ideally 2 - 3 people will be available to facilitate each debriefing.

The general format of the debriefings is as follows:

1. **T**eam check (is everyone OK?)
2. **I**ngest and imbibe (if possible, take a break to eat, drink, and recharge)
3. **Et**hical concern causing moral distress is named
4. **D**ebrief, discuss

General guidelines:

Use open ended questions. Assess safety. Assure safety.

Examples:

"How are you feeling?"

"What could be done differently?"

"What information would be helpful to better understand the situation and decision?

"What do you need from us? How can we help?"

Debrief:

Step 1.Choose a lead facilitator (must have debriefing/ facilitation skills)

Gather the team in a quiet and confidential space.

Establish the ground rules:

- Acknowledge the difficult work being done
- Goal is to understand what happened and why, support each other, and consider what can be changed for next time
- Everyone's voice matters
- Everything discussed is confidential (the Chatham House rule applies)
  Chatham House Rule

When a meeting is held under the Chatham House Rule, participants are free to use the information received, but neither the identity nor the affiliation of the speaker(s), nor that of any other participant, may be revealed. (2002)

- Explain who to contact if anyone needs more support or doesn't feel comfortable speaking in front of everyone.

Step 2. Have a "FAST" discussion (feelings/ facts, analysis, summary, take homes)

- Check initial reactions to how everyone is feeling.
- Go over the "facts" of the event (explain what happened and check that everyone is on the same page)
- Analyze any issues:
  "What was troubling about the situation?
  "What aspects of the case would we want to change?"

- Check if there are any outstanding issues after exploring these and ensure everyone has had an opportunity to have their say
- Summarize the discussion

Step 3. "Close the loop"

- identify (and assign) any actions that need to be taken
- this may include things like checking in on people affected by the event, following up a patient's outcome, reporting a sentinel event, instigating a guideline change

References and Resources

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Kessler DO, Cheng A, Mullan PC. Debriefing in the emergency department after clinical events: a practical guide. Annals of emergency medicine. 2015; 65(6):690-8. [pubmed]
Mullan P, Kessler D, Cheng A. Educational opportunities with postevent debriefing. JAMA. 2014;312(22):2333-2334. [pubmed]
Debrief2Learn — Podcast 005: Clinical Debriefing (2017)
INTENSIVE — The Alfred ICU FAST-PAGE guide to debriefing (2015)
St Emlyns — It's Good to Talk – Debrief in the Emergency Department (2013)

Adapted from *Amazing and Awesome Hot debriefs for critical Incidents*.
https://intensiveblog.com/amazing-awesome-hot-debriefs-critical-incidents/

APPENDIX 3

Processes for Triage Team Utilization of the BLIS COVID-19 Database

Triage Teams

- There are currently five triage teams: Team A, B, C, D, and E.
- Each team consists of six members that includes a team leader.
- If the Protocol is invoked triage teams will be expanded to seven teams of six members.

Process for Reassessing Vented Patients in Simulation

This process requires at least two participants and is performed twice daily at 7:30 am and 7:00 pm via a password protected Zoom meeting. One triage team member will be designated to enter data in the BLIS COVID-19 database and one triage team member will be designated as a scribe.

- Log in to the BLIS COVID-19 Database: blis.urmc.rochester.edu/covid19
- Click 'View Assessments'
- The team member designated for data entry shares their BLIS COVID-19 current assessment period screen.
- The team member designated for data entry identifies and reads aloud the following:
    - Current date and time
    - Assessment period date and time as listed on screen
- Patient reassessment begins.
- The assigned scribe will take notes on patient color coding.
- The team member designated for data entry identifies and reads aloud the following:
    - Last three digits of patient ID
    - Timepoint i.e. reassessment 1, 2, 3, etc.
    - Previous SOFA score
    - Previous assessment color
    - Current SOFA score
- Triage team members refer to the interval measurements and color-coding flow diagram to determine patient's reassessment color.
- Team confers and one member of the team announces the bullet point from the flow diagram that led to this reassessment color determination.
- When agreement is reached:
    - The scribe records the last three digits of the patient ID and the reassessment color.
    - The team member designated for data entry completes the following steps:
        - Hover over the row to show the edit icon  located at the beginning of each row
        - Click the edit icon to enter in the assessment data
        - Identify and read aloud the last three digits of the patient ID
        - Read aloud and enter assessment date
        - Identify, read aloud, and enter assessment color
        - Identify, read aloud, and enter assessment basis: Current SOFA only, comparison with prior SOFA, other (describe in free text)
        - Triage team approves data
        - Click submit
- Process is repeated for all patients requiring reassessment.
    - For data verification the scribe reads aloud the last three digits of each patient ID and their corresponding reassessment color. The data entry person cross-checks the information in the BLIS COVID-19 database.
    - Once completed, the data entry person clicks on the randomization button.
    - Data entry person exports reassessment table to an excel spreadsheet by clicking 

- Data entry person password protects excel spreadsheet. In excel click Tools > Protection > Protect Sheet and add password.
- Send two emails, one with spreadsheet and one with password, to the FLOW team: Richard Dees, Chin-Lin Ching, and Jessica Shand.

Process for Reassessing Vented Patients In-Person

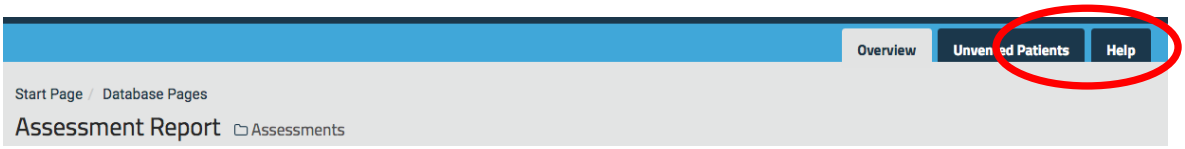
This process involves one triage team and is performed twice daily at 7:00 am and 7:00 pm. Triage team members will be assigned to subgroups of two with one individual from each pair designated to enter data in the BLIS COVID-19 database.

- Team lead logs in to the BLIS COVID-19 Database: blis.urmc.rochester.edu/covid19
    - Click 'View Assessments'
    - Print two copies of the patient reassessment list by clicking the button at the top of the table. Be sure to set printer settings to landscape.
    - Patient reassessment pages are distributed equally between the three subgroups with each member of a subgroup receiving the same copy of the list.
    - Triage team members independently refer to the interval measurements and color-coding flow diagram to determine patient reassessment color. This data is manually entered on the paper copy of the reassessment list.
    - Once complete, subgroups cross-check each patient's reassessment color until an agreement is reached.
    - One member of the team identifies and reads aloud the bullet point from the flow diagram that led to this reassessment color determination.
    - Once all the data is verified, the team member designated for data entry completes the following steps in the BLIS COVID-19 database while the other team member monitors and verifies data entry:
    - Hover over the row to show the edit icon located at the beginning of each row
    - Click the edit icon to enter the assessment data
    - Identify and read aloud the last three digits of the patient ID
    - Read aloud and enter assessment date
    - Identify, read aloud, and enter assessment color
    - Identify, read aloud, and enter assessment basis: Current SOFA only, comparison with prior SOFA, other (describe in free text)
    - Review data by announcing last three digits of patient ID and reassessment color
    - When both team members agree data is correct, click submit
  - Process is repeated for all patients requiring reassessment.
  - When all subgroups have entered reassessment data, the team lead clicks on the randomization button.
  - Print a copy of the new randomized patient reassessment list by clicking the button at the top of the table. Be sure to set printer settings to landscape.
  - Highlight blue, yellow, red colors and tape list to white board.
  - File all paper copies of the reassessment data.

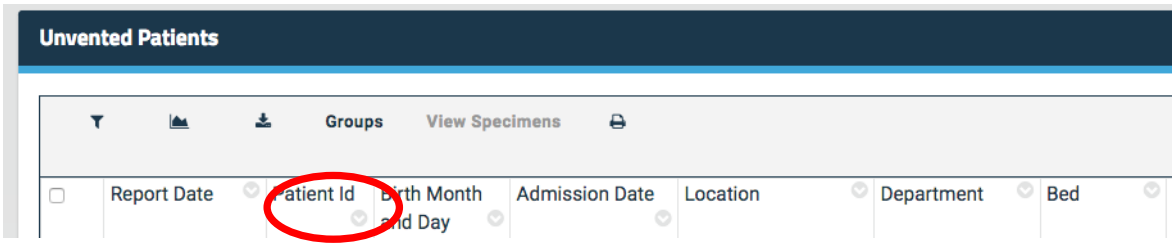
Processing Ventilator Requests

- All ventilator requests will be received via phone.
- For each call, complete a ventilator request form.
- After receiving patient ID, instruct the provider to continue manual ventilation of the patient and they will be called back with a decision ASAP.

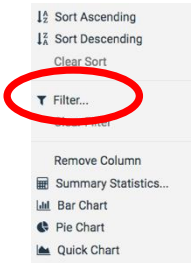
- Notify other triage team members that a request has been received in the event that a second request is received while the current request is processed.
- Requests will be prioritized based on the time they are received.
- Login to the BLIS COVID-19 Database: blis.urmc.rochester.edu/covid19
- Click 'Unvented Patients' tab.



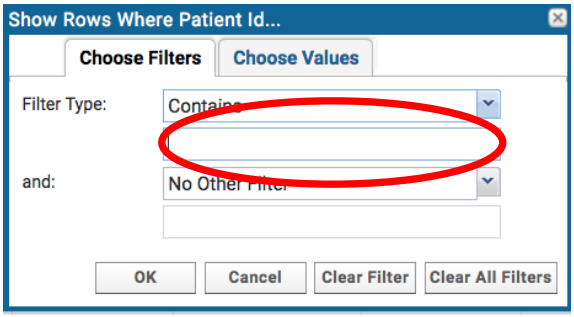
- Hover cursor over 'Patient Id' heading and left click.



- Navigate to 'filter' and click.



- Enter new patient ID in the filter field and click OK.



- Click on the patient ID to view patient details: SOFA score, color, location.
- Print patient details for records.
- Record patient SOFA score and color on ventilator request form.
- Record if patient is eligible for ventilator based on color assignment.
- Determine if there is an unused ventilator available for this patient.

<u>If Unused Ventilators are Available</u>

- Call provider and notify them that a ventilator is available and update ventilator request form.

If No Unused Ventilators are Available

- If the patient is color-coded as BLUE, they cannot be reallocated a ventilator from another patient.
- If the patient is color-coded as RED or YELLOW access the latest reassessment randomization list and identify the appropriate color group and navigate to the patient at the top of that list for that color group (#1).
    - A RED patient is allocated a ventilator from a patient in the BLUE group. If there are no patients in the BLUE group, the RED patient is allocated a ventilator from a patient in the YELLOW group.
    - A YELLOW patient is allocated a ventilator from a patient in the BLUE group. If there are no patients in the BLUE group, a YELLOW patient cannot be allocated a ventilator from another patient in the YELLOW group.
- Update ventilator request form.
- Click on patient ID to view patient details: SOFA score, color, location.
- Print patient details for records.
- Complete ventilator reallocation form.
- Fax completed form to medical records.

APPENDIX 4

STAGGERED TRIAGE TEAM SCHEDULE – TWO WEEK VIEW

Team A	Team B	Team C	Team D	Team E	Team F	Team G
A-1	B-1	C-1	D-1	E-1	F-1	G-1
A-2	B-2	C-2	D-2	E-2	F-2	G-2
A-3	B-3	C-3	D-3	E-3	F-3	G-3
A-4	B-4	C-4	D-4	E-4	F-4	G-4
A-5	B-5	C-5	D-5	E-5	F-5	G-5
A-6	B-6	C-6	D-6	E-6	F-6	G-6

Shifts
7a - 3p
9a - 5p
3p - 11p
5p - 1a
11p - 7a
1a - 9a

Week 1

Hour	Monday						Tuesday						Wednesday						Thursday						Friday						Saturday						Sunday					
12a	G-1	G-2	G-3	F-4	F-5	F-6	C-1	C-2	C-3	B-4	B-5	B-6	F-1	F-2	F-3	E-4	E-5	E-6	B-1	B-2	B-3	A-4	A-5	A-6	E-1	E-2	E-3	D-4	D-5	D-6	A-1	A-2	A-3	G-4	G-5	G-6	D-1	D-2	D-3	C-4	C-5	C-6
1a	G-1	G-2	G-3	G-4	G-5	G-6	C-1	C-2	C-3	C-4	C-5	C-6	F-1	F-2	F-3	F-4	F-5	F-6	B-1	B-2	B-3	B-4	B-5	B-6	E-1	E-2	E-3	E-4	E-5	E-6	A-1	A-2	A-3	A-4	A-5	A-6	D-1	D-2	D-3	D-4	D-5	D-6
2a	G-1	G-2	G-3	G-4	G-5	G-6	C-1	C-2	C-3	C-4	C-5	C-6	F-1	F-2	F-3	F-4	F-5	F-6	B-1	B-2	B-3	B-4	B-5	B-6	E-1	E-2	E-3	E-4	E-5	E-6	A-1	A-2	A-3	A-4	A-5	A-6	D-1	D-2	D-3	D-4	D-5	D-6
3a	G-1	G-2	G-3	G-4	G-5	G-6	C-1	C-2	C-3	C-4	C-5	C-6	F-1	F-2	F-3	F-4	F-5	F-6	B-1	B-2	B-3	B-4	B-5	B-6	E-1	E-2	E-3	E-4	E-5	E-6	A-1	A-2	A-3	A-4	A-5	A-6	D-1	D-2	D-3	D-4	D-5	D-6
4a	G-1	G-2	G-3	G-4	G-5	G-6	C-1	C-2	C-3	C-4	C-5	C-6	F-1	F-2	F-3	F-4	F-5	F-6	B-1	B-2	B-3	B-4	B-5	B-6	E-1	E-2	E-3	E-4	E-5	E-6	A-1	A-2	A-3	A-4	A-5	A-6	D-1	D-2	D-3	D-4	D-5	D-6
5a	G-1	G-2	G-3	G-4	G-5	G-6	C-1	C-2	C-3	C-4	C-5	C-6	F-1	F-2	F-3	F-4	F-5	F-6	B-1	B-2	B-3	B-4	B-5	B-6	E-1	E-2	E-3	E-4	E-5	E-6	A-1	A-2	A-3	A-4	A-5	A-6	D-1	D-2	D-3	D-4	D-5	D-6
6a	G-1	G-2	G-3	G-4	G-5	G-6	C-1	C-2	C-3	C-4	C-5	C-6	F-1	F-2	F-3	F-4	F-5	F-6	B-1	B-2	B-3	B-4	B-5	B-6	E-1	E-2	E-3	E-4	E-5	E-6	A-1	A-2	A-3	A-4	A-5	A-6	D-1	D-2	D-3	D-4	D-5	D-6
7a	A-1	A-2	A-3	G-4	G-5	G-6	D-1	D-2	D-3	C-4	C-5	C-6	G-1	G-2	G-3	F-4	F-5	F-6	C-1	C-2	C-3	B-4	B-5	B-6	F-1	F-2	F-3	E-4	E-5	E-6	B-1	B-2	B-3	A-4	A-5	A-6	E-1	E-2	E-3	D-4	D-5	D-6
8a	A-1	A-2	A-3	G-4	G-5	G-6	D-1	D-2	D-3	C-4	C-5	C-6	G-1	G-2	G-3	F-4	F-5	F-6	C-1	C-2	C-3	B-4	B-5	B-6	F-1	F-2	F-3	E-4	E-5	E-6	B-1	B-2	B-3	A-4	A-5	A-6	E-1	E-2	E-3	D-4	D-5	D-6
9a	A-1	A-2	A-3	A-4	A-5	A-6	D-1	D-2	D-3	D-4	D-5	D-6	G-1	G-2	G-3	G-4	G-5	G-6	C-1	C-2	C-3	C-4	C-5	C-6	F-1	F-2	F-3	F-4	F-5	F-6	B-1	B-2	B-3	B-4	B-5	B-6	E-1	E-2	E-3	E-4	E-5	E-6
10a	A-1	A-2	A-3	A-4	A-5	A-6	D-1	D-2	D-3	D-4	D-5	D-6	G-1	G-2	G-3	G-4	G-5	G-6	C-1	C-2	C-3	C-4	C-5	C-6	F-1	F-2	F-3	F-4	F-5	F-6	B-1	B-2	B-3	B-4	B-5	B-6	E-1	E-2	E-3	E-4	E-5	E-6
11a	A-1	A-2	A-3	A-4	A-5	A-6	D-1	D-2	D-3	D-4	D-5	D-6	G-1	G-2	G-3	G-4	G-5	G-6	C-1	C-2	C-3	C-4	C-5	C-6	F-1	F-2	F-3	F-4	F-5	F-6	B-1	B-2	B-3	B-4	B-5	B-6	E-1	E-2	E-3	E-4	E-5	E-6
12p	A-1	A-2	A-3	A-4	A-5	A-6	D-1	D-2	D-3	D-4	D-5	D-6	G-1	G-2	G-3	G-4	G-5	G-6	C-1	C-2	C-3	C-4	C-5	C-6	F-1	F-2	F-3	F-4	F-5	F-6	B-1	B-2	B-3	B-4	B-5	B-6	E-1	E-2	E-3	E-4	E-5	E-6
1p	A-1	A-2	A-3	A-4	A-5	A-6	D-1	D-2	D-3	D-4	D-5	D-6	G-1	G-2	G-3	G-4	G-5	G-6	C-1	C-2	C-3	C-4	C-5	C-6	F-1	F-2	F-3	F-4	F-5	F-6	B-1	B-2	B-3	B-4	B-5	B-6	E-1	E-2	E-3	E-4	E-5	E-6
2p	A-1	A-2	A-3	A-4	A-5	A-6	D-1	D-2	D-3	D-4	D-5	D-6	G-1	G-2	G-3	G-4	G-5	G-6	C-1	C-2	C-3	C-4	C-5	C-6	F-1	F-2	F-3	F-4	F-5	F-6	B-1	B-2	B-3	B-4	B-5	B-6	E-1	E-2	E-3	E-4	E-5	E-6
3p	B-1	B-2	B-3	A-4	A-5	A-6	E-1	E-2	E-3	D-4	D-5	D-6	A-1	A-2	A-3	G-4	G-5	G-6	D-1	D-2	D-3	C-4	C-5	C-6	G-1	G-2	G-3	F-4	F-5	F-6	C-1	C-2	C-3	B-4	B-5	B-6	F-1	F-2	F-3	E-4	E-5	E-6
4p	B-1	B-2	B-3	A-4	A-5	A-6	E-1	E-2	E-3	D-4	D-5	D-6	A-1	A-2	A-3	G-4	G-5	G-6	D-1	D-2	D-3	C-4	C-5	C-6	G-1	G-2	G-3	F-4	F-5	F-6	C-1	C-2	C-3	B-4	B-5	B-6	F-1	F-2	F-3	E-4	E-5	E-6
5p	B-1	B-2	B-3	B-4	B-5	B-6	E-1	E-2	E-3	E-4	E-5	E-6	A-1	A-2	A-3	A-4	A-5	A-6	D-1	D-2	D-3	D-4	D-5	D-6	G-1	G-2	G-3	G-4	G-5	G-6	C-1	C-2	C-3	C-4	C-5	C-6	F-1	F-2	F-3	F-4	F-5	F-6
6p	B-1	B-2	B-3	B-4	B-5	B-6	E-1	E-2	E-3	E-4	E-5	E-6	A-1	A-2	A-3	A-4	A-5	A-6	D-1	D-2	D-3	D-4	D-5	D-6	G-1	G-2	G-3	G-4	G-5	G-6	C-1	C-2	C-3	C-4	C-5	C-6	F-1	F-2	F-3	F-4	F-5	F-6
7p	B-1	B-2	B-3	B-4	B-5	B-6	E-1	E-2	E-3	E-4	E-5	E-6	A-1	A-2	A-3	A-4	A-5	A-6	D-1	D-2	D-3	D-4	D-5	D-6	G-1	G-2	G-3	G-4	G-5	G-6	C-1	C-2	C-3	C-4	C-5	C-6	F-1	F-2	F-3	F-4	F-5	F-6
8p	B-1	B-2	B-3	B-4	B-5	B-6	E-1	E-2	E-3	E-4	E-5	E-6	A-1	A-2	A-3	A-4	A-5	A-6	D-1	D-2	D-3	D-4	D-5	D-6	G-1	G-2	G-3	G-4	G-5	G-6	C-1	C-2	C-3	C-4	C-5	C-6	F-1	F-2	F-3	F-4	F-5	F-6
9p	B-1	B-2	B-3	B-4	B-5	B-6	E-1	E-2	E-3	E-4	E-5	E-6	A-1	A-2	A-3	A-4	A-5	A-6	D-1	D-2	D-3	D-4	D-5	D-6	G-1	G-2	G-3	G-4	G-5	G-6	C-1	C-2	C-3	C-4	C-5	C-6	F-1	F-2	F-3	F-4	F-5	F-6
10p	B-1	B-2	B-3	B-4	B-5	B-6	E-1	E-2	E-3	E-4	E-5	E-6	A-1	A-2	A-3	A-4	A-5	A-6	D-1	D-2	D-3	D-4	D-5	D-6	G-1	G-2	G-3	G-4	G-5	G-6	C-1	C-2	C-3	C-4	C-5	C-6	F-1	F-2	F-3	F-4	F-5	F-6
11p	C-1	C-2	C-3	B-4	B-5	B-6	F-1	F-2	F-3	E-4	E-5	E-6	B-1	B-2	B-3	A-4	A-5	A-6	E-1	E-2	E-3	D-4	D-5	D-6	A-1	A-2	A-3	G-4	G-5	G-6	D-1	D-2	D-3	C-4	C-5	C-6	G-1	G-2	G-3	F-4	F-5	F-6

Week 2

Hour	Monday						Tuesday						Wednesday						Thursday						Friday						Saturday						Sunday					
12a	G-1	G-2	G-3	F-4	F-5	F-6	C-1	C-2	C-3	B-4	B-5	B-6	F-1	F-2	F-3	E-4	E-5	E-6	B-1	B-2	B-3	A-4	A-5	A-6	E-1	E-2	E-3	D-4	D-5	D-6	A-1	A-2	A-3	G-4	G-5	G-6	D-1	D-2	D-3	C-4	C-5	C-6
1a	G-1	G-2	G-3	G-4	G-5	G-6	C-1	C-2	C-3	C-4	C-5	C-6	F-1	F-2	F-3	F-4	F-5	F-6	B-1	B-2	B-3	B-4	B-5	B-6	E-1	E-2	E-3	E-4	E-5	E-6	A-1	A-2	A-3	A-4	A-5	A-6	D-1	D-2	D-3	D-4	D-5	D-6
2a	G-1	G-2	G-3	G-4	G-5	G-6	C-1	C-2	C-3	C-4	C-5	C-6	F-1	F-2	F-3	F-4	F-5	F-6	B-1	B-2	B-3	B-4	B-5	B-6	E-1	E-2	E-3	E-4	E-5	E-6	A-1	A-2	A-3	A-4	A-5	A-6	D-1	D-2	D-3	D-4	D-5	D-6
3a	G-1	G-2	G-3	G-4	G-5	G-6	C-1	C-2	C-3	C-4	C-5	C-6	F-1	F-2	F-3	F-4	F-5	F-6	B-1	B-2	B-3	B-4	B-5	B-6	E-1	E-2	E-3	E-4	E-5	E-6	A-1	A-2	A-3	A-4	A-5	A-6	D-1	D-2	D-3	D-4	D-5	D-6
4a	G-1	G-2	G-3	G-4	G-5	G-6	C-1	C-2	C-3	C-4	C-5	C-6	F-1	F-2	F-3	F-4	F-5	F-6	B-1	B-2	B-3	B-4	B-5	B-6	E-1	E-2	E-3	E-4	E-5	E-6	A-1	A-2	A-3	A-4	A-5	A-6	D-1	D-2	D-3	D-4	D-5	D-6
5a	G-1	G-2	G-3	G-4	G-5	G-6	C-1	C-2	C-3	C-4	C-5	C-6	F-1	F-2	F-3	F-4	F-5	F-6	B-1	B-2	B-3	B-4	B-5	B-6	E-1	E-2	E-3	E-4	E-5	E-6	A-1	A-2	A-3	A-4	A-5	A-6	D-1	D-2	D-3	D-4	D-5	D-6
6a	G-1	G-2	G-3	G-4	G-5	G-6	C-1	C-2	C-3	C-4	C-5	C-6	F-1	F-2	F-3	F-4	F-5	F-6	B-1	B-2	B-3	B-4	B-5	B-6	E-1	E-2	E-3	E-4	E-5	E-6	A-1	A-2	A-3	A-4	A-5	A-6	D-1	D-2	D-3	D-4	D-5	D-6
7a	A-1	A-2	A-3	G-4	G-5	G-6	D-1	D-2	D-3	C-4	C-5	C-6	G-1	G-2	G-3	F-4	F-5	F-6	C-1	C-2	C-3	B-4	B-5	B-6	F-1	F-2	F-3	E-4	E-5	E-6	B-1	B-2	B-3	A-4	A-5	A-6	E-1	E-2	E-3	D-4	D-5	D-6
8a	A-1	A-2	A-3	G-4	G-5	G-6	D-1	D-2	D-3	C-4	C-5	C-6	G-1	G-2	G-3	F-4	F-5	F-6	C-1	C-2	C-3	B-4	B-5	B-6	F-1	F-2	F-3	E-4	E-5	E-6	B-1	B-2	B-3	A-4	A-5	A-6	E-1	E-2	E-3	D-4	D-5	D-6
9a	A-1	A-2	A-3	A-4	A-5	A-6	D-1	D-2	D-3	D-4	D-5	D-6	G-1	G-2	G-3	G-4	G-5	G-6	C-1	C-2	C-3	C-4	C-5	C-6	F-1	F-2	F-3	F-4	F-5	F-6	B-1	B-2	B-3	B-4	B-5	B-6	E-1	E-2	E-3	E-4	E-5	E-6
10a	A-1	A-2	A-3	A-4	A-5	A-6	D-1	D-2	D-3	D-4	D-5	D-6	G-1	G-2	G-3	G-4	G-5	G-6	C-1	C-2	C-3	C-4	C-5	C-6	F-1	F-2	F-3	F-4	F-5	F-6	B-1	B-2	B-3	B-4	B-5	B-6	E-1	E-2	E-3	E-4	E-5	E-6
11a	A-1	A-2	A-3	A-4	A-5	A-6	D-1	D-2	D-3	D-4	D-5	D-6	G-1	G-2	G-3	G-4	G-5	G-6	C-1	C-2	C-3	C-4	C-5	C-6	F-1	F-2	F-3	F-4	F-5	F-6	B-1	B-2	B-3	B-4	B-5	B-6	E-1	E-2	E-3	E-4	E-5	E-6
12p	A-1	A-2	A-3	A-4	A-5	A-6	D-1	D-2	D-3	D-4	D-5	D-6	G-1	G-2	G-3	G-4	G-5	G-6	C-1	C-2	C-3	C-4	C-5	C-6	F-1	F-2	F-3	F-4	F-5	F-6	B-1	B-2	B-3	B-4	B-5	B-6	E-1	E-2	E-3	E-4	E-5	E-6
1p	A-1	A-2	A-3	A-4	A-5	A-6	D-1	D-2	D-3	D-4	D-5	D-6	G-1	G-2	G-3	G-4	G-5	G-6	C-1	C-2	C-3	C-4	C-5	C-6	F-1	F-2	F-3	F-4	F-5	F-6	B-1	B-2	B-3	B-4	B-5	B-6	E-1	E-2	E-3	E-4	E-5	E-6
2p	A-1	A-2	A-3	A-4	A-5	A-6	D-1	D-2	D-3	D-4	D-5	D-6	G-1	G-2	G-3	G-4	G-5	G-6	C-1	C-2	C-3	C-4	C-5	C-6	F-1	F-2	F-3	F-4	F-5	F-6	B-1	B-2	B-3	B-4	B-5	B-6	E-1	E-2	E-3	E-4	E-5	E-6
3p	B-1	B-2	B-3	A-4	A-5	A-6	E-1	E-2	E-3	D-4	D-5	D-6	A-1	A-2	A-3	G-4	G-5	G-6	D-1	D-2	D-3	C-4	C-5	C-6	G-1	G-2	G-3	F-4	F-5	F-6	C-1	C-2	C-3	B-4	B-5	B-6	F-1	F-2	F-3	E-4	E-5	E-6
4p	B-1	B-2	B-3	A-4	A-5	A-6	E-1	E-2	E-3	D-4	D-5	D-6	A-1	A-2	A-3	G-4	G-5	G-6	D-1	D-2	D-3	C-4	C-5	C-6	G-1	G-2	G-3	F-4	F-5	F-6	C-1	C-2	C-3	B-4	B-5	B-6	F-1	F-2	F-3	E-4	E-5	E-6
5p	B-1	B-2	B-3	B-4	B-5	B-6	E-1	E-2	E-3	E-4	E-5	E-6	A-1	A-2	A-3	A-4	A-5	A-6	D-1	D-2	D-3	D-4	D-5	D-6	G-1	G-2	G-3	G-4	G-5	G-6	C-1	C-2	C-3	C-4	C-5	C-6	F-1	F-2	F-3	F-4	F-5	F-6
6p	B-1	B-2	B-3	B-4	B-5	B-6	E-1	E-2	E-3	E-4	E-5	E-6	A-1	A-2	A-3	A-4	A-5	A-6	D-1	D-2	D-3	D-4	D-5	D-6	G-1	G-2	G-3	G-4	G-5	G-6	C-1	C-2	C-3	C-4	C-5	C-6	F-1	F-2	F-3	F-4	F-5	F-6
7p	B-1	B-2	B-3	B-4	B-5	B-6	E-1	E-2	E-3	E-4	E-5	E-6	A-1	A-2	A-3	A-4	A-5	A-6	D-1	D-2	D-3	D-4	D-5	D-6	G-1	G-2	G-3	G-4	G-5	G-6	C-1	C-2	C-3	C-4	C-5	C-6	F-1	F-2	F-3	F-4	F-5	F-6
8p	B-1	B-2	B-3	B-4	B-5	B-6	E-1	E-2	E-3	E-4	E-5	E-6	A-1	A-2	A-3	A-4	A-5	A-6	D-1	D-2	D-3	D-4	D-5	D-6	G-1	G-2	G-3	G-4	G-5	G-6	C-1	C-2	C-3	C-4	C-5	C-6	F-1	F-2	F-3	F-4	F-5	F-6
9p	B-1	B-2	B-3	B-4	B-5	B-6	E-1	E-2	E-3	E-4	E-5	E-6	A-1	A-2	A-3	A-4	A-5	A-6	D-1	D-2	D-3	D-4	D-5	D-6	G-1	G-2	G-3	G-4	G-5	G-6	C-1	C-2	C-3	C-4	C-5	C-6	F-1	F-2	F-3	F-4	F-5	F-6
10p	B-1	B-2	B-3	B-4	B-5	B-6	E-1	E-2	E-3	E-4	E-5	E-6	A-1	A-2	A-3	A-4	A-5	A-6	D-1	D-2	D-3	D-4	D-5	D-6	G-1	G-2	G-3	G-4	G-5	G-6	C-1	C-2	C-3	C-4	C-5	C-6	F-1	F-2	F-3	F-4	F-5	F-6
11p	C-1	C-2	C-3	B-4	B-5	B-6	F-1	F-2	F-3	E-4	E-5	E-6	B-1	B-2	B-3	A-4	A-5	A-6	E-1	E-2	E-3	D-4	D-5	D-6	A-1	A-2	A-3	G-4	G-5	G-6	D-1	D-2	D-3	C-4	C-5	C-6	G-1	G-2	G-3	F-4	F-5	F-6

APPENDIX 5

UR MEDICINE

Ventilator Re-allocation Documentation Form **Bar Code**

Patient Information (patient currently on the ventilator)

Patient Identifiers: eMRN:_____ DOB (mm/dd):_____ Admit date: _____

Patient location: ☐SMH ☐Highland ☐Thompson ☐Noyes ☐Jones ☐St. James
Unit/floor:_____ Unit telephone number: _____

Data Timepoint (date/time data was reviewed to base decision): Date_____ Time_____

Patient Ventilator ID:_____

At time of review, patient's color code was assessed as:
- ☐ Yellow
- ☐ Blue

☐ **Pediatric patient?** ☐**Yes** ☐ **No**
- ☐ **If yes, date of most recent pediatric clinical consultation_____**

Patient's Attending physician: _____
Date and time decision discussed with Attending: _____

☐ **Appeals process requested?** ☐ **Yes** ☐**No**
- ☐ **If yes, when was appeal decision made? Date_____ Time_____**
- **Appeal Outcome: _____**
- **Additional Appeal Comments: _____**

Recipient Information (patient to receive the ventilator)

At time of review, recipient's color code was assessed as:
- ☐**Red**
- ☐**Yellow**

☐ **Pediatric patient?** ☐**Yes** ☐ **No**

Final Determination (per application of the Ventilator Allocation Protocol)

☐**Patient's ventilator was re-allocated to a patient predicted to have greater chance of short term survival. Additional notes:**

When completed, fax this form to Medical Records: ###-####
Triage Team completing this form: ☐Team A ☐Team B ☐Team C ☐Team D ☐Team E ☐Team F

APPENDIX 6

Ventilator Request Form

Please manually enter all details for each ventilator request. Information will be entered into a database at the end of each triage team's shift.

Date and time:

Name of provider requesting ventilator:

Patient eMRN: **Patient DOB (mm/dd):**

Attending physician name:

Patient location: ☐ SMH ☐ Highland ☐ Thompson ☐ Noyes ☐ Jones ☐ St. James

Unit/floor:_____

Call back telephone number:

*****Repeat information back to caller*****

Patient SOFA score and color code: **Report Date and Time:**

Is patient eligible to receive a ventilator based on current allocation of resources? Yes No
Explain decision:

- ☐ Unused ventilators are available
- ☐ Patient's color code prioritizes them for reallocation of a ventilator from a patient in a lower priority category
- ☐ Patient's color code *does not* prioritize them for reallocation of a ventilator from a patient in another priority category

Additional notes:

Ventilator ID and location:

If Ventilator Reallocation - Information on Patient to be Extubated

Bed #: **Attending Physician Name:**

Call back date and time:

If patient is not offered a ventilator at the time of the request, and a ventilator later becomes available for which this patient is eligible, call Attending physician back to assess patient's status and appropriateness of ventilator allocation

Please print Unventilated Patient Detail Page and attach to this sheet

APPENDIX 7

Ventilator Allocation Flow Diagram

Color Code Vent Priority	Reassessment #2, #3, #4, etc.
RED: FIRST PRIORITY	a. If SOFA score decreases numerically by ≥1 points remains RED. b. If SOFA score remains the same or increases numerically and SOFA ≤ 7 then downgrade to YELLOW. c. If SOFA score does not change or increases numerically and SOFA ≥ 8 then downgrade to BLUE. d. If SOFA score is zero, see note 4.
YELLOW: SECOND PRIORITY	e. If SOFA score decreases numerically by ≥1 points upgrade to RED. f. If SOFA score does not change or increases numerically downgrade to BLUE.
BLUE: THIRD PRIORITY	g. If SOFA score decreases numerically to SOFA 0-7 upgrade to RED. h. If SOFA score decreases numerically to SOFA 8-11 upgrade to YELLOW. i. If SOFA score decreases numerically to SOFA ≥12, does not change, or increases numerically remains BLUE.

Notes

1. A patient who is intubated for airway protection without organ failure is designated as RED. Once assigned a ventilator, RED patients keep the ventilator as long as they remain RED.
2. YELLOW patients are allowed a fair trial of intubation, until the first assessment at 120 hours. Once assigned a ventilator, they keep it until the next assessment. But after each assessment, any patient designated YELLOW can be displaced by a new RED patient during the first 12 hours after their assessment. After that point, they will remain on the ventilator until their next formal assessment.
3. BLUE patients may receive ventilators if they are available. However, they are always subject to reallocation. Any new RED or YELLOW patient needing a ventilator takes priority.
4. Some patients may advance to SOFA = 0, but still require ventilation. Once patients have reached SOFA=0, they may remain on the ventilator through the next assessment cycle to see if they can be weaned. If they can still not be weaned after two cycles at SOFA = 0, then they are downgraded to YELLOW.
5. YELLOW patients who require a ventilator cannot take a ventilator from another YELLOW patient on a ventilator. If there are no BLUE patients and only YELLOW and RED patients on a ventilator, the patient waiting for a ventilator cannot be allocated one, and will need to be supported until either a new ventilator becomes available or the next assessment point.

APPENDIX 8

University of Rochester COVID-19 Pandemic ECMO Document

April 2, 2020

ECMO Subcommittee Members: Leway Chen, Anna Lambert, Joseph Delehanty, Sunil Prasad, Karin Chase, Karen Smith, Lisa Owens

Introduction:
The URMC (Strong Memorial Hospital and the Golisano Children's Hospital) has a general capacity of 10 adult ECMO circuits--V-V (venous-venous) or V-A (venous-arterial) ECMO-- and 3 pediatric circuits at any given time. The COVID-19 pandemic may affect the Rochester region and result in limitation of resources including ICU beds, ICU staff, ventilators, ECMO circuits, ECMO pumps, and qualified ECMO staff. Based upon our review of the current literature and current data, no absolute ECMO guidance has been determined to be optimal in situations of severe resource shortages. URMC status during the COVID-19 pandemic will dictate ECMO capacity and is likely to be fluid and changing.

General tenets:

1. The URMC will attempt to provide usual standards of care as the largest tertiary/quaternary care center supporting the Upstate New York region.
2. All healthcare facilities in our region should continue to fully utilize their available resources to care for patients at their institutions.

Adult ECMO tenets:

1. Adult patients with COVID and severe ARDS may be referred to URMC for consideration of V-V ECMO.
    a. Transfer requests will be reviewed on a case-by-case basis
    b. Referrals and transport should occur during daytime period.
2. The URMC Critical Care transport team has the ability to transfer COVID-19 patients on ECMO to URMC, although this must be given careful consideration.
3. URMC COVID-19 patients with ARDS who are being considered for V-V ECMO will be evaluated by combined ICU and ECMO Leadership (D. Kaufman/ S. Prasad)
    a. Individuals will be considered on a case-by-case basis for V-V ECMO.
    b. There are <u>no age restrictions</u> for ECMO at the time of the preparation of this document.
    c. However, generally younger patients and those with fewer comorbidities, and minimal end organ dysfunction will do better with ECMO support.
4. These tenets will be addressed weekly if not daily as the situation changes at URMC.
5. A patient on ECMO support will be evaluated for maintenance of ECMO support on a daily basis.

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APPENDIX 9

Triage Team Command Center – Edward G. Miner Library

Computing

- The Bhagat Classroom (1-6200D) has a lectern computer and 84" display that was used for training and group case review.
- The classroom contained two production command center computers. A third production command center computer was located just outside of the classroom. This configuration allowed space for users to be socially distanced.
  - All computers required Google Chrome browser required to be installed.
  - A shortcut to Covid-19 VAC utility was located on desktop to facilitate access for users. (This required a login script to ensure the proper shortcut was added to every user's desktop who logs into the computer.)
  - A backup PC, with the same production configurations, was also located in the classroom to support potential issues or malfunctions of production computers, especially during overnight hours when IT support is diminished.

Printing

- Multiple printers (while we didn't have them available, color printers would be ideal) were required. One was placed in the training room in Classroom 1 in Miner's Computing Center, one in the Bhagat Classroom, and the last was on the production command center printer outside of the Bhagat Classroom.
- Every print job required a time stamp. This requires a custom login script to force the HP printer driver to be configured to enable and add timestamps for every user that logs into that computer.

Telecommunications

- Six wireless IP phones were procured along with one 'hotline' phone number.
  - The phones ring in a round robin. Phone 1 rings, if no answer, Phone 2 rings, then 3. If it gets to phone 6 with no answer, it loops back to Phone 1.
  - All phones were labeled with their number.
  - Additional batteries and hip phone holsters/clips were also supplied.
- A fax machine was requested. The command center used the all in one printer located behind Miner Library's Answer Desk. Instructions and passcodes for the all in one printer were provided.

Training room

- A training room with large screen display and computer with the same configuration as the command center production computers was created in Miner Library's Classroom 1. This room could be used for training and support during a time when the command center was up and running 24/7 and there might be training needed.

Beds and bedding

- The Center for Experiential Learning supplied two beds and linens for command center users who might need a rest. Beds were located in the study space behind the Bhagat Classroom.

Supporting Signage

- Computer log on and log off instruction
- Phone usage and charging instruction
- Support phone numbers for ISD Help Desk, IIE Executive Director, IIE Director of Information Technology, Facilities

Additional supplies provided

- Extra printer paper, notepads, pens, rolling white boards, hand sanitizer, gloves, masks, power strips to support charging of personal devices, backup keyboards, backup mice