



VENTILATOR ALLOCATION GUIDELINES

**New York State Task Force on Life and the Law
New York State Department of Health**

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Task Force reports should not be regarded as reflecting the views of the organizations with which
Task Force members are associated.

Letter from the Commissioner of Health

Dear New Yorkers,

Protecting the health and well-being of New Yorkers is a core objective of the Department of Health. During flu season, we are reminded that pandemic influenza is a foreseeable threat, one that we cannot ignore. In light of this possibility, the Department is taking steps to prepare for a pandemic and to limit the loss of life and other negative consequences. An influenza pandemic would affect all New Yorkers, and we have a responsibility to plan now. Part of the planning process is to develop guidance on how to ethically allocate limited resources (i.e., ventilators) during a severe influenza pandemic while saving the most lives.

As part of our emergency preparedness efforts, the Department, together with the New York State Task Force on Life and the Law, is releasing the 2015 Ventilator Allocation Guidelines, which provide an ethical, clinical, and legal framework to assist health care providers and the general public in the event of a severe influenza pandemic. The first guidelines in 2007 focused on the allocation of ventilators for adults, and were among the first of their kind in the United States. The 2015 version is also groundbreaking in that it includes two new detailed clinical ventilator allocation protocols – one for pediatric patients and another for neonates. The first Guidelines were widely cited and followed by other states. We expect these revised Guidelines to have a similar effect.

The Guidelines were written to reflect the values of New Yorkers, and extensive efforts were made to obtain public input during their development. While these Guidelines are comprehensive, they are by no means final. We will continue to seek public input and will revise the Guidelines as societal norms change and clinical knowledge advances.

It is my sincere hope that these Guidelines will never need to be implemented. But as a physician and servant in public health, I know that such preparations are essential should we ever experience an influenza pandemic. I want to thank the members and staff of the Task Force on Life and the Law for their efforts in creating these Guidelines, which once again demonstrate New York's strong commitment to safeguarding the health of its citizens.

Sincerely,



Howard A. Zucker, M.D., J.D., LL.M.
New York State Commissioner of Health

VENTILATOR ALLOCATION GUIDELINES

New York State Task Force on Life & the Law New York State Department of Health

Preface

These Ventilator Allocation Guidelines (Guidelines) are an update to the 2007 draft guidelines, which presented a clinical ventilator allocation protocol for adults and included a brief section on the legal issues associated with implementing the guidelines. This update of the Guidelines consists of four chapters: (1) the adult guidelines, (2) the pediatric guidelines, (3) the neonatal guidelines, and (4) legal considerations. The adult guidelines were revised to reflect recent medical advances and further clinical analysis. The pediatric and neonatal guidelines are new and address important and previously overlooked segments of the population. Finally, the legal section provides a comprehensive examination of the various legal issues that may arise when implementing the Guidelines.

The underlying goal of this work is to provide a thorough ethical, clinical, and legal analysis of the development and implementation of the Guidelines in New York State. In addition to detailed clinical ventilator allocation protocols, this document provides an account of the logic, reasoning, and analysis behind the Guidelines. The clinical ventilator allocation protocols are grounded in a solid ethical and legal foundation and balance the goal of saving the most lives with important societal values, such as protecting vulnerable populations, to build support from both the general public and health care staff.

These Ventilator Allocation Guidelines provide an ethical, clinical, and legal framework that will assist health care workers and facilities and the general public in the ethical allocation of ventilators during an influenza pandemic. Because the Guidelines are a living document, intended to be updated and revised in line with advances in clinical knowledge and societal norms, the ongoing feedback from clinicians and the public has and will continue to be sought. In developing a protocol for allocating scarce resources in the event of an influenza pandemic, the importance of genuine public outreach, education, and engagement cannot be overstated; they are critical to the development of just policies and the establishment of public trust.

Acknowledgements

The participation of clinicians, researchers, and legal experts was critical to the deliberations of the Task Force. In addition to the members of the adult, pediatric, and clinical workgroups (see Appendix B of each respective chapter) and legal subcommittee, we would like to thank Armand H. Matheny Antommaria, Kenneth A. Berkowitz, Penelope R. Buschman, Sandro Cinti, Laura Evans, W. Bradley Poss, William Schechter, and Mary Ellen Tresgallo for their invaluable insights.

We would like to thank former Task Force policy interns Apoorva Ambavane, Sara Bergstresser, Jason Keehn, Jordan Lite, Daniel Marcus-Toll, Felisha Miles, Nicole Naudé, Katy Skimming, and Maryanne Tomazic for their research and editing contributions. In addition, we would like to extend special thanks to former legal interns Carol Brass, Bryant Cobb, Andrew Cohen, Marissa Geoffroy, Victoria Kusel, Brendan Parent, Lillian Ringel, Phoebe Stone, David Trompeter, and Esther Warshauer-Baker.

Finally, we would like to acknowledge the work of former Task Force staff members who contributed to the Guidelines. We thank former Executive Directors Tia Powell and Beth Roxland, who initiated and moved the report forward, respectively. Carrie Zoubul served as the Senior Attorney during a large portion of the research and writing of these Guidelines and oversaw the 2011 public engagement project.

The Task Force's previous reports have been instrumental in developing policy on issues arising at the intersection of law, medicine, and ethics and have impacted greatly the delivery of health care in New York. While the Task Force hopes that the Guidelines will never need to be implemented, we believe the Guidelines will help to ensure that the State is adequately and appropriately prepared in the event of an influenza pandemic.

Sincerely,

Susie A. Han, M.A., M.A.
Deputy Director, Principal Policy Analyst
Project Chair of the Guidelines

Valerie Gutmann Koch, J.D.
Special Advisor; Former Senior Attorney

On behalf of the New York State Task Force on Life and the Law

VENTILATOR ALLOCATION GUIDELINES

Executive Summary

I. Introduction

Influenza pandemics occur with unpredictable frequency and severity. Recent influenza outbreaks, including the emergence of a powerful strain of avian influenza in 2005 and the novel H1N1 pandemic in 2009, have generated concern about the possibility of a severe influenza pandemic. While it is uncertain whether or when a pandemic will occur, the better prepared New York State is, the greater its chances of reducing associated morbidity, mortality, and economic consequences.

A pandemic that is especially severe with respect to the number of patients affected and the acuity of illness will create shortages of many health care resources, including personnel and equipment. Specifically, many more patients will require the use of ventilators than can be accommodated with current supplies. New York State may have enough ventilators to meet the needs of patients in a moderately severe pandemic. In a severe public health emergency on the scale of the 1918 influenza pandemic, however, these ventilators would not be sufficient to meet the demand. Even if the vast number of ventilators needed were purchased, a sufficient number of trained staff would not be available to operate them. If the most severe forecast becomes a reality, New York State and the rest of the country will need to allocate ventilators.

II. Development of the Ventilator Allocation Guidelines

In 2007, the New York State Task Force on Life and the Law (the Task Force) and the New York State Department of Health (the Department of Health) released draft ventilator allocation guidelines for adults. New York's innovative guidelines were among the first of their kind to be released in the United States and have been widely cited and followed by other states. Since then, the Department of Health and the Task Force have made extensive public education and outreach efforts and have solicited comments from various stakeholders. Following the release of the draft guidelines, the Task Force: (1) reexamined and revised the adult guidelines within the context of the public comments and feedback received (see Chapter 1), (2) developed guidelines for triaging pediatric and neonatal patients (see Chapters 2 and 3), and (3) expanded its analysis of the various legal issues that may arise when implementing the clinical protocols for ventilator allocation (see Chapter 4).

To revise the adult clinical ventilator allocation protocol, a clinical workgroup comprised of individuals from the fields of medicine and ethics was convened in 2009 to develop and refine specific aspects of the clinical ventilator allocation protocol. To obtain additional public comment, the Task Force oversaw a public engagement project in 2011, which consisted of 13 focus groups held throughout the State. Furthermore, based on the results of these focus groups and its own analysis, the Task Force made additional recommendations to elaborate and expand certain sections and to include a more robust discussion of the reasoning and logic behind certain features of the protocol. These revisions appear as Chapter 1, the revised adult guidelines (the Adult Guidelines).

The Task Force approached the pediatric ventilator allocation guidelines (the Pediatric Guidelines) in two stages. First, the Task Force addressed the special considerations for pediatric and neonatal emergency preparedness and the ethical issues related to the treatment and triage of children in a pandemic, with particular focus on whether children should be prioritized for ventilator therapy over adults. Second, the Task Force convened a pediatric clinical workgroup (including specialists in pediatric, neonatal, emergency, and maternal-fetal medicine, as well as in critical care, respiratory therapy, palliative care, public health, and ethics), to develop a clinical ventilator allocation protocol for pediatric patients. Chapter 2 presents these new Pediatric Guidelines.

The Task Force also organized a neonatal clinical workgroup, consisting of neonatal and maternal-fetal specialists, to discuss and develop neonatal guidelines (the Neonatal Guidelines), which appear as Chapter 3.

Finally, a legal subcommittee was organized in 2008, and the Task Force devoted substantial resources to exploring the various legal issues that may arise when implementing the clinical ventilator allocation protocols. Thus, the brief summary on legal issues from the 2007 draft guidelines is replaced with a substantial discussion in Chapter 4.

As a result of the Task Force's efforts, the Ventilator Allocation Guidelines (the Guidelines) incorporate comments, critiques, feedback, and values from numerous stakeholders, including experts in the medical, ethical, legal, and policy fields. The Guidelines draw upon the expertise of clinical workgroups and committees, literature review, public feedback, and insightful commentary. Furthermore, in developing and revising the Guidelines, extensive efforts were made to obtain public input. For the public to accept the Guidelines, they must reflect the values of New Yorkers.

Because research and data on this topic are constantly evolving, the Guidelines are a living document intended to be updated and revised in line with advances in clinical knowledge and societal norms. The Guidelines incorporate an ethical framework and evidence-based clinical data to support the goal of saving the most lives in an influenza pandemic where there are a limited number of available ventilators.

III. Chapter Overviews

This report consists of four chapters, described below. Each chapter has an abstract that summarizes the chapter. While each chapter may stand alone, the underlying ethical framework and clinical concepts are discussed in more detail in Chapter 1, Adult Guidelines. For ease of reference, at the end of the report are the adult (Appendix A), pediatric (Appendix B), and neonatal (Appendix C) clinical ventilator allocation protocols (the Clinical Protocols for Ventilator Allocation). In addition, this report has a companion document, Frequently Asked Questions, which is intended to supplement the Guidelines and answer commonly asked questions.

Chapter 1, Adult Guidelines. This chapter provides a detailed overview of the development of the Guidelines as a whole and a background on moderate and severe pandemic influenza scenarios. It also examines surge capacity, stockpiling ventilators, and creation of specialized facilities for influenza patients. An overview of the concepts used in triage (i.e., modified definitions of triage and survival), the ethical framework underlying the Guidelines, the use of triage officers or committees, pitfalls of an allocation system, and triaging ventilator-dependent chronic care patients are also discussed. Next, the chapter reviews various non-clinical approaches to allocating ventilators, including distributing ventilators on a first-come first-serve basis, randomizing ventilator allocation (e.g., lottery), requiring only informal physician clinical judgment in making allocation decisions, and prioritizing certain patient categories (i.e., health care workers, patients of advanced age, and patients with certain social criteria) for ventilator therapy, and provides an analysis of other clinical ventilator allocation protocols. New York’s clinical ventilator allocation protocol for adults is presented, followed by a discussion alternative forms of medical intervention and palliative care. Finally, the chapter concludes with a discussion on communication about the Guidelines, real-time data collection and analysis, and future modification of the Adult Guidelines.

Chapter 2, Pediatric Guidelines. This chapter addresses the unique considerations for pediatric emergency preparedness, explores the ethical issues related to triaging children, and discusses the pediatric clinical ventilator allocation protocol. It begins by describing how children with influenza may respond better to treatment because they have fewer underlying medical conditions that hinder recovery, and continues by examining how triaging children requires special attention. An overview of the concepts used in triage is repeated (i.e., modified definitions of triage and survival) and the use of young age as a triage factor is discussed. Next, potential features of a pediatric protocol are examined (i.e., exclusion criteria, pediatric clinical scoring systems, physician clinical judgment, time trials, response to ventilation, and duration of ventilator need/resource utilization), followed by summaries of various available pediatric guidelines (Ontario, Canada; Alaska; Florida; Indiana; Michigan; Minnesota; Wisconsin; and Utah). The chapter then discusses what age (pediatric age cut-off) should be used to determine who is a pediatric patient and weighs how to triage chronic care pediatric patients who are ventilator dependent. The second half of the chapter is devoted to the details of New York’s pediatric clinical ventilator allocation protocol, including the logic and reasoning behind the inclusion and exclusion of particular features. The chapter also discusses alternative forms of medical intervention and pediatric palliative care. Finally, the chapter addresses communication about triage, real-time data collection and analysis, and future modification of the Pediatric Guidelines.

Chapter 3, Neonatal Guidelines. This chapter examines the unique challenges when triaging neonates and discusses the neonatal clinical ventilator allocation protocol. It begins with an exploration of the special considerations involved when triaging neonates, including the possible increase in the number of extremely premature neonates as a result of influenza-related complications from pregnant women. Next, the possible components of a neonatal protocol are analyzed (i.e., neonatal clinical scoring systems, physician clinical judgment, Apgar score, gestational age, and birth weight). The second half of the chapter presents New York’s neonatal clinical ventilator allocation protocol, and includes detailed explanations of why the possible factors discussed earlier are not appropriate to include. The chapter closes with comments on

alternative forms of medical intervention, palliative care, communication about triage, real-time data collection and analysis, and future modification of the Neonatal Guidelines.

Chapter 4, Implementing New York State’s Ventilator Allocation Guidelines: Legal Considerations. This chapter addresses the various legal issues associated with effectively implementing the Guidelines and presents recommendations to encourage adherence to the Guidelines. This chapter begins with a discussion of the form of the Guidelines themselves as voluntary and non-binding. It then focuses on a number of constitutional considerations that may arise when implementing the clinical ventilator allocation protocols. It discusses the “trigger” for the implementation of the adult, pediatric, and neonatal clinical ventilator allocation protocols and enumerates the New York statutes that could interfere with adherence to the Guidelines in a pandemic influenza. This chapter then examines existing liability protections at the federal and State levels and recommends passage of legislation granting the New York Commissioner of Health authority to adopt a modified medical standard of care specific to the emergency, coupled with civil and criminal liability protections and professional discipline protections for all health care workers and entities who provide care in a pandemic emergency. This chapter also considers alternatives to legislation that would mitigate civil and criminal liability and encourage adherence to the Guidelines. The approaches include: (1) caps on damages; (2) expedited discovery and statutes of limitations; (3) alternative dispute resolution, including arbitration, pretrial review boards, and compensation pools; and (4) professional education. This chapter concludes with a consideration of the various approaches to an appeals process for those who object to decisions made pursuant to the clinical ventilator allocation protocols.

IV. The Guidelines’ Primary Goal: Saving the Most Lives

The primary goal of the Guidelines is to save the most lives in an influenza pandemic where there are a limited number of available ventilators. To accomplish this goal, patients for whom ventilator therapy would most likely be lifesaving are prioritized. The Guidelines define survival by examining a patient’s short-term likelihood of surviving the acute medical episode and not by focusing on whether the patient may survive a given illness or disease in the long-term (e.g., years after the pandemic). Patients with the highest probability of mortality *without* medical intervention, along with patients with the smallest probability of mortality *with* medical intervention, have the *lowest* level of access to ventilator therapy. Thus, patients who are most likely to survive *without* the ventilator, together with patients who will most likely survive *with* ventilator therapy, increase the overall number of survivors.

V. Ethical Considerations and Possible Methods to Allocate Ventilators

The clinical ventilator allocation protocols are based on an ethical framework which includes five components: duty to care, duty to steward resources, duty to plan, distributive justice, and transparency. First, duty to care is the fundamental obligation for providers to care for patients. Duty to steward resources is the need to responsibly manage resources during periods of true scarcity. Duty to plan is the responsibility of government to plan for a foreseeable crisis. Distributive justice requires that an allocation protocol is applied broadly and consistently to be fair to all. Finally, transparency ensures that the process of developing a clinical ventilator

allocation protocol is open to feedback and revision, which helps promote public trust in the Guidelines.

To ensure that patients receive the best care possible in a pandemic, a patient's attending physician does not determine whether his/her patient receives (or continues) with ventilator therapy; instead a triage officer or triage committee makes the decision. While the attending physician interacts with and conducts the clinical evaluation of a patient, a triage officer or triage committee does not have any direct contact with the patient. Instead, a triage officer or triage committee examines the data provided by the attending physician and makes the determination about a patient's level of access to a ventilator. This role separation allows the clinical ventilator allocation protocol to operate smoothly. The decision regarding whether to use either a triage officer or committee is left to each acute care facility (i.e., hospital) because available resources will differ at each site.

The Task Force explored various non-clinical approaches to allocating ventilators, including distributing ventilators on a first-come first-serve basis, randomizing ventilator allocation (e.g., lottery), requiring only physician clinical judgment in making allocation decisions, and prioritizing certain patient categories (i.e., health care workers and patients with certain social criteria). However, the Task Force determined that these approaches should not be used as the primary method to allocate scarce resources because they are often subjective and/or do not support the goal of saving the most lives. Furthermore, advanced age was rejected as a triage criterion because it discriminates against the elderly. Age already factors indirectly into any criteria that assess the overall health of an individual (because the likelihood of having chronic medical conditions increases with age) and there are many instances where an older person could have a better clinical outlook than a younger person. Thus, the Task Force concluded that an allocation protocol should utilize clinical factors only to evaluate a patient's likelihood of survival and to determine the patient's access to ventilator therapy.

However, because of a strong societal preference for saving children, the Task Force recommended that *young* age may be considered as a tie-breaking criterion in limited circumstances. When the pool of patients eligible for ventilator therapy includes both adults and children (17 years old and younger), the Task Force determined that when all available clinical factors have been examined and the probability of mortality among the pool of patients has been found equivalent, only then may young age be utilized as a tie-breaker to select a patient for ventilator therapy. Thus, Guidelines that emphasize probability of mortality while incorporating the use of young age solely as a tie-breaker criterion acknowledge general societal values and advance the goal of saving the most lives.

Similarly, in its consideration to protect vulnerable populations, the Task Force determined that ventilator-dependent chronic care patients are subject to the clinical ventilator allocation protocol only if they arrive at an acute care facility for treatment. Once they arrive at a hospital, they are treated like any other patient who requires ventilator therapy. This policy balances the need to protect vulnerable populations with the principle of treating all patients in need of a ventilator equally. The unacceptable alternative would be to triage all stable, long-term ventilator-dependent patients, which may result in likely fatal extubations, and it would violate several principles of the ethical framework.

VI. Implementation of the Guidelines

Before the Guidelines are implemented, facilities must develop surge capacity to reduce the demand for ventilators when a pandemic is occurring. Steps must be taken to conserve scarce resources, such as equipment and staffing, by limiting elective procedures that require ventilators and by adjusting staff-to-patient ratios. The Guidelines should be implemented Statewide to avoid large variations in ventilator access and distribution among facilities and to ensure that the same resources are available and in use at similarly situated facilities.

VII. Clinical Ventilator Allocation Protocols

The Neonatal Guidelines apply to infants less than 28 days old. The Pediatric Guidelines apply to children aged 17 years old and younger. The Adult Guidelines apply to individuals aged 18 years old and older. All acute care patients in need of a ventilator, whether due to influenza or other conditions, are subject to the clinical ventilator allocation protocol. Ventilator-dependent chronic care patients are only subject to the clinical ventilator allocation protocol if they arrive at an acute care facility. Using clinical criteria, patients deemed most likely to survive with ventilator therapy have the highest level of access to this treatment.

While the Adult, Pediatric, and Neonatal Guidelines do not utilize the exact same clinical tools to evaluate patients, the overall framework of all three clinical ventilator allocation protocols is the same. For all three clinical ventilator allocation protocols, there are three steps: (1) application of exclusion criteria, (2) assessment of mortality risk, and (3) periodic clinical assessments (“time trials”). A patient’s attending physician conducts the patient’s clinical assessments. In Step 1, patients who do not have a medical condition that will result in immediate or near-immediate mortality even with aggressive therapy are eligible for ventilator therapy. In Step 2, patients who have a moderate risk of mortality and for whom ventilator therapy would most likely be lifesaving are prioritized for treatment. In Step 3, official clinical assessments at 48 and 120 hours after ventilator therapy has begun are conducted to determine whether a patient continues with this treatment. Triage decisions are made based on ongoing clinical measures and data trends of a patient’s health condition, consisting of: (1) the overall prognosis estimated by the patient’s clinical indicators, which is indicative of mortality risk by revealing the presence (or likelihood), severity, and number of acute organ failure(s), and (2) the magnitude of improvement or deterioration of overall health, which provides additional information about the likelihood of survival with ventilator therapy. Thus, the guiding principle for the triage decision is that the likelihood of a patient’s continuation of ventilator therapy depends on the severity of the patient’s health condition and the extent of the patient’s medical deterioration. In order for a patient to continue with ventilator therapy, s/he must demonstrate an improvement in overall health status at each official clinical assessment. After the 120 hour assessment, patients are evaluated every 48 hours with the same clinical framework used in previous time trial assessments.

A patient’s attending physician provides all clinical data to a triage officer/committee. At Steps 2 and 3, a triage officer/committee examines a patient’s clinical data and uses this information to assign a color code to the patient. The color (blue, red, yellow, or green) determines the level of access to a ventilator. Blue code patients (lowest access/palliate/

discharge) are those who have a medical condition on the exclusion criteria list or those who have a high risk of mortality and these patients do not receive ventilator therapy when resources are scarce. Instead, alternative forms of medical intervention and/or palliative care are provided. However, if more resources become available, patients in the blue color category, or those with exclusion criteria, are reassessed and may be eligible for ventilator therapy. Red code patients (highest access) are those who have the highest priority for ventilator therapy because they are most likely to recover with treatment (and likely to not recover without it) and have a moderate risk of mortality. Patients in the yellow category (intermediate access) are those who are very sick, and their likelihood of survival is intermediate and/or uncertain. These patients may or may not benefit (i.e., survive) with ventilator therapy. They receive such treatment if ventilators are available after all patients in the red category receive them. Patients in the green color code (defer/discharge) are those who do not need ventilator therapy.

In some circumstances, a triage officer/committee must select one of many eligible red color code patients to receive ventilator therapy. A patient's likelihood of survival (i.e., assessment of mortality risk) is the most important consideration when evaluating a patient. However, there may be a situation where multiple patients have been assigned a red color code, which indicates they all have the highest level of access to ventilator therapy, and they all have equal (or near equal) likelihoods of survival. If the eligible patient pool consists of *only adults* or *only children*, a randomization process, such as a lottery, is used each time a ventilator becomes available because there are no other evidence-based clinical factors available to consider. Patients waiting for ventilator therapy wait in an eligible patient pool. However, in limited circumstances, if: (1) the pool of patients eligible for ventilator therapy includes *both adults and children*, and (2) all available clinical data suggest that the probability of mortality among the pool of patients have been found equivalent (i.e., all patients are assigned a red color code), then young age (i.e., 17 years old and younger) may be utilized as a tie-breaker to select a patient for ventilator therapy.

In addition, there may be a scenario where there is an incoming red code patient(s) eligible for ventilator therapy and a triage officer/committee must remove a ventilator from a patient whose health is not improving. In this situation, first, patients in the blue category (or the yellow category if there are no blue code patients receiving ventilator therapy) are vulnerable for removal from ventilator therapy if they fail to meet criteria for continued ventilator use. If the pool of ventilated patients vulnerable for removal consists of *only adults* or *only children*, a randomization process, such as a lottery, is used each time to select the (blue or yellow) patient who will no longer receive ventilator therapy. However, in limited circumstances, if: (1) the pool of ventilated patients eligible for ventilator withdrawal includes *both adults and children*, and (2) all available clinical data suggest that the probability of mortality among the pool of ventilated patients has been found equivalent (i.e., all patients are assigned a blue (or yellow) color code), then young age (i.e., 17 years old and younger) may be utilized as a tie-breaker and the ventilator is withdrawn from the adult patient. A patient may only be removed from a ventilator after an official clinical assessment has occurred or where the patient develops a medical condition on the exclusion criteria list. However, if all ventilated patients are in the red category (i.e., have the highest level access), *none* of the patients are removed from ventilator therapy, even if there is an eligible (red color code) patient waiting.

Patients who have a medical condition on the exclusion criteria list or who no longer meet the clinical criteria for continued ventilator use receive alternative forms of medical intervention and/or palliative care. The same applies to patients who are eligible for ventilator therapy but for whom no ventilators are currently available. Alternative forms of medical intervention, such as other methods of oxygen delivery and pharmacological antivirals, should be provided to those who are not eligible or waiting for a ventilator. In addition, actively providing palliative care, especially to patients who do not or no longer qualify for ventilator therapy, decreases patient discomfort and fulfills the provider's duty to care, even when the clinician can no longer offer ventilator therapy.

Efforts will be made to inform and gather feedback from the public before a pandemic. Public outreach will inform people about the goals and steps of the clinical ventilator allocation protocols. Information should emphasize that pandemic influenza is potentially fatal, that health care providers are doing their best with the limited resources, and the public must adjust to a different way of providing and receiving health care than is customary. Instead, a protocol based only on clinical factors will be used to determine whether a patient receives (or continues with) ventilator treatment to support the goal of saving the greatest number of lives in an influenza pandemic where there are a limited number of available ventilators. Patients and families should be informed that ventilator therapy represents a *trial* of therapy that may not improve a patient's condition sufficiently and that the ventilator will be removed if this approach does not enable the patient to meet specific criteria.

Finally, once the Guidelines are implemented, there must be real-time data collection and analysis to modify the Guidelines based on new information. Data collection and analysis on the pandemic viral strain, such as symptoms, disease course, treatments, and survival, are necessary so that the clinical ventilator allocation protocols may be adjusted accordingly to ensure that patients receive the best care possible. In addition, data collection must include real-time availability of ventilators so that triage decisions are made to allocate resources most effectively. Knowing the exact availability of ventilators also assists a triage officer/committee in providing the most appropriate treatment options for patients.

VIII. Legal Considerations

The Guidelines address many of the legal issues that may arise in the event that the clinical ventilator allocation protocols are implemented. The Department of Health is empowered to issue voluntary, non-binding guidelines for health care workers and facilities; such guidelines are readily implemented and provide hospitals with an ethical and clinical framework for decision-making. The complex legal issues raised by a modified medical standard of care in a public health emergency create vulnerabilities for individual facilities as they draft their own policies, and they have therefore requested detailed procedural advice from the State.

Among the most challenging legal questions related to a pandemic scenario is the issue of liability protection for clinicians and facilities that adhere to clinical ventilator allocation protocols in a public health crisis. Voluntary guidelines issued by the Department of Health for ventilator allocation provide evidence for an acceptable modified medical standard of care during the dire circumstances of a pandemic. However, there is no guarantee that a court will accept

adherence to the Guidelines as a defense against liability should lawsuits arise, and at this time there is no statutory protection for individuals and institutions for actions taken during a public health emergency. Thus, the Task Force recommends the enactment of new legislation granting the New York State Commissioner of Health authority to adopt a modified medical standard of care specific to the emergency, coupled with civil and criminal liability protections and professional discipline protections for all health care workers and entities who provide care in a pandemic emergency.

The Guidelines recognize that an ethical and clinically sound system for allocating ventilators in a pandemic includes an appeals process. After consideration of a real-time or a retrospective form of review of triage decisions, the Task Force recommends implementing a hybrid system of review – combining limited on-going individual appeals with retrospective, periodic review – which incorporates the advantageous features of both under the constraints of the pandemic. Under this system, individual appeals would be limited to procedural/technical injustices only (e.g., when a withdrawal decision was made without considering all relevant clinical triage criteria) that could remedy a potential injustice prior to the implementation of a triage decision. Retrospectively, all cases would be reviewed periodically to verify adherence the Guidelines, and would enable evaluation of triage decisions to improve subsequent decisions.

Importantly, the clinical ventilator allocation protocols contained in the Guidelines remain untested in actual circumstances; issuing them as binding regulations may produce unforeseen consequences. A clinical ventilator allocation protocol must be designed to allow for sufficient flexibility to adjust to changing clinical information. The static nature of regulation or legislation makes these an inadequate approach for clinically detailed recommendations. For this reason, voluntary guidelines are preferable in this instance.

IX. Conclusion

The Guidelines rely upon both ethical and clinical standards in an effort to offer the best possible care under gravely compromised conditions to support the goal of saving the most lives in an influenza pandemic where there are a limited number of available ventilators.

While the Guidelines will assist a triage officer/committee as they evaluate potential patients for ventilator therapy, decisions regarding treatment should be made on an individual (patient) basis, and all relevant clinical factors should be considered. A triage decision is not performed in a vacuum; instead, it is an adaptive process, based on fluctuating resources and the overall health of a patient. Examining each patient within the context of his/her health status and of available resources provides a more flexible decision-making process, which results in a fair, equitable plan that supports the goal of saving the most lives where there are limited resources.

Because the Guidelines are a living document, intended to be updated and revised in line with advances in clinical knowledge and societal norms, the Task Force and Department of Health will continue to seek feedback from stakeholders and the public. In developing Guidelines for allocating ventilators in the event of an influenza pandemic, the importance of genuine public outreach, education, and engagement cannot be overstated; they are critical to the development of just policies and the establishment of public trust.

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CHAPTER 1

ADULT GUIDELINES

Abstract

A severe influenza pandemic on the scale of the 1918 influenza outbreak will significantly strain medical resources, including ventilators. It has been estimated that during a severe 6-week outbreak, 89,610 influenza patients will require ventilators in New York State and there will not be enough ventilators in the State to meet the demand. A clinical ventilator allocation protocol will need to be implemented to ensure that ventilators are allocated in the most efficient manner to support the goal of saving the greatest number of lives.

In 2007, the New York State Task Force on Life and the Law (the Task Force) and the New York State Department of Health (the Department of Health) released draft ventilator allocation guidelines for adults. New York's innovative guidelines were among the first of their kind to be released in the United States and have been widely cited and followed by other states. Since then, the Department of Health and the Task Force have made extensive public education and outreach efforts and have solicited comments from various stakeholders and the Task Force reexamined and revised the adult guidelines (Adult Guidelines).

The primary goal of the Guidelines is to save the most lives in an influenza pandemic where there are a limited number of available ventilators. To accomplish this goal, patients for whom ventilator therapy would most likely be lifesaving are prioritized. The Guidelines define survival by examining a patient's short-term likelihood of surviving the acute medical episode and not by focusing on whether the patient may survive a given illness or disease in the long-term (e.g., years after the pandemic). Patients with the highest likelihood of survival *without* medical intervention, along with patients with the smallest likelihood of survival *with* medical intervention, have the *lowest* level of access to ventilator therapy. Thus, patients who are most likely to survive without the ventilator, together with patients who will most likely survive with ventilator therapy, increase the overall number of survivors.

There are five components of the ethical framework that underlie the Adult Guidelines. The duty to care is the fundamental obligation for providers to care for patients. The duty to steward resources is the need to responsibly manage resources during periods of true scarcity. The duty to plan is the responsibility of government to plan for a foreseeable crisis. Distributive justice requires that an allocation system is applied broadly and consistently to be fair to all. Transparency ensures that the process of developing a clinical ventilator allocation protocol is open to feedback and revision, which helps promote public trust in the Adult Guidelines.

In order to maintain a clinician's duty to care, a patient's attending physician does not determine whether his/her patient receives (or continues) with ventilator therapy; instead a triage officer or triage committee makes the decision. While the attending physician interacts with and conducts the clinical evaluation of a patient, a triage officer or triage committee does not have any direct contact with the patient. Instead, a triage officer or triage committee examines the data provided by the attending physician and makes the decision about a patient's level of access to a

ventilator. The decision to use a triage officer or committee is left to each acute care facility (i.e., hospital) because available resources will differ at each site.

In addition, the Task Force recognized the pitfalls of an allocation system. These pitfalls include using emergency planning as a method to resolve long-standing disparities in health care access, rigid clinical protocols that are unable to adapt to real-time data, quality of life judgments that may impose on the rights of the disabled, and the reluctance to withdraw ventilators from patients.

In its consideration to protect vulnerable populations, i.e., ventilator-dependent chronic care patients, the Task Force determined that these individuals are subject to the clinical ventilator allocation protocol only if they arrive at an acute care facility for treatment. Once they arrive at a hospital, they are treated like any other patient who requires ventilator therapy. This policy balances the need to protect vulnerable populations with the principle of treating all patients in need of a ventilator equally. The unacceptable alternative would be to triage all stable, long-term ventilator-dependent patients, which may result in likely fatal extubations, and it would violate several principles of the ethical framework underlying the Guidelines.

The Task Force explored various non-clinical approaches to allocating ventilators, including distributing ventilators on a first-come first-serve basis, randomizing ventilator allocation (e.g., lottery), requiring only physician clinical judgment in making allocation decisions, and prioritizing certain patient categories (i.e., health care workers and patients with certain social criteria). However, the Task Force determined that these approaches would not be the best primary method to allocate scarce resources because they are often subjective and/or does not support the goal of saving the most lives. Furthermore, advanced age was rejected as a triage criterion because it discriminates against the elderly. Age already factors indirectly into any criteria that assess the overall health of an individual (because the likelihood of having chronic medical conditions increases with age) and there are many instances where an older person could have a better clinical outlook than a younger person. Thus, the Task Force concluded that a ventilator allocation protocol should utilize clinical factors only to give patients who are deemed most likely to survive with ventilator therapy an opportunity for treatment. After reviewing various clinical protocols, the Task Force developed New York's clinical ventilator allocation protocol for adults.

Before the adult clinical ventilator allocation protocol is implemented, facilities must develop surge capacity to reduce the demand for ventilators when a pandemic is occurring. Steps must be taken to conserve scarce resources, such as equipment and staffing, by limiting elective procedures that require ventilators and by adjusting staff-to-patient ratios. Once the clinical ventilator allocation protocol is implemented, it should apply Statewide to reduce inequalities of ventilator access and distribution among facilities and to ensure that the same resources are available and in use at similarly situated facilities. Furthermore, the adult clinical ventilator allocation protocol applies to all acute care patients in need of a ventilator, whether due to influenza or other conditions.

The adult clinical ventilator allocation protocol applies to individuals 18 years old and older in acute care facilities Statewide and consists of three steps:

- Step 1 – Exclusion Criteria: A patient is screened for exclusion criteria, and if s/he has a medical condition on the exclusion criteria list, the patient is not eligible for ventilator therapy. Instead, a patient receives alternative forms of medical intervention and/or palliative care.

The purpose of applying exclusion criteria is to identify patients with a short life expectancy irrespective of their current acute illness, in order to prioritize patients most likely to survive with ventilator therapy. The medical conditions that qualify as exclusion criteria are limited to those associated with immediate or near-immediate mortality even with aggressive therapy. While selecting medical conditions that qualify as exclusion criteria is challenging, this list makes essential contributions to the goals of efficient ventilator distribution and saving the most lives. In the Draft Guidelines, resource utilization (i.e., renal dialysis) was a consideration, but the revised Adult Guidelines removed resource intensive medical conditions because of the lack of correlation to a patient’s likelihood of survival.

- Step 2 – Mortality Risk Assessment Using SOFA (Sequential Organ Failure Assessment): A patient is assessed using SOFA, which may be used as a proxy for mortality risk. A triage officer/committee examines clinical data from Steps 1 and 2 and allocates ventilators according to a patient’s SOFA score.

A clinical scoring system, SOFA, is used to assess a patient’s likelihood of survival. SOFA is simple to use, with few variables or lab parameters, and the calculation of the score is straightforward, which makes SOFA a good tool to provide a consistent, clinical approach to allocate ventilators. A SOFA score adds points based on clinical measures of function in six key organs and systems: lungs, liver, brain, kidneys, blood clotting, and blood pressure. A patient’s SOFA score determines the level of access (high, intermediate, or low) to ventilator therapy.

- Step 3 – Time Trials: Periodic clinical assessments at 48 and 120 hours using SOFA are conducted on a patient who has begun ventilator therapy to evaluate whether s/he continues with the treatment. The decision whether a patient remains on a ventilator is based on his/her SOFA score and the magnitude of change in the SOFA score compared to the results from the previous official clinical assessment.

Periodic evaluations are necessary to determine whether the therapy is effective for a patient while allowing for efficient allocation of scarce ventilators. Time trials are necessary because they provide as many patients as possible with sufficient opportunity to benefit from ventilator therapy. The use of time trials ensures uniform official assessments and provides valuable information about the status and real-time availability of ventilators. Until data about the pandemic viral strain and clarification of a more precise time trial period for adults become available during a pandemic, 48 and 120 hours were selected at this time.

A triage decision is made based on a patient’s SOFA score, which reveals: (1) the overall prognosis estimated by the patient’s clinical indicators, which is indicative of mortality risk by revealing the presence (or likelihood), severity, and number of acute organ failure(s), and

(2) the magnitude of improvement or deterioration of overall health (i.e., change in SOFA scores compared to the previous official assessment), which provides additional information about the likelihood of survival with ventilator therapy. The results from the current assessment are compared to the results from the previous assessment. The SOFA score itself and any changes in a patient's score after 48 and 120 hours help guide the triage decision. The extent of change in SOFA scores indicates whether a patient is improving, worsening, or experiencing no change in health status. Thus, the guiding principle for the triage decision is that the likelihood of a patient's continuation of ventilator therapy depends on the severity of the patient's health condition and the extent of the patient's medical deterioration. In order for a patient to continue with ventilator therapy, s/he must demonstrate an improvement in overall health status at each official clinical assessment.

The primary difference between the 48 and 120 hour assessment is the extent of improvement in overall health prognosis and of the trajectory of a patient's health status required to continue to be eligible for ventilator therapy. At 48 hours, because a patient has only had two days to benefit from ventilator therapy, the progress required to justify continued ventilator use is not expected to be dramatic. However, after 120 hours, a patient must demonstrate a pattern of *further* significant improvement in health to continue. After the 120 hour clinical assessment, a patient who is eligible to continue with ventilator therapy is reassessed every 48 hours with the SOFA clinical scoring system.

Although additional clinical assessments may be performed, the official SOFA assessments only occur after 48 and 120 hours of ventilator therapy. No formal triage decision or action may be taken until a patient's official assessment. However, at any point during the time trial, even before an official assessment occurs, if a patient develops a condition on the exclusion criteria list and there is an eligible patient waiting, then the ventilator is reallocated. A patient who no longer meets the criteria for continued use receives alternative forms of medical intervention and/or palliative care.

In addition to the three steps described above, additional components of the clinical ventilator allocation protocol include:

Color Codes and Level of Access to Ventilator Therapy: A patient's attending physician provides all clinical data to a triage officer/committee. At Steps 2 and 3, a triage officer/committee examines a patient's clinical data and uses this information to assign a color code to the patient. The color (blue, red, yellow, or green) determines the level of access to a ventilator. Patients with the red color code have the highest level of access to a ventilator.

Blue code patients (lowest access/palliate/discharge) are those who have a medical condition on the exclusion criteria list or those who have a high risk of mortality and these patients do not receive ventilator therapy when resources are scarce. Instead, alternative forms of medical intervention and/or palliative care are provided. However, if more resources become available, patients in the blue color category, or those with exclusion criteria, are reassessed and may be eligible for ventilator therapy. Red code patients (highest access) are those who have the highest priority for ventilator therapy because they are most likely to recover with treatment (and likely to not recover without it) and have a moderate risk of mortality. Patients in the yellow

category (intermediate access) are those who are very sick, and their likelihood of survival is intermediate and/or uncertain. These patients may or may not benefit (i.e., survive) with ventilator therapy. They receive such treatment if ventilators are available after all patients in the red category receive them. Patients in the green color code (defer/discharge) are those who do not need ventilator therapy.

Decision-Making Process for Selecting an Eligible Patient for a Ventilator: In some circumstances, a triage officer/committee must select one of many eligible red color code patients to receive ventilator therapy. A patient's likelihood of survival (i.e., assessment of mortality risk) is the most important consideration when evaluating a patient. However, there may be a situation where multiple patients have been assigned a red color code, which indicates they all have the highest level of access to ventilator therapy, and they all have equal (or near equal) likelihoods of survival. If the eligible patient pool consists of *only adults*, a randomization process, such as a lottery, is used each time a ventilator becomes available because there are no other evidence-based clinical factors available to consider. Patients waiting for ventilator therapy wait in an eligible patient pool and receive alternative forms of medical intervention and/or palliative care until a ventilator becomes available.

Decision-Making Process for Removing a Patient from a Ventilator: There may be a scenario where there is an incoming red code patient(s) eligible for ventilator therapy and a triage officer/committee must remove a ventilator from a patient whose health is not improving. In this situation, first, patients in the blue category (or the yellow category if there are no blue code patients receiving ventilator therapy) are vulnerable for removal from ventilator therapy if they fail to meet criteria for continued ventilator use. If the pool of ventilated patients vulnerable for removal consists of *only adults*, a randomization process, such as a lottery, is used each time to select the (blue or yellow) patient who will no longer receive ventilator therapy. A patient may only be removed from a ventilator after an official clinical assessment has occurred or where the patient develops a medical condition on the exclusion criteria list. However, if all ventilated patients are in the red category (i.e., have the highest level access), *none* of the patients are removed from ventilator therapy, even if there is an eligible (red color code) patient waiting.

Alternative Forms of Medical Intervention and Palliative Care: Patients who have a medical condition on the exclusion criteria list or who no longer meet the clinical criteria for continued ventilator use receive alternative forms of medical intervention and/or palliative care. The same applies to patients who are eligible for ventilator therapy but for whom no ventilators are currently available. Alternative forms of medical intervention, such as other methods of oxygen delivery and pharmacological antivirals, should be provided to those who are not eligible or waiting for a ventilator. However, the use of ambu-bags for manual ventilation is discouraged for several reasons: the technique may not be effective against pandemic influenza, it may contribute to transmission of the virus, and possible isolation/quarantine orders, lack of health care staff, and burden on the families may make it difficult to conduct for extended periods of time. Actively providing palliative care, especially to patients who do not or no longer qualify for ventilator therapy, decreases patient discomfort and fulfills the provider's duty to care, even when the clinician cannot offer ventilator therapy.

Logistics regarding Implementation of the Guidelines: Once the Guidelines are implemented, there must be communication about triage, and real-time data collection and analysis to modify the Guidelines based on new information. Efforts will be made to inform and gather feedback from the public before a pandemic. Public outreach will inform people about the goals and steps of the clinical ventilator allocation protocols. Information should emphasize that pandemic influenza is potentially fatal, that health care providers are doing their best with limited resources, and that the public must adjust to a different way of providing and receiving health care than is customary. Instead, a protocol based only on clinical factors will be used to determine whether a patient receives (or continues with) ventilator therapy to support the goal of saving the greatest number of lives in an influenza pandemic where there are a limited number of available ventilators. Patients and families should be informed that ventilator therapy represents a *trial* of therapy that may not improve a patient's condition sufficiently and that the ventilator will be removed if this approach does not enable the patient to meet specific criteria.

Data collection and analysis on the pandemic viral strain, such as symptoms, disease course, treatments, and survival, are necessary so that the clinical ventilator allocation protocol may be modified accordingly to ensure that patients receive the best care possible. In addition, data collection must include real-time availability of ventilators so that triage decisions are made to allocate resources most effectively. Knowing the exact availability of ventilators also assists a triage officer/committee in providing the most appropriate treatment options for patients.

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I. Introduction

Although influenza pandemics occur with unpredictable frequency and severity, experts acknowledge that an influenza pandemic is probable and foreseeable. The better prepared New York State is, the greater its chances of reducing morbidity, mortality, and economic consequences of a severe influenza pandemic.¹

A. Development of the 2007 Draft Guidelines for Adults

Both federal and state governments have drafted plans for a possible pandemic. In 2005, the federal Department of Health and Human Services (HHS) released its first of many pandemic influenza preparedness plans, which offers an assessment of public health and medical preparedness, as well as guidance to state and local health departments.² The New York State Department of Health (the Department of Health) released its draft preparedness plan for pandemic influenza in February 2006, updated it in 2008, and a revision is forthcoming.³ The State plan includes a review of actions to be taken by health officials, emergency responders, and health care providers during a pandemic.

Although the Department of Health addressed the myriad of issues with emergency planning for an influenza pandemic in the State plan's first iteration, in March 2006, the Department requested that the New York State Task Force on Life and the Law (the Task Force)⁴ consider ethical and clinical issues in the allocation of ventilators in an influenza pandemic. To assist with this directive, the Task Force convened a workgroup (the 2006 Adult Clinical Workgroup), whose membership was comprised by experts in law, medicine, policy, and ethics. The 2006 Adult Clinical Workgroup had representatives from medical facilities and city, county, and state government to address allocation of scarce resources during an influenza pandemic.⁵ The goal of this workgroup was to develop recommendations to guide health care professionals and others to allocate ventilators in a public health emergency in a manner consistent with ethical principles while maximizing the number of survivors.

B. Release of the 2007 Draft Guidelines for Adults

In March 2007, a draft of the ventilator guidelines (the Draft Guidelines) was released for public comment. The Draft Guidelines were featured in several media outlets, including the *New*

¹ Although this document is intended to respond to the allocation of ventilators during an influenza pandemic, the general framework could be adapted – with appropriate modifications – to any public health emergency where resources will be scarce. These guidelines use the term pandemic to reference a pandemic caused by the influenza virus.

² United States Department of Health and Human Services, *HHS Pandemic Influenza Plan*, <http://www.flu.gov/planning-preparedness/federal/hhsPandemicInfluenzaPlan.pdf>

³ For general information about pandemic influenza by the New York State Department of Health, see <http://www.health.ny.gov/diseases/communicable/influenza/pandemic/>

⁴ Established by Executive Order in 1985, the Task Force is comprised of 23 Governor-appointed leaders in the fields of religion, philosophy, law, medicine, nursing, and bioethics. The Task Force develops public policy on issues arising at the interface of medicine, law, and ethics, and has issued influential reports on cutting-edge bioethics issues. See Appendix A for a list of the Task Force members who participated in this project.

⁵ See Appendix B for a list of the 2006 Adult Clinical Workgroup members.

York Times.⁶ In addition, a summary of the Draft Guidelines was published in the peer-reviewed journal, *Disaster Medicine and Public Health Preparedness* in an effort to foster further dialogue.⁷ The Draft Guidelines were cited and discussed extensively in the academic literature⁸ and served as a model for many states' ventilator allocation plans.⁹

1. Public Outreach Efforts

The Task Force and the Department of Health recognized the importance of public engagement and outreach to not only inform the public but to also gather feedback to modify the Guidelines.¹⁰ For an allocation system such as the Guidelines to be accepted by the public, the

⁶ See Cornelia Dean, *Guidelines for Epidemics: Who Gets a Ventilator?*, N.Y. TIMES (March 25, 2008), <http://www.nytimes.com/2008/03/25/health/25vent.html?n=Top%2fReference%2fTimes%20Topics%2fSubjects%2f%2fInfluenza>; Sheri Fink, *Worst Case: Choosing who Survives in a Flu Epidemic*, N.Y. TIMES (Oct. 24, 2009), <http://www.nytimes.com/2009/10/25/weekinreview/25fink.html?ref=influenza>.

⁷ Tia Powell et al., *Allocation of Ventilators in a Public Health Disaster*, 2 DISASTER MED. PUB. HEALTH PREP. 20 (2008).

⁸ See, e.g., Asha V. Devereaux et al., *Definitive Care for the Critically Ill During a Disaster: A Framework for Allocation of Scarce Resources in Mass Critical Care: From a Task Force for Mass Critical Care Summit Meeting, January 26–27, 2007, Chicago, IL*, 133 CHEST 51S, 51S-66S (2008b) (hereinafter Devereaux, *Definitive Care for the Critically Ill During a Disaster*); Lewis Rubinson et al., *Allocating Mechanical Ventilators During Mass Respiratory Failure: Kudos to New York State, but More Work to be Done*, 2 DISASTER MED. PUB. HEALTH PREP. 7-9 (2008); Institute of Medicine, *Guidance for Establishing Crisis Standards of Care for Use in Disaster Situations*, 86 Washington, DC (Bruce Altevogt et al. eds., The National Academies Press 2009); Douglas White et al., *Who Should Receive Life Support During a Public Health Emergency? Using Ethical Principles to Improve Allocation Decisions*, 150 ANN. INTERN. MED. 132-38 (2009); Centers for Disease Control and Prevention, *Ethical Considerations for Decision Making Regarding Allocation of Mechanical Ventilators during a Severe Influenza Pandemic or Other Public Health Emergency*, (July 1, 2011), http://www.cdc.gov/od/science/integrity/phethics/docs/Vent_Document_Final_Version.pdf. In addition, the CHEST Task Force for Mass Critical Care from 2008 reconvened in 2012 and 2013 to update the 2008 recommendations. The Task Force for Mass Critical Care released articles that issued recommendations for the management of all critically ill adults and children resulting from a mass casualty event and not primarily focused on caring for patients in an ICU setting. The articles address surge capacity principles; surge capacity logistics; evacuation of an ICU; triage; special populations; system-level planning, coordination, and communication; business and continuity of operations; engagement and education; legal preparedness; ethical considerations; resource-poor settings; infrastructure and capacity building; and resource-poor settings: response, recovery, and research. See Michael D. Christian et al., *Introduction and Executive Summary Care of the Critically Ill and Injured During Pandemics and Disasters: CHEST Consensus Statement*, 146(4 Suppl.) CHEST 8S-34S (2014).

⁹ See e.g., New Mexico Health Policy Comm'n, *House Memorial 71, Healthcare Professional Disaster Response: Legal and Ethical Considerations for Healthcare Professionals during Catastrophic Disasters or Public Health Emergencies* (2009) (includes New York Draft Guidelines as Appendix B); South Carolina Pandemic Influenza Ethics Task Force, *South Carolina Prepares for Pandemic Influenza: An Ethical Perspective* (September 2009).

¹⁰ See e.g., Public Health – Seattle & King County, *Public Engagement Project on Medical Service Prioritization During an Influenza Pandemic* (Sept. 2009), <http://www.kingcounty.gov/healthservices/health/preparedness/%7e/media/health/publichealth/documents/pandemicflu/MedicalServicePrioritization.ashx>. See also Elizabeth L. Daugherty Biddison et al., *The Community Speaks: Understanding Ethical Values in Allocation of Scarce Lifesaving Resources during Disaster*, 11 ANN. AM. THORACIC SOC. 777-783 (2014) (noting that preparedness planning efforts should include public engagement to incorporate the life experiences of individuals from diverse communities. In addition, members of the public are able to engage in the planning process in a productive and thoughtful manner, which helps planners as they refine their emergency plans and their approach to informing the public once the plans are completed.) Similarly, the 2011 public engagement project by the Task Force was useful in gathering input from the public as the Adult Guidelines were being revised and the Pediatric and Neonatal Guidelines were being developed.

public and stakeholders need to be able to provide input so that the Guidelines reflect the public's values and goals. The public has an important role in developing and revising the Guidelines to ensure that the allocation system is fair and in line with advances in clinical knowledge and societal norms so that patients receive the most appropriate care.

The Draft Guidelines were published in the State Register and on the Department of Health's website with instructions on how to submit comments, and letters were sent to stakeholders to introduce the Draft Guidelines and gather feedback. The Department of Health and Task Force staff made extensive Statewide efforts to solicit input on the Draft Guidelines and to raise public awareness about the potential threat of an influenza outbreak.

Public outreach efforts included numerous public presentations on the Draft Guidelines at professional medical associations, bar associations, and medical centers. In addition, Task Force staff conducted meetings with regional hospitals and local health departments, a videoconference for county health officials and senior hospital administrators, and continuing medical education audioconferences.

The content of the Draft Guidelines was also presented for comment at community meetings on pandemic influenza preparedness and tabletop exercises with health care and allied professionals. In 2008, the Department of Health held four community meetings on general influenza pandemic preparedness, where the issue of a potential ventilator shortage was presented and discussed.¹¹ In 2009, the Department of Health conducted three tabletop exercises with health care providers in the New York City metropolitan area to discuss the Draft Guidelines and receive feedback from the stakeholders.

The Task Force and Department of Health also undertook focus groups throughout the State to solicit public feedback to the Draft Guidelines. In 2008, the Department of Health oversaw its first focus group in Albany, and in 2011 the Task Force staff planned and oversaw an extensive community engagement project comprised of 13 focus groups conducted across the State.¹²

The solicitation of public comment was not limited to New York State residents, and efforts to reach a national audience of hospitals and clinicians were extremely successful. Task Force and Department of Health staff presented the Draft Guidelines at professional conferences nationally.¹³ To further contribute to the national dialogue, members of the various Clinical

¹¹ The community meetings were held in the counties of Albany, Cortland, Chautauqua, and Nassau. Each meeting consisted of 25-50 participants.

¹² These focus groups were conducted by a third party vendor. The focus groups were held in Albany, Long Island, Syracuse, Westchester, Buffalo, and New York City. The participants were a demographically representative mix of age, race, employment, education, and income that mirrored each region. Groups included different combinations of participants who had a personal experience with illness, as well as specific groups composed of a common demographic.

¹³ For example, conferences where the Draft Guidelines were presented for comment included: "Confronting the Ethics of Pandemic Planning: The Summit of the States," (2008), the Institute of Medicine Workshop on "Altered Standards of Care in A Mass Casualty Event" (2009), the American Medical Association's "Third National Congress on Health System Readiness" (2009), the Public Health Preparedness Summit (2011), and the American Society for Bioethics and Humanities Annual Meeting (2011 and 2012).

Workgroups have lent their expertise to federal planning efforts, such as those undertaken at the Institute of Medicine and the Centers for Disease Control and Prevention (CDC).

C. Updates to the 2015 Ventilator Allocation Guidelines

Following the release of the Draft Guidelines, the Task Force: (1) reexamined the Draft Guidelines within the context of the public comments and feedback received, (2) developed guidelines for triaging pediatric and neonatal patients, and (3) expanded its analysis of the various legal issues that may arise when implementing the clinical protocols for ventilator allocation.

To address public comments to the adult clinical ventilator allocation protocol, an additional adult Clinical Workgroup was convened in 2009.¹⁴ Members discussed the public comments and made recommendations to refine specific aspects of the clinical ventilator allocation protocol. Furthermore, the Task Force made additional recommendations to elaborate and expand certain sections, in order to include a more robust discussion of the reasoning and logic behind certain features of the protocol. Finally, public feedback from more recent outreach efforts was also incorporated. These revisions appear below as the revised adult guidelines (the Adult Guidelines).

The Task Force approached the pediatric ventilator allocation guidelines (the Pediatric Guidelines) in two stages. First, the Task Force addressed the special considerations for pediatric and neonatal emergency preparedness and the ethical issues related to the treatment and triage of children in a pandemic, with particular focus on whether children should be prioritized for ventilator treatment¹⁵ over adults. Second, the Task Force convened a pediatric clinical workgroup (the Pediatric Clinical Workgroup) to develop a clinical ventilator allocation protocol for pediatric patients.¹⁶ The Pediatric Clinical Workgroup consisted of specialists in pediatric, neonatal, emergency, and maternal-fetal medicine, as well as in critical care, respiratory therapy, palliative care, public health, and ethics from across New York State. The Pediatric Clinical Workgroup met numerous times in person and also provided comments by e-mail and telephone.¹⁷

In addition to the Pediatric Workgroup, the Task Force organized a neonatal clinical workgroup (the Neonatal Clinical Workgroup), consisting of neonatal and maternal-fetal specialists, who met via teleconference to discuss and develop neonatal guidelines (the Neonatal Guidelines).¹⁸

Finally, although the Draft Guidelines contained a section on the various legal matters associated with effectively implementing the guidelines, this section did not sufficiently address the myriad of legal issues that may arise. Accordingly, a legal issues committee was organized

¹⁴ See Appendix B for a list of the 2006 and 2009 Adult Clinical Workgroup members.

¹⁵ The terms “ventilator treatment” is used interchangeably with “ventilator therapy.”

¹⁶ See Chapter 2, Pediatric Guidelines, for a list of the pediatric workgroup members.

¹⁷ Meetings were held in November 2009, March 2012, May 2012, July 2012, September 2012, January 2013, two meetings in February 2013, and a conference call in March 2013.

¹⁸ See Chapter 3, Neonatal Guidelines, for a list of the neonatal workgroup members. Conference calls were held in February, March, April, October, and November 2013.

in 2008.¹⁹ Thus, the brief summary on legal issues from the 2007 Draft Guidelines is replaced with a substantial discussion.²⁰

As a result of these efforts, the Ventilator Allocation Guidelines (the Guidelines)²¹ incorporate comments, critiques, feedback, and values by numerous stakeholders, including the general public and experts in the medical, ethical, legal, and policy fields. The Guidelines draw upon the expertise of the initial and subsequent workgroups, literature review, public feedback, and insightful commentary.

However, because the Guidelines are a living document, intended to be updated and revised in line with advances in clinical knowledge and societal norms, the Task Force and the Department of Health will continue to seek feedback from clinicians and the public. The Guidelines will be posted on the Department of Health's website and extensive public outreach and education efforts will be made. In developing a protocol for allocating scarce resources in an influenza pandemic, the importance of genuine public engagement cannot be overstated; it is critical to the development of just policies and the establishment of public trust.

II. Background

Influenza is a respiratory disease caused by flu viruses. Most people are familiar with seasonal influenza, and although it often results in a large number of deaths, it can be predicted and managed with planning. However, pandemic influenza is not predictable and its impact can be devastating.

A. Seasonal Influenza

Despite the availability of vaccines and immunity present in the population, each year, seasonal influenza kills 250,000 – 500,000 people worldwide.²² Each year in the United States, seasonal influenza is associated with approximately 34,000 deaths,²³ over 200,000 hospitalizations²⁴ and \$6.7 billion in economic costs.²⁵ Despite the availability of adequate health care resources, such as vaccines and antiviral drugs, a large number of the very young and

¹⁹ The legal issues committee met in January 2008.

²⁰ See Chapter 4, Implementing New York State's Ventilator Allocation Guidelines: Legal Considerations.

²¹ The Ventilator Allocation Guidelines consist of four chapters: (1) Adult Guidelines (contained here), (2) Pediatric Guidelines, (3) Neonatal Guidelines, and (4) Implementing New York State's Ventilator Allocation Guidelines: Legal Considerations.

²² World Health Organization, *Influenza (Seasonal): Fact Sheet No. 211* (2014), www.who.int/mediacentre/factsheets/fs211/en/.

²³ This figure represents the mean annual deaths in the U.S. from influenza and influenza-related conditions including pneumonia, and respiratory and circulatory dysfunction from 1976 through 1999. See William Thompson et al., *Mortality Associated with Influenza and Respiratory Syncytial Virus in the United States*, 289 JAMA 179, 182 (2003) (hereinafter Thompson, *Mortality Associated with Influenza*).

²⁴ This figure represents the average influenza-related hospitalizations in the U.S. from 1979 through 2001. See William Thompson et al., *Influenza-Associated Hospitalizations in the United States*, 292 JAMA 1333, 1335 (2004).

²⁵ See The World Bank, *People, Pathogens and Our Planet: Volume 2*, Report Number 69145-GLB 1 (2012), www.wds.worldbank.org/external/default/WDSContentServer/WDSP/IB/2012/06/12/000333038_20120612015653/Rend ered/PDF/691450ESW0whit0D0ESW120PPPvol120web.pdf.

elderly (i.e., more vulnerable populations) die every year.²⁶ The outbreaks of seasonal influenza are predictable and run from November through March. Although vaccines are available, in the 2013-2014 influenza season only 46.2% of American adults and children older than 6 months received an annual vaccination.²⁷

B. Pandemic Influenza

Pandemics vary widely in the number of people affected, the severity of disease, and specific populations selectively targeted by the disease. A pandemic is generally defined as an illness that extends over a wide geographic area and affects a significant proportion of the population.²⁸ According to the World Health Organization (WHO), there are three prerequisites for a pandemic: (1) emergence of a new virus to which there is little or no immunity, (2) virus replication that can cause serious illness in humans, and (3) efficient human-to-human transmission.²⁹ Because such a virus is new and there is no vaccine available immediately, efficient transmission could have a devastating global impact. Pandemics differ from seasonal influenza because pandemic outbreaks are rare and unpredictable, healthy people are at risk for complications and death, and depending on the severity of the pandemic, health care systems are not able to address the needs of the increased number of critically ill patients.³⁰

There have been four influenza pandemics during the 20th century. The 1918 influenza was the deadliest, killing an estimated 40 – 50 million people worldwide, when the world population was less than a third of today's population.³¹ The influenza pandemics of 1957 and 1968 were less severe, causing an estimated two million and one million deaths, respectively.³² Unlike seasonal influenza, which affected the very young, elderly, and individuals with compromised health, pandemics may target a specific group. For example, the 1918 pandemic primarily affected healthy young adults and this group suffered the largest percentage of deaths.³³

Generally, influenza viruses are highly species-specific, meaning that viruses that infect an individual species (humans, certain species of birds, pigs, horses, and seals) stay 'true' to that species, and only rarely spill over to cause infection in other species. The three pandemics described above likely resulted from a virus that contained genetic material from human and

²⁶ See Thompson, *Mortality Associated with Influenza*, *supra* note 23, at 179.

²⁷ See Centers for Disease Control and Prevention, *Flu Vaccination Coverage, United States, 2013-14 Influenza Season*, 3 (2014) <http://www.cdc.gov/flu/pdf/fluview/vax-coverage-1314estimates.pdf>. Every year, the seasonal influenza vaccine protects against three or four different strains of the virus, based on predictions experts believe will be the most virulent strains affecting humans. See Centers for Disease Control and Prevention, *Selecting the Viruses in the Seasonal Influenza (Flu) Vaccine: Questions and Answers* (2014) <http://www.cdc.gov/flu/professionals/vaccination/virusqa.htm>.

²⁸ See David Morens et al., *What is a Pandemic?*, 200 J. INFECT. DIS. 1018 (2009).

²⁹ World Health Organization, *Pandemic Influenza Preparedness and Response*, 14 (2009), www.who.int/influenza/resources/documents/pandemic_guidance_04_2009/en/index.html.

³⁰ See United States Department of Health and Human Services, *About Pandemics*, www.flu.gov/pandemic/about/index.html#.

³¹ John M. Barry, *The Great Influenza: The Story of the Deadliest Pandemic in History* 452 (rev. ed. 2004).

³² *Id.*

³³ See Jeffery K. Taubenberger & David Morens, *1918 Influenza: The Mother of All Pandemics*, 12 EMERG. INFECT. DIS. 15, 19 (2006).

avian viral strains that the human body did not recognize.³⁴ The most commonly known strains of influenza are avian flu (H5N1) and the novel H1N1 (i.e., swine flu). The highly pathogenic avian influenza (HPAI) subtype H5N1, which emerged in 1997, is one of few HPAI viruses that crossed the species barrier to infect humans.³⁵ While the H5N1 avian influenza has caused some concern because of reported human cases which resulted in death, this strain rarely affects humans.³⁶ The novel H1N1 strain appeared in Spring 2009, and while it was readily transmitted between humans, this particular strain was not extremely lethal. It resulted in fewer deaths compared to other influenza pandemics, with nearly 20,000 deaths in confirmed cases worldwide.³⁷

Although a significant mutation in an influenza virus is rare, when such a change happens, people have little or no immunity and a dangerous pandemic can occur. At any time, any influenza viral strain could evolve into a more or less hazardous form. Unlike seasonal influenza, there will be no vaccine available to the public for a pandemic viral strain early in a pandemic, and vaccines produced to thwart yearly seasonal influenza outbreaks will be ineffective. While an influenza pandemic on the scale of the 1918 pandemic has not occurred, public health officials acknowledge that an outbreak of this magnitude is likely to occur, and emergency preparedness plans must be developed to address this foreseeable event.

An influenza pandemic will likely result in an overwhelming number of patients who are critically ill, commonly presenting symptoms such as high fever, lower respiratory tract infection, abdominal pain, diarrhea, and vomiting. Pneumonia, acute respiratory distress syndrome, and multi-organ failure are probable for many influenza patients and a ventilator, a device that facilitates breathing for patients experiencing respiratory failure, will be needed.

C. Ventilators and Surge Capacity

There are various types of ventilators that can support adults and/or children, depending on the ventilator's circuitry and measurement values.³⁸ Some ventilators are suitable for adults, children, and neonates, while others are only usable for one segment of the population.³⁹

³⁴ World Health Organization, *Avian influenza: assessing the pandemic threat*, 18 (2005) whqlibdoc.who.int/hq/2005/WHO_CDS_2005_29.pdf.

³⁵ H5N1 virus is highly contagious in wild waterfowl and can easily infect domestic poultry. Bird-to-human transmission has occurred, mostly via direct human contact with the secretions and/or excretions of infected poultry. See World Health Organization, *Avian influenza: significance of mutations in the H5N1 virus* (2006), http://www.who.int/csr/2006_02_20/en/; and Centers for Disease Control and Prevention, *Avian Influenza A Virus Infections in Humans*, (2014) www.cdc.gov/flu/avianflu/avian-in-humans.htm.

³⁶ Human-to-human transmission is inefficient and limited. However, the virus is adept at mutating and can gain the ability to spread among humans after initial bird-to-human transmission. Highly pathogenic avian influenza is associated with a range of illnesses, from conjunctivitis only, to serious respiratory illness with multiple organ failure and can lead to death. *Id.*

³⁷ See World Health Organization, *Pandemic (H1N1) 2009 – Update 112* (August 6, 2010), http://www.who.int/csr/don/2010_08_06/en/index.html.

³⁸ The two most common ventilators are bed-side and transport ventilators. Bed-side ventilators are stationary machines while transport ventilators can be moved with a patient.

³⁹ While some “adult” ventilators could be modified for children, not all facilities have the software, equipment, and skilled staff to ventilate pediatric patients. See Lewis Rubinson et al., *Mechanical Ventilators in US Acute Care Hospitals*, 4 DISASTER MED. PUB. HEALTH PREP. 199, 203-204 (2010). In addition, equipment for pediatric patients must account for a wide range of sizes, from young infants to teenagers. Furthermore, it may be difficult to adapt

Currently, New York State has 7,241 ventilators available in acute care facilities, of which approximately 2% are restricted for neonatal patients only; 8% are suitable for pediatric patients only; 50% could support either an adult or pediatric patient (“dual-use” ventilators); and nearly 41% are for adult patients only.⁴⁰ In addition, 1,750 ventilators are stockpiled,⁴¹ which can be used for pediatric or adult patients, bringing the total number of ventilators available to 8,991.⁴²

During an influenza pandemic, with the dramatic increase of patients requiring ventilator therapy, facilities should institute all available means of creating “surge capacity,” particularly for ventilators, to reduce the demand for ventilators. During non-emergency, normal conditions, there is an 85% utilization rate of ventilators in acute care facilities, leaving only 15% of ventilators available. Efforts should be made to increase the number of available ventilators. For example, as the pandemic spreads, hospitals should limit the non-critical use of ventilators. Elective procedures should be canceled and/or postponed during the period of emergency. As a pandemic stretches from days to weeks, facilities will require a review system for procedures that decrease morbidity or mortality, but are not of an emergency nature. In addition, outpatient procedures that require a back-up option of hospital admission and ventilator therapy if complications arise may be limited.

In addition to ventilators, facilities should address surge capacity for other important components of the health care system, including staff and medical equipment and supplies. Staffing issues are critical, because personnel are the most valuable resource in any health care facility. Staff members may become ill, leave work to care for loved ones, or decline to serve from fear of contagion. Alternate levels of staffing (i.e., patients to staff ratio) should be permitted during the pandemic emergency, and systems for extending the skills of available staff must be utilized. Furthermore, the stockpiling of protective personnel equipment, including masks and gloves, is a critical planning responsibility for facilities. Without adequate protective measures, facilities may undermine their capacity to provide adequate staffing during a public health emergency.

Surge capacity could also be assisted by activating systems for sharing information about the number and severity of influenza cases, equipment availability, and staffing shortages throughout hospital systems and regional networks. For instance, not all facilities may be equipped to care for infants who need ventilator treatment; clinicians need rapid access to information about where such support is available.

these machines for neonates and small infants. Desmond Bohn et al., *Supplies and Equipment for Pediatric Emergency Mass Critical Care*, 12 PEDIATR. CRIT. CARE MED. S120, S121, S123 (2011).

⁴⁰ Ventilators used for neonates and young children are specific to the age and/or weight of a patient and cannot be used for older adolescents or adults. Of the 7,241 ventilators in New York State, 124 ventilators can only support neonates, 731 can only support pediatric patients, 2,717 can support either children or adults, and 3,669 can only support adult patients. New York State Department of Health, Office of Health Emergency Preparedness Program, *Critical Assets Survey*, September 2015.

⁴¹ A small number (566) of these stockpiled ventilators already have been distributed to hospitals for daily use. The remainder is in storage facilities. *Id.*

⁴² *Id.*

D. Estimates of the Possible Impact of Pandemic Influenza in New York State

The Department of Health has examined moderate and severe pandemic influenza outbreak scenarios to estimate the potential impact and ventilator need at acute care facilities during a pandemic. These two scenarios were modeled using software developed by the Centers for Disease Control and Prevention (CDC), FluSurge 2.0.⁴³ The moderate scenario is based on the characteristics of the 1957 and 1968 influenza pandemics. The severe scenario, which is meant to approximate the 1918 pandemic, is based on applying a multiplier (approximately 8.22) to the moderate scenario.⁴⁴

The following baseline assumptions were made for the models:

- (1) a vaccine specific to the pandemic viral strain will not be available for at least six months, and will be in short supply thereafter,
- (2) antiviral medications may be ineffective and in short supply,
- (3) the attack rate (percentage of people with pandemic influenza out of the total population at risk) will vary, but may be as high as 35%, with an outbreak duration as short as six weeks,⁴⁵
- (4) a 3% increase in patients will be arriving at a hospital compared to the previous day,⁴⁶
- (5) 70% of deaths related to pandemic influenza are projected to occur in a hospital,⁴⁷
- (6) 7.5% of the admitted patients with pandemic influenza will require ventilators,⁴⁸
- (7) the population of New York State is 19,651,127,⁴⁹
- (8) there are currently 7,241 ventilators in acute care settings in New York State,⁵⁰
- (9) there are currently 1,750 stockpiled ventilators available at all times that may be used during a pandemic, for a total of 8,991 ventilators in the State,⁵¹ and
- (10) at any given time, 85% of the ventilators (6,154) in acute care settings are in use (i.e., 15% of ventilators (1,086) in acute care settings are available).⁵²

⁴³ FluSurge 2.0 is a program designed to provide estimates of the surge in demand for hospital-based services. FluSurge estimates the number of hospitalizations and deaths of an influenza pandemic (of which length and attack rates are determined by the user) and compares the number of persons hospitalized, the number of persons requiring ICU care, and the number of persons requiring ventilator therapy during a pandemic with existing hospital capacity. See CDC, FluSurge 2.0, updated Aug. 31, 2011, <http://www.cdc.gov/flu/pandemic-resources/tools/flusurge.htm>.

⁴⁴ Other than death rate (which was 8.22 times higher during the 1918 pandemic than during the moderate pandemics of 1957 and 1968), the characteristics of the 1918 pandemic are unknown.

⁴⁵ The assumptions were from the CDC. See Xinshi Zhang, Martin I. Meltzer, and Pascale M. Wortley, *FluSurge – A Tool to Estimate Demand for Hospital Services During the Next Pandemic Influenza*, 26 MED. DECISION MAKING (2006), 617, 618. These numbers were used in the FluSurge 2.0 model to produce a short pandemic of high intensity and maximum hospital surge.

⁴⁶ The assumption was from the CDC. *Id.*

⁴⁷ *Id.*

⁴⁸ *Id.*

⁴⁹ From July 1, 2013 New York State population estimates. See U.S. Census Bureau, American FactFinder, New York, http://factfinder2.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=PEP_2013_PEPAGESEX&prodType=table

⁵⁰ New York State Department of Health, Office of Health Emergency Preparedness Program, *Critical Assets Survey*, September 2015.

⁵¹ *Id.*

⁵² *Id.*

1. Moderate Pandemic Scenario

Table 1 presents a moderate influenza pandemic scenario using midpoint estimates. Using the assumptions above, 19,799 total influenza-related deaths could be anticipated over the duration of a six week pandemic. In addition, there could be 97,791 total influenza-related hospital admissions. More than 10,896 cumulative influenza patients would need ventilator treatment and 2,264 would need them simultaneously at the peak of the moderate pandemic. Because 15% of hospital-owned ventilators are assumed available at any given time and the State has stockpiled 1,750 ventilators, there could be a projected *surplus* of ventilators during peak week demand (+572) during a moderate influenza pandemic that has the characteristics assumed above.⁵³ While there may be a surplus of ventilators using data points projecting the most likely scenario in a moderate pandemic, data points using other possible characteristics of a moderate pandemic likely would result in a *shortfall* of ventilators.⁵⁴ In addition, the model does not differentiate between the supply of and demand for pediatric or adult ventilators, although some “dual-use” ventilator can support either an adult or a child.

2. Severe Pandemic Scenario

Although data from the 1918 pandemic are scant and the available models were not designed to predict a severe influenza pandemic scenario, Table 1 also presents a severe scenario using one suggested but unvalidated approach. This approach uses a “scaling factor” applied to the moderate scenario’s health outcomes to calculate possible outcomes under a severe scenario.⁵⁵ However, using this approach,⁵⁶ more than 162,000 influenza-related deaths could

⁵³ The 2007 Draft Guidelines projected a ventilator shortfall of 406 during the peak week of a moderate pandemic. However, since the 2007 Draft Guidelines, the total number of ventilators in the State has increased by approximately 2,000, and this increase has eliminated the previous estimate of a shortage of ventilators.

⁵⁴ For this criteria, FluSurge 2.0 does not estimate a maximum shortfall/surplus of ventilators during a peak week.

⁵⁵ The proposed scaling factor of 8.224143 was calculated by dividing the age-adjusted death rate during the 1918 pandemic by the age-adjusted death rate during the 1968 pandemic while assuming a 15% clinical attack rate. Other health outcomes (e.g., hospital admissions or need for ventilators) are calculated by using the same scaling factor, however, there are no data to suggest that such an approach is reasonable. See Martin I. Meltzer, *Basic Instructions and Template of Draft Report: Using FluAid and FluSurge to Estimate the Potential Impact of the Next Influenza Pandemic upon Locale Y* (Mar. 22, 2006), 35-37, <http://www.cdc.gov/flu/pandemic-resources/tools/downloads/pandemic-impact-estimate-instructions.pdf>.

⁵⁶ It is reasonable to assume that during a severe influenza pandemic there would be a significant shortage of ventilators and there will be a need to devise a plan to ethically allocate ventilators. However, the exact figures derived from the severe scenario calculations should be interpreted with caution for several interrelated reasons. First, characteristics of the 1918 pandemic such as rates of infection or hospitalization are unknown and thus the severe scenario was estimated based only upon the differences in death rates. Second, if the 1918 pandemic were to occur today, outcomes such as mortality rate might be much lower because the health care landscape is much different. Modern influenza treatments (e.g., ventilators) and infection control techniques, if they were available in 1918, might have dramatically reduced infection and mortality rates. Likewise, it is probably not reasonable to project the death rate from 1918 onto today’s population. Last, the scaling factor (approximately 8.22) was derived by comparing death rates between the severe and moderate pandemics. This approach “works backward” from deaths, which given modern medicine might not be as high as observed in 1918. Unfortunately, the lack of data from the 1918 pandemic prevents an approach to “work forward” from infection rates, illness severity, and duration of illness to the number of ventilators that might be needed simultaneously in a severe pandemic. Given these caveats, it is likely not possible to accurately calculate the impact of a severe pandemic, including ventilator need, given the tools provided. Given these disclaimers, it is likely that the approach used overestimates the number of ventilators that would be needed during a severe pandemic.

occur. In addition, there could be 804,247 total influenza-related hospital admissions during the course of the pandemic. More than 89,610 cumulative influenza patients would need ventilator treatment and 18,619 would need them simultaneously at the peak of the severe pandemic. Because the baseline assumption that 85% of ventilators in an acute care setting are in use during any given (non-pandemic) week, during a severe influenza pandemic, there is likely to be a projected *shortfall* of ventilators (-15,783) during peak week demand.

Table 1
Moderate and Severe Influenza Pandemic Scenarios

Features	Moderate Scenario (1957/1968-like)¹	Severe Scenario (1918-like)²
Total Influenza-Related Hospital Admissions ³	97,791	804,247
Peak Week Influenza-Related Admissions	20,536	168,891
Peak Influenza-Related Admissions per Day	3,200	26,317
Peak Week Number of Influenza-Related Hospitalized Patients	15,631	128,552
Total Influenza-Related Deaths	19,799	162,830
Total Influenza-Related Deaths in Hospital	13,860	113,987
Peak Week Influenza-Related Deaths	4,158	34,196
Peak Week Influenza-Related Deaths in Hospital	2,911	23,940
Total Patients Requiring Ventilators	10,896	89,610
Peak Week Ventilator Need	2,264	18,619
Total Ventilators in the State ⁴	8,991	8,981
Available Ventilators at Any Given Time ⁵	2,836	2,836
Ventilator Shortfall or Surplus in Peak Week⁶	+572	-15,783

¹ Midpoint Estimates from FluSurge 2.0

² Severe scenario calculated by multiplying each row by 8.224143

³ Includes all influenza patients (i.e., those who survive and die while hospitalized)

⁴ Includes stockpiled ventilators (1,750)

⁵ Assumes 85% routine utilization rate (i.e., 15% of hospital-owned ventilators are routinely available) and includes the 1,750 stockpiled ventilators

⁶ Available Ventilators at Any Given Time minus Peak Week Ventilator Need

If an influenza pandemic on the scale of the 1918 pandemic were to occur, it is possible that New York would face a significant shortage of ventilators. Because influenza pandemics are unpredictable and their impact unknown in advance of the pandemic, officials must consider and plan for a worst-case scenario.

E. Stockpiling Ventilators

New York State pandemic planning includes careful consideration of the potential shortage of ventilators, based on the estimates discussed above. There is a federal government stockpile of ventilators, but its use is limited for any one locality; there are not enough ventilators to be distributed to meet demand if many regions need them at once.

New York State has stockpiled 1,750 ventilators⁵⁷ to help reduce ventilator need in the face of the moderate scenario;⁵⁸ however, there are no current plans to buy enough ventilators for the most severe model. The State's current approach to stockpiling a limited number of ventilators balances the need to prepare for a potential pandemic against the need to maintain adequate funding for current and ongoing health care expenses. Furthermore, severe staffing shortages are anticipated, and purchasing additional ventilators beyond a threshold will not save additional lives, because there will not be a sufficient number of trained staff to operate them. In the event of an overwhelming burden on the health care system, New York will not have sufficient ventilators to meet critical care needs despite its emergency stockpile. If the most severe forecast becomes a reality, New York State and the rest of the country will need to allocate ventilators and other scarce resources.

F. Specialized Facilities for Influenza Patients

The majority of patients in need of ventilator therapy will be those affected by the pandemic influenza virus and these patients could easily overwhelm acute care facilities. The Task Force and various Clinical Workgroups discussed the creation of special "influenza facilities" to care exclusively for influenza patients, while non-designated hospitals perform a greater share of health care services not related to influenza.⁵⁹ Benefits of a specialized center include the ability to concentrate resources to fewer facilities that have the best infrastructure and expertise to care for influenza patients, increase the probability of limiting the spread of the influenza to other patients (who have been transferred to other facilities), and reduce the number of facilities affected by the pandemic.

However, such a concept is controversial. This strategy could prove financially burdensome to hospitals designated as influenza facilities. Elective surgeries would be canceled and well-compensated procedural work not related to influenza may not be performed, would be a significant loss of revenue. Furthermore, for patients living in rural areas, it may not be feasible to travel long distances to influenza specialty centers, because it is likely these centers will be in major metropolitan areas. In addition, it would be unfair to concentrate risks and burdens of

⁵⁷ New York State Department of Health, Office of Health Emergency Preparedness Program, *Critical Assets Survey*, September 2015.

⁵⁸ Depending on the severity of the moderate scenario, it may be possible that a clinical protocol for ventilator allocation may not be needed because the ventilator stockpile is sufficient to address any possible ventilator shortage.

⁵⁹ In Toronto, during the 2003 SARS (Severe Acute Respiratory Syndrome) outbreak, four hospitals (out of 24) were designated centers for SARS patients. C. David Naylor, et al., *Learning from SARS in Hong Kong and Toronto*, 291 JAMA, 2483, 2484 (2004). However, such an arrangement may be more feasible under Canada's single payer health care system than in the United States. SARS cases never reached the magnitude of likely cases in a severe influenza pandemic, even in Toronto and other heavily impacted cities.

influenza (i.e., infection risk, emotional and mental distress, etc.) to a few facilities, especially for the health care staff.

If influenza specialty centers are created, they may only be appropriate for pediatric patients, because the requisite expertise needed to treat critically ill children is already concentrated in larger, regional facilities. Most local/community hospitals do not have pediatric intensive care units, the specialized equipment, or expertise to provide extended care for pediatric patients. However, a specialized facility strategy may not be suitable for the reasons mentioned above and because most parents and legal guardians of children will travel to the nearest acute care facility for medical attention for their child.⁶⁰ For a discussion on the special considerations for pediatric and neonatal preparedness, see Chapters 2 and 3, Pediatric and Neonatal Guidelines, respectively.

G. Implementation of the Guidelines and Statewide Application

The Guidelines are implemented only if the State is confronted with an influenza pandemic of the severity described above, where all preventative and preparatory measures have been exhausted and ventilator allocation becomes necessary. The ventilator allocation protocols, as described in the Guidelines, will be implemented by the appropriate governmental authorities and should be followed only as long as the circumstances require. For a more detailed discussion on the process for implementing the Guidelines, see Chapter 4, Implementing New York State's Ventilator Allocation Guidelines: Legal Considerations.

In addition, once the Guidelines are implemented, it applies Statewide. It is in the nature of a pandemic that some facilities are hit harder, or sooner, than others; one facility may run out of critical supplies, including ventilators, while other facilities still have capacity. The Task Force and the Clinical Workgroups considered a number of options for balancing need and resources. One suggestion was to transfer patients to facilities with available resources, although the transfer of large numbers of critically ill and highly infectious patients would not be easily, or perhaps wisely, undertaken. Instead, it may be more appropriate to transfer equipment and staff in an emergency. Hospitals within a region should coordinate and plan such transfer and loan agreements before a pandemic occurs as part of their emergency preparedness planning.⁶¹ In addition, State and federal assets, including ventilator stockpiles, should be allocated to areas with the greatest discrepancy between population and resources to help alleviate any shortages.

Consistent Statewide policies are crucial to avoid large variations among facilities and inequities in outcomes. Equitable allocation systems, particularly ones that contemplate limiting access to lifesaving treatment, must assure that the same resources are available and in use at similarly situated facilities, i.e., all facilities in one area affected by the pandemic, to reduce inequalities of access and distribution among facilities. It is unacceptable for a system that

⁶⁰ See Wanda D. Barfield et al., *Neonatal and Pediatric Regionalized Systems in Pediatric Emergency Mass Critical Care*, 12 PEDIATR. CRIT. CARE MED. S128, S130 (2011) (noting that for emergency care, nearly 90 percent of children are taken to an emergency department based upon location of the facility). See also Erik Auf de Heide, *The Importance of Evidenced-Based Disaster Planning*, 47 ANN. EMERG. MED. 34, 41 (2006).

⁶¹ A decision whether to divert ventilators from one part of the State to another would be made based on the specific circumstances of the pandemic. However, in a severe pandemic, it is likely that all regions of the State would be affected at some point.

permitted removal of ventilators from patients at one hospital, while similarly situated patients survived by virtue of being in a neighboring hospital. Furthermore, hospitals in less affluent neighborhoods typically serve a far larger population base, which penalizes a disadvantaged population. A system of allocation that permits wide variation between hospitals in different areas will result in excess mortality of vulnerable individuals.

III. Overview of Concepts Used in Triage

The Task Force examined several key concepts of triage to advance the goal of saving the most lives within the specific context of ventilators as the scarce resource in an influenza pandemic.

A. Definition of Triage

The concept of triage was developed in the battlefield, where scarce resources were provided to benefit the largest number of people.⁶² Critically injured/ill individuals who normally received full medical attention during a non-crisis situation were not provided with optimal care so that the less/moderately injured could receive the scarce resource, thereby saving the most lives by caring for a larger number of people. Thus, the goal of triage is to “do the greatest good for the greatest number” of people.⁶³

However, in the context of ventilator allocation during a public health emergency, the Task Force and other pandemic planning organizations have modified the definition of triage. Patients for whom ventilator treatment would most likely be lifesaving are prioritized. Patients with the highest likelihood of survival *without* medical intervention, along with patients with the smallest likelihood of survival *with* medical intervention, have the lowest level of access to ventilator therapy.⁶⁴ Allocating scarce resources in this manner utilizes them effectively and increases the number of survivors by providing ventilators to those who are most likely to survive *with* ventilator therapy. Thus, patients who are most likely to survive without ventilator therapy, together with patients who survive with ventilator treatment, increase the overall number of survivors.

⁶² See Lewis C. Vollmar, Jr., *Military Medicine in War: The Geneva Conventions Today*, in *MILITARY MEDICAL ETHICS*, VOL. 2, (Thomas E. Beam, ed., 2005).

⁶³ See Ontario Health Plan for an Influenza Pandemic, *Critical Care During a Pandemic*, 8 (2006), www.cidrap.umn.edu/sites/default/files/public/php/21/21_report.pdf (hereinafter OHPIP 2006). See also Pandemic Ethics Initiative Work Group, *Meeting the Challenge of Pandemic Influenza: Ethical Guidance for Leaders and Health Care Professionals in the Veterans Health Administration*, Veterans Health Administration, National Center for Ethics in Health Care, v (July 2010) (hereinafter VHA Guidelines) http://www.ethics.va.gov/docs/pandemicflu/Meeting_the_Challenge_of_Pan_Flu-Ethical_Guidance_VHA_20100701.pdf

⁶⁴ When the Guidelines are no longer being implemented, all patients in need of a ventilator are eligible regardless of their medical conditions.

B. Application of the Clinical Ventilator Allocation Protocol to All Patients in Need of a Ventilator

A just allocation system must be applied to all acute care patients in need of a ventilator, whether due to influenza or other conditions. As a practical matter, health care providers could not limit the use of triage criteria to patients solely with influenza; critically ill patients may have multiple diagnoses or no clear diagnosis. Furthermore, a system that suggests a preference of one disease over others might result in inaccurate reporting of diagnoses and heighten the danger of contagion.

C. Definition of Survival

In general, the Task Force and most medical scholars and policy experts agreed that the primary goal in a public health emergency should be saving the most lives.⁶⁵ Prioritizing individuals based on their chances of survival during an emergency is the most equitable, as it does not consider non-clinical factors, such as race, ethnicity, sexual orientation, socio-economic status, education, religion, or quality of life. As discussed above, the most effective use of scarce resources is to allocate them to patients who have the highest likelihood of survival with the use of the scarce resource.

In a public health emergency such as an influenza pandemic, the term “survival” must be adequately defined. During a pandemic, the majority of patients who need a ventilator are those afflicted with influenza. However, not all patients in need of a ventilator are sick with influenza; others may be car crash victims, emergency post-operative patients, or individuals with impaired lung function. Thus, for the Guidelines, survival is based on a patient’s ability to survive the acute medical episode for which ventilator therapy is necessary.

The Guidelines’ definition of survival is based on the short-term likelihood of survival of the acute medical episode and is not focused on whether a patient may survive a given illness or disease in the long-term (e.g., years after the pandemic). By adopting this approach, every patient is held to a consistent standard. Triage decision-makers should not be influenced by subjective determinations of long-term survival, which may include biased personal values or quality of life opinions.

IV. Ethical Framework for Allocating Ventilators

An ethical framework must serve as the starting basis for a plan that proposes to allocate ventilators fairly. A ventilator allocation plan that does not directly incorporate ethical considerations into its clinical protocol is unlikely to withstand ethical scrutiny. Discourse in medical ethics has generated various sets of principles and values. Different ethical principles are given greater or lesser consideration in the process of resolving any particular dilemma and a

⁶⁵ John L. Hick & Daniel T. O’Laughlin, *Concept of Operations for Triage of Mechanical Ventilation in an Epidemic*, 3 ACAD. EMERG. MED. 223, 225 (2006). See also Devereaux, *Definitive Care for the Critically Ill During a Disaster*, *supra* note 8, at 61-2S.

number of authors have addressed ethical principles for decision-making in public health crises.⁶⁶

The 2006 Adult Clinical Workgroup articulated the following ethical framework in support of this specific effort to allocate ventilators in a pandemic:⁶⁷

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|--|
| <p style="text-align: center;">Ethical Framework for Allocating Ventilators</p> <ul style="list-style-type: none">• Duty to Care• Duty to Steward Resources• Duty to Plan• Distributive Justice• Transparency |
|--|

A. Duty to Care

First and most importantly, an ethical allocation scheme must respect the fundamental obligation of health care providers to care for patients. Indeed, in an influenza pandemic, health care providers try to care for and save the lives of as many patients as possible. However, the existing medical standard of care necessitates that doctors, nurses, and other health care professionals offer care at the bedside to individual patients, not to populations. Health care workers are concerned with their patients' well-being. Even during a pandemic, medical staff may be unwilling to overlook their responsibilities to their patients. An ethically sound allocation system must sustain rather than erode this relationship between patient and provider. Physicians must not abandon, and patients should not fear abandonment, in a just system of allocation. Patients who do not receive ventilators are still under their physician's care and obtain alternative forms of medical intervention and/or palliative care.

In the delivery of day-to-day health care in the United States, the preferences of capable patients are generally the deciding factor in whether recommended treatments will or will not be initiated. However, patient preference is not and cannot be the primary factor in devising an allocation system for ventilators in an influenza pandemic; more patients will want ventilators than can be accommodated. A public health emergency such as an influenza pandemic, by virtue of severe resource scarcity, imposes harsh limits on decision-making autonomy for patients and health care providers. An allocation system must reflect those limits. Nonetheless, a just scheme must endeavor to support autonomy, when possible, in ways that also honor the duties of care

⁶⁶ See generally Benjamin Berkman, *Incorporating Explicit Ethical Reasoning Into Pandemic Influenza Policies*, 26 J. CONTEMP HEALTH LAW POLICY 1 (2009); Kristen DiGirolamo, *Legal Preparedness for Pandemic Influenza: Is Virginia Ready?*, 13 RICH. J. LAW & PUB. INT. 385 (2010); University of Toronto Joint Centre for Bioethics Pandemic Influenza Working Group, *Stand on Guard for Thee: Ethical Considerations in Preparedness Planning for Pandemic Influenza*, (2005), http://reportal.jointcentreforbioethics.ca/news/documents/pandemic_Stand-on-guard-for-thee_report_JCB2005.pdf; Lewis Rubinson et al., *Augmentation of Hospital Critical Care Capacity After Bioterrorist Attacks or Epidemics: Recommendations of the Working Group on Emergency Mass Critical Care*, 33 CRIT. CARE MED. E1 (2005) (hereinafter Rubinson, *Augmentation of Capacity After Attack*); John Arras, *Rationing Vaccine During An Avian Influenza Pandemic: Why it Won't Be Easy*, 78 YALE J. BIOL. MED. 287 (2005).

⁶⁷ Subsequent clinical Workgroups since the release of the 2007 Draft Guidelines have supported this framework.

and stewardship. For example, where an eligible patient for ventilator therapy has appropriately articulated the wish to forgo such treatment, that expression of autonomy should be honored. Furthermore, an allocation system should stress the provision of care that may be possible when ventilator therapy is not. An ethically sound allocation system includes alternative forms of medical intervention and/or palliative care for patients not eligible for ventilator therapy.

B. Duty to Steward Resources

The second element in the ethical framework for allocating ventilators is the obligation for government and health care providers to responsibly manage resources during a period of true scarcity. The effort to balance this obligation to the community of patients against the primary duty to care for each patient generates the ethical tension in devising an allocation system. Even under ordinary, non-emergency circumstances, health care providers may question whether the estimated benefit of an intervention merits the use of scarce resources. For example, health care providers currently struggle to decide whether a blood transfusion (or antibiotics, or surgical intervention) is appropriate or justified for a particular patient, given that the quantity of a particular resource is limited. Yet an emergency on the scale of a severe influenza pandemic forces health care providers to confront limits far more starkly than they now do. Patients, some of whom might survive under ordinary circumstances, cannot be given the standard level of resources at the expense of numerous other patients who will likely die without any resources at all. Providers need to balance the obligation to save the greatest possible number of lives against that of the obligation to care for each single patient. As the number of affected patients increase, accommodating these two goals require more and more difficult decisions. An allocation system incorporates ethical decision-making processes so that the duty to steward resources and the limitations it may place on individual care is recognized as fair and acceptable under emergency circumstances.

C. Duty to Plan

A motivating force in designing an allocation system is the knowledge that planning is an obligation. An absence of a plan leaves allocation decisions to exhausted, over-taxed, front-line health care providers, who already bear a disproportionate burden in an emergency. A failure to produce an acceptable plan for a foreseeable crisis amounts to a failure of responsibility toward both patients and providers. Guidelines are essential to uphold health care staff's commitment to patients, ethics, and to professionalism during a time of crisis. In addition, health care providers are aware that some who served in the aftermath of Hurricane Katrina faced accusations of criminal conduct. Appropriate guidance may help prevent both the actuality and the fear of similar consequences for those who provide care in a future emergency.

Although plans are obligatory, the Guidelines represent a starting point for the public and decision-makers to discuss how scarce resources, particularly ventilators, should be allocated. The Task Force acknowledged that current access to health care is unequal; no allocation system for a crisis can resolve inequities in pre-existing health status resulting from unequal access. In addition, because the clinical parameters of an influenza pandemic are as yet uncertain, increasing the difficulty of predicting survival or duration of critical symptoms, the specifics of the clinical ventilator allocation protocol may evolve as data about the pandemic viral strain

become available during a pandemic. Nevertheless, the government has a duty to plan for foreseeable emergencies, and this work product embodies the current, best efforts at an effective, fair plan aimed at saving the most lives in an influenza pandemic where there are a limited number of available ventilators.

D. Distributive Justice

A just system of allocation must be applied consistently and broadly to be fair to all. Applying the clinical ventilator allocation protocol uniformly (i.e., treating like cases alike) helps the public recognize and accept that the allocation procedures are fair and ensure that vulnerable groups are not disproportionately affected. In addition, the same allocation system should be implemented across the State, and the decision to implement clinical ventilator allocation protocols must be authorized by the State. The timing and content of a just allocation system cannot fall to individual hospitals, but must be coordinated with the State. A just and equitable health care system cannot allow for more expansive access at a prestigious private facility and more restrictive access at a community or public hospital. Cooperative agreements to pool scarce resources among local hospitals may help alleviate initial shortages. The allocation of ventilators from State and federal stockpiles must take into account the ratio of local populations to available resources, and supplement those resources accordingly. Ethically sound responses to a public health emergency must not exacerbate disparities in access to care. Rather, planners must designate appropriate resources for the most vulnerable, whom are most likely to suffer the greatest impact in a public health emergency.

E. Transparency

Any just plan allocating ventilators requires robust efforts to promote transparency, by seeking broad input in the design of the plan and educating the public. The Department of Health and the Task Force will continue to publicize the Guidelines, and share them with health care leaders and the community. The general public's values must be evaluated and included, because it is the public that ultimately must live with the outcomes of the Guidelines. The assessment of public comment and feedback has been integrated into the Guidelines and contributes to the development of a just allocation process. The ongoing process of obtaining and incorporating feedback helps promote public trust in the Guidelines.

V. Triage Decision-Makers: Officer or Committee

A physician attending to a patient should have neither the main nor the sole responsibility for determining whether his/her patient is eligible for ventilator therapy. Instead, a triage officer or triage committee makes the determination about a patient's level of access to a ventilator. Neither a triage officer nor any members of the triage committee should have any direct contact with patients. A patient's attending physician provides a patient's clinical data to a triage officer/committee who examines the data and makes the decision whether a patient is eligible for (or continues with) ventilator therapy based on the clinical ventilator allocation protocol.

Use of a separate person/team to triage is essential for an effective clinical ventilator allocation protocol for several reasons. First, this framework permits attending physicians to

fulfill their obligation to care for their individual patients without facing a conflict of interest; they can advocate for their patients and not also be responsible for deciding to withhold or withdraw ventilator treatment. Second, separating the attending physicians from the triage decision-makers also ensure that the person(s) in this role is a senior/supervisory clinician (i.e., has the most clinical experience and/or relevant training).⁶⁸ This person(s) will have access to real-time information, which helps with balancing the need for ventilator treatment versus resource availability. Further, this person(s) will make allocation decisions consistently across a group of patients. Finally applying role sequestration enhances the capacity for maintaining professionalism by helping to decrease burnout and stress for health care providers providing direct critical care during the epidemic and for the decision-makers, and for all clinicians to sustain their integrity as healers.

It is probable that patients in need of a ventilator are individuals who may be familiar to a triage officer/committee and efforts should be made by the facility to ensure that a triage officer/committee does not have access to the identity of patients. To minimize decision bias and potential conflicts of interest, a triage officer or triage committee member should recuse him/herself where appropriate. In the event a recusal occurs, the facility should have plans for qualified staff – but not a physician currently attending to patients – to temporarily fulfill the responsibilities of a triage decision-maker.

While the Draft Guidelines suggested the use of a triage officer, these revised Adult Guidelines acknowledge that because acute care facilities differ in size and available resources, it is not appropriate to conclude that a triage officer is the best model for all facilities. Thus, the Task Force recommended that individual institutions should determine whether a triage officer or triage committee is appropriate. For either a triage officer/committee model, the individual(s) should have the appropriate background and training to apply the protocol with confidence. The benefits and drawbacks of both paradigms are presented below and each hospital should determine which model best suits its needs.

The use of a triage officer is beneficial for several reasons. In normal ICU conditions, the intensivist on duty determines whether a patient should be admitted into the ICU based on who will most likely to benefit from critical care in the ICU. The physician on duty must avoid unnecessary ICU admissions and transfer patients to lower levels of care when they no longer need critical care services. This command model is structured so that one person, the supervising ICU physician, makes admittance and transfer decisions. Because one individual is in charge of these crucial decisions in normal, non-pandemic conditions, it is logical to utilize the same model for the Guidelines. Ideally, an intensivist may be the best specialist to be a triage officer, because this type of physician has more experience with critical care patients. The use of a triage officer ensures consistency and efficiency because only one person makes the triage decisions.

However, there are several disadvantages to using a triage officer. In a pandemic, an overwhelming amount of patient data may need to be examined, and a triage officer may experience burn-out. Rotating a triage officer responsibility among a small group of people could

⁶⁸ See Centers for Disease Control and Prevention, *Ethical Considerations for Decision Making Regarding Allocation of Mechanical Ventilators during a Severe Influenza Pandemic or Other Public Health Emergency*, 17 (July 1, 2011), http://www.cdc.gov/od/science/integrity/phethics/docs/Vent_Document_Final_Version.pdf.

help prevent burn-out. In addition, if a triage officer is unable to perform his/her duties, there is the question of who makes the triage decisions. Finally, although it is often recommended that a triage officer should be an intensivist,⁶⁹ some smaller acute care facilities and community hospitals do not have ICU units or intensivists on staff.

Use of a triage committee also has several benefits and drawbacks. A triage team could help decrease burn-out and stress for the triage decision-makers, who could share the responsibility and obtain support from other members. In addition, inclusion of individuals from outside the medical or clinical community, such as ethicists or religious/pastoral care representatives, in the triage committee could provide a perspective from “outside the medical profession,” which may be comforting to the general public. However, the contribution of these non-medical members may be limited because the triage decision is based on clinical factors alone.

Shortcomings of a triage committee include questions related to how to resolve disagreement about triage decisions between members⁷⁰ and how decisions are made if all members are not available during the pandemic. In addition, staffing may be a problem, particularly in smaller community hospitals that may not have the resources to form a triage committee.

VI. Pitfalls of an Allocation System

In building a clinical ventilator allocation protocol, there are pitfalls that an allocation system must avoid. Emergency planning must not serve as a means to resolve long-standing disparities in health care access. For instance, an allocation system does not alleviate the need to provide adequate resources. In a resource-constrained environment, triage may lead to the acceptance of a lack of resources without challenging the problem of scarcity. A just system seeks to avoid triage by first implementing less drastic means of limiting and deferring the use of scarce resources. Before implementing any allocation system, appropriate steps may include cancellation of elective surgeries and altering patient to staff ratios. Triage should be reserved for situations of true scarcity.

While the Guidelines incorporate specific clinical parameters on how to allocate ventilators to ensure that protocols are applied consistently throughout the State, there are drawbacks to a framework that is too rigid. Specifically, flexibility is necessary so that, if and when the Guidelines are needed, they are “current” with the latest data on the pandemic viral strain. As currently written, the Guidelines are based, when possible, on scientific data and previous emergency planning experiences, and reflect the most up to date and commonly accepted medical data. The Guidelines are intended to allow for flexibility; they should be updated and revised as there are advances in clinical knowledge or changes in societal norms. As a severe pandemic is unfolding and real-time data on the pandemic viral strain become

⁶⁹ See Rubinson et al., *Augmentation of Capacity After Attack*, *supra* note 66, at E8.

⁷⁰ To avoid a situation where there is a “tie” with respect to a triage decision for a patient, a triage committee should consist of an odd number of members (e.g., three or five).

available, the Guidelines may be revised accordingly to reflect the unique nature of the particular virus and address the challenges it presents.

Additionally, the Guidelines must not be used to summarily resolve the controversial question of ventilator use for severely and permanently impaired patients. Quality of life judgments must not serve as a substitute for ethically sound principles that are available for public scrutiny. The Guidelines must reflect our common duty to protect the rights of the disabled, even while potentially encompassing them in an allocation system.

Health care providers and family members will be reluctant to withhold/withdraw ventilators from patients. Guidelines that rely heavily on withdrawal of ventilators generate great concern and controversy and may be set aside in an emergency. Further, the experience of withdrawing ventilation is traumatic for all concerned, including health care staff. Doctors and nurses forced to extubate patients, even to save other patients, may not recover full professional confidence until long after the pandemic is resolved. Finally, the withdrawal of ventilation without patient consent raises significant liability issues;⁷¹ again, appropriate guidelines limit instances of tragic choices.

The Task Force and the various Workgroups involved in developing these Guidelines accepted the concept of removing patients with the highest probability of mortality from ventilators to give patients with a higher likelihood of survival an opportunity for ventilator therapy. However, they struggled with the notion of removing less ill patients from ventilators, particularly those who might recover with continued ventilator treatment beyond a certain time period that is longer than that prescribed in an allocation protocol. The Guidelines reflect an effort to address this tension by minimizing circumstances that require patient extubation, the most ethically and emotionally challenging aspect of any clinical ventilator allocation protocol.

VII. Triaging Ventilator-Dependent Chronic Care Patients

Notably, the number of ventilators in chronic care facilities is not insignificant. The Department of Health estimates 1,902 ventilators are in nursing homes and chronic care facilities.⁷² There was considerable debate both before and after the publication of the Draft Guidelines on whether ventilator-dependent chronic care patients should be triaged by the clinical criteria at the chronic care facilities.

After additional consideration and review of public comments, the Task Force agreed with the 2006 Adult Clinical Workgroup's recommendation that distinctions should be maintained between acute and chronic care facilities once the Guidelines are implemented, permitting chronic care facilities to maintain their specific mission. Patients using ventilators in chronic care facilities are not subject to the clinical protocol. If such patients require transfer to an acute care facility, then they are assessed by the same criteria as all other patients, and the possibility exists that these patients may fail to meet criteria for continued ventilator use.

⁷¹ See Chapter 4, Implementing New York State's Ventilator Allocation Guidelines: Legal Considerations, for a discussion of the liability issues involved.

⁷² New York State Department of Health, Office of Health Emergency Preparedness Program, *Critical Assets Survey*, September 2015.

Chronically ill patients are vulnerable to the pandemic, and chronic care facilities should be able to provide more intensive care on site as part of the general emergency planning process of expanding care beyond standard locations. These facilities should implement procedures that would treat these patients onsite as much as possible so that only urgent cases are sent to acute care facilities.⁷³ Barriers to transfer are appropriate and likely during a phase in which acute care hospitals are overwhelmed.

However, this approach may be problematic because it may not provide equitable health care to person with disabilities, and may place ventilator-dependent individuals in a difficult position of choosing between life-sustaining ventilation and urgent medical care.⁷⁴ Some argued that this strategy was contrary to the aim of saving the most lives because denying ventilator therapy to a ventilator-dependent person is different from denying the ventilator to someone who has a high probability of mortality who might have qualified for a ventilator under non-pandemic circumstances. Thus, if the ventilator is removed from a person known to depend upon it, s/he will not survive, regardless of the reason requiring hospitalization.

The Task Force examined the alternative approach, which requires assessing all intubated patients, whether in acute or chronic care facilities, by the same set of criteria. This method does not violate the duty to steward resources and subjects all patients, not just the acutely ill, to a modified medical standard of care. Depending on the design of the criteria, the result might be likely fatal extubations of stable, long-term ventilator-dependent patients in chronic care facilities. The proposed justification for such a strategy is that more patients could ultimately survive if these ventilators were instead allocated to the previously healthy individuals of the influenza pandemic. This strategy, however, makes victims of the disabled. This approach fails to follow the ethical principle of duty to care and could be construed as taking advantage of a very vulnerable population. More patients might survive, but they would be also different types of survivors, i.e., none of the survivors would be from the disabled community. The Task Force concluded that such a strategy relies heavily upon ethically unsound judgments based on third-party assessments of quality of life.

Although the Task Force believed that the five ethical principles described above are the foundation of the Guidelines, if any actions seemed to contradict commonly held societal beliefs, such as the need to protect vulnerable populations, then in certain circumstances, exceptions could be made when implementing the Guidelines. To triage patients in chronic care facilities once the Guidelines are implemented may theoretically maximize resources and result in more lives saved, but conflicts with the societal norm of defending vulnerable individuals and communities.

Applying the clinical ventilator allocation protocols to chronic care facilities fail to adhere to the duty to care – the ethical principle of providing care for each patient, including the most vulnerable. The second principle of using resources wisely must also be considered. Ventilators in chronic care settings may not be usable even if they were to be reallocated to the

⁷³ Ideally, there should be communication between the chronic care facility and the hospital to coordinate and determine whether a transfer is necessary and feasible.

⁷⁴ One Task Force member, Paul Edelson, expressed concern regarding triaging ventilator-dependent chronic care patients who need admission to a hospital.

general resource pool, so they may offer little additional benefit.⁷⁵ Furthermore, if chronic care patients become so ill that they must be transferred to an acute facility, they may not be eligible for ventilator therapy and lose access to the ventilator at that point. The ventilator may eventually enter the wider pool without prospectively triaging these patients at chronic care facilities. Therefore, the ventilators in chronic care facilities should remain there for the chronically ill, who are likely to have severely limited access to ventilators in acute care facilities, which offers an appropriate balance between the duties to care and to steward resources wisely.

The Task Force reaffirmed that chronic care patients are only subject to the Guidelines when they arrive at an acute care facility. With their arrival at the hospital, they are treated like any other patient who requires a ventilator and need to meet certain criteria to be eligible for ventilator therapy.⁷⁶ While a policy to triage upon arrival may deter chronic care patients from going to an acute care facility for fear of losing access to their ventilator, it is unfair and in violation of the principles upon which this allocation scheme is based to allow them to remain on a ventilator without assessing their eligibility. Distributive justice requires that all patients in need of a certain resource be treated equally; if chronic care patients were permitted to keep their ventilators rather than be triaged, the policy could be viewed as favoring this group over the general public. Allowing sick patients to remain in long-term care facilities as an alternative to transfer may increase the burden on these facilities. However, it is appropriate for the health care providers at these facilities to balance the burdens of treating an acute condition against the risk of a patient losing access to the ventilator upon transfer, and act accordingly.

Finally, there are a small but increasing number of ventilator-dependent individuals who reside in the community, rather than in institutions. The Task Force concurred that community-dwelling persons should not be denied access to their ventilators and the Guidelines are only applied to these patients upon their arrival at an acute care facility.

VIII. Non-Clinical Approaches to Allocating Ventilators

This section addresses several non-clinical strategies that might be used as a primary method to allocate scarce resources in an emergency and evaluates their advantages and disadvantages.

A. First-Come First-Serve

Ventilators may be allocated to patients on a first-come first-serve basis, which is how ICU beds, and to some degree organs for transplant, are currently distributed. This system is familiar to the public and straight-forward. However, this scheme will likely penalize disadvantaged populations, such as those of lower socio-economic means who may not have access to information about the pandemic or to reliable transportation, or minority populations who might initially avoid going to a hospital because of distrust of the health care system.

⁷⁵ Staff from acute care facilities may not be familiar the operation of ventilators from chronic care facilities. In addition, circuitry and other related equipment to operate these ventilators may not be available at hospitals.

⁷⁶ However, it is also possible for a ventilator-dependent patient to retain access to their ventilator, depending on his/her mortality risk. See Section XI.B.2. Triage Chart for Step 2, footnote 121.

B. Randomization

Alternatively, allocation may be based on a randomization process, such as a lottery, which permits all individuals an equal opportunity to access a ventilator.⁷⁷ To many, this approach seems the fairest because it assigns ventilators solely by chance, without regard to additional factors, such as race, ethnicity, sexual orientation, or socio-economic status, and eliminates potential biases and opportunity for discrimination. Use of randomization is appealing because any aspects that could differentiate individuals are eliminated and everyone has the same opportunity for ventilator treatment. In short, all lives are weighed equally valuable and important and all individuals receive an equal chance to receive ventilator therapy.

Randomization's strength is also its weakness, however, because blind allocation will not likely result in effective resource stewardship or support the goal of saving the most number of lives. It is likely that patients who are too sick to benefit receive ventilator therapy, which prevent less ill patients who would recover with ventilator treatment, from receiving this resource.⁷⁸ In addition, randomization could also engender distrust in the allocation system because of the lack of public discourse on how the random process is carried out. For example, questions such as how many random processes are conducted – a single random selection event at the start of the pandemic or multiple events throughout the pandemic? If only those individuals selected are eligible for ventilator therapy, what happens if the individual selected is not ill enough to require a ventilator, is the machine unused? Furthermore, if there was a single randomization event, it may penalize individuals who are not informed about the pandemic or are distrustful of the health care system to participate. Finally, there may be administrative and logistical issues if a randomization process occurs every time a ventilator becomes available, which may not be the best use of limited staff and resources.

C. Physician Clinical Judgment

Another alternative is to leave the decisions about who should receive a ventilator to the discretion of the physicians caring for patients at the bedside. Physicians, especially those with extensive experience working with critically ill patients, have amassed clinical wisdom that carefully guides their decisions about health care treatment. Patients and the general public may feel comfortable with this allocation method because they assume that the health care providers' decisions are based on clinical expertise and up-to-date medical knowledge.

However, there are several difficulties using this approach as a primary method to allocate ventilators. First, as discussed earlier, it is problematic to have a patient's attending physician determine whether the patient receives ventilator therapy because it conflicts with the physician's duty to care for the patient. Second, providers are subject to extreme stress, as caring

⁷⁷ One Task Force member, Adrienne Asch, preferred this allocation method because it explicitly disregards all factors that could be improperly considered in an allocation decision. Despite the weaknesses associated with a random selection process, Ms. Asch was partial to this allocation method for its objectivity and ease of use.

⁷⁸ For example, if Patient A, whose medical complications make it unlikely she survives even with ventilator treatment, receives the ventilator, a ventilator is not available for Patient B who is sick, but not past the point of recovery with ventilator treatment.

for patients in a pandemic situation is professionally, emotionally, and physically taxing, especially where health care professionals have not been provided with any parameters to guide their decisions. It is both inappropriate and burdensome to ask clinicians to make these decisions under such intense pressure, particularly about patients under their care. Third, decisions made at the bedside represent an individualized rather than collective approach to ventilator allocation, which result in inconsistencies and increase the potential for inequity, unintentional bias, and ineffectiveness. Without a consistent decision-making framework for physician clinical judgment, processes and outcomes will vary between physicians, hospitals, and locales. Finally, allowing for physician clinical judgment may leave clinicians feeling vulnerable to the threat of civil or criminal liability resulting from the decisions they make.

D. Patient Categories

Another strategy is to allocate ventilators according to the categories by which an individual falls. These include prioritizing access according to individuals' occupation as a health care worker or first responder, age, preexisting medical conditions, or societal roles.

1. Occupation as a Health Care Worker or First Responder

The 2006 Adult Clinical Workgroup and the Task Force debated the question of offering priority access to ventilators to health care providers, first responders, or other special groups. Specifically, those who provide essential health care functions, (i.e., provide direct patient care during an influenza pandemic) are exposed to a significant amount of risk to their own health and the health of their loved ones. Although health care workers are bound by a duty to care, there are concerns about the extent to which those in the health care field would tolerate risks of infection. To address these fears, it may be useful for health care workers and first responders to receive priority access to ventilators, as a form of "insurance" in the event these individuals become sick while fulfilling their responsibilities.⁷⁹ However, in the Draft Guidelines, the Task Force determined that these individuals should not be prioritized in a clinical ventilator allocation protocol.

Upon reexamination of this issue, the Task Force confirmed that patients should be assessed on medical factors only, regardless of their occupation. In a pandemic, if a health care worker with influenza needs ventilator therapy, s/he will be unlikely to return to work or care for patients. Thus, the argument that these individuals should receive priority access to ventilators

⁷⁹ For example, during the 2014 ebola outbreak in West Africa, health care workers who become infected with ebola were prioritized for treatment. Front-line workers who become infected with ebola were treated at the newly constructed Monrovia Medical Unit, a high quality 25 bed hospital, which is staffed by U.S. Public Health Service Commissioned Corps. This facility provides medical care to Liberian and international health care workers and United Nationals and other NGO staff who are ill with ebola. Because there were a shortage of health care providers to help fight the spread of ebola, the use of international workers was necessary and to encourage people to volunteer, many non-African countries agreed that they would provide the "best possible care for international health care workers in the event they contract the virus." See USAID, *Information regarding Care and Evacuation of International Responders* Dec. 12, 2014, <http://www.usaid.gov/ebola/medevac> and U.S. Department of State, Office of the Spokesperson, *G-7 Foreign Ministers' Joint Statement on Ebola*, Sept. 25, 2014 <http://www.state.gov/r/pa/prs/ps/2014/09/232122.htm>. In the context of pandemic influenza, however, this approach was rejected as discussed in this subsection.

so that they may continue to treat patients is moot. Second, workers in many occupations risk exposure and provide crucial services in a pandemic. Doctors and nurses face risks, but so do respiratory therapists, orderlies who keep rooms clean, morgue workers, laundry workers, ambulance staff, security personnel, fire fighters, police, and others. Nor is it always easy to determine who is a health care worker. Part-time volunteers staff ambulances in some communities; and an unpaid family member may serve as the full-time caregiver for a disabled relative. These unpaid providers take risks comparable to or greater than some paid health care providers. Expanding the category of privilege to include all the workers listed above may mean that only health care workers obtain access to ventilators in certain communities. This approach may leave no ventilators for community members, including children; this alternative was unacceptable to the Task Force.

The 2006 Adult Clinical Workgroup also objected strongly to the appearance of favoritism, in which those who devised the clinical ventilator allocation protocol appeared to reserve special access for themselves. Thus, the Task Force reaffirmed the Workgroup's conclusion that access to ventilators should depend on clinical factors only. However, the allocation of other scarce resources, such as vaccine or anti-viral medications, as well as personal protective equipment, may well favor health care workers based on differing ethical and clinical considerations.⁸⁰

2. Age

Another non-clinical allocation strategy is to examine a patient's age, and prioritize access for the young over the old. The Draft Guidelines recommended that advanced age should not be a factor that prevents a patient from being eligible for ventilator therapy. However, because of significant public comment on this topic, specifically with regards to children, the Task Force revisited the use of age as a triage criterion.

The Task Force recognized that some clinical ventilator allocation protocols incorporate advanced age (i.e., greater than 85 years of age) as an exclusion criterion (i.e., a patient is not eligible for ventilator therapy).⁸¹ Proponents of excluding elderly adults believe that children should be offered ventilator therapy over individuals who have lived long lives, arguing that it is more appropriate to maximize the life-years saved rather than the number of lives saved. However, the Task Force believed that to exclude older adults discriminates against the elderly, especially where there is a greater likelihood that the advanced-aged patient will survive. Because age already factors indirectly into any criteria that assess the overall health of an individual (because the likelihood of having chronic medical conditions increases with age), the Task Force affirmed that the use of advanced age as a stand-alone triage factor should be

⁸⁰ See DiGirolamo, *supra* note 66, at 404 (explaining the CDC's suggestion that in a pandemic, "those individuals who are essential to the provision of health care, public safety and the functioning of key aspects of society should receive priority in the distribution of vaccine, antivirals and other scarce resources."). See generally Arras, *supra* note 66; Mark Rothstein, *Should Health care Providers Get Treatment Priority in an Influenza Pandemic?*, 38 J. LAW MED. ETHICS 412 (2010).

⁸¹ Devereaux, *Definitive Care for the Critically Ill During a Disaster*, *supra* note 8, at 60S. See also Michael D. Christian et al., *Development of a Triage Protocol for Critical Care During an Influenza Pandemic*, 175 CAN. MED. ASSOC. J. 1377, 1379 (2006) (hereinafter Christian, *Development of a Triage Protocol*).

rejected. The Task Force examined the possible use of young age as a triage criterion, and a detailed discussion on this age spectrum appears in Chapter 2, Pediatric Guidelines.

3. Other Categories

Ventilators may also be allocated according to other patient categories. Such allocation strategies may be based on a patient's preexisting medical conditions (i.e., chronic diseases, pregnancy,⁸² etc.) and social criteria (i.e., job function, role in society, criminal status, and parental status). For example, in non-emergency conditions, ICU beds are allocated based on severity of illness as well as first-come first-serve. However, giving preference to a specific preexisting medical condition over others is not feasible because it may encourage inaccurate reporting of symptoms by patients and/or diagnoses by clinicians and could increase the danger of contagion.

Similarly, it is difficult to apply a social criteria standard when determining whether a patient receives ventilator treatment. Questions such as how to determine which job function/status in society is more important or whether a parent should have priority over a nonparent are biased by personal values and raise concerns about biases and unfair discrimination. For example, while individuals who are parents may seem to be prime candidates for ventilator treatment because of the societal desire to maintain families, such a policy discriminates against those who choose not to have or are unable to have children and those who are primary caregivers to dependents who are not children. Thus, the Task Force reaffirmed that social criteria should not be a triage consideration.

IX. Clinical Approach to Allocating Ventilators

Providing ventilators to patients using the non-clinical approaches described above as a primary method to allocate ventilators, without individually gauging likelihood of survival, do not necessarily allocate them to the patients who may benefit the most. Under these approaches, ventilators inevitably are given to patients who would not survive, regardless of ventilator treatment, which would result in more lives lost overall, rather than given to those who might actually benefit from it. Because the primary goal of a triage plan is to save the most lives where there is a limited number of an available resource, prioritizing individuals based on clinical factors is the most equitable method to increase the number of survivors. This strategy gives all patients an equal opportunity to obtain ventilator therapy.⁸³

⁸² It is likely that pregnant women are more susceptible to influenza, and if a baby is delivered prematurely, the neonate may also require medical attention. Treatment of these patients is coordinated by both the adult and neonatal clinical teams. While outside the scope of these Guidelines, it is highly likely that at the initial outbreak of an influenza pandemic, pregnant women would be prioritized for vaccine and anti-viral medications, which would reduce the number of pregnant women and neonates affected. For more details about the neonatal clinical ventilator allocation protocol, *see* Chapter 3, Neonatal Guidelines.

⁸³ However, the Task Force acknowledged that while survival of the greatest number of people may be the goal of triage, in certain circumstances, the public may assign higher value to certain normative principles, and an allocation system should make an attempt to accommodate these principles, so long as they do not run counter to the goal. For example, the decision to not triage ventilator-dependent chronic care patients unless they arrive at an acute care facility was made to conform to the societal norm of protecting vulnerable populations from exploitation, *see* Section VII: Triageing Ventilator-Dependent Chronic Care Patients. Furthermore, the Task Force examined the

In order to design a fair allocation system, a method to accurately differentiate those patients who survive without critical care, those who survive only with critical care, and those who die despite treatment is necessary. However, although several systems for estimating critical care mortality exist, none were specifically designed to demonstrate the most efficient use of scarce resources or developed for the purpose of triaging patients.

For adult patients, nearly all clinical ventilator allocation protocols utilize a clinical scoring system that provides a score based on clinical factors. This score provides some insight on a patient's mortality risk. Some scoring systems require resource-intensive tests that might be scarce during an epidemic; others were developed for trauma patients and so are less applicable for an influenza pandemic.⁸⁴ Further, no scoring system is accurate enough to provide finely calibrated, reliable distinctions among similar patients; existing data may support estimates of survival among broad categories of patients. In sum, no known clinical scoring system offers a quick, resource-sparing, and accurate prediction of mortality in an influenza pandemic. The limited ability to assess survival capacity (except in broad categories) has critical implications for the design of a ventilator allocation system.

X. Overview of Clinical Ventilator Allocation Protocols

The Draft Guidelines were heavily influenced by two clinical ventilator allocation protocols, the Hick and O'Laughlin proposal and the Ontario Health Plan for an Influenza Pandemic plan.

A. Hick and O'Laughlin Proposal

Hick and O'Laughlin were among the first to propose guidelines that: (1) are implemented on a regional, rather than an institutional basis; (2) utilize tiers so that as the number of patients increase and resources are depleted, the criteria to be eligible for the scarce resource become more stringent.⁸⁵

Hick and O'Laughlin devised three tiers of criteria for patients with respiratory failure in need of ventilator therapy. Depending on the severity of the pandemic and resources, different tiers are used to allocate ventilators. The first tier eliminates access to ventilators for patients with the highest probability of mortality. If resources continue to fall short, the second tier denies access to patients who require a high use of additional resources, including patients who

societal value of protecting children and the role of young age as a triage criterion, *see* Chapter 2, Pediatric Guidelines.

⁸⁴ *See generally* Wendy Hensel & Lisa Wolf, *Playing God: The Legality of Plans Denying Scarce Resources to People With Disabilities in Public Health Emergencies*, 63 FLORIDA LAW REV. 719 (2011) (citing NY State Task Force on Life and the Law); Flavio L. Ferreira et al., *Serial Evaluation of the SOFA Score to Predict Outcome in Critically Ill Patients*, 286 JAMA 1754 (2001) (hereinafter Ferreira, SOFA); Jack Zimmerman et al., *Acute Physiology and Chronic Health Evaluation (APACHE) IV: Hospital Mortality Assessment for Today's Critically Ill Patients*, 34 CRIT. CARE MED. 1297 (2006); and Daliana Bota et al., *The Multiple Organ Dysfunction Score (MODS) Versus the Sequential Organ Failure Assessment (SOFA) Score in Outcome Prediction*, 28 INTENSIVE CARE MED. 1619 (2002).

⁸⁵ *See* Hick & O'Laughlin, *supra* note 65.

also have a pre-existing illness with a poor prognosis. The third tier in this model is more restrictive and patients are triaged based on criteria that are developed as needed by a committee, which could include the use of a clinical scoring system to “score” patients. Finally, the authors proposed the extubation of any patient “who might be stable, or even improving, but whose objective assessment indicates a worse prognosis than other patients who require the same resource.”⁸⁶

The 2006 Adult Clinical Workgroup members applauded Hick and O’Laughlin’s effort to address the problem of ventilator allocation, and in particular to develop an analysis of regional, as opposed to local allocation. They agreed that a clinical approach, examining a patient’s health status, was the best method to allocate ventilators. They were uncertain whether resource utilization should be a clinical consideration,⁸⁷ and decided additional input was needed to determine whether patients who require extensive resources, such as renal dialysis, should be ineligible for ventilator therapy when ventilators were scarce. For the 2007 Draft Guidelines, the consensus was to include renal dialysis as a medical condition that warrants exclusion from ventilator therapy, with the understanding that more analysis and input was needed and such resource intensive conditions may be removed from consideration.⁸⁸

While the use of tiers was an interesting concept, the 2006 Adult Clinical Workgroup rejected its use. Because the Guidelines would only be implemented once demand for ventilators exceeds supply, which meant that the situation was dire, there was no need for a tiered approach. Instead, facilities should conduct surge capacity to reduce the demand for ventilators which may meet the demand during a moderate pandemic and avoid implementing the Guidelines. Furthermore, having a tiered approach would result in several possible clinical ventilator allocation protocols, one for each tier, which would be difficult to manage during an emergency situation.

In addition, the 2006 Adult Clinical Workgroup expressed significant reservations about the plan to extubate a patient because a newly arriving patient had a better health assessment for several reasons. First, a patient would require a sufficient trial on the ventilator to determine whether the patient was benefiting from the treatment. More importantly, though, a patient expects that doctors provide treatment, to the extent possible, based on assessments of his/her health as individuals. If ventilator use is primarily determined by the health of *other* potential users of the ventilator, clinicians would abandon their obligation to advocate/care for an

⁸⁶ See *id.*, at 226. For example, patient A’s continued use of the ventilator depends not only on the estimated survival likelihood of patient A, but also upon that of newly arriving patient B. If patient B has a better predicted survival outcome than patient A (even though patient A may be stable or improving), patient A is removed from the ventilator for patient B. Patient B has access to the ventilator until another patient arrives (patient C) and patient B’s continued use of the ventilator then is determined by the predicted mortality outcome of patient C.

⁸⁷ Some allocation planning experts do recommend that patients who require a high level of ongoing resources be excluded from receiving critical care resources. Such exclusion is seen to be ethically permissible because the protocol’s goal of achieving the greatest good for the greatest number of people” can be better achieved. See Lee Daugherty Biddison et al., *Ethical Considerations Care of the Critically Ill and Injured During Pandemics and Disaster: CHEST Consensus Statement*, 146 (4 Suppl.) CHEST e145S, e149S (2014) (herein after Biddison et al., *Ethical Considerations*).

⁸⁸ Subsequent clinical workgroups eliminated resource intensive medical conditions as a triage factor. The Adult Guidelines do not list resource intensive medical conditions (i.e., renal dialysis) as an exclusion criterion. See Section XI.A. Step 1: Exclusion Criteria.

individual patient. This proposal evokes an ICU war of all-against-all that ignores health care workers' deep professional obligations to advocate and care for individual patients. Though Hick and O'Laughlin offered many useful insights on the design of a triage system, the 2006 Adult Clinical Workgroup members rejected this aspect of the proposal on ethical grounds and they also believed that clinicians would resist implementing a protocol based upon these premises.

B. Ontario Health Plan for an Influenza Pandemic (OHPIP) Plan

An additional pandemic clinical ventilator allocation protocol that the 2006 Adult Clinical Workgroup considered was proposed in April 2006 by the OHPIP Working Group on Adult Critical Care Admission, Discharge and Triage Criteria.^{89, 90} The OHPIP clinical ventilator allocation protocol is based on three evaluative components: inclusion criteria, exclusion criteria, and minimum qualifications for survival (MQS). Inclusion criteria focus on respiratory failure and identify patients who would benefit from admission to critical/intensive care.⁹¹ Exclusion criteria identifies patients who: (1) currently have a very poor prognosis/likelihood of survival even with aggressive treatment in an intensive care unit, (2) require a high level of resources that cannot be met during a pandemic, and (3) have significant, advanced medical conditions and have a poor prognosis with a high probability of short-term mortality even without the concomitant illness.⁹² MQS, a term taken from military triage, refers to limits placed on resources used to care for any individual patient. This concept is used to identify early those patients who are not improving with ventilator treatment and will likely have a poor outcome even with treatment.⁹³

A patient is assessed initially for inclusion and exclusion criteria; if inclusion criteria are present and exclusion criteria are absent, patients are then evaluated using a clinical scoring system to determine whether the patient should receive a ventilator therapy trial. Finding that no triage system had been developed for use in critical care or medical emergencies, the OHPIP committee presented a new critical care triage tool based in part on the Sequential Organ Failure

⁸⁹ See OHPIP 2006, *supra* note 63, at 10-11. A summary of the 2006 OHPIP clinical ventilator allocation protocol was also published. See Christian, *Development of a Triage Protocol*, *supra* note 81. Application of the OHPIP 2006 Plan to two retrospective cohorts of patients at two ICUs during an eight week period of peak occupancy revealed that the "triage protocol can help to direct resources to patients who are most likely to benefit, and help to decrease the demands on critical care resources, thereby making available more resources to treat other critically ill patients." Michael D. Christian et al., *A retrospective cohort pilot study to evaluate a triage tool for use in a pandemic*, 13 CRIT. CARE R170, [p.8] (2009). See also Sheri L. Fink, *Worst care: rethinking tertiary triage protocols in pandemics and other health emergencies*, 14 CRIT. CARE 103 (2010) (noting that the study above triaged patients to not survive at the last time trial clinical assessment (i.e., after 120 hours of ventilator therapy) but these patients had substantial survival rates had they continued with ventilator therapy).

⁹⁰ During Superstorm Sandy in 2012, Bellevue Hospital in New York City adapted and applied the OHPIP plan. It was expected that power loss would occur in two hours and a triage committee was assembled to evaluate ICU patients and select six patients who would receive the limited resource (i.e., electrical power via a backup generator). See Amit Uppal et al., *In Search of the Silver Lining: The Impact of Superstorm Sandy on Bellevue Hospital*, 10 ANN. AMERICAN THORACIC SOC. 135, 138 (2013).

⁹¹ The ability to provide ventilator treatment is what distinguishes intensive care units from other acute care areas, such as step-down units. See *id.*, at 9.

⁹² See *id.*

⁹³ See *id.*, at 10.

Assessment (SOFA) score.⁹⁴ The SOFA score adds points based on clinical measures of function in six key organs and systems: lungs, liver, brain, kidneys, blood clotting, and blood pressure. For each variable, dysfunction is measured on a zero to four scale, with four being the worst score. A perfect SOFA score, indicating normal function in all six categories, is 0; the worst possible score is 24 and indicates life-threatening abnormalities in all six systems.⁹⁵

Depending on a patient's SOFA score, s/he is placed into a color category that determines level of access to a ventilator. SOFA score cutoffs place a patient into blue, red, yellow, and green categories.⁹⁶ Blue code patients are those who have a high risk of mortality who should not receive ventilator treatment when resources are scarce. Instead, alternative forms of medical intervention and/or palliative care should be provided. Red code patients are those who have the highest priority for ventilator treatment because they most likely will recover with treatment⁹⁷ (and likely to not recover without it). This category includes patients with single organ failure (i.e., respiratory failure because of influenza) and who otherwise have a very low SOFA score, which suggests a moderate risk of mortality. Patients in the yellow category are those who at the initial assessment are very sick and may or may not benefit from ventilator therapy. They receive such treatment if ventilators are available after all patients in the red category receive them. Patients in the green color code are those who will likely survive without ventilator therapy.

Ventilated patients are reevaluated at 48 and 120 hours and either continue with the ventilator therapy or are reassigned to a different color category, based on their SOFA scores and any exclusion criteria. Patients may lose access to ventilators if their SOFA score increases within the designated time interval, which indicates that their health is deteriorating and their mortality risk is increasing. In addition, if patients develop a medical condition considered to be an exclusion criterion at any point they are receiving ventilator treatment, they are removed from the ventilator so that patients with a high likelihood of survival have an opportunity for ventilator therapy.

The 2006 Adult Clinical Workgroup believed that the OHPIP proposal presented an ethically promising approach to triage. Appropriately, a patient's access to a ventilator depends on the patient's own clinical status, as objectively measured, rather than on a direct competition with other patients presenting for care. Further, a patient receives a set amount of time to benefit from ventilator treatment before s/he is evaluated on whether s/he is eligible for continued ventilator use. A patient who does not benefit over time (i.e., demonstrate improvement in overall health after receiving ventilator treatment) will lose access to the ventilator. Thus, this system honors the ethical principles of caring for patients while also stewarding resources wisely.

⁹⁴ SOFA has also been described as the Sepsis-related Organ Failure Assessment. See Jean-Louis Vincent et al., European Society of Intensive Care Medicine, *The SOFA (Sepsis-related Organ Failure Assessment) Score to Describe Organ Dysfunction/Failure*, 22 INTENSIVE CARE MED. 707 (1996).

⁹⁵ By design, SOFA weighs all six systems equally. *Id.*

⁹⁶ See OHPIP 2006, *supra* note 63, at 10.

⁹⁷ Red color code patients are sick enough to require ventilator therapy to survive and will do poorly if they do not receive it. However, although these patients are ill, they are likely to recover if they receive care. Prioritizing these patients for ventilator therapy ideally increases the number of survivors by ensuring that patients receiving ventilator therapy are those who have a high likelihood of recovering.

However, the 2006 Adult Clinical Workgroup noted several technical limitations. OHPIP's list of exclusion criteria required additional refinement as well as simplification for use in an emergency. Furthermore, the Workgroup concluded that factors that reflect quality of life judgments rather than estimates of mortality should be eliminated from the triage process. In addition, all the components of a SOFA score upon which the OHPIP proposal relies may not be available during an emergency. Although some clinical variables of SOFA require only simple laboratory tests such as bilirubin and creatinine, it may be possible that staffing at laboratories will not have the capacity to return the results to the physicians in a timely manner.⁹⁸

C. Other States' Ventilator Allocation Plans

Since the publication of the Draft Guidelines in 2007, numerous other states have developed triage plans for ventilator allocation, many incorporating aspects of the protocol presented in the Draft Guidelines.⁹⁹ Most of the plans follow the framework used by OHPIP:

⁹⁸ To address possible lab staffing shortages, it has been proposed that SOFA be modified to include fewer lab variables. A modified SOFA (MSOFA) system eliminates platelet count used for the blood clotting variable and replaces the liver function variable (serum bilirubin) with a clinical (visual) assessment of scleral icterus or jaundice. It also replaces partial pressure of arterial oxygen (PaO₂) lab variable with an arterial oxygen saturation measured by a pulse oximeter (SpO₂). See Colin K. Grissom et al, *A Modified Sequential Organ Failure Assessment Score for Critical Care Triage*, 2 DISASTER MED. PUB. HEALTH PREPAREDNESS 277, 277-279 (2010).

⁹⁹ See, e.g., Alabama Emergency Management Agency, *Criteria for Mechanical Ventilator Triage Following Proclamation of Mass-Casualty Respiratory Emergency*, (2010); Alaska Medical Emergency Preparedness Pediatrics Project, *Alaskan Technical Recommendation for Pediatric Medical Triage and Resource Allocation in a Disaster: For Patients Post Nursery Discharge Until 18 Years of Age* (2008); Colorado Dep't of Public Health & Environment, *Guidance for Alterations in the Health care System During a Moderate to Severe Influenza Pandemic* (2009); Florida Dep't of Health Pandemic Influenza Technical Advisory Committee, *Pandemic Influenza: Triage and Scarce Resources Allocation Guidelines* (2011) (hereinafter Florida Guidelines); Indiana State Dep't of Health, Crisis Standards of Care Community Advisory Group, *Crisis Standards of Patient Care Guidance with an Emphasis on Pandemic Influenza: Triage and Ventilator Allocation Guidelines*, (2014) (hereinafter Indiana Guidelines); Iowa Dep't of Public Health, *An Ethical Framework for Use in a Pandemic: Report of the Iowa Pandemic Influenza Ethics Committee* (2007); Kansas Department of Health and Environment, Gianfranco Pezzino and Steven Q. Simpson, Chairs, *Guidelines for the Use of Modified Health Care Protocols in Acute Care Hospitals During Public Health Emergencies*, 2nd Revision (2013); Minnesota Center for Health care Ethics & University of Minnesota Center for Bioethics, *For the Good of Us All: Ethically Rationing Health Resources in Minnesota in a Severe Influenza Pandemic: Minnesota Pandemic Ethics Project Report* (2010) (hereinafter Minnesota Center, *Ethically Rationing Health Resources*); New Mexico Health Policy Comm'n, *House Memorial 71, Health care Professional Disaster Response: Legal and Ethical Considerations for Health care Professionals during Catastrophic Disasters or Public Health Emergencies* (2009) (includes New York Draft Ventilator Allocation Guidance as Appendix B); Oklahoma State Dep't of Health, *Mechanical Ventilation Strategies for Scarce Resource Situations (Draft)* (2010); South Carolina Dep't of Health and Environmental Control, South Carolina Pandemic Influenza Ethics Task Force, *South Carolina Prepares for Pandemic Influenza: An Ethical Perspective* (2009); Texas Pandemic Influenza Medical Ethics Work Group, *A Medical Ethics Framework to Support Decision-Making in the Allocation and Distribution of Scarce Medical Resources During Pandemic Influenza A Report to the Texas Department of State Health Services* (2010); Utah Hospitals and Health Systems Association for the Utah Department of Health, *Utah Pandemic Influenza Hospital and ICU Triage Guidelines for Adults*, 5 (version 4b, 2010) (hereinafter Utah Guidelines); Wisconsin Dep't of Health Services Pandemic Influenza Program, *Adult Ventilator Guidelines* (2008). Other states provide general pandemic preparedness plans, some of which project a shortfall of ventilators, but do not recommend a system by which they should be allocated. See, e.g., California Dep't of Health Services (CDHS), *Pandemic Influenza Preparedness and Response Plan* (2006); Missouri Department of Health and Senior Services, *Missouri Pandemic Influenza Response Plan* (2009); Washington State Dep't of Health, *Preparing for Pandemic Influenza: A Washington State Overview* (2006); Wyoming Dep't of Health, *Public Health Pandemic Influenza*

exclusion criteria, clinical scoring system to determine whether a patient has access to ventilator treatment, and reevaluation of the ventilated patient at set time intervals using the same clinical scoring system to determine if the patient continues with ventilator treatment.

Some of the other state plans have distinguishing characteristics, either in the clinical details or the scope of the coverage. For example, Alabama’s plan is similar to the Hick and O’Laughlin proposal, and uses tiers of triage based on the severity of the pandemic to implement its guidelines. As the pandemic worsens, the more restrictive the clinical ventilator allocation protocol becomes to account for more patients who need ventilator therapy. Utah’s plan uses a modified version of SOFA that uses fewer laboratory variables. Minnesota’s guidelines are particularly notable that they incorporate an expansive and successful public engagement effort and provide detailed information about the methods used to solicit input from stakeholders and the public.¹⁰⁰

XI. New York’s Clinical Ventilator Allocation Protocol for Adults: Rationale and Clinical Components

A brief summary of the adult clinical ventilator allocation protocol developed by the Adult Clinical Workgroups and the Task Force is presented below, followed by an explanation of the details and rationales.

New York’s clinical ventilator allocation protocol for adults is based on the OHPIP protocol and on the SOFA score which have been adapted for use.¹⁰¹ Reliance on clinical criteria to support triage decisions promote fairness and consistency, as well as provide clinicians with guidance to follow when they are faced with this difficult situation.¹⁰²

All acute care patients in need of a ventilator, whether due to influenza or other conditions, are subject to the clinical ventilator allocation protocol.¹⁰³ Using clinical criteria, patients who are deemed most likely to survive with ventilator treatment have an opportunity for ventilator therapy to maximize the number of survivors. The adult clinical ventilator allocation protocol applies to all patients aged 18 and older in all acute care facilities Statewide. Ventilator-dependent chronic care patients are only subject to the clinical ventilator allocation

Response Plan Version 7.0, 48 (2009) (recognizing that a shortage of ventilators is possible, but leaving triage decisions to “the local health care system, including health care providers and facilities” and urging triage policy development).

¹⁰⁰ See Minnesota Center, *Ethically Rationing Health Resources*, *supra* note 99.

¹⁰¹ Ontario Ministry of Health and Long-Term Care, *Ontario Health Plan for an Influenza Pandemic* (2008), http://www.health.gov.on.ca/en/pro/programs/emb/pan_flu/docs/plan_full.pdf (hereinafter OHPIP 2008). The OHPIP protocol was revised in 2008 and again in 2013. The 2008 version contains detailed guidance on emergency preparedness and the 2013 version is a response plan that describes the roles/responsibilities of local health partners during a pandemic. See also Ferreira, *SOFA*, *supra* note 84.

¹⁰² See Institute of Medicine, *Crisis Standards of Care: Summary of a Workshop Series*, 28 Washington, DC (The National Academies Press 2010); Rebecca Mansbach, *Altered Standards of Care: Needed Reform for When the Next Disaster Strikes*, 14 J. HEALTH CARE L. & POLICY 209, 238 (2009).

¹⁰³ Certain patients or families may decide to decline ventilator therapy. Such decisions to withhold or withdraw ventilator treatment should be implemented in the same way they are in a non-emergency situation.

protocol if they arrive at a hospital.¹⁰⁴ The protocol consists of three steps (each of which are discussed in greater detail in the following subsections):

- **Step 1 – Exclusion Criteria:** A patient is screened for exclusion criteria, and if s/he has a medical condition on the exclusion criteria list, the patient is not eligible for ventilator therapy. Instead, a patient receives alternative forms of medical intervention and/or palliative care.
- **Step 2 – Mortality Risk Assessment Using SOFA:** A patient is assessed using SOFA, which may be used as a proxy for mortality risk. A triage officer/committee examines clinical data from Steps 1 and 2 and allocates ventilators according to a patient’s SOFA score.
- **Step 3 – Time Trials:** Periodic clinical assessments at 48 and 120 hours using SOFA are conducted on a patient who has begun ventilator therapy to evaluate whether s/he continues with the treatment. The decision whether a patient remains on a ventilator is based on his/her SOFA score and the magnitude of change in the SOFA score compared to results from the previous official clinical assessment.

The person (triage officer) or group of people (triage committee) who determines whether a patient receives (or continues with) ventilator treatment is not the physician attending to the patient.¹⁰⁵ The attending physician’s role is to evaluate a patient for exclusion criteria in Step 1 and to assess the patient’s mortality risk and organ failure risk in Steps 2 and 3. In order to facilitate the triage process, a patient’s clinical data are presented to a triage officer/committee who determines the patient’s level of access to a ventilator (i.e., who is eligible and/or continues with ventilator therapy).

A triage officer/committee examines a patient’s clinical data and uses this information to assign a color code to the patient at Steps 2 and 3. The color (blue, red, yellow, or green) determines the level of access to a ventilator (blue = lowest access/palliate/discharge, red = highest access, yellow = intermediate access, and green = defer/discharge).¹⁰⁶ Patients with the red color code have the highest level of access to a ventilator because they are most likely to recover with treatment (and not likely to recover without it) and have a moderate risk of mortality. If resources are available, patients in the yellow category also have access to ventilator treatment.¹⁰⁷ Those assigned the blue code are patients who potentially have the worst outlook for survival, even with ventilator therapy, and therefore have lowest access. The green category represents patients who are most likely to survive without ventilator therapy or are eligible for ventilator weaning. If resources become available, patients in the blue color

¹⁰⁴ For a discussion on triaging ventilator-dependent individuals, *see* Section VII. Triaging Ventilator-Dependent Chronic Care Patients.

¹⁰⁵ Since facilities differ in size and available resources, each facility should determine whether a triage officer or committee is more appropriate. For a discussion of the benefits and drawbacks of both models, *see* Section V. Triage Decision-Makers: Officer or Committee.

¹⁰⁶ These colors are consistent with other tertiary triage protocols and are universally recognized for triage purposes.

¹⁰⁷ However, during the peak of the pandemic, it is unlikely that patients in the yellow category have access to ventilators because there will be more red code patients than available ventilators.

category, or those with exclusion criteria, are reassessed and may become eligible for ventilator therapy.

Alternative forms of medical intervention are provided to those who are not eligible for a ventilator or these patients may be discharged. In addition, palliative care is provided to all patients throughout the triage process, regardless of prognosis. Furthermore, patients and/or their families may decide to decline ventilator therapy and these patients would also receive appropriate medical care. Patients with a high risk of mortality and poor response to ventilation have a low likelihood of improving within a reasonable time frame, such that the ventilator may be allocated to another patient with a higher likelihood of survival. These patients are provided with alternative forms of medical intervention and/or palliative care, where appropriate.¹⁰⁸

Finally, the Task Force and the various Clinical Workgroups acknowledged that the triage process requires regular reassessments of the status of the pandemic, available resources, and of all patients. Thus, as new data and information about the pandemic viral strain become available during a pandemic, the adult clinical ventilator allocation protocol may be revised accordingly to ensure that triage decisions are made commensurate with updated clinical criteria.

A. Step 1: Exclusion Criteria

Summary of Step 1: A patient is screened for exclusion criteria, and if s/he has a medical condition on the exclusion criteria list, the patient is not eligible for ventilator therapy. Instead, a patient receives alternative forms of medical intervention and/or palliative care.

1. Exclusion Criteria

The 2006 Adult Clinical Workgroup determined that applying exclusion criteria will identify patients with the highest probability of mortality, even with ventilator therapy, to prioritize patients most likely to survive with ventilator therapy in a situation of scarce resources. Health care providers assess patients for exclusion criteria to determine the appropriateness of both the initiation and continuation of ventilator use. Selecting and defining exclusion criteria is a challenging aspect of designing a triage system. A model set of exclusion criteria defines those patients with a high risk of mortality even with ventilator therapy, but does not rely on subjective judgments of quality of life. Exclusion criteria focuses primarily on current organ function, rather than on specific disease entities.

The 2006 Adult Clinical Workgroup proposed a set of exclusion criteria in the Draft Guidelines that drew from the work of OHPIP. However, after subsequent Clinical Workgroups reviewed the exclusion criteria, it was determined that the list included conditions that were difficult and ambiguous for a physician to use to predict mortality risk with any accuracy and such a prediction was not evidence-based. For example, the previous exclusion criteria list included metastatic malignancy with poor prognosis, which is subject to a wide (and subjective) range of interpretation.

¹⁰⁸ For a discussion of palliative care, see Section XII.B. Palliative Care.

In addition, because the Task Force modified the definition of survival to be based on the short-term likelihood of survival of the acute medical episode and is not focused on whether a patient may survive a given illness or disease in the long-term (e.g., years after the pandemic), many of the previous exclusion criteria from the Draft Guidelines are not suitable for use.¹⁰⁹ The purpose of applying exclusion criteria is to identify patients with a short life expectancy irrespective of the current acute illness, in order to prioritize patients most likely to survive with ventilator therapy. The medical conditions that qualify as exclusion criteria are limited to those associated with immediate or near-immediate mortality even with aggressive therapy. For example, for the revised Adult Guidelines, renal dialysis was removed, because it does not serve as a predictor of immediate or near-immediate mortality and is not based strictly on likelihood of survival.¹¹⁰

The exclusion criteria list is, by necessity, flexible. Because it would be impossible to list every medical condition that would result in immediate or near-immediate mortality, the exclusion criteria list includes a “catch all” phrase that encompasses other possibilities. In addition, real-time data of the pandemic viral strain may require altering the list of exclusion criteria. For example, it may become apparent that patients affected with influenza and a particular medical condition never survive regardless of ventilator treatment. In such cases, this condition would be added to the exclusion criteria list.

Incomplete medical information could complicate clinical assessments upon presentation in the emergency room with respect to exclusion criteria. It is conceivable that information about exclusion criteria may be unknown or unavailable. Reliable information from medical records may be inaccessible, forcing clinicians to rely on self-reporting from patients or their families. A potential downside of this is the provision of inaccurate information to health care providers, which may become more likely as exclusion criteria become well known and understood by the public. Furthermore, information about exclusion criteria may be unavailable—for instance, an unaccompanied patient could arrive in a critical condition, unable to communicate with health care providers.

Similarly, some patients may arrive to the emergency department with endotracheal tubes¹¹¹ already inserted by EMS personnel. Workgroup members discussed whether EMS personnel should continue to intubate patients before arrival at the hospital. They expressed concern that EMS personnel might not have sufficient data to apply the clinical ventilator allocation protocol in the field. However, the Clinical Workgroups concurred that hospital emergency department staff would reassess patients upon arrival.

In the situations described above, any patient whose exclusion criteria was not discovered initially continues to the next triage step. However, this patient likely will be ruled ineligible for

¹⁰⁹ For a discussion of the modified definition of survival, *see* Section III.C. Definition of Survival.

¹¹⁰ Provision of renal dialysis during a public health emergency is extremely resource intensive, however, to use it as an exclusion criterion for this reason necessitates the addition of other resource intensive conditions to the list. In addition, because the purpose of applying exclusion criteria is to identify patients with an immediate or near-immediate probability of death even with aggressive treatment, renal dialysis does not fit into this framework.

¹¹¹ Endotracheal tubes are inserted via a patient’s mouth into the trachea in order to ventilate the lungs using a ventilator.

ventilator therapy during the subsequent triage steps, because precise real-time clinical data about the patient's health continue to be gathered.

While several states' ventilator allocation plans include Do Not Resuscitate (DNR) orders as an exclusion criterion,¹¹² the Task Force and Clinical Workgroups did not find it appropriate to include DNR. A DNR order informs health care professionals that a patient does not wish to receive cardiopulmonary resuscitation (CPR), which is a procedure to restart the patient's heartbeat and breathing after cardiac arrest. Such an order is only a decision about CPR and does not relate to any other treatment. DNR orders are not an individual or medical professional's assessment of a patient's survival; instead they reflect the patient's medical treatment preferences in a particular context. A patient's decision about CPR/DNR status is not necessarily indicative of what s/he would choose about access to a ventilator or other potentially lifesaving care, and so does not hold up as a reliable proxy for autonomous decision-making under these circumstances. Therefore, a patient with a DNR order who needs ventilator therapy is eligible to be evaluated for treatment under this plan.

2. Triage Chart for Step 1

A revised set of exclusion criteria, drawing upon the work of OHPIP and incorporating suggestions from the Clinical Workgroups and additional critical care experts, is presented below. The list focuses primarily on medical conditions limited to those associated with immediate or near-immediate mortality even with aggressive therapy. (See Appendix 1 for additional clinical information on exclusion criteria.) A patient's attending physician examines his/her patient for an exclusion criterion and will forward this clinical data to a triage officer/committee to make the triage decision. Patients with exclusion criteria do not have access to ventilator therapy and instead are provided with alternative forms of medical intervention and/or palliative care.¹¹³

¹¹² See, e.g., Florida Guidelines, *supra* note 99, at, 6; Utah Guidelines, *supra* note 99, at 5.

¹¹³ See Section XII. Alternative Forms of Medical Intervention and Palliative Care. However, if a ventilator becomes available and no other patient is in need of ventilator therapy, a patient with an exclusion criterion may be eligible for this treatment.

Step 1 - List of Exclusion Criteria for Adult Patients¹¹⁴
Medical Conditions that Result in Immediate or Near-Immediate Mortality
Even with Aggressive Therapy

- Cardiac arrest: unwitnessed arrest, recurrent arrest without hemodynamic stability, arrest unresponsive to standard interventions and measures; trauma-related arrest
- 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)
- Severe burns: where predicted survival $\leq 10\%$ even with unlimited aggressive therapy (See Appendix 1)
- Any other conditions resulting in immediate or near-immediate mortality even with aggressive therapy¹

¹This “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.

B. Step 2: Mortality Risk Assessment Using SOFA

Summary of Step 2: A patient is assessed using SOFA, which may be used as a proxy for mortality risk. A triage officer/committee examines clinical data from Steps 1 and 2 and allocates ventilators according to a patient’s SOFA score.

1. SOFA

SOFA is used to assess mortality risk. Despite the drawbacks of SOFA,¹¹⁵ it is simple to use, with few variables or lab parameters, and the calculation of the score (i.e., simple addition) is straightforward, which makes SOFA a good tool to provide a consistent, clinical approach to allocate ventilators. The score is calculated only from clinical factors based on available medical evidence, and not personal values or subjective judgments, such as quality of life. A SOFA score describes a patient’s health status and assesses the patient’s likelihood of survival.

¹¹⁴ New York’s exclusion criteria are loosely based on the exclusion criteria from OHPIP 2008’s clinical ventilator allocation protocol. See OHPIP 2008, *supra* note 101.

¹¹⁵ See Section X.B. Ontario Health Plan for an Influenza Pandemic (OHPIP) Plan for additional discussion on the limitations of SOFA as a clinical evaluation tool during an emergency. Furthermore, recent studies based applying SOFA using the medical records of patients admitted to the ICU, which also included patients admitted for the novel H1N1 influenza, to determine how well SOFA would triage patients and predict which patients would benefit from intensive care, have shown that SOFA may not adequately determine prognosis for individual patients in all circumstances. See Biddison et al., *Ethical Considerations*, *supra* note 87, at e149S and Michael D. Christian et al., *Triage Care of the Critically Ill and Injured During Pandemics and Disasters: CHEST Consensus Statement*, 146 CHEST e61S, e69S-e70S (2014). See also T. Guest et al., *An observational cohort study of triage for critical care provision during pandemic influenza: ‘clipboard physicians’ or ‘evidenced based medicine’?*, 64 ANAESTHESIA 1199-1206 (2009), Z. Khan et al., *An assessment of the validity of SOFA score based triage in H1N1 critically ill patients during an influenza pandemic*, 64 ANAESTHESIA 1283-1288 (2009), Reza Shahpori et al., *Sequential Organ Failure Assessment in H1N1 pandemic planning*, 39 CRIT. CARE MED. 827-832. Despite the criticisms of SOFA, the Adult Clinical Workgroups determined that at this time, SOFA would be used until a better clinical tool was developed to assess a patient’s mortality risk.

A SOFA score adds points based on clinical measures of function in six key organs and systems: lungs, liver, brain, kidneys, blood clotting, and blood pressure (See Appendix 2 for additional clinical information on the variables of a SOFA score).¹¹⁶ Each variable is measured on a zero to four scale, with four being the worst score. A perfect SOFA score, indicating normal function in all six categories, is 0; the worst possible score is 24 and indicates life-threatening abnormalities in all six systems. The clinical assessment for a SOFA score is performed by a patient's attending physician.

A patient's clinical data from Steps 1 and 2 are provided to a triage officer/committee who examines the information and assigns the patient a color code (i.e., blue, red, yellow, or green), which determines the patient's level of access to ventilator therapy (see chart below).¹¹⁷ Blue code patients (lowest access/palliate/discharge) are those who have a medical condition on the exclusion criteria list or those who have a high risk of mortality and these patients do not receive ventilator treatment.¹¹⁸ Instead, alternative forms of medical intervention and/or palliative care are provided. Red code patients (highest access) are those who have the highest priority for ventilator treatment because they are most likely to recover with treatment¹¹⁹ (and likely to not recover without it) and have a moderate risk of mortality. Patients in the yellow category (intermediate access) are those who are very sick and their likelihood of survival is intermediate and/or uncertain. These patients may or may not benefit (i.e., survive) with ventilator therapy. They receive such treatment if ventilators are available after all patients in the red category receive them. Patients in the green color code (defer/discharge) are those who do not need ventilator therapy.

¹¹⁶ By design SOFA weighs all six systems equally.

¹¹⁷ The triage chart is adapted from OHPIP 2006, *supra* note 63, and from VHA Guidelines, *supra* note 63.

¹¹⁸ However, if a ventilator becomes available and no other patients are in need of ventilator therapy, a patient with a blue color code may be eligible for this treatment.

¹¹⁹ Red color code patients are sick enough to require ventilator therapy to survive and will do poorly if they do not receive it. However, these patients are not so severely ill that they will still benefit (i.e., survive) with ventilator treatment. Prioritizing these patients for ventilator therapy, ideally, increases the number of survivors by ensuring that patients receiving ventilator therapy are those who have a high likelihood of recovering.

2. Triage Chart for Step 2

A triage officer/committee allocates ventilators according to the color code assigned.¹²⁰

Step 2 – Mortality Risk Assessment Using SOFA ¹	
Color Code and Level of Access	Assessment of Mortality Risk/ Organ Failure
<p>Blue</p> <p>No ventilator provided. Use alternative forms of medical intervention and/or palliative care or discharge.</p> <p>Reassess if ventilators become available.</p>	<p>Exclusion criterion</p> <p>OR</p> <p>SOFA > 11</p>
<p>Red</p> <p>Highest</p> <p>Use ventilators as available</p>	<p>SOFA < 7</p> <p>OR</p> <p>Single organ failure²</p>
<p>Yellow</p> <p>Intermediate</p> <p>Use ventilators as available</p>	<p>SOFA 8 – 11</p>
<p>Green</p> <p>Use alternative forms of medical intervention or defer or discharge.</p> <p>Reassess as needed.</p>	<p>No significant organ failure</p> <p>AND/OR</p> <p>No requirement for lifesaving resources</p>

¹ If a patient develops a condition on the exclusion criteria list at any time from the initial assessment to the 48 hour assessment, change color code to blue. Remove the patient from the ventilator and provide alternative forms of medical intervention and/or palliative care.

² Intubation for control of the airway (without lung disease) is not considered lung failure.

For most patients who are sick with only influenza and have no other comorbidities, the single organ failure is limited to their lungs, which gives them a low SOFA score. However, because the clinical ventilator allocation protocol applies to all patients in need of a ventilator, a patient may also have a comorbidity(s) that affects another organ system(s) which will increase his/her SOFA score.¹²¹ Intubation for control of the airway (without lung disease) is not considered lung failure.

¹²⁰ A triage officer/committee determines whether a patient in the red (and possibly yellow) color category receives ventilator therapy. Decisions also need to be made regarding which patient within each color code receives ventilator treatment. For a discussion on how such decisions are made, see Section XI.B.3. Decision-Making Process for Selecting an Eligible Patient for a Ventilator.

¹²¹ While it is possible for a ventilator-dependent chronic care patient to lose access to ventilation, the triage decision would be contingent on several factors, such as the severity of the medical condition requiring attention and number of available ventilators. For example, it is feasible for such a patient to be assigned the highest level of access to a

3. Decision-Making Process for Selecting an Eligible Patient for a Ventilator

At Step 2, a triage officer/committee may encounter a situation where there are several patients in the red color code,¹²² who are equally eligible for ventilator therapy. Further clinical examination of these patients in the red color category may not be useful or possible in a pandemic because it has already been determined using exclusion criteria and a SOFA score that all the individuals have equal (or near equal) likelihoods of survival.¹²³ Therefore, the question of how a triage officer/committee should select an eligible patient must be addressed.¹²⁴

It is not appropriate for a triage officer/committee to compare patients within the same color category. A patient expects that doctors provide treatment, to the extent possible, based on assessments of the patient's health as an individual. If ventilator use is primarily determined by the health of *other* patients, clinicians must abandon their obligation to advocate/care for their individual patient. This proposal evokes a war of all against all that ignores health care workers' deep professional obligations to advocate and care for individual patients. To compare patients with each other could force a triage officer/committee to prematurely withdraw ventilators from patients more often, and could lead to fewer patients surviving. Furthermore, such comparisons may intensify inherent biases in the health care system and the disproportionate and disparate provision of care for already disadvantaged populations.

Because a clinical evaluation has been performed and there are no other evidence-based clinical factors available to consider, a non-clinical method must be used to determine which patient among the eligible patients receives ventilator therapy. A secondary allocation system may be first-come first-serve or a randomization process (such as a lottery). While these approaches were problematic to use to initially triage patients,¹²⁵ they are useful and acceptable to use as secondary triage criteria. A non-clinical system used at this triage step only is employed after a triage officer/committee determines that all available clinical measures are (nearly) equivalent for the eligible patients, which implies that all of these individuals have equal (or near equal) likelihoods of survival (i.e., in the same color category), and all patients are adults.

ventilator, because the clinical evaluation provides some flexibility. Because a SOFA score of ≤ 7 is the highest level of access to ventilation, a ventilator-dependent patient could score a 4 for PaO₂/FiO₂ (the worst score because his/her lungs are not functional without a ventilator), which still leaves a margin of 3 points to allocate for the medical condition requiring hospitalization. In addition, if a ventilator is available and there are no patients waiting for ventilator treatment, a ventilator-dependent patient regardless of his/her risk of mortality would be eligible for ventilator therapy.

¹²² While the yellow category may also have eligible patients waiting for ventilator therapy, all red code patients must be attended to first. If there are no red code patients, and only yellow code patients, then the same decision-making process applies.

¹²³ While a SOFA score does provide discrete numbers, it is not appropriate to suggest that a score of 5 is indicative of a lower risk of mortality than a score of 6. Instead, both of these scores suggest that both patients have near equal probabilities of survival. Thus, all patients in the same color category have the same likelihood of survival.

¹²⁴ For a discussion on review of a triage decision and the appeals process, see Chapter 4, Implementing New York State's Ventilator Allocation Guidelines: Legal Considerations, Section VI. Appeals.

¹²⁵ See Section VIII. Non-clinical Approaches to Allocating Ventilators.

The Task Force and the Clinical Workgroups considered both first-come first-serve and random selection (e.g., lottery) methods. While first-come first-serve is straight-forward and is easy to implement, it disadvantages those who are of lower socio-economic means who may not have access to information about the pandemic or to reliable transportation, or minority populations who might initially avoid going to a hospital because of distrust of the health care system. Despite the various administrative and logistical barriers of conducting a random selection process,¹²⁶ the Task Force and Workgroups recommended this approach because such a system is easy to understand and can be implemented with some advance planning.

A random process should be used to choose an adult patient for ventilator therapy when there are more eligible adult patients than ventilators available.¹²⁷ In addition, a random selection method is conducted each time a ventilator becomes available. Finally, patients waiting for ventilator therapy wait in an eligible patient pool and receive alternative forms of medical intervention and/or palliative care until a ventilator becomes available.

C. Step 3: Periodic Assessments for Continued Ventilator Use (Time Trials)

Summary of Step 3: Periodic clinical assessments at 48 and 120 hours using SOFA are conducted on a patient who has begun ventilator therapy to evaluate whether s/he continues with the treatment. The decision whether a patient remains on a ventilator is based on his/her SOFA score and the magnitude of change in the SOFA score compared to the results from the previous official clinical assessment.

1. Time Trials

In a public health emergency, periodic evaluations of a patient after s/he has begun ventilator therapy is necessary to determine whether the therapy is effective for that patient while allowing for efficient allocation of scarce ventilators. It also assists health care workers responsible for the day-to-day care of a patient by presenting uniform guidance on when official assessments are to occur. Finally, the use of time trials gives a triage officer/committee valuable information about the status and real-time availability of ventilators.

Time trials are necessary to determine whether a patient receiving ventilator therapy continues with this form of medical intervention. A patient showing improvement continues with ventilator therapy until the next assessment, and if the patient no longer meets the criteria for continued use, s/he receives alternative forms of medical intervention and/or palliative care. Until more data about the pandemic viral strain become available during a pandemic, the length of an appropriate time trial is unknown. Shorter trials (e.g., 24 hours) permit more patients access to ventilator therapy, but require more extubations for a larger number of patients, a

¹²⁶ See Section VIII.B. Randomization.

¹²⁷ However, if the pool of eligible patients includes both children and adults, and assuming both sets of patients have equal (or near equal) probabilities of survival, a random selection process is not conducted and instead the child is selected for ventilator therapy. See Chapter 2, Pediatric Guidelines, Section V.A.3.b. Use of Young Age as a Secondary Triage Factor (Tie-Breaker) and Section IX.F. Interface between Pediatric and Adult Patients.

situation the Guidelines should attempt to minimize.¹²⁸ In contrast, long time trials result in fewer patients receiving ventilator therapy.

The 2006 Adult Clinical Workgroup suggested time trials of 48 and 120 hours, which reflect the expected duration of beneficial treatment for acute respiratory distress or other likely complications of severe influenza. In the case of an influenza pandemic, as data about the viral strain and clarification of a more precise time trial period for adults become available during a pandemic, the length of adult time trials may be adjusted accordingly.

A SOFA score is used to evaluate a patient who has begun ventilator therapy. A patient's attending physician performs the clinical assessments involved in a SOFA score and provides the data and score to a triage officer/committee who assigns the patient a color code based on the SOFA score. The score determines whether the ventilator is reallocated.

The Task Force and subsequent Workgroups affirmed the logic and reasoning required to justify continued ventilator eligibility. In order for a patient to continue with ventilator treatment, s/he must demonstrate an improvement in overall health status after receiving ventilator therapy. Thus, a patient's health prognosis and trajectory guide the triage decision.

A triage decision is made based on a patient's SOFA score, which reveals: (1) the overall prognosis estimated by a patient's clinical indicators, which is indicative of mortality risk by revealing the presence (or likelihood), severity, and number of acute organ failure(s), and (2) the magnitude of improvement or deterioration of overall health (i.e., change in SOFA scores compared to the previous official assessment), which provides additional information about the likelihood of survival with ventilator therapy. The guiding principle for the triage decision is that the more severe a patient's health condition (i.e., higher the SOFA score) and worsening/no change in mortality risk (i.e., increase or little/no change in the SOFA score), the less likely the patient continues with ventilator therapy. Conversely, the less severe a patient's health condition (i.e., low SOFA score) and demonstration of improvement with ventilator therapy (i.e., significant decrease in the SOFA score and in mortality risk), the higher the likelihood the patient continues with this form of treatment.

The SOFA score itself and any changes in a patient's score after 48 and 120 hours help guide the triage decision. The extent of change in SOFA scores indicates whether a patient is improving, worsening, or experiencing no change in health status. A triage decision can determine that a patient is: (1) no longer ventilator dependent and may be weaned off the ventilator,¹²⁹ (2) ventilator dependent and meets the criteria to continue with ventilator therapy, or (3) ventilator dependent but no longer meets the criteria for continued ventilator treatment. A patient who exhibits improvement (i.e., decreasing SOFA scores) continues to be eligible for ventilator therapy until the next official assessment. Depending on the real-time availability of ventilators, a patient who remains stable may or may not be eligible, and a patient who no longer meets the criteria (i.e., develops a condition from the exclusion criteria list, or SOFA score

¹²⁸ Removing a patient from a ventilator likely is a stressful experience not only for the family members of the patient, but also for the health care staff involved.

¹²⁹ Ventilator weaning procedures are often based on physician preference, experience, and available resources, and each facility should plan accordingly.

worsens) is removed from the ventilator and provided with alternative forms of medical intervention and/or palliative care.¹³⁰

Although additional clinical assessments may be performed by a patient's attending physician on a regular basis, the official SOFA assessments only occur after 48 and 120 hours of ventilator therapy. No formal triage decision or action may be taken until a patient's official assessment. The decision to continue or discontinue with ventilator treatment is not made until a patient has had a full time period to benefit from this treatment. However, at any point during the time trial, even before an official assessment occurs, if a patient develops a condition on the exclusion criteria list and there is an eligible patient waiting, then the ventilator is reallocated.

The Task Force and Clinical Workgroups recognized the immense difficulty and potential trauma to patients, their families, and health care staff if a patient no longer qualifies for continued use of the ventilator based upon the time trial assessment. However, removing a ventilator from a patient who worsens or does not improve so that another patient with a strong likelihood of survival may have an opportunity for treatment helps support the goal of saving the greatest number of lives in an influenza pandemic where there are a limited number of available ventilators.

2. Triage Charts for Step 3

At the 48 and 120 hour assessments, a patient is examined for organ failure/mortality risk based on a SOFA score. The results of the time trial clinical assessments are then provided to a triage officer/committee who assigns a color code (blue, red, yellow, or green) to the patient. The color code assigned is dependent on the SOFA score itself and the extent of change between the SOFA score at the current assessment and the SOFA score from the previous assessment. The decision whether to continue ventilator therapy for a patient is dependent on the trend of the SOFA score data. Triage decisions are made based on ongoing clinical measures and data trends of a patient's health condition, consisting of: (1) the overall prognosis estimated by the patient's clinical indicators, which is indicative of mortality risk by revealing the presence (or likelihood), severity, and number of acute organ failure(s), and (2) the magnitude of improvement or deterioration of overall health, which provides additional information about the likelihood of survival with ventilator therapy.

Criteria for each color code at the 48 and 120 hour assessments are presented below.¹³¹

¹³⁰ A patient who is no longer receiving ventilator therapy is not abandoned; instead s/he receives alternative forms of medical intervention and/or palliative care, where appropriate. For a more detailed discussion, *see* Section XII. Alternative Forms of Medical Intervention and Palliative Care. If no eligible patients are waiting for ventilator treatment, a patient who does not meet the time trial criteria would continue with the treatment and be evaluated again at the next official assessment.

¹³¹ The triage charts are adapted from OHPIP 2006, *supra* note 63, and from VHA Guidelines, *supra* note 63.

a. 48 Hour Clinical Assessment Chart

Step 3 - Ventilator Time Trials (48 Hour Assessment)¹	
Color Code and Level of Access	Assessment of Mortality Risk/ Organ Failure
<p style="text-align: center;">Blue</p> <p style="text-align: center;">No ventilator provided.² Use alternative forms of medical intervention and/or palliative care or discharge. Reassess if resources become available.</p>	<p style="text-align: center;">Exclusion criterion</p> <p style="text-align: center;">OR</p> <p style="text-align: center;">SOFA > 11</p> <p style="text-align: center;">OR</p> <p style="text-align: center;">SOFA 8 – 11 <u>and</u> No Change in SOFA Score Compared to the Initial Assessment³</p>
<p style="text-align: center;">Red</p> <p style="text-align: center;">Highest</p> <p style="text-align: center;">Use lifesaving resources as available.</p>	<p style="text-align: center;">SOFA < 7 <u>and</u> Decrease in SOFA Score Compared to the Initial Assessment⁴</p> <p style="text-align: center;">OR</p> <p style="text-align: center;">SOFA < 11 <u>and</u> Decrease in SOFA Score Compared to the Initial Assessment⁵</p>
<p style="text-align: center;">Yellow</p> <p style="text-align: center;">Intermediate</p> <p style="text-align: center;">Use lifesaving resources as available.</p>	<p style="text-align: center;">SOFA < 7 <u>and</u> No Change in SOFA Score Compared to the Initial Assessment</p>
<p style="text-align: center;">Green</p> <p style="text-align: center;">Use alternative forms of medical intervention or defer or discharge. Reassess as needed.</p>	<p style="text-align: center;">No longer ventilator dependent / Actively weaning from ventilator</p>

¹ If a patient develops a condition on the exclusion criteria list at any time from the initial assessment to the 48 hour assessment, change color code to blue. Remove the patient from the ventilator and provide alternative forms of medical intervention and/or palliative care.

² A patient assigned a blue color code is removed from the ventilator and alternative forms of medical intervention and/or palliative care are provided.

³ The patient remains significantly ill.

⁴ These criteria apply to a patient who was placed into the red category at the initial assessment.

⁵ These criteria apply to a patient who was placed into the yellow category at the initial assessment but because a ventilator was available the patient began ventilator therapy.

At 48 hours, in order to continue ventilator therapy, a patient must exhibit progress in both current health prognosis (i.e., a lower SOFA score compared to the initial assessment) and in the magnitude of improvement in the SOFA score (compared to the SOFA score at the initial assessment). At 48 hours, a patient must exhibit a trend in improvement to retain access to the ventilator. Because a patient has only had 48 hours to benefit from ventilator therapy, the progress required to justify continued ventilator use is not expected to be dramatic.

For a patient who was placed in the red category at the initial assessment, in order to retain ventilator treatment and continue to be in the red color code, his/her SOFA score must be < 7 and the score must have decreased as compared to the SOFA score at the initial assessment. In some cases, a patient who was categorized into the yellow color code receives ventilator treatment because there were no eligible red code patients. For this patient to continue with treatment, s/he must be placed in the red category, meaning that his/her SOFA score must be < 11 (the patient initially had a SOFA score between 8 and 11) and there must be a decrease in the score compared to the SOFA score at the initial assessment.

For a patient receiving ventilator treatment, if his/her SOFA score is < 7 and there is no change in the SOFA score compared to the initial assessment, the patient is placed into the yellow code. Because a patient has had a ventilator time trial, it is expected that s/he should show improvement as a result of receiving ventilator treatment. Although a SOFA score of < 7 is a good score, if there is no improvement (i.e., the same SOFA score compared to the SOFA score at the initial assessment), then the patient is not eligible for continued ventilator use.¹³² If a patient develops an exclusion criterion, has a SOFA score > 11 , or the SOFA score has increased (8 – 11) and there is no change in the score compared to the initial assessment (i.e., the patient remains significantly ill), the patient is assigned a blue color code and is no longer eligible for continued ventilator therapy.¹³³

¹³² If there are no patients waiting for ventilator therapy, a yellow color code patient may continue ventilator therapy until the next assessment.

¹³³ If there are no patients waiting for ventilator therapy, a blue color code patient may continue ventilator therapy until the next assessment.

b. 120 Hour Clinical Assessment Chart

Step 3 - Ventilator Time Trials (120 Hour Assessment)¹	
Color Code and Level of Access	Assessment of Mortality Risk/ Organ Failure
<p>Blue</p> <p>No ventilator provided.² Use alternative forms of medical intervention and/or palliative care or discharge. Reassess if resources become available.</p>	<p>Exclusion criterion</p> <p>OR</p> <p>SOFA > 11</p> <p>OR</p> <p>SOFA < 7 <u>and</u> No Change in SOFA Score Compared to the Previous Assessment</p>
<p>Red</p> <p>Highest</p> <p>Use lifesaving resources as available.</p>	<p>SOFA < 7 <u>and</u> Progressive Decrease in SOFA Score Compared to the Previous Assessment</p>
<p>Yellow</p> <p>Intermediate</p> <p>Use lifesaving resources as available.</p>	<p>SOFA < 7 <u>and</u> Minimal Decrease in SOFA Score (< 3 Point Decrease in Previous 72 Hours) Compared to the Previous Assessment</p>
<p>Green</p> <p>Use alternative forms of medical intervention or defer or discharge. Reassess as needed.</p>	<p>No longer ventilator dependent / Actively weaning from ventilator</p>

¹ If a patient develops a condition on the exclusion criteria list at any time from the 48 hour assessment to the 120 hour assessment, change color code to blue. Remove the patient from the ventilator and provide alternative forms of medical intervention and/or palliative care.

² A patient assigned a blue color code is removed from the ventilator and alternative forms of medical intervention and/or palliative care are provided.

At 120 hours, in order to continue ventilator therapy, a patient must demonstrate a pattern of further significant improvement in both current health prognosis (i.e., a lower SOFA score than at the 48 hour assessment) and in the magnitude of improvement in the SOFA score (compared to the SOFA score at the 48 hour assessment). The Workgroups concluded that by 120 hours, it would be apparent whether a patient is benefiting from ventilator therapy. Thus, in order to justify continued use beyond 120 hours requires a noteworthy positive change in a patient’s health, otherwise, the ventilator is reallocated to another eligible patient.

For a patient to retain ventilator treatment and be assigned the red color code, his/her SOFA score must be < 7 and the score must have progressively decreased as compared to the SOFA score at the 48 hour assessment. A patient is placed in the yellow category if his/her SOFA score is < 7 and there is a minimal decrease in the score (i.e., < 3 point decrease in the

previous 72 hours) compared to the 48 hour assessment SOFA score. A patient is in the blue category if s/he develops an exclusion criterion, has a SOFA score > 11, or the SOFA score is < 7 and there is no change in the score compared to the score at the 48 hour assessment. Again, while a SOFA score < 7 is a positive sign, a patient must exhibit significant improvement in the SOFA score as compared to the 48 hour assessment.

Thus, the primary difference between the 48 and 120 hour assessment is the *extent* of improvement in overall health prognosis and of the trajectory of a patient's health status required to continue to be eligible for ventilator therapy. At 48 hours, a patient must exhibit a pattern of significant improvement to be placed in the red color code. Because a patient has only had 48 hours to benefit from ventilator therapy, the progress required to justify continued ventilator use is not expected to be dramatic. However, after 120 hours, a patient must demonstrate a pattern of *further* significant improvement in health to be placed in the red color code. By 120 hours, it would be apparent whether a patient is benefiting from ventilator therapy. To justify continued use beyond 120 hours requires a noteworthy positive change in a patient's health, otherwise, the ventilator is reallocated to an eligible patient.

D. Clinical Assessment(s) Beyond 120 Hours

After the 120 hour clinical assessment, a patient who is allotted another time trial for ventilator therapy is reassessed every 48 hours. Every 48 hours, a clinical evaluation with the SOFA clinical scoring system is conducted and a triage officer/committee determines whether a patient continues with ventilator therapy. The decision may consider several factors, but first, a patient must continue to exhibit signs of improvement. If there is clear evidence of deterioration that is irreversible, a patient may no longer be eligible for ventilator treatment. Other considerations may include the known progression of the disease,¹³⁴ updated data on the pandemic viral strain,¹³⁵ availability of alternative treatments,¹³⁶ current supply and demand data at the facility (e.g., number of available or soon to be available ventilators and incoming patients requiring ventilator therapy), alternative sites of health care,¹³⁷ and whether there are any patients waiting for a ventilator therapy trial.¹³⁸

¹³⁴ For most patients requiring ventilator therapy, the disease affecting them is the pandemic. As the disease progression becomes known, clinicians will have a better understanding of the duration and recovery periods to assist with triage decisions. However, some patients may be afflicted with other diseases that need to be considered independently when evaluating a patient's clinical status. Other co-morbid factors may alter the trend of a patient's health status.

¹³⁵ As the pandemic progresses, and more data about the pandemic viral strain become available, it may be necessary to modify the triage criteria. For example, as the disease progression becomes known, clinicians will have a better understanding of the duration and recovery periods to assist with triage decisions.

¹³⁶ Alternative treatments include other forms of oxygen delivery or pharmaceutical measures. For a more detailed discussion, see Section XII.A. Alternative Forms of Medical Intervention for a Patient Without Access to a Ventilator.

¹³⁷ Some patients may require transfer to long-term care facilities, such as assisted living facilities. While planning and implementation of such a transition is beyond the scope of the Guidelines, hospitals, residential health care facilities, and emergency planners should address this issue.

¹³⁸ If there are no eligible (red code) patients waiting for ventilator therapy, ventilated patients may continue with this treatment.

E. Decision-Making Process for Removing a Patient from a Ventilator

There may be a scenario where there is an incoming red code patient(s)¹³⁹ eligible for ventilator treatment and a triage officer/committee must remove a ventilator from a patient whose health is not improving at the 48, 120, or subsequent 48 hour time trial assessments, so that the red code patient receives ventilator treatment. As discussed earlier, no formal triage decision or action may be taken until an official time trial assessment of the ventilated patient is performed. A triage officer/committee follows these steps to determine which patient should be removed from the ventilator.¹⁴⁰ First, patient(s) with the worst likelihood of survival and/or with a pattern of significant deterioration even with ventilator therapy (i.e., a blue code patient) is the first patient(s) vulnerable for ventilator removal. If there are no patients in the blue category, then a triage officer/committee proceeds to the yellow code patients (i.e., patients who have high/uncertain risk of mortality and no significant change in overall health after ventilator therapy).

A triage officer/committee is not permitted to compare the health of patients within the same color category. As discussed earlier, a patient expects that doctors provide treatment, to the extent possible, based on assessments of the patient's health as an individual. If ventilator use is primarily determined by the health of *other* patients, clinicians must abandon their obligation to advocate/care for their individual patient. This proposal evokes a war of all against all that ignores health care workers' deep professional obligations to advocate and care for individual patients. Furthermore, such comparisons may intensify inherent biases in the health care system and the disproportionate and disparate provision of care for already disadvantaged populations.

Instead, a triage officer/committee utilizes the following framework to select which patient(s) is removed. Because the assumption is made that all patients¹⁴¹ in the blue¹⁴² (or yellow) category have substantially equal likelihoods of survival, a randomization process such as a lottery is used to select which patient is removed from the ventilator so that another eligible (red code) patient has an opportunity to benefit from ventilator therapy.¹⁴³ A patient may only be

¹³⁹ While there may be yellow color code patients waiting for ventilator therapy, all red code patients must be attended to first. In limited circumstances, where incoming patients are only yellow code, these patients may only receive ventilator therapy if there are any blue code patients currently receiving ventilator treatment. Already ventilated yellow code patients would *not* be removed from the ventilator with the arrival of an incoming yellow code patients since both of these patients have equivalent likelihoods of survival (i.e., both are in the same color category).

¹⁴⁰ For a discussion on review of a triage decision and the appeals process, *see* Chapter 4, Implementing New York State's Ventilator Allocation Guidelines: Legal Considerations, Section VI. Appeals.

¹⁴¹ However, if the ventilated patients include both adults and children, a different non-clinical method is used (i.e., young age). *See* Chapter 2, Pediatric Guidelines, Section V.A.3.b. Use of Young Age as a Secondary Triage Factor (Tie-Breaker) and Section IX.F. Interface between Pediatric and Adult Patients.

¹⁴² In certain circumstances, it is possible for a patient with an exclusion criterion or who has been triaged into the blue category to obtain ventilator therapy because there are no other eligible patients waiting for ventilator therapy. If there is more than one blue code patients, they are subject to the procedures described above when no ventilators are available and there is an eligible (non-blue code) patient waiting for ventilator therapy.

¹⁴³ For a discussion of how randomization could be used to select a patient for removal, *see* Section XI.B.3. Decision-Making Process for Selecting an Eligible Patient for a Ventilator (the same randomization process used for selection could be applied for removal).

removed from a ventilator after an official clinical assessment has occurred or where the patient develops a medical condition on the exclusion criteria list.

Finally, if all ventilated patients at the 48, 120, and subsequent 48 hour time trial assessments receive a red color code, then none of these patients discontinue ventilator therapy. The incoming red code patient(s) remains in an eligible patient pool and receives alternative forms of medical intervention and/or palliative care until a ventilator becomes available.

XII. Alternative Forms of Medical Intervention and Palliative Care

During a public health emergency, non-emergency medical standard of care and decision-making autonomy may not be feasible. In a pandemic, some patients who might have been successfully treated during ordinary conditions may not survive. Policy aimed at maximizing the number of lives saved suggests that in the unfortunate event in which continually more patients require ventilator treatment and as ventilator resources become increasingly scarce, patients whose clinical conditions indicate they are less likely to survive may be denied access to or withdrawn from a ventilator.

Under these circumstances, health care providers should endeavor to follow standard protocols for withholding and withdrawing life-sustaining care. While an emergency may require withholding or withdrawing of a ventilator, health care workers continue to have obligations and a duty to care for their patients. Clinically indicated and appropriate care, such as alternative forms of medical intervention and/or palliative care, within the context of the pandemic situation should be provided to patients who do not meet clinical criteria for continued ventilator therapy, as well as to patients who were not eligible for ventilator treatment.

A. Alternative Forms of Medical Intervention for a Patient without Access to a Ventilator

Although ventilators are the most effective medical intervention for patients experiencing severe respiratory distress or failure, in emergency circumstances, alternative forms of medical intervention for oxygen delivery may be examined, if appropriate.¹⁴⁴ For example, various types of nasal cannula,¹⁴⁵ oxygen face masks,¹⁴⁶ BiPAP/CPAP,¹⁴⁷ transtracheal catheters,¹⁴⁸ or other supplements to breathing may be utilized if medically indicated and available. While none of

¹⁴⁴ Some facilities may not have the oxygen supply, staff, resources, supplies, or equipment to offer these alternative forms of medical intervention.

¹⁴⁵ Nasal cannula is a thin tube with two small prongs that extend into a patient's nostrils. It is typically used to deliver oxygen to patients who require low flow, low to medium oxygen concentration, and are in a stable state.

¹⁴⁶ Oxygen face masks are semi-rigid masks that fit over a person's nose and mouth. They are designed to provide a medium flow and concentration of oxygen.

¹⁴⁷ BiPAP (Bilevel positive airway pressure) and CPAP (continuous positive airway pressure) machines are used to treat sleep apnea disorders. In both systems, oxygen is delivered via a face mask. BiPAP machines are more effective for patients who are unable to completely breathe on their own. For an example of a state ventilator allocation plan that considers BiPAP as an alternative to ventilator treatment, *see* Indiana Guidelines, *supra* note 99, at 24.

¹⁴⁸ Transtracheal catheters are small flexible tubes inserted into the trachea (windpipe) and enable oxygen delivery directly to the lungs. This procedure is often used to assist patients who are extubated to ensure better outcomes with ventilator weaning.

these treatments offer long-term support for a patient with severe influenza, they may sustain the patient long enough for a ventilator to become available.¹⁴⁹ Furthermore, pharmacological antivirals may provide some benefit for patients.

Another alternative for oxygen delivery in lieu of ventilators is the use of hand-held devices, such as a bag-valve mask, or ambu-bags.¹⁵⁰ Commentators have argued that a patient's family and loved ones should be provided with the option to manually ventilate the patient.¹⁵¹ In developing countries, anecdotal evidence has revealed that ventilating a patient via a bag-valve mask can stabilize the patient for extended periods of time.¹⁵² It may be unreasonable to inform a patient's loved ones that they cannot attempt to ventilate the patient using an ambu-bag, because these individuals are likely to explore all possible scenarios to increase the patient's likelihood of survival. Despite the risks involved (i.e., the risk of infection is likely high), this option may be pursued by those who understand and are willing to assume the risks, or have already been sickened by the pandemic viral strain and recovered.

With regards to ambu-bagging, the Task Force and the Clinical Workgroups recommended that this form of ventilation should not be permitted at the acute care facility. There are many risks and shortcomings associated with bag-valve ventilation. From a clinical perspective, the 2009 Adult Clinical Workgroup did not recommend the use of ambu-bag as a feasible alternative for several reasons. The Workgroup was not convinced that this method of ventilation was effective against a severe pandemic viral strain of influenza. The complications associated with influenza likely would require a more powerful oxygen delivery system. Furthermore, the Clinical Workgroups agreed that the risk of infection would be very high, which could compromise the health and safety of the individuals bagging a patient and other staff at the facility.

From a logistical perspective, it would not be feasible to permit ambu-bagging at the acute care facility. Hospitals may be overwhelmed with patients and there may not be physical space to house individuals who are providing this care. In addition, isolation/quarantine orders designed to limit the spread of infection may not permit access to those sick with the virus, which makes ambu-bagging impossible. Limited health care staff may make it impossible to bag patients. Ambu-bagging requires an extensive use of resources – constant attention is required to ensure the bag is used correctly – which is not feasible during staff shortages.¹⁵³

¹⁴⁹ A patient receiving an alternative form of oxygen delivery may be eligible for a ventilator depending on the real-time availability of these machines and whether there are patients waiting for a ventilator.

¹⁵⁰ Bag-valve masks are used often to ventilate a patient who is no longer breathing, especially as part of resuscitation techniques (i.e., mouth-to-mouth). It consists of three parts: (1) bag, generally about the size of a football (for adults), (2) face mask, and (3) one-way valve that is between the bag and face mask. The mask is held tightly over the mouth and nose of a patient to ensure the air from the squeezed bag enters the lungs and does not leak out. Two people are required to ambu-bag efficiently, one to squeeze the bag and the other to hold the mask in place.

¹⁵¹ See Hick and O'Laughlin, *supra* note 65, at 224.

¹⁵² P.K. Maurya et al., *Manual AMBU Ventilation is Still Relevant in Developing Countries*, 12 QJM 990, 991 (2008).

¹⁵³ However, ambu-bagging may be permitted by the facility in a limited case-by-case scenario, such as when a ventilator is expected to become available in a short period of time and staff resources are available.

Finally, the potential ramifications of shifting this burden of caring for the sick to loved ones may be traumatizing. Although family members and loved ones may have the best intentions of bagging a patient, the procedure requires non-stop attention. These individuals may be unable to walk away once the effort has begun and the effort is impossible for one person to sustain. Disputes regarding who should be responsible for the bagging are inevitable and take a considerable toll on a patient's family and loved ones. Furthermore, if the manual ventilator effort is unsuccessful, those involved may feel personally responsible.

B. Palliative Care

Available forms of palliative care are offered to patients who are not eligible for ventilator treatment as well as patients who fail to meet clinical criteria for continued use of a ventilator. Palliative care is an interdisciplinary service designed to ease the discomfort that can accompany serious or life-threatening illness. Its provision respects the dignity of a patient who does not or can no longer receive ventilator treatment. Palliative care is aimed at providing comfort, both physically and emotionally, under the circumstances.¹⁵⁴

Actively providing effective palliative care to patients who do not or no longer qualify for ventilator therapy decreases patient discomfort and fulfills the provider's duty to care, even when the clinician cannot offer ventilator treatment. Care should include pain management and non-pharmacological interventions, such as holding a hand or offering words of comfort. Efforts should include educating a patient and his/her loved ones. Information regarding a patient's condition, prognosis, and the general circumstances of the influenza pandemic situation aids a patient and loved ones in making informed decisions regarding care. Providing the physical and emotional care required to keep a patient as comfortable as possible is important to both the patient and his/her family.

In the ventilator withdrawal context, appropriate measures should be taken to prepare for and ease the process of withdrawal for patients and their loved ones. Palliative care providers are well-versed in the clinical implications of ventilator withdrawal as well as with the parameters of end-of-life decision-making, and therefore can help loved ones prepare both practically and emotionally. Preferences regarding extubation procedures, including agreed upon levels of sedation and pain management, should be respected and followed when appropriate and available. Ideally, decisions concerning the withholding and withdrawing of treatment includes a patient's loved ones; however, their involvement may be limited by the pandemic situation. Standard protocols for extubation may offer guidance for appropriate medications and dosing, length of weaning process, and other associated procedures. Medical decisions should intend to provide comfort care and reduce the risk of shortness of breath appropriately as ventilator treatment is withdrawn. Transparency is a crucial element in adhering to ethical standards; clinicians should clearly document their rationale and decisions regarding the process of ventilator withdrawal. Finally, facilities should prepare for a significant increase in demand for

¹⁵⁴ See VHA Guidelines, *supra* note 63; Institute of Medicine, *Crisis Standards of Care: A Systems Framework for Catastrophic Disaster Response*, 78-79 Washington, DC (Dan Hanfling et al., eds., The National Academies Press 2012).

palliative care supplies and expertise, and they should become familiar with State and local palliative care resources to help meet the demand.¹⁵⁵

For patients who are not eligible for ventilator therapy, health care providers should administer pain management and non-pharmacological interventions. In addition, alternative forms of medical intervention should be provided.

XIII. Logistics Regarding the Implementation of the Guidelines

There are several non-legal issues¹⁵⁶ to consider once the Guidelines are implemented, including communication about triage, and real-time data collection and analysis to modify the Guidelines based on new information.

A. Communication about the Guidelines and Clinical Ventilator Allocation Protocol

Implementation of the Guidelines requires clear communication to the public about the goals and steps of the clinical ventilator allocation protocol. Efforts will be made to inform and gather feedback from the public before a pandemic, and may include posting of the Guidelines on government websites; open comment periods; presenting the Guidelines at conferences, meetings, webinars, community meetings; and conducting tabletop exercises and focus groups. In addition, a public awareness and education campaign on the Guidelines using various print, radio, and social media outlets will be performed.

Public outreach should include a component that informs people that the medical standard of care during an influenza pandemic will be different than the normal (i.e., non-pandemic) medical standard of care. It will also include information that during this specific scenario, patient preference will not determine ventilator access. Instead, a protocol based only on clinical factors will be used to determine whether a patient receives (or continues with) ventilator treatment to support the goal of saving the greatest number of lives in an influenza pandemic where there are a limited number of available ventilators.

Many people, however, will not be aware of the Guidelines until a pandemic is declared. At that time, the public should be informed about the goals and steps of the clinical ventilator allocation protocols. Information should emphasize that pandemic influenza is potentially fatal, that health care providers are doing their best with limited resources, and the public must adjust

¹⁵⁵ The Hospice and Palliative Care Network of New York State has compiled comprehensive resources to inform and educate providers and family members about the provision of palliative care in a pandemic, including symptom management guidelines for pediatric, adult, and elderly patients, bereavement resources, a flowchart that details steps to take if a patient is denied access to or removed from a ventilator, as well as planning resources, such as curricula for health care providers and laypersons about palliative care in a pandemic. See Hospice and Palliative Care Association of New York, *Emergency Preparedness Resource Center*, <http://www.hpcanys.org/members/resource-center-tool-kits/family-healthcare-decision-act-hospice-resource-center/>; for information about palliative care providers in New York State, see Center to Advance Palliative Care, *Provider Directory: New York*, www.getpalliativecare.org.

¹⁵⁶ For a discussion of the legal issues involved when implementing the Guidelines, see Chapter 4, Implementing New York State's Ventilator Allocation Guidelines: Legal Considerations.

to a different way of providing and receiving health care than is customary. Patients and families should be informed that ventilator therapy represents a *trial* of therapy that may not improve a patient's condition sufficiently and that the ventilator will be removed if this approach does not enable the patient to meet specific criteria. Training of staff for pandemic readiness should include guidance on how to discuss the clinical ventilator allocation protocols. Communication should be clear upon hospital admission and ICU admission, as well as upon initiation of ventilator treatment.

B. Real-Time Data Collection and Analysis and Modification of the Guidelines

Public health officials and clinicians operating during a pandemic must engage in real-time data collection and analysis,¹⁵⁷ to modify the Guidelines based on new information. As data become available during a pandemic, experts learn more about the particular viral strain and should adjust response measures accordingly. For example, data analysis may discern relevant factors such as how the virus affects certain patient populations, the average duration of sickness and the time necessary for recovery, or whether particular patient groups have a greater likelihood of survival (or mortality), which permit evidence-based modification of the clinical ventilator allocation protocol. Specific components of the clinical ventilator allocation protocol that may need to be modified in the face of new information include, for example, exclusion criteria, the SOFA score values that correspond to color codes, and the time allotted for time trials once a patient begins ventilator treatment.

Data collection and analysis on the pandemic viral strain, such as symptoms, disease course, treatments, and survival are necessary so that the clinical ventilator allocation protocol may be adjusted accordingly to ensure that patients receive the best care possible. Furthermore, data collection must include real-time availability of ventilators so that resources can be allocated most effectively. Knowing the exact availability of ventilators also assists a triage officer/committee in providing the most appropriate treatment options for patients.

XIV. Conclusion

With any luck, a severe influenza pandemic will never emerge in New York. With planning, even if a pandemic does occur, community members, health care providers, and public officials may be able to diminish its impact. The Guidelines rely upon both ethical and clinical standards in an effort to offer the best possible care under gravely compromised conditions to support the goal of saving the most lives in an influenza pandemic where there are a limited number of available ventilators.

While the Adult Guidelines developed by the Task Force and the 2006 and 2009 Adult Clinical Workgroups assist a triage officer/committee as they evaluate potential patients for ventilator therapy, decisions regarding treatment should be made on an individual (patient) basis, and all relevant clinical factors should be considered. A triage decision is not performed in a

¹⁵⁷ See e.g., Asha V. Devereaux et al., *Engagement and Education Care of the Critically Ill and Injured During Pandemics and Disasters: CHEST Consensus Statement*, 146(4 Suppl.) CHEST e118S, e121S (2014) (noting that situational awareness, which consists of integrated communications systems and electronic health records can assist with tracking the people affected)

vacuum; instead, it is an adaptive process, based on fluctuating resources and the overall health of a patient. Examining each patient within the context of his/her health status and of available resources provides a more flexible decision-making process, which results in a fair, equitable plan that saves the most lives.

Finally, the adult clinical ventilator allocation protocol is a set of guidelines to assist clinicians in distributing limited ventilators and may be revised as more information on the nature of the pandemic viral strain is gathered. It may be modified to ensure that the recommended approach reflects strain-specific influenza progression so that patients receive the most appropriate care.

Appendix 1
Additional Clinical Information regarding Exclusion Criteria (Step 1)

Determining Traumatic Brain Injury

No Motor Response to Painful Stimulus (i.e., Best Motor Response = 1)

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

American Burn Association (ABA)
Triage Decision Table for Burn Victims Based on Anticipated Outcomes
Compared with Resource Allocation¹⁵⁸

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.

¹⁵⁸ See Utah Guidelines, *supra* note 99, at 7.

Appendix 2
Additional Clinical Information regarding
Sequential Organ Failure Assessment (SOFA) Score Scale (Steps 2 and 3)¹⁵⁹

Variable	0	1	2	3	4	Score (0-4)
PaO₂/FiO₂ mmHg	> 400	< 400	< 300	< 200	< 100	
Platelets, x 10³/μL (x 10⁶/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):						

Dopamine [Dop], epinephrine [Epi], and norepinephrine [Norepi] doses in μg/kg/min (administered for at least one hour). SI units in parentheses ()

Explanation of variables:

- PaO₂/FiO₂ indicates the level of oxygen in a patient's blood.
- Platelets are a critical component of blood clotting.
- Bilirubin is measured by a blood test and indicates liver function.
- Hypotension indicates low blood pressure; scores of 2, 3, and 4 indicate that blood pressure must be maintained by the use of powerful medications that require ICU monitoring (including dopamine, epinephrine, and norepinephrine).
- The Glasgow Coma Scale Score is a standardized measure that indicates neurologic function; low score indicates poorer function. See the worksheet on next page to calculate the score.
- Creatinine is measured by a blood test and indicates kidney function.

¹⁵⁹ See Ferreira, SOFA, *supra* note 84.

Appendix 2 Continued
Additional Clinical Information regarding
Sequential Organ Failure Assessment (SOFA) Score Scale (Steps 2 and 3)
Glasgow Coma Scale Score Criteria

Criteria	Adults	Score	Criteria Score
Best Eye Response (1 – 4)	No eye opening	1	
	Eye opens to painful stimulus	2	
	Eye opens to verbal command	3	
	Eyes open spontaneously	4	
Best Verbal Response (1 – 5)	No verbal response	1	
	Incomprehensible sounds	2	
	Inappropriate words	3	
	Confused	4	
	Oriented	5	
Best Motor Response (1 – 6)	No motor response	1	
	Extension to painful stimulus	2	
	Flexion to painful stimulus	3	
	Withdraws from painful stimulus	4	
	Localizes to painful stimulus	5	
	Obeys commands	6	
Total Score (add three subscores, range from 3 to 15):			

Appendix A- Members of the Task Force on Life and the Law

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CHAPTER 2

PEDIATRIC GUIDELINES

Abstract

Introduction

A severe influenza pandemic on the scale of the 1918 influenza outbreak will significantly strain medical resources, including ventilators. It has been estimated that roughly 30 percent of the overall population in New York State will become ill during a similar pandemic, with school-aged children suffering at a rate of about 40 percent – a higher illness rate than that of adults. There will not be enough ventilators in the State to meet the demand and a clinical ventilator allocation protocol will need to be implemented to ensure that ventilators are allocated in the most efficient manner to support the goal of saving the greatest number of lives.

Policy-makers and emergency management experts recognize that a one-size-fits-all approach to emergency planning is not appropriate and that the differences between adult and pediatric patients warrant specialized attention, especially in the context of an influenza pandemic and the allocation of scarce resources, i.e., ventilators. Acknowledging the need for a thorough evaluation and development of a clinical ventilator allocation protocol for pediatric populations in an influenza pandemic, the New York State Task Force on Life and the Law (the Task Force) and the New York State Department of Health (the Department of Health), undertook a comprehensive project to draft clinically sound and ethical ventilator allocation guidelines (Pediatric Guidelines).

The Pediatric Guidelines reflect a synthesis of pediatric clinical experts' (the Pediatric Clinical Workgroup) and the Task Force's recommendations on ventilator allocation for children during an influenza pandemic. Because research and data on this topic are constantly evolving, the Pediatric Guidelines are a living document intended to be updated and revised in line with advances in clinical knowledge and societal norms. The Guidelines incorporate an ethical framework and evidence-based clinical data to support the goal of saving the most lives in an influenza pandemic where there are a limited number of available ventilators.

The Pediatric Guidelines contain three main sections. The first section examines the unique considerations for pediatric emergency preparedness and explores the ethical issues related to the treatment of children in a pandemic. The second section provides an overview of various clinical components that could be used to triage pediatric patients. The third section presents New York's pediatric clinical ventilator allocation protocol.

Section 1: Special Considerations for Pediatric Emergency Preparedness and the Ethical Issues related to the Treatment of Children in a Pandemic

The challenges presented by the allocation of ventilators and other scarce resources among children are likely more pronounced than those among other patient populations. In non-emergency conditions, children are critically ill less often than adults; consequently, there are

fewer health and critical care resources – i.e., facilities, supplies, and equipment – for children than for adults. While stockpiling ventilators has been suggested as a solution, the shortage of other resources, such as health care staff to operate ventilators, does not obviate the need for an allocation plan.

In addition, an increase in the number of children in acute care facilities requires planning. Appropriate supervision, size-appropriate supplies and equipment for infants to adolescents, family reunification procedures, special considerations for children with disabilities or specific health care needs, and the emotional complexities and psychological trauma for children, family members, caregivers, and health care staff, need to be addressed.

The Task Force examined several key concepts of triage to advance the goal of saving the most lives within the specific context of ventilators as the scarce resource in an influenza pandemic. To accomplish this goal, patients for whom ventilator therapy would most likely be lifesaving are prioritized. The Guidelines define survival by examining a patient’s short-term likelihood of surviving the acute medical episode and not by focusing on whether the patient may survive a given illness or disease in the long-term (e.g., years after the pandemic). Patients with the highest likelihood of survival *without* medical intervention, along with patients with the smallest likelihood of survival *with* medical intervention, have the *lowest* level of access to ventilator therapy. Thus, patients who are most likely to survive without the ventilator, together with patients who will most likely survive with ventilator therapy, increase the overall number of survivors.

The ethical framework that underlies the adult clinical ventilator allocation protocol – duty to care, duty to steward resources, duty to plan, distributive justice, and transparency – also applies to the pediatric clinical protocol (see Chapter 1, Adult Guidelines). However, the treatment of pediatric patients requires special ethical and clinical considerations in light of children’s unique needs and their role in society. The Task Force examined the use of young age as a triage criterion within the context of safeguarding children because they are a vulnerable population and represent the future. The theories of “fair innings” and “life years saved” were also analyzed, as they support a child’s opportunity to live through all of life’s phases and to reach old age.

The Task Force concluded that ventilators should be allocated in a manner to maximize the number of survivors, and young age should not be a primary triage factor. Instead, clinical criteria should be used to give patients who were deemed most likely to survive with ventilator therapy an opportunity for treatment. There were several disadvantages to selecting patients based solely on young age for ventilator therapy. Prioritizing children over adults for ventilators in every case, without considering likelihood of survival, would almost certainly result in far fewer people surviving the pandemic. In addition, granting children preference may only result in the youngest children receiving ventilator therapy. Furthermore, this allocation system may discriminate against adults and the elderly, and the adult clinical ventilator allocation protocol rejected using advanced age as a criterion for clinical reasons. Finally, children are not the only vulnerable populations in society, and the belief that children should be always prioritized is not universally held.

However, because of a strong societal preference for saving children, the Task Force recommended that *young* age may be considered as a tie-breaking criterion in limited circumstances. When the pool of patients eligible for ventilator therapy includes both adults and children, the Task Force determined that when all available clinical factors have been examined and the likelihood of survival among the pool of eligible patients has been found equivalent, only then may young age be utilized as a tie-breaker to select a patient for ventilator therapy. Thus, Guidelines that emphasize likelihood of survival while incorporating the use of young age solely as a tie-breaker criterion acknowledge general societal values and advance the goal of saving the most lives.

Section 2: Overview of Various Clinical Components when Triageing Pediatric Patients

Prior to the development of New York's Pediatric Guidelines, possible clinical components of a pediatric ventilator allocation protocol were examined.

The use of a pediatric clinical scoring system (mSOFA, PRISM III, PIM 2, P-MODS, or PELOD), which assigns scores to patients based on mortality risk or severity of organ dysfunction, was not included. In theory, a clinical scoring system might provide a consistent approach to resource allocation; however, in practice, its use may not be effective or ethical, because none of the clinical scoring systems above have been validated for triage purposes. In lieu of a scoring system, physician clinical judgment, using a structured decision-making process that carefully considers only specific clinical factors based on available medical evidence, is used to evaluate a patient's likelihood of survival, to determine whether a pediatric patient is eligible for ventilator therapy. While physician clinical judgment may not be optimal to use during a pandemic, a ventilator allocation decision based on an unvalidated scoring system is more problematic and may not optimize limited resources.

Exclusion criteria are a list of medical conditions that will likely result in immediate or near-immediate death even with aggressive therapy. Applying exclusion criteria help identify patients with a short life expectancy, in order to prioritize patients most likely to survive with ventilator therapy. While selecting medical conditions that qualify as exclusion criteria is challenging, this list makes essential contributions to the goals of efficient ventilator distribution and saving the most lives.

When determining whether a ventilator patient continues with ventilator therapy, the most common clinical factors to examine include time trials, oxygenation index (OI) and resource utilization/duration of ventilator need. Time trials are periodic evaluations of a ventilated patient to determine whether the patient is improving as a result of receiving ventilator therapy. Time trials are necessary because they provide as many patients as possible with sufficient opportunity to benefit from ventilator therapy. However, until a pandemic is occurring and data analysis about the viral strain becomes available, it is difficult to define prior to a pandemic what the optimal length of a time trial should be. In addition, a patient's response to ventilation using oxygenation index (OI) may be a useful clinical tool to evaluate whether a patient continues with ventilator therapy, while resource utilization (i.e., estimated duration of ventilator need) may not be appropriate to employ until better data about the pandemic viral strain become available.

In addition to reviewing possible components of a pediatric triage plan, existing pediatric clinical ventilator allocation protocols were examined. Only a few U.S. states (Alaska, Florida, Kansas, Indiana, Michigan, Minnesota, Utah, and Wisconsin) and a Canadian province (Ontario) have ventilator allocation guidelines designed specifically for pediatric patients. These guidelines differ on several key aspects, including: (1) the age at which the pediatric, rather than the adult, clinical ventilator allocation protocol is applied; (2) the use of exclusion criteria; (3) which clinical scoring system, if any, is used; (4) the extent of physician clinical judgment used; (5) whether to consider a patient's estimated ongoing resources demands (i.e., duration of ventilator need); and (6) the amount of time allotted to gauge whether a patient is benefiting from ventilator therapy. An analysis of the various pediatric plans reveals a lack of consistency between plans at every step of the triage process.

Section 3: New York's Pediatric Clinical Ventilator Allocation Protocol

While the adult and pediatric clinical ventilator allocation protocols do not utilize the exact same clinical tools to evaluate a patient, the ethical and clinical frameworks remain the same. As with the adult clinical ventilator allocation protocol, first, facilities should develop surge capacity to reduce the demand for ventilators when a pandemic is occurring. The pediatric clinical ventilator allocation protocol applies to all children aged 17 years old and younger, (i.e., under 18 years old), in all acute care facilities Statewide. All pediatric acute care patients in need of a ventilator, whether due to influenza or other conditions, are subject to the clinical protocol. Ventilator-dependent chronic care patients are only subject to the clinical ventilator allocation protocol if they arrive at an acute care facility. Using clinical criteria, patients deemed most likely to survive with ventilator therapy have an opportunity for this treatment to maximize the number of survivors. The pediatric clinical ventilator allocation protocol consists of three steps:

- Step 1 – Exclusion Criteria: A patient is screened for exclusion criteria. The purpose of applying exclusion criteria is to identify patients with the highest probability of mortality, even with ventilator therapy, in order to prioritize patients most likely to survive with ventilator therapy. The medical conditions that qualify as exclusion criteria are limited to those associated with immediate or near-immediate mortality even with aggressive therapy. If a patient has a medical condition on the exclusion criteria list, s/he is not eligible for ventilator therapy. Instead, a patient receives alternative forms of medical intervention and/or palliative care.
- Step 2 – Mortality Risk Assessment Using Physician Clinical Judgment: Physician clinical judgment is used to assess a patient's risk of mortality. Because none of the currently available pediatric clinical scoring systems have been validated for triage purposes, physician clinical judgment, using a structured decision-making process that carefully considers only specific clinical factors, is used to assess a patient's risk of mortality. When evaluating a patient's mortality risk, the patient's attending physician may consider the following: the acute severity of the patient's current medical condition, the epidemiology of the disease, and the existence and status of any severe underlying diseases or medical conditions (co-morbidities) that may hinder recovery. Finally,

resource utilization with respect to estimated duration of ventilator need as a stand-alone triage factor was rejected because it does not affect a patient's likelihood of survival. A triage officer/committee examines clinical data from Steps 1 and 2 and allocates ventilators according to a patient's mortality risk.

- Step 3 – Time Trials: Periodic clinical assessments are conducted at 48 and 120 hours on a patient who has begun ventilator therapy to evaluate whether s/he continues with the treatment. Various clinical parameters are examined at this step to assess the possibility of organ failure and to measure lung function. The decision whether a patient remains on a ventilator is based on ongoing clinical measures and data trends of the patient's health condition, consisting of: (1) the overall prognosis estimated by the patient's clinical indicators, which is indicative of mortality risk by revealing the presence (or likelihood), severity, and number of acute organ failure(s), and (2) the magnitude of improvement or deterioration of overall health, which provides additional information about the likelihood of survival with ventilator therapy. The results from the current assessment are compared to the results from the previous official clinical assessment. Any changes (improving, worsening, or experiencing no change) in a patient's health status after 48 and 120 hours help guide the triage decision. Thus, the guiding principle for the triage decision is that the likelihood of a patient's continuation of ventilator therapy depends on the severity of the patient's health condition and the extent of the patient's medical deterioration. In order for a patient to continue with ventilator therapy, s/he must demonstrate an improvement in overall health status at each official clinical assessment.

Because a clinical scoring system is not used, a triage decision is based on continuous evaluation of a patient's health data trend, which consists of two parts. The first is the prognosis determined by a patient's results for six clinical parameters (Glasgow Coma Scale Score, hypotension, oxygenation index (OI)/ arterial oxygen saturation, whole blood/serum lactate, serum creatinine, and serum bilirubin/scleral icterus). These results reveal the presence (or likelihood), severity, and number of acute organ failure(s), which indicate mortality risk. The second part is the magnitude of improvement or deterioration of overall health based on these parameters, which provides additional information about the likelihood of survival with ventilator therapy. Together, these clinical variables provide an overall health assessment of a patient.

While no triage decision should be based on a single clinical variable, a triage officer/committee should place more weight on the health data trends from the OI/arterial oxygen saturation, hypotension, and Glasgow Coma Scale Score factors because these are stronger predictors of mortality risk. The other clinical factors reveal whether a patient is experiencing multiple organ failure, and while useful, they should *never* be the *sole* reason to justify a triage decision involving extubation.

The primary difference between the 48 and 120 hour assessment is the extent of improvement in overall health prognosis and of the trajectory of a patient's health status required to continue to be eligible for ventilator therapy. At 48 hours, because a patient has only had two days to benefit from ventilator therapy, the progress required to justify continued ventilator use is not expected to be dramatic. However, after 120 hours, a

patient must demonstrate a pattern of *further* significant improvement in health to continue. After the 120 hour clinical assessment, a patient who is eligible to continue with ventilator therapy is reassessed every 48 hours with the same six clinical parameters listed above.

Although additional clinical assessments may be performed, the official assessments only occur after 48 and 120 hours of ventilator therapy. No formal triage decision or action may be taken until a patient's official assessment. However, at any point during the time trial, even before an official assessment occurs, if a patient develops a condition on the exclusion criteria list and there is an eligible patient waiting, then the ventilator is reallocated. A patient who no longer meets the criteria for continued use receives alternative forms of medical intervention and/or palliative care.

In addition to the three steps described above, additional components of the pediatric clinical ventilator allocation protocol include:

Triage Officer/Committee: To ensure that patients receive the best care possible, a patient's attending physician does not determine whether his/her patient receives (or continues) ventilator therapy; instead a triage officer or triage committee makes the decision. The attending physician's role is to evaluate a patient for exclusion criteria in Step 1 and to assess the patient's mortality risk and organ failure risk in Steps 2 and 3. A triage officer/committee does not have any direct contact with a patient. Instead, a triage officer/committee examines the data provided by the attending physician and makes the determination about a patient's level of access to a ventilator. Ideally, a triage officer/committee has experience working with pediatric patients.

Color Codes/Level of Access to Ventilator Therapy: A patient's attending physician provides all clinical data to a triage officer/committee. At Steps 2 and 3, a triage officer/committee examines a patient's clinical data and uses this information to assign a color code to the patient. The color (blue, red, yellow, or green) determines the level of access to a ventilator (blue = lowest access/palliate/discharge, red = highest access, yellow = intermediate access, and green = defer/discharge). Patients with the red color code have the highest level of access to a ventilator.

Blue code patients (lowest access/palliate/discharge) are those who have a medical condition on the exclusion criteria list or those who have a high risk of mortality and these patients do not receive ventilator therapy when resources are scarce. Instead, alternative forms of medical intervention and/or palliative care are provided. However, if more resources become available, patients in the blue color category, or those with exclusion criteria, are reassessed and may be eligible for ventilator therapy. Red code patients (highest access) are those who have the highest priority for ventilator therapy because they are most likely to recover with treatment (and likely to not recover without it) and have a moderate risk of mortality. Patients in the yellow category (intermediate access) are those who are very sick, and their likelihood of survival is intermediate and/or uncertain. These patients may or may not benefit (i.e., survive) with ventilator therapy. They receive such treatment if ventilators are available after all patients in the

red category receive them. Patients in the green color code (defer/discharge) are those who do not need ventilator therapy.

Decision-Making Process for Selecting an Eligible Patient for a Ventilator: In some circumstances, a triage officer/committee must select one of many eligible red color code patients to receive ventilator therapy. A patient's likelihood of survival (i.e., assessment of mortality risk) is the most important consideration when evaluating a patient. However, there may be a situation where multiple patients have been assigned a red color code, which indicates they all have the highest level of access to ventilator therapy, and they all have equal (or near equal) likelihoods of survival. If the eligible patient pool consists of *only children*, a randomization process, such as a lottery, is used each time a ventilator becomes available because there are no other evidence-based clinical factors available to consider. Patients waiting for ventilator therapy wait in an eligible patient pool and receive alternative forms of medical intervention and/or palliative care until a ventilator becomes available.

Decision-Making Process for Removing a Patient from a Ventilator: There may be a scenario where there is an incoming red code patient(s) eligible for ventilator therapy and a triage officer/committee must remove a ventilator from a patient whose health is not improving. In this situation, first, patients in the blue category (or the yellow category if there are no blue code patients receiving ventilator therapy) are vulnerable for removal from ventilator therapy if they fail to meet criteria for continued ventilator use. If the pool of ventilated patients vulnerable for removal consists of *only children*, a randomization process, such as a lottery, is used each time to select the (blue or yellow) patient who will no longer receive ventilator therapy. A patient may only be removed from a ventilator after an official clinical assessment has occurred or where the patient develops a medical condition on the exclusion criteria list. However, if all ventilated patients are in the red category (i.e., have the highest level access), *none* of the patients are removed from ventilator therapy, even if there is an eligible (red color code) patient waiting.

Interface between Pediatric and Adult Patients: Because many ventilators can be used for either an adult or a pediatric patient, there may be circumstances where a triage officer/committee must select one for ventilator therapy. While the framework of the pediatric and adult clinical ventilator allocation protocols is the same, a triage officer/committee may need to evaluate the mortality risks of children and adults using different clinical assessment tools (physician clinical judgment and SOFA clinical scoring system, respectively). Although a patient with the greatest chance of survival with ventilator therapy should receive (or continue with) this treatment, it is not obvious how this determination should be made when the mechanisms used to predict mortality risk are not the same. The use of different clinical tools to assess mortality is acceptable, primarily because no other appropriate alternative exists. Ideally, experienced clinicians with appropriate training in both pediatric and adult mass casualty scenarios will be able to provide an overall assessment of survivability for both populations.

When either selecting or removing a patient in the eligible patient pool consists of both children and adults, a triage officer/committee is not permitted to compare the health of patients; instead they must assume that all patients in a color category have substantially equal likelihoods of survival because no other evidence-based clinical tools are available to further differentiate a patient's mortality risk. The Task Force determined that only in this unique circumstance, when

the patients all have equal (or near equal) likelihoods of survival, may young age play a tie-breaking role in determining whether a patient receives/continues with ventilator therapy. In this situation, the child (i.e., a child 17 years old and younger) receives/continues with ventilator therapy and the adult receives alternative forms of medical intervention and/or palliative care.

Alternative Forms of Medical Intervention and Palliative Care: Patients who have a medical condition on the exclusion criteria list or who no longer meet the clinical criteria for continued ventilator use receive alternative forms of medical intervention and/or palliative care. The same applies to patients who are eligible for ventilator therapy but for whom no ventilators are currently available. Actively providing palliative care, especially to patients who do not or no longer qualify for ventilator therapy, decreases patient discomfort and fulfills the provider's duty to care, even when the clinician cannot offer ventilator therapy. In addition, alternative forms of medical intervention, such as other methods of oxygen delivery and pharmacological antivirals, should be provided to those who are not eligible or waiting for a ventilator. However, the use of ambu-bags is discouraged for several reasons: the technique may not be effective against pandemic influenza, it may contribute to transmission of the virus, and possible isolation/quarantine orders, lack of health care staff, and burden on the families may make it difficult to conduct for extended periods of time.

Palliative care is provided to all patients, regardless of prognosis. The resilience and significantly lower mortality rates for serious illness in children, limited physician education and expertise in pediatric palliative care, and the extent of involvement of parents, caregivers, and other family members of children may significantly affect the extent of palliative care administered to a child.

Logistics regarding Implementation of the Guidelines: Once the Guidelines are implemented, there must be communication about triage, and real-time data collection and analysis to modify the Guidelines based on new information. Efforts will be made to inform and gather feedback from the public before a pandemic. In addition, there must be real-time data collection and analysis on the pandemic viral strain, such as symptoms, disease course, treatments, and survival, so that the clinical ventilator allocation protocol may be modified accordingly to ensure that patients receive the best care possible. Data collection must include real-time availability of ventilators so that triage decisions are made to allocate resources most effectively. Knowing the exact availability of ventilators also assists a triage officer/committee in providing the most appropriate treatment options for patients.

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I. Introduction

The majority of the U.S. population has little first-hand experience with the infectious diseases and pandemics that have resulted in widespread mortality. In light of historic influenza outbreaks and recent foreign cases of avian influenza, it is foreseeable that a pandemic will occur in the future, and society will have to confront the difficult reality of significant numbers of people, including children, are critically ill.

Much has been written on the clinical and ethical issues regarding ventilator allocation for adults during an influenza pandemic. In particular, in 2007 the New York State Task Force on Life and the Law (the Task Force),¹ and the New York State Department of Health (the Department of Health) developed draft ventilator allocation guidelines for adults in New York (the Draft Guidelines). However, emergency preparedness plans, including the New York's Draft Guidelines, did not include information on how to provide optimal pediatric care with limited resources in a public health emergency scenario.² Although much has been written on the clinical and ethical issues regarding ventilator allocation for adults during an influenza pandemic, emergency preparedness plans often lack specific instructions on how to care for children.³ While it is widely acknowledged that children have different needs than adults, the dearth of guidance on how to address special requirements for pediatric patients⁴ is troublesome.

Due to their unique vulnerabilities, children may be disproportionately affected by an influenza pandemic. Young children often are more susceptible because they are exposed to

¹ Established by Executive Order in 1985, the Task Force is comprised of 23 Governor-appointed leaders in the fields of religion, philosophy, law, medicine, nursing, and bioethics. The Task Force develops public policy on issues arising at the interface of medicine, law, and ethics, and has issued influential reports on cutting-edge bioethics issues. See Appendix A for a list of the Task Force members who participated in this project.

² Although this document is intended to respond to the allocation of ventilators during an influenza pandemic, the general framework could be adapted – with appropriate modifications – to any public health emergency where resources will be scarce. These guidelines use the term pandemic to reference a pandemic caused by the influenza virus.

³ Institute of Medicine, *Crisis Standards of Care: Summary of a Workshop Series*, 28 Washington, DC (The National Academies Press 2010). There are, however, useful and comprehensive guidelines that have been developed to assist New York hospitals with pediatric emergency preparation. See, e.g., Centers for Bioterrorism Preparedness Program and New York City Department of Health and Mental Hygiene, *Children in Disasters: Hospital Guidelines for Pediatric Preparedness*, NEW YORK CITY HEALTH 3rd Ed. (2008), <http://home2.nyc.gov/html/doh/downloads/pdf/bhpp/bhpp-hospital-pediatric-guidelines.pdf>; and New York State Department of Health, Health Emergency Preparedness Program & Division of Family Health, *Pediatric and Obstetric Emergency Preparedness Toolkit: A Guide for Pediatric and Obstetric Emergency Planning*, NEW YORK STATE DEPARTMENT OF HEALTH (2010), (hereinafter New York Pediatric Emergency Guidelines) http://www.health.ny.gov/facilities/hospital/emergency_preparedness/guideline_for_hospitals/docs/emergency_prep_aredness_manual.pdf. In addition, in 2011, a pediatric emergency mass critical care task force, sponsored by the Centers for Disease Control and Prevention (CDC), released several articles to call attention to various pediatric considerations as emergency preparedness plans are being developed. Niranjan Kisson et al., *Deliberations and Recommendations of the Pediatric Emergency Mass Critical Care Task Force: Executive Summary*, 12 PEDIATR. CRIT. CARE MED. S103 (2011).

⁴ The terms “pediatric patient(s)” is used interchangeably with “child/children,” “adolescent(s)/teenager(s),” and “neonates/infants.”

influenza viruses more frequently, and they do not have the acquired immunity of adults.⁵ In addition, children rapidly transmit infectious disease due to their lack of familiarity and difficulty complying with preventative measures,⁶ such as diligent hand-washing.

Policy-makers and emergency management experts recognize that a one-size-fits-all approach to emergency planning may not be appropriate and that the differences between adult and pediatric patients warrant specialized attention. Children are not just small versions of adults; their immature anatomy and developing physiology often result in a distinct response to disease. Furthermore, unlike the adult clinical ventilator allocation protocol, which relies on a clinical scoring system to evaluate a patient's health status to predict mortality risk, there is no comparable validated clinical scoring system for triage purposes for pediatric patients.⁷ The lack of an objective clinical scoring system for children makes fair allocation planning in advance of an emergency more challenging.

Acknowledging the need for a thorough evaluation and development of a clinical ventilator allocation protocol for pediatric populations in an influenza pandemic, the Task Force and the Department of Health undertook a comprehensive project to develop clinically sound and ethical guidance as part of an undertaking to expand the Ventilator Allocation Guidelines (the Guidelines).⁸ This project proceeded in two stages. First, the Task Force focused on the considerable practical and ethical issues involved in allocating scarce ventilators, including the sensitive issue of whether young patients should be given priority over older patients. Second, a pediatric clinical Workgroup (the Pediatric Clinical Workgroup) was convened, consisting of specialists in pediatric, neonatal, emergency, and maternal-fetal medicine, as well as in critical care, respiratory therapy, palliative care, public health, and ethics, to develop the clinical ventilator allocation protocol.⁹ The Pediatric Clinical Workgroup met numerous times in person and also provided comments by e-mail and telephone.¹⁰

As a result of these discussions, the pediatric ventilator allocation guidelines (the Pediatric Guidelines) were developed to accompany the recently updated guidelines regarding the allocation of ventilators for adults in the event of a pandemic outbreak of influenza (the Adult Guidelines). The Pediatric Guidelines reflect a synthesis of pediatric expert clinicians' and ethicists' opinions on ventilator allocation for children. These guidelines represent a starting point for the public and decision-makers to discuss how scarce resources, particularly ventilators, should be allocated to and within the pediatric population. Because research and data on this

⁵ Debra Weiner, *Lessons Learned from Disasters Affecting Children*, 10 CLIN. PEDIATR. EMERG. MED. 149, 150 (2009) (noting that children are "more likely to spread infectious disease given their close proximity to each other in school and daycare and poor hygiene.")

⁶ Armand H. Matheny Antommara & Emily A. Thorell, *Non-Pharmaceutical Interventions to Limit the Transmission of a Pandemic Virus: The Need for Complimentary Programs to Address Children's Diverse Needs*, 22 J. CLIN. ETHICS 25, 26 (2011) (stating that non-pharmaceutical measures designed to contain the spread of the virus must account for the role of children and their "particular contributions to the transmission of influenza.")

⁷ For a discussion of the adult clinical ventilator allocation protocol, see Chapter 1, Adult Guidelines.

⁸ The Ventilator Allocation Guidelines consist of four chapters: (1) Adult Guidelines, (2) Pediatric Guidelines, (3) Neonatal Guidelines, and (4) Implementing New York State's Ventilator Allocation Guidelines: Legal Considerations.

⁹ See Appendix B for a list of the Pediatric Clinical Workgroup members.

¹⁰ Meetings were held in November 2009, March 2012, May 2012, July 2012, September 2012, January 2013, two meetings in February 2013, and a conference call in March 2013.

topic are constantly evolving, the Guidelines are a living document and are intended to be updated and revised in line with advances in clinical knowledge and societal norms. The Guidelines incorporate an ethical framework and evidence-based clinical data to support the goals of saving the most lives in an influenza pandemic where there are a limited number of available ventilators.

The first half of the Pediatric Guidelines examines the unique considerations for pediatric emergency preparedness and explores the ethical issues related to the treatment of children in a pandemic. The second half provides clinical guidance on how to triage pediatric patients.

II. Pediatric Responses and Resource Needs During an Influenza Pandemic

A severe influenza pandemic on the scale of the 1918 influenza outbreak will likely strain medical resources, including ventilators. It has been estimated that 35 percent of the overall population in New York State will become ill during a similar pandemic, with children suffering as at a rate of about 40 percent,¹¹ a higher illness rate than that of adults.

While children may experience more severe influenza infections that require hospitalization than adults,¹² they often respond better to treatment because they have few or no underlying conditions that could hinder recovery.¹³ Children generally overcome the most serious complications caused by life-threatening influenza, such as acute respiratory distress syndrome, multiple organ system failure, and sepsis, at a much higher rate than adults. Most children do not have chronic medical conditions associated with advanced age, which can also complicate one's ability to survive influenza. For instance, the Centers for Disease Control and Prevention (CDC) reported that during the novel H1N1 pandemic in 2009, adults were six times more likely to die than pediatric patients.¹⁴ Likewise, during a similar time period, in New York

¹¹ Paul V. Effler, *Every Year is an Influenza Pandemic for Children: Can We Stop Them?* 130 PEDIATR. 554 (2012).

¹² For example, the CDC reported that during the novel H1N1 pandemic of 2009-10, the hospitalization rate for laboratory-confirmed influenza was nearly 2.5 times higher for patients aged zero to four years than for adults aged 18 and older. From September 2009 to March 2010, laboratory-confirmed influenza (for all strains, including novel H1N1) was associated with hospitalization rates of 6.5 per 10,000 for patients between the ages of 0-4. Rates for children aged 5-17 were 2.5 per 10,000, followed by lower rates for adults aged 18-49, 50-64, and ≥ 65 (2.4, 3.1, and 2.7 per 10,000, respectively). Centers for Disease Control and Prevention, *Flu View: A weekly influenza surveillance report prepared by the influenza division, 2009-2010 Influenza Season Week 11 ending March 20, 2010*, (hereinafter, CDC) <http://www.cdc.gov/flu/weekly/weeklyarchives2009-2010/weekly11.htm>. Furthermore, in New York State, approximately 59 percent of hospitalized influenza patients at select New York hospitals were 18 years or younger. New York State Department of Health, *2009-2010 Flu Monitoring, Week ending March 20, 2010*, <http://www.health.ny.gov/diseases/communicable/influenza/surveillance/2009-2010/archive/2010-03-20/>.

¹³ For seasonal influenza, children have better outlook for recovery than other age groups. However, depending on the pandemic viral strain, it is impossible to know with certainty which age group is most vulnerable. For example, in the 1918 pandemic, young adults were most at risk and were subject to the highest mortality rates. It is also possible for a pandemic viral strain to specifically single out children or only the elderly. Recovery/ mortality conclusions are broad generalizations for children and adults as a group and may not necessarily be applicable to an individual child or adult.

¹⁴ From August 2009 to March 2010, there were 268 laboratory-confirmed influenza-associated pediatric deaths and 1,809 adult deaths. These statistics include all types of influenza, including novel H1N1. CDC, *2009-2010 Influenza Season Week 11 ending March 20, 2010*, <http://www.cdc.gov/flu/weekly/weeklyarchives2009-2010/weekly11.htm>.

State, adults had nearly seven times the mortality rate than patients who were 17 years or younger.¹⁵

Nevertheless, during a severe pandemic, resource requirements for pediatric patients will be enormous. In a severe influenza pandemic, with a 35 percent attack rate, nearly 1.5 million of New York State's 4.2 million children may be affected, with 7.5 percent of these children (110,250) requiring ventilator therapy.^{16, 17}

There are various types of ventilators that can support adults and/or children, depending on the ventilator's circuitry and measurement values.¹⁸ Some ventilators are suitable for adults, children, and neonates, while others are only usable for one segment of the population.¹⁹ Currently, New York State has 7,241 ventilators available in acute care facilities (i.e., hospitals), of which approximately two percent are restricted for neonatal patients only; eight percent are suitable for pediatric patients only; 50 percent could support either an adult or pediatric patient ("dual-use" ventilators); and nearly 41 percent are for adult patients only.²⁰ During a pandemic, distributing more of the dual-use ventilators to children would help mitigate the disadvantage

¹⁵ Between September 2009 and March 2010, there were 16 influenza-related deaths for patients 17 years old and younger and 108 influenza-related deaths for adults aged 18 years and older in New York State. Data for pediatric deaths from influenza include both the seasonal flu and novel H1N1. For pediatric data and for adult deaths from influenza and pneumonia for New York residents outside of New York City, see New York State Department of Health, 2009-2010 Flu Monitoring, Week ending March 20, 2010, <http://www.health.ny.gov/diseases/communicable/influenza/surveillance/2009-2010/archive/2010-03-20/>. New York State Department of Health collects data on all pediatric deaths statewide, but does not collect data on New York City adult residents. Total number of adult deaths for New York State have been compiled by examining both state and city departments of health data. For data on adult deaths for New York City residents attributed to novel H1N1 (no data on adult seasonal influenza deaths are available), see New York City Department of Health and Mental Hygiene, Surveillance Data, Mortality, <http://www.nyc.gov/html/doh/downloads/pdf/epi/datatable5.pdf>. (Note that the statistics for adult influenza deaths in New York City are not available for September 2009 and begin October 2009.)

¹⁶ The CDC assumes that an influenza pandemic would have a 35 percent attack rate and 7.5 percent of admitted patients with pandemic influenza will require ventilators. See Xinshi Zhang, Martin I. Meltzer, and Pascale M. Wortley, *FluSurge – A Tool to Estimate Demand for Hospital Services During the Next Pandemic Influenza*, 26 MEDICAL DECISION MAKING (2006), 617, 618. In New York State, there are approximately 4.2 million children aged 18 and younger, accounting for approximately 22 percent of the population. From July 1, 2013 New York State population estimates. See U.S. Census Bureau, American FactFinder, New York, http://factfinder2.census.gov/faces/tableservices/jsf/pages/productview.xhtml?pid=PEP_2013_PEPAGESEX&prodType=table.

¹⁷ The terms "ventilator therapy" is used interchangeably with "ventilator treatment."

¹⁸ The two most common ventilators are bed-side and transport ventilators. Bed-side ventilators are stationary machines while transport ventilators can be moved with a patient, such as those in ambulances.

¹⁹ While some "adult" ventilators could be modified for children, not all facilities have the software, equipment, and skilled staff to ventilate pediatric patients. See Lewis Rubinson et al., *Mechanical Ventilators in US Acute Care Hospitals*, 4 DISASTER MED. PUB. HEALTH PREP. 199, 203-204 (2010). In addition, equipment for pediatric patients must account for a wide range of sizes, from young infants to teenagers. Furthermore, it may be difficult to adapt these machines for use for neonates and small infants. Desmond Bohn et al., *Supplies and Equipment for Pediatric Emergency Mass Critical Care*, 12 PEDIATR. CRIT. CARE MED. S120, S121, S123 (2011).

²⁰ Ventilators used for neonates and young children are specific to the age and/or weight of a patient and cannot be used for older adolescents or adults. Of the 7,241 ventilators in New York State, 124 ventilators can only support neonates, 731 can only support pediatric patients, 2,717 can support either children or adults, and 3,669 can only support adult patients. New York State Department of Health, Office of Health Emergency Preparedness Program, *Critical Assets Survey*, September 2015.

children have with regards to health care resources.²¹ In addition, 1,750 ventilators are stockpiled,²² which can be used for pediatric or adult patients, bringing the total number of ventilators available to 8,991.²³ Depending on whether the pandemic affects more children than adults, these stockpiled ventilators may be dedicated to children should the need arise.

III. Special Considerations for Pediatric/Neonatal Emergency Preparedness

During an influenza pandemic, facilities and health care providers may need to modify the usual rules that govern how health care is delivered, particularly with regard to the allocation of scarce resources. Although individualized care ideally is maintained to the fullest extent possible, the same level of care is not be available when critical care must be provided to a much larger number of patients than usual. The realities imposed by this shift demand special thought and analysis when children are affected.

The challenges presented by the allocation of scarce resources among children are likely more pronounced than among other patient populations.²⁴ Health care priorities are usually organized with the needs and demands of adults in mind rather than children. In non-emergency conditions, there are fewer health and critical care resources for children than adults, because at any one time there are almost always fewer critically ill children than adults. For example, the number of facilities in the State capable of addressing the serious medical needs of children on a large scale is significantly fewer than for adults. Although most local/community hospitals are able to treat infants and children to stabilize their medical conditions, critically ill pediatric patients are transferred typically to larger (regional) facilities that have the specific equipment and expertise to provide ongoing care.²⁵ However, while specialized hospitals and units likely have the most age-appropriate resources and tailored health care staff available, many New York State residents do not have ready access to such facilities, particularly those who reside in rural communities.²⁶

²¹ There are 2,717 dual-use ventilators and allocating these machines to children could significantly reduce the resource disparity for children. *Id.*

²² A small number (566) of these stockpiled ventilators already have been distributed to hospitals for daily use. The remainder is in storage facilities. *Id.*

²³ *Id.*

²⁴ Robert K. Kanter and Arthur Cooper, *Mass Critical Care: Pediatric Considerations in Extending and Rationing Care in Public Health Emergencies*, 3 DISASTER MED. PUB. HEALTH PREP. S166-S171 (2009) (providing a general overview of pediatric critical care needs and resources, responsibilities of local/community and regional hospitals, and strategies and concerns involving ventilating children and infants). *See also* David Markenson, *Developing Consensus on Appropriate Standards of Hospital Disaster Care: Ensuring that the Needs of Children are Addressed*, 3 DISASTER MED. PUB. HEALTH PREP. 5, 6 (2009) (noting that prospective planning for pediatric disaster care assists providers with handling this difficult scenario).

²⁵ While outside the scope of these guidelines, some patients may be transferred/diverted to facilities outside of the State. These patients are not subject to New York's Guidelines, but may be required to abide by the local/state jurisdictional guidelines.

²⁶ Most of the pediatric specialty centers in New York State are located in metropolitan areas. Outside of New York City, some local/community hospitals may not have pediatric intensive care units. Most people are unaware of whether or not the acute care facility closest to their home provides comprehensive neonatal/pediatric care. Regardless, most parents and guardians of children travel to the closest acute care facility for medical attention for their child. *See* Wanda D. Barfield et al., *Neonatal and Pediatric Regionalized Systems in Pediatric Emergency Mass Critical Care*, 12 PEDIATR. CRIT. CARE MED. S128, S130 (2011) (noting that for emergency care, nearly 90

The ongoing disparity of health care resources for children is not only limited to facilities, but it also includes essential lifesaving supplies and equipment. Items such as ventilators, intravenous fluid resuscitation, vasoactive/inotropic agents, antibiotics and antidotes, sedation and analgesia, and other medical interventions, such as renal replacement therapy, are also needed for pediatric populations.²⁷ Due to the disproportionate distribution of these limited resources, efforts should be made to help normalize health care resources for children, including, for example, commitments by facilities to continue to replace adult-only ventilators with dual-use ventilators, and develop emergency plans that address the needs of pediatric patients.

Certain facilities are unlikely to have the particular equipment, supplies, or expertise necessary to care for neonatal or other pediatric patients for extended time periods. Particularly at non-specialized pediatric hospitals, necessary steps should be taken to stockpile appropriate supplies and establish clinical plans for pediatric care to assist non-pediatric providers.²⁸ Furthermore, stockpiles should ensure that size-appropriate medical equipment, such as pediatric ventilator circuitry, is available, in addition to medication formulation and dosing information for children.²⁹

Although stockpiling these items has been suggested as a short-term solution,³⁰ many facilities still will not likely have sufficient amounts of the abovementioned essential supplies and equipment to accommodate a surge in sick children, and preparedness plans must still address the topic of allocation of scarce resources. With respect to ventilators, limitlessly increasing the number of ventilators and ventilator-associated supplies does not obviate the need for an allocation plan, as other resources required to utilize ventilators effectively, such as medical staff, also would be strained.³¹

Because of the lack of pediatric expertise at some facilities, it is important to ensure that technology is in place for hospitals to communicate regarding ventilator availability, pediatric transport, and other aspects related to treating pediatric patients.³² During a pandemic, real-time collection of data, analysis, and efficient exchange of information regarding resource availability and pediatric transport is imperative. Furthermore, as the pandemic progresses, sharing details

percent of children are taken to an emergency department based upon location of the facility). *See also* Erik Auf de Heide, *The Importance of Evidenced-Based Disaster Planning*, 47 ANN. EMERG. MED. 34, 41 (2006).

²⁷ *See* Bohn et al., *supra* note 19, at S121.

²⁸ *See* New York Pediatric Emergency Guidelines, *supra* note 3.

²⁹ Katherine Mason & Michael Anderson, *Challenges Facing Pediatric Preparedness*, 10 CLIN. PEDIATR. EMERG. MED. 159, 159-160 (2009).

³⁰ There are significant financial burdens associated with obtaining, storing, and maintaining equipment and supplies. In addition, stockpiling results in significant opportunity costs when choosing stockpiling over another priority. *See* Michael D. Christian et al., *Treatment and Triage Recommendations for Pediatric Emergency Mass Critical Care*, 12 PEDIATR. CRIT. CARE MED. S109, S111 (2011) (hereinafter Christian et al., *Treatment and Triage Recommendations*)

³¹ During a pandemic, it is expected that the number of available health care staff will decrease significantly as they become ill, leave work to care for loved ones, or decline to serve from fear of contagion. Thus, even with enough ventilators, a sufficient number of trained staff would not be available to operate them. For discussion on health care staffing during a pandemic, *see* Chapter 1, Adult Guidelines, Section II.C. Ventilators and Surge Capacity.

³² *See* Weiner, *supra* note 5, at 151.

about the particular pandemic viral strain and how it affects different populations allows for fact-based modifications of the allocation protocol where necessary.³³

In addition, children's presence in the medical setting may exert additional pressure on an already strained staffing situation,³⁴ as children often require supervision to preclude injury and exposure to hazards. Appropriate protective measures may include dedicating staff solely to the care of children and preventing access to dangers, such as electrical outlets and medical equipment. Infants and toddlers need the most attention, as well as extra supplies, such as infant formula, diapers, baby bottles, baby food, and age-appropriate clothing.

Facilities may be presented with children who have been separated from their parents or other caregivers, which impairs treatment and reunification procedures.³⁵ For children who arrive alone, there are additional challenges in providing proper supervision and other general caregiving responsibilities.³⁶ Complicating this situation, some children may be too young to communicate or understand the situation, and many will be unable to provide full information about their past medical history or current health requirements.³⁷ Other pediatric patients may have disabilities or special health care needs, which need to be considered when caring for these children.³⁸ Providers would benefit from a summary of these children's medical condition, history of illness, and any precautions and/or special management required to properly care for them.

For health care providers, the emotional and mental health complexities of caring for children in an emergency are likely to be significant.³⁹ For pediatric-specific health care staff, the implementation of a clinical ventilator allocation protocol, including no longer being able to devote extensive resources and time to patients, may be overwhelming and result in emotional distress.⁴⁰ For those providers who do not treat children regularly, it may be difficult to confront the gravity of the situation and potential anxiety of caring for a population with whom they have little experience working. Health care workers, especially those not accustomed to treating critically ill children, may be traumatized by the deaths of pediatric patients.⁴¹

³³ As important as data collection may be, it is important that researchers are careful to mitigate any vulnerabilities to victims of disaster. For example, there may be potential for emotional trauma for research participants asked to "re-live" their experiences and the issue of how to maintain confidentiality during a time where there may be concentrated media attention on the disaster must be considered. *See, e.g.,* Lauren K. Collogan et al., *Research with Victims of Disaster: IRB Considerations*, 26 IRB: ETHICS & HUMAN RES. 9, 10 (2004).

³⁴ Markenson, *supra* note 24, at 6.

³⁵ For more information on recommendations regarding family reunification procedures, *see* Katherine E. Mason et al., *Pediatric Emergency Mass Critical Care: Focus on Family-Centered Care*, 12 PEDIATR. CRIT. CARE MED. S157, S159-S160 (2011).

³⁶ *See* Weiner, *supra* note 5, at 150.

³⁷ *See id.* *See also* Mason et al., *supra* note 35, at S161.

³⁸ Often families play a key role due to their knowledge of their special needs children; they are "in a better position to diagnose emergent conditions better than the health care providers." Mason et al., *supra* note 35, at S159.

³⁹ *See id.*, at S161.

⁴⁰ For example, conveying the decision to discontinue ventilator therapy to the family would be a stressful situation. *See id.*, at S160.

⁴¹ Research suggests that people perceive the death of a child more acutely than the death of an adult. Carol K. Sigelman and Elizabeth A. Rider, LIFE-SPAN HUMAN DEVELOPMENT, 503 (7th ed. 2010).

Despite children’s physical resiliency, they may potentially be susceptible to short- and long-term mental health effects as a result of an influenza pandemic,⁴² including anxiety from being separated from their families.⁴³ Children’s reactions to a pandemic are often contingent upon their age, and they respond to the emotional cues of the adults around them.⁴⁴ Children may also need appropriate mental health services that address their specific needs, both during and after the pandemic.⁴⁵

Further, parents and caregivers of children may also suffer from psychological trauma as a result of not being able to be engaged fully in their child’s medical care. During a pandemic, active participation and interaction between family members and health care staff may not be possible, especially if family separation must occur for treatment or to prevent the spread of influenza.⁴⁶ Families may direct their frustration and anger at health care workers, further exacerbating a stressful situation for all parties involved.⁴⁷

IV. Overview of Concepts Used in Triage

The Task Force examined several key concepts of triage to advance the goal of saving the most lives within the specific context of ventilators as the scarce resource in an influenza pandemic.

A. Definition of Triage

The concept of triage was developed in the battlefield, where scarce resources were provided to benefit the largest number of people.⁴⁸ Critically injured/ill individuals who normally received full medical attention during a non-crisis situation were not provided with optimal care so that the less/moderately injured could receive the scarce resource, thereby saving the most lives by caring for a larger number of people. Thus, the goal of triage is to “do the greatest good for the greatest number” of people.⁴⁹

⁴² See Mason et al., *supra* note 35, at S160.

⁴³ Peter M. Ginter et al., *Creating a Regional Pediatric Medical Disaster Preparedness Network: Imperative and Issues*, 10 *MATERN. CHILD HEALTH J.* 391, 393 (2006).

⁴⁴ See *id.*

⁴⁵ To make mental health assessments, facilities may consider employing a tool for disaster mental health triage to identify pediatric patients who could benefit from mental health interventions. For an example of a mental health triage system, see “PsyStart.” Merrit Schreiber, *The PysSTART Rapid Mental Health Triage and Incident Management System* (2010) <http://www.cdms.uci.edu/PDF/PsySTART-cdms02142012.pdf>.

⁴⁶ Normally, health care staff works closely with the families to provide education and support to ensure the best possible health care experience for patients and their families. For recommendations regarding how to accommodate the role of family during pediatric health care delivery in emergency mass critical care, see Mason et al., *supra* note 35, at S158 and S160.

⁴⁷ See Mason et al., *supra* note 35, at S160.

⁴⁸ See Lewis C. Vollmar, Jr., *Military Medicine in War: The Geneva Conventions Today*, in *MILITARY MEDICAL ETHICS*, VOL. 2, (Thomas E. Beam, ed., 2005). In the battlefield context, the goal was the return injured soldiers to the battle as soon as possible.

⁴⁹ Working Group on Adult Critical Care Admission, Discharge, and Triage Criteria, *Critical Care During a Pandemic*, Ontario Health Plan for an Influenza Pandemic (OHPIP), 8 (2006), http://www.cidrap.umn.edu/sites/default/files/public/php/21/21_report.pdf (hereinafter OHPIP 2006). See also Pandemic Ethics Initiative Work Group, *Meeting the Challenge of Pandemic Influenza: Ethical Guidance for Leaders and Health Care Professionals in the Veterans Health Administration*, Veterans Health Administration,

However, in the context of ventilator allocation during a public health emergency, the Task Force and other pandemic planning organizations have modified the definition of triage. Patients for whom ventilator treatment would most likely be lifesaving are prioritized. Patients with the highest likelihood of survival *without* medical intervention, along with patients with the smallest likelihood of survival *with* medical intervention, have the lowest level of access to ventilator therapy.⁵⁰ Allocating scarce resources in this manner utilizes them effectively and increases the number of survivors by providing ventilators to those who are most likely to survive *with* ventilator therapy. Thus, patients who are most likely to survive without ventilator therapy, together with patients who survive with ventilator treatment, increase the overall number of survivors.

B. Application of the Clinical Ventilator Allocation Protocol to All Patients in Need of a Ventilator

A just allocation system must be applied to all acute care patients in need of a ventilator, whether due to influenza or other conditions. As a practical matter, health care providers could not limit the use of triage criteria to patients solely with influenza; critically ill patients may have multiple diagnoses or no clear diagnosis. Furthermore, a system that suggests a preference of one disease over others might result in inaccurate reporting of diagnoses, and heighten the danger of contagion.

C. Definition of Survival

In general, the Task Force and most medical scholars and policy experts agreed that the primary goal in a public health emergency should be saving the most lives.⁵¹ Prioritizing individuals based on their chances of survival during an emergency is the most equitable, as it does not consider non-clinical factors, such as race, ethnicity, sexual orientation, socio-economic status, education, religion, or quality of life. As discussed above, the most effective use of scarce resources is to allocate them to patients who have the highest likelihood of survival with the use of the scarce resource.

In a public health emergency such as an influenza pandemic, the term “survival” must be adequately defined. During a pandemic, the majority of patients who need a ventilator are those afflicted with influenza. However, not all patients in need of a ventilator are sick with influenza; others may be car crash victims, emergency post-operative patients, or individuals with impaired

National Center for Ethics in Health Care, v (July 2010), http://www.ethics.va.gov/docs/pandemicflu/Meeting_the_Challenge_of_Pan_Flu-Ethical_Guidance_VHA_20100701.pdf (hereinafter VHA Guidelines).

⁵⁰ When the Guidelines are no longer being implemented, all patients in need of ventilators are eligible regardless of their medical conditions.

⁵¹ John L. Hick & Daniel T. O’Laughlin, *Concept of Operations for Triage of Mechanical Ventilation in an Epidemic*, 3 ACAD. EMERG. MED. 223, 225 (2006). See also Asha V. Devereaux et al., *Definitive Care for the Critically Ill During a Disaster: A Framework for Allocation of Scarce Resources in Mass Critical Care: From a Task Force for Mass Critical Care Summit Meeting, January 26–27, 2007, Chicago, IL*, 133 CHEST 51S, 61-2S (2008b).

lung function. Thus, for the Guidelines, survival is based on a patient’s ability to survive the acute medical episode for which ventilator therapy is necessary.

The Guidelines’ definition of survival is based on the short-term likelihood of survival of the acute medical episode and is not focused on whether a patient may survive a given illness or disease in the long-term (e.g., years after the pandemic). By adopting this approach, every patient is held to a consistent standard. Triage decision-makers should not be influenced by subjective determinations of long-term survival, which may include biased personal values or quality of life opinions.

V. Ethical Considerations

The ethical framework that underlies the adult clinical ventilator allocation protocol – duty to care, duty to steward resources, duty to plan, distributive justice, and transparency – applies equally to the pediatric clinical protocol.⁵² However, while the ethical framework is the same for all populations, treatment of pediatric patients requires special ethical and clinical considerations in light of children’s unique needs and their role in society.⁵³ A plan that does not reflect normative societal values, such as the importance of protecting children, may go unheeded, thereby defeating the purpose of planning in advance of an emergency.

A. Use of Young Age as Triage Factor

Some commentators have argued that the public may not always agree that survival of the greatest number of people should be the goal of an allocation protocol, and that in certain circumstances, the public may place higher value in different normative principles. For example, many people have suggested prioritizing certain vulnerable populations such as children during emergencies.⁵⁴

Using age as a triage criterion is controversial. The following sub-sections discuss the potential merits and disadvantages of incorporating young age⁵⁵ as a factor.

⁵² For a detailed discussion of the application of these principles to the development of a clinical ventilator allocation protocol, *see* Chapter 1, Adult Guidelines, Section IV. Ethical Framework for Allocating Ventilators.

⁵³ Markenson, *supra* note 24, at 6.

⁵⁴ In 2010, the American Academy of Pediatrics, together with the Children’s Health Fund, conducted a national opinion poll that found broad public support for the notion of prioritizing children over adults for medical treatment when resources are scarce. American Academy of Pediatrics & Marist College Institute for Public Opinion, *National Survey October 2010*, (2010), (hereinafter AAP & Marist) <http://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/Children-and-Disasters/Documents/AAP-Opinion-Poll-Data-Oct2010.pdf>. Key findings are summarized in the document as follows: “(1) 76 percent of Americans agree that if resources are limited, children should be given a higher priority for life-saving treatments; (2) 75 percent believe that if tough decisions must be made, life-saving treatments should be provided to children rather than adults with the same medical condition; and (3) 92 percent agree that if there were a terrorist attack, our country should have the same medical treatments available for children as are now available for adults.”

⁵⁵ The term “young age” represents the childhood years, and may include adolescence.

1. Societal Role of Children

Adults often express a preference for saving children over adults for several reasons. Children, especially young ones, may not be able to speak for themselves or attend to their most basic needs without assistance. There is a strong inclination to care for those who are younger or seen as more vulnerable, and the notion of protection is a basic tenet of society.⁵⁶ Children often also lack the emotional maturity to handle a crisis and need to be comforted and reassured, which reinforces the desire to protect and devote resources to them. Finally, people often refer to the responsibility society has to ensure that children survive, as they comprise the future generation. What happens to children not only affects them individually, but also society as a whole. Accordingly, many people believe that children should be saved first in an emergency and deserve extra attention during crises.⁵⁷

2. “Fair Innings” and “Life Years Saved” Theories

Ethical arguments that support the use of young age as a triage factor include the “fair innings” and the “life years saved” theories. The “fair innings” theory places value on whether a patient has had the opportunity to experience all stages of life⁵⁸ (i.e., infancy, adolescence, adulthood, and old age). Application of this theory in a pandemic prioritizes younger individuals for ventilator treatment to increase their chances to live through all life phases.⁵⁹

A consideration of the number of “years of life saved” – which examines an individual’s remaining life years⁶⁰ – might also be used to justify devoting more scarce resources to children. This theory aims to maximize the number of life years actually saved rather than the number of

⁵⁶ See Greg Forster, *John Locke’s Politics of Moral Consensus*, 209 (Cambridge University Press, 2005). See *Universal Declaration of the Rights of the Child*, G.A. Res. 1386 (XIV), U.N. Doc. A/RES/1386(XIV) (Dec. 10, 1959) (stating “The child shall enjoy special protection, and shall be given opportunities and facilities, by law and other means, to enable him to develop physically, mentally, morally, spiritually and socially in a health and normal manner and in conditions of freedom and dignity. In the enactment of laws for this purpose, the best interests of the child shall be the paramount consideration. ... The child shall in all circumstances be among the first to receive protection and relief.”).

⁵⁷ See AAP & Marist, *supra* note 54 (noting that 75 percent believe that if tough decisions must be made, life-saving treatments should be provided to children rather than adults with the same medical condition).

⁵⁸ See Alan Williams, *Intergenerational Equity: An Exploration of the ‘Fair Innings’ Argument*, 6 HEALTH ECON. 117, 119 (1997). Another version of the fair innings argument is the “life-cycle principle, holding that “each person should have an opportunity to live through all stages of life.” Ezekiel J. Emanuel & Alan Wertheimer, *Who Should Get Influenza Vaccine When Not All Can?*, 312 SCIENCE 854, 854-855 (2006). In a subsequent publication, the principle of “youngest-first” is modified and combined with other allocation principles to create a system referred to as “complete lives,” which does not prioritize infants for treatment, but rather adolescents and young adults. Govind Persad et al., *Principles for Allocation of Scarce Medical Interventions*, 373 LANCET 423, 428 (noting that “[a]dolescents have received substantial education and parental care, investments that will be wasted without a complete life.”).

⁵⁹ See Douglas White et al., *Who Should Receive Life Support During a Public Health Emergency? Using Ethical Principles to Improve Allocation Decisions*, 150 ANN. INTERN. MED. 132, 135 (2009); see also Marcel Verweij, *Moral Principles for Allocating Scarce Medical Resources in an Influenza Pandemic*, 6 BIOETHICAL INQUIRY 159, 164-5 (2009).

⁶⁰ White, *supra* note 59, at 135 (providing an example of two individuals with the same age and chance of survival, but with different prognoses, to illustrate how more “life years” are likely to be saved if the healthier individual is given priority for a life-saving resource).

lives saved.⁶¹ Since children generally have more years left to live than adults, saving more children results in more life years saved overall. Thus, scarce resources are directed to children to improve their probability of living to old age.

Both of these theories limit health care resources for individuals who have lived extended lives in favor of those who have not. Since the process of aging affects everyone, it may be argued that using age as a criterion for allocation of scarce resources does not discriminate against any one person or group.⁶²

3. Task Force’s Conclusions Regarding the Use of Young Age in Triage

The Task Force concluded that, consistent with the adult clinical ventilator allocation protocol, ventilators should be allocated in a manner to maximize the number of survivors, and young age should not be a primary triage factor. The recommended clinical ventilator allocation protocol should use clinical criteria to give patients who were deemed most likely to survive with ventilator therapy an opportunity for treatment. Despite the arguments in favor of prioritizing children, the Task Force identified several drawbacks to selecting patients based solely on young age for ventilator therapy. However, the Task Force determined that in limited circumstances, young age may be used as a secondary triage factor, i.e., when the likelihood of (short-term) survival is substantially equal.⁶³

a. Rationales Against Prioritizing Based Solely on Young Age

Prioritizing children over adults in allocating ventilators in every case, without considering likelihood of survival, would almost certainly result in far fewer people surviving the pandemic. Choosing children over adults for ventilator therapy, without evaluating their current health statuses and determining whether children are good candidates for this form of treatment, would not be an efficient use of scarce resources. Not all children provided with ventilator therapy will survive, whereas some healthy adults may benefit (i.e., survive) if provided with those same ventilators. Furthermore, it may be possible that adults may survive in greater numbers if they require shorter durations of ventilator treatment than children. Because the overall goal is to ensure the greatest number of survivors, providing ventilators to only children does not further this objective.⁶⁴

Although children are a vulnerable population, there are other segments of society, such as those with disabilities, that may require special protection or accommodation, and therefore it may be unfair to prioritize children over other groups based solely on their vulnerability. Many

⁶¹ See *id.* (stating that this principle should be applied broadly in conjunction with saving the most lives to achieve “the greatest good for the greatest number.”).

⁶² Armand H. Matheny Antommara et al., *Critical Appraisal of: Triage Pediatric Critical Care Resources During A Pandemic: Ethical and Medical Considerations*, 11 PEDIATR. CRIT. CARE MED. 396, 398 (2010) (explaining Norman Daniels’ reasoning that such an approach should instead be framed as “resource allocation for individuals at different stages of life.”); See also Persad, *supra* note 58, at 425 (also citing Norman Daniels).

⁶³ For a discussion on the definition of survival as it pertains to ventilator allocation, see Section IV.C. Definition of Survival.

⁶⁴ Furthermore, devoting scarce resources only to children may result in the survival of too few adults, which may have a temporary, but noticeable impact on the short-term stability of a community.

populations have unique needs and considerations that should be addressed in emergency planning. Giving an exclusive right or even a preference to children potentially ignores the needs of other members of society.

In addition, it may be argued that prioritizing on the basis of young age may discriminate against adults and the elderly. Notably, the Task Force and the Department of Health rejected using advanced age as a criterion in the adult ventilator allocation protocol for clinical reasons.⁶⁵ Although age indirectly factors into any medical assessment because the likelihood of having a chronic medical condition, which can hinder recovery, increases with age, advanced age alone does not necessarily indicate likelihood of survival.⁶⁶

Although the “fair innings” and “life years saved” theories are arguments in favor of using young age as a triage factor, if applied literally, they justify granting priority to the youngest patient even when the age difference is negligible.⁶⁷ For example, a four year old receives ventilator therapy over a six year old, even if the latter has less severe symptoms and a better chance of survival. These principles only ensure that the absolute youngest patients (i.e., infants and toddlers) receive ventilator treatment.⁶⁸

Furthermore, while it has been argued that children should be prioritized in an emergency, not all members of society support this belief.⁶⁹ For example, the historic notion of “women and children first” has evolved and does not necessarily hold today.⁷⁰ As assumptions and roles surrounding children and parenting transform, there are segments of the public that do not choose to prioritize children when the overall survival rate of the entire population is impacted negatively.

b. Use of Young Age as a Secondary Triage Factor (Tie-Breaker)

Although the Task Force recommended that ventilators be allocated on the basis of likelihood of survival, it also suggested that in the unique circumstance where all other clinical

⁶⁵ For a discussion of the use of advanced age as a triage criterion, see Chapter 1, Adult Guidelines, Section VIII.D.2. Age.

⁶⁶ For example, a 70 year old with no chronic conditions may be more likely to survive influenza than a 40 year old with severe heart disease. While aging may affect all individuals, a person may be “healthier” than his/her age and age is only a number that is not necessarily representative of a person’s health status. See White, *supra* note 59, at 135.

⁶⁷ Clare M. Clarke, *Rationing Scarce Life-Sustaining Resources on the Basis of Age*, 35 J. ADV. NURS. 799, 801 (2001).

⁶⁸ In practice, an allocation plan could establish age cutoffs to determine which age range(s) have priority access to ventilators over another age group. However, reaching consensus on age cutoffs is extremely difficult since the reasoning behind such thresholds is subjective.

⁶⁹ For example, public engagement forums held in Seattle-King County revealed that while participants initially prioritized children for treatment during disasters, the strength of this opinion dramatically diminished through the course of the meetings. See Public Health – Seattle & King County, *Public Engagement Project on Medical Service Prioritization During an Influenza Pandemic*, 9,10, 23 (Sept. 2009), <http://www.kingcounty.gov/healthservices/health/preparedness/%7e/media/health/publichealth/documents/pandemicflu/MedicalServicePrioritization.ashx>.

⁷⁰ This concept rested on the historical importance of preserving future generations. However, this perception is not as important today because science and medicine have vastly decreased infant mortality rates, increased fertility options and rates, and increased life expectancies.

factors are substantially equal, young age may play a secondary role in triage. Thus, when allocating scarce ventilators among both adults and children, young age may be an ethically acceptable triage criterion only in the limited circumstance when all available clinical factors have been examined and the likelihood of survival among these patients has been found equivalent.

After adult and pediatric patient(s) have been given clinical examinations per their respective clinical ventilator allocation protocols, some adults and children will be identified as having a strong likelihood of survival with ventilator treatment. While the decision regarding whether a patient(s) receives ventilator therapy is based on prioritizing those who have the highest likelihood of survival, the clinical evidence may indicate that both an adult and child have equal (or near equal) likelihoods. In the situation where there are more eligible patients for ventilator treatment than machines, because no other evidence-based clinical factor is available to further differentiate which patient has a slightly better likelihood of survival, only then may young age be utilized as a tie-breaker when deciding whether a patient should receive ventilator therapy.

An allocation protocol that emphasizes likelihood of survival while incorporating the use of young age solely as a tie-breaker criterion not only includes the public's values with regard to children, but it also advances the overall goal of saving the most lives. It is also possible that using young age as a triage tie-breaker might lead to more people surviving the pandemic, because children generally may be more likely to respond better to ventilator therapy in an influenza pandemic. Although a policy regarding the acceptability of using young age but not old age as a triage factor may appear somewhat contradictory, society overall has a strong inclination to protect and care for children. In addition, the death of a child often implicates the loss of future milestones of a long life, such as graduation, marriage, and parenthood. Thus, in utilizing young age as a secondary criterion, the Task Force recommended a measured application of the "fair innings" and "life years saved," where the theory behind both is conceptually embraced but does not require that the youngest child always receive ventilator treatment.

Further, incorporating young age as a secondary criterion may lead to greater public recognition of and adherence to the pediatric clinical ventilator allocation protocol. Thus, the value generally attributed to a child's innocence and future promise must be acknowledged in any emergency planning protocol. Otherwise, the likelihood of the public accepting (and abiding by) such a plan is greatly diminished.

VI. Possible Features of a Pediatric Clinical Ventilator Allocation Protocol

This section describes possible components of a pediatric clinical ventilator allocation protocol and evaluates their advantages and disadvantages. The Pediatric Clinical Workgroup did not assume that the components of the clinical ventilator protocol for adults should be applied to children and set to evaluate all potential considerations to determine what aspects were relevant for pediatric patients. These discussions informed the Pediatric Clinical Workgroup in designing New York's pediatric clinical ventilator allocation protocol, which is discussed in Section IX.

A. Exclusion Criteria

Many clinical ventilator allocation protocols apply exclusion criteria to identify patients who are expected to have a highest risk of mortality within a short time frame, regardless of ventilator therapy. During an influenza pandemic, exclusion criteria consist of severe medical conditions that even with ventilator therapy will likely result in death. In emergency circumstances, scarce resources arguably are better allocated to patients who are most likely to survive.

Selecting and defining exclusion criteria is a challenging aspect of developing a clinical ventilator allocation protocol. A model set of exclusion criteria defines those patients with a high risk of mortality even with ventilator therapy, and such a list should focus primarily on current organ function, rather than on specific disease entities. It should never rely on subjective judgments on quality of life. Proponents of applying exclusion criteria suggest that it is a logical method to help ensure that the patients who receive ventilator therapy are those who are most likely to survive. Furthermore, without a method to decrease the number of patients who may be eligible for treatment, a triage officer/committee and the entire health care system could be overwhelmed by the sheer number of children who need ventilators.

On the other hand, applying exclusion criteria in pediatric populations may not significantly reduce the number of patients who need treatment because children have low mortality rates overall.⁷¹ Even the use of an extensive list of criteria may not be sufficient to have substantial impact, thus diminishing the effectiveness of exclusion criteria.

B. Pediatric Clinical Scoring Systems

A review of medical literature identified the most commonly used pediatric clinical scoring systems that potentially could be utilized to allocate critical care resources. However, almost all of the scoring systems discussed below were developed to evaluate individual pediatric intensive care units (PICU) or to measure various PICU outcomes, such as overall mortality and organ dysfunction for an entire unit.⁷² These systems have not been validated to measure an individual patient's outcomes during a public health emergency or as a method to triage patients for critical care resources.⁷³ The available pediatric-specific systems, mSOFA,⁷⁴ PRISM III, PIM 2, P-MODS, and PELOD, and their advantages and disadvantages are explored in further detail below.

⁷¹ See Christian et al., *Treatment and Triage Recommendations*, supra note 30, at S115 (noting that “given the physiologic resiliency that children possess, mortality rates even in the most critically ill children are still very low compared to the adult ICU populations.”).

⁷² See James P. Marcin & Murray M. Pollack, *Review of the Acuity Scoring Systems for the Pediatric Intensive Care Unit and their Use in Quality Improvement*, 22 J. OF INTENSIVE CARE MED. 131 (2007).

⁷³ See Institute of Medicine, *Guidance for Establishing Crisis Standards of Care for Use in Disaster Situations*, 86 Washington, DC (Bruce Altevogt et al. eds., The National Academies Press 2009) (hereinafter IOM, *Guidance for Crisis Standards of Care*).

⁷⁴ mSOFA is sometimes also referred to as MPSOFA (Modified Pediatric SOFA).

1. Modified Sequential Organ Failure Assessment (mSOFA)

The SOFA (Sequential Organ Failure Assessment) system employed in most adult clinical ventilator allocation protocols is not validated for use in children.⁷⁵ However, a modified version of SOFA⁷⁶ has been proposed for children, which similarly collects information on six clinical variables (cardiovascular, pulmonary, hepatic, hematologic, neurologic and either renal or tissue perfusion).⁷⁷ Evaluation and calculation of the mSOFA score is relatively straightforward using simple addition (organ dysfunction is measured on a zero to four scale, with four being the worst score). However, mSOFA is not validated for use in pediatric patients for triage purposes and thus, it may not be suitable to use.

2. Pediatric Risk of Mortality (PRISM III)

PRISM III estimates the mortality outcome of a PICU generally and could be used to predict the mortality risk of a patient admitted to a PICU. It collects information on 17 clinical variables in six organ systems (cardiovascular, pulmonary, hepatic, hematologic, renal, and neurologic) and several other parameters within 12 to 24 hours of PICU admission.⁷⁸ While PRISM III is comprehensive in its measurements, it is not optimal for use in emergency situations because calculation of the score is complicated due to the large number of lab values it requires. Consistent data collection is a challenge because data collectors tend to interpret the variables differently.⁷⁹ Furthermore, PRISM III is only available with an expensive annual license,⁸⁰ which may be impractical for hospitals without PICUs to purchase and maintain trained staff for its implementation.

3. Pediatric Index of Mortality (PIM 2)

Similar to PRISM III, PIM 2 is designed to estimate mortality outcome of a PICU and could be used to predict mortality risk of a PICU patient. It gathers information on 10 clinical variables in four organ systems (cardiovascular, pulmonary, hematologic, and neurologic) and several other non-physiological parameters generally within the first hour of PICU admission.⁸¹

⁷⁵ See Flavio L. Ferreira et al., *Serial Evaluation of the SOFA Score to Predict Outcome in Critically Ill Patients*, 286 JAMA 1754, 1755 (2001) and IOM, *Guidance for Crisis Standards of Care*, supra note 73, at 86.

⁷⁶ Colin K. Grissom et al., *A Modified Sequential Organ Failure Assessment Score for Critical Care Triage*, 2 DISASTER MED. PUB. HEALTH PREPAREDNESS 277-279 (2010).

⁷⁷ See Jill Sweney et al., *Comparison of Severity of Illness Scores to Physician Clinical Judgment for Potential Use in Pediatric Critical Care Triage*, 6 DISASTER MED. PUB. HEALTH PREP. 126, 127 (2012). Other mSOFA models examine slightly fewer and different clinical variables. See Medical Emergency Preparedness – Pediatrics (MEP-P) Ethics Workgroup, *Alaskan Technical Recommendations for Pediatric Medical Triage and Resource Allocation in a Disaster: For Patients Post Nursery Discharge Until 18 Years of Age*, (July 2008) (hereinafter Alaska Guidelines).

⁷⁸ See Murray Pollack et al., *The Updated Pediatric Risk of Mortality III- Acute Physiology Score (PRISM III-APS): A Method of Assessing Physiologic Instability for Pediatric Intensive Care Unit Patients*, 16 J. OF PEDIATR., 575, 575 (1997).

⁷⁹ See J.G. van Keulen et al., *Reliability of PRISM and PIM Scores in Paediatric Intensive Care*, 90 ARCH. DIS. CHILD, 211, 211, 213 (2005).

⁸⁰ See Anthony Brady et al., *Assessment and Optimization of Mortality Prediction Tools for Admissions to Pediatric Intensive Care in the United Kingdom*, 117 PEDIATR. e733, e734 (2006).

⁸¹ See Anthony Slater et al., *PIM 2: A Revised Version of the Paediatric Index of Mortality*, 29 INTENSIVE CARE MED. 278, 283-284 (2003).

PIM 2 is relatively easy to use because the data points needed are readily available.⁸² However, consistent data collection is a problem and calculation of the PIM 2 score is complicated.⁸³ While PIM 2 predicts mortality risk well overall, when patients are divided into mortality risk categories (e.g., high, moderate, or low risk of death), the predicted probability of death does not necessarily reflect actual mortality outcomes.⁸⁴

4. Pediatric Multiple Organ Dysfunction Score (P-MODS)

P-MODS estimates the severity of multiple organ dysfunction in pediatric patients. P-MODS collects information on five clinical variables in five organ systems (cardiovascular, pulmonary, hepatic, hematologic, and renal).⁸⁵ Calculation of the P-MODS score is simple because individual organ dysfunction is rated on a zero to four scale, with a score of four indicating the highest level of organ dysfunction. The worst values for each variable of the day are compiled for the score. While P-MODS is easy to calculate, it does not include a neurologic variable. Although its creators have demonstrated that P-MODS predicts mortality rates well,⁸⁶ it has yet to be validated by data external to the study for which it was developed.⁸⁷

5. Pediatric Logistic Organ Dysfunction (PELOD)

PELOD is similar to P-MODS in that it estimates the severity of multiple organ dysfunction in pediatric patients. PELOD collects information on 12 clinical variables in six organ systems (cardiovascular, pulmonary, hepatic, hematologic, renal, and neurologic). The worst values for each variable of the day are compiled for the score. PELOD has been criticized for its discontinuous score scale, which results in missing mortality predictions for several score intervals.⁸⁸ While this scoring system is able to estimate mortality risk well overall, it under-predicts mortality in the lower PELOD score range and over-predicts mortality with higher scores. Furthermore, although determining a PELOD score is less complex than PRISM III or PIM 2, it still requires a significant amount of time to calculate, which may prohibit its use during an emergency.

⁸² See *id.*, at 278.

⁸³ See van Keulen, *supra* note 79.

⁸⁴ See Marcin & Pollack, *supra* note 72, at 134.

⁸⁵ See Ana Graciano et al., *The Pediatric Multiple Organ Dysfunction Score (P-MODS): Development and validation of an objective scale to measure the severity of multiple organ dysfunction in critically ill children*, 33 CRIT. CARE MED. 1484, 1485 (2005).

⁸⁶ See Troy Dominguez & Jimmy Huh, *Do we need another pediatric severity of illness score?* 33 CRIT. CARE MED. 1643, 1644 (2005).

⁸⁷ See Marcin & Pollack, *supra* note 72, at 135.

⁸⁸ PELOD score intervals do not predict risk of mortality in the intervals of 0.3 – 0.9% (PELOD scores 5 – 9), 3.1 – 16.2% (PELOD scores 15 – 19), 40 – 80% (PELOD scores 25 – 29), and 92 – 99% (PELOD scores 35 – 39). These scoring gaps are caused by the weighting of severe conditions in each organ system. Each organ system that is evaluated can receive a zero, one, 10, or 20 score, with 20 being the worst possible score. Since the individual organ system scores do not increase by increments of one, but rather in steps of one or 10, the final PELOD score does not reflect certain totals since the score is limited to various combinations of zero, one, 10 and 20. See Pedro Garcia et al., *External validation of the paediatric logistic organ dysfunction score*, 36 INTENSIVE CARE MED. 116, 118 (2010).

6. Advantages and Disadvantages of a Clinical Scoring System

A clinical scoring system that examines a patient's overall health and provides an accurate assessment of mortality risk based on medical data would be a valuable resource when determining whether a patient will survive after a reasonable duration of ventilator treatment.⁸⁹ It should be simple to use, with few variables or lab parameters, and the calculation of the score should not be complicated. Such a system would provide a consistent, objective approach to resource allocation.

There are several disadvantages of utilizing a pediatric clinical scoring system to triage patients for scarce resources. First, it may not be appropriate to use a model that evaluates PICUs as a whole to estimate mortality risk for an individual pediatric patient. More specifically, while most of the systems discussed above may be applied to determine whether an individual patient may survive generally, the accuracy level varies when attempting to separate patients with an extremely high risk of dying – who are not likely to benefit from ventilator therapy – from those who have a moderate/low risk of dying – who have a stronger likelihood of benefiting from ventilator use. While pediatric clinical scoring systems may be able to generally categorize patients, they may not precisely identify whether an individual patient survives or who should receive ventilator therapy when there are limited resources.

Furthermore, none of these systems have been validated to measure an individual patient's outcomes during a public health emergency. While a validation study examining the various systems would be extremely useful, such a study is difficult to conduct because most validation studies require that the threshold of mortality be 80 percent. However, the proportion of children with high mortality risk, i.e., greater than 80 percent, is extremely small (mortality rates in most PICUs are less than 10 percent),⁹⁰ and it is challenging to find a large enough sample size to effectively examine and validate the use of these systems as a method to triage patients for critical care resources. Furthermore, a public health emergency that significantly affected children has not occurred where such a sample could be analyzed.⁹¹

Finally, pediatric clinical scoring systems may not be substantially functional as a method to triage patients for critical care resources because only a small number of pediatric patients meet the estimated mortality threshold to withhold ventilator therapy.⁹² Thus, existing pediatric clinical scoring systems alone may not optimize limited resources.

⁸⁹ A clinical system that utilizes evidence-based criteria would be superior to physician clinical judgment alone for triage decisions. However, clinical scoring systems that are not evidence-based and that perform poorly may result in worse population outcomes than a first-come, first-serve allocation method. Robert K. Kanter, *Would Triage Predictors Perform Better than First-Come, First-Served in Pandemic Ventilator Allocation?* 147 CHEST 102, 107 (2015).

⁹⁰ See Dominguez & Huh, *supra* note 86, at 1643.

⁹¹ Previous public health pandemics such as SARS and novel H1N1 did not cause widespread deaths in the pediatric population to provide an appropriate sample size.

⁹² See Christian et al., *Treatment and Triage Recommendations supra* note 30, at S115.

C. Physician Clinical Judgment

Due in part to the absence of clinical scoring systems validated for use in public health emergencies, some allocation protocols rely almost solely on physician judgment, based on clinical expertise and up-to-date medical knowledge, to determine mortality risk and thereby allocate ventilators. Since children have different anatomy and physiology than adults, physician clinical judgment plays a significant role in treating pediatric patients. Physicians, especially those with extensive experience working with critically ill pediatric patients, have amassed vast evidence-based expertise and clinical practice that carefully guide their decisions about medical treatment. In addition, studies have revealed that pediatric physicians may predict children's mortality risk just as well as pediatric clinical scoring systems.⁹³

However, the extreme circumstances of a public health emergency such as an influenza pandemic, may severely compromise normally reliable clinical expertise. Not only will the number of available health care staff be reduced, but extreme fatigue and other constraints may adversely affect clinical judgment. In addition, many hospitals do not have the capacity to treat pediatric or neonatal patients, and staff at these facilities may not have sufficient experience with the unique clinical considerations of children and infants to make informed triage decisions. Finally, the use of physician clinical judgment may be vulnerable to inconsistencies and increases the potential for inequity and unintentional bias.

D. Time Trials

Clinical assessments of a patient receiving ventilator treatment at periodic time intervals may be useful in determining whether the patient is improving and if s/he continues with ventilator therapy. Time trials provide a patient with sufficient opportunity to benefit from ventilator therapy, while concurrently ensure that as many children as possible who could benefit from ventilator treatment receive it.

Although the length of a time trial should reflect the expected duration of treatment for severe pulmonary conditions such as influenza, determining the ideal length of a time trial for a pediatric patient is challenging. A lengthy time trial reduces ventilator turnover and fewer patients have access to potentially lifesaving machines. In contrast, excessively brief trials permit more patients an opportunity to receive ventilator therapy, but may not decrease overall mortality rates. If a time trial is too short, more patients may be able to access ventilator therapy, but those patients may not survive because they are not given an adequate time frame to benefit from the treatment. In addition, the "churning" of patients requires extubations of a larger number of patients, which may be psychologically difficult for health care staff to implement and such actions may add to the already stressful environment.

E. Response to Ventilation

As part of the clinical assessments that occur during the time trials, response to ventilation using oxygenation index (OI) may be an important factor to consider after a patient begins ventilator therapy and is used in some clinical ventilator allocation protocols.

⁹³ See Sweney, *supra* note 77, at 130.

OI represents the ratio between the level of oxygen being delivered to the lungs by a ventilator and the amount diffusing into the blood. OI is calculated by multiplying mean airway pressure (MAP) by fraction of inspired oxygen (FiO₂) multiplied by 100 and dividing the product by partial pressure of oxygen in arterial blood (PaO₂). It measures the intensity of ventilator therapy needed to maintain a certain amount of oxygen in the arterial blood.

It may be advantageous to incorporate OI into a clinical ventilator allocation protocol, especially when influenza is the primary condition that affects ventilator need. Since most patients require a ventilator because influenza has compromised their lung function, measuring OI offers numerical data on current lung function. Improving or deteriorating values provides additional evidence to help guide triage decisions. OI may also be a useful variable because a worsening OI over time may be a marker of increased risk of mortality.⁹⁴ Furthermore, this measurement is relatively easy to obtain and calculate.

While this parameter may be helpful, it may not be appropriate to singularly rely on because it may over-emphasize lung function rather than examining the overall health of a patient. In addition, because OI is not measured in most adult clinical ventilator allocation protocols, using it as part of a triage decision for children may unfairly subject pediatric patients to a higher standard than adults to justify ventilator use.

F. Duration of Ventilator Need/Resource Utilization

Depending on the severity of a patient's medical condition, resource demands – including the estimated length of time the patient may need ventilator therapy – varies. During an influenza pandemic, shortages of resources necessitate curbing the amount of care that would normally be provided. Consideration of duration of ventilator need could assist with the identification of patients who may recover more quickly (i.e., those who may not need long treatment) so that these patients have priority access to ventilator therapy.

Excluding patients who require a disproportionate amount of dedicated resources – such as staff attention, medical equipment, and time – to care for a larger number of people who do not demand such heavy resource consumption may be considered reasonable in certain circumstances. In an influenza pandemic, ventilators are the most obvious intensely used resource.⁹⁵ For example, a ventilator may either be used for one patient for a prolonged period of time or for multiple patients for a short period of time each. In line with the goal of saving the most lives, expeditious ventilator turnaround is advantageous so that a greater number of people could benefit from this treatment. An estimation of the expected amount of ventilator therapy required by a patient could help determine more precisely whether the patient should be prioritized in an attempt to maximize scarce resources.

⁹⁴ John L. Hick et al., *Clinical Review: Allocating ventilators during large-scale disasters- problems, planning and process*, 11 CRIT. CARE 217, 223 (2007).

⁹⁵ While extracorporeal membrane oxygenation (ECMO) machines are also capable of ventilating a patient, there are significantly fewer ECMO machines than ventilators. In addition, there is fewer health care staff available to operate these machines. The use of ECMO is decided on a case-by-case basis using the clinical ventilator allocation protocol described in Section IX. New York's Clinical Ventilator Allocation Protocol for Pediatric Patients: Rationale and Clinical Components.

However, implementation of the concept of resource utilization may be difficult. Currently, there is no objective method or system that accurately estimates the many variables associated with resource use. It is a qualitative determination that is heavily dependent on the experience of the clinician. Not all health care staff are qualified or trained in pediatrics or have a thorough understanding of children's anatomy and physiology, and it may not be prudent to rely on estimations of a pediatric patient's ventilator need. Finally, this concept is not a triage criterion in the Adult Guidelines and its application in the pediatric clinical ventilator allocation protocol may be perceived as unfair.

VII. Pediatric Ventilator Allocation Plans from Other Jurisdictions and Facilities

Only a few U.S. states and a Canadian province have ventilator allocation plans designed specifically for pediatric patients. These plans differ on several key aspects, including: (1) the age at which the pediatric, rather than the adult, clinical protocol is applied; (2) the use of exclusion criteria; (3) which clinical scoring system, if any, is used; (4) the extent of physician clinical judgment used; (5) whether to consider a patient's estimated ongoing resource demands (i.e., duration of ventilator need); and (6) the amount of time allotted to gauge whether a patient is benefiting from ventilator therapy.

A. Ontario, Canada

The Ontario Health Plan for Influenza Pandemic's (OHPIP) plan has a separate plan for children, which also includes neonatal patients.⁹⁶ OHPIP's pediatric plan does not utilize exclusion criteria or a clinical scoring system; instead, a triage officer/committee examines a patient's likelihood of survival, which is not translated into a numerical value.⁹⁷ Each patient is evaluated, and a patient who is not predicted to survive certain conditions⁹⁸ or who has underlying chronic conditions associated with severe morbidity⁹⁹ is not eligible for ventilator therapy and is directed to non-ventilator treatments.¹⁰⁰

OHPIP provides an extensive summary of factors that should be considered when evaluating pediatric and neonatal patients. A triage officer/committee is instructed to examine a patient's physiology, the presence of any diseases or medical conditions and the expected prognosis with and without influenza, expected response to influenza/presenting illnesses, and expected demand on resources.¹⁰¹ In addition, the child's "best interest," which includes chances of survival, harms and benefits of treatment, evidence regarding long- and short-term medical outcomes of treatment, and any long-term consequences that may cause suffering or affect a

⁹⁶ Ontario Ministry of Health and Long-Term Care, *Ontario Health Plan for an Influenza Pandemic* (2008), 18-8 – 18-13, 18A, http://www.health.gov.on.ca/en/pro/programs/emb/pan_flu/docs/plan_full.pdf (hereinafter OHPIP 2008). The 2006 OHPIP protocol was revised in 2008 and again in 2013. The 2008 version is a preparedness guide and the 2013 version is a response plan.

⁹⁷ *See id.*, at 18-8, 18-10.

⁹⁸ Examples include post-cardiac arrest or prolonged neonatal resuscitation. *See id.*, at 18-10.

⁹⁹ Examples include late-stage degenerative conditions requiring chronic life support, extreme prematurity, or low birth weight. *See id.*

¹⁰⁰ *See id.*, at 18-9 – 18-10.

¹⁰¹ *See id.*, at 18-8.

child's quality of life, may be considered.¹⁰² Patients receiving ventilator therapy are limited to time trials, and although an exact time interval is not recommended explicitly, the plan suggests 24 hours as an option.¹⁰³

B. Alaska

The pediatric plan for Alaska applies to newborns discharged from the hospital up to patients who are 18 years old.¹⁰⁴ They also incorporate pediatric exclusion criteria. Alaska utilizes a modified SOFA system, called Modified Pediatric SOFA (MPSOFA),¹⁰⁵ which examines the level of oxygen in the arterial blood, liver function, blood pressure, neurologic function, and lactate level of a patient.¹⁰⁶ MPSOFA is different from SOFA in that it examines five, not six, variables.¹⁰⁷ A different measurement is used to examine oxygen levels in the blood, and instead of examining kidney function, lactate level is measured.

As with adults, pediatric patients are prioritized for ventilator therapy based on their MPSOFA score, but the cutoff scores are different than the adult SOFA scores. After receiving ventilator therapy, a pediatric patient is assessed every 12 hours to determine his/her continued priority for the ventilator.¹⁰⁸ Resource utilization is not a triage consideration.

C. Florida

Florida's guidelines for allocating scarce resources to children are adapted from Alaska's pediatric recommendations and apply to children "post-nursery" to age 18.¹⁰⁹ To be considered for a ventilator, children in Florida must not meet any of the state's pediatric exclusion criteria.¹¹⁰ Florida's plan also utilizes a modified version of SOFA (MSOFA) to prioritize children's ventilator eligibility and continued usage is reassessed using MSOFA every 12 hours.¹¹¹ MSOFA examines five variables: the level of oxygen in the blood, liver function,

¹⁰² See *id.*

¹⁰³ See *id.*, 18-10. OHPIP's plan is unclear whether incoming patients are compared to patients currently receiving ventilator therapy (similar to the pediatric plans of both Minnesota and Wisconsin) or if patients are evaluated and those with a high likelihood of survival are placed on a ventilator only when an already ventilated patient receives a poor prognosis at the end of his/her time trial.

¹⁰⁴ See Alaska Guidelines, *supra* note 77, at 1. Alaska's plan is adapted primarily from Utah's pediatric guidelines.

¹⁰⁵ MPSOFA variables are: (1) SpO₂/FiO₂ ratio or nasal cannula or O₂ mask required to keep SpO₂ > 90%, (2) total bilirubin (mg/dL), (3) hypotension, (4) Glasgow coma score, and 5) lactate (mmol/L). See Alaska Guidelines, *supra* note 77, at 8.

¹⁰⁶ Increased lactate level in the blood may be caused by shock, heart failure, or lung disease and some studies have linked higher lactate levels with critical illness and increased mortality rates. See Jan Bakker & Tim Jansen, *Don't take vitals, take a lactate*, 33 INTENSIVE CARE MED. 1863 (2007) (citing several studies that support the morbidity and mortality predictive power of lactate measurement).

¹⁰⁷ Alaska's MPSOFA does not examine coagulation (platelets).

¹⁰⁸ See Alaska Guidelines, *supra* note 77, at 6.

¹⁰⁹ Florida Department of Health, Pandemic Influenza Technical Advisory Committee, *Pandemic Influenza: Triage and Scarce Resource Allocation Guidelines*, 25 (2011), http://www.floridahealth.gov/programs-and-services/emergency-preparedness-and-response/healthcare-system-preparedness/_documents/acs-guide.pdf.

¹¹⁰ The list of exclusion criteria for children overlaps considerably with the exclusion criteria for adults. In addition, various modifications have been made to the criteria to be age appropriate for pediatric patients. See *id.*, at 6, 27.

¹¹¹ See *id.*, at 26-27.

blood pressure, neurologic function, and creatinine level of a patient.¹¹² The plan does not explicitly comment on withdrawal of ventilators from children, but the reassessment protocol includes consideration of palliative care or discharge if a child no longer meets the priority criteria for continued ventilation.¹¹³ Resource utilization is not a factor.

D. Indiana

In Indiana, all children between the ages of two months to 12 years are classified as pediatric patients.¹¹⁴ Despite the use of an age cutoff for pediatric patients, the state applies the general adult allocation protocol to children.¹¹⁵ The same medical conditions from an exclusion criteria list and SOFA score ranges from the adult protocol are applied to pediatric patients and time trials are used at 48 and 120 hours.¹¹⁶ The plan notes that if lab or radiology resources are exhausted, clinician judgment, along with a physical examination and patient medical history, should be used to make a triage decision.¹¹⁷

Indiana's plan is unique in that it explicitly states that a ventilator may not be withdrawn from a ventilated patient who continues to have intermediate or high priority SOFA scores within the 120 hour time frame. However, the ventilator may be withdrawn from a patient and given to another patient if the ventilated patient's SOFA score measured after 120 hours classifies him/her as being of intermediate priority for ventilation and the person waiting has a SOFA score indicating high priority.¹¹⁸

E. Kansas

Kansas's plan to allocate ventilators to children is brief.¹¹⁹ Pediatric patients are those who are less than 18 years old.¹²⁰ The plan applies the adult exclusion criteria to children.¹²¹ Kansas acknowledges that SOFA is not appropriate to use to triage children and recommends PELOD to determine a pediatric patient's access to a ventilator.¹²² At the initial assessment, PELOD scores of > 33, < 21, and 21 – 33, correspond to low, high, and medium priority, respectively, for ventilator treatment.¹²³ A ventilated patient is evaluated at 48 and 120 hours to

¹¹² MSOFA uses SpO₂/FiO₂ ration or nasal cannula or O₂ mask required to keep SpO₂ > 90% to examine oxygen level in the blood. Values for all variables mirror the value ranges for adults. *See id.*, at 28.

¹¹³ *See id.*, at 26.

¹¹⁴ Indiana State Dep't of Health, Crisis Standards of Care Community Advisory Group, *Crisis Standards of Patient Care Guidance with an Emphasis on Pandemic Influenza: Triage and Ventilator Allocation Guidelines*, 4 and 10 (2014) (hereinafter Indiana Guidelines).

¹¹⁵ The protocol used for adults have age appropriate modifications for children. *See id.*, at 10, 19.

¹¹⁶ *See id.*, at 10-12.

¹¹⁷ *See id.*, at 14.

¹¹⁸ *See id.*, at 12.

¹¹⁹ Kansas Department of Health and Environment, Gianfranco Pezzino and Steven Q. Simpson, Chairs, *Guidelines for the Use of Modified Health Care Protocols in Acute Care Hospitals During Public Health Emergencies*, 2nd Revision (2013) (hereinafter Kansas Guidelines).

¹²⁰ *See id.*, at 24.

¹²¹ *See id.*

¹²² *See id.*, at 18 and 23-24.

¹²³ *See id.*, at 24. *See also* Kristin M. Kim et al., *Triage of Mechanical Ventilation for Pediatric Patients During a Pandemic*, 6 DISASTER MED. PUB. HEALTH PREP. (2012): 131-137.

determine whether s/he continues with the ventilator or whether the ventilator should be reallocated.¹²⁴

F. Michigan

Michigan released guidelines for the allocation of limited resources and services during a public health emergency and included specific guidance for the allocation of ventilators and ICU services during a respiratory (e.g., influenza) pandemic.¹²⁵ The plan includes guidance for triaging pediatric patients and the protocol applies to patients who are under 18 years of age.¹²⁶ The guidelines apply the same exclusion criteria to adults and children,¹²⁷ and it employs PELOD to determine a patient's priority for ventilator therapy.¹²⁸

At the initial assessment, PELOD scores of > 33, < 21, and 21 – 33, correspond to low, high, and medium priority, respectively, for ventilator treatment.¹²⁹ Ongoing resource demands by a patient are not considered. A ventilated patient is evaluated at 48 and 120 hours to determine whether s/he continues with the ventilator or whether the ventilator should be reallocated.¹³⁰

G. Minnesota

Minnesota does not have separate ventilator allocation plan for pediatric and adult patients, and children are triaged using the same parameters as adults. Unlike other states, Minnesota does not apply exclusion criteria followed by the use of a scoring system to make triage decisions. Instead, a triage officer examines (in order of importance): (1) a patient's SOFA score, (2) duration of benefit/prognosis, including consideration of any severe underlying disease, (3) estimated number of days ventilator therapy is needed, and (4) response to ventilation.¹³¹

Priority is given to patients who have a greater likelihood of survival followed by patients who may only require a short duration of use of critical care resources.¹³² If it is determined that an incoming patient has a significantly better outlook for survival compared to the already

¹²⁴ *See id.*

¹²⁵ State of Michigan Department of Community Health, Office of Public Health Preparedness, *Guidelines for Ethical Allocation of Scarce Medical Resources and Services During Public Health Emergencies in Michigan, Version 2.0*, <http://www.mimedicalethics.org/Documentation/Michigan%20DCH%20Ethical%20Scarce%20Resources%20Guidelines%20v2%20rev%20Nov%202012.0.pdf>.

¹²⁶ *See id.*, at 64.

¹²⁷ *See id.*, at 59.

¹²⁸ *See id.*, at 62-64.

¹²⁹ *See id.*, at 64.

¹³⁰ *See id.*, at 60

¹³¹ Minnesota Department of Health, Minnesota Healthcare System Preparedness Program, *Patient Care: Strategies for Scarce Resource Situations* 11 (version 2.0, 2011). Response to ventilation is based on improving ventilator parameters (oxygenation index) over time.

¹³² *See* Dorothy E. Vawter et al., Minnesota Center for Health Care Ethics & University of Minnesota Center for Bioethics, *For the Good of Us All: Ethically Rationing Health Resources in Minnesota in a Severe Influenza Pandemic*, 53 (prelim. report 2010), <http://www.health.state.mn.us/divs/idepc/ethics/ethics.pdf>.

ventilated patient, the ventilator is reallocated.¹³³ For each incoming patient who needs a ventilator, a triage officer/committee compares the status of all patients. The less time a patient has received ventilator therapy, the more significant the potential benefit must be for an incoming patient to reallocate the ventilator to the new patient.¹³⁴

When all clinical considerations are equal and there are not enough ventilators for patients who need them, Minnesota recommends a random process (e.g., lottery) to determine whether the patient(s) receive a ventilator treatment. However, when the pool of eligible patients includes both children and adults, patients 17 years and younger have priority before adults.¹³⁵ When children are competing for a ventilator with other children, a random process would be used to select patients. Only during severe ventilator scarcity are exclusion criteria and time trials (e.g., 48 hour intervals) used.

H. Wisconsin

Wisconsin's pediatric guidelines are similar to Minnesota's plan. Wisconsin does not specify the age range of pediatric patients; however, its guidelines permit age to be used in conjunction with other variables to determine the length of a ventilator time trial.¹³⁶ Instead of applying exclusion criteria and a scoring system, Wisconsin examines a patient's PELOD score, prognosis based on oxygenation data, estimated number of ventilator days needed, and duration of benefit (prognosis based on any underlying diseases and ongoing resource demands).¹³⁷ A patient with a PELOD score > 35, 17 – 34, and < 17 has low, medium, and high priority, respectively, for ventilator treatment.¹³⁸ Similar to Minnesota, a triage officer/committee evaluates both already ventilated patients and incoming patients to determine whether a child receives (or continues with) a ventilator treatment. Wisconsin's guidelines are unusual in that it allows the consideration of age in conjunction with other disease variables to determine duration of benefit.¹³⁹ However, age may not be considered as a criterion itself and may not be used when determining prognosis.¹⁴⁰

I. Utah

Utah's pediatric guidelines apply to patients 13 years old and younger.¹⁴¹ It utilizes a list of exclusion criteria that differs from the adult exclusion criteria because pediatric patients rarely

¹³³ See *id.*, at 54.

¹³⁴ See *id.*

¹³⁵ See *id.*

¹³⁶ No information on time trials for pediatric patients is available. See Wisconsin Department of Health Services, Pandemic Influenza Program, *Introduction to Pediatric Ventilator Guidelines*, 3 (2008)

http://www.health.gov.fj/wp-content/uploads/2014/05/z_Appendix-2_Paediatric-ventilation-decision-tool.pdf.

¹³⁷ See *id.*, at 2.

¹³⁸ See *id.*

¹³⁹ See *id.*, at 3.

¹⁴⁰ The Wisconsin plan states, "Age is to be used in conjunction with other disease variables *only* to determine duration of benefit, not as stand-alone criteria or affecting prognosis." See *id.*

¹⁴¹ Utah's pediatric guidelines briefly refer to neonatal patients and state that resuscitation of extremely premature infants with anticipated mortality rates > 80% should not be offered. Utah Hospitals and Health Systems Association for the Utah Department of Health, *Utah Pandemic Influenza Hospital and ICU Triage Guidelines for Pediatrics*, 5 (version 4b, 2010) (hereinafter Utah Guidelines).

experience end-stage organ failure. The plan does not incorporate a pediatric clinical scoring system to determine whether a patient initially is eligible for ventilator treatment and instead, recommends relying on physician clinical judgment.¹⁴² Resource utilization is not a factor for triage decisions. After a patient is determined to be eligible and if there are more patients than available ventilators, the patient is placed on a waiting list. A pediatric patient's continued use of the ventilator is reassessed every 48 – 72 hours.¹⁴³ In determining whether a patient continues with this therapy, Utah decided to incorporate a pediatric clinical scoring system, PIM 2, together with physician judgment. A triage officer may consider withdrawal of the ventilator if the PIM 2 score predicts more than 80 percent mortality risk for a patient.¹⁴⁴

J. Comments on the Pediatric Ventilator Allocation Plans

An analysis of the various pediatric plans reveals a lack of consistency between plans at every step of the triage process.

The plans do not uniformly identify a specific pediatric age cutoff, either because they do not provide a specific age, or they use different ages (i.e., 12, 13, 17, or 18) to classify a patient as a child versus an adult. Some plans explicitly triage children and adults together and do not establish a separate clinical ventilator allocation protocol for pediatric patients.

With respect to exclusion criteria, some clinical ventilator allocation protocols do not utilize exclusion criteria, while the majority of plans provide a detailed list of medical conditions that preclude a person from ventilator therapy. Other plans use the same exclusion criteria proposed for the adult population and no additional modifications of the criteria are made for children.

While some plans employ a pediatric clinical scoring system at the beginning of the clinical ventilator allocation protocol – SOFA, modified SOFA, or PELOD are the systems of choice – other protocols rely on physician clinical judgment¹⁴⁵ to evaluate whether a patient is initially eligible. However, none of these clinical ventilator allocation protocols provide any guidance for when and why physician judgment is appropriate.

Not all plans incorporate time trials. However, when time trials are used, the range for the first assessment varies between 12, 24, or 48 hours, and for the second assessment from 24, 72, or 120 hours.

In addition, while many plans include several clinical variables for consideration, such as mortality risk assessment and estimated resource use, most of these plans (with the exception of Minnesota) do not offer any guidance on the relative importance of such appraisals in the triage

¹⁴² *See id.*, at 4.

¹⁴³ *See id.*

¹⁴⁴ *See id.*

¹⁴⁵ Utah does not use a scoring system to determine whether a patient is eligible for ventilator therapy. Instead, physical clinical judgment is used. However, Utah utilizes PIM 2 to determine if a ventilated patient continues with this form of treatment. *See* Utah Guidelines, *supra* note 141, at 4.

decision. There is little information available regarding whether the parameters should be weighed equally, or if one variable should be emphasized more than others.

The few triage plans that compare patients to each other are controversial, because they could require the withdrawal of the ventilator from a ventilated patient every time a new patient with a better prognostic health assessment arrives at the facility. This policy could result in not providing any patient sufficient time to benefit from ventilator treatment if there is a constant influx of new patients who have a higher likelihood of survival. To compare patients with each other could force a triage officer/committee to prematurely withdraw ventilators from patients more often, and could, in essence, pit patients against each other for access to lifesaving treatments. Furthermore, such comparisons may intensify inherent biases in the health care system and the disproportionate and disparate provision of care for already disadvantaged populations.

Finally, most of these plans do not offer a discussion of incorporating young age. However, some states, such as Minnesota and Alaska, examine the advantages and disadvantages of incorporating age as a triage factor. While Alaska concludes that children should be “considered equally with adults” and if “a child has comparable survival rate to an adult, given his/her clinical triage scores, then s/he should receive a comparable level of medical care,”¹⁴⁶ in contrast Minnesota explicitly states that among those similarly situated, children (ages 18 and younger) may be prioritized over adults in scarce resource allocation decisions.¹⁴⁷

VIII. Pediatric Age Cutoff and Ventilator-Dependent Chronic Care Patients

A. Pediatric Age Cutoff

Identifying the appropriate age cutoff for classifying an individual as a pediatric or adult patient implicates a myriad of clinical, legal, and societal issues. The most commonly suggested ages are 13/14, the age by which puberty usually has begun; 16/17, the age used for consent to sexual intercourse; and age 18, the age which a person is legally classified as an adult. Although a person may be under the care of a pediatrician until roughly the age of 18 or for some through the college years, there is physiological diversity within the medical category of pediatrics, and delineating subcategories within the group is challenging because individuals mature physically at different rates. Even if specialized care were warranted for most younger children, particularly those whose anatomy and physiology are least like adults’, most older adolescents (ages 15 to 18), particularly those whose anatomy and physiology are most like adults’, might be grouped with adults. Thus, from a biological and clinical perspective, it might be appropriate to consider some mature teenagers alongside adults when making triage decisions.¹⁴⁸

The Pediatric Clinical Workgroup and Task Force recommended that the Pediatric Guidelines apply to all patients 17 years old and younger, that is, under 18 years old, with the

¹⁴⁶ See Alaska Guidelines, *supra* note 77, at 6.

¹⁴⁷ See Vawter et al., *supra* note 132, at 62.

¹⁴⁸ While the anatomy and physiology of an adolescent may be similar to a young adult, this age group may not be mentally mature enough to handle the emergency situation. Furthermore, if the age of a patient is not available, the patient’s height and weight may be a useful gauge to estimate age.

understanding that the age cutoff may change, depending on the circumstances of the public health emergency.

A presumptive pediatric age cutoff of 17 might be appropriate for several reasons. During normal (non-pandemic) conditions, many patients up to the age of 18 are often treated under the pediatric rubric and at pediatric specialty facilities. Furthermore, because SOFA, the clinical scoring systems used to triage patients in the adult protocol, was developed using medical records of patients 18 years and older, the use of this clinical scoring system for patients ages 0 – 17 remain unvalidated. Although older adolescents may have the anatomy and physiology of an adult, it might be inappropriate to triage this group under the adult clinical framework (i.e., SOFA clinical scoring system), without evidence and data.

However, the Pediatric Clinical Workgroup acknowledged that during a pandemic, it may be appropriate to adjust the pediatric cutoff to patients 14 years old and younger, depending on the progression of the influenza pandemic, the age group most at risk, and the needs and resources available.¹⁴⁹ Based on the typical onset of puberty by age 14, older children have the anatomy and physiology of young adults.¹⁵⁰ If the pandemic is primarily affecting young children and pediatric resources are overwhelmed more than adult resources, it would be appropriate to transfer these teenagers (ages 15 and older) to adult facilities, because they may be cared for in these settings, unlike their younger peers. By lowering the pediatric age cutoff, pediatric surge capacity could be increased, especially since generally, there are fewer health and critical care resources available to children than adults. Conversely, if the pandemic disproportionately affects older adults, it would be better to keep the pediatric cutoff at 17 or younger to avoid overwhelming adult facilities with additional patients.¹⁵¹ The pediatric age cutoff is useful to determine where pediatric patients should be placed, (i.e., pediatric only, adult only, or mixed population facilities), and such a determination is heavily dependent on the real-time availability of resources and what population the pandemic viral strain targets.

Furthermore, with regards to ventilators, a large number of these machines could be adjusted to accommodate either a pediatric or adult patient, thus supporting the concept of a

¹⁴⁹ Due to variability of the pandemic viral strain, it is impossible to know with certainty which age group would be the most vulnerable. For example, in the 1918 pandemic, young adults were most at risk and subject to the highest mortality rates. It is possible a future pandemic would disproportionately affect only children or the elderly. Furthermore, it may be possible that the pediatric age cutoff would be lowered (i.e., 12 years old) depending on the pandemic viral strain, the needs of the affected population, and the available resources of the acute care facilities.

¹⁵⁰ The Pediatric Clinical Workgroup referenced the American Heart Association's (AHA) guidelines for basic advanced life support (BLS), which includes cardio-pulmonary resuscitation (CPR), as justification for treating some older children as adults. The AHA concluded that there was no scientific evidence to identify a precise age cutoff to determine whether a patient received adult or pediatric CPR techniques. Instead, the AHA made a consensus decision for age cutoff that was based on practical criteria and consistent teaching practices. The AHA guidelines recommend that for all infants, children, and adults, a 30:2 compression to ventilation ratio should be used. Furthermore, the AHA recommends adult protocols for all individuals who have exhibited signs of puberty (breast development in females and the presence of axillary hair in males). See American Heart Association, 2005 *American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care*, 112 CIRCULATION IV-12 (2005); Marc D. Berg et al., 2010 *American Heart Association Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care*, 122, CIRCULATION S862, S863(2010).

¹⁵¹ It may be possible to increase the pediatric age cutoff (i.e., 21 years old).

flexible age cutoff framework.¹⁵² However, while some ventilators could be modified for children, not all facilities have the software, equipment, or skilled staff to ventilate pediatric patients. While the Pediatric Clinical Workgroup acknowledged such limitations, they concluded that because teenagers/older pediatric patients have the anatomy and physiology of young adult patients, these normally “adult” facilities could quickly adapt and care for this group of children.

Finally, the pediatric age cutoff may also determine which clinical ventilator allocation protocol (adult or pediatric) is applied for triage purposes. For example, some facilities may choose to bring in pediatric specialist(s) to help with the triage process. Based on information on the pandemic viral strain and the circumstances of the pandemic, it may be acceptable to triage older adolescents with SOFA (despite its unvalidated status for children) based on the conclusion that puberty is a marker for adulthood and transfer younger pediatric patients to other facilities.¹⁵³ Thus, practical implications of the pandemic may also affect the age cutoff of pediatric patients.

B. Ventilator-Dependent Chronic Care Patients

All pediatric acute care patients who need ventilator therapy, including those currently using a ventilator, are subject to the pediatric clinical protocol. Similar to the adult plan, a pediatric patient using ventilators in chronic care facilities will not be triaged. However, if a ventilator-dependent patient requires transfer to an acute care facility, s/he is evaluated by the same criteria as all other pediatric patients who require a ventilator.¹⁵⁴

IX. New York’s Clinical Ventilator Allocation Protocol for Pediatric Patients: Rationale and Clinical Components

A brief summary of the pediatric clinical ventilator allocation protocol, developed by the Pediatric Clinical Workgroup and the Task Force, is presented below, followed by an explanation of the details and rationales. Although the Adult Guidelines and Pediatric Guidelines do not utilize the exact same clinical tools to evaluate the patient, the ethical and clinical frameworks remain the same.¹⁵⁵

¹⁵² As facilities replace older machines that previously only accommodated an adult patient, many hospitals are purchasing “dual-use” ventilators, which can be used for pediatric and adult patients.

¹⁵³ Several members of the Pediatric Clinical Workgroup suggested that children, including older adolescents, may benefit from the application of SOFA because most children will have better organ function scores than adults as a result of generally having better overall health. However, these assumptions are only suppositions since no clinical evidence/data exist to validate the use of SOFA to triage children.

¹⁵⁴ For a discussion on whether the clinical ventilator allocation protocol should apply to ventilator-dependent chronic care patients, *see* Chapter 1, Adult Guidelines, Section VII. Triage Ventilator-Dependent Chronic Care Patients.

¹⁵⁵ Both the Task Force and the Pediatric Clinical Workgroup concluded that the adult ventilator allocation protocol could not be applied to children. However, efforts were made, where appropriate, to adhere to the basic framework of the adult protocol (i.e., three steps) to provide uniformity for a triage officer/committee.

As with the adult clinical ventilator allocation protocol,¹⁵⁶ all pediatric acute care patients who are in need of a ventilator, whether due to influenza or other conditions, are subject to the clinical ventilator allocation protocol.¹⁵⁷ Ventilator-dependent chronic care patients are only subject to the clinical ventilator allocation protocol if they arrive at an acute care facility. Using clinical criteria, patients who are deemed most likely to survive with ventilator treatment have an opportunity for ventilator therapy to maximize the number of survivors. The pediatric clinical ventilator allocation protocol applies to all children aged 17 and younger in all acute care facilities Statewide and it consists of three steps (each of which is discussed in greater detail in the following subsections):

- **Step 1 – Exclusion Criteria:** A patient is screened for exclusion criteria, and if s/he has a medical condition on the exclusion criteria list, the patient is not eligible for ventilator therapy. Instead, a patient receives alternative forms of medical intervention and/or palliative care.
- **Step 2 – Mortality Risk Assessment Using Physician Clinical Judgment:** Physician clinical judgment by a patient’s attending physician is used to assess the patient’s risk of mortality. A triage officer/committee examines clinical data from Steps 1 and 2 and allocates ventilators according to a patient’s mortality risk.
- **Step 3 – Time Trials:** Periodic clinical assessments at 48 and 120 hours are conducted on a patient who has begun ventilator therapy to evaluate whether s/he continues with the treatment. Various clinical parameters are examined at this step to assess the possibility of organ failure/mortality risk and to measure lung function. The decision whether a patient remains on a ventilator is based on ongoing clinical measures and data trends of a patient’s health condition, consisting of: (1) the overall prognosis estimated by the patient’s clinical indicators, which is indicative of mortality risk by revealing the presence (or likelihood), severity, and number of acute organ failure(s), and (2) the magnitude of improvement or deterioration of overall health, which provides additional information about the likelihood of survival with ventilator therapy. These results are compared to the results from the previous official clinical assessment.

The person (triage officer) or group of people (triage committee) who determines whether a patient receives (or continues with) ventilator treatment is not the physician attending to the patient.¹⁵⁸ The attending physician’s role is to evaluate a patient for exclusion criteria in Step 1 and to assess the patient’s mortality risk and organ failure risk in Steps 2 and 3. In order to facilitate the triage process, the patient’s clinical data are presented to a triage officer/committee

¹⁵⁶ For the Guidelines, survival is defined as survival of the acute medical episode that necessitates ventilator therapy. Some patients may be hospitalized for influenza, but others may be hospitalized for different reasons including emergency surgery. Likelihood of survival is based on whether a patient is alive at hospital discharge, and not based on whether a patient survives long-term after discharge (e.g., one year later). See Section IV. Overview of Concepts Used in Triage.

¹⁵⁷ Certain families on behalf of their children may decide to decline ventilator therapy. Such decisions to withhold or withdraw ventilator treatment should be implemented in the same way they are in a non-emergency situation.

¹⁵⁸ Because facilities differ in size and available resources, each facility should determine whether a triage officer or committee is more appropriate. For a discussion of the benefits and drawbacks of both models, see Chapter 1, Adult Guidelines, Section V. Triage Decision-Makers: Officer or Committee.

who determines a patient's level of access to a ventilator (i.e., who is eligible and/or continues with ventilator therapy). Ideally, a triage officer/committee has experience working with pediatric patients.¹⁵⁹

A triage officer/committee examines a patient's clinical data and uses this information to assign a color code to the patient at Steps 2 and 3. The color (blue, red, yellow, or green) determines the level of access to a ventilator (blue = lowest access/palliate/discharge, red = highest access, yellow = intermediate access, and green = defer/discharge).¹⁶⁰ Patients with the red color code have the highest level of access to a ventilator because they are most likely to recover with treatment (and not likely to recover without it) and have a moderate risk of mortality. If resources are available, patients in the yellow category also have access to ventilator treatment.¹⁶¹ Those assigned the blue code are patients who potentially have the worst outlook for survival, even with ventilator therapy, and therefore have lowest access. The green category represents patients who are most likely to survive without ventilator therapy or are eligible for ventilator weaning. If resources become available, patients in the blue color category, or those with exclusion criteria, are reassessed and may become eligible for ventilator therapy.

Alternative forms of medical intervention are provided to those who are not eligible for a ventilator or these patients may be discharged. In addition, palliative care is provided to all patients throughout the triage process, regardless of prognosis. Furthermore, patients and/or their families may decide to decline ventilator therapy and these patients would also receive appropriate medical care. Patients with a high risk of mortality and poor response to ventilation have a low likelihood of improving within a reasonable time frame, such that the ventilator may be allocated to another child with a higher likelihood of survival. These patients are provided with alternative forms of medical intervention and/or palliative care, where appropriate.¹⁶²

Finally, the Task Force and the Pediatric Clinical Workgroup acknowledged that the triage process requires regular reassessments of the status of the pandemic, available resources, and of all patients.¹⁶³ Thus, as new data and information about the pandemic viral strain become available during a pandemic, the pediatric clinical ventilator allocation protocol may be revised accordingly to ensure that triage decisions are made commensurate with updated clinical criteria.

¹⁵⁹ It is possible that a triage officer/committee at the facility would triage both adult and pediatric patients. Ideally, the person or committee should have experience working with pediatric patients. Some facilities, depending on the availability of specialized staff, may designate a pediatric or neonatal specialist as a member of the triage committee. For an example of a pediatric triage committee in practice during an emergency disaster, see Amir Ytzhak et al., *Pediatric ventilation in a disaster: Clinical and ethical decision making*, 40 CRIT. CARE MED. 603, 604 (2012).

¹⁶⁰ These colors are consistent with the colors and recommended actions of the adult clinical ventilator allocation protocol. In addition, these colors are also consistent with other tertiary triage protocols and are universally recognized for triage purposes.

¹⁶¹ However, during the peak of the pandemic, it is unlikely that patients in the yellow category have access to ventilators because there will be more red code patients than available ventilators.

¹⁶² For a discussion of palliative care, see Section X.B. Palliative Care and Chapter 1, Adult Guidelines, Section XII.B. Palliative Care

¹⁶³ For a discussion of real-time data collection and analysis, see Chapter 1, Adult Guidelines, Section XIII.B. Real-Time Data Collection and Analysis and Modification of the Guidelines.

A. Step 1: Exclusion Criteria

Summary of Step 1: A patient is screened for exclusion criteria, and if s/he has a medical condition on the exclusion criteria list, the patient is not eligible for ventilator therapy. Instead, a patient receives alternative forms of medical intervention and/or palliative care.

1. Exclusion Criteria

The Task Force and the Pediatric Clinical Workgroup determined that although the use of exclusion criteria may not significantly reduce the number of children eligible for ventilator therapy, it still may be a useful tool in the initial stage of the triage process.¹⁶⁴ Applying exclusion criteria will identify patients with the highest probability of mortality, even with ventilator therapy, to prioritize patients most likely to survive with ventilator therapy in a situation of scarce resources. In addition, evaluating a patient for exclusion criteria may not consume large amounts of time or resources, as the presence of an exclusion criterion may be obvious. Alternatively, if medical information is not readily available or accessible, it may be assumed a patient is free of exclusion criteria and may proceed to the next step of the clinical ventilator allocation protocol.

Once it had determined that the use of exclusion criteria was acceptable as an initial triage step, the Pediatric Clinical Workgroup addressed the acceptable time frame of expected mortality for a condition to be placed on the exclusion criteria list. The Workgroup agreed that a long window of expected mortality, such as 12 to 24 months, was too difficult and ambiguous for a physician to predict with any accuracy. Several members proposed the use of a shorter time frame, such as six months. However, for most medical conditions, there is a lack of evidence-based data to indicate that mortality indeed occurs within six months. Workgroup members acknowledged that, in many circumstances, children with severe and likely fatal medical conditions may not necessarily have an expected mortality within this shorter window.¹⁶⁵

Furthermore, because the Task Force modified the definition of survival to be based on the short-term likelihood of survival of the acute medical episode and is not focused on whether a patient may survive a given illness or disease in the long-term (e.g., years after the pandemic), many conditions that may be fatal within a few years were not relevant to consider. Thus, the Pediatric Clinical Workgroup determined that because the purpose of applying exclusion criteria is to identify patients with a short life expectancy irrespective of the current acute illness, in order to prioritize patients most likely to survive with ventilator therapy. The medical conditions that qualify as exclusion criteria are limited to those associated with immediate or near-immediate mortality even with aggressive therapy.

The exclusion criteria list is, by necessity, flexible. Because it would be impossible to list every medical condition that would result in immediate or near-immediate mortality, the

¹⁶⁴ In contrast, the use of exclusion criteria in the adult clinical protocol will likely reduce the number of eligible patients for ventilator therapy more significantly.

¹⁶⁵ For example, a pediatric patient with a known fatal chromosomal abnormality who is ill with influenza is not necessarily excluded from ventilator therapy, since his overall health is stable and he is only ill with influenza. This patient could recover from influenza and live more than six months.

exclusion criteria list includes a “catch all” phrase that encompasses other possibilities. In addition, real-time data of the pandemic viral strain may require altering the list of exclusion criteria. For example, it may become apparent that patients affected with influenza and a particular medical condition never survive regardless of ventilator treatment. In such cases, this condition would be added to the exclusion criteria list.

Both the Task Force and the Pediatric Clinical Workgroup recognized that as with all medical decisions made during emergency conditions, decisions regarding the application of exclusion criteria may be made with limited information about a patient’s medical history.¹⁶⁶ Any patient whose exclusion criterion was not discovered initially continues to the next triage step. However, this patient likely will be ruled ineligible for ventilator therapy during the subsequent triage steps, because precise real-time clinical data about the patient’s health continue to be gathered.

2. Triage Chart for Step 1

The Pediatric Clinical Workgroup reached consensus on the following exclusion criteria list. This list focuses primarily on medical conditions limited to those associated with immediate or near-immediate mortality even with aggressive therapy. (See Appendix 1 for additional clinical information on exclusion criteria.) A patient’s attending physician examines his/her patient for an exclusion criterion and will forward this clinical data to a triage officer/committee to make the triage decision. Patients with exclusion criteria do not have access to ventilator therapy and instead are provided with alternative forms of medical intervention and/or palliative care.¹⁶⁷

¹⁶⁶ For example, in some cases, patients may arrive at the emergency department with endotracheal tubes already inserted by EMS personnel. In such instances, hospital staff would reassess patients and extubate these tubes as necessary. *See* Chapter 1, Adult Guidelines, XI.A. Step 1: Exclusion Criteria.

¹⁶⁷ *See* Section X. Alternative Forms of Medical Intervention and Pediatric Palliative Care. However, if a ventilator becomes available and no other patient is in need of ventilator therapy, a patient with an exclusion criterion may be eligible for this treatment.

Step 1 - List of Exclusion Criteria for Pediatric Patients¹⁶⁸
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 (See Appendix 1)
- Any other conditions resulting in immediate or near-immediate mortality even with aggressive therapy¹

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.

B. Step 2: Mortality Risk Assessment Using Physician Clinical Judgment

Summary of Step 2: Physician clinical judgment by a patient’s attending physician is used to assess the patient’s risk of mortality. A triage officer/committee examines clinical data from Steps 1 and 2 and allocates ventilators according to a patient’s mortality risk.

1. Physician Clinical Judgment

While the adult clinical ventilator allocation protocol uses a clinical scoring system (SOFA) to assess mortality risk to determine whether a patient is eligible initially for ventilator therapy,¹⁶⁹ currently available pediatric clinical scoring systems cannot be applied in the same manner. The Pediatric Clinical Workgroup rejected the use of a pediatric clinical scoring system at this step of the triage process. A majority of the most common pediatric clinical scoring systems require data that are only available *after* a patient has received medical intervention and therefore should not be used to determine which prospective patient would benefit from ventilator therapy. In addition, the few systems that could be used at point of triage entry, such as SOFA, have not been validated for this purpose in children.

Until a pediatric clinical scoring system is developed and validated for triage use,¹⁷⁰ the Pediatric Clinical Workgroup recommended that physician judgment based on clinical expertise

¹⁶⁸ New York’s exclusion criteria are based loosely on the exclusion criteria from Utah’s pediatric triage plan. See Utah Guidelines, *supra* note 141, at 5.

¹⁶⁹ See Chapter 1, Adult Guidelines, Section XI.B. Step 2: Mortality Risk Assessment Using SOFA.

¹⁷⁰ The Pediatric Clinical Workgroup recognized that there was an urgent need for a new pediatric clinical scoring system that not only predicts a patient’s likelihood of survival at initial triage, but also incorporates short-term utilization of intensive care resources, such as ventilators. This novel system would provide better accuracy regarding whether a pediatric patient will recover with low resource use. This system would identify more precisely whether a pediatric patient would benefit the most from a short-term trial of ventilator therapy and would ensure the

be used to evaluate the likelihood of survival, to determine whether a pediatric patient is eligible for ventilator therapy. Despite the various reservations physician clinical judgment entails, the Workgroup concluded its strengths outweighed its weaknesses. Physician clinical judgment consists of a structured decision-making process that carefully considers only specific clinical factors based on available medical evidence and not personal values or subjective judgments, such as quality of life. Although the clinical assessment does not provide a numerical score (unlike the adult protocol that provides a quantitative SOFA score), it offers an organized, rational framework to make allocation decisions in a uniform manner. Ideally, in order to make informed decisions, the attending physician and triage officer/committee should have experience working with children.¹⁷¹

The attending physician's evaluation is based solely on clinical criteria, including the acute severity of a patient's current medical condition, the epidemiology of the disease, and the existence and status of any severe underlying diseases or medical conditions (co-morbidities) that may hinder recovery.¹⁷² A mortality risk prediction is based on whether a patient could survive the acute medical episode that necessitates ventilator therapy. It is not focused on whether a patient survives in the long-term (e.g., years after the pandemic). Physicians should use all appropriate and available medical tools to conduct the most thorough examination possible in emergency circumstances. Given the potential constraints associated with an influenza pandemic, mortality risk predictions should be based on the best clinical evidence available.

The Pediatric Clinical Workgroup concluded that in Step 2, physicians may also consider severe, end-stage chronic medical conditions when assessing mortality risk. The presence of comorbidities complicates a patient's ability to survive and may also cause the patient's acute

greatest number of survivors. See Christian et al., *Treatment and Triage Recommendations*, *supra* note 30, at S117. The first step to achieve the goal of such a pediatric clinical scoring system was performed. Using data from 150,000 records of pediatric patients in the PICU Performance Systems Database, prediction equations were developed that considered only clinical variables that (1) were available at PICU admission, and (2) affected mortality, length of stay, and duration of mechanical ventilation. In addition, the thresholds for PICU admission could be adjusted as the emergency event progresses in order to account for real-time availability of resources in a particular region. The triage system would assign patients to three categories: (1) high risk- patient does not receive a ventilator because she exceeds the threshold of risk or has excessive resource utilization needs, (2) optimal- patient receives the ventilator because she is most likely to benefit and does not have excessive resource needs, and (3) low risk- she does not receive the ventilator because she is too healthy. Although the proposed system has significant strengths, including being developed using only evidence-based clinical data to guide resource allocation, validation has not yet been published. Philip Toltzis et al., *Evidence-Based Pediatric Outcome Predictors to Guide the Allocation of Critical Care Resources in a Mass Casualty Event*, 16 PEDIATR. CRIT. CARE MED. e207, e214 (2015). See also, Niranjan Kissoon, *Allocation of Resources During Crisis: Data Infused With Wisdom, Ethics, and Transparency*, 16 PEDIATR. CRIT. CARE MED. 682, 683 (2015).

¹⁷¹ Unfortunately, many facilities that do not normally provide long-term health care treatment to children may not have clinicians with sufficient pediatric experience. These facilities need to make accommodations to implement this recommendation, such as provide pediatric health care training to a triage officer/committee. For more information on pediatric emergency preparation for facilities that do not have pediatric or newborn care services, see New York Pediatric Emergency Guidelines, *supra* note 3.

¹⁷² Examples of evidence-based clinical factors that can be used to evaluate pediatric patients, include, but are not limited to: cardiac arrest immediately preceding hospital admission, severe combined immunodeficiency, leukemia or lymphoma after first induction, spontaneous cerebral hemorrhage, cardiomyopathy, HIV infection, liver failure as the primary reason for admission, neurodegenerative disorder, asthma, bronchiolitis, croup, obstructive sleep apnea, and diabetic ketoacidosis. See Toltzis et al., *supra* note 170, at e211 for a complete list of variables considered.

illness (i.e., influenza) to be more severe. However, existence of such a condition should not, by itself, preclude a patient from being eligible for ventilator therapy. Instead, physicians should examine a patient's overall health to evaluate the patient's current health status. Even for a patient diagnosed with a fatal condition, periods of relatively good health are possible and the mere presence of a grave illness should not necessarily preclude the patient from receiving ventilator therapy. In some circumstances, a patient with a severe medical condition may require ventilator therapy because of influenza and not because of the chronic care disease itself.¹⁷³

Furthermore, the Pediatric Clinical Workgroup and the Task Force were reluctant to incorporate resource utilization, such as estimated duration of ventilator need, as a stand-alone (primary) triage factor.¹⁷⁴ The Pediatric Clinical Workgroup recognized that accurately predicting the estimated length of time a patient may need ventilator therapy may be useful to identify ideal patients for treatment so that ventilators could be utilized by as many people as possible who have a high likelihood of survival. However, at this time, it is impossible to offer any reasonable quantitative projection regarding need without information about the pandemic viral strain. Furthermore, while it may be feasible to estimate duration of ventilator need for many non-influenza conditions, such a prediction may be difficult to assess when influenza is an additional affliction for the patient. Instead, the Pediatric Clinical Workgroup reasoned that a patient's co-morbidity(s) (which could include influenza) implies a general exacerbation of mortality risk and duration of ventilator need beyond what is typical for the acute illness/injury that requires medical attention. Thus, the Workgroup recognized that duration of ventilator need may be considered indirectly as a qualitative factor in a triage decision.¹⁷⁵

In addition, the Task Force believed that because resource utilization/duration of ventilator need is not a stand-alone criterion of the adult clinical ventilator allocation protocol, it is not appropriate to include such a triage factor in pediatric protocol, especially because its consideration does not affect a patient's likelihood of survival.¹⁷⁶ It may only be useful to identify patients who may only require a short treatment so that the number of patients treated by ventilation could be increased. Finally, incorporating resource use/duration of ventilator need as an explicit criterion in the pediatric clinical ventilator allocation protocol unfairly subjects children to a more complex triage process.

¹⁷³ For example, a child with a serious condition may not have a long-term survival prognosis, but if the patient's health is relatively stable, the child may still be eligible for ventilator therapy, i.e., be placed in the red or yellow categories. However, if the same child was in failing health, this patient would be placed in the blue category and given alternative forms of medical intervention and/or palliative care rather than a ventilator.

¹⁷⁴ However, a pediatric mass casualty population-outcome predictive tool currently being developed does consider the utilization of resources (i.e., length of hospitalization stay and days of mechanical ventilation), when considering PICU admission during an emergency event. See Toltzis et al., *supra* note 170.

¹⁷⁵ As more data become available about the viral strain during a pandemic, it may be possible to know how many days of ventilation are required to recover, which may influence the mortality risk assessment and the triage decision.

¹⁷⁶ For example, the 2007 Draft Guidelines included renal dialysis as an exclusion criterion in the adult clinical ventilator allocation protocol. However, the Task Force reassessed the list of exclusion criteria and determined that, although renal failure increases the morbidity and mortality risks to a patient, excluding a patient who is dialysis-dependent was based on heavy resource utilization issues rather than likelihood of survival and this criterion was removed from the exclusion criteria list. See Chapter 1, Adult Guidelines, Section XI.A. Step 1: Exclusion Criteria.

A patient's clinical data from Steps 1 and 2 are provided to a triage officer/committee who examines the information and assigns a patient a color code (i.e., blue, red, yellow, or green), which determines the patient's level of access to ventilator therapy (see chart below).¹⁷⁷ Blue code patients (lowest access/palliate/ discharge) are those who have a medical condition on the exclusion criteria list or those who have a high risk of mortality and these patients do not receive ventilator treatment.¹⁷⁸ Instead, alternative forms of medical intervention and/or palliative care are provided. Red code patients (highest access) are those who have the highest priority for ventilator treatment because they are most likely to recover with treatment¹⁷⁹ (and likely to not recover without it) and have a moderate risk of mortality. Patients in the yellow category (intermediate access) are those who are very sick and their likelihood of survival is intermediate and/or uncertain. These patients may or may not benefit (i.e., survive) with ventilator therapy. They receive such treatment if ventilators are available after all patients in the red category receive them. Patients in the green color code (defer/discharge) are those who do not need ventilator therapy.

¹⁷⁷ The triage chart is adapted from New York's Adult Guidelines; OHPIP 2006, *supra* note 49; and from VHA Guidelines, *supra* note 49.

¹⁷⁸ However, if a ventilator becomes available and no other patients are in need of ventilator therapy, a patient with a blue color code may be eligible for this treatment.

¹⁷⁹ Red color code patients are sick enough to require ventilator therapy to survive and will do poorly if they do not receive it. However, these patients are not so severely ill that they will still benefit (i.e., survive) with ventilator treatment. Prioritizing these patients for ventilator therapy, ideally, increases the number of survivors by ensuring that patients receiving ventilator therapy are those who have a high likelihood of recovering.

2. Triage Chart for Step 2

A triage officer/committee allocates ventilators according to the color code assigned.¹⁸⁰

Step 2 - Mortality Risk Assessment Using Physician Clinical Judgment¹	
Color Code and Level of Access	Assessment of Mortality Risk/Organ Failure
<p>Blue</p> <p>No ventilator provided. Use alternative forms of medical intervention and/or palliative care or discharge.</p> <p>Reassess if ventilators become available.</p>	<p>Exclusion criterion</p> <p>OR</p> <p>HIGHEST risk of mortality associated with acute illness/injury (including epidemiology of the disease, if known) and</p> <p>Presence of SEVERE chronic comorbidity likely to worsen mortality risk or duration of ventilator treatment beyond that typical for the acute illness/injury</p>
<p>Red</p> <p>Highest</p> <p>Use ventilators as available</p>	<p>MODERATE risk of mortality, such as single organ failure,² associated with acute illness/injury (including epidemiology of the disease, if known) and</p> <p>NO severe chronic comorbidity likely to worsen mortality risk or duration of ventilator treatment beyond that typical for the acute illness/injury</p>
<p>Yellow</p> <p>Intermediate</p> <p>Use ventilators as available</p>	<p>HIGH/UNCERTAIN risk of mortality associated with acute illness/injury (including epidemiology of the disease, if known) and</p> <p>Presence of MODERATE chronic comorbidity likely to worsen mortality risk or duration of ventilator treatment beyond that typical for the acute illness/injury</p>
<p>Green</p> <p>Use alternative forms of medical intervention or defer or discharge. Reassess as needed.</p>	<p>LOW risk of mortality associated with acute illness/injury (including epidemiology of the disease, if known) and</p> <p>NO chronic comorbidity likely to worsen mortality risk or duration of ventilator treatment beyond that typical for the acute illness/injury</p>

¹If a patient develops a condition on the exclusion criteria list at any time from the initial assessment to the 48 hour assessment, change color code to blue. Remove the patient from the ventilator and provide alternative forms of medical intervention and/or palliative care.

²Intubation for control of the airway (without lung disease) is not considered lung failure.

¹⁸⁰ A triage officer/committee determines whether a patient in the red (and possibly yellow) color category receives ventilator therapy. Decisions also need to be made regarding which patient within each color code receives ventilator treatment. For a discussion on how such decisions are made, see Section IX.B.3. Decision-Making Process for Selecting an Eligible Patient for a Ventilator.

Physicians may also consider severe, end-stage chronic medical conditions when assessing mortality risk. However, the extent of functional health impairment, rather than the medical diagnosis itself, should guide decision-making when evaluating a patient's current health status. The mere existence of such a condition should not, by itself, preclude a patient from being eligible for ventilator therapy. Examples of severe chronic conditions that adversely impact health functionality include, but are not limited to: severe end-stage lung or liver failure; Trisomy 13; known untreatable metabolic diseases, such as Zellweger Syndrome; spinal muscular atrophy (SMA) type 1; severe end-stage pulmonary hypertension; metastatic malignancy with poor prognosis; and severe irreversible immunocompromise in the presence of unremitting infection(s).

Furthermore, additional medical complications may also be considered when assessing risk of mortality, such as, but not limited to: morbid obesity with its associated complications, impaired growth and nutrition, recurrent aspiration, pharyngeal airway obstruction, intractable seizures, or end-stage organ disease.

When examining chronic comorbidity, severe comorbidity is functionally defined as significant chronic impairment/deteriorating of health prior to the acute illness/injury. Moderate comorbidity is functionally defined as significant chronic impairment of health but a patient is in a steady health state prior to the acute illness/injury.

For most patients who are sick with only influenza and have no other comorbidities, the single organ failure is limited to their lungs. However, because the pediatric clinical ventilator allocation protocol applies to all patients in need of a ventilator, a patient may also have a comorbidity(s) that affects another organ system(s) and his/her mortality risk assessment.¹⁸¹ Intubation for control of the airway (without lung disease) is not considered lung failure.

Finally, when assigning patients color codes, the Pediatric Clinical Workgroup concluded that a triage officer/committee must determine how to define what the cutoffs should be for highest, high/uncertain, moderate, and low risk of mortality risk categories because there are no evidence-based data early in a pandemic. Given the potential constraints associated with an influenza pandemic, mortality risk predictions should be based on the best clinical evidence available. However, the basic principle is that the more severe a patient's health condition is based on the clinical factors delineated above, the less likely s/he survives, even with ventilator therapy. Therefore, triage decisions should be made accordingly. As more data become available during a pandemic regarding patient outcomes and best practices for treatment, a triage officer/committee will incorporate this evidence-based data into the triage decision.

¹⁸¹ While it is possible for a ventilator-dependent chronic care patient to lose access to ventilation, the triage decision would be contingent on several factors, such as the severity of the medical condition requiring attention and number of available ventilators. For example, it is feasible for such a patient to be assigned the highest level of access to a ventilator, because the clinical evaluation provides some flexibility. In addition, if a ventilator is available and there are no patients waiting for ventilator treatment, a ventilator-dependent patient regardless of his/her risk of mortality would be eligible for ventilator therapy.

3. Decision-Making Process for Selecting an Eligible Patient for a Ventilator

At Step 2, a triage officer/committee may encounter a situation where there are several pediatric patients in the red color code,¹⁸² who are equally eligible for ventilator therapy. Further clinical examination of these patients in the red color category may not be useful or possible in a pandemic because it has already been determined using exclusion criteria and physician clinical judgment that all the individuals have equal (or near equal) likelihoods of survival.¹⁸³ Therefore, the question of how a triage officer/committee should select an eligible patient must be addressed.¹⁸⁴

It is not appropriate for a triage officer/committee to compare patients within the same color category. Patients and their parents/legal guardians expect that doctors provide treatment, to the extent possible, based on assessments of a patient's health as an individual. If ventilator use is primarily determined by the health of *other* patients, clinicians must abandon their obligation to advocate/care for their individual patient. This proposal evokes a war of all against all that ignores health care workers' deep professional obligations to advocate and care for individual patients. To compare patients with each other could force a triage officer/committee to prematurely withdraw ventilators from patients more often, and could lead to fewer patients surviving. Furthermore, such comparisons may intensify inherent biases in the health care system and the disproportionate and disparate provision of care for already disadvantaged populations.

Because a clinical evaluation has been performed and there are no other evidence-based clinical factors available to consider, a non-clinical method must be used to determine which pediatric patient among the eligible patients receives ventilator therapy.¹⁸⁵ A secondary allocation system may be first-come first-serve or a randomization process (such as a lottery). While these approaches are problematic to use to initially triage patients,¹⁸⁶ they are useful and acceptable to use as secondary triage criteria. A non-clinical system used at this triage step only is employed after a triage officer/committee determines that all available clinical measures are (nearly) equivalent for the eligible patients, which implies that all of these individuals have equal (or near equal) likelihoods of survival (i.e., in the same color category), and all patients are pediatric patients.

The Task Force and the Pediatric Clinical Workgroup considered both first-come first-serve and random selection (e.g., lottery) methods. While first-come first-serve is straightforward and is easy to implement, it disadvantages those who are of lower socio-economic means who may not have access to information about the pandemic or to reliable transportation, or minority populations who might initially avoid going to a hospital because of distrust of the health

¹⁸² While the yellow category may also have eligible patients waiting for ventilator therapy, all red code patients must be attended to first. If there are no red code patients, and only yellow code patients, then the same decision-making process applies.

¹⁸³ For these Guidelines, all patients in the same color category have the same likelihood of survival.

¹⁸⁴ For a discussion on review of a triage decision and the appeals process, *see* Chapter 4, Implementing New York State's Ventilator Allocation Guidelines: Legal Considerations, Section VI. Appeals.

¹⁸⁵ If the eligible patient pool includes both adults and children, a different non-clinical method is used (i.e., young age). *See* Section V.A.3.b. Use of Young Age as a Secondary Triage Factor (Tie-Breaker) and Section IX.F. Interface between Pediatric and Adult Patients.

¹⁸⁶ *See* Chapter 1, Adult Guidelines, Section VIII. Non-Clinical Approaches to Allocating Ventilators.

care system. Despite the various administrative and logistical barriers of conducting a random selection process,¹⁸⁷ the Task Force and Pediatric Clinical Workgroup recommended this approach because such a system is easy to understand and can be implemented with some advance planning.

A random process should be used to choose a pediatric patient for ventilator therapy when there are more eligible pediatric patients than ventilators available.¹⁸⁸ In addition, a random selection method is conducted each time a ventilator becomes available. Finally, patients waiting for ventilator therapy wait in an eligible patient pool and receive alternative forms of medical intervention and/or palliative care until a ventilator becomes available.

C. Step 3: Periodic Assessments for Continued Ventilator Use (Time Trials)

Summary of Step 3: Periodic clinical assessments at 48 and 120 hours are conducted on a patient who has begun ventilator therapy to evaluate whether s/he continues with the treatment. Various clinical parameters are examined at this step to assess the possibility of organ failure/mortality risk and to measure lung function. The decision whether a patient remains on a ventilator is based on ongoing clinical measures and data trends of the patient's health condition, consisting of: (1) the overall prognosis estimated by the patient's clinical indicators, which is indicative of mortality risk by revealing the presence (or likelihood), severity, and number of acute organ failure(s), and (2) the magnitude of improvement or deterioration of overall health, which provides additional information about the likelihood of survival with ventilator therapy. These results are compared to the results from the previous official clinical assessment.

1. Time Trials

In a public health emergency, periodic evaluations of a patient after s/he has begun ventilator therapy is necessary to determine whether the therapy is effective for that patient while allowing for efficient allocation of scarce ventilators. It also assists health care workers responsible for the day-to-day care of a patient by presenting uniform guidance on when official assessments are to occur. Finally, the use of time trials gives a triage officer/committee valuable information about the status and real-time availability of ventilators.

Time trials are necessary to determine whether a patient receiving ventilator therapy continues with this form of medical intervention. A patient showing improvement continues with ventilator therapy until the next assessment, and if the patient no longer meets the criteria for continued use, s/he receives alternative forms of medical intervention. Until more data about the pandemic viral strain become available during a pandemic, the length of an appropriate time trial is unknown. Shorter trials (e.g., 24 hours) permit more patients access to ventilator therapy, but require more extubations for a larger number of patients, a situation the Guidelines should

¹⁸⁷ See Chapter 1, Adult Guidelines, Section VIII.B. Randomization.

¹⁸⁸ However, if the pool of eligible patients includes both children and adults, and assuming both sets of patients have equal (or near equal) likelihoods of survival, a random selection method is not conducted and instead the child is selected for ventilator therapy. See Section V.A.3.b. Use of Young Age as a Secondary Triage Factor (Tie-Breaker) and Section IX.F. Interface between Pediatric and Adult Patients.

attempt to minimize.¹⁸⁹ In contrast, long time trials result in fewer patients receiving ventilator therapy.

The Pediatric Clinical Workgroup suggested time trials of 48 and 120 hours, which mirror the adult intervals, are acceptable. Because there are no evidence-based data to suggest what a time trial for ventilator use should be for children, the Workgroup and the Task Force concluded that for ease of use and consistency, time trials for pediatric patients should be the same as for adult patients.¹⁹⁰ In the case of an influenza pandemic, as data about the viral strain and clarification of a more precise time trial period for children become available during a pandemic, the length of pediatric time trials may be adjusted accordingly.

Physician clinical judgment is used to evaluate a patient who has begun ventilator therapy. A patient's attending physician performs the clinical assessments and provides the data to a triage officer/committee who assigns the patient a color code based on the results of the clinical assessment. This assessment determines whether the ventilator is reallocated.

The Task Force and Pediatric Clinical Workgroup concluded that while the clinical elements involved in evaluating pediatric and adult patients at the time trial assessments were different, the logic and reasoning required to justify continued ventilator eligibility remained consistent. In order for a patient to continue with ventilator treatment, s/he must demonstrate an improvement in overall health status after receiving ventilator therapy. Thus, for both the pediatric and adult clinical ventilator allocation protocols, a patient's health prognosis and trajectory guide the triage decision, even though different clinical tools are used to evaluate the patient's health status.

A triage decision is made based on ongoing clinical measures and data trends of a patient's health condition, consisting of: (1) the overall prognosis estimated by the patient's clinical indicators, which is indicative of mortality risk by revealing the presence (or likelihood), severity, and number of acute organ failure(s), and (2) the magnitude of improvement or deterioration of overall health, which provides additional information about the likelihood of survival with ventilator therapy. Similar to the lack of evidence-based data on how to triage children for ventilator allocation, there are no data on how to determine whether the pediatric patient continues with ventilator treatment. Thus, the guiding principle for the triage decision is that the more severe a patient's health condition (i.e., presence (or likelihood), number, and severity of acute organ failure) and the extent of deterioration, the less likely the patient continues with ventilator therapy. Conversely, the less severe a patient's health condition (i.e., little risk of acute organ failure) and demonstration of improvement with ventilator therapy (i.e., lower mortality risk), the higher the likelihood the patient continues with this form of treatment.

Any changes (improving, worsening, or experiencing no change) in a patient's health data after 48 and 120 hours help guide the triage decision. A triage decision can determine that a

¹⁸⁹ Removing a patient from a ventilator is likely be a stressful experience not only for the family members of the patient, but also for the health care staff involved.

¹⁹⁰ It is possible that a triage officer/committee may need to triage both adults and children and having consistent time intervals would be helpful.

patient is: (1) no longer ventilator dependent and may be weaned off the ventilator,¹⁹¹ (2) ventilator dependent and meets the criteria to continue with ventilator therapy, or (3) ventilator dependent but no longer meets the criteria for continued ventilator treatment. A patient who exhibits improvement continues to be eligible for ventilator therapy until the next official assessment. Depending on the real-time availability of ventilators, a patient who remains stable may or may not be eligible, and the patient who no longer meets the criteria (i.e., develops a condition from the exclusion criteria list, or overall condition worsens) is removed from the ventilator and provided with alternative forms of medical intervention and/or palliative care.¹⁹²

Although there are no clinical scores in the pediatric protocol that mirrors the SOFA scores in the adult clinical ventilator allocation protocol for time trials at the 48 and 120 hour assessments,¹⁹³ the pediatric protocol essentially replaces the numerical SOFA scores with narrative descriptions of what the scores represent from a clinical perspective. Because the key to a triage decision is the *change* in health status at 48 and 120 hours after receiving ventilator therapy, comparing a change in a clinical score or individual clinical variables is essentially the same. Both the pediatric and adult clinical ventilator allocation protocols examine a patient's health data trends. A patient who shows improvement at time trial assessments is more likely to survive, which supports the overall goal of the triage plan, i.e., to save the most lives.

Although additional clinical assessments may be performed by a patient's attending physician on a regular basis, the official assessments only occur after 48 and 120 hours of ventilator therapy. No formal triage decision or action may be taken until a patient's official assessment. The decision to continue or discontinue with ventilator treatment is not made until a patient has had a full time period to benefit from this treatment. However, at any point during the time trial, even before an official assessment occurs, if a patient develops a condition on the exclusion criteria list and there is an eligible patient waiting, then the ventilator is reallocated.

The Pediatric Clinical Workgroup and the Task Force recognized the immense difficulty and potential trauma to pediatric patients, their families, and health care staff if a patient no longer qualifies for continued use of the ventilator based upon the time trial assessment. However, removing a ventilator from a patient who worsens or does not improve so that another patient with a strong likelihood of survival may have an opportunity for treatment helps support the goal of saving the greatest number of lives in an influenza pandemic where there are a limited number of available ventilators.

¹⁹¹ Ventilator weaning procedures are often based on physician preference, experience, and available resources, and each facility should plan accordingly.

¹⁹² A patient who is no longer receiving ventilator therapy is not abandoned; instead s/he receives alternative forms of medical intervention and/or palliative care, where appropriate. For a more detailed discussion, *see* Section X. Alternative Forms of Medical Intervention and Pediatric Palliative Care and Chapter 1, Adult Guidelines, Section XII. Alternative Forms of Medical Intervention and Palliative Care. If no other eligible patients are waiting for ventilator therapy, a patient who does not meet the time trial criteria would continue with the treatment until the next evaluation.

¹⁹³ In the adult clinical ventilator allocation protocol, the triage decision for continued ventilator treatment is dependent on the change in the SOFA score. For example, if the SOFA score at the 48 and 120 hour assessments continues to decrease, a patient is exhibiting signs of recovery (lower risk of organ failure and mortality), a patient continues to be eligible for ventilator therapy. However, if the SOFA score increases, the likelihood of survival is lower and a patient may not be eligible for ventilator treatment. *See* Chapter 1, Adult Guidelines, Section XI.C. Step 3: Periodic Assessments for Continued Ventilator Use (Time Trials).

2. Use of Six Clinical Parameters to Evaluate a Patient

The Pediatric Clinical Workgroup discussed whether a clinical scoring system could be used later in triage (i.e., Step 3, time trials) as a tool to determine whether a patient continues with ventilator treatment; but after further examination, the Workgroup also rejected the use of a scoring system in this step. The Workgroup initially contemplated the possibility that one of the currently available pediatric clinical scoring systems could be useful at the later triage stage, when determining whether a ventilated patient continues with this form of treatment because more clinical data are available. The pediatric clinical scoring systems discussed earlier have been validated for assessing mortality risk for PICUs only *after* medical intervention had been provided to patients; thus, there was speculation that perhaps these models could be applied to an individual patient after s/he received ventilator therapy.¹⁹⁴

After review of the available pediatric clinical scoring systems, the Pediatric Clinical Workgroup rejected the use of PRISM III, PIM 2, and PELOD because none of these systems have been validated to triage children. The proprietary nature of PRISM III and its numerous lab values, complicated data collection, and intricate score calculation made it too cumbersome to use. PIM 2 was dismissed because of its problem with consistent data collection and complex score calculation. PELOD was also eliminated because of its potentially problematic design and its detailed score calculation.

The Pediatric Clinical Workgroup considered using SOFA, a modified version of mSOFA, or P-MODS, but concluded none were appropriate for several reasons. First, none of these clinical scoring systems have been validated for use in children or for triage purposes. SOFA is not validated for use for patients under the age of 18, and a modified version of SOFA has neither been validated for use in children nor as a triage method. P-MODS is also an unvalidated system for use in triage and is relatively unknown. The Workgroup members were particularly concerned about the lack of evidence to justify use of these clinical scoring systems as a method to triage patients for scarce resources.

The Pediatric Clinical Workgroup agreed that a simple clinical framework was necessary to evaluate a patient and guide triage decisions in a consistent and transparent manner. While the Workgroup rejected the concept of assigning a cumulative score to a patient based on clinical factors, they accepted that certain clinical parameters could be used to determine quickly whether the patient was improving or deteriorating over time. These clinical variables could be used to analyze the severity and overall trend of a patient's health condition to help guide the decision of whether the patient continues with ventilator therapy.

¹⁹⁴ As previously discussed above, none of the pediatric clinical scoring systems have been validated to predict mortality risk for an individual patient. Instead, these systems were developed to evaluate PICUs as a whole. However, several pediatric clinical ventilator allocation protocols utilize these scoring systems to assess an individual patient's mortality risk.

The Pediatric Clinical Workgroup recommended the following variables as the clinical framework in Step 3: Glasgow Coma Scale Score,¹⁹⁵ hypotension,¹⁹⁶ oxygenation index (OI)¹⁹⁷/arterial oxygen saturation,¹⁹⁸ whole blood/serum lactate,¹⁹⁹ serum creatinine,²⁰⁰ and serum bilirubin²⁰¹/scleral icterus.²⁰² These clinical variables represent major organ systems and/or are linked to mortality risk. Because the Workgroup rejected the concept of a “score,” none of these variables are assigned a numerical value; instead, they are divided into categories of best, intermediate, and worst. These variables are the clinical framework by which an attending physician evaluates a patient to determine the severity of his/her overall health and whether the patient’s health condition was improving, deteriorating, or experiencing no change.

No single factor independently represents a patient’s overall health trajectory and a triage officer/committee should never base a triage decision on a single clinical variable. Instead, a triage decision should examine all clinical variables so that an *overall* health assessment of a patient can be made. Furthermore, the first three variables – Glasgow Coma Scale Score (cerebral function/level of consciousness), hypotension (cardiovascular function), and OI/arterial oxygen saturation (lung function) – are more important for a triage officer/committee to consider, compared to the other three variables (whole blood/serum lactate, serum creatinine, and serum bilirubin/scleral icterus). While a triage decision to discontinue ventilator therapy may rely heavily on the assessments from the Glasgow Coma Scale Score, hypotension, and OI/arterial oxygen saturation, such a decision should *never* be made based *solely* on a patient’s whole blood/serum lactate, serum creatinine, or serum bilirubin/scleral icterus levels. The latter three variables may be more useful when deciding whether a patient eligible for continued ventilator therapy should be placed into the red or yellow color categories. It reveals whether a patient is experiencing multiple organ failure, which decreases the likelihood of survival. Also, depending on the extent of staff and equipment shortages, it may not be possible to obtain the

¹⁹⁵ The Glasgow Coma Scale Score is used to assess the level of consciousness of a patient and can be followed for trends. (Lower values imply worsening status.) If a patient is deeply sedated and/or paralyzed, a clinical evaluation using the Glasgow Coma Scale Score is not valid.

¹⁹⁶ Hypotension is abnormally low blood pressure that results from a patient’s inability to compensate for injury. Untreated, it is a prelude to death.

¹⁹⁷ OI is the ratio between the amount of oxygen delivered to a patient and the amount of oxygen in the patient’s arterial blood, taking into account the amount of pressure delivered by a ventilator if one is being used. It serves as a measure of the severity of a patient’s lung disease, has prognostic implications, and can be followed for trends. (Higher values imply worsening status.) $OI = \text{mean airway pressure (MAP)} \times \text{fraction of inspired oxygen (FiO}_2) \times 100 / \text{partial pressure of oxygen in arterial blood (PaO}_2)$. (PaO₂ may be estimated from peripheral oxygen saturation by using the oxygen dissociation curve if blood gas measurements are unavailable.)

¹⁹⁸ Arterial oxygen saturation refers to the fraction of hemoglobin that is bound to oxygen in arterial blood. It can be measured non-invasively and can be followed for trends. (Lower values imply worsening status.)

¹⁹⁹ Whole blood/serum lactate measures the amount of lactate in (usually arterial) blood. Lactate is a byproduct of cellular metabolism when oxygen is not present or cannot be utilized (anaerobic metabolism) and is therefore a measure of deranged physiology. It can be followed for trends. (Higher values imply worsening status.)

²⁰⁰ Serum creatinine is a measure of creatinine in blood. Creatinine is a normal byproduct of muscle metabolism and is normally cleared by the kidney. Abnormally high values are an indicator of kidney dysfunction and can be followed for trends. (Higher values imply worsening status.)

²⁰¹ Serum bilirubin is a measure of bilirubin in blood. Bilirubin is a normal byproduct of the breakdown of red blood cells and is cleared by the liver. Abnormally high values (associated with jaundice because of the yellow color of bilirubin) are often an indicator of liver dysfunction and can be followed for trends. (Higher values imply worsening status.)

²⁰² Scleral icterus is abnormal yellowing of the white part of the eye. It is a clinical measure of jaundice and is associated with a higher than normal bilirubin level.

necessary lab work for whole blood/serum lactate, serum creatinine, or serum bilirubin levels. Thus, these factors may only play a role in the triage decision if the appropriate data are available.

Again, because there are no evidence-based data on how to triage children for ventilator allocation based on these clinical factors, a triage officer/committee must use best clinical judgment. However, the basic principle is that the more severe a patient's health condition is based on these clinical factors, the less likely s/he survives even with ventilator therapy, and triage decisions should be made accordingly.

The clinical parameters appear below. The bold line separates the “primary” clinical variables from the “secondary” factors.

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) <u>OR</u> > 88% (Best) 80 – 88% (Intermediate) < 80% (Worst)
Hypotension	Adequate circulation, with <u>no</u> vasoactive drugs (Best) Adequate circulation, with vasoactive drugs (Intermediate) Hypotension, with vasoactive drugs (Worst)
Glasgow Coma Scale Score⁴ (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 icterus⁵	< 3 (Best) 3 – 6 (Intermediate) > 6 (Worst) <u>OR</u> No scleral icterus (Best) Scleral icterus (Intermediate) Clinical jaundice (Worst)

¹ OI = mean airway pressure (MAP) x fraction of inspired oxygen (FiO₂) x 100 / partial pressure of oxygen in arterial blood (PaO₂). (PaO₂ 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.)

a. Justification for the Use of the Six Clinical Parameters

The Pediatric Clinical Workgroup examined the various clinical factors examined in SOFA and modified SOFA and recommended that certain variables from these systems be

examined during the time trial assessment for children. Similar to SOFA, the pediatric clinical ventilator allocation protocol examines Glasgow Coma Scale Score, hypotension, and creatinine. While the Pediatric Clinical Workgroup also endorsed the use of SOFA's bilirubin factor, the members also suggested that scleral icterus be examined if lab values for bilirubin are unavailable. Instead of collecting PaO₂/FiO₂ (mmHg) from SOFA, or SpO₂/FiO₂ (mmHg) from modified SOFA,²⁰³ the Workgroup recommended the use of oxygenation index (OI) because blood gas measurements may be difficult to obtain. If OI values are unavailable, arterial oxygen saturation percentages may be used as an acceptable alternative.²⁰⁴ Finally, the Pediatric Clinical Workgroup also recommended the use of lactate.²⁰⁵ Because the Glasgow Coma Score Scale, hypotension, creatinine, and bilirubin are included as part of the adult clinical ventilator allocation protocol in Step 3 (Time Trials), the Pediatric Clinical Workgroup and the Task Force only provided justification for the inclusion of OI/arterial oxygen saturation and whole blood/serum lactate.

Most clinical ventilator allocation protocols, including New York's Adult Guidelines, do not include response to ventilation (OI) as a triage criterion.²⁰⁶ Although there was discussion that the use of OI in the pediatric protocol did not mirror the adult clinical protocol, both the Pediatric Clinical Workgroup and the Task Force concluded that the use of OI in the pediatric clinical ventilator allocation protocol was acceptable.

The Workgroup recognized that there was a strong correlation between OI and survivability,²⁰⁷ thereby justifying its use. Since children generally do not have underlying chronic medical conditions that hinder their ability to recover from the acute illness/medical condition necessitating ventilator treatment, response to ventilation measured by OI can provide additional evidence regarding the extent of a patient's lung improvement. During a pandemic, the assumption can be made that a majority of patients hospitalized require ventilator therapy because of influenza's direct impact on the lungs' ability to move air and exchange various blood gases. Examining OI provides important information about the lung function of a patient and offers clinical data that supplements other clinical factors.

The Pediatric Clinical Workgroup recognized that during a severe emergency, clinical data that normally are available may not be easily acquired, such as a blood gas measurement used for OI. In such circumstances, clinicians may use arterial oxygen saturation data when PaO₂ measurements for OI are unavailable. Although OI is the superior of the two measurements in providing a more complete picture of lung function, arterial oxygen saturation percentages are acceptable to use.

²⁰³ In the adult ventilator allocation protocol, replacing PaO₂/FiO₂ (mmHg) from SOFA with OI was not considered because SOFA as a system was designed to use PaO₂/FiO₂ (mmHg).

²⁰⁴ If resources are severely strained, it may be challenging to obtain the OI values and clinicians may rely on oxygen saturation when PaO₂ measurements are unavailable.

²⁰⁵ Lactate is used in Alaska's modified SOFA system. See Alaska Guidelines, *supra* note 77.

²⁰⁶ Only one state, Minnesota, incorporated this factor as a triage criterion, but explains its limited prognostic significance. See Minnesota Department of Health, *supra* note 131, at 11.

²⁰⁷ Daniel Trachsel et al., *Oxygenation Index Predicts Outcome in Children with Acute Hypoxemic Respiratory Failure*, 172 AM. J. RESPIR. CRIT. CARE MED. 206, 209 (2005) (finding that peak OI measurements *after* the first 12 hours of ventilator treatment reliably correlated with mortality outcomes).

The Task Force acknowledged that some commentators may believe that the use of OI in the pediatric clinical ventilator allocation protocol unfairly subjects pediatric patients to a higher standard than adults to justify ventilator use. This reasoning is similar to the logic used to *not* include resource utilization/duration of ventilator use as a stand-alone triage criterion. However, the Task Force concluded that unlike a resource utilization variable, which is a subjective determination and is not indicative of likelihood of survival, OI can be used as a predictor of mortality risk and therefore is a practical consideration for a triage decision. The Task Force also reasoned that OI is relatively easy to calculate, without any unnecessary burden on a patient or health care provider. In addition, OI offers a straightforward quantitative result that provides more insight as to the likelihood a patient is benefiting from ventilator therapy based on lung function and outlook for recovery.

Although most clinical ventilator allocation protocols do not examine whole blood/serum lactate as a triage criterion, the Pediatric Clinical Workgroup recommended its use.²⁰⁸ Increased whole blood/serum lactate level in the blood may be caused by shock, heart failure, or lung disease, and some studies have linked higher whole blood/serum lactate levels with critical illness and increased mortality rates.²⁰⁹ Although the sole use of whole blood/serum lactate levels is never sufficient to justify a triage decision, together with the other clinical variables, whole blood/serum lactate levels may potentially provide valuable clinical information about a patient's overall health.²¹⁰

The question of whether the use of whole blood/serum lactate levels holds pediatric patients to a higher standard than adults during time trial assessments was also discussed. The Task Force determined that similarly with regards to the use of OI, because whole blood/serum lactate levels provided objective clinical data regarding a patient's health status and mortality risk, such data are useful for a triage decision. As stated earlier, whole blood/serum lactate and the other "secondary" clinical variables, (i.e., serum bilirubin and serum creatinine) independently do not represent a patient's overall health trajectory and a triage officer/committee should never base a triage decision on a single clinical variable. However, this information provides supplementary data for a triage officer/committee to consider along with the other clinical factors so that an *overall* health assessment of a patient can be made. Thus, both the Task Force and the Pediatric Clinical Workgroup concluded that more clinical information was better than less when making triage decisions.

²⁰⁸ Alaska's pediatric protocol, which uses a modified SOFA, incorporates lactate levels as a variable. See Alaska Guidelines, *supra* note 77, at 8.

²⁰⁹ Panagiotis Manikis et al., *Correlation of Serial Blood Lactate Levels to Organ Failure and Mortality After Trauma*, 13 AM. J. EMERG. MED. 619, 619 (1995); Stephen Trzeciak et al., *Serum Lactate as a Predictor of Mortality in Patients with Infection*, 33 INTENSIVE CARE MED. 970, 970 (2007); Mark Hatherill et al., *Mortality and the Nature of Metabolic Acidosis in Children with Shock*, 29 INTENSIVE CARE MED. 286, 286-287 (2003).

²¹⁰ Nathan Shapiro et al., *Serum Lactate as a Predictor of Mortality in Emergency Department Patients With Infection*, 45 ANN. EMERG. MED. 524, 524-525 (2005); Robert Lavery et al., *The Utility of Venous Lactate to Triage Injured Patients in the Trauma Center*, 40 J. AM. COLL. SURG. 656, 663 (2000); Hatherill et al., *supra* note 209, 289.

3. Triage Charts for Step 3

At the 48 and 120 hour assessments, a patient is examined for organ failure/mortality risk based on six clinical variables described above. The results of the time trial clinical assessments are then provided to a triage officer/committee who assigns a color code (blue, red, yellow, or green) to the patient. The decision whether to continue ventilator therapy for a patient is dependent on the trend of the health data from the clinical framework. Triage decisions are made based on ongoing clinical measures and data trends of a patient's health condition, consisting of: (1) the overall prognosis estimated by the patient's clinical indicators, which is indicative of mortality risk by revealing the presence (or likelihood), severity, and number of acute organ failure(s), and (2) the magnitude of improvement or deterioration of overall health, which provides additional information about the likelihood of survival with ventilator therapy.

A triage officer/committee evaluates the ongoing clinical measures and data trends of a patient's health condition from the clinical framework and assigns a color code (blue, red, yellow, or green) to the patient.²¹¹ It is possible that a patient may exhibit better outcomes in some clinical variables, but not in others. In this situation, a triage officer/committee should place more weight on the health data trends from the OI/arterial oxygen saturation percentages, hypotension, and Glasgow Coma Scale Score factors because these are stronger predictors of mortality risk. The other clinical factors (whole blood/serum lactate, serum creatinine, or serum bilirubin/scleral icterus levels), reveal whether a patient is experiencing multiple organ failure, and while useful, they should *never* be the *sole* reason to justify a triage decision involving extubation. The latter three variables may be more useful when deciding whether a patient eligible for continued ventilator therapy should be placed into the red or yellow color categories.

Criteria for each color code at the 48 and 120 hour assessments are presented below.

²¹¹ See also the discussion on assigning a patient a color code in Section IX.B.2. Triage Chart for Step 2.

a. 48 Hour Clinical Assessment Chart

Step 3 - Ventilator Time Trials (48 Hour Assessment)¹	
Color Code and Level of Access	Assessment of Mortality Risk/Organ Failure (Examining Six Clinical Variables)
<p>Blue</p> <p>No ventilator provided.² Use alternative forms of medical intervention and/or palliative care or discharge. Reassess if resources become available.</p>	<p>Exclusion criterion OR HIGHEST risk of mortality and Pattern of significant deterioration (or no change³) of overall health compared to the initial assessment</p>
<p>Red Highest</p> <p>Use lifesaving resources as available.</p>	<p>MODERATE risk of mortality and Pattern of significant improvement of overall health compared to the initial assessment</p>
<p>Yellow Intermediate</p> <p>Use lifesaving resources as available.</p>	<p>HIGH / UNCERTAIN risk of mortality and No significant change or slight deterioration in overall health compared to the initial assessment</p>
<p>Green</p> <p>Use alternative forms of medical intervention or defer or discharge. Reassess as needed.</p>	<p>LOW risk of mortality and No longer ventilator dependent / Actively weaning from ventilator</p>

¹ If a patient develops a condition on the exclusion criteria list at any time from the initial assessment to the 48 hour assessment, change color code to blue. Remove the patient from the ventilator and provide alternative forms of medical intervention and/or palliative care.

² A patient assigned a blue color code is removed from the ventilator and alternative forms of medical intervention and/or palliative care are provided.

³ The patient remains significantly ill.

b. 120 Hour Clinical Assessment Chart

Step 3 - Ventilator Time Trials (120 Hour Assessment)¹	
Color Code and Level of Access	Assessment of Mortality Risk/Organ Failure (Examining Six Clinical Variables)
<p>Blue</p> <p>No ventilator provided.² Use alternative forms of medical intervention and/or palliative care or discharge. Reassess if resources become available.</p>	<p>Exclusion criterion OR HIGHEST risk of mortality and Pattern of significant deterioration (or no change³) of overall health compared to the previous assessment</p>
<p>Red Highest</p> <p>Use lifesaving resources as available.</p>	<p>MODERATE risk of mortality and Pattern of <i>further</i> significant improvement of overall health compared to the previous assessment</p>
<p>Yellow Intermediate</p> <p>Use lifesaving resources as available.</p>	<p>HIGH / UNCERTAIN risk of mortality and No significant change in overall health compared to the previous assessment</p>
<p>Green</p> <p>Use alternative forms of medical intervention or defer or discharge. Reassess as needed.</p>	<p>LOW risk of mortality and No longer ventilator dependent / Actively weaning from ventilator</p>

¹ If a patient develops a condition on the exclusion criteria list at any time from the 48 hour assessment to the 120 hour assessment, change color code to blue. Remove the patient from the ventilator and provide alternative forms of medical intervention and/or palliative care.

² A patient assigned a blue color code is removed from the ventilator and alternative forms of medical intervention and/or palliative care are provided.

³ The patient remains significantly ill.

The primary difference between the 48 and 120 hour assessment is the *extent* of improvement in overall health prognosis and of the trajectory of a patient’s health status required to continue to be eligible for ventilator therapy. While the health assessment outcomes for the blue, yellow, and green categories are the same for the 48 and 120 hour assessments, the extent of health improvement for the red category is different. At 48 hours, a patient must exhibit a pattern of significant improvement to be placed in the red color code. Because a patient has only had 48 hours to benefit from ventilator therapy, the progress required to justify continued ventilator use is not expected to be dramatic. However, after 120 hours, a patient must demonstrate a pattern of *further* significant improvement in health to be placed in the red color code. The Pediatric Clinical Workgroup concluded that by 120 hours, it would be apparent whether a patient is benefiting from ventilator therapy. To justify continued use beyond 120

hours requires a noteworthy positive change in a patient's health, otherwise, the ventilator is reallocated to an eligible patient.

When assigning patients color codes, the Pediatric Clinical Workgroup concluded that a triage officer/committee must determine how to define what the cutoffs should be for highest, high/uncertain, moderate, and low risk of mortality risk categories because there are no evidence-based data early in a pandemic. Given the potential constraints associated with an influenza pandemic, mortality risk predictions should be based on the best clinical evidence available. In addition, because there are no evidence-based data on what the extent of improvement of the six clinical variables examined should be after 48 and 120 hours of ventilator treatment to determine whether a patient continues with ventilator therapy, the Pediatric Clinical Workgroup concluded that a triage officer/committee must determine how to define a "pattern of significant improvement/deterioration." Because patients are not competing against each other for ventilator treatment, a triage officer/committee is not comparing a patient's level of improvement to another patient. Instead, the extent of improvement (or deterioration) is evaluated based on a patient's previous official assessment. A patient is only "competing" against him/herself and must demonstrate improvement to continue with the treatment.

The basic principle is that the more severe a patient's health condition is based on the clinical factors delineated above, the less likely s/he survives, even with ventilator therapy. Therefore, triage decisions should be made accordingly. It is at the discretion of each acute care facility to develop oversight mechanisms to help ensure that such determinations of improvement or deterioration are made in a consistent manner as possible.²¹² As more data become available during a pandemic regarding patient outcomes and best practices for treatment, a triage officer/committee will incorporate this evidence-based data into the triage decision.

D. Clinical Assessment(s) Beyond 120 Hours

After the 120 hour clinical assessment, a patient who is allotted another time trial for ventilator therapy is reassessed every 48 hours. This time trial mirrors what occurs after the 120 hour assessment in the adult clinical ventilator allocation protocol. Every 48 hours, a clinical evaluation using the same parameters used in the previous assessments is conducted, and a triage officer/committee determines whether a patient continues with ventilator therapy. The decision may consider several factors, but first, a patient must continue to exhibit signs of improvement. If there is clear evidence of deterioration that is irreversible, a patient may no longer be eligible for ventilator treatment. Finally, other considerations may include the known progression of the

²¹² However, as more data about the pandemic viral strain become available during a pandemic, it may be necessary to revise the definition of "significant improvement/deterioration" accordingly.

disease,²¹³ updated data on the pandemic viral strain,²¹⁴ availability of alternative treatments,²¹⁵ current supply and demand data at the facility (e.g., number of available or soon to be available ventilators and incoming patients requiring ventilator therapy), alternative sites of health care²¹⁶ and whether there are any patients waiting for a ventilator therapy trial.²¹⁷

E. Decision-Making Process for Removing a Patient from a Ventilator

There may be a scenario where there is an incoming red code patient(s)²¹⁸ eligible for ventilator treatment and a triage officer/committee must remove a ventilator from a patient whose health is not improving at the 48, 120, or subsequent 48 hour time trial assessments, so that the red code patient receives ventilator treatment. As discussed earlier, no formal triage decision or action may be taken until an official time trial assessment of the ventilated patient is performed. A triage officer/committee follows these steps to determine which patient should be removed from the ventilator.²¹⁹ First, patient(s) with the worst likelihood of survival and/or with a pattern of significant deterioration even with ventilator therapy (i.e., a blue code patient) is the first patient(s) vulnerable for ventilator removal. If there are no patients in the blue category, then a triage officer/committee proceeds to the yellow code patients (i.e., patients who have high/uncertain risk of mortality and no significant change in overall health after ventilator therapy).

A triage officer/committee is not permitted to compare the health of patients within the same color category. As discussed earlier, a patient expects that doctors provide treatment, to the extent possible, based on assessments of the patient's health as an individual. If ventilator use is primarily determined by the health of *other* patients, clinicians must abandon their obligation to advocate/care for their individual patient. This proposal evokes a war of all against all that ignores health care workers' deep professional obligations to advocate and care for individual

²¹³ For most patients requiring ventilator therapy, the disease affecting them is the pandemic influenza. As the disease progression becomes known, clinicians will have a better understanding of the duration and recovery periods to assist with triage decisions. However, some patients may be afflicted with other diseases that need to be considered independently when evaluating a patient's clinical status. Other co-morbid factors may alter the trend of a patient's health status.

²¹⁴ As the pandemic progresses, more data are available regarding the particular viral strain which may modify the triage criteria. For example, as the disease progression becomes known, clinicians have a better understanding of the duration and recovery periods to assist with triage decisions.

²¹⁵ Alternative treatments include other forms of oxygen delivery or pharmaceutical measures. For a more detailed discussion, see Section X.A. Alternative Forms of Medical Intervention for a Patient Without Access to a Ventilator.

²¹⁶ Some patients may require transfer to long-term care facilities, such as assisted living facilities. While planning and implementation of such a transition is beyond the scope of the Guidelines, hospitals, residential health care facilities, and emergency planners should address this issue.

²¹⁷ If there are no eligible (red code) patients waiting for ventilator therapy, ventilated patients may continue with this treatment.

²¹⁸ While there may be yellow color code patients waiting for ventilator therapy, all red code patients must be attended to first. In limited circumstances, where incoming patients are only yellow code, these patients may only receive ventilator therapy if there are any blue code patients currently receiving ventilator treatment. Already ventilated yellow code patients would *not* be removed from the ventilator with the arrival of an incoming yellow code patients since both of these patients have equivalent likelihoods of survival (i.e., both are in the same color category).

²¹⁹ For a discussion on review of a triage decision and the appeals process, see Chapter 4, Implementing New York State's Ventilator Allocation Guidelines: Legal Considerations, Section VI. Appeals.

patients. Furthermore, such comparisons may intensify inherent biases in the health care system and the disproportionate and disparate provision of care for already disadvantaged populations.

Instead, a triage officer/committee utilizes the following framework to select which patient(s) is removed. Because the assumption is made that all patients²²⁰ in the blue²²¹ (or yellow) category have substantially equal likelihoods of survival, a randomization process such as a lottery is used to select which patient is removed from the ventilator so that another eligible (red code) patient has an opportunity to benefit from ventilator therapy.²²² A patient may only be removed from a ventilator after an official clinical assessment has occurred or where the patient develops a medical condition on the exclusion criteria list.

Finally, if all ventilated patients at the 48, 120, and subsequent 48 hour time trial assessments receive a red color code, then none of these patients discontinue ventilator therapy. The incoming red code patient(s) remains in an eligible patient pool and receives alternative forms of medical intervention and/or palliative care until a ventilator becomes available.

F. Interface between Pediatric and Adult Patients

Although the Guidelines underscore the goal of selecting and treating patients who will most likely survive the acute medical episode that necessitated ventilator treatment, a triage officer/committee may not be able to compare easily the probability of mortality predictions between adult and pediatric patients. The same triage officer/committee may need to evaluate the mortality risks of adults and children using different clinical assessment tools. The difficulties in doing so are most apparent when a dual-use ventilator becomes available and both an adult and a pediatric patient are in need of treatment. While the adult clinical ventilator allocation protocol uses the SOFA scoring system to estimate a patient's mortality risk, nothing comparable exists to estimate a child's mortality risk. Instead, the pediatric clinical ventilator allocation protocol relies on physician clinical judgment to gauge a child's risk of mortality. Although a patient with the greatest chance of survival with ventilator therapy should receive (or continue with) this treatment, it is not obvious how this determination should be made when the mechanisms used to predict mortality risk are not the same.²²³

Until a clinical scoring system is validated for use for both adults and pediatric patients, the Task Force and the Pediatric Clinical Workgroup recognized that use of different

²²⁰ However, if the ventilated patients include both adults and children, a different non-clinical method is used (i.e., young age). See Section V.A.3.b. Use of Young Age as a Secondary Triage Factor (Tie-Breaker) and Section IX.F. Interface between Pediatric and Adult Patients.

²²¹ In certain circumstances, it is possible for a patient with an exclusion criterion or who has been triaged into the blue category to obtain ventilator therapy because there are no other eligible patients waiting for ventilator therapy. If there is more than one blue code patients, they are subject to the procedures described above when no ventilators are available and there is an eligible (non-blue code) patient waiting for ventilator therapy.

²²² For a discussion of how randomization could be used to select a patient for removal, see Section XI.B.3. Decision-Making Process for Selecting an Eligible Patient for a Ventilator (the same randomization process used for selection could be applied for removal).

²²³ For a discussion of the clinical tools a triage officer/committee uses to gauge an adult and pediatric patient's immediate or near-immediate mortality risk, see Chapter 1, Adult Guidelines, Section XI.B. Step 2: Mortality Risk Assessment Using SOFA (on the SOFA scoring system) and Pediatric Guidelines, Section IX.C.2. Use of Six Clinical Parameters to Evaluate a Patient, respectively.

methodologies to assess mortality risk is ethically acceptable, primarily because no other appropriate evidence-based alternative exists. In an influenza pandemic, the same triage officer/committee may need to allocate ventilators to both populations, the Task Force and the Pediatric Clinical Workgroup agreed that, ideally, experienced clinicians should have the appropriate training in both pediatric and adult mass casualty scenarios.²²⁴ In the absence of a universal triage tool, a triage officer/committee should be able to gauge whether patients have substantial equality in the likelihood of survival with ventilator therapy. While the details of the clinical evaluations may differ between the two groups, properly trained clinicians will be able to provide an overall assessment of survivability.

When either selecting or removing a patient in a patient pool that consists of both children and adults, a triage officer/committee is not permitted to compare the health of patients. A triage officer/committee must assume that all patients in a color category have substantially equal likelihoods of survival because no other evidence-based clinical tools are available to further differentiate a patient's mortality risk. The Task Force determined that only in this unique circumstance, when adult and pediatric patients all have equal (or near equal) likelihoods of survival, may young age play a tie-breaking role in determining which patient receives/continues with ventilator treatment.²²⁵ In this situation, the child (i.e., 17 years old and younger) receives/continues with ventilator treatment and the adult receives alternative forms of medical intervention and/or palliative care.

X. Alternative Forms of Medical Intervention and Pediatric Palliative Care

During a public health emergency, non-emergency medical standard of care and decision-making autonomy may not be feasible. In a pandemic, some patients who might have been successfully treated during ordinary conditions may not survive. Policy aimed at maximizing the number of lives saved suggests that in the unfortunate event in which continually more patients require ventilator treatment and as ventilator resources become increasingly scarce, patients whose clinical conditions indicate they are less likely to survive may be denied access to or withdrawn from a ventilator.

Under these circumstances, health care providers should endeavor to follow standard protocols for withholding and withdrawing life-sustaining care. While an emergency may require withholding or withdrawing of a ventilator, health care workers continue to have obligations and a duty to care for their patients. Clinically indicated and appropriate care, such as alternative forms of medical intervention and/or palliative care, within the context of the pandemic situation should be provided to patients who do not meet clinical criteria for continued ventilator therapy, as well as to patients who were not eligible for ventilator treatment.

²²⁴ Some facilities that use a triage committee instead of a triage officer may designate a pediatric or neonatal specialist as a member of the triage committee.

²²⁵ For a discussion on the role of age as a secondary (tie-breaker) triage factor, *see* Section V.A.3.b. Use of Young Age as a Secondary Triage Factor (Tie-Breaker).

A. Alternative Forms of Medical Intervention Palliative Care for a Patient Without Access to a Ventilator

Although ventilators are the most effective medical intervention for patients experiencing severe respiratory distress or failure, in emergency circumstances, alternative forms of medical intervention for oxygen delivery may be examined, if appropriate.²²⁶ For example, various types of nasal cannula,²²⁷ oxygen face masks,²²⁸ BiPAP/CPAP,²²⁹ transtracheal catheters,²³⁰ or other supplements to breathing may be utilized if medically indicated and available. While none of these treatments offer long-term support for a patient with severe influenza, they may sustain the patient long enough for a ventilator to become available.²³¹ Furthermore, pharmacological antivirals may provide some benefit for patients. For a more detailed discussion on alternative forms of medical intervention, see Chapter 1, Adult Guidelines, Section XII.A.

B. Palliative Care

Another alternative for oxygen delivery in lieu of ventilators is the use of hand-held devices, such as a bag-valve mask, or ambu-bags.²³² However, the Task Force and Clinical Workgroups recommended that manual ventilation should not be permitted at the acute care facility for several reasons, including the strong possibility of the technique not being effective against pandemic influenza, a high risk of transmission of the virus, possible isolation/quarantine orders that may not permit access to the sick patients, lack of health care staff, and burden on the families may make it difficult to conduct for extended periods of time.²³³

²²⁶ Some facilities may not have the oxygen supply, staff, resources, supplies, or equipment to offer these alternative forms of medical intervention.

²²⁷ Nasal cannula is a thin tube with two small prongs that extend into a patient's nostrils. It is typically used to deliver oxygen to patients who require low flow, low to medium oxygen concentration, and are in a stable state.

²²⁸ Oxygen face masks are semi-rigid masks that fit over a person's nose and mouth. They are designed to provide a medium flow and concentration of oxygen.

²²⁹ BiPAP (Bilevel positive airway pressure) and CPAP (continuous positive airway pressure) machines are used to treat sleep apnea disorders. In both systems, oxygen is delivered via a face mask. BiPAP machines are more effective for patients who are unable to completely breathe on their own. For an example of a state ventilator allocation plan that considers BiPAP as an alternative to ventilator treatment, *see* Indiana Guidelines, *supra* note 114, at 23.

²³⁰ Transtracheal catheters are small flexible tubes inserted into the trachea (windpipe) and enable oxygen delivery directly to the lungs. This procedure is often used to assist patients who are extubated to ensure better outcomes with ventilator weaning.

²³¹ A patient receiving an alternative form of oxygen delivery may be eligible for a ventilator depending on the real-time availability of these machines and whether there are patients waiting for a ventilator. *See* Chapter 1, Adult Guidelines, Section XII.A. Alternative Forms of Medical Intervention for a Patient Without Access to a Ventilator, for a discussion on other possible medical interventions.

²³² Bag-valve masks are used often to ventilate a patient who is no longer breathing, especially as part of resuscitation techniques (i.e., mouth-to-mouth). It consists of three parts: (1) bag, generally about the size of a football (for adults), (2) face mask, and (3) one-way valve that is between the bag and face mask. The mask is held tightly over the mouth and nose of a patient to ensure the air from the squeezed bag enters the lungs and does not leak out. Two people are required to ambu-bag efficiently, one to squeeze the bag and the other to hold the mask in place.

²³³ *See* Chapter 1, Adult Guidelines, Section XII.A. Alternative Forms of Medical Intervention for a Patient Without Access to a Ventilator for a discussion on ambu-bagging. However, ambu-bagging may be permitted by the facility in specific circumstances, such as when a ventilator is expected to become available in a short period of time and staff resources are available.

Available forms of palliative care are offered to pediatric patients who are not eligible for ventilator treatment as well as to patients who fail to meet clinical criteria for continued use of a ventilator. Palliative care is focused on the prevention and relief of both physical and emotional discomfort.²³⁴ Palliative care treatment does not necessarily suggest a patient is dying, but rather it is aimed at providing comfort, both physically and emotionally, under the circumstances. It should include pain management and non-pharmacological interventions. Actively providing palliative care, especially to patients who do not or no longer qualify for ventilator therapy, decreases patient discomfort and fulfills the provider's duty to care, even when the clinician cannot offer ventilator therapy.

In the ventilator withdrawal context, appropriate measures should be taken to prepare for and ease the process of withdrawal for patients and their families.²³⁵ Ideally, decisions concerning the withholding and withdrawing of treatment include a patient's parents or legal guardians; however, their involvement may be limited by the pandemic situation.

Similar to adult palliative care, education and communication among patients, health care providers, and families are imperative in the care and management of pediatric patients' receiving palliative care. A patient and family should be educated and made aware of possible treatment options in light of available resources, which may be less than ideal during a pandemic. Appropriate measures should be taken to clarify what a patient and his/her family can expect, so they can better prepare for possible outcomes. Information regarding a patient's condition, prognosis, and the general circumstances of the influenza pandemic situation aids the patient's family in making informed decisions regarding care. Finally, open communication also helps to ensure that everyone understands the progression of treatment and can minimize conflict.

1. Differences between Adult and Pediatric Palliative Care

While the underlying focus and goals of adult and pediatric palliative care are the same, there are several aspects that are unique to the care of children.

Because most people do not have first-hand experience with pandemics or other mass tragedy events that significantly affect children, the general public is not comfortable with the idea of children dying en masse. When a child dies, s/he cannot reach his/her potential or experience the milestones of a full life. The death of a child is often seen as more tragic than the death of an adult. Furthermore, many people, including health care staff who normally do not care for pediatric patients, may be unprepared for the increased number of children's deaths and may be reluctant to offer palliative care, despite the pressing need for this care.

Furthermore, the course of illness in pediatric patients is frequently cited as being different from that in adults. While children may experience more severe symptoms, they have better recovery rates for serious illnesses. Because of their resilience and significantly lower rates of mortality, it is sometimes difficult to determine the prognosis of children. Thus, it is

²³⁴ For a discussion on palliative care, *see* Chapter 1, Adult Guidelines, Section XII.B. Palliative Care.

²³⁵ *See id.*

likely that families and health care providers may desire to pursue curative treatment until these options are exhausted and death is certain, which may not be feasible during pandemic conditions.

Although the concept of palliative care is not new, its incorporation into a pediatric patient's medical treatment plan is sometimes less well developed than for adults.²³⁶ However, in a pandemic, it is likely that there will be an increased demand for palliative care in both the adult and pediatric contexts. However, pain in children is often inadequately assessed and treated.²³⁷ Current physician education and expertise are limited with regards to palliative care for pediatric patients²³⁸ and emergency planning should include palliative care for this population.

Another difference between adult and pediatric palliative care is the capacity for patient understanding and communication. While most non-cognitively impaired adults can adequately understand their conditions to communicate their feelings and concerns about palliative care, children have varying abilities to understand and communicate their experiences.²³⁹ Parents and caregivers should use comprehensive methods of interpretation (verbal and behavioral) to understand the child's level of discomfort and determine the course of treatment, while tempering inclinations to under-appreciate the severity of the child's experience.²⁴⁰

Pediatric palliative care should also include emotional and psychological care. Even if children lack the cognitive maturity to comprehend the severity of their medical condition, they are still likely to recognize cues from their family and health care providers regarding the situation. How information is communicated, and to which parties (only the parents/caregivers, or also include the child), is crucial for promoting the least difficult experience for a patient and family.²⁴¹ Parents of dying children are also particularly vulnerable to misunderstanding due to shock, confusion, and grief.²⁴² Thus, families and health care providers should be sensitive to their actions around patients and provide adequate attention to the mental and emotional well-being of the child and the family.²⁴³

Furthermore, parents, caregivers, and other family members may influence the extent of palliative care administered to the child. Because of the child's age, the family is likely to be more involved in medical decision-making. Families may be better at soothing and easing the distress of a pediatric patient and it may be better to ease the family's emotional distress to see and comfort the patient.²⁴⁴ Ideally, measures that assist both a patient and family should be

²³⁶ Larry R. Frankel, *Pediatric Palliative Care: The Role of the Intensivist*, in *Current Concepts in Pediatric Critical Care*, 104 (Edward E. Conway, Jr., ed., Society of Critical Care Medicine, 2007).

²³⁷ Task Force on Pain in Infants, Children, and Adolescents, *The Assessment and Management of Acute Pain in Infants, Children, and Adolescents*, 108, *PEDIATR.*, 793, 793 (2001).

²³⁸ *See id.*

²³⁹ *See id.*, at 794.

²⁴⁰ *See id.*, at 793.

²⁴¹ Institute of Medicine, *When Children Die: Improving Palliative and End of Life Care for Children and their Families*, 14 Washington, DC (The National Academies Press 2003).

²⁴² *See id.*, at 114.

²⁴³ *See id.*, at 153-155.

²⁴⁴ *See Frankel, supra* note 236, at 108 (noting that attempts to preserve the parent-child relationship not only helped with the bereavement process, but also improved the quality of end-of-life care).

balanced and considered, and will vary depending on the individual situation and family. However, many of these practices may not be feasible if there is a significantly high rate of transmission and a need to isolate affected patients to protect individuals without the disease.

XI. Logistics Regarding the Implementation of the Guidelines

There are several non-legal issues²⁴⁵ to consider once the Guidelines are implemented, including communication about triage, and real-time data collection and analysis to modify the Guidelines based on new information.²⁴⁶

Implementation of the Guidelines requires clear communication to the public about the goals and steps of the clinical ventilator allocation protocol. Efforts will be made to inform and gather feedback from the public before a pandemic. Public outreach should include a component that informs people that the medical standard of care during an influenza pandemic will be different than the normal (i.e., non-pandemic) medical standard of care. It will also include information that during this specific scenario, patient preference will not determine ventilator access. Instead, a protocol based only on clinical factors will be used to determine whether a patient receives (or continues with) ventilator treatment to support the goal of saving the greatest number of lives where there are a limited number of available ventilators.

Data collection and analysis on the pandemic viral strain, such as symptoms, disease course, treatments, and survival are necessary so that the clinical ventilator allocation protocol may be adjusted accordingly to ensure that patients receive the best care possible. Furthermore, data collection must include real-time availability of ventilators so that triage decisions are made to allocate resources most effectively. Knowing the exact availability of ventilators also assists a triage officer/committee in providing the most appropriate treatment options for patients.

XII. Conclusion

With any luck, a severe influenza pandemic will never emerge in New York. With planning, even if a pandemic does occur, community members, health care providers, and public officials may be able to diminish its impact. The Guidelines rely upon both ethical and clinical standards in an effort to offer the best possible care under gravely compromised conditions to support the goal of saving the most lives in an influenza pandemic where there are a limited number of available ventilators.

While the Pediatric Guidelines developed by the Task Force and the Pediatric Clinical Workgroup assist a triage officer/committee as they evaluate potential patients for ventilator therapy, decisions regarding treatment should be made on an individual (patient) basis, and all relevant clinical factors should be considered. A triage decision is not performed in a vacuum; instead, it is an adaptive process, based on fluctuating resources and the overall health of the

²⁴⁵ For a discussion of the legal issues involved when implementing the Guidelines, *see* Chapter 4, Implementing New York State's Ventilator Allocation Guidelines: Legal Considerations.

²⁴⁶ For a more detailed discussion on communication about the Guidelines and clinical ventilator allocation protocol and real-time data collection and analysis and modification of the Guidelines, *see* Chapter 1, Adult Guidelines, Section XIII. Logistics Regarding the Implementation of the Guidelines.

patient. Examining each patient within the context of his/her health status and of available resources provides a more flexible decision-making process, which results in a fair, equitable plan that saves the most lives.

Finally, the pediatric clinical ventilator allocation protocol is a set of guidelines to assist clinicians in distributing limited ventilators and may be revised as more information on the nature of the pandemic viral strain is gathered. It may be modified to ensure that the recommended approach reflects strain-specific influenza progression so that patients receive the most appropriate care.

Appendix 1
Additional Clinical Information regarding Exclusion Criteria (Step 1)

Determining Traumatic Brain Injury

No Motor Response to Painful Stimulus (i.e., Best Motor Response = 1)

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

American Burn Association (ABA)
Triage Decision Table for Burn Victims Based on Anticipated Outcomes
Compared with Resource Allocation²⁴⁷

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%+
0 - 1.9	Very high	Very high	Very high	High	Medium	Medium	Medium	Low	Low	Low/expectant
2.0 - 4.9	Out-patient	Very high	Very high	High	High	High	Medium	Medium	Low	Low
5.0 - 19.9	Out-patient	Very high	Very high	High	High	High	Medium	Medium	Medium	Low

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.

²⁴⁷ See Utah Guidelines, *supra* note 141, at 7.

Appendix 2
Additional Clinical Information regarding Time Trials (Step 3)
Glasgow Coma Scale Score Criteria

Criteria	Pediatric Patients	Score	Criteria Score
Best Eye Response (1 – 4)	No eye opening	1	
	Eye opens to painful stimulus	2	
	Eye opens to verbal command	3	
	Eyes open spontaneously	4	
Best Verbal Response (1 – 5)	No verbal response	1	
	Incomprehensible sounds	2	
	Inappropriate words	3	
	Confused	4	
	Oriented	5	
Best Motor Response (1 – 6)	No motor response	1	
	Extension to painful stimulus	2	
	Flexion to painful stimulus	3	
	Withdraws from painful stimulus	4	
	Localizes to painful stimulus	5	
	Obeys commands	6	
Total Score (add three subscores, range from 3 to 15):			

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CHAPTER 3

NEONATAL GUIDELINES

Abstract

Introduction

As described in the adult and pediatric guidelines, a severe influenza pandemic on the scale of the 1918 influenza outbreak will significantly strain medical resources, including ventilators. Although a small subset of the general population, neonates (infants less than 28 days old) may also require ventilators and there will not be enough ventilators in New York State to meet the demand. A clinical ventilator allocation protocol will need to be implemented to ensure that ventilators are allocated in the most efficient manner to support the goal of saving the greatest number of lives.

Policy-makers and emergency management experts recognize that similar to how an adult clinical ventilator allocation protocol may not be appropriate to apply to a child, the pediatric protocol should not be applied to neonates. Acknowledging the need for a thorough evaluation and development of a clinical ventilator allocation protocol for neonatal populations in an influenza pandemic, the New York State Task Force on Life and the Law (the Task Force) and the New York State Department of Health (the Department of Health), undertook a comprehensive project to draft clinically sound and ethical ventilator allocation guidelines (the Neonatal Guidelines).

The Task Force examined the ethical issues and convened a neonatal clinical workgroup (the Neonatal Clinical Workgroup) to develop the specifics of a clinical ventilator allocation protocol. While a large portion of the Neonatal Guidelines is adapted from the Pediatric Guidelines, several aspects are different to address the unique characteristics of neonates.

The Neonatal Guidelines reflect a synthesis of neonatal clinical experts' and Task Force's recommendations on ventilator allocation for neonates during an influenza pandemic. Because research and data on this topic are constantly evolving, the Neonatal Guidelines are a living document intended to be updated and revised in line with advances in clinical knowledge and societal norms. The Guidelines incorporate an ethical framework and evidence-based clinical data to support the goal of saving the most lives in an influenza pandemic where there are a limited number of available ventilators.

The Neonatal Guidelines contain three main sections. The first section examines the unique considerations when triaging neonates. The second section provides an overview of various clinical components that could be used to triage neonates. The third section presents New York's neonatal clinical ventilator allocation protocol.

Section 1: Unique Challenges when Triage Neonates

The ethical framework that underlies the adult clinical ventilator allocation protocol – duty to care, duty to steward resources, duty to plan, distributive justice, and transparency – also applies to the neonatal clinical protocol (see Chapter 1, Adult Guidelines). The Task Force examined several key concepts of triage to advance the goal of saving the most lives within the specific context of ventilators as the scarce resource in an influenza pandemic. To accomplish this goal, patients for whom ventilator therapy would most likely be lifesaving are prioritized. The Guidelines define survival by examining a patient’s short-term likelihood of surviving the acute medical episode and not by focusing on whether the patient may survive a given illness or disease in the long-term (e.g., years after the pandemic). Patients with the highest likelihood of survival *without* medical intervention, along with patients with the smallest likelihood of survival *with* medical intervention, have the *lowest* level of access to ventilator therapy. Thus, patients who are most likely to survive without the ventilator, together with patients who will most likely survive with ventilator therapy, increase the overall number of survivors.

Neonatal patients are infants less than 28 days old and include babies born prematurely. Premature infants often need ventilators because their lungs are not fully developed or functional. During an influenza pandemic, more neonates than usual would require ventilator therapy because their mothers – ill with influenza – are at increased risk of delivering their babies before full term. Unlike pediatric patients, whose overall mortality rates are low, neonates, depending on their weight and gestational age, generally have higher mortality rates.

In addition to the special considerations when triaging children discussed in Chapter 2, Pediatric Guidelines, there are additional concerns when neonates are involved. Designing a clinical process by which to triage neonates is difficult because the physiologic and pathophysiologic processes for newborns are different than those of pediatric and adult patients. Furthermore, the patterns of newborn intensive care can also differ from adult and pediatric intensive care because neonates also experience physiologic maturation of their bodies. Another consideration is the even more limited number of health and critical care resources available to this population and the concentration of such resources in metropolitan areas. In addition, the equipment and expertise required to treat neonates may not be compatible with resources available at facilities that normally treat adults and older children. Finally, dedicating intensive resources and staffing necessary for an individual neonate, may not be possible during a pandemic. As staff and resources become scarce, it will be necessary to triage these patients and prioritize neonates who will have the highest likelihood of survival with ventilator therapy.

Finally, rather than relying on age as a determining triage criterion, the Neonatal Clinical Workgroup supported the conclusions of the Task Force and previous Clinical Workgroups that it would be best to rely instead on the core principles of triage to determine whether a patient receives ventilator therapy. The goal of saving the most number of lives would be best achieved by using a clinical framework to determine whether a patient is eligible for ventilator therapy based on his/her likelihood of survival with this treatment.

Section 2: Overview of Various Clinical Components when Triage Neonatal Patients

Currently, no U.S. state or other jurisdiction has a clinical protocol specifically for neonatal ventilator allocation. New York's neonatal clinical ventilator allocation protocol is novel in that it is unique to neonates and is extremely detailed.

When developing the neonatal clinical ventilator allocation protocol, the Neonatal Clinical Workgroup used the pediatric protocol as a template to inform their discussions. The discussions involving the advantages and disadvantages of incorporating exclusion criteria, time trials, response to ventilation (oxygenation index), and duration of ventilator need/resource utilization were similar to the discussions on these topics by the Pediatric Clinical Workgroup (see Chapter 2, Pediatric Guidelines), and therefore are not repeated in this chapter. However, a few components that are different or unique to neonates, such as neonatal clinical scoring systems (SNAP II, CRIB II, NTISS, and NICHD NRN Data), physician clinical judgment, Apgar Score, gestational age, and birth weight, were examined.

The use of a neonatal clinical scoring system (SNAP II, CRIB II, NTISS, and NICHD NRN Data) was not included, despite its ease of use and consistent approach to allocate scarce resources, because none of the clinical scoring systems above have been validated for triage purposes. In lieu of a scoring system, physician clinical judgment, using a structured decision-making process that carefully considers only specific clinical factors based on available medical evidence, is used to evaluate a patient's likelihood of survival, to determine whether a pediatric patient is eligible for ventilator therapy. The care of neonates is a highly specialized field where clinical expertise and judgment play a significant role. While physician clinical judgment may not be optimal to use during a pandemic, a ventilator allocation decision based on an unvalidated scoring system is more problematic and may not optimize limited resources.

The Neonatal Clinical Workgroup also discussed incorporating Apgar Scores, gestational age, and birth weight. While an Apgar score is used to evaluate a newborn's respiratory and circulatory status, its utility as a tool to assess a patient's overall health is limited because it does not assess mortality risk. Gestational age may be used as a factor to evaluate a neonate's mortality risk, because there is a high correlation between young gestational age and mortality, but such information may not always be available, or accurate. Finally, birth weight is also a strong indicator of survival; however, it may be difficult to determine an exact birth weight cutoff that could be used as a triage criterion.

Section 3: New York's Neonatal Triage Protocol

While the neonatal clinical ventilator allocation protocol does not utilize the exact same clinical tools as the pediatric and adult protocols to evaluate the patient, the ethical and clinical frameworks remain the same. As with the adult clinical ventilator allocation protocol, first, facilities should develop surge capacity to reduce the demand for ventilators when a pandemic is occurring. The neonatal clinical ventilator allocation protocol applies to all patients 28 days old and younger in all acute care facilities Statewide. As with the other protocols, all neonatal acute care patients in need of a ventilator, whether due to influenza or other conditions, are subject to the clinical protocol. Ventilator-dependent chronic care patients are only subject to the clinical

ventilator allocation protocol if they arrive at an acute care facility. Using clinical criteria, patients deemed most likely to survive with ventilator therapy have an opportunity for this treatment to maximize the number of survivors. The neonatal clinical ventilator allocation protocol consists of three steps:

- Step 1 – Exclusion Criteria: A patient is screened for exclusion criteria. The purpose of applying exclusion criteria is to identify patients with the highest probability of mortality, even with ventilator therapy, in order to prioritize patients most likely to survive with ventilator therapy. The medical conditions that qualify as exclusion criteria are limited to those associated with immediate or near-immediate mortality even with aggressive therapy. While most of the exclusion criteria from the Pediatric Guidelines were adopted for the Neonatal Guidelines, the Neonatal Clinical Workgroup decided to include additional conditions, such as gestational age and birth weight, which are specific to the population. If a patient has a medical condition on the exclusion criteria list, s/he is not eligible for ventilator therapy. Instead, a patient receives alternative forms of medical intervention and/or palliative care.
- Step 2 – Mortality Risk Assessment Using Physician Clinical Judgment: Physician clinical judgment is used to assess a patient’s risk of mortality. Because none of the currently available neonatal clinical scoring systems have been validated for triage purposes, physician clinical judgment, using a structured decision-making process that carefully considers only specific clinical factors, is used to assess a patient’s risk of mortality. When evaluating a patient’s mortality risk, the patient’s attending physician may consider the following: the acute severity of the patient’s current medical condition, the epidemiology of the disease, and the existence and status of any severe underlying diseases or medical conditions (co-morbidities) that may hinder recovery. Finally, resource utilization with respect to estimated duration of ventilator need as a stand-alone triage factor was rejected because it does not affect a patient’s likelihood of survival. A triage officer/committee examines clinical data from Steps 1 and 2 and allocates ventilators according to a patient’s mortality risk.
- Step 3 – Time Trials: Periodic clinical assessments are conducted at 48 and 120 hours on a patient who has begun ventilator therapy to evaluate whether s/he continues with the treatment. Various clinical parameters are examined at this step to assess the possibility of organ failure and to measure lung function. The decision whether a patient remains on a ventilator is based on ongoing clinical measures and data trends of the patient’s health condition, consisting of: (1) the overall prognosis estimated by the patient’s clinical indicators, which is indicative of mortality risk by revealing the presence (or likelihood), severity, and number of acute organ failure(s), and (2) the magnitude of improvement or deterioration of overall health, which provides additional information about the likelihood of survival with ventilator therapy. The results from the current assessment are compared to the results from the previous official clinical assessment. Any changes (improving, worsening, or experiencing no change) in a patient’s health status after 48 and 120 hours help guide the triage decision. Thus, the guiding principle for the triage decision is that the likelihood of a patient’s continuation of ventilator therapy depends on the severity of the patient’s health condition and the extent of the patient’s medical deterioration. In order for a patient to

continue with ventilator therapy, s/he must demonstrate an improvement in overall health status at each official clinical assessment.

Because a clinical scoring system is not used, a triage decision is based on continuous evaluation of a patient's health data trend, which consists of two parts. The first is the prognosis determined by a patient's results for three clinical parameters (oxygenation index (OI)/ arterial oxygen saturation, hypotension, and serum creatinine). These results reveal the presence (or likelihood), severity, and number of acute organ failure(s), which indicate mortality risk. The second part is the magnitude of improvement or deterioration of overall health based on these parameters, which provides additional information about the likelihood of survival with ventilator therapy. Together, these clinical variables provide an overall health assessment of a patient.

While no triage decision should be based on a single clinical variable, a triage officer/committee should place more weight on the health data trends from the OI/arterial oxygen saturation and hypotension factors because these are stronger predictors of mortality risk. The other clinical factor reveals whether a patient is experiencing kidney failure, and while useful, it should *never* be the *sole* reason to justify a triage decision involving extubation.

The primary difference between the 48 and 120 hour assessment is the extent of improvement in overall health prognosis and of the trajectory of a patient's health status required to continue to be eligible for ventilator therapy. At 48 hours, because a patient has only had two days to benefit from ventilator therapy, the progress required to justify continued ventilator use is not expected to be dramatic. However, after 120 hours, a patient must demonstrate a pattern of *further* significant improvement in health to continue. After the 120 hour clinical assessment, a patient who is eligible to continue with ventilator therapy is reassessed every 48 hours with the same three clinical parameters listed above.

Although additional clinical assessments may be performed, the official assessments only occur after 48 and 120 hours of ventilator therapy. No formal triage decision or action may be taken until a patient's official assessment. However, at any point during the time trial, even before an official assessment occurs, if a patient develops a condition on the exclusion criteria list and there is an eligible patient waiting, then the ventilator is reallocated. A patient who no longer meets the criteria for continued use receives alternative forms of medical intervention and/or palliative care.

In addition to the three steps described above, additional components of the neonatal clinical ventilator allocation protocol include:

Triage Officer/Committee: To ensure that patients receive the best care possible, a patient's attending physician does not determine whether his/her patient receives (or continues) ventilator therapy; instead a triage officer or triage committee makes the decision. The attending physician's role is to evaluate a patient for exclusion criteria in Step 1 and to assess the patient's mortality risk and organ failure risk in Steps 2 and 3. A triage officer/committee does not have any direct contact with a patient. Instead, a triage officer/committee examines the data provided

by the attending physician and makes the determination about a patient's level of access to a ventilator. Ideally, a triage officer/committee has experience working with neonatal patients.

Color Codes/Level of Access to Ventilator Therapy: A patient's attending physician provides all clinical data to a triage officer/committee. At Steps 2 and 3, a triage officer/committee examines a patient's clinical data and uses this information to assign a color code to the patient. The color (blue, red, yellow, or green) determines the level of access to a ventilator (blue = lowest access/palliate/discharge, red = highest access, yellow = intermediate access, and green = defer/discharge). Red color code patients have the highest level of access to a ventilator.

Blue code patients (lowest access/palliate/discharge) are those who have a medical condition on the exclusion criteria list or those who have a high risk of mortality and these patients do not receive ventilator therapy when resources are scarce. Instead, alternative forms of medical intervention and/or palliative care are provided. However, if more resources become available, patients in the blue color category, or those with exclusion criteria, are reassessed and may be eligible for ventilator therapy. Red code patients (highest access) are those who have the highest priority for ventilator therapy because they are most likely to recover with treatment (and likely to not recover without it) and have a moderate risk of mortality. Patients in the yellow category (intermediate access) are those who are very sick, and their likelihood of survival is intermediate and/or uncertain. These patients may or may not benefit (i.e., survive) with ventilator therapy. They receive such treatment if ventilators are available after all patients in the red category receive them. Patients in the green color code (defer/discharge) are those who do not need ventilator therapy.

Decision-Making Process for Selecting an Eligible Patient for a Ventilator: In some circumstances, a triage officer/committee must select one of many eligible red color code patients to receive ventilator therapy. A patient's likelihood of survival (i.e., assessment of mortality risk) is the most important consideration when evaluating a patient. However, there may be a situation where multiple patients have been assigned a red color code, which indicates they all have the highest level of access to ventilator therapy, and they all have equal (or near equal) likelihoods of survival. If the eligible patient pool consists of *only neonates*, a randomization process, such as a lottery, is used each time a ventilator becomes available because there are no other evidence-based clinical factors available to consider. Patients waiting for ventilator therapy wait in an eligible patient pool.

Decision-Making Process for Removing a Patient from a Ventilator: There may be a scenario where there is an incoming red code patient(s) eligible for ventilator therapy and a triage officer/committee must remove a ventilator from a patient whose health is not improving. In this situation, first, patients in the blue category (or the yellow category if there are no blue code patients receiving ventilator therapy) are vulnerable for removal from ventilator therapy if they fail to meet criteria for continued ventilator use. If the pool of ventilated patients vulnerable for removal consists of *only neonates*, a randomization process, such as a lottery, is used each time to select the (blue or yellow) patient who will no longer receive ventilator therapy. A patient may only be removed from a ventilator after an official clinical assessment has occurred or where the patient develops a medical condition on the exclusion criteria list. However, if all ventilated patients are in the red category (i.e., have the highest level access), *none* of the patients are removed from ventilator therapy, even if there is an eligible (red color code) patient waiting.

Interface between Neonatal and Pediatric Patients: Because some ventilators can be used for either a pediatric or a neonatal patient, there may be circumstances where a triage officer/committee must select one for ventilator therapy. While the framework of the neonatal and pediatric clinical ventilator allocation protocols is the same, a triage officer/committee may need to evaluate the mortality risks of children and neonates using different clinical assessment tools. Although a patient with the greatest chance of survival with ventilator therapy should receive (or continue with) this treatment, it is not obvious how this determination should be made when the mechanisms used to predict mortality risk are not the same. The use of different clinical tools to assess mortality is acceptable, primarily because no other appropriate alternative exists. Ideally, experienced clinicians with appropriate training in both neonatal and pediatric mass casualty scenarios will be able to provide an overall assessment of survivability for both populations.

When either selecting or removing a patient in a patient pool that consists of both neonates and pediatric patients, a triage officer/committee is not permitted to compare the health of patients; instead they must assume that all patients in a color category have substantially equal likelihoods of survival because no other evidence-based clinical tools are available to further differentiate a patient's mortality risk. The Task Force determined that it would not be appropriate to use young age as a tie-breaker criterion when a patient pool consists only of children. It would be nearly impossible to have consensus on which age range(s) would have priority access to ventilators over another age group because the reasoning behind such thresholds is subjective. Instead, a random process (e.g. lottery) should be used to choose between eligible neonatal and pediatric patients for ventilator therapy when there are more patients than ventilators available.

Alternative Forms of Medical Intervention and Palliative Care: Alternative forms of medical intervention, such as other methods of oxygen delivery and pharmacological antivirals, should be provided to those who are not eligible or waiting for a ventilator. Palliative care is provided to all patients, regardless of prognosis. Patients who have a medical condition on the exclusion criteria list or who no longer meet the clinical criteria for continued ventilator use receive alternative forms of medical intervention and/or palliative care. The same applies to patients who are eligible for ventilator therapy but for whom no ventilators are currently available. Actively providing palliative care, especially to patients who do not or no longer qualify for ventilator therapy, decreases patient discomfort and fulfills the provider's duty to care, even when the clinician cannot offer ventilator therapy.

Logistics Regarding Implementation of the Guidelines: Once the Guidelines are implemented, there must be communication about triage, and real-time data collection and analysis to modify the Guidelines based on new information. Efforts will be made to inform and gather feedback from the public before a pandemic. In addition, there must be real-time data collection and analysis on the pandemic viral strain, such as symptoms, disease course, treatments, and survival, so that the clinical ventilator allocation protocol may be modified accordingly to ensure that patients receive the best care possible. Data collection must include real-time availability of ventilators so that triage decisions are made to allocate resources most effectively. Knowing the exact availability of ventilators also assists a triage officer/committee in providing the most appropriate treatment options for patients.

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I. Neonatal Triage

Although much has been written on the clinical and ethical issues regarding ventilator allocation for adults during an influenza pandemic, most emergency preparedness plans do not address how to treat children. While some policy-makers are starting to develop pediatric specific guidance, none have any detailed information or instruction on neonatal triage. Because neonates have different physiological processes and levels of maturation and development, applying a pediatric plan to neonates is not appropriate.

To address this gap, the New York State Task Force on Life and the Law¹ (the Task Force) and the New York State Department of Health (the Department of Health) developed neonatal ventilator allocation guidelines² (the Neonatal Guidelines) to accompany the recently updated guidelines regarding the allocation of ventilators for adults (the Adult Guidelines) and the new pediatric ventilator allocation guidelines (the Pediatric Guidelines), collectively the Ventilator Allocation Guidelines (the Guidelines).³ The Task Force considered the practical and ethical issues involved in allocating scarce ventilators to neonates. The Task Force also convened a Neonatal Clinical Workgroup,⁴ consisting of specialists in neonatal, maternal-fetal, obstetrics, pediatric, ethics, palliative care, and critical care fields to develop the neonatal clinical ventilator allocation protocol.

Neonatal patients are infants less than 28 days old and include babies born prematurely. Premature infants often need ventilators because their lungs are not fully developed or functional. During an influenza pandemic, more neonates than usual would require ventilator treatment⁵ because their mothers – ill with influenza – are at increased risk of delivering their babies before full term.⁶ Unlike pediatric patients, whose overall mortality rates are low, neonates, depending on their weight and gestational age, generally have higher mortality rates.

The ethical framework that underlies the adult clinical ventilator allocation protocol – duty to care, duty to steward resources, duty to plan, distributive justice, and transparency –

¹ Established by Executive Order in 1985, the Task Force is comprised of 23 Governor-appointed leaders in the fields of religion, philosophy, law, medicine, nursing, and bioethics. The Task Force develops public policy on issues arising at the interface of medicine, law, and ethics, and has issued influential reports on cutting-edge bioethics issues. See Appendix A for a list of the Task Force members who participated in this project.

² Although this document is intended to respond to the allocation of ventilators during an influenza pandemic, the general framework could be adapted – with appropriate modifications – to any public health emergency where resources will be scarce. These guidelines use the term pandemic to reference a pandemic caused by the influenza virus.

³ The Ventilator Allocation Guidelines consist of four chapters: (1) Adult Guidelines, (2) Pediatric Guidelines, (3) Neonatal Guidelines, and (4) Implementing New York State’s Ventilator Allocation Guidelines: Legal Considerations.

⁴ See Appendix B for a list of the Pediatric Clinical Workgroup members. Meetings were held via teleconference and were held in February, March, April, October, and November 2013.

⁵ The terms “ventilator treatment” is used interchangeably with “ventilator therapy.”

⁶ During the novel H1N1 pandemic in California in 2009-10, of 94 pregnant women with influenza, 13 infants were born during their mothers’ hospitalization and 11 of whom were born preterm and needed intensive medical attention as a result of their prematurity and not because of influenza infection. Janice K. Louie et al., *Severe 2009 H1N1 Influenza in Pregnant and Postpartum Women in California*, 362 NEW ENG. J. MED. 27, 31 (2010).

applies equally to the neonatal clinical protocol.⁷ However, while the ethical framework is the same for all populations, there are special considerations when triaging children (see Chapter 2, Pediatric Guidelines) and additional concerns when neonates are involved.

There is broad societal consensus that children are vulnerable and should be protected, however, it is not clear whether the public would be more or less sensitive to the loss of neonates compared with toddlers and other children. Young babies may be perceived as the most vulnerable of all populations, and there may be a strong preference in devoting resources for their survival. Conversely, older children may have had time to build relationships with more individuals who have formed deeper emotional attachments to these children. While the loss of a neonate is tragic, the general public may have a preference for saving older children because of the bonds that people have already developed with these children.⁸ Furthermore, while policy-makers have at least acknowledged that preparedness efforts should also address pediatric issues, it is unclear whether this awareness includes neonates as evidenced by the dearth of guidance for this specific population. For example, currently, no U.S. state or other jurisdiction has a clinical protocol specifically for neonatal ventilator allocation.⁹

The Task Force and Neonatal Clinical Workgroup discussed that while young age does play a limited, but important, role in clinical ventilator allocation decisions, applying it as a triage criterion for neonates is not appropriate. As discussed in the Pediatric Guidelines, there is a strong justification to incorporate young age as a tie-breaking triage criterion when there are both children and adults eligible for ventilator therapy.¹⁰ However, the same reasoning does not apply when all patients are children. Both groups agreed that the application of young age as a triage criterion when a patient pool consists of *only* children was not appropriate because it would be nearly impossible to have consensus on which age range(s) would have the highest level of access to ventilators because the reasoning behind such threshold(s) is subjective.

Rather than relying on age as a determining triage criterion, the Neonatal Clinical Workgroup supported the conclusions of the Task Force and previous Clinical Workgroups that it would be best to rely instead on the core principles of triage to determine whether a patient

⁷ For a detailed discussion of the application of these principles to the development of a clinical ventilator allocation protocol, see Chapter 1, Adult Guidelines, Section IV. Ethical Framework for Allocating Ventilators.

⁸ Annie Javier et al., *The Best Interest Standard is not Applied for Neonatal Resuscitation Decisions*, 121 PEDIATR. 963, 968 (2008) (noting that the survey participants reduced the value of life of newborns, and particularly the preterm infant, and suggesting that newborns “do not have the same status as older individuals, because they lack personhood.”).

⁹ Utah’s pediatric triage guidelines briefly mention “premature infants” when examining patients for exclusion and inclusion criteria, although it does not specifically address the triage of neonates. Utah Hospitals and Health Systems Association for the Utah Department of Health, Utah Pandemic Influenza Hospital and ICU Triage Guidelines for Pediatrics, Version 4b (Jan. 29, 2010). While Ontario’s plan does include neonatal patients, they are subject to the same triage protocol for pediatric patients along with physician clinical judgment to determine whether a neonate is a candidate for a ventilator therapy trial. Ontario Ministry of Health and Long-Term Care, *Ontario Health Plan for an Influenza Pandemic* (2008), Chapter #18: Paediatric Services, http://www.health.gov.on.ca/en/pro/programs/emb/pan_flu/docs/plan_full.pdf.

¹⁰ For a discussion of the use of young age as a tie-breaking criterion when both adults and children are eligible for ventilator therapy, see Chapter 2, Pediatric Guidelines, Section V.A.3.b. Use of Young Age as a Secondary Triage Factor (Tie-Breaker). The Task Force proposed where all other clinical factors are substantially equal, young age may play a secondary (tie-breaker) role in triage and the ventilator may be allocated to the child.

receives ventilator therapy. The goal of saving the most number of lives would be best achieved by using a clinical framework to determine whether a patient is eligible for ventilator treatment based on his/her likelihood of survival with ventilator therapy. Specifically, the Task Force modified the definitions of triage and survival to ensure that patients for whom ventilator treatment would most likely be lifesaving are prioritized when the clinical ventilator allocation protocol is implemented.¹¹ Survival is based on the short-term likelihood of surviving the acute medical episode and is not focused on whether a patient will survive a given illness or disease in the long-term (e.g., years after the pandemic). Thus, all patients are subject to the same clinical ventilator allocation protocol and age would not be a primary triage criterion when the pool of patients eligible for ventilator treatment only consisted of children, including neonates.

Designing a clinical process by which to triage neonates raises a number of complicated issues. The physiologic and pathophysiologic processes for newborns are different than those of pediatric and adult patients. Furthermore, the patterns of newborn intensive care can also differ from adult and pediatric intensive care. For example, care given to neonates must often also consider physiologic maturation, i.e., lung development.

In addition, a clinical ventilator allocation protocol must also consider current resource levels for neonates. Health and critical care resources for neonates are even more limited than they are for older children due to the low numbers of critically ill neonatal patients in non-emergency circumstances.¹² For example, most of the neonatal intensive care units (NICUs) in New York State are located in metropolitan areas and primarily in New York City. In addition, outside of New York City, many facilities that provide basic maternity and newborn services will not have NICUs. Generally, depending on the acute care facility and the level of expertise and resources available, neonates use ventilators specific for infants and there is little potential to “share” ventilators with adults or older children.¹³ However, there may be circumstances where younger pediatric patients would be cared for in NICUs and vice versa, depending on the pandemic viral strain and available resources.

Generally, neonates that have been born in the hospital and require intensive care will be transferred to a NICU. For neonates who were previously discharged from the hospital, but require subsequent medical attention, these infants would be cared for in a pediatric intensive care unit (PICU) or admitted to a general floor for care. However, most people are unaware whether the hospital closest to their home provides comprehensive neonatal and/or pediatric care. Regardless, most parents of children will travel to the nearest acute care facility for medical attention.¹⁴

¹¹ For a discussion on the definitions of triage and survival, and application of the protocol to all patients in need of ventilator therapy, see Chapter 2, Pediatric Guidelines, Section IV. Overview of Concepts Used in Triage.

¹² Currently, there are 124 neonatal ventilators in the State compared to more than approximately 5,198 that could be used for pediatric patients. New York State Department of Health, Office of Health Emergency Preparedness Program, *Critical Assets Survey*, September 2015.

¹³ However, there are some ventilators that could be adjusted to accommodate all patients (i.e., neonates, pediatric, and adult patients). The conversion of a ventilator for use by neonates would require special equipment and staff expertise with regards to treating neonates.

¹⁴ Wanda D. Barfield et al., *Neonatal and Pediatric Regionalized Systems in Pediatric Emergency Mass Critical Care*, 12 PEDIATR. CRIT. CARE MED. S128, S130 (2011) (noting that for emergency care, nearly 90 percent of children are taken to an emergency department based upon location of the facility).

For pregnant women,¹⁵ health care providers must treat both the mother and fetus/neonate. Normally, for women who have been determined to have a “high-risk” pregnancy, plans for health care would be made in advance at a regional perinatal center that could accommodate the special needs of both pregnant women and neonates.¹⁶ For women with low-risk pregnancies, they would deliver their babies at the local facility that provides basic maternity and newborn services. However, if these women are suffering from influenza, they are at a high risk for preterm labor and delivery. With the complication of a possible extremely premature neonate, it may be difficult for the facility that typically only provides basic newborn services to provide long-term care for a very premature infant.¹⁷ Because treating neonates is such a specialized field that requires specific training, supplies, and equipment, it may be challenging for some hospitals, particularly rural ones, to care for a neonate when diversion to a facility with a NICU is not possible. In these circumstances, these women would be transferred to a regional perinatal center or an affiliated tertiary care hospital before the birth. If such a transfer is not possible and the baby is born, then the local facility should stabilize the infant and then arrange for transfer of the infant (and mother), if possible.

One must consider also the effects of dedicating intensive resources and staffing necessary for an individual neonate, especially for premature babies, which may not be possible during a pandemic. As staff and resources become scarce, it will be necessary to triage these patients and prioritize neonates who will have the highest likelihood of survival with ventilator therapy. Furthermore, extremely preterm neonates may require longer hospital stays, which further reduce the number of available ventilators. It is likely that the majority of the neonatal patients would be those born prematurely, because their mothers are ill with influenza, which could result in a longer duration for ventilator treatment.

Finally, although there are some ventilator-dependent chronic care patients who are neonates, the number of these patients is limited, compared to the numbers of pediatric and adult ventilator-dependent chronic care patients. Because the cutoff age for a neonate – up to 28 days old – is a small age range, these patients would quickly transition to become pediatric ventilator-dependent chronic care patients. Similar to the pediatric and adult protocols, the Task Force and Neonatal Clinical Workgroup agreed that neonatal ventilator-dependent chronic care patients are

¹⁵ Pregnant women do not receive special access to ventilator treatment and are subject to the adult clinical ventilator allocation protocol. However, while outside the scope of these Guidelines, pregnant women should be prioritized for vaccines and other prophylactic measures to *prevent* influenza. By preventing influenza, they would have better outcomes, including averting preterm delivery.

¹⁶ According to Department of Health vital records data, during non-emergency conditions, more than 80% of mothers identified as high risk were transferred to a regional perinatal center prior to delivering, and more than 90% of very low birth weight infants were delivered at a hospital designated at an appropriately high level, i.e., Level III or regional perinatal center. New York State Department of Health, Vital Records, 2012.

¹⁷ Many facilities that normally do not offer pediatric services would be able to at least stabilize or treat pediatric patients for short periods of time. The Department of Health has issued guidance to assist facilities that do not normally offer pediatric services with emergency planning preparation that is specific to children. However, the guidance does not provide specifics with regards to neonates. See New York State Department of Health, Health Emergency Preparedness Program & Division of Family Health, *Pediatric and Obstetric Emergency Preparedness Toolkit: A Guide for Pediatric and Obstetric Emergency Planning* (2010), http://www.health.state.ny.us/facilities/hospital/emergency_preparedness/guideline_for_hospitals/docs/emergency_preparedness_manual.pdf.

only subject to the neonatal clinical ventilator allocation protocol if they are transferred to an acute care facility.¹⁸

II. Possible Features of a Neonatal Clinical Ventilator Allocation Protocol

There is significant overlap in the various possible components of a neonatal clinical ventilator allocation protocol with a pediatric protocol. The Neonatal Clinical Workgroup used the pediatric protocol as a template to inform their discussions. The advantages and disadvantages of incorporating exclusion criteria, time trials, response to ventilation (oxygenation index), and duration of ventilator need/resource utilization will not be examined in this chapter, because they have been discussed in the Pediatric Guidelines (see Chapter 2, Pediatric Guidelines, Section VI. Possible Features of a Pediatric Clinical Ventilator Allocation Protocol). However, a few components that are different or unique to neonates are analyzed below.

A. Neonatal Clinical Scoring Systems

A review of medical literature identified the most commonly used neonatal clinical scoring systems that potentially could be utilized to allocate critical care resources. However, almost all of the scoring systems discussed below were developed to evaluate individual neonatal intensive care units (NICU) or to measure various NICU outcomes, such as overall mortality and organ dysfunction for an entire unit. These systems have not been validated to measure individual patient outcomes during a public health emergency or as a method to triage patients for critical care resources. The available neonatal-specific systems, SNAP II, CRIB II, NTISS, and NICHD NRN data, and their advantages and disadvantages are explored in further detail below.

1. Score for Neonatal Acute Physiology II (SNAP II)

SNAP II and its variation, SNAPPE-II,¹⁹ estimate the mortality outcome of a NICU generally. It collects information on six clinical variables (cardiovascular, pulmonary, hepatic, hematologic, renal, and neurologic) within 12 hours of NICU admission.²⁰ Data collection is relatively straightforward; each variable is assigned a numeric value and calculation of the score involves simple addition.²¹ SNAPPE-II does well with discrimination, i.e., predicting mortality risk overall, and also does fairly well with calibration (i.e., the ability to predict mortality in different ranges of mortality risk, such as high, moderate, or low risk categories).²² Although the data are collected within the first 12 hours of NICU admission, it includes responses to early

¹⁸ For a more detailed discussion on triaging ventilator-dependent chronic care patients, see Chapter 1, Adult Guidelines, Section VII. Triage Ventilator-Dependent Chronic Care Patients.

¹⁹ SNAPPE-II is known as SNAP-Perinatal Extension, which examines the SNAP variables with birth weight, Apgar score, and whether the infant is small for gestational age. Douglas K. Richardson et al., *Birth Weight and Illness Severity: Independent Predictors of Neonatal Mortality*, 91 PEDIATR. 969, 973 (1993).

²⁰ Douglas K. Richardson et al., *SNAP-II and SNAPPE-II: Simplified Newborn Illness Severity and Mortality Risk Scores*, 138 J. PEDIATR. 92, 94-95 (2001).

²¹ *Id.*, at 94.

²² *Id.*, at 96-97.

medical interventions and would not be applicable to the triage setting (i.e., triaging patients before admission into the NICU).

2. Clinical Risk Index for Babies II (CRIB II)

CRIB II examines five clinical variables (sex, birth weight, gestational age, temperature, and pH) within the first 12 hours after NICU admission.²³ Each variable is assigned a value and the score is calculated using simple addition.²⁴ While CRIB II has good discrimination (i.e., in predicting mortality risk overall), it only had adequate calibration (i.e., ability to predict mortality in different ranges of mortality risk).²⁵

3. Neonatal Therapeutic Intervention Scoring System (NTISS)

NTISS is a modification of TISS, the adult Therapeutic Intervention Scoring System, and was developed to examine mortality rates in NICUs. It consists of 63 clinical variables, which fall under the following categories: respiratory, cardiovascular, drug therapy, monitoring, metabolic/nutrition, transfusion, procedural considerations, and vascular access.²⁶ Data are collected within the first 24 hours of NICU admission and each variable is assigned a value.²⁷ The score is calculated by adding the sum of the values (score can be from 0 to 47).²⁸ While data collection is straightforward, the large number of data points to be collected may not be convenient during an emergency setting when time and resources are limited. Furthermore, for triage purposes, the large time window for data collection (24 hours) would not provide an accurate picture of a patient's mortality risk because medical interventions would have already been administered.

4. National Institute of Child Health & Human Development (NICHD) Neonatal Research Network (NRN): Extremely Preterm Birth Outcome Data

The NICHD NRN Data examined outcomes for infants born at NRN centers, based on specific standardized assessments, to help guide clinicians as they make health care decisions for extremely preterm infants.²⁹ Examining gestational age (weeks), birth weight (grams), sex, singleton or multiple birth, and use of antenatal corticosteroids³⁰ provided a more accurate predictor of infant outcomes than the use of gestational age alone, which was the standard practice in the past. The information for these factors is entered into an NICHD NRN web-based

²³ Gareth Parry et al., *CRIB II: An Update of the Clinical Risk Index for Babies Score*, 361 LANCET 1789, 1790 (2003).

²⁴ *Id.*, at 1791.

²⁵ *Id.*

²⁶ James E. Gray et al., *Neonatal Therapeutic Intervention Scoring System: A Therapy-Based Severity-of-Illness Index*, 90 PEDIATR. 561, 562 (1992).

²⁷ *Id.*

²⁸ *Id.*, at 563.

²⁹ Jon E. Tyson et al., *Intensive Care for Extreme Prematurity- Moving Beyond Gestational Age*, 358 NEW ENG. J. MED. 1672-1681 (2008) (data were collected from approximately 4,500 preterm infants born at Neonatal Research Network affiliated facilities between 1998 and 2003).

³⁰ Antenatal corticosteroids refer to whether the mother received any corticosteroids within seven days before giving birth to help the infant's lungs mature faster.

calculator and the possible outcomes: survival, death, and level of neurodevelopment impairment (moderate to severe or profound), are provided.³¹ While data collection is straightforward and can be easily calculated, it may not be possible to know the exact gestational age of the infant or whether the mother received antenatal corticosteroids. While this system may offer an estimate of mortality risk overall, it is unable to predict mortality in different risk ranges. Finally, like all other systems, it was never meant to predict an individual patient's outcome and is not validated for triage use.

5. Advantages and Disadvantages of a Clinical Scoring System

A clinical scoring system that examines a patient's overall health and provides an accurate assessment of mortality risk based on medical data would be a valuable resource when determining whether the patient will survive after a reasonable duration of ventilator treatment. It should be simple to use, with few variables or lab parameters, and the calculation of the score should not be complicated. Such a system would provide a consistent, objective approach to resource allocation. Furthermore, in the case of neonates, the system should incorporate other risk factors beyond the traditional ones, i.e., birth weight, gestational age, sex, race, and Apgar scores.

There are several disadvantages of utilizing a neonatal clinical scoring system to triage patients for scarce resources. First, it may not be appropriate to use a model that evaluates NICUs as a whole to estimate mortality risk for an individual patient. More specifically, while most of the systems discussed above may be applied to determine whether an individual patient may survive generally, the accuracy level varies when attempting to separate patients with an extremely high risk of dying – who are not likely to benefit from ventilator therapy – from those who have a moderate/low risk of dying – who have a stronger likelihood of benefiting from ventilator use. While neonatal clinical scoring systems may be able to generally categorize patients, they may not precisely identify whether an individual patient survives or who should receive ventilator therapy when there are limited resources.

Furthermore, none of these systems have been validated to measure individual patient's outcomes during a public health emergency and their use may not optimize limited resources.

B. Physician Clinical Judgment

Often, physician clinical judgment is an important component of neonatal care. The care of neonates is a highly specialized field where clinical expertise and judgment play a significant role. Physicians, especially those with extensive experience working with neonates in NICUs, have amassed vast evidence-based expertise and clinical practice that carefully guide their decisions about medical treatment.

However, some neonates may be disadvantaged when health care providers evaluating them are not neonatologists or pediatricians. Many facilities, particularly in more rural areas,

³¹ NIH, Eunice Kennedy Shriver National Institute of Child Health and Human Development, *NICHD Neonatal Research Network (NRN): Extremely Preterm Birth Outcome Data*, (Nov. 2012), http://www.nichd.nih.gov/about/org/der/branches/ppb/programs/epbo/pages/epbo_case.aspx.

will not have NICUs or neonatologists (or perhaps even pediatricians) on staff.³² Furthermore, the available staff may not have sufficient expertise with the unique clinical considerations of neonates to make informed triage decisions. In addition, the extreme circumstances of a public health emergency, such as an influenza pandemic, may severely compromise normally reliable clinical expertise. Not only will the number of available health care staff be reduced, but extreme fatigue, and other constraints may adversely affect clinical judgment. Finally, the use of physician clinical judgment may be vulnerable to inconsistencies and increases the potential for inequity and unintentional bias and may not be better than neonatal clinical scoring systems.³³

C. Apgar Score

An Apgar Score measures a newborn's appearance, pulse, reflex irritability, muscle tone, and respiration. Each variable is scored on a 0 to 2 scale, and the Apgar Score is based on the sum of these scores. The highest score is 10 and the higher the score, the better overall physical condition of the newborn. Generally, scores seven or higher are normal and scores lower than seven may indicate that the baby needs medical attention. The Apgar test is usually given to a baby twice – one minute after birth and again at five minutes after birth. If a score is low at the first minute, the score usually is within normal range (≥ 7) at the five minute evaluation. A low Apgar Score does not indicate that the baby will have serious or long-term health problems, because it was not developed to predict the future health of the baby. Instead, it is merely an indication of whether the baby may need assistance with breathing or circulation.³⁴

The Apgar Score is a convenient and simple tool to rapidly assess the physical condition/status of a newborn. However, because this test only applies to newborns, it would not apply to neonates who arrive at an acute care facility after their post-nursery discharge from the hospital. Furthermore, because it only is concerned with variables related to respiration and circulation, its utility as a tool to assess a patient's overall health is limited. Finally, it is not a tool to predict mortality because it does not differentiate between survivors and non-survivors.³⁵

³² Although neonatologists will not be available at many local/community hospitals, neonates would always be transferred – even in non-pandemic circumstances – to the nearest facility with neonatology expertise. Unlike pediatric patients, where local/community facilities could treat or at least temporarily care for these patients with appropriate planning, it would be highly unlikely that these hospitals would have the necessary equipment and expertise readily available to treat neonates either temporarily or for an extended amount of time.

³³ William Meadow et al., *Just, in Time: Ethical implications of Serial Predictions of Death and Mortality for Ventilated Premature Infants*, 208 PEDIATR. 732, 739 (2008) (noting that both clinical scoring systems (SNAP II and SNAPPE-II) and clinical intuitions of nurses, neonatal nurse practitioners, residents, fellows, and attending physicians offered approximately 50% in predicting whether sick, ventilated NICU patients would die in the NICU or survive to be discharged). However, when comparing physician clinical judgment and pediatric clinical scoring systems for pediatric patients, physician clinical judgment (i.e., physicians who worked closely with pediatric patients) was as good as or better than three scoring systems (M-SOFA, PEWS, and PRISA-II) evaluated. See Jill Sweney et al., *Comparison of Severity of Illness Scores to Physician Clinical Judgment for Potential Use in Pediatric Critical Care Triage*, 6 DISASTER MED. PUB. HEALTH PREP. 126, 129-130 (2012).

³⁴ Brian M. Casey et al., *The Continuing Value of the Apgar Score for the Assessment of Newborn Infants*, 344 NEW ENG. J. MED. 467, 467 (2001); National Institute of Health and National Library of Medicine, MedlinePlus, APGAR, <http://www.nlm.nih.gov/medlineplus/ency/article/003402.htm>.

³⁵ Casey et al., *supra* note 34, at 522.

D. Gestational Age

Gestational age, measured in weeks, is the length of time between the mother's first day of her last menstrual period and birth. A normal pregnancy can range from 37 to 42 weeks. The most accurate method of determining gestational age is during a woman's pregnancy (i.e., in utero), but it can also be estimated when the baby is born using a Ballard Score. If the gestational age is unknown, a neuromuscular and physical assessment of a newborn infant can also be performed to estimate gestational age. The condition of a neonate's skin, hair, eyes, ears, genitals, reflexes, muscle tone, posture, can provide a good estimate of gestational age.³⁶

Gestational age is important because it can offer insight regarding expected or potential health problems and is helpful to manage appropriately the medical needs of a neonate, especially a premature baby. For example, health care decisions may vary depending if the neonate is 24 weeks or 34 weeks gestational age.

Furthermore, depending on the extent of prematurity, gestational age may also be used as a factor to evaluate mortality risk, because there is a high correlation between young gestational age and mortality,³⁷ which could be helpful for triage purposes. Most medical guidelines suggest that before 23 weeks gestation, resuscitation should not be performed, while such procedures should be implemented for infants whose gestational age is 25 weeks or more.³⁸ However, there is not necessarily consensus on what the gestational age cutoff should be, which could complicate the use of this clinical factor in a triage protocol. Furthermore, while Ballard scores are often used, studies have demonstrated the inaccuracy of these scores for infants less than 28 weeks gestational age.³⁹ These scores often lead to a bias of overestimation of gestational age, which would affect the interpretation of a neonate's prognosis.⁴⁰

E. Birth Weight

Similar to gestational age, birth weight is also a strong indicator of viability,⁴¹ with particular regards to likelihood of survival. Very low birth weight is when a baby is born weighing less than 1500 grams (3.3 pounds or 53 ounces) and extremely low birth weight is

³⁶ Jeanne L. Ballard et al., *New Ballard Score, Expanded to Include Extremely Premature Infants*, 119 J. PEDIATR. 417, 418 (1991).

³⁷ Tyson et al., *supra* note 29, at 1673 and 1677.

³⁸ Dominic J.C. Wilkinson, *Gestational Ageism*, 166 ARCH. PEDIATR. ADOLESCENT MED. 567, 568 (2012) (examining guidelines issued by the American Academy of Pediatrics, American Heart Association, British Association of Perinatal Medicine, Dutch Pediatric Association, and the European Resuscitation Council). *See also* American Academy of Pediatrics and American Heart Association, *Textbook of Neonatal Resuscitation*, John Kattwinkel, ed. 5th edition, (2013) p. 9-5 (noting that non-initiation of resuscitation is appropriate for neonates less than 23 weeks confirmed gestational age).

³⁹ *See* Edward F. Donovan et al., *Inaccuracy of Ballard Scores Before 28 Weeks' Gestation*, 135 J. PEDIATR. 147, 151(1999).

⁴⁰ *Id.*

⁴¹ Viability indicates the possibility for a newborn to live to a specified endpoint (for purposes of these Guidelines, the endpoint is discharge from the acute care facility).

defined as less than 1000 grams (2.2 pounds or 35 ounces).⁴² Extremely low birth weight babies are more likely to suffer from complications related to their preterm birth, both in the immediate neonatal period and post-nursery discharge, which can increase their mortality risk.

The most common cause of low birth weight is preterm labor, which causes the baby to be delivered before 37 weeks gestational age. During an influenza pandemic, it is expected that pregnant women suffering from complications of the virus will deliver their babies before full term, and depending on the gestational age at the time of birth, the care of low birth weight babies could potentially be a problem for facilities, especially at hospitals without NICUs. Caring for such fragile patients will be an issue because they do not have the resources, such as staff expertise and equipment, to properly care for this population.

While birth weight is an important factor that does affect mortality rates, similar to the concept of gestational age, it may be difficult to determine an exact birth weight value that could be used as a triage criterion. However, there is a certain threshold where there is a high correlation between extremely low birth weight and mortality where resuscitation may not be appropriate.⁴³ Often, outcomes rely heavily on the available medical treatments and physician clinical judgment, which may be more important than birth weight.

III. New York's Clinical Ventilator Allocation Protocol for Neonates: Rationale and Clinical Components

A brief summary of the neonatal clinical ventilator allocation protocol, developed by the Neonatal Clinical Workgroup and the Task Force, is presented below, followed by an explanation of the details and rationales. Although the Adult, Pediatric, and Neonatal Guidelines do not utilize the exact same clinical tools to evaluate the patient, the ethical and clinical frameworks of all three remain the same.⁴⁴

As with the adult and pediatric clinical ventilator allocation protocols,⁴⁵ all neonatal acute care patients who are in need of a ventilator, whether due to influenza or other conditions, are subject to the clinical protocol.⁴⁶ Using clinical criteria, patients who are deemed most likely to survive with ventilator treatment have an opportunity for ventilator therapy to maximize the

⁴² K.N. Siva Subramanian et al., WebMD, Medscape Reference, Extremely Low Birth Weight Infant, <http://emedicine.medscape.com/article/979717-overview#a1>.

⁴³ American Academy of Pediatrics and American Heart Association, Textbook of Neonatal Resuscitation, John Kattwinkel, ed. 5th edition (2013) p. 9-5 (noting that an example where non-initiation of resuscitation is appropriate may include a birth weight of less than 400 grams).

⁴⁴ Both the Task Force and the Neonatal Clinical Workgroup concluded that the pediatric ventilator allocation protocol could not be applied to neonates. However, efforts were made, where appropriate, to adhere to the basic framework of the adult and pediatric clinical ventilator allocation protocols (i.e., three steps) to provide uniformity for a triage officer/committee.

⁴⁵ For the Guidelines, survival is defined as survival of the acute medical episode that necessitates ventilator therapy. Some patients may be hospitalized for influenza, but others may be hospitalized for different reasons including emergency surgery. Likelihood of survival is based on whether a patient is alive at hospital discharge, and not based on whether the patient survives long-term after discharge (e.g., one year later). See Chapter 2, Pediatric Guidelines, Section IV. Overview of Concepts Used in Triage.

⁴⁶ Certain families on behalf of their infant may decide to decline ventilator therapy. Such decisions to withhold or withdraw ventilator treatment should be implemented in the same way they are in a non-emergency situation.

number of survivors. The neonatal clinical ventilator allocation protocol applies to all patients 28 days old and younger in all acute care facilities Statewide and it consists of three steps (each of which is discussed in greater detail in the following subsections):

- **Step 1 – Exclusion Criteria.** A patient is screened for exclusion criteria, and if s/he has a medical condition on the exclusion criteria list, the patient is not eligible for ventilator therapy. Instead, a patient receives alternative forms of medical intervention and/or palliative care.
- **Step 2 – Mortality Risk Assessment Using Physician Clinical Judgment.** Physician clinical judgment by a patient’s attending physician is used to assess the patient’s risk of mortality. A triage officer/committee examines clinical data from Steps 1 and 2 and allocates ventilators according to a patient’s mortality risk.
- **Step 3 – Time Trials.** Periodic clinical assessments at 48 and 120 hours are conducted on a patient who has begun ventilator therapy to evaluate whether s/he continues with treatment. Various clinical parameters are examined at this step to assess the possibility of organ failure/mortality risk and to measure lung function. The decision whether a patient remains on a ventilator is based on ongoing clinical measures and data trends of the patient’s health condition, consisting of: (1) the overall prognosis estimated by the patient’s clinical indicators, which is indicative of mortality risk by revealing the presence (or likelihood), severity, and number of acute organ failure(s), and (2) the magnitude of improvement or deterioration of overall health, which provides additional information about the likelihood of survival with ventilator therapy. These results are compared to the results from the previous official clinical assessment.

The person (triage officer) or group of people (triage committee) who determines whether a patient receives (or continues with) ventilator treatment is not the physician attending to the patient.⁴⁷ The attending physician’s role is to evaluate a patient for exclusion criteria in Step 1 and to assess the patient’s mortality risk and organ failure risk in Steps 2 and 3. In order to facilitate the triage process, the patient’s clinical data are presented to a triage officer/committee who determines a patient’s level of access to a ventilator (i.e., who is eligible and/or continues with ventilator therapy). Ideally, a triage officer/committee has experience working with neonatal patients.⁴⁸

A triage officer/committee examines a patient’s clinical data and uses this information to assign a color code to the patient at Steps 2 and 3. The color (blue, red, yellow, or green) determines the level of access to a ventilator (blue = lowest access/palliate/discharge, red =

⁴⁷ Because facilities differ in size and available resources, each facility should determine whether a triage officer or committee is more appropriate. For a discussion of the benefits and drawbacks of both models, *see* Chapter 1, Adult Guidelines, Section V. Triage Decision-Makers: Officer or Committee.

⁴⁸ It is possible that a triage officer/committee at the facility would triage both pediatric and neonatal patients. Ideally, the person or committee should have experience working with neonatal patients. Some facilities, depending on the availability of specialized staff, may designate a neonatal specialist as a member of the triage committee.

highest access, yellow = intermediate access, and green = defer/discharge).⁴⁹ Patients with the red color code have the highest level of access to a ventilator because they are most likely to recover with treatment (and not likely to recover without it) and have a moderate risk of mortality. If resources are available, patients in the yellow category also have access to ventilator treatment.⁵⁰ Those assigned the blue code are patients who potentially have the worst outlook for survival, even with ventilator therapy, and therefore have lowest access. The green category represents patients who are most likely to survive without ventilator therapy or are eligible for ventilator weaning. If resources become available, patients in the blue color category, or those with exclusion criteria, are reassessed and may become eligible for ventilator therapy.

Alternative forms of medical intervention are provided to those who are not eligible for a ventilator or these patients may be discharged. In addition, palliative care is provided to all patients throughout the triage process, regardless of prognosis. Furthermore, patients' families may decide to decline ventilator therapy and these patients would also receive appropriate medical care. Patients with a high risk of mortality and poor response to ventilation have a low likelihood of improving within a reasonable time frame, such that the ventilator may be allocated to another patient with a higher likelihood of survival. These patients are provided with alternative forms of medical intervention and/or palliative care, where appropriate.⁵¹

Finally, the Task Force and the Neonatal Clinical Workgroup acknowledged that the triage process requires regular reassessments of the status of the pandemic, available resources, and of all patients.⁵² Thus, as new data and information about the pandemic viral strain become available during a pandemic, the neonatal clinical ventilator allocation protocol may be revised accordingly to ensure that triage decisions are made commensurate with updated clinical criteria.

A. Step 1: Exclusion Criteria

Summary of Step 1: A patient is screened for exclusion criteria, and if s/he has a medical condition on the exclusion criteria list, the patient is not eligible for ventilator therapy. Instead, a patient receives alternative forms of medical intervention and/or palliative care.

1. Exclusion Criteria

The Task Force and the Neonatal Clinical Workgroup determined that although the use of exclusion criteria may not significantly reduce the number of neonates eligible for ventilator therapy, it still may be a useful tool in the initial stage of the triage process.⁵³ Applying

⁴⁹ These colors are consistent with the colors and recommended actions of the adult clinical ventilator allocation protocol. In addition, these colors are also consistent with other tertiary triage protocols and are universally recognized for triage purposes.

⁵⁰ However, during the peak of the pandemic, it is unlikely that patients in the yellow category have access to ventilators because there will be more red code patients than available ventilators.

⁵¹ For a discussion of pediatric palliative care, *see* Chapter 2, Pediatric Guidelines, Section X.B. Palliative Care.

⁵² For a discussion of real-time data collection and analysis, *see* Chapter 1, Adult Guidelines, Section XIII.B. Real-Time Data Collection and Analysis and Modification of the Guidelines.

⁵³ In contrast, the use of exclusion criteria in the adult clinical ventilator allocation protocol will likely reduce the number of eligible patients for ventilator therapy more significantly.

exclusion criteria will identify patients with the highest probability of mortality, even with ventilator therapy, to prioritize patients most likely to survive with ventilator therapy in a situation of scarce resources. In addition, evaluating a patient for exclusion criteria may not consume large amounts of time or resources, as the presence of an exclusion criterion may be obvious. Alternatively, if medical information is not readily available or accessible, it may be assumed a patient is free of exclusion criteria and may proceed to the next step of the clinical ventilator allocation protocol.

Once it had determined that the use of exclusion criteria was acceptable as an initial triage step, the Neonatal Clinical Workgroup addressed the acceptable time frame of expected mortality for a condition to be placed on the exclusion criteria list.⁵⁴ The Workgroup agreed that there was little evidence-based data to indicate that mortality for a medical condition with a short life expectancy would occur within a six, 12, or 24 month window.⁵⁵ Furthermore, because the Task Force modified the definition of survival to be based on the short-term likelihood of survival of the acute medical episode and is not focused on whether a patient may survive a given illness or disease in the long-term (e.g., years after the pandemic), many conditions that may be fatal within a few years were not relevant to consider. Thus, the Neonatal Clinical Workgroup reaffirmed that because the purpose of applying exclusion criteria is to identify patients with a short life expectancy irrespective of the current acute illness, in order to prioritize patients most likely to survive with ventilator therapy. The medical conditions that qualify as exclusion criteria are limited to those associated with immediate or near-immediate mortality even with aggressive therapy.

While a majority of medical conditions from the pediatric clinical ventilator allocation protocol's exclusion criteria list were adopted with some minor modifications for the neonatal clinical ventilator allocation protocol,⁵⁶ the Neonatal Clinical Workgroup included additional conditions that were more specific to the population. For example, two conditions specific to neonates, gestational age and birth weight, were added because limited to those with there is robust evidence that gestational age and birth weight are strong indicators of mortality.⁵⁷

Furthermore, as with the adult and pediatric clinical protocols, the exclusion criteria list for neonates is also, by necessity, flexible. Because it would be impossible to list every medical condition that would result in immediate or near-immediate mortality, the exclusion criteria list includes a “catch all” phrase that encompasses other possibilities. In addition, real-time data of the pandemic viral strain may require altering the list of exclusion criteria. For example, it may

⁵⁴ For a discussion on the acceptable time frame of expected mortality for a condition to be listed as an exclusion criterion, *see* Chapter 2, Pediatric Guidelines, Section IX.A.1. Step 1: Exclusion Criteria.

⁵⁵ For example, a neonatal patient with a known fatal chromosomal abnormality who is ill with influenza is not necessarily excluded from ventilator therapy, because his overall health is stable and he is only ill with influenza. This patient could recover from influenza and live more than six months.

⁵⁶ For the exclusion criteria list in the pediatric clinical ventilator allocation protocol, *see* Chapter 2, Pediatric Guidelines, Section IX.A.1. Step 1: Exclusion Criteria. The burns criterion was deleted because it was highly improbable that a neonate would have such a condition. Other medical conditions were modified to account for the standard of care provided to neonates.

⁵⁷ American Academy of Pediatrics and American Heart Association, *Textbook of Neonatal Resuscitation*, John Kattwinkel, ed. 6th edition, 2011. p. 288 (noting that examples where non-initiation of resuscitation is appropriate may include a confirmed gestational age of less than 23 weeks or a birth weight of less than 400 grams).

become apparent that patients affected with influenza and a particular medical condition never survive regardless of ventilator treatment. In such cases, this condition would be added to the exclusion criteria list.

Finally, any patient whose exclusion criterion was not discovered initially continues to the next triage step. However, this patient likely will be ruled ineligible for ventilator therapy during the subsequent triage steps, because precise real-time clinical data about the patient's health continue to be gathered.

2. Triage Chart for Step 1

The Neonatal Clinical Workgroup reached consensus on the following exclusion criteria list. This list focuses primarily on medical conditions limited to those associated with immediate or near-immediate mortality even with aggressive therapy. A patient's attending physician examines his/her patient for an exclusion criterion and will forward this clinical data to a triage officer/committee to make the triage decision. Patients with exclusion criteria do not have access to ventilator therapy and instead are provided with alternative forms of medical intervention and/or palliative care.⁵⁸

Step 1 - List of Exclusion Criteria for Neonatal Patients⁵⁹ 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 therapy¹

¹This "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.

⁵⁸ See Section IV. Alternative Forms of Medical Intervention and Palliative Care. However, if a ventilator becomes available and no other patient is in need of ventilator therapy, a patient with an exclusion criterion may be eligible for this treatment.

⁵⁹ Because there is often misunderstanding regarding the immediate or near-immediate mortality risk of many medical conditions, the Neonatal Clinical Workgroup provided some examples of conditions that would not be part of the exclusion criteria. Examples of conditions that would be not exclusionary, include, but are not limited to: trisomy 21, operable congenital heart disease, DiGeorge Sequence, gastroschisis/omphalocele, VACTERL association, Turner's syndrome, Klinefelter syndrome, congenital diaphragmatic hernia, meningomyelocele (low thoracic, lumbar), hydrocephalus, congenital infection with or without central nervous system involvement, hypoxic-ischemic encephalopathy regardless of severity, grade III/IV intracranial hemorrhage, and holoprosencephaly sequence.

B. Step 2: Mortality Risk Assessment Using Physician Clinical Judgment

Summary of Step 2: Physician clinical judgment by a patient's attending physician is used to assess the patient's risk of mortality. A triage officer/committee examines clinical data from Steps 1 and 2 and allocates ventilators according to a patient's mortality risk.

1. Physician Clinical Judgment

While the adult clinical ventilator allocation protocol uses a clinical scoring system, SOFA (Sequential Organ Failure Assessment), to assess mortality risk to determine whether a patient is eligible initially for ventilator therapy,⁶⁰ currently available neonatal clinical scoring systems cannot be applied in the same manner. Similar to the Pediatric Clinical Workgroup, the Neonatal Clinical Workgroup also rejected the use of a neonatal clinical scoring system at this step of the triage process. The neonatal clinical scoring systems require data that are only available *after* a patient has received medical intervention and therefore should not be used to determine which prospective patient would benefit from ventilator therapy. In addition, none of the systems have been validated for triage purposes in neonates.

Until a neonatal clinical scoring system is developed and validated for triage use,⁶¹ the Neonatal Clinical Workgroup recommended that physician judgment based on clinical expertise be used to evaluate the likelihood of survival, to determine whether a neonatal patient is eligible for ventilator therapy. Despite the various reservations physician clinical judgment entails, the Workgroup concluded its strengths outweighed its weaknesses. Physician clinical judgment consists of a structured decision-making process that carefully considers only specific clinical factors based on available medical evidence and not personal values or subjective judgments, such as quality of life. Although the clinical assessment does not provide a numerical score (unlike the adult protocol that provides a quantitative SOFA score), it offers an organized, rational framework to make allocation decisions in a uniform manner. Ideally, in order to make informed decisions, the attending physician and triage officer/committee should have experience working with neonates.⁶²

The attending physician's evaluation is based solely on clinical criteria, including the acute severity of a patient's current medical condition, the epidemiology of the disease, and the existence and status of any severe underlying diseases or medical conditions (co-morbidities) that may hinder recovery. A mortality risk prediction is based on whether a patient could survive

⁶⁰ See Chapter 1, Adult Guidelines, Section XI.B. Step 2: Mortality Risk Assessment Using SOFA.

⁶¹ The Neonatal Clinical Workgroup recognized that there was an urgent need for a new neonatal scoring system that not only predicts a patient's likelihood of survival at initial triage, but also incorporates short-term utilization of intensive care resources, such as ventilators. This novel system would provide better accuracy regarding whether a neonatal patient will recover with low resource use. This system would identify whether a neonatal patient would benefit from a short-term trial of ventilator therapy and would ensure the greatest number of neonatal survivors.

⁶² Unfortunately, many facilities that do not normally provide long-term health care treatment to children may not have clinicians with sufficient neonatal experience. These facilities need to make accommodations to implement this recommendation, such as provide neonatal health care training to a triage officer/committee. For more information on emergency preparation for facilities that do not have pediatric or newborn care services, see New York State Department of Health, Health Emergency Preparedness Program & Division of Family Health, *Pediatric and Obstetric Emergency Preparedness Toolkit: A Guide for Pediatric and Obstetric Emergency Planning*, NEW YORK STATE DEPARTMENT OF HEALTH (2010).

the acute medical episode that necessitates ventilator therapy. It is not focused on whether a patient survives in the long-term (e.g., years after the pandemic). Physicians should use all appropriate and available medical tools to conduct the most thorough examination possible in emergency circumstances. Given the potential constraints associated with an influenza pandemic, mortality risk predictions should be based on the best clinical evidence available.

The Neonatal Clinical Workgroup, similar to the Pediatric Clinical Workgroup, also concluded that in Step 2, physicians may also consider severe, end-stage chronic medical conditions when assessing mortality risk. The presence of comorbidities complicates a patient's ability to survive and may also cause the patient's acute illness (i.e., influenza) to be more severe. However, existence of such a condition should not, by itself, preclude a patient from being eligible for ventilator therapy. Instead, physicians should examine a patient's overall health to evaluate the patient's current health status. Even for a patient diagnosed with a fatal condition, periods of relatively good health are possible and the mere presence of a grave illness should not necessarily preclude the patient from receiving ventilator therapy. In some circumstances, a patient with a severe medical condition may require ventilator therapy because of influenza and not because of the chronic care disease itself.⁶³

Furthermore, the Neonatal Clinical Workgroup agreed with the Pediatric Clinical Workgroup and the Task Force and was reluctant to incorporate resource utilization, such as estimated duration of ventilator need, as a stand-alone (primary) triage factor. Both Workgroups recognized that accurately predicting the estimated length of time a patient may need ventilator therapy may be useful to identify ideal patients for treatment so that ventilators could be utilized by as many people as possible who have a high likelihood of survival. However, at this time, it is impossible to offer any reasonable quantitative projection regarding need without information about the pandemic viral strain. Instead, the Workgroups reasoned that a patient's comorbidity(s) (which could include influenza) implies a general exacerbation of mortality risk and duration of ventilator need beyond what is typical for the acute illness/injury that requires medical attention. Thus, the Workgroups recognized that duration of ventilator need may be considered indirectly as a qualitative factor in a triage decision.⁶⁴

In addition, the Task Force believed that because resource utilization/duration of ventilator need is not a stand-alone criterion of the adult clinical ventilator allocation protocol, it is not appropriate to include such a triage factor in pediatric or neonatal protocols, especially because its consideration does not affect a patient's likelihood of survival.⁶⁵ It may only be

⁶³ For example, a neonate with a serious condition may not have a long-term survival prognosis, but if the patient's health is currently, relatively stable, the child may still be eligible for ventilator therapy, i.e., be placed in the red or yellow categories. However, if the same infant was in failing health, this patient would be placed in the blue category and given alternative forms of medical intervention and/or palliative care rather than a ventilator.

⁶⁴ As more data become available about the viral strain during a pandemic, it may be possible to know how many days of ventilation are required to recover, which may influence the mortality risk assessment and the triage decision.

⁶⁵ For example, the 2007 Draft Guidelines included renal dialysis as an exclusion criterion in the adult clinical ventilator allocation protocol. However, the Task Force reassessed the list of exclusion criteria and determined that although renal failure increases the morbidity and mortality risks to a patient, excluding a patient who is dialysis dependent was based on heavy resource utilization issues rather than likelihood of survival and this criterion was removed from the exclusion criteria list. *See* Chapter 1, Adult Guidelines, Section XI.A. Step 1: Exclusion Criteria.

useful to identify patients who may only require a short treatment so that the number of patients treated by ventilation could be increased. Finally, in order to incorporate resource use/duration of ventilator need as an explicit criterion in the neonatal clinical ventilator allocation protocol unfairly subjects children to a more complex triage process.

A patient's clinical data from Steps 1 and 2 are provided to a triage officer/committee who examines the information and assigns a patient a color code (i.e., blue, red, yellow, or green), which determines the patient's level of access to ventilator therapy (see chart below).⁶⁶ Blue code patients (lowest access/palliate/ discharge) are those who have a medical condition on the exclusion criteria list or those who have a high risk of mortality and these patients do not receive ventilator treatment.⁶⁷ Instead, alternative forms of medical intervention and/or palliative care are provided. Red code patients (highest access) are those who have the highest priority for ventilator treatment because they are most likely to recover with treatment⁶⁸ (and likely to not recover without it) and have a moderate risk of mortality. Patients in the yellow category (intermediate access) are those who are very sick and their likelihood of survival is intermediate and/or uncertain. These patients may or may not benefit (i.e., survive) with ventilator therapy. They receive such treatment if ventilators are available after all patients in the red category receive them. Patients in the green color code (defer/discharge) are those who do not need ventilator therapy.

⁶⁶ The triage chart is adapted from New York's Adult Guidelines, the Working Group on Adult Critical Care Admission, Discharge, and Triage Criteria, *Critical Care During a Pandemic*, Ontario Health Plan for an Influenza Pandemic (OHPiP), 8 (2006), http://www.cidrap.umn.edu/sites/default/files/public/php/21/21_report.pdf, and the Pandemic Ethics Initiative Work Group, *Meeting the Challenge of Pandemic Influenza: Ethical Guidance for Leaders and Health Care Professionals in the Veterans Health Administration*, Veterans Health Administration, National Center for Ethics in Health Care, v (July 2010), http://www.ethics.va.gov/docs/pandemicflu/Meeting_the_Challenge_of_Pan_Flu-Ethical_Guidance_VHA_20100701.pdf.

⁶⁷ However, if a ventilator becomes available and no other patients are in need of ventilator therapy, a patient with a blue color code may be eligible for this treatment.

⁶⁸ Red color code patients are sick enough to require ventilator therapy to survive and will do poorly if they do not receive it. However, these patients are not so severely ill that they will still benefit (i.e., survive) with ventilator treatment. Prioritizing these patients for ventilator therapy, ideally, increases the number of survivors by ensuring that patients receiving ventilator therapy are those who have a high likelihood of recovering.

2. Triage Chart for Step 2

A triage officer/committee allocates ventilators according to the color code assigned.⁶⁹

Step 2 - Mortality Risk Assessment Using Physician Clinical Judgment¹	
Color Code and Level of Access	Assessment of Mortality Risk/Organ Failure
<p>Blue</p> <p>No ventilator provided.</p> <p>Use alternative forms of medical intervention and/or palliative care or discharge.</p> <p>Reassess if ventilators become available.</p>	<p>Exclusion criterion</p> <p>OR</p> <p>HIGHEST risk of mortality associated with acute illness/injury (including epidemiology of the disease, if known) and</p> <p>Presence of SEVERE chronic comorbidity likely to worsen mortality risk or duration of ventilator treatment beyond that typical for the acute illness/injury</p>
<p>Red</p> <p>Highest</p> <p>Use ventilators as available</p>	<p>MODERATE risk of mortality, such as single organ failure,² associated with acute illness/injury (including epidemiology of the disease, if known) and</p> <p>NO severe chronic comorbidity likely to worsen mortality risk or duration of ventilator treatment beyond that typical for the acute illness/injury</p>
<p>Yellow</p> <p>Intermediate</p> <p>Use ventilators as available</p>	<p>HIGH/UNCERTAIN risk of mortality associated with acute illness/injury (including epidemiology of the disease, if known) and</p> <p>Presence of MODERATE chronic comorbidity likely to worsen mortality risk or duration of ventilator treatment beyond that typical for the acute illness/injury</p>
<p>Green</p> <p>Use alternative forms of medical intervention or defer or discharge.</p> <p>Reassess as needed.</p>	<p>LOW risk of mortality associated with acute illness/injury (including epidemiology of the disease, if known) and</p> <p>NO chronic comorbidity likely to worsen mortality risk or duration of ventilator treatment beyond that typical for the acute illness/injury</p>

¹ If a patient develops a condition on the exclusion criteria list at any time from the initial assessment to the 48 hour assessment, change color code to blue. Remove the patient from the ventilator and provide alternative forms of medical intervention and/or palliative care.

² Intubation for control of the airway (without lung disease) is not considered lung failure.

⁶⁹ A triage officer/committee determines whether a patient in the red (and possibly yellow) color category receives ventilator therapy. Decisions also need to be made regarding which patient within each color code receives ventilator treatment. For a discussion on how such decisions are made, *see* Section III.B.3. Decision-Making Process for Selecting an Eligible Patient for a Ventilator.

Physicians may also consider severe, end-stage chronic medical conditions when assessing mortality risk. However, the extent of functional health impairment, rather than the medical diagnosis itself, should guide decision-making when evaluating a patient's current health status. The mere existence of such a condition should not, by itself, preclude a patient from being eligible for ventilator therapy. Examples of severe chronic conditions that adversely impact health functionality include, but are not limited to: Trisomy 13 and 18, anencephaly, and high thoracic meningocele.

When examining chronic comorbidity, severe comorbidity is functionally defined as significant chronic impairment/deteriorating of health prior to the acute illness/injury. Moderate comorbidity is functionally defined as significant chronic impairment of health but a patient is in a steady health state prior to the acute illness/injury.

For most patients who are sick with only influenza and have no other comorbidities, the single organ failure is limited to their lungs. However, because the neonatal clinical ventilator allocation protocol applies to all patients in need of a ventilator, a patient may also have a comorbidity(s) that affects another organ system(s) and his/her mortality risk assessment. Intubation for control of the airway (without lung disease) is not considered lung failure.

Finally, when assigning patients color codes, the Neonatal Clinical Workgroup concluded that a triage officer/committee must determine how to define what the cutoffs should be for highest, high/uncertain, moderate, and low risk of mortality risk categories because there are no evidence-based data early in a pandemic. Given the potential constraints associated with an influenza pandemic, mortality risk predictions should be based on the best clinical evidence available. However, the basic principle is that the more severe a patient's health condition is based on the clinical factors delineated above, the less likely s/he survives, even with ventilator therapy. Therefore, triage decisions should be made accordingly. As more data become available during a pandemic regarding patient outcomes and best practices for treatment, a triage officer/committee will incorporate this evidence-based data into the triage decision.

3. Decision-Making Process for Selecting an Eligible Patient for a Ventilator

At Step 2, a triage officer/committee may encounter a situation where there are several neonatal patients in the red color code,⁷⁰ who are equally eligible for ventilator therapy. Further clinical examination of these patients in the red color category may not be useful or possible in a pandemic because it has already been determined using exclusion criteria and physician clinical judgment that all the individuals have equal (or near equal) likelihoods of survival.⁷¹ Therefore, the question of how a triage officer/committee should select an eligible patient must be addressed.⁷²

⁷⁰ While the yellow category may also have eligible patients waiting for ventilator therapy, all red code patients must be attended to first. If there are no red code patients, and only yellow code patients, then the same decision-making process applies.

⁷¹ For these Guidelines, all patients in the same color category have the same likelihood of survival.

⁷² For a discussion on review of a triage decision and the appeals process, *see* Chapter 4, Implementing New York State's Ventilator Allocation Guidelines: Legal Considerations, Section VI. Appeals.

It is not appropriate for a triage officer/committee to compare patients within the same color category. The parents/legal guardians of neonates expect that doctors provide treatment, to the extent possible, based on assessments of a patient's health as an individual. If ventilator use is primarily determined by the health of *other* patients, clinicians must abandon their obligation to advocate/care for their individual patient. This proposal evokes a war of all against all that ignores health care workers' deep professional obligations to advocate and care for individual patients. To compare patients with each other could force a triage officer/committee to prematurely withdraw ventilators from patients more often, and could lead to fewer patients surviving. Furthermore, such comparisons may intensify inherent biases in the health care system and the disproportionate and disparate provision of care for already disadvantaged populations.

Because a clinical evaluation has been performed and there are no other evidence-based clinical factors available to consider, a non-clinical method must be used to determine which neonatal patient among the eligible patients receives ventilator therapy. A secondary allocation system may be first-come first-serve or a randomization process (such as a lottery). While these approaches were problematic to use to initially triage patients,⁷³ they are useful and acceptable to use as secondary triage criteria. A non-clinical system used at this triage step only is employed after a triage officer/committee determines that all available clinical measures are (nearly) equivalent for the eligible patients, which implies that all of these individuals have equal (or near equal) likelihoods of survival (i.e., in the same color category), and all patients are neonatal patients.

The Task Force and the Neonatal and Pediatric Workgroups considered both first-come first-serve and random selection (e.g., lottery) methods. While first-come first-serve is straightforward and is easy to implement, it disadvantages those who are of lower socio-economic means who may not have access to information about the pandemic or to reliable transportation, or minority populations who might initially avoid going to a hospital because of distrust of the health care system. Despite the various administrative and logistical barriers of conducting a random selection process,⁷⁴ the Task Force and Workgroups recommended this approach because such a system is easy to understand and can be implemented with some advance planning.

A random process should be used to choose a neonatal patient for ventilator therapy when there are more eligible neonatal patients than ventilators available.⁷⁵ In addition, a random selection method is conducted each time a ventilator becomes available. Finally, patients waiting for ventilator therapy wait in an eligible patient pool and receive alternative forms of medical intervention and/or palliative care until a ventilator becomes available.

⁷³ See Chapter 1, Adult Guidelines, Section VIII. Non-Clinical Approaches to Allocating Ventilators.

⁷⁴ See Chapter 1, Adult Guidelines, Section VIII.B. Randomization.

⁷⁵ If the pool of eligible patients includes both neonates and children, and assuming both sets of patients have equal (or near equal) probabilities of survival, a random selection method is still used. In theory, an allocation plan could establish age cutoffs to determine which age range(s) have priority access to ventilators over another age group. However, reaching consensus on age cutoffs is extremely difficult since the reasoning behind such thresholds is subjective. If the eligible patient pool includes both adults and children, a different non-clinical method is used (i.e., young age). See Chapter 2, Pediatric Guidelines, Section V.A.3.b. Use of Young Age as a Secondary Triage Factor (Tie-Breaker) and Section IX.F. Interface between Pediatric and Adult Patients.

C. Step 3: Periodic Assessments for Continued Ventilator Use (Time Trials)

Summary of Step 3: Periodic clinical assessments at 48 and 120 hours are conducted on a patient who has begun ventilator therapy to evaluate whether s/he continues with treatment. Various clinical parameters are examined at this step to assess the possibility of organ failure/mortality risk and to measure lung function. The decision whether a patient remains on a ventilator is based on ongoing clinical measures and data trends of the patient's health condition, consisting of: (1) the overall prognosis estimated by the patient's clinical indicators, which is indicative of mortality risk by revealing the presence (or likelihood), severity, and number of acute organ failure(s), and (2) the magnitude of improvement or deterioration of overall health, which provides additional information about the likelihood of survival with ventilator therapy. These results are compared to the results from the previous official clinical assessment.

1. Time Trials

In a public health emergency, periodic evaluations of a patient after s/he has begun ventilator therapy is necessary to determine whether the therapy is effective for that patient while allowing for efficient allocation of scarce ventilators. It also assists health care workers responsible for the day-to-day care of a patient by presenting uniform guidance on when official assessments are to occur. Finally, the use of time trials gives a triage officer/committee valuable information about the status and real-time availability of ventilators.

Time trials are necessary to determine whether a patient receiving ventilator therapy continues with this form of medical intervention. A patient showing improvement continues with ventilator therapy until the next assessment, and if the patient no longer meets the criteria for continued use, s/he receives alternative forms of medical intervention. Until more data about the pandemic viral strain become available during a pandemic, the length of an appropriate time trial is unknown. Shorter trials (e.g., 24 hours) permit more patients access to ventilator therapy, but require more extubations for a larger number of patients, a situation the Guidelines should attempt to minimize.⁷⁶ In contrast, long time trials result in fewer patients receiving ventilator therapy.

The Neonatal Clinical Workgroup suggested time trials of 48 and 120 hours, which mirror the pediatric (and adult) intervals, are acceptable. Because there are no evidence-based data to suggest what a time trial for ventilator use should be for neonates, the Workgroup and the Task Force concluded that for ease of use and consistency, time trials for neonatal patients should be the same as for pediatric patients.⁷⁷ In the case of an influenza pandemic, as data about the viral strain and clarification of a more precise time trial period for neonates become available during a pandemic, the length of neonatal time trials may be adjusted accordingly.

⁷⁶ Removing a patient from a ventilator is likely to be a stressful experience not only for the family members of the patient, but also for the health care staff involved.

⁷⁷ It is possible that a triage officer/committee may need to triage both pediatric and neonatal patients and having consistent time intervals would be helpful.

Physician clinical judgment is used to evaluate a patient who has begun ventilator therapy. A patient's attending physician performs the clinical assessments and provides the data to a triage officer/committee who assigns a patient a color code based on the results of the clinical assessment. This assessment determines whether the ventilator is reallocated.

The Task Force and Neonatal Clinical Workgroup concluded that while the clinical elements involved in evaluating neonatal and pediatric patients at the time trial assessments were different, the logic and reasoning required to justify continued ventilator eligibility remained consistent. In order for a patient to continue with ventilator treatment, s/he must demonstrate an improvement in overall health status after receiving ventilator therapy. Thus, for the neonatal, pediatric, and adult clinical ventilator allocation protocols, a patient's health prognosis and trajectory guide the triage decision, even though different clinical tools are used to evaluate the patient's health status.

A triage decision is made based on ongoing clinical measures and data trends of a patient's health condition, consisting of: (1) the overall prognosis estimated by the patient's clinical indicators, which is indicative of mortality risk by revealing the presence (or likelihood), severity, and number of acute organ failure(s), and (2) the magnitude of improvement or deterioration of overall health, which provides additional information about the likelihood of survival with ventilator therapy. Similar to the lack of evidence-based data on how to triage neonates for ventilator allocation, there are no data on how to determine whether the neonatal patient continues with ventilator treatment. Thus, the guiding principle for the triage decision is that the more severe a patient's health condition (i.e., presence (or likelihood), number, and severity of acute organ failure) and the extent of deterioration, the less likely the patient continues with ventilator therapy. Conversely, the less severe a patient's health condition (i.e., little risk of acute organ failure) and demonstration of improvement with ventilator therapy (i.e., lower mortality risk), the higher the likelihood the patient continues with this form of treatment.

Any changes (improving, worsening, or experiencing no change) in a patient's health data after 48 and 120 hours help guide the triage decision. A triage decision can determine that a patient is: (1) no longer ventilator dependent and may be weaned off the ventilator,⁷⁸ (2) ventilator dependent and meets the criteria to continue with ventilator therapy, or (3) ventilator dependent but no longer meets the criteria for continued ventilator treatment. A patient who exhibits improvement continues to be eligible for ventilator therapy until the next official assessment. Depending on the real-time availability of ventilators, a patient who remains stable may or may not be eligible, and the patient who no longer meets the criteria (i.e., develops a condition from the exclusion criteria list, or overall condition worsens) is removed from the ventilator and provided with alternative forms of medical intervention and/or palliative care.⁷⁹

⁷⁸ Ventilator weaning procedures are often based on physician preference, experience, and available resources, and each facility should plan accordingly.

⁷⁹ A patient who is no longer receiving ventilator therapy is not abandoned; instead s/he receives alternative forms of medical intervention and/or palliative care, where appropriate. For a more detailed discussion, *see* Section IV. Alternative Forms of Medical Intervention and Palliative Care. *See also* Chapter 2, Pediatric Guidelines, Section X. Alternative Forms of Medical Intervention and Pediatric Palliative Care and Chapter 1, Adult Guidelines, Section XII. Alternative Forms of Medical Intervention and Palliative Care. If no other eligible patients are waiting for ventilator therapy, a patient who does not meet the time trial criteria would continue with the treatment until the next evaluation.

Although there are no clinical scores in the neonatal protocol that mirrors the SOFA scores in the adult clinical ventilator allocation protocol for time trials at the 48 and 120 hour assessments,⁸⁰ the neonatal protocol – similar to the pediatric protocol – essentially replaces the numerical SOFA scores with narrative descriptions of what the scores represent from a clinical perspective. Because the key to a triage decision is the *change* in health status at 48 and 120 hours after receiving ventilator therapy, comparing a change in a clinical score or individual clinical variables is essentially the same. All the clinical ventilator allocation protocols examine a patient’s health data trends. A patient who shows improvement at time trial assessments is more likely to survive, which supports the overall goal of the triage plan, i.e., to save the most lives.

Although additional clinical assessments may be performed by a patient’s attending physician on a regular basis, the official assessments only occur after 48 and 120 hours of ventilator therapy. No formal triage decision or action may be taken until a patient’s official assessment. The decision to continue or discontinue with ventilator treatment is not made until a patient has had a full time period to benefit from this treatment. However, at any point during the time trial, even before an official assessment occurs, if a patient develops a condition on the exclusion criteria list and there is an eligible patient waiting, then the ventilator is reallocated.

The Neonatal Clinical Workgroup and the Task Force recognized the immense difficulty and potential trauma to neonatal patients, their families, and health care staff if a patient no longer qualifies for continued use of the ventilator based upon the time trial assessment. However, removing a ventilator from a patient who worsens or does not improve so that another neonate with a strong likelihood of survival may have an opportunity for treatment helps support the goal of saving the greatest number of lives in an influenza pandemic where there are a limited number of available ventilators.

2. Use of Three Clinical Parameters to Evaluate a Patient

Although the adult clinical ventilator allocation protocol uses a clinical scoring system (i.e. SOFA) to evaluate a patient at Step 3, the Neonatal Clinical Workgroup rejected the use of a neonatal scoring system, (SNAP II, CRIB II, NTISS, and NICHD NRN), because none of these systems have been validated to predict mortality risk for an individual patient or used for triage purposes.⁸¹ Instead, the Workgroup determined that the neonatal clinical ventilator allocation protocol should use physician clinical judgment, which is used in the pediatric protocol.

The Neonatal Clinical Workgroup agreed that a simple clinical framework was necessary to evaluate a patient and guide triage decisions in a consistent and transparent manner. While the

⁸⁰ In the adult clinical ventilator allocation protocol, the triage decision for continued ventilator treatment is dependent on the change in the SOFA score. For example, if the SOFA score at the 48 and 120 hour assessments continues to decrease, a patient is exhibiting signs of recovery (lower risk of organ failure and mortality), the patient continues to be eligible for ventilator therapy. However, if the SOFA score increases, the likelihood of survival is lower and a patient may not be eligible for ventilator treatment. *See* Chapter 1, Adult Guidelines, Section XI.C. Step 3: Periodic Assessments for Continued Ventilator Use (Time Trials).

⁸¹ As previously discussed above, these systems were developed to evaluate PICUs as a whole and not to assess an individual patient’s mortality risk.

Workgroup rejected the concept of assigning a cumulative score to a patient based on clinical factors, they accepted that certain clinical parameters could be used to determine quickly whether a patient was improving or deteriorating over time. These clinical variables could be used to analyze the severity and overall trend of a patient's health condition to help guide the decision of whether a patient continues with ventilator therapy.

The Neonatal Clinical Workgroup recommended the following variables as the clinical framework in Step 3⁸² hypotension,⁸³ oxygenation index (OI)⁸⁴/arterial oxygen saturation,⁸⁵ and serum creatinine.⁸⁶ These clinical variables represent major organ systems and/or are linked to mortality risk. Because the Workgroup rejected the concept of a "score," none of these variables are assigned a numerical value; instead, they are divided into categories of best, intermediate, and worst. These variables are the clinical framework by which an attending physician evaluates a patient to determine the severity of his/her overall health and whether the patient's health condition was improving, deteriorating, or experiencing no change.

No single factor independently represents a patient's overall health trajectory and a triage officer/committee should never base a triage decision on a single clinical variable. Instead, a triage decision should examine all clinical variables so that an *overall* health assessment of a patient can be made. Furthermore, the first two variables – hypotension (cardiovascular function) and OI/arterial oxygen saturation (lung function) – are more important for a triage officer/committee to consider, compared to serum creatinine. While a triage decision to discontinue ventilator therapy may rely heavily on the assessments from hypotension and OI/arterial oxygen saturation, such a decision should *never* be made based *solely* on a patient's serum creatinine level. The latter variable may be more useful when deciding whether a patient eligible for continued ventilator therapy should be placed into the red or yellow color categories. It reveals whether a patient is experiencing kidney failure, which decreases the likelihood of survival. Also, depending on the extent of staff and equipment shortages, it may not be possible

⁸² These three variables are variables also examined in the Pediatric Guidelines during time trials. See Chapter 2, Pediatric Guidelines, Section IX.C.2. Use of Six Clinical Parameters to Evaluate a Patient. While the pediatric clinical ventilator allocation protocol also examines Glasgow Coma Scale Score, blood/serum lactate, and serum bilirubin/scleral icterus, the Neonatal Clinical Workgroup declined to use these clinical variables. Glasgow Coma Scale Score is used to assess the level of consciousness of a patient and is not relevant for neonates since traumatic brain injury is rarely seen in this population. While increased blood/serum lactate level in the blood may indicate an increased mortality risk in pediatric patients, there are no evidence-based data to suggest a similar correlation in neonates. Finally, because a large number of neonates are afflicted with physiological jaundice, examining serum bilirubin/scleral icterus is not helpful for triage purposes.

⁸³ Hypotension is abnormally low blood pressure that results from a patient's inability to compensate for injury. Untreated, it is a prelude to death.

⁸⁴ OI is the ratio between the amount of oxygen delivered to a patient and the amount of oxygen in the patient's arterial blood, taking into account the amount of pressure delivered by a ventilator if one is being used. It serves as a measure of the severity of a patient's lung disease, has prognostic implications, and can be followed for trends. (Higher values imply worsening status.) $OI = \text{mean airway pressure (MAP)} \times \text{fraction of inspired oxygen (FiO}_2) \times 100 / \text{partial pressure of oxygen in arterial blood (PaO}_2)$. (PaO₂ may be estimated from peripheral oxygen saturation by using the oxygen dissociation curve if blood gas measurements are unavailable.)

⁸⁵ Arterial oxygen saturation refers to the fraction of hemoglobin that is bound to oxygen in arterial blood. It can be measured non-invasively and can be followed for trends. (Lower values imply worsening status.)

⁸⁶ Serum creatinine is a measure of creatinine in blood. Creatinine is a normal byproduct of muscle metabolism and is normally cleared by the kidney. Abnormally high values are an indicator of kidney dysfunction and can be followed for trends. (Higher values imply worsening status.)

to obtain the necessary lab work for serum creatinine. Thus, this factor may only play a role in the triage decision if the appropriate data are available.

Again, because there are no evidence-based data on how to triage children for ventilator allocation based on these clinical factors, a triage officer/committee must use best clinical judgment. However, the basic principle is that the more severe a patient’s health condition is based on these clinical factors, the less likely s/he survives even with ventilator therapy, and triage decisions should be made accordingly.

The clinical parameters appear below. The bold line separates the “primary” clinical variables from the “secondary” factor.

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}	<p>< 20 (Best) 20 – 40 (Intermediate) > 40 (Worst)</p> <p>OR</p> <p>> 88% (Best) 80 – 88% (Intermediate) < 80% (Worst)</p>
Hypotension	<p>Adequate circulation, with <u>no</u> vasoactive drugs (Best) Adequate circulation, with vasoactive drugs (Intermediate) Hypotension, with vasoactive drugs (Worst)</p>
Serum Creatinine (mg/dL)	<p>< 1 (Best) 1 < 3 (Intermediate) > 3 (Worst)</p>

¹ OI = mean airway pressure (MAP) x fraction of inspired oxygen (FiO₂) x 100 / partial pressure of oxygen in arterial blood (PaO₂). (PaO₂ 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.

a. Justification for the Use of the Three Clinical Parameters

The clinical parameters used in the neonatal clinical ventilator allocation protocol were modified from the pediatric protocol and follow similar justification for their use. As stated above, no single factor independently represents a patient’s overall health trajectory and a triage officer/committee should never base a triage decision on a single clinical variable. Instead, a

triage decision should examine all clinical variables so that an *overall* health assessment of a patient can be made.

Most clinical ventilator allocation protocols, including New York’s Adult Guidelines, do not include response to ventilation (OI) as a triage criterion;⁸⁷ however, OI is a clinical factor in the pediatric clinical ventilator allocation protocol and provides additional evidence regarding the extent of a patient’s lung improvement.⁸⁸ It is a useful variable to evaluate whether ventilation is effective and there is a strong correlation between OI and survivability,⁸⁹ and it may be helpful for triage decisions in the neonatal population. Examining OI provides important information about the lung function of a patient and offers clinical data that supplements other clinical factors.

The Neonatal Clinical Workgroup recognized that during a severe emergency, clinical data that normally are available may not be easily acquired, such as a blood gas measurement used for OI. In such circumstances, clinicians may use arterial oxygen saturation data when PaO₂ measurements for OI are unavailable. Although OI is the superior of the two measurements in providing a more complete picture of lung function, arterial oxygen saturation percentages are acceptable to use.

Hypotension is common in extremely low birth weight babies. Hypotension is a good marker for a patient’s health and untreated, it is a prelude to mortality. The Neonatal Clinical Workgroup agreed that persistent hypotension despite aggressive treatment would likely correlate with high mortality risk.

Similarly, creatinine is commonly used to measure kidney function, another important measure of mortality risk. Many clinical scoring systems and clinical ventilator allocation protocols also examine kidney function, and abnormally high creatinine values can be used to examine a patient’s health trajectory. Furthermore, because serum creatinine is never used independently to justify a triage decision, this information provides supplementary data for a triage officer/committee to consider. Both the Task Force and the Pediatric and Neonatal Clinical Workgroups concluded that more clinical information was better than less when making triage decisions.

⁸⁷ Only one state, Minnesota, incorporated this factor as a triage criterion, but explains its limited prognostic significance. See Minnesota Department of Health, Minnesota Healthcare System Preparedness Program, *Patient Care: Strategies for Scarce Resource Situations* 11 (version 2.0, 2011).

⁸⁸ See Chapter 2, Pediatric Guidelines, Section IX.C.2. Use of the Six Clinical Parameters to Evaluate a Patient.

⁸⁹ See MA Ziao-Lu et al., *Epidemiology of Respiratory Distress and the Illness Severity in Late Preterm of Term Infant: A Prospective Multi-Center Study*, 123 CHIN. MED. J. 2776, 2779 (2010); Yew-Wei Tan et al., *Using Serial Oxygenation Index as an Objective Predictor of Survival for Antenatally Diagnosed Congenital Diaphragmatic Hernia*, 47 J. PEDIATR. SURGERY 1984, 1988 (2012). While most medical literature confirms a strong correlation between OI and survivability, it is often in the context of patients with a specific medical condition. Although the premature infants included in the studies are late preterm infants (> 34 weeks), the correlation between OI and mortality risk is most likely even stronger for more premature infants. See also A. Karimova et al., *Neonatal Extracorporeal Membrane Oxygenation: Practice Patterns and Predictors of Outcome in the UK*, 94 ARCH. DIS. CHILD FETAL NEONATAL ED. F129, F132 (2009) (finding that there was a relationship between higher OI and mortality in non-congenital diaphragmatic hernia neonates, every five point increase in OI raised the risk of mortality by five percent).

3. Triage Charts for Step 3

At the 48 and 120 hour assessments, a patient is examined for organ failure/mortality risk based on three clinical variables described above. The results of the time trial clinical assessments are then provided to a triage officer/committee who assigns a color code (blue, red, yellow, or green) to the patient. The decision whether to continue ventilator therapy for a patient is dependent on the trend of the health data from the clinical framework. Triage decisions are made based on ongoing clinical measures and data trends of a patient's health condition, consisting of: (1) the overall prognosis estimated by the patient's clinical indicators, which is indicative of mortality risk by revealing the presence (or likelihood), severity, and number of acute organ failure(s), and (2) the magnitude of improvement or deterioration of overall health, which provides additional information about the likelihood of survival with ventilator therapy.

A triage officer/committee evaluates the ongoing measures and trends of a patient's health condition from the clinical framework and assigns a color code (blue, red, yellow, or green) to the patient.⁹⁰ It is possible that a patient may exhibit better outcomes in some clinical variables, but not in others. In this situation, a triage officer/committee should place more weight on the health data trends from the OI/arterial oxygen saturation percentages and hypotension factors because these are stronger predictors of mortality risk. The other clinical factor, serum creatinine, reveals whether a patient is experiencing kidney failure, and while useful, serum creatinine alone should *never* be the *sole* reason to justify a triage decision involving extubation. The latter variable may be more useful when deciding whether a patient eligible for continued ventilator therapy should be placed into the red or yellow color categories.

Criteria for each color code at the 48 and 120 hour assessments are presented below.

⁹⁰ See also the discussion on assigning a patient a color code in Section III.B.2. Triage Chart for Step 2.

c. 48 Hour Clinical Assessment Chart

Step 3 - Ventilator Time Trials (48 Hour Assessment)¹	
Color Code and Level of Access	Assessment of Mortality Risk/Organ Failure (Examining Three Clinical Variables)
<p>Blue</p> <p>No ventilator provided.² Use alternative forms of medical intervention and/or palliative care or discharge. Reassess if resources become available.</p>	<p>Exclusion criterion OR HIGHEST risk of mortality and Pattern of significant deterioration (or no change³) of overall health compared to the initial assessment</p>
<p>Red Highest</p> <p>Use lifesaving resources as available.</p>	<p>MODERATE risk of mortality and Pattern of significant improvement of overall health compared to the initial assessment</p>
<p>Yellow Intermediate</p> <p>Use lifesaving resources as available.</p>	<p>HIGH / UNCERTAIN risk of mortality and No significant change or slight deterioration in overall health compared to the initial assessment</p>
<p>Green</p> <p>Use alternative forms of medical intervention or defer or discharge. Reassess as needed.</p>	<p>LOW risk of mortality and No longer ventilator dependent / Actively weaning from ventilator</p>

¹ If a patient develops a condition on the exclusion criteria list at any time from the initial assessment to the 48 hour assessment, change color code to blue. Remove the patient from the ventilator and provide alternative forms of medical intervention and/or palliative care.

² A patient assigned a blue color code is removed from the ventilator and alternative forms of medical intervention and/or palliative care are provided.

³ The patient remains significantly ill.

d. 120 Hour Clinical Assessment Chart

Step 3 - Ventilator Time Trials (120 Hour Assessment)¹	
Color Code and Level of Access	Assessment of Mortality Risk/Organ Failure (Examining Three Clinical Variables)
<p>Blue</p> <p>No ventilator provided.² Use alternative forms of medical intervention and/or palliative care or discharge. Reassess if resources become available.</p>	<p>Exclusion criterion OR HIGHEST risk of mortality and Pattern of significant deterioration (or no change³) of overall health compared to the previous assessment</p>
<p>Red Highest</p> <p>Use lifesaving resources as available.</p>	<p>MODERATE risk of mortality and Pattern of <i>further</i> significant improvement of overall health compared to the previous assessment</p>
<p>Yellow Intermediate</p> <p>Use lifesaving resources as available.</p>	<p>HIGH / UNCERTAIN risk of mortality and No significant change in overall health compared to the previous assessment</p>
<p>Green</p> <p>Use alternative forms of medical intervention or defer or discharge. Reassess as needed.</p>	<p>LOW risk of mortality and No longer ventilator dependent / Actively weaning from ventilator</p>

¹ If a patient develops a condition on the exclusion criteria list at any time from the 48 hour assessment to the 120 hour assessment, change color code to blue. Remove the patient from the ventilator and provide alternative forms of medical intervention and/or palliative care.

² A patient assigned a blue color code is removed from the ventilator and alternative forms of medical intervention and/or palliative care are provided.

³ The patient remains significantly ill.

The primary difference between the 48 and 120 hour assessment is the *extent* of improvement in overall health prognosis and of the trajectory of a patient’s health status required to continue to be eligible for ventilator therapy. While the health assessment outcomes for the blue, yellow, and green categories are the same for the 48 and 120 hour assessments, the extent of health improvement for the red category is different. At 48 hours, a patient must exhibit a pattern of significant improvement to be placed in the red color code. Because a patient has only had 48 hours to benefit from ventilator therapy, the progress required to justify continued ventilator use is not expected to be dramatic. However, after 120 hours, a patient must demonstrate a pattern of *further* significant improvement in health to be placed in the red color code. The Neonatal Clinical Workgroup concluded that by 120 hours, it would be apparent whether a patient is benefiting from ventilator therapy. To justify continued use beyond 120

hours requires a noteworthy positive change in a patient’s health; otherwise, the ventilator is reallocated to an eligible patient.

When assigning patients color codes, the Pediatric Clinical Workgroup concluded that a triage officer/committee must determine how to define what the cutoffs should be for highest, high/uncertain, moderate, and low risk of mortality risk categories because there are no evidence-based data early in a pandemic. Given the potential constraints associated with an influenza pandemic, mortality risk predictions should be based on the best clinical evidence available. In addition, because there are no evidence-based data on what the extent of improvement of the three clinical variables examined should be after 48 and 120 hours of ventilator treatment to determine whether a patient continues with ventilator therapy, the Pediatric Clinical Workgroup concluded that a triage officer/committee must determine how to define a “pattern of significant improvement/deterioration.” Because patients are not competing against each other for ventilator treatment, a triage officer/committee is not comparing a patient’s level of improvement to another patient. Instead, the extent of improvement (or deterioration) is evaluated based on a patient’s previous official assessment. A patient is only “competing” against him/herself and must demonstrate improvement to continue with the treatment.

The basic principle is that the more severe a patient’s health condition is based on the clinical factors delineated above, the less likely s/he survives, even with ventilator therapy. Therefore, triage decisions should be made accordingly. It is at the discretion of each acute care facility to develop oversight mechanisms to help ensure that such determinations of improvement or deterioration are made in a consistent manner as possible.⁹¹ As more data become available during a pandemic regarding patient outcomes and best practices for treatment, a triage officer/committee will incorporate this evidence-based data into the triage decision.

D. Clinical Assessment(s) Beyond 120 Hours

After the 120 hour clinical assessment, a patient who is allotted another time trial for ventilator therapy is reassessed every 48 hours. This time trial mirrors what occurs after the 120 hour assessment in the pediatric clinical ventilator allocation protocol. Every 48 hours, a clinical evaluation using the same parameters used in the previous assessments is conducted and a triage officer/committee determines whether a patient continues with ventilator therapy. The decision may consider several factors, but first, a patient must continue to exhibit signs of improvement. If there is clear evidence of deterioration that is irreversible, a patient may no longer be eligible for ventilator treatment. Finally, other considerations may include the known progression of the

⁹¹ However, as more data about the pandemic viral strain become available during a pandemic, it may be necessary to revise the definition of “significant improvement/deterioration” accordingly.

disease,⁹² updated data on the pandemic viral strain,⁹³ availability of alternative treatments,⁹⁴ current supply and demand data at the facility (e.g., number of available or soon to be available ventilators and incoming patients requiring ventilator therapy), alternative sites of health care and whether there are any patients waiting for a ventilator therapy trial.⁹⁵

E. Decision-Making Process for Removing a Patient from a Ventilator

There may be a scenario where there is an incoming red code patient(s)⁹⁶ eligible for ventilator treatment and a triage officer/committee must remove a ventilator from a patient whose health is not improving at the 48, 120, or subsequent 48 hour time trial assessments, so that the red code patient receives ventilator treatment. As discussed earlier, no formal triage decision or action may be taken until an official time trial assessment of the ventilated patient is performed. A triage officer/committee follows these steps to determine which patient should be removed from the ventilator.⁹⁷ First, patient(s) with the worst likelihood of survival and/or with a pattern of significant deterioration even with ventilator therapy (i.e., a blue code patient) is the first patient(s) vulnerable for ventilator removal. If there are no patients in the blue category, then a triage officer/committee proceeds to the yellow code patients (i.e., patients who have high/uncertain risk of mortality and no significant change in overall health after ventilator therapy).

A triage officer/committee is not permitted to compare the health of patients within the same color category. As discussed earlier, parents and legal guardians of a pediatric patient expect that doctors provide treatment, to the extent possible, based on assessments of the patient's health as an individual. If ventilator use is primarily determined by the health of *other* patients, clinicians must abandon their obligation to advocate/care for their individual patient. This proposal evokes a war of all against all that ignores health care workers' deep professional obligations to advocate and care for individual patients. Furthermore, such comparisons may

⁹² For most patients requiring ventilator therapy, the disease affecting them is the pandemic influenza. As the disease progression becomes known, clinicians will have a better understanding of the duration and recovery periods to assist with triage decisions. However, some patients may be afflicted with other diseases that need to be considered independently when evaluating a patient's clinical status. Other co-morbid factors may alter the trend of a patient's health status.

⁹³ As the pandemic progresses, more data are available regarding the particular viral strain which may modify the triage criteria. For example, as the disease progression becomes known, clinicians have a better understanding of the duration and recovery periods to assist with triage decisions.

⁹⁴ Alternative treatments include other forms of oxygen delivery or pharmaceutical measures. For a more detailed discussion, *see* Chapter 2, Pediatric Guidelines, Section X.A. Alternative Forms of Medical Intervention for a Patient Without a Ventilator.

⁹⁵ If there are no eligible (red code) patients waiting for ventilator therapy, ventilated patients may continue with this treatment.

⁹⁶ While there may be yellow color code patients waiting for ventilator therapy, all red code patients must be attended to first. In limited circumstances, where incoming patients are only yellow code, these patients may only receive ventilator therapy if there are any blue code patients currently receiving ventilator treatment. Already ventilated yellow code patients would *not* be removed from the ventilator with the arrival of an incoming yellow code patients since both of these patients have equivalent likelihoods of survival (i.e., both are in the same color category).

⁹⁷ For a discussion on review of a triage decision and the appeals process, *see* Chapter 4, Implementing New York State's Ventilator Allocation Guidelines: Legal Considerations, Section VI. Appeals.

intensify inherent biases in the health care system and the disproportionate and disparate provision of care for already disadvantaged populations.

Instead, a triage officer/committee utilizes the following framework to select which patient(s) is removed. Because the assumption is made that all patients⁹⁸ in the blue⁹⁹ (or yellow) category have substantially equal likelihoods of survival, a randomization process such as a lottery is used to select which patient is removed from the ventilator so that another eligible (red code) patient has an opportunity to benefit from ventilator therapy.¹⁰⁰ A patient may only be removed from a ventilator after an official clinical assessment has occurred or where the patient develops a medical condition on the exclusion criteria list.

Finally, if all ventilated patients at the 48, 120, and subsequent 48 hour time trial assessments receive a red color code, then none of these patients discontinue ventilator therapy. The incoming red code patient(s) remains in an eligible patient pool until the results of the next time trial assessment to see if a ventilator becomes available.

F. Interface between Neonatal and Pediatric Patients

Although the Guidelines underscore the goal of selecting and treating patients who will most likely survive the acute medical episode that necessitated ventilator treatment, a triage officer/committee may not be able to compare easily the probability of mortality predictions between pediatric and neonatal patients. The same triage officer/committee may need to evaluate the mortality risks of children and neonates using different clinical assessment tools. The difficulties in doing so are most apparent when a ventilator capable of supporting both a pediatric and neonatal patient becomes available and both a pediatric and a neonatal patient are in need of treatment.¹⁰¹ While both protocols rely on physician clinical judgment to estimate a patient's mortality risk, the clinical variables used to make a mortality risk prediction are different. Although a patient with the greatest chance of survival with ventilator therapy should receive (or continue with) this treatment, it is not obvious how this determination should be made when the mechanisms used to predict mortality risk are not the same.¹⁰²

⁹⁸ However, if the ventilated patients include both adults and children, a different non-clinical method is used (i.e., young age). See Chapter 2, Pediatric Guidelines, Section V.A.3.b. Use of Young Age as a Secondary Triage Factor (Tie-Breaker) and Section IX.F. Interface between Pediatric and Adult Patients.

⁹⁹ In certain circumstances, it is possible for a patient with an exclusion criterion or who has been triaged into the blue category to obtain ventilator therapy because there are no other eligible patients waiting for ventilator therapy. If there is more than one blue code patients, they are subject to the procedures described above when no ventilators are available and there is an eligible (non-blue code) patient waiting for ventilator therapy.

¹⁰⁰ For a discussion of how randomization could be used to select a patient for removal, see Section III.B.3. Decision-Making Process for Selecting an Eligible Patient for a Ventilator (the same randomization process used for selection could be applied for removal).

¹⁰¹ While some "dual-use" ventilators that can ventilate either an adult or a pediatric patient could be used for a neonate, because the expertise and additional equipment required to care for neonates is specific to neonates, it would not be likely that a triage officer/committee would have to select between these two populations. While most facilities that care for adults could care for pediatric patients, it would be unlikely that these hospitals have the capacity to treat neonates. However, for hospitals with the capacity to care for pediatric patients, it is likely they could also treat neonates.

¹⁰² For a discussion of the clinical tools a triage officer/committee uses to gauge a neonatal and pediatric patient's immediate or near-immediate mortality risk, see Section III. New York's Neonatal Clinical Ventilator Allocation

Until a clinical scoring system is validated for use for pediatric and neonatal patients, the Task Force and the Pediatric and Neonatal Clinical Workgroups recognized that use of different methodologies to assess mortality risk is ethically acceptable, primarily because no other appropriate evidence-based alternative exists. In an influenza pandemic, the same triage officer/committee may need to allocate ventilators to both populations, the Task Force and the Clinical Workgroups agreed that, ideally, experienced clinicians should have the appropriate training in both neonatal/pediatric and mass casualty scenarios.¹⁰³ In the absence of a universal triage tool, a triage officer/committee should be able to gauge whether patients have substantial equality in the likelihood of survival with ventilator therapy. While the details of the clinical evaluations may differ between the two groups, properly trained clinicians will be able to provide an overall assessment of survivability.

When either selecting or removing a patient in a patient pool that consists of both neonatal and pediatric patients, a triage officer/committee is not permitted to compare the health of patients. A triage officer/committee must assume that all patients in a color category have substantially equal likelihoods of survival because no other evidence-based clinical tools are available to further differentiate a patient's mortality risk.

While the Task Force determined that young age may play a tie-breaking role in determining which patient receives/continues with ventilator treatment,¹⁰⁴ young age would not be a consideration when a patient pool consisted of only children. While it could be possible for a protocol to establish age cutoffs to determine which age range(s) has priority access to ventilators, reaching consensus on age cutoffs would be extremely difficult since the reasoning behind such thresholds is subjective. Furthermore, if youngest age was used as a tie-breaker criterion, then the youngest patient, even if the age difference is negligible, would receive the ventilator treatment. Finally, such a rationale would only ensure that the absolute youngest patients (i.e., neonates and toddlers) receive ventilator treatment. Thus, if the patients eligible for ventilator treatment include both neonatal and pediatric patients, a random process should be used to choose the patient for ventilator therapy when there are more patients than ventilators available. In addition, a random selection method is conducted each time a ventilator becomes available.

IV. Alternative Forms of Medical Intervention and Palliative Care

During a public health emergency, non-emergency medical standard of care and decision-making autonomy may not be feasible. In a pandemic, some patients who might have been successfully treated during ordinary conditions may not survive. Policy aimed at maximizing the number of lives saved suggests that in the unfortunate event in which continually more patients require ventilator treatment and as ventilator resources become increasingly scarce, patients

Protocol and Chapter 2, Pediatric Guidelines, Section IX. New York's Clinical Ventilator Allocation Protocol for Pediatric Patients, respectively.

¹⁰³ Some facilities that use a triage committee instead of a triage officer may designate a pediatric or neonatal specialist as a member of the triage committee.

¹⁰⁴ For a discussion on the role of age as a secondary (tie-breaker) triage factor, *see* Chapter 2, Pediatric Guidelines, Section V.A.3.b. Use of Young Age as a Secondary Triage Factor (Tie-Breaker).

whose clinical conditions indicate they are less likely to survive may be denied access to or withdrawn from a ventilator.

Under these circumstances, health care providers should endeavor to follow standard protocols for withholding and withdrawing life-sustaining care. While an emergency may require withholding or withdrawing of a ventilator, health care workers continue to have obligations and a duty to care for their patients. Clinically indicated and appropriate care, such as alternative forms of medical intervention and/or palliative care, within the context of the pandemic situation should be provided to patients who do not meet clinical criteria for continued ventilator therapy, as well as to patients who were not eligible for ventilator treatment. For a discussion of alternative forms of medical intervention and palliative care, see Chapter 2, Pediatric Guidelines, Section X.

V. Logistics Regarding the Implementation of the Guidelines

There are several non-legal issues¹⁰⁵ to consider once the Guidelines are implemented, including communication about triage and real-time data collection and analysis to modify the Guidelines based on new information.¹⁰⁶

Implementation of the Guidelines requires clear communication to the public about the goals and steps of the clinical ventilator allocation protocol. Efforts will be made to inform and gather feedback from the public before a pandemic. Public outreach should include a component that informs people that the medical standard of care during an influenza pandemic will be different than the normal (i.e., non-pandemic) medical standard of care. It will also include information that during this specific scenario, patient preference will not determine ventilator access. Instead, a protocol based only on clinical factors will be used to determine whether a patient receives (or continues with) ventilator treatment to support the goal of saving the greatest number of lives where there are a limited number of available ventilators.

Data collection and analysis on the pandemic viral strain, such as symptoms, disease course, treatments, and survival are necessary so that the clinical ventilator allocation protocol may be adjusted accordingly to ensure that patients receive the best care possible. Furthermore, data collection must include real-time availability of ventilators so that triage decisions are made to allocate resources most effectively. Knowing the exact availability of ventilators also assists a triage officer/committee in providing the most appropriate treatment options for patients.

VI. Conclusion

With any luck, a severe influenza pandemic will never emerge in New York. With planning, even if a pandemic does occur, community members, health care providers, and public officials may be able to diminish its impact. The Guidelines rely upon both ethical and clinical

¹⁰⁵ For a discussion of the legal issues involved when implementing the Guidelines, *see* Chapter 4, Implementing New York State's Ventilator Allocation Guidelines: Legal Considerations.

¹⁰⁶ For a more detailed discussion on communication about the Guidelines and the clinical ventilator allocation protocol and real-time data collection and analysis and modification of the Guidelines, *see* Chapter 1, Adult Guidelines, Section XIII. Logistics Regarding the Implementation of the Guidelines.

standards in an effort to offer the best possible care under gravely compromised conditions to support the goal of saving the most lives in an influenza pandemic where there are a limited number of available ventilators.

While the Neonatal Guidelines developed by the Task Force and the Neonatal Clinical Workgroup assist a triage officer/committee as they evaluate potential patients for ventilator therapy, decisions regarding treatment should be made on an individual (patient) basis, and all relevant clinical factors should be considered. A triage decision is not performed in a vacuum; instead, it is an adaptive process, based on fluctuating resources and the overall health of the patient. Examining each patient within the context of his/her health status and of available resources provides a more flexible decision-making process, which results in a fair, equitable plan that saves the most lives.

Finally, the neonatal clinical ventilator allocation protocol is a set of guidelines to assist clinicians in distributing limited ventilators and may be revised as more information on the nature of the pandemic viral strain is gathered. It may be modified to ensure that the recommended approach reflects strain-specific influenza progression so that patients receive the most appropriate care.

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CHAPTER 4

IMPLEMENTING NEW YORK STATE'S VENTILATOR ALLOCATION GUIDELINES: LEGAL CONSIDERATIONS

Abstract

In a severe influenza pandemic, many more patients would require the use of ventilators than can be accommodated with current supplies. Federal and state ventilator stockpiles would be inadequate to meet the needs of a disaster on the scale of the 1918 influenza pandemic, and the requisite number of trained healthy staff and amount of other resources, such as oxygen, may not be available in an emergency. Consequently, New York State's Ventilator Allocation Guidelines (the Guidelines) address the allocation of resources in preparation for the possibility of severe ventilator scarcity in an influenza pandemic. In evaluating the most effective and fair approach to implement the Guidelines, many legal and ethical questions arise, including concerns regarding federal and State constitutional issues, legal liability for adhering to the Guidelines, and an ethically-sound appeals process.

In devising the adult, pediatric, and neonatal guidelines for the allocation of ventilators in the event of a pandemic outbreak of influenza, the New York State Department of Health (the Department) and the New York State Task Force on Life and the Law (the Task Force) examined existing health laws, regulations, and policies at both the federal and State levels, including a thorough examination of existing laws in New York State. The conclusions and recommendations herein are based on analysis of current law, thorough consideration of the provisions of other states addressing legal liability in an emergency, deliberations by the Task Force, outreach to a legal issues subcommittee, and extensive legal and public policy research.

This chapter begins with a discussion of the form of the Guidelines themselves as voluntary and non-binding. Although voluntary, the Task Force strongly recommends that they be adopted and followed by all health care providers and entities in a pandemic. The chapter then focuses on a number of constitutional considerations that may arise in their implementation. It then discusses the "trigger" for the implementation of the adult, pediatric, and neonatal clinical ventilator allocation protocols, and enumerates New York statutes that could interfere with adherence to the Guidelines in a pandemic influenza.

Recognizing that, by necessity, the Guidelines represent a significant departure from standard medical practice, this chapter then examines existing liability protections at the federal and State levels. The Guidelines acknowledge that health care providers may be hesitant to conform to the modified medical standard of care contained therein because of concerns about liability arising from injury or death. Further, existing laws and regulations provide incomplete protections for health care workers and entities who follow the Guidelines. Thus, the Task Force recommends enactment of legislation granting the New York Commissioner of Health authority to adopt a modified medical standard of care specific to the emergency, coupled with civil and criminal liability protections and professional discipline protections for all health care workers and entities who provide care in a pandemic emergency. Any liability immunity-conferring

legislation ought to: (1) be subject to limitations such as a good faith requirement and exclusions for certain acts of gross negligence or willful misconduct; (2) cover compensated employees, independent contractors, and unpaid or paid volunteers; and (3) be extended to anyone who provides care during an emergency (rather than only to those complying with the Guidelines).

This chapter also considers alternatives to legislation that would mitigate civil and criminal liability and encourage adherence to the Guidelines. These approaches include: (1) caps on damages; (2) expedited discovery and statutes of limitations; (3) alternative dispute resolution, including arbitration, pretrial review boards, and compensation pools; and (4) professional education. The Task Force concludes that without the creation of legislative immunity-conferring protections, these alternative approaches would be insufficient to encourage widespread adherence to the Guidelines. These approaches would however, provide further protections for health care workers and entities who follow the Guidelines when combined with each other and new legislation.

This chapter concludes with a consideration of the various approaches to an appeals process for those who object to decisions made pursuant to the clinical ventilator allocation protocols. The Guidelines recognize that an ethical and clinically sound system for allocating ventilators in a pandemic includes an appeals process. Physicians, patients, and family members should have a means for requesting review of triage decisions. This chapter addresses the practicality of permitting appeals to the clinical ventilator allocation protocol and examines whether a real-time or a retrospective form of review would better complement a just and workable triage system during a public health emergency. The Task Force recommends implementing a hybrid system of review – combining limited on-going individual appeals with retrospective periodic review – which incorporates the advantageous features of both under the constraints of the pandemic.

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Legal Considerations**

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I. INTRODUCTION

This chapter will address various legal issues associated with effectively implementing New York State’s Ventilator Allocation Guidelines (the Guidelines). It begins with a discussion of the form of the Guidelines themselves, and then focuses on a number of constitutional considerations that may arise in their implementation. It will then discuss the “trigger” for the implementation of the clinical ventilator allocation protocol, and will enumerate New York statutes that could interfere with adherence to the Guidelines.

The discussion and recommendations in the next sections will address the critical issue of legal liability for health care workers and entities who follow New York’s Ventilator Allocation Guidelines during an influenza pandemic – a vital but previously under-explored area that was noted, but not fully addressed, in the 2007 draft Guidelines.¹ Individuals and health care workers who adhere to the Guidelines may be subject to three broad legal risks: (1) criminal penalties, (2) civil monetary damages, and (3) professional discipline. The chapter examines existing liability protections at the federal and State levels and explores unique alternatives for mitigating liability to encourage adherence to the Guidelines in an influenza pandemic. This chapter makes specific recommendations regarding the enactment of liability immunity-conferring legislation intended to protect health care workers and entities who follow the Guidelines. Finally, it concludes with a consideration of the various approaches to an appeals process for those who object to decisions made pursuant to the clinical ventilator allocation protocol.

In devising the adult and pediatric guidelines for the clinical allocation of ventilators in the event of a pandemic outbreak of influenza, the New York State Department of Health (the Department) and the New York State Task Force on Life and the Law (the Task Force)² examined existing health laws, regulations, and policies at both the federal and state levels, including a thorough examination of existing laws in New York State. The conclusions and recommendations herein are based on analysis of current law, thorough consideration of the provisions of other states addressing legal liability in an emergency, deliberations by the Task Force, outreach to a legal issues subcommittee,³ and extensive legal and public policy research.

II. VOLUNTARY GUIDELINES

Prior to 2007, the Department and the Task Force analyzed the advantages and disadvantages of the three forms in which the ventilator allocation recommendations could be implemented: guidelines, regulations, and legislation. First, the Department is empowered to issue voluntary and non-binding guidelines for all health care workers and entities. Alternatively, the Department, following approval of the Public Health and Health Planning

¹ The March 2007 draft Guidelines presented an adult clinical protocol for the allocation of ventilators in an influenza pandemic.

² Established by Executive Order in 1985, the Task Force is comprised of 23 Governor-appointed leaders in the fields of religion, philosophy, law, medicine, nursing, and bioethics. The Task Force develops public policy on issues arising at the interface of medicine, law, and ethics, and has issued influential reports on cutting-edge bioethics issues. See Appendix A for a list of the Task Force members who participated in this project.

³ The legal issues subcommittee met in January 2008 to discuss various legal questions associated with implementation of the Ventilator Guidelines, with a focus on legal liability for health care workers and entities who follow the Guidelines.

Council, may issue binding regulations for hospitals.⁴ Finally, the Department may propose that triage recommendations be drafted as new legislation.

After extensive deliberations, the Department determined that voluntary, non-binding guidelines are the most appropriate for the effective implementation of the clinical ventilator allocation protocol. Although it has been argued that voluntary guidelines may offer an insufficient guarantee of consistency, facility representatives stress that they are eager to follow State-level guidance and do not seek wide latitude in devising their own policies. Hospitals have expressed a preference for State guidance over drafting their own policies.

Because these clinical ventilator allocation protocols remain untested in an actual disaster emergency, issuing them as binding regulations for hospitals – or requesting that they be drafted as new legislation – may produce unforeseen consequences. A ventilator allocation system must be designed with flexibility to adjust to changing clinical information; thereby requiring the ability to make timely revisions to the ventilator allocation protocol contained in the Guidelines. Thus, the relatively static nature of regulation or legislation makes these inadequate approaches for clinically-detailed recommendations.

Although the Guidelines are voluntary, the Task Force strongly recommends that they be adopted and followed by all health care providers and entities in a pandemic. They are intended to provide an ethical and clinical framework for transparent decision-making.

III. CONSTITUTIONAL CONSIDERATIONS

A. Federal Constitutional Considerations

Guidelines for resource allocation during a public health emergency must comply with the tenets of the U.S. constitution, including the Supremacy Clause.⁵ For example, while states have the authority to implement public health legislation that prioritizes saving the most lives in a public health emergency,⁶ state law must not conflict with federal law.⁷ Moreover, while a state may suspend its own statutes upon a declaration of emergency, doing so must not conflict with individual rights guaranteed by the U.S. or its own constitution.

A public health emergency may necessitate a shift away from standard non-emergency medical practice under which health care providers prioritize the needs of the individual patient and the principle of informed consent. Resource limitations may require that ventilation therapy

⁴ However, statutory law precludes the Department from regulating physician practice. N.Y. EDUCATION LAW § 6532.

⁵ The Supremacy Clause establishes federal judicial power over the acts of state officials. It requires that state courts make decisions and state legislatures make laws in conformity with the rights conferred to persons under the Constitution. U.S. CONST. art. VI.

⁶ This power arises from the police powers of the states. *See Jacobson v. Mass.*, 197 U.S. 11, 27-28 (1905) (holding mandatory small pox vaccination constitutional, in part due to a real and substantial relation to the protection of public health and safety).

⁷ The Supremacy Clause implies that when federal law conflicts with state law, federal law will supersede. *See Altria Group v. Good*, 555 US 70, 76 (2008) (citing *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981)).

be withheld or withdrawn from some persons without obtaining prior first person (or proxy) consent.⁸

However, there is a dearth of legislation and case law specifically addressing withdrawal or denial of ventilation.⁹ Thus, the constitutionality of the Guidelines may hinge on prior cases where public welfare – the goal of saving the most lives overall – superseded individual rights or liberties during declared emergencies. These cases demonstrate that some emergency situations – such as those involving mandatory disease isolation or quarantine and compulsory vaccination – justify temporarily limiting individual rights to maximize population protection.¹⁰

Although there are historical cases addressing constitutional issues during health pandemics, courts have not clearly delineated the scope of individual rights during a public emergency. The Guidelines are carefully crafted to protect individual rights to the greatest extent possible. The following section addresses precedents for federal constitutional concerns in times of public emergency and how, in drafting the Guidelines, the Task Force and Department of Health considered and addressed these constitutional issues.

1. Fundamental Rights

Limitations placed upon fundamental rights in emergency circumstances have often been justified when such restrictions are found to benefit the population as a whole.¹¹ Through quarantine and mandatory vaccination,¹² restrictions on public congregation during disease outbreaks,¹³ and response to the U.S. AIDS outbreak,¹⁴ courts have recognized public

⁸ An action based on lack of informed consent is not cognizable for emergency treatment. See *Kasnetz v. Vieta*, 568 N.Y.2d 383 (1991) (citing NY CLS Pub Health §2805-d(2)).

⁹ Many laws addressing infectious diseases pre-date modern medical technology developments, such as mechanical ventilation. Lawrence O. Gostin, *The Law and the Public's Health: a Study of Infectious Disease Law in the United States*, 9 COLUM. L. REV. 59 (1999). The majority of relevant cases address the use of a health care proxy to consent to ventilation denial or removal. See generally *In re AB*, 196 Misc.2d 940 (Sup Ct., New York Co. 2003); *In re M.B.*, 6 N.Y.3d 437 (2006).

¹⁰ See e.g., *City of N.Y. v. Doe*, 205 A.D.2d 469 (1st Dep't 1994); *McCartney v. Austin, In re Baby Boy W.*, 3 Misc.3d 656 (Sur. Ct., Broome Co. 2004); 31 A.D.2d 370 (3rd Dep't 1969); *Viemeister v. White*, 179 N.Y. 235, 238 (1904). See also *Van Schaick v. Title & Mortg. Guar. Co. of Buffalo*, 264 N.Y. 69 (1934) (holding that the declaration of an insurance emergency temporarily empowered the State government to seize bank property: “[a]n individual may not justly complain of a reasonable legislative invasion of his usual rights or a reasonable legislative restriction of his usual liberty for the purpose of averting an immediate danger which threatens the safety and welfare of the community”); Daniel J. Barnett et al., *Resource Allocation on the Frontlines of Public Health Preparedness and Response: Report of a Summit on Legal and Ethical Issues*. 124 PUB. HEALTH REP. 295-303 (2009).

¹¹ See *City of N.Y. v. Doe*, 205 A.D.2d at 470 (holding that a tuberculosis patient may be detained in a hospital when there is no less restrictive means of public health protection); *Crayton v. Larabee*, 220 N.Y. 493, 503 (1917) (holding that a health officer may quarantine an individual with smallpox against her will when the officer deems it necessary to protect public health).

¹² See *City of N.Y. v. Doe*, 205 A.D.2d at 470; *Crayton*, 220 N.Y. at 503 (upholding quarantine restrictions); *Jacobson v. Massachusetts*, 197 U.S. 11, 27-28 (1905) (upholding mandatory vaccination).

¹³ See, e.g., *Alden v. State*, 20 Ariz. 235 (1919); *Board of Health v. Clayton*, 93 N.J.L. 64, 65 (N.J. 1919); *Com. ex rel. v. Keeper of Lycoming Cnty. Prison*, 47 Pa.C.C. 430 (1918) (all holding that restrictions on human congregation are valid exercises of police power during times of disease outbreak).

¹⁴ See Wendy E. Parmet, *AIDS & Quarantine: The Revival of an Archaic Doctrine*, 14 HOFSTRA L. REV. 53, 54-55 (1985) (describing legal feasibility of several AIDS quarantine measures). See also *U.S. v. Sargeant*, 29 M.J. 812, 817 (ACMR 1989) (holding that protection of public health outweighed the invasion of privacy involved

authorities' power to prioritize community health needs. During crises, relevant court decisions have consistently allowed contravention of individual rights when such action was necessary to protect public health.¹⁵

Commentators and policy-makers have provided relevant legal guidance on balancing individual rights with the public interest. The Guidelines' focus on encouraging allocation practices best suited to maximizing public health, supplemented by an appropriate appeals/grievances process,¹⁶ will help ensure that individuals are not arbitrarily deprived of their rights during a pandemic emergency.

As reflected in the Guidelines, any policy imposing restrictions in an emergency situation must only be in effect while there is an active and declared state of emergency.¹⁷ Furthermore, guidelines or legislation permitting restrictions upon personal liberties to benefit public health must be flexible enough to respond to changing emergency conditions – particularly as data about the pandemic or disease is collected and analyzed. Thus, any limitations on fundamental rights should be temporary and specific to the emergency conditions at the time.

2. Due Process

Section I of the Fourteenth Amendment of the U.S. constitution provides that no state shall “deprive any person of life, liberty, or property, without due process of law.”¹⁸ Due process has both procedural and substantive aspects,¹⁹ which must be considered when implementing the Guidelines.

The state's power to regulate in the area of public health is a function of its police power.²⁰ When regulating on behalf of the public's health, the state may act with broad discretion; however, its actions must not conflict with constitutional protections.²¹ In New York

in punishing an HIV positive soldier for unprotected sex in accordance with 10 U.S.C.S §890); *Montalvo v. Radcliffe*, 167 F.3d 873, 874 (4th Cir. 1998) (upholding the exclusion of an HIV positive boy from a karate class due to significant risk to the health and safety of others).

¹⁵ See David P. Fidler et al., *Emerging and Reemerging Infectious Diseases: Challenges for International, National, and State Law*, 31 INT'L LAW 773, 791-92 (1997).

¹⁶ See Section VI. Appeals.

¹⁷ See Gostin, *supra* note 9, at 69; *Charleston Corp. v. Sinclair*, 264 U.S. 543, 547-548 (1924) (holding that a law which depends upon an emergency for validity may cease to operate if the emergency ceases to exist).

¹⁸ U.S. CONST. amend. XIV, § 1. A constitutional due process inquiry consists of two steps: (1) whether a constitutionally protected interest in life, liberty, or property is at stake, and (2) whether the process of depriving a person of that interest is justified given: (a) the importance of the constitutionally protected interest, (b) the risk of erroneous deprivation, (c) the benefit of additional procedural safeguards, and (d) the government's countervailing interests. See *Mathews v. Eldridge*, 424 U.S. 319, 335 (1975).

¹⁹ The Due Process Clause places limitations on a state's right to act, rather than creating a duty for the state to provide a certain level of protection. *DeShaney v. Winnebago Cnty. Dep't Soc. Serv's*, 489 U.S. 189, 196 (1989) (“the Due Process Clauses generally confer no affirmative right to governmental aid, even where such aid may be necessary to secure life, liberty, or property interest of which the government itself may not deprive an individual”).

²⁰ See *Jacobson*, 197 U.S. at 25 (upholding a statute requiring mandatory smallpox vaccinations in Massachusetts). Recent developments in Constitutional due process “not yet tested in case law” may be relevant to public health activities carried out pursuant to state police powers. Brian Kamoie et al., *Assessing Laws and Legal Authorities for Public Health Emergency Preparedness*, 36 J.L. MED. & ETHICS 23, 25 (2008).

²¹ *Id.* However, the due process protections provided under the extreme circumstances of a public health emergency may be non-traditional and yet still found to be constitutional. James G. Hodge, Jr. & Evan D. Anderson, *Principles*

State, the police power has been relied upon to uphold public health measures including mandatory vaccination in schools,²² fluoridation of the water supply to reduce tooth decay,²³ and compulsory vaccinations as a condition of employment.²⁴

The Due Process Clause only applies to governmental action; it does not protect individuals from private action.²⁵ If governmental action is established, the deprivation of life, liberty, or property is permissible so long as it “has a reasonable relation to a proper government purpose.”²⁶ However, in order to qualify as governmental state action, the action must be “ordered” or “mandated,” not merely approved of or authorized.

Consequently, because adherence to the Guidelines is voluntary and therefore private entities (such as hospitals) have discretion about whether to follow the plan, courts may be reluctant to find “state action.” A finding of no state action would therefore preclude a due process claim against the government or its officers.

3. Equal Protection Considerations

The Equal Protection Clause of the Fourteenth Amendment of the U.S. constitution would be implicated if the state’s emergency measures intentionally discriminated against a suspect class of persons. A suspect class is characterized by members with immutable or highly visible traits, and limited ability to protect themselves in the political process.²⁷ The Equal Protection Clause prohibits states from engaging in unnecessary discriminatory behavior in both state legislation and administrative action.²⁸ Relevant analyses of legislation or policy by the courts have focused on: (1) the type of classification utilized; (2) the purpose of the legislation or

and Practice of Legal Triage During Public Health Emergencies, 64 N.Y.U. ANN. SUR. AM. LAW 249, 275 (2008) (for example, appeals of isolation orders may be delayed or conducted by electronic means).

²² See *Matter of Viemaster v. White*, 179 N.Y. 235 (1904).

²³ See *Paduano v. City of N.Y.*, 45 Misc.2d 718 (Sup. Ct., New York Co. 1965).

²⁴ See *Ritterband v. Axelrod*, 149 Misc. 2d 135 (Sup. Ct., Albany Co. 1990).

²⁵ See *Am. Mfrs. Mut. Ins. Co. v. Sullivan*, 526 U.S. 40, 51 (1999) (quoting *Jackson v. Metro. Edison Co.*, 419 U.S. 345, 350 (1974)); *DeShaney v. Winnebago Cnty. Dep’t Soc. Serv’s*, 489 U.S. 189, 195 (1989); *Jesinger v. NV Fed. Credit Union*, 24 F.3d 1127, 1132 (9th Cir. 1994); *Pure Air v. Davidsen*, 246 A.D.2d 786 (3d Dep’t 1998). The Second Circuit has established two exceptions to this rule: the “special relationship” exception and the “state-created danger” exception. See, e.g., *Matican v. City of N.Y.*, 524 F.3d 151, 155 (2d Cir. 2008). Only the “state-created danger” exception depends upon the relationship between the state and the private actor. See, e.g., *Pena v. Deprisco*, 432 F.3d 98, 109 (2d Cir. 2005). However, in some situations, private actions may be considered state action. See *Sharrock v. Dell*, 56 A.D.2d 446 (2d Dep’t 1978). According to the U.S. Supreme Court, “the inquiry must be whether there is a sufficiently close nexus between the State and the challenged action of the regulated entity so that the action of the latter may be fairly treated as that of the State itself.” *Jackson v. Metro. Edison Co.*, 419 U.S. 345, 350 (1974) (also stating that the fact that an industry is heavily regulated by the state does not in itself create state action).

²⁶ See generally *First Broad. v. Syracuse*, 78 A.D.2d 490 (4th Dep’t 1981) (explaining that the determination of whether the actions of a private entity rise to the level of state action is extremely context- and fact-specific).

²⁷ See *Lyng v. Castillo*, 477 U.S. 635, 638 (1986). The traditional example of a suspect class is a “discrete and insular minority.” *U.S. v. Carolene Products*, 304 U.S. 144, 153 (1938). Moreover, a facially neutral measure which has a disparate impact against a suspect class may violate the Equal Protection Clause even if the disparity is unintended. *Id.*

²⁸ See *Heller v. Doe*, 509 U.S. 312, 320-321 (1993); *City of Cleburne v. Cleburne Living Ctr.*, 473 U.S. 432, 446-448 (1985); *Shelley v. Kraemer*, 334 U.S. 1, 15 (1948).

administrative action; and (3) whether the legislation or administrative action infringes on a fundamental or non-fundamental right.²⁹

If governmental action targets a suspect class, a court will apply the strict scrutiny standard when determining whether it should be upheld.³⁰ However, federal case law has not held that individuals with particular clinical treatment response rates are members of a suspect class.³¹ The Guidelines use survival prognosis to determine resource allocation; they apply to all patients at acute care facilities who need a ventilator, not just a specific group of people. Thus, the Guidelines do not take into consideration any non-clinical traits such as race³² or sex,³³ and their implementation is premised on the state's interest in public health. Consequently, the Guidelines' approach to classification would likely be subject only to rational basis review.

There may be limited circumstances where, the likelihood of survival being equal, individuals 17 years old and younger may receive ventilator priority.³⁴ However, age is not a suspect class³⁵ and thus only subject to rational basis review.³⁶

4. Privacy

The Fourth Amendment to the U.S. constitution protects persons from “unreasonable searches and seizures.”³⁷ New York courts have held that “intrusions into the human body” are searches subject to the Fourth Amendment.³⁸ Determining “reasonableness” requires balancing

²⁹ See *Zablocki v. Redhail*, 434 U.S. 374, 383 (1978).

³⁰ See *U.S. v. Stevens*, 130 U.S. 1577, 1584 (2010); *Playboy Entm't Group*, 529 U.S. at 813 (2000) (defining strict scrutiny); *Carolene Products*, 304 U.S. at 155 (describing the higher level of review for laws targeting a suspect class).

³¹ Whether private hospital staff who might implement the Guidelines might run afoul of equal protection standards is an important question. Because they are non-governmental, their risk of such liability is virtually nil. However, whether governmental hospital staff who implement the Guidelines might be found liable for discriminatorily applying them is another difficult question.

³² See *McLaughlin v. Florida*, 379 U.S. 184, 191-192 (1964).

³³ See *Reed v. Reed*, 404 U.S. 71, 76-77 (1971).

³⁴ According to the clinical protocol, when all available clinical data suggest that the likelihood of survival for both a child (17 years old or younger) and an adult (18 years old or older) have been found equivalent, then young age (i.e., 17 years old or younger) may be used as a tie-breaker to select which patient receives ventilator treatment. See Chapter 2, Pediatric Guidelines, IX.F. Interface between Pediatric and Adult Patients.

³⁵ See *Gregory v. Ashcroft*, 501 U.S. 452, 470 (1991); *Vance v. Bradley*, 440 U.S. 93, 97 (1979).

³⁶ The state would only have to show that providing children with favorable treatment under limited circumstances is rationally related to the legitimate government purpose of maximizing public health. See *City of Cleburne*, 473 U.S. at 440 (describing rational basis review standards). The state would demonstrate that there is a tradition of prioritizing child-protection in times of emergency. Early Baby Doe cases addressed the withdrawal of treatment from severely disabled newborns based on § 504 of the Federal Rehabilitation Act of 1973, which prohibits discrimination based on disability. See, e.g., *Weber v. Stony Brook Hospital*, 467 N.Y.S. 2d 685 (AD 2 Dept. 1983). In *Bowen v. Am. Hosp. Ass'n*, 476 U.S. 610 (1986), the Supreme Court held that this type of treatment decision was not discrimination under § 504. These days, similar arguments could be made under the Americans with Disabilities Act of 1990 (ADA), 42 U.S.C. §12101, or the federal Child Abuse Amendments of 1984 (P.L. 98-457). As a general rule, patients and their attorneys are apt to involve several federal civil rights laws – not just the U.S. Constitution – to oppose ventilator allocation decisions.

³⁷ U.S. CONST. amend. IV.

³⁸ See *People v. Moore*, 97 N.Y.2d 209 (2002); *Patchogue-Medford Cong. of Teachers v. Bd. of Educ.*, 70 N.Y.2d 57 (1987).

the extent to which a search without consent invades personal privacy against the legitimacy of the government's interest in performing the search.³⁹

A medical examination required by the Guidelines may constitute a search subject to Fourth Amendment analysis.⁴⁰ Under the Guidelines, physicians must perform tests upon patients' bodies, tissues, and/or fluids to determine co-morbidities, which indicate likelihood of survival while using a ventilator. Co-morbidity analysis will inform ventilator triage decisions, where patients with greater survival probability will receive priority access to ventilation.⁴¹

Whether performing such a test without consent would be a violation of privacy depends on whether the government's interest in maximizing public health outweighs the test's invasiveness. As established earlier, courts have held that maximizing public health and saving the greatest number of lives are compelling government interests. For example, U.S. Supreme Court decisions have found urine tests for drug use minimally invasive when weighed against health protection measures.⁴²

The U.S. constitution also implicitly recognizes a more general right to privacy: the right to keep information about oneself from being known to others.⁴³ Privacy is considered to be a fundamental right and has been the basis for refusal of medical treatment or medical examinations as an exercise of bodily self-determination.⁴⁴ However, courts have also held that individuals may be required to undergo medical procedures to minimize a significant communal health threat,⁴⁵ indicating that the right to privacy is not indefeasible during a public health emergency. In addition, the right to privacy has been held not to apply to situations in which revealing information about a person will protect other persons.⁴⁶ Under this rule, it may be permissible to require a person to undergo medical examination pursuant to ventilator triage, because exam results might indicate that the individual's continued use of a ventilator will prevent others from surviving when the current patient has a minimal chance of survival.

³⁹ See *Wyoming v. Houghton*, 526 U.S. 295, 299-300 (1999).

⁴⁰ See *Vernonia v. Acton*, 515 U.S. 646, 656-657 (1995) (discussing medical examinations performed on students as searches in context of reasonableness).

⁴¹ See e.g., Chapter 1, Adult Guidelines, Section XI.A. Step 1: Exclusion Criteria. (A clinical examination may reveal that a patient has a medical condition on a list of exclusion criteria, which are conditions that would confer upon a patient a high risk of mortality even with ventilator therapy, and thus the patient would not be eligible for ventilator treatment). However, individuals seeking access to, or continued use of, ventilators might refuse to consent to medical tests that would reveal co-morbidities.

⁴² See *Bd. of Educ. v. Earls*, 536 U.S. 822, 834 (2002); *Vernonia*, 515 U.S. at 658-660 (holding that reasonably supervised urine collection for drug testing is negligibly intrusive for protecting student health and safety).

⁴³ The right to privacy is not explicitly enumerated within the text of the U.S. Constitution; however, courts have interpreted the Constitution to protect individuals' expectation of privacy in personal matters such as family life and medical decisions. See, e.g., *People v. Greene*, 36 A.D.3d 219, 228 (First Dep't 2006).

⁴⁴ See *Eichner v. Dillon*, 73 A.D.2d 431, 432 (2d Dep't 1980).

⁴⁵ See *In re Storar*, 52 N.Y.2d at 377 ("The State has a legitimate interest in protecting the lives of its citizens. It may require that they submit to medical procedures to eliminate a health threat to the community"). See also *Jacobson v. Massachusetts*, 197 U.S. at 27-28 (addressing mandated vaccination); *City of N.Y. v. Doe*, 205 A.D.2d at 470; *Crayton v. Larabee*, 220 N.Y. 493, 503 (1917) (addressing mandated quarantine).

⁴⁶ See *Bartnicki v. Vopper*, 532 U.S. 514, 539 (2001) ("Where publication of private information constitutes a wrongful act, the law recognizes a privilege allowing the reporting of threats to public safety"). This theory is based on threats against known, or "named" individuals; therefore, it is unclear how it may be applied when the threat is to the community at large and not an identifiable person.

B. New York State Constitutional Considerations

Several provisions of the New York State constitution may be implicated in times of public health emergencies and may be pertinent to the implementation of the Ventilator Allocation Guidelines. Some relevant provisions have parallels in the United States constitution (discussed in section III.A), including those related to due process,⁴⁷ unreasonable search and seizure,⁴⁸ and equal protection.⁴⁹ Despite their similarities, analyses under New York constitutional provisions may not proceed identically to their counterparts under the federal constitution.⁵⁰ The State constitution also has a provision concerning the promotion and protection of public health – a provision relevant to ventilator allocation without a federal parallel.⁵¹ This section first addresses instances when New York State analyses of due process, privacy, and equal protection differ from federal analyses and how these differences should be considered when considering the constitutionality of the Ventilator Allocation Guidelines. It then discusses how the Guidelines support the intentions of the public health provision of the New York constitution.

1. Parallel Provisions in the New York and Federal Constitutions

Ordinarily, New York State constitutional provisions that have federal counterparts will be interpreted to provide the same degree of protection as provided by the U.S. constitution.⁵² But New York has provided greater protection in some cases involving racially motivated search and seizure,⁵³ requirements of disclosure of exculpatory evidence,⁵⁴ and reasonable suspicion to

⁴⁷ NY CONST. art. I, §1, §6; US CONST.amend. V.

⁴⁸ NY CONST. art. I, §12; US CONST.amend. IV.

⁴⁹ NY CONST. art. I, §11; US CONST.amend. XIV.

⁵⁰ While state law protections must not sink below the U.S. constitutional “floor” for individual rights, they may provide more extensive protections. See *Hernandez v. Robles*, 7 Misc. 3d 459, 591-591 (Sup. Ct. New York Co. 2004) (citing *People v. LaValle*, 3 N.Y.3d 88, 129 (2004) (holding that the New York constitution may receive construction independent from the U.S. constitution and thus may afford greater protection); see also *Cooper v. Morin*, 49 N.Y.2d 69, 79 (1979)). The New York Court of Appeals has held that the mere presence of the New York constitution’s parallel provisions indicates “special meaning to the people of New York,” and if they were not independently analyzed, they would be “redundant.” *People v. Alvarez*, 70 N.Y.2d 375, 379 n.1 (1987).

⁵¹ NY CONST. art. XVII, § 3 (“Public Health: The protection and promotion of the health of the inhabitants of the state are matters of public concern and provision therefor shall be made by the state and by such of its subdivisions and in such manner, and by such means as the legislature shall from time to time determine.”).

⁵² See *Hernandez v. Robles*, 7 N.Y.3d 338 (2006) (citing *Under 21, Catholic Home Bur. For Dependent Children v. City of New York*, 65 N.Y. 2d 344, 350 fn. 6 (1985) (holding that “the State constitutional equal protection clause [(NY CONST. art. I, § 11)] is no broader in coverage than the Federal provision.”)).

⁵³ For example, a federal court dismissed an equal protection claim for failure to state sufficient facts, but the State court heard the state equal protection claim on the same facts. See *Brown v. State of New York*, 89 N.Y. 2d 172 (1996) (recognizing, among others, cause of action for damages resulting from alleged constitutional equal protection tort, specifically, racially motivated violations of N.Y. State constitution search and seizure clause); *Brown v. State of New York*, 250 A.D.2d 314 (1998) (granting class action status to plaintiffs for equal protection tort claim); *Brown v. City of Oneonta*, 221 F. 3d 329 (2nd Cir. 2000), *reh and reh en banc denied*, 235 F. 3d 769 (2000), *cert. denied*, 534 U.S. 816 (2001).

⁵⁴ State due process protections have been held to be broader than federal due process for requiring disclosure of exculpatory evidence. See *People v. Vilardi*, 76 N.Y.2d 67, 75-77 (1990).

use drug-seeking dogs.⁵⁵ While unrelated to matters of resource triage or public health, these examples indicate that constitutional concerns arising from the implementation of the Ventilator Guidelines under the State constitution may be analyzed differently than they would under the Federal constitution.⁵⁶

New York constitutional analysis may be different from federal analysis if the relevant provision is textually different from its federal counterpart; there is “any preexisting State statutory or common law defining the scope of the individual right in question;” the State has a particular history or tradition of protecting the individual right; the right is identified in the State constitution as being one of peculiar State or local concern; or the State’s citizens have “distinctive attitudes” toward the definition, scope or protection of the individual right that would indicate greater protection is due.⁵⁷ Although courts have disagreed whether New York due process protections are greater than those afforded by the federal constitution,⁵⁸ neither of the two “rights” discussed above that may be implicated in implementing the Guidelines – the right to medical treatment or the right to life – would necessarily require a distinct State constitutional analysis. Neither federal nor New York State courts have recognized the right to receive the best possible medical treatment,⁵⁹ let alone the specific right to receive any treatment during a public health emergency. In fact, courts in several federal cases described in Section III as well as New York cases⁶⁰ have held that individual rights may be sacrificed when necessary to preserve the common welfare.⁶¹ Further, New York’s due process clause neither specifically recognizes a right to life-sustaining ventilator treatment⁶² nor is sufficiently unique to support a broader such right than might be found under the federal due process clause. There is also no historical statutory or common law basis to find that such a right is of peculiar state or local concern or that New York’s citizens have any distinctive attitude toward it other than what might be found in the United States generally. As such, any analysis of constitutional rights under the State constitution should proceed as it would under the U.S. constitution.

⁵⁵ Under the New York State Constitution’s protection from unreasonable search and seizure, the use of dogs trained to seek out drugs requires reasonable suspicion, whereas this method of law enforcement does not implicate the Fourth Amendment of the U.S. constitution. See *People v. Dunn*, 77 N.Y.2d 19, 21 (1990).

⁵⁶ *Hernandez* also held that the instances where the New York constitution afforded greater protection than the US constitution generally involved criminal defendants or prisoners. See *Hernandez v. Robles*, 7 N.Y.3d at 362. This would not indicate greater or lesser protection for defendant health care workers accused of depriving patients of due process during ventilator triage.

⁵⁷ See *People v. P.J. Video*, 68 N.Y.2d 296, 303 (1986); Gail Donoghue and Jonathan I. Edelman, *Life After Brown: The Future of State Constitutional Tort Actions in New York*, 42 N.Y. SCH. L. REV. 447, fn. 266 (citing *P.J. Video, Inc.*, 68 N.Y.2d at 303 *cert. denied*, 479 U.S. 1091 (1987)) (“Although the court of appeals has since retreated from the P.J. Video test... it continues to use the P.J. Video standards as persuasive factors in determining when a New York constitutional right should be interpreted differently from its federal counterpart”).

⁵⁸ Compare *Hernandez*, 7 N.Y.3d at 338 and *Under 21*, 65 N.Y. 2d at 344 with *Brown*, 89 N.Y. 2d at 172; *Vilardi*, 76 N.Y.2d at 67; *Dunn*, 77 N.Y.2d at 19.

⁵⁹ See Section III.B.2. Public Health Provision.

⁶⁰ See, e.g., *Deschamps v. Deschamps*, 103 Misc. 2d 678, 685 (1980) (acknowledging that “a state may, in the exercise of the police power, enact a statute to promote the public health, safety, morals or general welfare. Such a statute, because of retroactive application or otherwise, may diminish in value or totally destroy an individual's right, whether in property as such or arising out of contract, provided that the public interest to be promoted sufficiently outweighs in importance the private right which is impaired.”).

⁶¹ *People v. P.J. Video*, 68 N.Y.2d at 296.

⁶² The terms “ventilator treatment” is used interchangeably with “ventilator therapy.”

2. Public Health Provision

While there is no explicit provision regarding the right to health in the U.S. constitution, the New York State constitution assigns responsibility for the “protection and promotion” of public health to the State.⁶³ In drafting the “public health” provision of the State constitution, the drafters included the delivery of health care in the form of medical services and the control of epidemics among its original goals.⁶⁴ Ventilator treatment and triage is both a medical service and a form of pandemic control. As a medical service, ventilator treatment is administered with the goal of protecting the health of the recipients. Under the Guidelines, each triage decision should optimize distribution of ventilators to increase total patient survival. During an influenza outbreak of pandemic proportions, preserving the greatest number of lives will restrict the disease’s fatal impact. As such, ventilator triage is a form of pandemic control. The Ventilator Guidelines’ objective of saving the greatest number of lives comports with the provision’s goals of protecting and promoting public health.⁶⁵

The text of the Public Health provision makes the State’s fulfillment of their public health responsibility mandatory⁶⁶ and gives the State’s legislature discretion to effectively meet this responsibility.⁶⁷

IV. EMERGENCY/DISASTER DECLARATIONS & EMERGENCY POWERS

All states and the federal government have procedures by which a person authorized to do so may declare a public health emergency or disaster. Both federal and state laws also may confer certain emergency powers upon specific individuals (e.g., the President, the Governor, or the Department of Health) when a public health or disaster emergency has been declared. An influenza pandemic of the sort contemplated in the Guidelines could meet the criteria needed to trigger such a declaration. Depending on the jurisdiction, the emergency powers conferred by an emergency declaration may include: (1) the power to suspend application of existing statutes, rules, and regulations to better cope with the situation, and/or (2) the provision of statutory liability protections for health care workers who provide care during a declared state of emergency.⁶⁸

⁶³ NY CONST. art. XVII, § 3.

⁶⁴ See Alan Jenkins & Sabrineh Ardalan, *Special Series on Health Care: Positive Health: The Human Right to Healthcare under the New York Constitution*, 35 FORDHAM URB. L.J. 479, 486, 490 (2008) (citing a report from the committee created to assist delegates to the 1938 Constitutional Convention that explained the vision for the public health provision. N.Y. State Constitutional Convention Committee, *Problems Relating to Bill of Rights and General Welfare* at 512 (1938)).

⁶⁵ Further evidence that the Guidelines comport with the Public Health provision come from the definition of “Public Health” as embodied by the provision. The drafters of the provision looked to guidance of the American Public Health Association, which held that “public health constitutes the science and art of preventing disease, prolonging life, and promoting physical health and efficiency through,” among other things, “...the control of community infection.” N.Y. CONST. art. XVII, § 3; Revised Record of the Constitutional Convention of the State of New York.

⁶⁶ See Jenkins & Ardalan *supra* note 64, at 485-486.

⁶⁷ See NY CONST. art. XVII, § 3 (“...and provision therefor shall be made by the state and by such of its subdivisions.”).

⁶⁸ New York State law does not include this latter emergency power.

A. Federal Declaration of Emergency

Under either the Robert T. Stafford Disaster Relief and Emergency Assistance Act⁶⁹ or the National Emergencies Act,⁷⁰ the President of the United States can declare a federal state of emergency or major disaster. Under the Public Health Service Act, the Secretary of Health and Human Services (the Secretary of HHS) may declare a public health emergency in the case of disease, disorder, or bioterrorist attack.⁷¹

B. New York State Declaration of Emergency and Emergency Powers

In New York State, the Governor has the authority, pursuant to Article 2-B of the New York State Executive Law (the Disaster Act), to declare a state of emergency whenever “a disaster has occurred or may be imminent for which local governments are unable to respond adequately.”⁷² A pandemic could meet the criteria of a “disaster” needed to trigger such a declaration.⁷³ This declaration permits the Governor to “temporarily suspend specific provisions of any statute, local law, ordinance, or orders, rules or regulations, or parts thereof, of any agency during a State disaster emergency, if compliance with such provisions would prevent, hinder, or delay action necessary to cope with the disaster.”⁷⁴ Suspensions are subject to “the state constitution, the federal constitution and federal statutes and regulations,” and “no suspension shall be made which does not safeguard the health and welfare of the public and which is not reasonably necessary to the disaster effort.”⁷⁵ Suspensions are limited to 30 days, but can be renewed for an additional 30 days thereafter.⁷⁶

Although New York’s Disaster Act allows suspension of some existing State laws, the Act itself does not permit the enactment, promulgation, or creation of new laws. In particular, it does not allow the creation of new liability protections to health care providers where none existed before. Furthermore, while the Disaster Act allows suspension of any State statute, local law, ordinance, agency order, rule, or regulation, it does not allow suspension of judicial orders or common law. Because much civil liability is governed by common law, there is much civil liability law which a Disaster Act suspension cannot suspend.

Further, the Commissioner of Health may issue a public health order to protect the public health.⁷⁷ Whenever the Commissioner, after investigation, is of the opinion that any person is causing, engaging in or maintaining a condition or activity which constitutes danger to the health

⁶⁹ Federal Emergency Management Act, 42 U.S.C. §§ 5121-5296.

⁷⁰ Declaration of National Emergency by President, 50 U.S.C. § 1621. President Bush invoked this clause when he declared an emergency after the attacks of September 11, 2001.

⁷¹ Public Health Service Act, 42 U.S.C. § 247d. The Secretary of HHS invoked this provision in declaring public health emergencies in the aftermath of the attacks of September 11, 2001 and Hurricane Katrina.

⁷² N.Y. EXEC. LAW § 28(1) (the New York State and Local Natural Disaster and Man-Made Disaster Act).

⁷³ New York does not have a public health emergency statute delineated as such, nor is “public health emergency” defined in New York law or administrative regulations. Enacting such a statute might create new authority to promulgate a binding standard of care in a crisis or new authority to modify immunity standards for workers in an emergency.

⁷⁴ N.Y. EXEC. LAW § 29-a.

⁷⁵ *Id.*

⁷⁶ N.Y. EXEC. LAW § 29-a(2)(a).

⁷⁷ N.Y. PUB. HEALTH LAW § 16.

of the people, the Commissioner shall order the person, including any State agency or political subdivision having jurisdiction, by written notice to discontinue such dangerous condition or activity or take certain action immediately or within a specified period of less than 15 days.⁷⁸ Within 15 days, the Commissioner must provide an opportunity to be heard and to present any proof that such condition or activity does not constitute a danger to the health of the people.

However, no State action would insulate health care workers from liability for breaches of federal law. For example, State action could not protect health care workers from alleged HIPAA⁷⁹ or EMTALA⁸⁰ violations. Liability (or sanctions) under HIPAA or EMTALA can only be waived by a declaration of a national public health emergency by the President or the Secretary of HHS. Likewise, Constitutional claims alleging violations of due process or equal protection would not be addressed by an application of State law as a result of a State declaration of emergency.

To encourage adherence to the Guidelines and in the interest of expediency, the Task Force recommends the drafting of model Executive Orders upon which the Governor may rely in a declared emergency. These draft orders should be narrowly tailored to suspend appropriate laws in a declared emergency to protect those who adhere to the Guidelines.⁸¹ Such orders could be modified to reflect the particular needs of the pandemic and would only go into effect if they are signed by the Governor at the time of the emergency.⁸²

C. New York State Statutes that Could Interfere with Adherence to the Guidelines

Prudence compels consideration of which laws might interfere with effective implementation of the clinical ventilator allocation protocol recommended by the Guidelines:

New York Public Health Law § 2801-d (“Private Actions by Patients of Residential Health Care Facilities”). This statute provides that residential health facilities that deprive patients of any “right or benefit” of such facilities will be liable for physical, emotional, or financial injuries suffered as a result. This law might be implicated in an influenza pandemic where patients are removed or refused access to ventilators pursuant to the Guidelines.

New York Public Health Law § 2803-c (“Rights of Patients in Certain Medical Facilities”). This law includes nursing homes and facilities providing health related services. In particular, Section 2803-c(3)(e) – which ensures that patients have the right to receive adequate and

⁷⁸ *Id.* See also *New York State Public Health Legal Manual: A Guide for Judges, Attorneys and Public Health Professionals* (Feb. 2010), <http://www.nycourts.gov/whatsnew/pdf/PublicHealthLegalManual.pdf>.

⁷⁹ HIPAA Privacy Rule, 45 C.F.R. § 160 *et seq.* The HIPAA Privacy Rule provides federal protections for personal health information held by covered entities and gives patients an array of rights with respect to that information.

⁸⁰ Emergency Medical Treatment and Active Labor Act, 42 U.S.C § 1395dd(a). EMTALA requires that hospital emergency rooms screen all patients who seek emergency treatment.

⁸¹ For examples of New York laws that could interfere with adherence to the Guidelines, see Section IV.C.

⁸² For examples of another state’s draft executive orders, see Colorado Department of Public Health & Environment (CDPHE) Internal Emergency Response Plan, Annex U, Appendix 1: Pandemic Influenza, Attachment 3, *Governor’s Expert Emergency Epidemic Response Committee Draft Executive Orders* (Apr. 26, 2006), The Governor’s Expert Emergency Epidemic Response Committee (GEEERC) was statutorily created in 2000 to develop a public health response to “acts of bioterrorism, pandemic influenza and epidemics caused by novel and highly fatal infectious agents.”

appropriate medical care, to be fully informed of his or her medical condition and proposed treatment unless medically contraindicated, and to refuse medication and treatment after being fully informed of and understanding the consequences of such actions – might conflict with applying the Guidelines.

New York Public Health Law § 2805-b(2)(a). In cities with a population greater than one million (i.e., New York City), hospitals are required to “provide emergency medical care and treatment to all persons in need of such care and treatment who arrive at the entrance to such hospital therefor” and failure to do so constitutes a misdemeanor with conviction carrying a fine and imprisonment of up to one year.⁸³ This law might be implicated in a flu pandemic should patients be refused access to ventilators pursuant to the Guidelines.

Article 29-C of the Public Health Law (“Health Care Agents and Proxies”). Section 2981 (“Appointment of Health Care Agent; Health Care Proxy”) may be incompatible with the clinical ventilator allocation protocol described in the Guidelines. The proxy decision-making law grants the guardian the right to withhold or withdraw life-sustaining treatment when it is in the patient’s best interest, based on the patient’s wishes, including his or her moral and religious beliefs.

Article 29-CC of the Public Health Law (Family Health Care Decisions Act (FHCDA)). The sections of the FHCDA that could interfere with adherence to the Guidelines include, but may not be limited to: (1) § 2994-d(5), “Health Care Decisions for Adult Patients by Surrogates;” (2) § 2994-g(5), “Health Care Decisions for Adults without Surrogates;” (3) § 2994-f, “Obligations of Attending Physician;” (4) § 2994-i, “Specific Policies for Orders not to Resuscitate;” and (5) § 2995-j, “Revocation of Consent.”

Education Law, Articles 130 and 131-A (“Professional Misconduct”). While the Department of Health regulates hospitals,⁸⁴ the State Education Department regulates the professions.⁸⁵ While the Education Law defines professional misconduct for all professions, including – among others – nurses⁸⁶ and physicians, physician’s assistants, and specialist’s assistants,⁸⁷ and while the Education Department enforces professional discipline for most professions including nursing,⁸⁸ the Department of Health enforces such discipline for physicians, physician’s assistants, and specialist’s assistants.⁸⁹ It is professional misconduct to practice with repeated or gross negligence, to practice with repeated or gross incompetence, to be convicted of committing an act constituting a crime under New York or federal law, to be found guilty by another jurisdiction of certain improper professional practice, to commit conduct in the practice of medicine which evidences moral unfitness to practice medicine, to reveal personally identifiable data without prior patient consent, except as authorized or required by law, or to abandon or neglect a patient under and in need of immediate professional care without making reasonable

⁸³ The law applies to “general” hospitals and may be exempted where the hospital is structured to provide specialized or limited treatment.

⁸⁴ N.Y. PUB. HEALTH LAW §§ 10-22; N.Y. PUB. HEALTH LAW §§ 2800-2823; N.Y. COMP. CODE R. & REGS tit. 10, pts. 400-794.

⁸⁵ NY. ED. LAW Arts. 130-166; N.Y. COMP. CODE R. & REGS tit. 8, pts. 17, 29, 59-60, 64.

⁸⁶ NY. ED. LAW Art. 131, §§ 6509-6511.

⁸⁷ NY. ED. LAW Art. 131, §§ 6530-6531.

⁸⁸ NY. ED. LAW Art. 130, §§ 6510-6511.

⁸⁹ NY. ED. LAW § 6532; N.Y. PUB. HEALTH LAW §§ 230-230-D.

arrangements for the continuation of such care.⁹⁰ The threat of professional discipline under these provisions might inhibit health care professionals from following the Guidelines in a flu pandemic. Accordingly, suspension of these professional misconduct statutes – to the extent they would punish compliance with the Guidelines – might encourage professionals to follow the Guidelines.

Ed. Law § 6530 (“Definitions of Professional Misconduct”). Education Law Section 6530 defines professional misconduct of physicians, physician’s assistants, and specialist’s assistants, as (among other definitions) “[p]ractic[ing] the profession with negligence on more than one occasion.”⁹¹ However, the law allows charges to “be dismissed in the interest of justice,” thereby potentially rendering suspension of the law unnecessary.⁹²

V. LEGAL LIABILITY

A. Existing Liability Protections

The Guidelines represent a significant departure from standard non-emergency medical practice. In a non-crisis setting, the prevailing medical standard of care focuses on the needs of each individual patient and is centered on the principle of informed consent. In a public health emergency, however, such concentrated care may be impossible or inadvisable due to: (1) resource limitations, and (2) the goal of saving the most lives overall.

Recent events have underscored the need for systematic protection of health care providers and entities who follow a modified medical standard of care in a public health emergency. In the most well-known case, Dr. Anna Pou, a surgeon on the faculty at the Louisiana State University School of Medicine, remained in New Orleans in the immediate aftermath of Hurricane Katrina to care for patients.⁹³ She was later arrested for the alleged murder of four patients to whom she provided palliative care during the emergency. Although the Louisiana Grand Jury declined to indict her on the murder counts, Dr. Pou still faces civil suits brought by the decedents’ families.⁹⁴ Similar threats of criminal and civil liability, or threats of professional discipline, might discourage other physicians, nurses, and health care professionals – as well as entities such as hospitals – from providing appropriate care and following state guidance that deviates from standard non-emergency medical practice in a future public health emergency.

In order to encourage adherence to the Guidelines, health care workers and entities who follow in good faith the adult and pediatric clinical ventilator allocation protocols must be provided some measure of liability protection. The following section examines the current status of federal and New York State liability protections, and consider, where relevant, provisions in other states. The section concludes that existing laws and regulations are inadequate to protect

⁹⁰ NY. ED. LAW § 6530(3)-(6), (9), (16), (20), (23), (30). Many of the same acts constitute professional misconduct for nurses as well. NY. ED. LAW § 6530(5),(9); N.Y. COMP. CODE R. & REGS tit.29.

⁹¹ NY. ED. LAW § 6530(3).

⁹² *Id.*

⁹³ Susan Okie, *Dr. Pou and the Hurricane – Implications for Patient Care During Disasters*, 358 NEW ENGL. J. MED. 1 (2008).

⁹⁴ *Id.*

caregivers during a public health emergency. Various measures – implemented either alone or in combination with each other – merit consideration as additional approaches to mitigating civil and criminal liability.

At both the State and federal level, no uniform legal protection exists for the provision of care pursuant to disaster plans or guidance during a health crisis in New York State. Although no law provides complete immunity from suit, various laws provide different levels of protection. For example, some laws provide civil liability *immunity* (e.g., the health care provider or entity cannot be found liable for harm to the patient) while others *indemnify* providers for civil liability (e.g., the health care provider or entity will not be required to pay damages, or will be reimbursed for such payments, to the harmed patient). Notably, no applicable law in New York State provides immunity against criminal liability or professional discipline. Further, the majority of applicable laws provide only qualified – rather than absolute – immunity. In other words, most laws protect providers conditionally (e.g., where the defendant has not engaged in willful or intentional misconduct or gross negligence), rather than offering unconditional protections against civil or criminal liability. Moreover, although current laws offer some legal safeguards for health care workers and entities, they vary according to the population they cover: some apply only to unpaid volunteers,⁹⁵ while fewer offer protections for compensated health care providers. In sum, the current legal system does not insulate all health care workers and entities who provide care within New York State pursuant to the Guidelines from the burdens and costs of defending a criminal prosecution, a civil lawsuit, or a professional disciplinary proceeding.

1. Federal Liability Protections

a. The Public Readiness and Emergency Preparedness Act (PREP Act)

Enacted in 2005, the PREP Act limits liability under both state and federal law with respect to the use of “covered countermeasures” for pandemic influenza or other public health threats.⁹⁶ Specifically, upon a determination by the Secretary of HHS that either a public health emergency or the credible risk of such emergency exists, the Secretary of HHS may issue a declaration that certain “covered persons” shall be immune to claims arising from the administration or use of a covered countermeasure.⁹⁷ Covered persons include manufacturers of countermeasures, distributors of countermeasures, program planners of countermeasures (i.e., individuals and entities involved in planning and administering programs for distribution of a countermeasure); qualified persons who prescribe, administer, or dispense countermeasures (i.e.,

⁹⁵ Broadly, volunteers are health care workers from unaffected areas who may provide assistance in a place of emergency, or retirees or students with medical training who volunteer their services during a declared disaster emergency. “Spontaneous” untrained volunteers are less of a concern in cases concerning ventilator allocation in an influenza pandemic than in dealing with other public health emergencies, and will therefore not be addressed here. See Sharon Hoffman, *Responders’ Responsibility: Liability and Immunity in Public Health Emergencies*, 96 GEO. L. J. 1913, 1957-58 (2008).

⁹⁶ *Targeted Liability Protections for Pandemic and Epidemic Products and Security Countermeasures*, 42 U.S.C. § 247d-6d.

⁹⁷ *Id.*

health care and other providers). Covered persons will not be held liable unless a “death or serious physical injury” was caused by “willful misconduct.”⁹⁸

Notably, the PREP Act would likely not provide liability protection to persons and entities adhering to the Guidelines during a pandemic. As an initial matter, the PREP Act appears not to have been designed for these specific types of circumstances.⁹⁹ It is similarly unclear whether ventilator treatment would qualify as a “countermeasure” under the Act. Furthermore, even if ventilator therapy did qualify as a countermeasure, it is unlikely that the PREP Act would provide any protection to those withholding or withdrawing such therapy, even if done in compliance with the Guidelines. Thus, it would be unwise to rely on the PREP Act for liability protection for caregivers adhering to the Guidelines in an emergency.

b. The Volunteer Protection Act (VPA)

Enacted in 1997, the VPA: (1) provides immunity from liability for economic damages to volunteers serving governmental entities and non-profit organizations (but not to the non-profit organizations or governmental entities themselves), and (2) limits the volunteer’s liability for non-economic damages.¹⁰⁰ The VPA’s protections do not apply where the harm was caused by willful or criminal misconduct, gross negligence, reckless misconduct, or a conscious, flagrant indifference to the rights or safety of the individual harmed by the volunteer.¹⁰¹ The VPA also excludes protection for crimes of violence, acts of international terrorism, hate crimes, sexual offenses, or violations of federal or state civil rights law. The Act preempts any inconsistent state law, but does not preempt state law that provides additional protection from liability for volunteers. Moreover, the VPA’s protections do *not* depend on a federal or state declaration of emergency.

The VPA only provides protection to volunteers; it provides no coverage to those most likely to be involved in ventilator allocation during an emergency (i.e., health care workers who are employed and compensated for their services, and the hospitals and other entities that may be

⁹⁸ Under the PREP Act, “willful misconduct” is defined as an act or omission that is taken “(i) intentionally to achieve a wrongful purpose; (ii) knowingly without legal or factual justification; and (iii) in disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit.” Public Readiness and Emergency Preparedness Act, 42 U.S.C. § 247d-6d(c)(1)(A). The Secretary of HHS, in consultation with the U.S. Attorney General, “shall promulgate regulations . . . that further restrict the scope of actions or omissions by a covered person that may qualify as ‘willful misconduct.’” 42 U.S.C. § 247d-6d(c)(2)(A). Furthermore, “the plaintiff shall have the burden of proving by clear and convincing evidence willful misconduct by each covered person sued and that such willful misconduct caused death or serious physical injury.” 42 U.S.C. § 247d-6d(c)(3). The “clear and convincing” standard is higher than the proof by a “preponderance of the evidence,” the usual burden of proof in civil cases.

⁹⁹ See, e.g., Eva B. Stensvad, *Note, Immunity for Vaccine Manufacturers: The Vaccine Act and Preemption of Design Defect Claims*, 95 MINN. L. REV. 315, 335 (2011).

¹⁰⁰ Volunteer Protection Act, 42 U.S.C. § 14501, *et. seq.* “Volunteer” is defined as an individual performing services for a nonprofit organization or a governmental entity who does not receive compensation in excess of \$500 per year. The volunteer’s liability for non-economic damages is only limited if the volunteer was acting within the scope of his or her responsibilities at the time of the act or omission and the volunteer was properly licensed, certified, or authorized by the appropriate state authorities for the activities or practice, where the activities were undertaken within the scope of the volunteer’s responsibilities.

¹⁰¹ *Id.*

engaged in the provision of care during a pandemic). Thus, it would be unwise to rely on the VPA for liability protection for caregivers who adhere to the Guidelines in an emergency.

2. New York State Liability Protections

a. Background

Individual health care providers and entities adhering to the Guidelines, or any protocol recommending a modified medical standard of care during an emergency, may face both State civil¹⁰² and criminal liability. Potential civil liability claims against individual clinicians and other caregivers are likely to be based in negligence, particularly medical malpractice.¹⁰³ Claims against entities are likely to be based on corporate negligence theories and vicarious liability.¹⁰⁴

New York State has a number of existing laws intended to protect volunteers, health care providers, and entities from liability in a public health emergency, such as an influenza pandemic.¹⁰⁵

b. The Disaster Act

The Disaster Act permits the Governor to declare a state of emergency.¹⁰⁶ With respect to liability, the Disaster Act also grants immunity to actions taken by political subdivisions “for any claim based upon the exercise or performance or the failure to exercise or perform a discretionary function or duty on the part of any officer or employee in carrying out the

¹⁰² In most cases, civil liability protections apply to tort liability, such as medical malpractice. A tort is a wrongful act by one person that gives another person the right to sue him or her for damages.

¹⁰³ Except where a federal cause of action is established by statute, medical malpractice claims are governed by state common law. In New York, courts apply the “prudent doctor standard” and the “same community” standard to determine the propriety of a clinician’s conduct, requiring that the physician exercise due care, “as measured against the conduct of his or her own peers” in the same geographic community. *McCullough v. Univ. Rochester Strong Mem. Hosp.*, 17 A.D.3d 1063 (2005); *Nestorowich v. Ricotta*, 97 N.Y.2d 393 (2002); *Caristo v. Sanzone*, 96 N.Y.2d 172, 175 (2001) (applying the common-law emergency doctrine, whereby an individual faced with “a sudden and unexpected circumstance which leaves little or no time for thought, deliberation or consideration” is judged on whether the response is that of a reasonably prudent person under the circumstances). Application of the “same community standard” may be very relevant when comparing the conduct typical of physicians in a very rural community to the conduct typical of physicians in an urban setting. In some cases, courts have deviated from applying the locality rule and instead sometimes apply a minimum statewide standard of care or even a nationwide standard.

¹⁰⁴ Hoffman, *supra* note 95, at 1918.

¹⁰⁵ In addition to those laws discussed herein, the New York State Defense Emergency Act (SDEA), provides a grant of immunity for civil defense workers for actions taken “in good faith carrying out, complying with or attempting to comply with any law, any rule, regulation or order duly promulgated or issued pursuant to” the SDEA and “relating to civil defense, including but not limited to activities pursuant thereto, in preparation for anticipated attack, during attack, or following attack or false warning thereof, or in connection with an authorized drill or test.” N.Y. UNCONSOL. LAW Ch. 131, § 113. The immunity provision also extends to government, partnerships, and corporations, as well as to individuals. However, although the Governor may invoke the SDEA following an “attack,” pandemics may not qualify under the SDEA, where such a pandemic is considered foreseeable. In the New York Court of Appeals’ only case addressing the SDEA’s immunity provisions, the court noted that, “[I]mmunity is the rule, immunity the exception . . . The rule of non-liability is out of tune with life about us, at variance with modern-day needs and with concepts of justice and fair dealing.” *Abbott v. Page Airways, Inc.*, 23 N.Y.2d 502, 507 n. 2, (1969) (quoting *Bing v. Thunig*, 2 N.Y.2d 656, 666-67, (1957) (alterations in original)).

¹⁰⁶ See discussion, Section IV.B. New York State Declaration of Emergency and Emergency Powers.

provisions of this section.”¹⁰⁷ “Immunity” is not immunity from suit, however; covered parties may still be subject to significant expenses, stresses and damage to reputation while defending allegations against them, but the Disaster Act may prevent a finding of liability.¹⁰⁸ The Act’s protections also would be unlikely to extend beyond political subdivisions and their employees and officers and may therefore not cover a physician’s conduct if his or her conduct is within the normal scope of duties.¹⁰⁹ Amending the Disaster Act to explicitly grant immunity from liability to private non-government actors may promote compliance with the Guidelines by providing some measure of protection, although it would not insulate providers who follow the Guidelines from suit or immunize caregivers from federal constitutional claims.

c. Good Samaritan Laws

Under State Good Samaritan Laws, certain health care providers who provide care at the scene of an accident or emergency are protected against civil liability.¹¹⁰ However, these laws apply only to care provided *outside* a hospital, doctor’s office, or any other place having proper and necessary medical equipment. Significantly, the Guidelines are intended for application in the exact locations that the Good Samaritan Laws exclude – those with ventilators, such as hospitals.

Moreover, the State’s Good Samaritan Laws apply only to voluntary and uncompensated care and not to: (1) professionals with a pre-established duty of care to the patient; (2) those acting in the context of their normal duties; or (3) entities such as hospitals and businesses. Consequently, Good Samaritan Laws exclude a majority of those health care professionals and entities likely to be involved in disaster response and those whose adherence to the clinical ventilator allocation protocol enunciated in the Guidelines are sought. Amending the State’s Good Samaritan Laws to explicitly render both paid and unpaid providers and entities such as hospitals immune from civil liability might provide more adequate protection. However, such amendments would cover all those providing care during a declared emergency, including those who neglect or refuse to follow the Guidelines. Thus, it is unwise to rely on the Good Samaritan Laws as they currently stand to encourage adherence to the Guidelines, and they may be difficult to amend without unintentionally providing over-broad protections.

d. Public Officers Law § 17

¹⁰⁷ N.Y. EXEC. LAW § 25(5). *See also In re World Trade Ctr. Disaster Site Litig.*, 456 F. Supp. 2d 520, 558 (2d Cir. 2008).

¹⁰⁸ *In re World Trade Ctr. Disaster Site Litig.*, 456 F. Supp. 2d at 558.

¹⁰⁹ At least one court has opined that “[h]ad the legislature intended for immunity to extend to private actors, it could easily have so provided.” *Id.*

¹¹⁰ N.Y. PUB. HEALTH LAW § 3000-a(1); N.Y. ED. LAW § 6527 (applying nonliability to licensed physicians providing voluntary and uncompensated first aid or emergency treatment at the scene of an accident or other emergency outside a hospital, doctor’s office or any other place having proper and necessary medical equipment, to a person who is unconscious, ill, or injured), § 6547 (stating that a physician assistant rendering first aid or emergency treatment at the scene of an accident or outside a hospital or doctor’s office is not liable for damages, injuries, or death unless it is established that the injuries or death are caused by gross negligence), § 6737 (applying nonliability for licensed physical therapists for first aid or emergency treatment), § 6909 (applying nonliability for nurses for providing uncompensated first aid or emergency treatment), § 7006 (applying nonliability for podiatrists for providing uncompensated first aid or emergency treatment), § 6611 (applying nonliability for dentists for providing uncompensated first aid or emergency treatment).

This statute requires New York State to provide defense and indemnity to State “employees” in certain civil actions arising out of acts or omissions alleged to have occurred while the employee was acting within the scope of public employment or duties, unless the alleged damage “resulted from intentional wrongdoing.”¹¹¹ “Employee” is broadly defined and may encompass health care providers if they are “volunteer[s] expressly authorized to participate in a state-sponsored volunteer program,¹¹² but does not cover independent contractors.¹¹³ Section 17 was extended by Section 14 of New York Public Health Law to any physician, dentist, nurse or other health care professional who “is licensed to practice pursuant to [New York State Education Law] and who is rendering professional treatment or consultation in connection with professional treatment authorized under such license at the request of the Department, or at a departmental facility.”¹¹⁴

The Legislature could amend Section 17 to provide broader protections to all classes of caregivers, but this may be inadvisable. Modifying Section 17 to offer defense and/or indemnity to all health care providers – whether or not employed by the State or participating in a State-sponsored volunteer program – would subject the State to significant unbudgeted costs. Furthermore, such an action would not confer immunity from suit *or* liability, so health care

¹¹¹ N.Y. PUB. OFFICERS LAW §§ 17(2)-(3). The duties to defend and indemnify are conditioned on the employee’s prompt notice of the action and cooperation in the defense. They do not arise where the action is brought by or on behalf of the State. The duty to defend is broader than the duty to indemnify. The duty to defend arises where the act or omission occurred or is alleged in the complaint to have occurred while the employee was acting within the scope of his or her public employment. The duty to indemnify arises where the Attorney General determines that the act or omission leading to liability actually occurred while the employee was acting within the scope of his or her public employment and that the injury or damages did not arise from intentional wrongdoing on the part of the employee. The State’s duty to indemnify pursuant to Public Officers Law § 17(3) is secondary to any primary insurance to the defendant-employee. N.Y. PUB. OFFICERS LAW § 17(7).

¹¹¹ Further, New York City provides for the defense and indemnification of employees (including some volunteers and some caregivers) pursuant to N.Y. PUB. OFFICERS LAW § 18(1)(b).

¹¹² N.Y. PUB. OFFICERS LAW § 17(1)(a). *See also* New York State Dep’t Health Office of Health Emergency Preparedness, *Questions and Answers*, http://www.health.state.ny.us/funding/rfa/1007161051/questions_and_answers.pdf. Among others, an employee can be “any person holding a position by election, appointment or employment in the service of the state... whether or not compensated, or a volunteer expressly authorized to participate in a state-sponsored volunteer program, but shall not include an independent contractor.” Health care providers employed by the State are covered if they are otherwise eligible. Persons employed by the Roswell Park Cancer Institute and engaged in clinical practice pursuant to a clinical practice plan established by the Commissioner of Health pursuant to N.Y. PUB. OFFICERS LAW § 206(14) are covered if they are otherwise eligible.

¹¹³ N.Y. PUB. OFFICERS LAW § 17(1)(a). The section appears to cover most health care providers employed by New York State – for example, in hospitals run by the Department of Health, or in prison clinics run by Department of Correctional Services. It expressly covers employees of Roswell Park Cancer Institute, including those licensed health care professionals engaged in clinical practice at Roswell Park Cancer Institute. N.Y. PUB. OFFICERS LAW § 17(1)(a), N.Y. PUB. HEALTH LAW § 206(14). Health care providers at SUNY teaching hospitals fall into a gray area. While those employees paid solely by a New York State salary are probably covered, N.Y. PUB. OFFICERS LAW § 17(1)(a), those physicians who supplement their income through participation in SUNY approved plans for the management of clinical practice income might not be so covered for acts or omissions in the scope of such clinical practice. N.Y. PUB. OFFICERS LAW § 17(11). *But see Frontier Ins. Co. v. State*, 179 AD2d 177 (3rd Dept., 1994). The definition of covered employee extends to certain volunteers expressly authorized to participate in a state-sponsored volunteer program. N.Y. PUB. OFFICERS LAW § 17(1)(a). And it extends to any physician, dentist, nurse or other licensed health care professional who is rendering professional treatment or consultation in connection with professional treatment authorized under such license at the request of the Department of Health.

¹¹⁴ N.Y. PUB. HEALTH LAW § 14.

workers may still be exposed to many of the negative consequences associated with defending a suit and/or a finding of liability.

e. Public Officers Law § 19

Section 19 authorizes reimbursement for criminal defense expenses incurred by “employees” – defined similarly to Section 17, but without the extension of Section 14 of New York Public Health Law – in any criminal action arising out of the scope of the employee’s public employment or duties; reimbursement occurs at the discretion of the State Attorney General after the employee has been acquitted or the charges against him or her have been dismissed.¹¹⁵

Thus, with appropriate amendments, Section 19’s protections might encourage health care workers to follow the clinical ventilator allocation protocol in the Guidelines with less fear of criminal prosecution. However, as with Section 17, this provision does not confer immunity from suit *or* liability, and thus individuals and entities – even those acquitted – would still be required to bear many of the burdens of litigation.

f. Conclusions

Currently, existing laws and regulations provide incomplete protections. Thus, the next three sections address the Task Force’s recommendations regarding new liability immunity-conferring legislation and discuss additional approaches to mitigating liability that might provide some level of protection and thereby encourage adherence to the Guidelines.

B. Task Force Recommendation for Policy: New Liability Immunity-Conferring Legislation

In contemplating new legislation, the Task Force considered three primary options for legislative protections for individuals and entities who adhere to the Guidelines: (1) providing immunity from suit; (2) providing immunity from liability; or (3) providing indemnification, such that the caregiver would be compensated if sued and found liable.

The Task Force recommends the second approach: that the New York State Legislature enact new legislation granting the Commissioner of the Department of Health authority to adopt a modified medical standard of care specific to the emergency,¹¹⁶ coupled with civil and criminal liability protections and professional discipline protections for all health care workers and

¹¹⁵ N.Y. PUB. OFFICERS LAW § 19(2)(a)-(b).

¹¹⁶ Although voluntary and non-binding, the Guidelines may serve as evidence of the standard of care. Some state courts, including those in New York, consider evidence of compliance with clinical guidelines to be probative, but not conclusive, evidence on the issue of the defendant’s duty. In other words, following State-issued guidelines in a public health emergency may weigh in a defendant’s favor, but would not conclusively establish that his or her behavior was non-negligent. See Michelle M. Mello, *Of Swords and Shields: the Role of Clinical Practice Guidelines in Medical Malpractice Litigation*, 149 U. PA. L. REV. 645, 665 (2001) (“[t]he prevailing practice is to admit CPGs [clinical practice guidelines] in connection with expert testimony, but not to give them determinative weight.”). Mello provides a useful summary of the various proposals for giving guidelines a greater role in negligence litigation, including the “contract model,” and the “judicial notice model” (which proposes that courts take judicial notice of CPGs as representing the legal standard of care). *Id.*

entities who provide care in a pandemic emergency.¹¹⁷ The Task Force considers this approach to be the most targeted and appropriate. The first option could prove to be overbroad, offering protections beyond those the legislation would intend to protect. As discussed in the context of Public Officers Law Section 17, defense or indemnification may be inadequate to appropriately incentivize adherence to the Guidelines. Health care providers and entities would continue to be exposed to many of the negative consequences associated with defending a suit and/or a finding of liability, including being responsible for the time and burden of litigation and experiencing damage to one's professional reputation.

Publication of the Guidelines for clinical allocation of ventilators would best serve as the modified medical standard of care, as they are flexible enough to be adapted to the actual emergency. Under such legislation, proof of compliance with the Guidelines might serve as conclusive, non-rebuttable evidence of compliance with professional standards.

Further, any immunity-conferring legislation must strike a balance between safeguarding patients, on the one hand, and protecting all health care workers and entities who follow the Guidelines, on the other. Thus, enactment of new liability immunity-conferring legislation ought to: (1) be subject to limitations such as a good faith requirement and exclusions for acts of gross negligence or willful misconduct;¹¹⁸ (2) treat equally compensated employees, independent contractors, and unpaid or paid volunteers;¹¹⁹ and (3) be extended to anyone who provides care during an emergency (rather than only those complying with the Guidelines). In summary, the law should extend protection to all those who provide, in good faith and in the absence of gross

¹¹⁷ By way of comparison, Virginia currently provides arguably the most extensive immunity protections in the U.S., including offering protections to health care workers in a declared state of emergency, regardless of pay. VA. CODE ANN. § 8.01-225.02 (“In the absence of gross negligence or willful misconduct, *any* health care provider who responds to a disaster shall not be liable for any injury or wrongful death of any person arising from the delivery or withholding of health care when (i) a state or local emergency has been or is subsequently declared in response to such disaster, and (ii) the emergency and subsequent conditions caused a lack of resources, attributable to the disaster, rendering the health care provider unable to provide the level or manner of care that otherwise would have been required in the absence of the emergency and which resulted in the injury or wrongful death at issue.”) (emphasis added). Commentators in other states have advocated for using Virginia's legislation as a model for protecting health care providers who provide care in a crisis. *See* Stephen P. Williams & Haynsworth Sinkler Boyd, *Is There Much Limited Legal Liability Protection for Physicians in Crisis Standards of Care in SC?* 107 J.S.C. MED. ASSOC. 96 (2011).

¹¹⁸ In most states that confer liability protections in an emergency, the laws shield health care workers from negligence liability, but not gross negligence. *But see* Darren P. Mareiniss et al., *ICU Triage: The Potential Legal Liability of Withdrawing ICU Care During a Catastrophic Event*, 6 AM. J. DISASTER MED. 329, 333 (2011) (noting that Black's Law Dictionary “defines willful, reckless, wanton, and gross negligence as acts that are intentionally done despite the known risk that it is ‘highly probable that harm will follow.’”). It has been argued that liability immunity-conferring statutes that exempt “willful misconduct” would not adequately protect health care providers who extubate a patient pursuant to the Guidelines. Such an act might be considered to be willful, or in conscious disregard of the safety of the individual harmed, and therefore beyond the protective scope of the law. However, it is the Task Force's belief that extubation pursuant to the Guidelines is not reckless, wanton, or grossly negligent and so is not *misconduct*, and so would be immunized despite the exclusion.

¹¹⁹ This provision may also obviate one author's concern that immunizing only volunteers would create a distinction between wealthy patients of non-volunteer physicians and indigent patients of volunteer physicians in patients' access to legal recourse if they are harmed by substandard medical care. Mark A. Rothstein, *Malpractice Immunity for Volunteer Physicians in Public Health Emergencies: Adding Insult to Injury*, 38 J. L. MED. & ETHICS 149, 151 (2010).

negligence,¹²⁰ care in a disaster emergency.¹²¹ This approach could provide the greatest assurance against liability and eliminate the patchwork approach to liability protections currently in effect in the State. New legislation could also substantially ease the burden on health care workers and hospitals during a pandemic and encourage adherence to the Guidelines.

Further, the Legislature ought to specify some of the characteristics which a pandemic must have before liability protections for adhering to any ventilator allocation guidelines may become effective. Examples might include: (1) a gubernatorial declaration of a disaster emergency under the Disaster Act, (2) a finding by the Commissioner that there are not enough ventilators to treat all patients, and (3) an announcement by the Commissioner that the Guidelines should be applied to allocate ventilators.¹²² The liability-immunizing guidelines should be required to have: (1) a three-pronged triage system; (2) triage based on objective clinical criteria for predicting survival; (3) clinically appropriate palliative care for all patients, including those from whom a ventilator is withheld or withdrawn; (4) an appeals process; and/or (5) clear and transparent communication with patients or their representatives about triage, appeals and palliative care. Examples of prohibited features that would not provide liability protection might include: (1) prioritization based on first-come first-serve, or social, economic or public official status; (2) discrimination based on non-clinical factors such as race, ethnicity, national origin, sex, religion; or (3) age as a proxy for prognosis, except as a tie-breaker. Further, the legislation should specify a mechanism for determining when it is no longer necessary to provide immunity for compliance with Guidelines.

The Task Force recognizes the ongoing debate in the academic and policy spheres regarding the adoption of a modified medical standard of care.¹²³ Public and political acceptance of the clinical protocols contained in the Guidelines as the medical standard of care in a

¹²⁰ New York malpractice law provides that “any person who, *in good faith and without malice*, provides information to further the purposes of the medical, dental and podiatric malpractice prevention program or who, in good faith and without malice, participates on the quality assurance committee *shall not be subject to an action for civil damages or other relief as a result of such activity.*” N.Y. PUB. HEALTH LAW § 2805-j (emphasis added). Such language may serve as an effective model for immunity-conferring legislation in a pandemic emergency in New York State. *See also* N.Y. PUB. HEALTH LAW § 230(11)(b); §2803-e.

¹²¹ No state has explicitly specified the particular classes or types of actions taken by health care workers during an emergency that qualified for liability protections. Instead they provide general protections for any care provided in good faith and in the absence of gross negligence. For example, Colorado’s Disaster Act is quite broad in its liability protections, providing that a “hospital, physician, health insurer or managed health care organization, health care provider, public health care worker, or emergency medical services provider” who completely complies in good faith with executive orders issued to combat an emergency epidemic shall be immune from civil liability. COLO. REV. STAT. § 24-32-2111.5(2). *See also* WYO. STAT. § 35-4-114 (“[A]ny health care provider or other person who in good faith follows the instructions of the state health officer in responding to the public health emergency is immune from any liability arising from complying with those instructions,” excluding “acts or omissions constituting gross negligence or willful or wanton misconduct . . .”); MD. PUB. SAFETY CODE ANN. § 14-3A-06; VA. CODE ANN. § 8.01-225.02.

¹²² The Legislature also ought to specify what effect proof of compliance with such guidelines will have in criminal prosecutions, civil suits for monetary damages, and professional misconduct proceedings.

¹²³ *See* George Annas, *Standard of Care – In Sickness and in Health and in Emergencies*, 362 NEW ENGL. J. MED. 2126 (2010); Rothstein, *supra* note 119, at 150 (“[I]n stark contrast to suggestions by some ‘altered standards of care’ advocates, the current standard of care applied to all medical malpractice cases is sufficiently flexible and situation-specific that it need not be altered”); Hoffman, *supra* note 95. *But see* Mareiniss, *supra* note 118 (arguing that relying on the flexibility of the legal standard of care may be inadequate and therefore special immunities and protections may be required).

pandemic scenario, however, would provide health care providers with legal protections for deviating from the medical standard of care in non-crisis circumstances. Following the Guidelines would therefore be non-rebuttable evidence of the medical standard of care to judges, lawyers, and other persons who may be forced to evaluate claims arising out of care provided under emergency circumstances.

Without the creation of legislative immunity-conferring protections, each of the alternative approaches discussed below would be insufficient to encourage widespread adherence to the Guidelines. Moreover, many of these approaches would also require legislative action, but would be incompletely effective in easing the burden on individuals and entities who follow the clinical ventilator allocation protocols established by the Guidelines. Statutes granting immunity from liability, on the other hand, would encourage compliance by physicians, nurses, and other health care workers, as well as hospitals and other health care entities.

C. Approaches to Mitigating Civil Liability

In addition to enacting new liability immunity-conferring legislation, various alternative protections – some of which might require their own statutory amendments – should be explored and instituted to encourage adherence to the Guidelines. Alone, these approaches are unlikely to provide sufficient protection to health care workers and entities who respond to a public health emergency. However, in conjunction with each other, these approaches may provide further protections for health care workers and entities who follow the Guidelines.

1. Caps on Damages

Under existing New York state law, there are no caps on the damages that may be awarded for successful malpractice claims.¹²⁴ Damages caps, however, “have been found to generate small increases in the supply of physicians,” which demonstrates that “diminished concerns about liability are associated with greater willingness on the part of individuals to serve as health care providers.”¹²⁵ Thus, capping damages may incentivize caregivers to comply with the Guidelines. A number of other states have instituted caps on the amount of damages awardable in malpractice cases.¹²⁶ Whether or not New York should institute a universal cap on

¹²⁴ New York allows punitive damages without limitation for tort actions. *See Pearlman v. Friedman Alpren & Green*, 300 A.D.2d 203 (1st Dep’t 2002) (allowing punitive damages for intentional or deliberate wrongdoing, aggravating or outrageous circumstances, fraudulent or evil motive, or conscious act in willful and wanton disregard of another’s rights). Further, the Appellate Division has a statutory responsibility to reduce excessive damages awards, which is often exercised in medical malpractice cases. N.Y. C.P.L.R. § 5501(c) (“In reviewing a money judgment in an action in which an itemized verdict is required by rule forty-one hundred eleven of this chapter in which it is contended that the award is excessive or inadequate and that a new trial should have been granted unless a stipulation is entered to a different award, the appellate division shall determine that an award is excessive or inadequate if it deviates materially from what would be reasonable compensation.”).

¹²⁵ Hoffman, *supra* note 95, at 1956.

¹²⁶ As of 2011, 38 states had laws limiting damages in malpractice cases. National Conference of State Legislatures, *Medical Liability/Malpractice Laws* (Aug. 15, 2011), <http://www.ncsl.org/default.aspx?tabid=18516>.

damages is the subject of ongoing debate – as is the constitutionality of capped non-economic damages.¹²⁷

However, legislation instituting a cap on damages in liability claims arising out of declared emergencies would not insulate those complying with the Guidelines from suit or from a finding of liability.

2. Expedited Discovery and Statutes of Limitations

Under existing law, it is within the discretion of the court to set the schedule for discovery.¹²⁸ In some cases, the discovery phase may be time- and labor-intensive, requiring multiple depositions, responses to interrogatories, and substantial document production. To ease the burden on individuals and entities who comply with the Guidelines, courts may be able to expedite the initial phase of discovery in tort suits arising out of circumstances related to a public health disaster and limit such discovery to the production of evidence that the Guidelines were followed. Thus, after producing such evidence, the defendant health care provider could move for summary judgment¹²⁹ or dismissal before being required to undergo further discovery on additional issues.

Furthermore, it may be advisable to shorten the statute of limitations for instituting legal action for medical malpractice arising out of care rendered during, and in relationship to, a declared health emergency. In New York State, the existing statute of limitations for instituting most medical malpractice claims, regardless of the circumstances out of which the claim arises, is 2.5 years.¹³⁰ Shortening this time period – through statutory amendment – for actions arising out of a disaster emergency may protect some health care providers from the obligation of defending a lawsuit.

Thus, although modification of the discovery process and statutes of limitation would provide neither immunity nor indemnity, it might lessen the time and resources health care providers expend when defending a suit.

3. Alternative Dispute Resolution

The use of alternative dispute resolution procedures and the establishment of substituted methods of handling civil liability suits that might arise from adhering to the Guidelines could

¹²⁷ Some states have found such caps unconstitutional. *See, e.g., Brannigan v. Usitalso*, 587 A.2d 1232 (N.H. 1991). New York State has a constitutional barrier to the enactment of any cap on damages recoverable for injuries resulting in death. *See* NY STATE CONST. art. I § 16.

¹²⁸ Discovery is the pre-trial phase in a lawsuit in which each party, through the law of civil procedure, can obtain evidence from the opposing party. N.Y. C.P.L.R. art. 31.

¹²⁹ Summary judgment, or judgment as a matter of law, is used during civil litigation to dismiss a case without a trial when there is no dispute as to the material facts of the case. N.Y. C.P.L.R. § 3212.

¹³⁰ N.Y. C.P.L.R. § 214-a (“An action for medical, dental or podiatric malpractice must be commenced within two years and six months of the act, omission or failure complained of or last treatment where there is continuous treatment for the same illness, injury or condition which gave rise to the said act, omission or failure.”). The period of limitations is three years for a personal injury claim and six years for a breach of contract claim. N.Y. C.P.L.R. § 214(5); N.Y. C.P.L.R. § 213(2). N.Y. C.P.L.R. § 213-B allows seven years for the commencement of an action by a victim of a criminal offense.

also ease the potential burdens of litigation on both health care providers and the court system. Claims related to health care provided during an emergency could: (1) be settled by arbitration; (2) be subjected to pretrial review panels; or (3) be covered by monies gathered in a compensation pool in lieu of instituting suit. Each approach has advantages as well as limitations.

a. Arbitration

Arbitration may be generally less expensive, time-consuming, and burdensome than litigation. However, requiring parties – again, via statutory amendment – to a civil suit arising from compliance with the Guidelines to engage in binding arbitration may be subject to constitutional attacks. Compulsory binding arbitration may violate the Seventh Amendment right to a jury trial¹³¹ and/or impinge on due process guarantees.¹³² However, New York courts have found that compulsory and binding arbitration may, in fact, be constitutional in certain circumstances.¹³³ While the easiest way to ensure constitutionality would be to allow only voluntary arbitration (thereby avoiding the jury trial issue) with review *de novo* in the courts (thereby avoiding the due process issue),¹³⁴ this route would obviate the advantages of arbitration because parties dissatisfied with the outcome of arbitral proceedings would simply turn to litigation. In order to preserve the benefits of arbitration, it is important that courts consider it “binding” so that the ability to challenge the decision is limited.¹³⁵ Thus, the most effective approach to instituting resolution by arbitration would be to offer voluntary, binding arbitration as an alternative to traditional litigation.

¹³¹ Although the Seventh Amendment right to a trial by jury only applies to federal cases, the New York State Constitution also provides for a right to trial by jury. U.S. CONST. amend. VII (“In suits at common law, where the value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved . . .”); NY STATE CONST. art. I § 1 (“No member of this state shall be . . . deprived of any . . . rights or privileges . . . unless by the law of the land, or the judgment of his or her peers . . .”). Additionally, a case brought in or removed to federal court may require a jury trial pursuant to the Seventh Amendment even if the underlying cause of action sounds in state law. *Simler v. Conner*, 372 U.S. 221, 222 (1963) (finding “that the right to a jury trial in the federal courts is to be determined as a matter of federal law in diversity . . . actions. The federal policy favoring jury trials is of historic and continuing strength.”).

¹³² The due process guarantees of the U.S. Constitution apply at both the federal and state levels. U.S. CONST. amend. V (“No person shall . . . be deprived of life, liberty, or property, without due process of law . . .”); *id.* amend. XIV (“[N]or shall any State deprive any person of life, liberty, or property, without due process of law . . .”). Commentators have noted that “the paucity of decisions [regarding the legality of compulsory arbitration] in cases involving such statutes bars the formulation of any general rule as to their constitutionality.” *Constitutionality of Arbitration Statutes*, 55 A.L.R.2d 432 (2009).

¹³³ *Lyeth v. Chrysler Corp.*, 929 F.2d 891, 895-896 (2d Cir. 1991) (finding compulsory arbitration under New York’s “lemon law” meets due process requirements because litigants were entitled to review under the arbitrary and capricious standard enunciated in New York Civil Practice Laws and Rules); *Mount St. Mary’s Hosp. of Niagara Falls*, 26 N.Y.2d 466; *Long Is. Coll. Hosp. v. Catherwood*, 54 Misc.2d 712 (1967), *judgment aff’d*, 28 A.D.2d 1092 (1st Dep’t 1967), *judgment aff’d as modified on other grounds*, 29 A.D.2d 642 (1st Dep’t 1968) (permitting the Legislature to resolve labor disputes in nonprofit hospitals through compulsory and binding arbitration where substantive and procedural due process of law are upheld); *City of Amsterdam v. Helsby*, 37 N.Y.2d 19 (1975); *City of Buffalo v. N.Y. State Pub. Employment Relations Bd.*, 80 Misc.2d 741 (1975) (finding mandatory arbitration constitutional).

¹³⁴ R.D. Hursh, Annotation, *Constitutionality of Arbitration Statutes*, 55 A.L.R.2d 432 (2009). *De novo* review is a form of appeal in which the appeals court holds a trial as if no prior trial had been held, considering all evidence anew.

¹³⁵ New York C.P.L.R. § 7511(b)(1)(iii) authorizes judicial vacatur of arbitration awards where the arbitrator has exceeded his power.

b. Pretrial Review Boards

A number of states – but not New York – already require pretrial review boards for medical malpractice claims.¹³⁶ Such a board acts as a filter, reviewing claims before a suit is filed and permitting only meritorious claims to proceed to litigation. Legislation establishing a special panel, comprised of individuals familiar with disaster medicine protocols and New York’s Guidelines, might serve as an effective screening mechanism. However, the use of review boards would require convening a group of specialized volunteers willing to review a potentially large number of cases, or finding funds to hire and pay reviewers. Further, such screening panels would not eliminate the burdens of suit on health care providers, although they might significantly decrease the number of suits permitted to proceed, thereby lowering the overall litigation burden.

c. Compensation Pools

Establishment of a compensation pool for use as a no-fault method of claim settlement in lieu of instituting suit might decrease the likelihood of litigation and lessen the burden on potential litigants. The effective use of compensation pools by other states might serve as a model for one in New York State. For example, Virginia was the first state to develop a state-wide Birth-Related Neurological Injury Compensation Program (NICP) to pay for the care of infants sustaining certain neurological injuries at birth.¹³⁷ The program is funded by hospitals, physicians, and liability insurers who choose to participate in the program – no state funds are used. Awards issued under the NICP are the exclusive remedy for families, meaning that if an injury is covered by the NICP, the family is not entitled to compensation for other legal action.¹³⁸ Similar pools for addressing birth-related neurological injuries have also been established or proposed in other states, including New York.¹³⁹

However, two primary concerns exist in relation to using compensation pools as a remedy for harm arising from adherence to the Guidelines: (1) those claimants seeking larger payouts might still choose to pursue litigation unless compensation pools were made an

¹³⁶ Indiana courts only permit a claim against a health care provider to move forward if (i) the claimant seeks less than \$15,000 in damages or (ii) the complaint has been presented to, and an opinion has been rendered by, a medical review panel. BURNS IND. CODE § 34-18-8-4 *et seq.* Nebraska requires that medical review panels review all malpractice claims against health care providers covered by the Nebraska Hospital-Medical Liability Act in advance of filing a civil action, unless such procedure is waived. NEB. REV. STAT. § 44-2840 *et seq.*

¹³⁷ Virginia Birth-Related Neurological Injury Compensation Program, <http://www.vabirthinjury.com/>.

¹³⁸ *Id.*

¹³⁹ Florida Birth-Related Neurological Injury Compensation Association (NICA), <http://www.nica.com/>. According to the NICA website, “NICA ensures that birth-injured infants receive the care they need while reducing the financial burden on medical providers and families.” Every year since 2001, a version of the New York Birth-Related Neurological Impairment Compensation Act was introduced in the New York Assembly. *See, e.g.*, A.2814, Assem., 234th Sess. (N.Y. 2011) (enacting the New York birth-related neurological injury compensation act; directing the workers’ compensation board to determine all claims for compensation for birth-related impairment, and if the injury falls within the defined scope of neurological injuries, direct compensation by the fund, similar to a no fault system).

exclusive remedy; and (2) even if made an exclusive remedy, it is unclear how funding for the compensation pool would be sustained.

4. Professional Education

There is a significant need for professional education within the legal community regarding how medical care may change during a public health emergency. Attorneys, judges, and other legal professionals ought to have an appreciation for the crisis circumstances during a public health emergency and the impact of emergency protocols on the provision of care. The provision of such information to legal personnel may better prepare them to consider and argue for modified medical standards of care and to provide instructions to the jury regarding appropriate conduct in an emergency. This education, in turn, may reduce the liability risk to health care workers who provide care pursuant to the Guidelines.

A number of states, including New York, have published guidance for their judiciary on issues that arise in a public health emergency, particularly with regard to matters such as isolation and quarantine and determination of jurisdiction and venue.¹⁴⁰ “Bench books” are compilations of materials for use by courts in the wake of public health emergencies that are specifically aimed at providing guidance for judges.¹⁴¹ Such educational resources should also be provided to attorneys through published material and Continuing Legal Education (CLE) and to judges through Continuing Judicial Education (CJE) courses.

D. Mitigating Criminal Liability

Currently, no New York law provides criminal immunity to health care workers who provide care in a disaster,¹⁴² although, as discussed above, New York’s Public Officers Law Section 19 may offer reimbursement to the successful criminal defendant. In fact, very few states

¹⁴⁰ See, e.g., Florida Court Education Council, *Pandemic Influenza Benchguide: Legal Issues Concerning Quarantine and Isolation* (2013), http://www.flcourts.org/core/fileparse.php/304/urlt/pandemic_benchguide.pdf; Georgia *Pandemic Influenza Benchbook* (2008), <https://web.archive.org/web/20100610024520/http://www2.cdc.gov/phlp/docs/Judiciary%20-%20Georgia%20Pandemic%20Bench%20Guide%20V1.pdf>; Minnesota Judicial Branch, *Isolation and Quarantine Benchbook* (Nov. 2008), http://www.mncourts.gov/Documents/0/Public/Isolation_and_Quarantine/Isolation_and_Quarantine_Benchbook.pdf; North Carolina Administrative Office of the Courts, *Pandemic Emergency Bench Book for Trial Judges* (Aug. 2009), https://web.archive.org/web/20100616001914/http://www.sog.unc.edu/programs/judicial_authority_administration/documents/PandemicEmergencyBenchBook_Dec2009.pdf (“What judicial officials might expect when dealing with isolation, quarantine and “safekeeper” orders amid an ongoing health emergency”); Judge Robert P. Ringland, *Public Health Preparedness Bench Book: A Guide for the Ohio Judiciary & Bar on Legal Preparedness for Public Health Emergencies & Routine Health Cases*, <http://www.supremecourt.ohio.gov/Boards/courtSecurity/PandemicPrepareGuide.pdf>; Supreme Court of Virginia’s Pandemic Flu Preparedness Commission, *Pandemic Influenza Bench Book for Virginia’s Court System* (2013), <http://www.courts.state.va.us/programs/pfp/benchbook.pdf>. However, these publications do not offer any guidance for allocation of scarce resource.

¹⁴¹ *New York State Public Health Legal Manual: A Guide for Judges, Attorneys and Public Health Professionals* (2011), <http://www.nycourts.gov/whatsnew/pdf/PublicHealthLegalManual.pdf>.

¹⁴² See Thaddeus Mason Pope & Mitchell F. Palazzo, *Legal Briefing: Crisis Standards of Care and Legal Protections During Disasters and Emergencies*, 21 J. CLIN. ETHICS 358-368, 362 (2010).

provide criminal liability protections to health care workers during a public health emergency.¹⁴³ At a minimum, a jury could consider evidence of compliance with the Guidelines as probative evidence of a health care provider's appropriate action in criminal cases. However, evidence of reliance on the Guidelines would not insulate a health care provider from criminal prosecution and would only serve as evidence that would help clear the defendant of guilt.

E. Mitigating Professional Discipline

Similarly, no New York law immunizes health care professionals from professional disciplinary action for compliance with an altered medical standard of care in a flu pandemic, nor does any State law provide reimbursement for attorney's fees incurred by a successful respondent. Further, although compliance with the Guidelines would constitute evidence that a certain action was not professional misconduct, reliance on the Guidelines would not insulate a health care professional from disciplinary action.

The Task Force recommends that, as a matter of policy, the Department of Health refrain from engaging in professional discipline of physicians who, in the absence of gross negligence or its equivalent, provide care pursuant to the Guidelines in a declared emergency. Similarly, the Task Force recommends that the New York State Education Department refrain from engaging in professional discipline of nurses and other health care professionals who follow the Guidelines.

VI. APPEALS

The Guidelines recognize that an ethical and clinically sound system for allocating ventilators in a pandemic includes an appeals process. Physicians, patients, and family members should have a means for requesting review of triage decisions. Decisions that determine whether a patient is eligible to receive or retain ventilator therapy and whether a patient is removed from or denied such support will inevitably produce dissatisfaction. The Guidelines address the practicality of permitting appeals to the clinical ventilator allocation protocol and examine whether a real-time (pre-decision) or a retrospective form of review would better complement a just and workable triage system during a public health emergency.

This section addresses the benefits, burdens, practicability, and legal considerations of three systems of review as applied to the Guidelines. Absent an actual emergency, the feasibility of each system can only be estimated, and any system implemented may need to be adjusted as new information about the developing pandemic is received.

¹⁴³ Colorado, Hawaii, and Maryland are the three states that provide criminal liability protections. *See* COLO. REV. STAT. § 24-32-2111.5 (providing civil and criminal immunity to hospitals, physicians, and emergency medical service providers in a disaster emergency who in “good faith comply completely with board of health rules regarding the emergency epidemic and with executive orders regarding disaster emergency shall be immune from civil or criminal liability for any action taken to comply with the executive order or rule”); HAW. REV. STAT. § 325-20 (providing immunity to licensed health care providers and facilities under certain circumstances); MD. PUB. SAFETY CODE ANN. § 14-3A-06 (providing civil and criminal immunity to health care providers acting in good faith during a public health emergency).

A. On-Going Individual Appeals

The 2006 Ontario Health Plan for an Influenza Pandemic (OHPIP) and others also recommend that institutions should consider implementing an appeals system for on-going triage decisions.¹⁴⁴ OHPIP also recommends that, even under limited staffing conditions, the appeals personnel for on-going review should be composed of members distinct from those making the initial triage determination, and if possible, the review should be performed by several persons.¹⁴⁵

The New York Guidelines recognize that an on-going appeals process provides the greatest patient protection against unjust denial of life-sustaining treatment. This model would allow a patient or family member to seek a remedy before the decision is carried out. It would offer review for individual cases and promote a sense of fairness and trust in the system. It would also serve to prevent erroneous or inappropriate allocation decisions. Although unapproved deviation from the Guidelines might be detected in a retrospective review, an on-going appeals process would be better suited to recognize systematic abuse or individual errors at an earlier stage.

However, an on-going appeals process will require significant time and personnel, both of which may be in short supply during an influenza pandemic. This system may also create unreasonable delays in implementing triage decisions. The disparity between available ventilators and the number of people in need may lead to an overwhelming number of appeals, which could undermine the goal of the Guidelines to maximize the number of lives saved. Furthermore, a physician's traditional ethical duty to advocate for his or her patient may drive physicians to challenge triage decisions calling for removal or withdrawal of ventilation from their patient regardless of whether they would survive even with ventilator treatment.

Although a real-time review system may seem most consistent with individual rights, preliminary feedback indicates that the public understands the challenges inherent in real-time review of decisions in a pandemic, and that such review is somewhat unfeasible.¹⁴⁶

Importantly, the Guidelines use only clinical standards, including evaluation of a patient's likelihood of survival, to evaluate whether a patient is eligible for ventilator treatment. Given the clinical nature of the allocation eligibility determination, it is unlikely that a real-time appeals process would change the outcome of decisions that comply with the Guidelines.

B. Retrospective Review

An alternative to real-time appeals process is retrospective, periodic review by a triage review committee. For example, OHPIP proposes the utilization of such a committee to monitor the efficacy of ventilator allocation guidelines. All decisions to withhold or withdraw ventilators

¹⁴⁴ Ontario Health Plan for an Influenza Pandemic (OHPIP) Working Group on Adult Critical Care Admission, Discharge, and Triage Criteria, *Critical Care During a Pandemic*, August 2008.

¹⁴⁵ *Id.*

¹⁴⁶ Focus groups concluded that real-time review of triage decisions were not possible during a pandemic. See Chapter 1, Adult Guidelines, Section I.B.1. Public Outreach Efforts, footnote 12.

would be reviewed on a regular basis (e.g., each day) during the emergency.¹⁴⁷ This system would provide oversight and accountability for triage decisions by monitoring allocation decisions to verify adherence with the Guidelines and enabling evaluation of the pandemic viral strain to improve subsequent decisions. If implemented, retrospective review should be transparent and demonstrate concern for constitutional compliance.¹⁴⁸

However, a retrospective review system alone may not be adequately time-sensitive to protect vulnerable patients because it does not allow for timely intervention in individual triage decisions. Triage decisions that deviate from the Guidelines may not be discovered before irreversible harm or death is caused. Moreover, retrospective review could also present substantial burdens on resources and personnel.¹⁴⁹

C. Hybrid System of Review

The Task Force recommends a hybrid system of review – combining limited on-going individual appeals with retrospective periodic review – which incorporates the advantageous features of both under the constraints of pandemic. This model may avoid or correct individual deviations from the Guidelines while allowing health care providers to use accumulated data to improve subsequent triage decisions.

Under a hybrid system of review, real-time individual case appeals would be limited to procedural/technical injustices only (e.g., when a withdrawal decision was made without considering all relevant clinical triage criteria) that could remedy a potential injustice prior to the implementation of a triage decision. The retrospective aspect would allow review of all cases periodically to verify adherence with the Guidelines, and would enable evaluation of triage decisions to improve subsequent decisions. A hybrid review system is more likely to be viewed by courts as in compliance with federal due process requirements because it affords a means of protecting individuals by preventing erroneous deprivations of ventilator treatment while permitting continuous monitoring and improvement of the clinical ventilator allocation protocol.

Finally, similar to the clinical ventilator allocation protocols, the appeals process may also be modified based on the specifics of the pandemic. For example, data collection and analysis on the pandemic virus may reveal that an influenza patient may not immediately require ventilator treatment, which permits facilities to adopt a real-time (pre-decision) appeals system. Conversely, if an influenza pandemic is so severe that resources are not available for any time of real-time review, then facilities may be forced to only examine cases under a retrospective review model.

¹⁴⁷ Under the OHPIP model, the Central Triage Committee’s first responsibility would be to periodically review the appropriateness of ventilator allocation decision criteria in relation to the goal of saving the greatest number of lives during an influenza pandemic. OHPIP, *supra* note 144.

¹⁴⁸ See Section III. Constitutional Considerations for a comprehensive discussion of the constitutional issues.

¹⁴⁹ Indiana State Dep’t of Health, Crisis Standards of Care Community Advisory Group, *Crisis Standards of Patient Care Guidance with an Emphasis on Pandemic Influenza: Triage and Ventilator Allocation Guidelines*, 13 (2014) <http://www.phe.gov/coi/Documents/Indiana%20Crisis%20Standards%20of%20Care%202014.pdf> (“The scarcity of resources and personnel may make careful record keeping and retrospective review difficult or impossible. While meticulous record keeping is desirable, in such cases, it is ethically important to prioritize energies spent in the direct saving of lives over those spent keeping records and in post-hoc analyses.”).

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Appendix A

New York’s Adult Clinical Ventilator Allocation Protocol¹

All acute care patients who are in need of a ventilator, whether due to influenza or other conditions, are subject to the clinical ventilator allocation protocol. Using clinical criteria, patients who are deemed most likely to survive with ventilator treatment have an opportunity for ventilator therapy to maximize the number of survivors. The Guidelines’ definition of survival is based on the short-term likelihood of survival of the acute medical episode and is not focused on whether a patient may survive a given illness or disease in the long-term (e.g., years later).

The adult clinical ventilator allocation protocol applies to all patients aged 18 and older in all hospitals Statewide. Ventilator-dependent chronic care patients are only subject to the clinical ventilator allocation protocol if they arrive at a hospital. A patient’s attending physician cares for his/her patient and performs all clinical evaluations. A triage officer or triage committee examines a patient’s clinical data and determines who determines the patient’s level of access to a ventilator (i.e., who is eligible and/or continues with ventilator therapy). The protocol consists of three steps: (1) application of exclusion criteria, (2) assessment of mortality risk, and (3) periodic clinical assessments (“time trials”).

1. Step 1: Exclusion Criteria

A patient’s attending physician examines his/her patient for an exclusion criterion and will forward this clinical data to a triage officer/committee to make the triage decision. Patients with exclusion criteria do not have access to ventilator therapy and instead are provided with alternative forms of medical intervention and/or palliative care.² If medical information is not readily available or accessible, it may be assumed a patient is free of exclusion criteria and may proceed to the next step of the clinical ventilator allocation protocol.

Step 1 - List of Exclusion Criteria for Adult Patients
Medical Conditions that Result in Immediate or Near-Immediate Mortality
Even with Aggressive Therapy

- Cardiac arrest: unwitnessed arrest, recurrent arrest without hemodynamic stability, arrest unresponsive to standard interventions and measures; trauma-related arrest
- 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 chart below)
- Severe burns: where predicted survival $\leq 10\%$ even with unlimited aggressive therapy (See chart below)
- Any other conditions resulting in immediate or near-immediate mortality even with aggressive therapy^{*}

^{*}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.

¹ Please see Chapter 1, Adult Guidelines, Section XI. for a comprehensive analysis of all aspects of the protocol.

² However, if a ventilator becomes available and no other patient is in need of ventilator therapy, a patient with an exclusion criterion may be eligible for this treatment.

Additional Clinical Information regarding Exclusion Criteria (Step 1)

Determining Traumatic Brain Injury

No Motor Response to Painful Stimulus (i.e., Best Motor Response = 1)

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

American Burn Association (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 \geq 90%) with aggressive and comprehensive resource allocation, including aggressive fluid resuscitation, admission \geq 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 \geq 14 – 21 days, multiple surgeries and prolonged rehabilitation.

Low: Survival < 50% even with long-term aggressive treatment and resource allocation.

Expectant: Predicted survival \leq 10% even with unlimited aggressive treatment.

2. Step 2: Mortality Risk Assessment Using SOFA

A clinical scoring system, SOFA (Sequential Organ Failure Assessment), is used to assess a patient's mortality risk.

Sequential Organ Failure Assessment (SOFA) Score Scale

Variable	0	1	2	3	4	Score (0-4)
PaO₂/FiO₂ mmHg	> 400	< 400	< 300	< 200	< 100	
Platelets, x 10³/μL (x 10⁶/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):						

Dopamine [Dop], epinephrine [Epi], and norepinephrine [Norepi] doses in μg/kg/min (administered for at least one hour). SI units in parentheses ()

Explanation of variables:

- PaO₂/FiO₂ indicates the level of oxygen in a patient's blood.
- Platelets are a critical component of blood clotting.
- Bilirubin is measured by a blood test and indicates liver function.
- Hypotension indicates low blood pressure; scores of 2, 3, and 4 indicate that blood pressure must be maintained by the use of powerful medications that require ICU monitoring (including dopamine, epinephrine, and norepinephrine).
- The Glasgow Coma Scale Score is a standardized measure that indicates neurologic function; low score indicates poorer function. See the worksheet on next page to calculate the score.
- Creatinine is measured by a blood test and indicates kidney function.

**Additional Clinical Information regarding SOFA
Glasgow Coma Scale Score Criteria**

Criteria	Adults	Score	Criteria Score
Best Eye Response (1 – 4)	No eye opening	1	
	Eye opens to painful stimulus	2	
	Eye opens to verbal command	3	
	Eyes open spontaneously	4	
Best Verbal Response (1 – 5)	No verbal response	1	
	Incomprehensible sounds	2	
	Inappropriate words	3	
	Confused	4	
	Oriented	5	
Best Motor Response (1 – 6)	No motor response	1	
	Extension to painful stimulus	2	
	Flexion to painful stimulus	3	
	Withdraws from painful stimulus	4	
	Localizes to painful stimulus	5	
	Obeys commands	6	
Total Score (add three subscores, range from 3 to 15):			

For most patients who are sick with only influenza and have no other comorbidities, the single organ failure is limited to their lungs. However, because the adult clinical ventilator allocation protocol applies to all patients in need of a ventilator, a patient may also have a comorbidity(s) that affects another organ system(s) and his/her mortality risk assessment. Intubation for control of the airway (without lung disease) is not considered lung failure.

A patient’s clinical data from Steps 1 and 2 are provided to a triage officer/committee who examines the information and assigns the patient a color code (i.e., blue, red, yellow, or green), which determines the patient’s level of access to ventilator therapy (see chart below). Patients with the red color code have the highest level of access to a ventilator because they are most likely to recover with treatment (and not likely to recover without it) and have a moderate risk of mortality. If resources are available, patients in the yellow category also have access to

ventilator treatment. Those assigned the blue code are patients who potentially have the worst outlook for survival, even with ventilator therapy, and therefore have lowest access. The green category represents patients who are most likely to survive without ventilator therapy or are eligible for ventilator weaning. If resources become available, patients in the blue color category, or those with exclusion criteria, are reassessed and may become eligible for ventilator therapy.

Triage Chart for Step 2

A triage officer/committee allocates ventilators according to the color code assigned.

Step 2 – Mortality Risk Assessment Using SOFA¹	
Color Code and Level of Access	Assessment of Mortality Risk/Organ Failure
<p style="text-align: center;">Blue</p> <p style="text-align: center;">No ventilator provided. Use alternative forms of medical intervention and/or palliative care or discharge. Reassess if ventilators become available.</p>	<p style="text-align: center;">Exclusion criterion OR SOFA > 11</p>
<p style="text-align: center;">Red</p> <p style="text-align: center;">Highest Use ventilators as available</p>	<p style="text-align: center;">SOFA < 7 OR Single organ failure²</p>
<p style="text-align: center;">Yellow</p> <p style="text-align: center;">Intermediate Use ventilators as available</p>	<p style="text-align: center;">SOFA 8 – 11</p>
<p style="text-align: center;">Green</p> <p style="text-align: center;">Use alternative forms of medical intervention or defer or discharge. Reassess as needed.</p>	<p style="text-align: center;">No significant organ failure AND/OR No requirement for lifesaving resources</p>

¹ If a patient develops a condition on the exclusion criteria list at any time from the initial assessment to the 48 hour assessment, change color code to blue. Remove the patient from the ventilator and provide alternative forms of medical intervention and/or palliative care.

² Intubation for control of the airway (without lung disease) is not considered lung failure.

Decision-Making Process for Selecting an Eligible Patient for a Ventilator

At Step 2, a triage officer/committee may encounter a situation where there are several patients in the red color code,³ who are equally eligible for ventilator therapy⁴ and must select a patient for the ventilator. It is not appropriate for a triage officer/committee to compare patients within the same color category. If all the eligible patients are adults, a random process (e.g., lottery) should be used to choose an adult patient for ventilator therapy when there are more eligible adult patients than ventilators available.⁵ In addition, a random selection method is conducted each time a ventilator becomes available. Patients waiting for ventilator therapy wait in an eligible patient pool and receive alternative forms of medical intervention and/or palliative care until a ventilator becomes available.

3. Step 3: Periodic Assessments for Continued Ventilator Use (Time Trials)

Periodic clinical assessments at 48 and 120 hours (time trials) using SOFA are conducted on a patient who has begun ventilator therapy to evaluate the patient's risk of organ failure/mortality. A patient's attending physician performs the clinical assessments involved in a SOFA score. The results of the time trial clinical assessments are provided to a triage officer/committee who assigns a color code (blue, red, yellow, or green) to the patient. The color code assigned is dependent on the SOFA score itself and the magnitude of change between the SOFA score at the current assessment and the SOFA score from the previous assessment. The decision whether to continue ventilator therapy for a patient is dependent on the trend of the SOFA score data.

The guiding principle for the triage decision is that the more severe a patient's health condition (i.e., higher the SOFA score) and worsening/no change in mortality risk (i.e., increase or little/no change in the SOFA score), the less likely the patient continues with ventilator therapy. Conversely, the less severe a patient's health condition (i.e., low SOFA score) and demonstration of improvement with ventilator therapy (i.e., significant decrease in the SOFA score and in mortality risk), the higher the likelihood the patient continues with this form of treatment. Thus, the extent of change in SOFA scores indicates whether a patient is improving, worsening, or experiencing no change in health status.

At 48 hours, a patient must exhibit a pattern of significant improvement to be placed in the red color code. After 120 hours, a patient must demonstrate a pattern of *further* significant improvement in health to be placed in the red color code.

³ While the yellow category may also have eligible patients waiting for ventilator therapy, all red code patients must be attended to first. If there are no red code patients, and only yellow code patients, then the same decision-making process applies.

⁴ While a SOFA score does provide discrete numbers, it is not appropriate to suggest that a score of 5 is indicative of a lower risk of mortality than a score of 6. Instead, both of these scores suggest that both patients have near equal probabilities of survival. Thus, all patients in the same color category have the same likelihood of survival.

⁵ However, if the pool of eligible patients includes both children and adults, young age plays a tie-breaking role. See Appendix B, Pediatric Clinical Allocation Protocol.

After the 120 hour clinical assessment, a patient who continues with ventilator therapy is reassessed every 48 hours using SOFA.⁶ A triage officer/committee determines whether a patient continues with ventilator therapy based on the extent of change in SOFA scores.

The official SOFA assessments only occur after 48 and 120 hours (and subsequent 48 hours) of ventilator therapy. No formal triage decision or action may be taken until a patient's official assessment. However, at any point during the time trial, even before an official assessment occurs, if a patient develops a condition on the exclusion criteria list and there is an eligible patient waiting, then the ventilator is reallocated. Patients removed from the ventilator are provided with alternative forms of medical intervention and/or palliative care.⁷

Triage Charts for Step 3

Criteria for each color code at the 48 and 120 hour assessments are presented below.

⁶ Other considerations may include the known progression of the disease, updated data on the pandemic viral strain, availability of alternative treatments, current supply and demand data at the facility (e.g., number of available or soon to be available ventilators and incoming patients requiring ventilator therapy), alternative sites of health care, and whether there are any patients waiting for a ventilator therapy trial.

⁷ If no eligible patients are waiting for ventilator treatment, a patient who does not meet the time trial criteria would continue with the treatment and be evaluated again at the next official assessment.

48 Hour Clinical Assessment Chart

Step 3 - Ventilator Time Trials (48 Hour Assessment) ¹	
Color Code and Level of Access	Assessment of Mortality Risk/Organ Failure
<p style="text-align: center;">Blue</p> <p style="text-align: center;">No ventilator provided.² Use alternative forms of medical intervention and/or palliative care or discharge. Reassess if resources become available.</p>	<p style="text-align: center;">Exclusion criterion</p> <p style="text-align: center;">OR</p> <p style="text-align: center;">SOFA > 11</p> <p style="text-align: center;">OR</p> <p style="text-align: center;">SOFA 8 – 11 <u>and</u> No Change in SOFA Score Compared to the Initial Assessment³</p>
<p style="text-align: center;">Red Highest</p> <p style="text-align: center;">Use lifesaving resources as available.</p>	<p style="text-align: center;">SOFA < 7 <u>and</u> Decrease in SOFA Score Compared to the Initial Assessment⁴</p> <p style="text-align: center;">OR</p> <p style="text-align: center;">SOFA < 11 <u>and</u> Decrease in SOFA Score Compared to the Initial Assessment⁵</p>
<p style="text-align: center;">Yellow Intermediate</p> <p style="text-align: center;">Use lifesaving resources as available.</p>	<p style="text-align: center;">SOFA < 7 <u>and</u> No Change in SOFA Score Compared to the Initial Assessment</p>
<p style="text-align: center;">Green</p> <p style="text-align: center;">Use alternative forms of medical intervention or defer or discharge. Reassess as needed.</p>	<p style="text-align: center;">No longer ventilator dependent / Actively weaning from ventilator</p>

¹ If a patient develops a condition on the exclusion criteria list at any time from the initial assessment to the 48 hour assessment, change color code to blue. Remove the patient from the ventilator and provide alternative forms of medical intervention and/or palliative care.

² A patient assigned a blue color code is removed from the ventilator and alternative forms of medical intervention and/or palliative care are provided.

³ The patient remains significantly ill.

⁴ These criteria apply to a patient who was placed into the red category at the initial assessment.

⁵ These criteria apply to a patient who was placed into the yellow category at the initial assessment but because a ventilator was available the patient began ventilator therapy.

120 Hour Clinical Assessment Chart

Step 3 - Ventilator Time Trials (120 Hour Assessment) ¹	
Color Code and Level of Access	Assessment of Mortality Risk/Organ Failure
<p style="text-align: center;">Blue</p> <p style="text-align: center;">No ventilator provided.² Use alternative forms of medical intervention and/or palliative care or discharge. Reassess if resources become available.</p>	<p style="text-align: center;">Exclusion criterion</p> <p style="text-align: center;">OR</p> <p style="text-align: center;">SOFA > 11</p> <p style="text-align: center;">OR</p> <p style="text-align: center;">SOFA < 7 <u>and</u> No Change in SOFA Score Compared to the Previous Assessment</p>
<p style="text-align: center;">Red</p> <p style="text-align: center;">Highest</p> <p style="text-align: center;">Use lifesaving resources as available.</p>	<p style="text-align: center;">SOFA < 7 <u>and</u> Progressive Decrease in SOFA Score Compared to the Previous Assessment</p>
<p style="text-align: center;">Yellow</p> <p style="text-align: center;">Intermediate</p> <p style="text-align: center;">Use lifesaving resources as available.</p>	<p style="text-align: center;">SOFA < 7 <u>and</u> Minimal Decrease in SOFA Score (< 3 Point Decrease in Previous 72 Hours) Compared to the Previous Assessment</p>
<p style="text-align: center;">Green</p> <p style="text-align: center;">Use alternative forms of medical intervention or defer or discharge. Reassess as needed.</p>	<p style="text-align: center;">No longer ventilator dependent / Actively weaning from ventilator</p>

¹ If a patient develops a condition on the exclusion criteria list at any time from the 48 hour assessment to the 120 hour assessment, change color code to blue. Remove the patient from the ventilator and provide alternative forms of medical intervention and/or palliative care.

² A patient assigned a blue color code is removed from the ventilator and alternative forms of medical intervention and/or palliative care are provided.

Decision-Making Process for Removing a Patient from a Ventilator

There may be a scenario where there is an incoming red code patient(s)⁸ eligible for ventilator treatment and a triage officer/committee must remove a ventilator from a patient whose health is not improving at the 48, 120, or subsequent 48 hour time trial assessments, so that the red code patient receives ventilator treatment. A triage officer/committee follows these steps to determine which patient should be removed from the ventilator.

⁸ While there may be yellow color code patients waiting for ventilator therapy, all red code patients must be attended to first. In limited circumstances, where incoming patients are only yellow code, these patients may only receive ventilator therapy if there are any blue code patients currently receiving ventilator treatment. Already ventilated yellow code patients would *not* be removed from the ventilator with the arrival of an incoming yellow code patients since both of these patients have equivalent likelihoods of survival (i.e., both are in the same color category).

First, a blue code patient(s) is the first patient(s) eligible for ventilator removal. If there are no patients in the blue category, then a triage officer/ committee proceeds to the yellow code patients. If there are several patients in the blue (or yellow) category, a triage officer/committee is not permitted to compare the health of patients within the same color category. Instead, a randomization process such as a lottery is used to select which patient is removed. A patient may only be removed from a ventilator after an official clinical assessment has occurred or where the patient develops a medical condition on the exclusion criteria list.

If all ventilated patients at the 48, 120, and subsequent 48 hour time trial assessments receive a red color code, then none of these patients discontinue ventilator therapy. The incoming red code patient(s) remains in an eligible patient pool and receives alternative forms of medical intervention and/or palliative care until a ventilator becomes available.

Alternative Forms of Medical Intervention and Palliative Care

Palliative care and/or alternative forms of medical intervention are provided to those who are waiting for or are not eligible for a ventilator. Palliative care is provided to all patients throughout the triage process, regardless of prognosis.

Conclusion

The triage process requires regular reassessments of the status of the pandemic, available resources, and of all patients. As new data and information about the pandemic viral strain become available during a pandemic, the adult clinical ventilator allocation protocol may be revised accordingly to ensure that triage decisions are made commensurate with updated clinical criteria.

Appendix B

New York’s Pediatric Clinical Ventilator Allocation Protocol¹

All acute care patients who are in need of a ventilator, whether due to influenza or other conditions, are subject to the clinical ventilator allocation protocol. Using clinical criteria, patients who are deemed most likely to survive with ventilator treatment have an opportunity for ventilator therapy to maximize the number of survivors. The Guidelines’ definition of survival is based on the short-term likelihood of survival of the acute medical episode and is not focused on whether a patient may survive a given illness or disease in the long-term (e.g., years later).

The pediatric clinical ventilator allocation protocol applies to all patients aged 17 years and younger in all hospitals Statewide. Ventilator-dependent chronic care patients are only subject to the clinical ventilator allocation protocol if they arrive at a hospital. A patient’s attending physician cares for his/her patient and performs all clinical evaluations. A triage officer or triage committee examines a patient’s clinical data and determines who determines the patient’s level of access to a ventilator (i.e., who is eligible and/or continues with ventilator therapy). The attending physician and triage officer/committee should have experience working with children. The protocol consists of three steps: (1) application of exclusion criteria, (2) assessment of mortality risk, and (3) periodic clinical assessments (“time trials”).

1. Step 1: Exclusion Criteria

A patient’s attending physician examines his/her patient for an exclusion criterion and will forward this clinical data to a triage officer/committee to make the triage decision. Patients with exclusion criteria do not have access to ventilator therapy and instead are provided with alternative forms of medical intervention and/or palliative care.² If medical information is not readily available or accessible, it may be assumed a patient is free of exclusion criteria and may proceed to the next step of the clinical ventilator allocation protocol.

Step 1 - 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 chart below)
- Burns > 91% of body surface area for children less than 2 years of age (See chart below)
- Any other conditions resulting in immediate or near-immediate mortality even with aggressive therapy*

* 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.

¹ Please see Chapter 2, Pediatric Guidelines, Section IV. for a comprehensive analysis of all aspects of the protocol.

² However, if a ventilator becomes available and no other patient is in need of ventilator therapy, a patient with an exclusion criterion may be eligible for this treatment.

Additional Clinical Information regarding Exclusion Criteria (Step 1)

Determining Traumatic Brain Injury

No Motor Response to Painful Stimulus (i.e., Best Motor Response = 1)

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

American Burn Association (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%+
0 - 1.9	Very high	Very high	Very high	High	Medium	Medium	Medium	Low	Low	Low/expectant
2.0 - 4.9	Out-patient	Very high	Very high	High	High	High	Medium	Medium	Low	Low
5.0 - 19.9	Out-patient	Very high	Very high	High	High	High	Medium	Medium	Medium	Low

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 \geq 90%) with aggressive and comprehensive resource allocation, including aggressive fluid resuscitation, admission \geq 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 \geq 14 – 21 days, multiple surgeries and prolonged rehabilitation.

Low: Survival < 50% even with long-term aggressive treatment and resource allocation.

Expectant: Predicted survival \leq 10% even with unlimited aggressive treatment.

2. Step 2: Mortality Risk Assessment Using Physician Clinical Judgment

Physician clinical judgment by a patient's attending physician is used to assess the patient's risk of mortality. The attending physician's evaluation is based solely on clinical criteria, including the acute severity of a patient's current medical condition, the epidemiology of the disease, and the existence and status of any severe underlying diseases or medical conditions (co-morbidities) that may hinder recovery.

Physicians may also consider severe, end-stage chronic medical conditions when assessing mortality risk. However, existence of such a condition should not, by itself, preclude a

patient from being eligible for ventilator therapy. Instead, physicians should examine a patient's overall health to evaluate the patient's current health status. The extent of functional health impairment, rather than the medical diagnosis itself, should guide decision-making when evaluating a patient's current health status.³ Furthermore, additional medical complications may also be considered when assessing risk of mortality, such as, but not limited to: morbid obesity with its associated complications, impaired growth and nutrition, recurrent aspiration, pharyngeal airway obstruction, intractable seizures, or end-stage organ disease.

When examining chronic comorbidity, severe comorbidity is functionally defined as significant chronic impairment/deteriorating of health prior to the acute illness/injury. Moderate comorbidity is functionally defined as significant chronic impairment of health but a patient is in a steady health state prior to the acute illness/injury. For most patients who are sick with only influenza and have no other comorbidities, the single organ failure is limited to their lungs. However, because the pediatric clinical ventilator allocation protocol applies to all patients in need of a ventilator, a patient may also have a comorbidity(s) that affects another organ system(s) and his/her mortality risk assessment. Intubation for control of the airway (without lung disease) is not considered lung failure.

A patient's clinical data from Steps 1 and 2 are provided to a triage officer/committee who examines the information and assigns the patient a color code (i.e., blue, red, yellow, or green), which determines the patient's level of access to ventilator therapy. Patients with the red color code have the highest level of access to a ventilator because they are most likely to recover with treatment (and not likely to recover without it) and have a moderate risk of mortality. If resources are available, patients in the yellow category also have access to ventilator treatment. Those assigned the blue code are patients who potentially have the worst outlook for survival, even with ventilator therapy, and therefore have lowest access. The green category represents patients who are most likely to survive without ventilator therapy or are eligible for ventilator weaning. If resources become available, patients in the blue color category, or those with exclusion criteria, are reassessed and may become eligible for ventilator therapy.

Finally, a triage officer/committee must determine how to define what the cutoffs should be for highest, high/uncertain, moderate, and low risk of mortality risk categories because there are no evidence-based data early in a pandemic. Given the potential constraints associated with an influenza pandemic, mortality risk predictions should be based on the best clinical evidence available. However, the basic principle is that the more severe a patient's health condition is based on the clinical factors delineated above, the less likely s/he survives, even with ventilator therapy.

³ Examples of severe chronic conditions that adversely impact health functionality include, but are not limited to: severe end-stage lung or liver failure; Trisomy 13; known untreatable metabolic diseases, such as Zellweger Syndrome; spinal muscular atrophy (SMA) type 1; severe end-stage pulmonary hypertension; metastatic malignancy with poor prognosis; and severe irreversible immunocompromise in the presence of unremitting infection(s). In some instances, a patient may require ventilator therapy because of influenza and not because of the chronic care disease itself.

Triage Chart for Step 2

A triage officer/committee allocates ventilators according to the color code assigned.

Step 2 - Mortality Risk Assessment Using Physician Clinical Judgment ¹	
Color Code and Level of Access	Assessment of Mortality Risk/Organ Failure
<p>Blue</p> <p>No ventilator provided. Use alternative forms of medical intervention and/or palliative care or discharge.</p> <p>Reassess if ventilators become available.</p>	<p>Exclusion criterion</p> <p>OR</p> <p>HIGHEST risk of mortality associated with acute illness/injury (including epidemiology of the disease, if known) and</p> <p>Presence of SEVERE chronic comorbidity likely to worsen mortality risk or duration of ventilator treatment beyond that typical for the acute illness/injury</p>
<p>Red</p> <p>Highest</p> <p>Use ventilators as available</p>	<p>MODERATE risk of mortality, such as single organ failure,² associated with acute illness/injury (including epidemiology of the disease, if known) and</p> <p>NO severe chronic comorbidity likely to worsen mortality risk or duration of ventilator treatment beyond that typical for the acute illness/injury</p>
<p>Yellow</p> <p>Intermediate</p> <p>Use ventilators as available</p>	<p>HIGH/UNCERTAIN risk of mortality associated with acute illness/injury (including epidemiology of the disease, if known) and</p> <p>Presence of MODERATE chronic comorbidity likely to worsen mortality risk or duration of ventilator treatment beyond that typical for the acute illness/injury</p>
<p>Green</p> <p>Use alternative forms of medical intervention or defer or discharge. Reassess as needed.</p>	<p>LOW risk of mortality associated with acute illness/injury (including epidemiology of the disease, if known) and</p> <p>NO chronic comorbidity likely to worsen mortality risk or duration of ventilator treatment beyond that typical for the acute illness/injury</p>

¹If a patient develops a condition on the exclusion criteria list at any time from the initial assessment to the 48 hour assessment, change color code to blue. Remove the patient from the ventilator and provide alternative forms of medical intervention and/or palliative care.

²Intubation for control of the airway (without lung disease) is not considered lung failure.

Decision-Making Process for Selecting an Eligible Patient for a Ventilator

At Step 2, a triage officer/committee may encounter a situation where there are several patients in the red color code,⁴ who are equally eligible for ventilator therapy and must select a patient for the ventilator. It is not appropriate for a triage officer/committee to compare patients within the same color category. If all the eligible patients are pediatric patients, a random process (e.g., lottery) should be used to choose a pediatric patient for ventilator therapy when there are more eligible pediatric patients than ventilators available.⁵ In addition, a random selection method is conducted each time a ventilator becomes available. Patients waiting for ventilator therapy wait in an eligible patient pool and receive alternative forms of medical intervention and/or palliative care until a ventilator becomes available.

3. Step 3: Periodic Assessments for Continued Ventilator Use (Time Trials)

Periodic clinical assessments at 48 and 120 hours using physician clinical judgment are conducted on a patient who has begun ventilator therapy to evaluate whether s/he continues with the treatment. The patient's attending physician examines six variables, (1) Glasgow Coma Scale Score, (2) hypotension, (3) oxygenation index (OI) /arterial oxygen saturation, (4) whole blood/serum lactate, (5) serum creatinine, and (6) serum bilirubin/scleral icterus, using a scale of best, intermediate, and worst. These variables determine the severity of a patient's overall health and whether the patient's health condition was improving, deteriorating, or experiencing no change. The results of the time trial clinical assessments are provided to a triage officer/committee.

No single factor independently represents a patient's overall health trajectory and a triage officer/committee should never base a triage decision on a single clinical variable. Instead, a triage decision should examine all clinical variables so that an *overall* health assessment of a patient can be made. Furthermore, the first three variables – Glasgow Coma Scale Score, hypotension, and OI/arterial oxygen saturation – are more important for a triage officer/committee to consider, compared to the other three variables (whole blood/serum lactate, serum creatinine, and serum bilirubin/scleral icterus).⁶ While a triage decision to discontinue ventilator therapy may rely heavily on the assessments from the Glasgow Coma Scale Score, hypotension, and OI/arterial oxygen saturation, such a decision should *never* be made based *solely* on a patient's whole blood/serum lactate, serum creatinine, or serum bilirubin/scleral

⁴ While the yellow category may also have eligible patients waiting for ventilator therapy, all red code patients must be attended to first. If there are no red code patients, and only yellow code patients, then the same decision-making process applies.

⁵ However, if the pool of eligible patients includes both children and adults, young age plays a tie-breaking role. See Interface between Pediatric and Adult Patients.

⁶ Depending on the extent of staff and equipment shortages, it may not be possible to obtain the necessary lab work for whole blood/serum lactate, serum creatinine, or serum bilirubin levels. Thus, these factors may only play a role in the triage decision if the appropriate data are available.

icterus levels.⁷ The latter three variables may be more useful when deciding whether a patient eligible for continued ventilator therapy should be placed into the red or yellow color categories.

The clinical parameters appear below. The bold line separates the “primary” clinical variables from the “secondary” factors.

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} <u>OR</u> Arterial Oxygen Saturation^{2,3}	< 20 (Best) 20 – 40 (Intermediate) > 40 (Worst) <u>OR</u> > 88% (Best) 80 – 88% (Intermediate) < 80% (Worst)
Hypotension	Adequate circulation, with <u>no</u> vasoactive drugs (Best) Adequate circulation, with vasoactive drugs (Intermediate) Hypotension, with vasoactive drugs (Worst)
Glasgow Coma Scale Score⁴ (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) <u>OR</u> Scleral icterus⁵	< 3 (Best) 3 – 6 (Intermediate) > 6 (Worst) <u>OR</u> No scleral icterus (Best) Scleral icterus (Intermediate) Clinical jaundice (Worst)

¹ OI = mean airway pressure (MAP) x fraction of inspired oxygen (FiO₂) x 100 / partial pressure of oxygen in arterial blood (PaO₂). (PaO₂ 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.

⁷ It is possible that a patient may exhibit better outcomes in some clinical variables, but not in others. In this situation, a triage officer/committee should place more weight on the health data trends from the OI/arterial oxygen saturation percentages, hypotension, and Glasgow Coma Scale Score factors.

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

Using the results of these six variables, a triage officer/ committee assigns a color code (blue, red, yellow, or green) to the patient. The color code assigned is dependent on ongoing clinical measures and data trends of the patient's health condition, consisting of: (1) the overall prognosis estimated by the patient's clinical indicators, which is indicative of mortality risk by revealing the presence (or likelihood), severity, and number of acute organ failure(s), and (2) the magnitude of improvement or deterioration of overall health, which provides additional information about the likelihood of survival with ventilator therapy. These results are compared to the results from the previous official clinical assessment. The decision whether to continue ventilator therapy for a patient is dependent on the trend of the health data.

The guiding principle for the triage decision is that the more severe a patient's health condition (i.e., presence (or likelihood), number, and severity of acute organ failure) and the extent of deterioration, the less likely the patient continues with ventilator therapy. Conversely, the less severe a patient's health condition (i.e., little risk of acute organ failure) and demonstration of improvement with ventilator therapy (i.e., lower mortality risk), the higher the likelihood the patient continues with this form of treatment. Thus, the extent of change in the six variables indicates whether a patient is improving, worsening, or experiencing no change in health status.

At 48 hours, a patient must exhibit a pattern of significant improvement to be placed in the red color code. After 120 hours, a patient must demonstrate a pattern of *further* significant improvement in health to be placed in the red color code.

After the 120 hour clinical assessment, a patient who continues with ventilator therapy is reassessed every 48 hours using the same parameters used in the previous assessments.⁸ A triage officer/committee determines whether a patient continues with ventilator therapy based on the extent of change in the six clinical variables.

When assigning a patient a color code, a triage officer/committee must determine how to define what the cutoffs should be for highest, high/uncertain, moderate, and low risk of mortality risk categories because there are no evidence-based data early in a pandemic. Given the potential constraints associated with an influenza pandemic, mortality risk predictions should be based on the best clinical evidence available. However, the basic principle is that the more severe a patient's health condition is based on the clinical factors delineated above, the less likely s/he survives, even with ventilator therapy.

In addition, a triage officer/committee must determine how to define a "pattern of significant improvement/deterioration." Because patients are not competing against each other for ventilator treatment, a triage officer/committee is not comparing a patient's level of

⁸ Other considerations may include the known progression of the disease, updated data on the pandemic viral strain, availability of alternative treatments, current supply and demand data at the facility (e.g., number of available or soon to be available ventilators and incoming patients requiring ventilator therapy), alternative sites of health care, and whether there are any patients waiting for a ventilator therapy trial.

improvement to another patient. Instead, the extent of improvement (or deterioration) is evaluated based on a patient's previous official assessment. A patient is only "competing" against him/herself and must demonstrate improvement to continue with the treatment.

The official assessments only occur after 48 and 120 hours (and subsequent 48 hours) of ventilator therapy. No formal triage decision or action may be taken until a patient's official assessment. However, at any point during the time trial, even before an official assessment occurs, if a patient develops a condition on the exclusion criteria list and there is an eligible patient waiting, then the ventilator is reallocated. Patients removed from the ventilator are provided with alternative forms of medical intervention and/or palliative care.⁹

Triage Charts for Step 3

Criteria for each color code at the 48 and 120 hour assessments are presented below.

⁹ If no eligible patients are waiting for ventilator treatment, a patient who does not meet the time trial criteria would continue with the treatment and be evaluated again at the next official assessment.

48 Hour Clinical Assessment Chart

Step 3 - Ventilator Time Trials (48 Hour Assessment) ¹	
Color Code and Level of Access	Assessment of Mortality Risk/Organ Failure (Examining Six Clinical Variables)
<p style="text-align: center;">Blue</p> <p style="text-align: center;">No ventilator provided.² Use alternative forms of medical intervention and/or palliative care or discharge. Reassess if resources become available.</p>	<p style="text-align: center;">Exclusion criterion OR HIGHEST risk of mortality and Pattern of significant deterioration (or no change³) of overall health compared to the initial assessment</p>
<p style="text-align: center;">Red Highest</p> <p style="text-align: center;">Use lifesaving resources as available.</p>	<p style="text-align: center;">MODERATE risk of mortality and Pattern of significant improvement of overall health compared to the initial assessment</p>
<p style="text-align: center;">Yellow Intermediate</p> <p style="text-align: center;">Use lifesaving resources as available.</p>	<p style="text-align: center;">HIGH / UNCERTAIN risk of mortality and No significant change or slight deterioration in overall health compared to the initial assessment</p>
<p style="text-align: center;">Green</p> <p style="text-align: center;">Use alternative forms of medical intervention or defer or discharge. Reassess as needed.</p>	<p style="text-align: center;">LOW risk of mortality and No longer ventilator dependent / Actively weaning from ventilator</p>

¹ If a patient develops a condition on the exclusion criteria list at any time from the initial assessment to the 48 hour assessment, change color code to blue. Remove the patient from the ventilator and provide alternative forms of medical intervention and/or palliative care.

² A patient assigned a blue color code is removed from the ventilator and alternative forms of medical intervention and/or palliative care are provided.

³ The patient remains significantly ill.

120 Hour Clinical Assessment Chart

Step 3 - Ventilator Time Trials (120 Hour Assessment) ¹	
Color Code and Level of Access	Assessment of Mortality Risk/Organ Failure (Examining Six Clinical Variables)
<p style="text-align: center;">Blue</p> <p style="text-align: center;">No ventilator provided.² Use alternative forms of medical intervention and/or palliative care or discharge. Reassess if resources become available.</p>	<p style="text-align: center;">Exclusion criterion</p> <p style="text-align: center;">OR</p> <p style="text-align: center;">HIGHEST risk of mortality and Pattern of significant deterioration (or no change³) of overall health compared to the previous assessment</p>
<p style="text-align: center;">Red</p> <p style="text-align: center;">Highest</p> <p style="text-align: center;">Use lifesaving resources as available.</p>	<p style="text-align: center;">MODERATE risk of mortality and Pattern of <i>further</i> significant improvement of overall health compared to the previous assessment</p>
<p style="text-align: center;">Yellow</p> <p style="text-align: center;">Intermediate</p> <p style="text-align: center;">Use lifesaving resources as available.</p>	<p style="text-align: center;">HIGH / UNCERTAIN risk of mortality and No significant change in overall health compared to the previous assessment</p>
<p style="text-align: center;">Green</p> <p style="text-align: center;">Use alternative forms of medical intervention or defer or discharge. Reassess as needed.</p>	<p style="text-align: center;">LOW risk of mortality and No longer ventilator dependent / Actively weaning from ventilator</p>

¹ If a patient develops a condition on the exclusion criteria list at any time from the 48 hour assessment to the 120 hour assessment, change color code to blue. Remove the patient from the ventilator and provide alternative forms of medical intervention and/or palliative care.

² A patient assigned a blue color code is removed from the ventilator and alternative forms of medical intervention and/or palliative care are provided.

³ The patient remains significantly ill.

Decision-Making Process for Removing a Patient from a Ventilator

There may be a scenario where there is an incoming red code patient(s)¹⁰ eligible for ventilator treatment and a triage officer/committee must remove a ventilator from a patient whose health is not improving at the 48, 120, or subsequent 48 hour time trial assessments, so

¹⁰ While there may be yellow color code patients waiting for ventilator therapy, all red code patients must be attended to first. In limited circumstances, where incoming patients are only yellow code, these patients may only receive ventilator therapy if there are any blue code patients currently receiving ventilator treatment. Already ventilated yellow code patients would *not* be removed from the ventilator with the arrival of an incoming yellow code patients since both of these patients have equivalent likelihoods of survival (i.e., both are in the same color category).

that the red code patient receives ventilator treatment. A triage officer/committee follows these steps to determine which patient should be removed from the ventilator.

First, a blue code patient(s) is the first patient(s) eligible for ventilator removal. If there are no patients in the blue category, then a triage officer/ committee proceeds to the yellow code patients. If there are several patients in the blue (or yellow) category, a triage officer/committee is not permitted to compare the health of patients within the same color category. Instead, a randomization process such as a lottery is used to select which patient is removed. A patient may only be removed from a ventilator after an official clinical assessment has occurred or where the patient develops a medical condition on the exclusion criteria list.

If all ventilated patients at the 48, 120, and subsequent 48 hour time trial assessments receive a red color code, then none of these patients discontinue ventilator therapy. The incoming red code patient(s) remains in an eligible patient pool and receives alternative forms of medical intervention and/or palliative care until a ventilator becomes available.

Interface between Pediatric and Adult Patients

In an influenza pandemic, the same triage officer/committee may need to allocate ventilators to both adult and pediatric patients. When either selecting or removing a patient in a patient pool that consists of both children and adults, a triage officer/committee is not permitted to compare the health of patients. A triage officer/committee must assume that all patients in a color category have substantially equal likelihoods of survival because no other evidence-based clinical tools are available to further differentiate a patient's mortality risk. When adult and pediatric patients all have equal likelihoods of survival (i.e., in the same color category), young age may play a tie-breaking role in determining which patient receives/continues with ventilator treatment. In this situation, the child (i.e., 17 years old and younger) receives/continues with ventilator treatment and the adult receives alternative forms of medical intervention and/or palliative care.

Alternative Forms of Medical Intervention and Palliative Care

Palliative care and/or alternative forms of medical intervention are provided to those who are waiting for or are not eligible for a ventilator. Palliative care is provided to all patients throughout the triage process, regardless of prognosis.

Conclusion

The triage process requires regular reassessments of the status of the pandemic, available resources, and of all patients. As new data and information about the pandemic viral strain become available during a pandemic, the pediatric clinical ventilator allocation protocol may be revised accordingly to ensure that triage decisions are made commensurate with updated clinical criteria.

Appendix C

New York’s Neonatal Clinical Ventilator Allocation Protocol¹

All neonatal acute care patients who are in need of a ventilator, whether due to influenza or other conditions, are subject to the clinical ventilator allocation protocol. Using clinical criteria, patients who are deemed most likely to survive with ventilator treatment have an opportunity for ventilator therapy to maximize the number of survivors. The Guidelines’ definition of survival is based on the short-term likelihood of survival of the acute medical episode and is not focused on whether a patient may survive a given illness or disease in the long-term (e.g., years later).

The neonatal clinical ventilator allocation protocol applies to all patients 28 days old and younger in all hospitals Statewide. A patient’s attending physician cares for his/her patient and performs all clinical evaluations. A triage officer or triage committee examines a patient’s clinical data and determines who determines the patient’s level of access to a ventilator (i.e., who is eligible and/or continues with ventilator therapy). The attending physician and triage officer/committee should have experience working with neonates. The protocol consists of three steps: (1) application of exclusion criteria, (2) assessment of mortality risk, and (3) periodic clinical assessments (“time trials”).

1. Step 1: Exclusion Criteria

A patient’s attending physician examines his/her patient for an exclusion criterion and will forward this clinical data to a triage officer/committee to make the triage decision. Patients with exclusion criteria do not have access to ventilator therapy and instead are provided with alternative forms of medical intervention and/or palliative care.² If medical information is not readily available or accessible, it may be assumed a patient is free of exclusion criteria and may proceed to the next step of the clinical ventilator allocation protocol.

¹ Please see Chapter 3, Neonatal Guidelines, Section III. for a comprehensive analysis of all aspects of the protocol.

² However, if a ventilator becomes available and no other patient is in need of ventilator therapy, a patient with an exclusion criterion may be eligible for this treatment.

Step 1 - List of Exclusion Criteria for Neonatal Patients³
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*

*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.

2. Step 2: Mortality Risk Assessment Using Physician Clinical Judgment

Physician clinical judgment by a patient’s attending physician is used to assess the patient’s risk of mortality. The attending physician’s evaluation is based solely on clinical criteria, including the acute severity of a patient’s current medical condition, the epidemiology of the disease, and the existence and status of any severe underlying diseases or medical conditions (co-morbidities) that may hinder recovery.

Physicians may also consider severe, end-stage chronic medical conditions when assessing mortality risk. However, existence of such a condition should not, by itself, preclude a patient from being eligible for ventilator therapy. Instead, physicians should examine a patient’s overall health to evaluate the patient’s current health status. The extent of functional health impairment, rather than the medical diagnosis itself, should guide decision-making when evaluating a patient’s current health status.⁴

When examining chronic comorbidity, severe comorbidity is functionally defined as significant chronic impairment/deteriorating of health prior to the acute illness/injury. Moderate comorbidity is functionally defined as significant chronic impairment of health but a patient is in a steady health state prior to the acute illness/injury. For most patients who are sick with only influenza and have no other comorbidities, the single organ failure is limited to their lungs. However, because the neonatal clinical ventilator allocation protocol applies to all patients in

³ Because there is often misunderstanding regarding the immediate or near-immediate mortality risk of many medical conditions, below are some examples of conditions that would not be part of exclusion criteria: trisomy 21, operable congenital heart disease, DiGeorge Sequence, gastroschisis/omphalocele, VACTERL association, Turner's syndrome, Klinefelter syndrome, congenital diaphragmatic hernia, meningomyelocele (low thoracic, lumbar), hydrocephalus, congenital infection with or without central nervous system involvement, hypoxic-ischemic encephalopathy regardless of severity, grade III/IV intracranial hemorrhage, and holoprosencephaly sequence.

⁴ Examples of severe chronic conditions that adversely impact health functionality include, but are not limited to: Trisomy 13 and 18, anencephaly, and high thoracic meningomyelocele. In some instances, a patient may require ventilator therapy because of influenza and not because of the chronic care disease itself.

need of a ventilator, a patient may also have a comorbidity(s) that affects another organ system(s) and his/her mortality risk assessment. Intubation for control of the airway (without lung disease) is not considered lung failure.

A patient's clinical data from Steps 1 and 2 are provided to a triage officer/committee who examines the information and assigns the patient a color code (i.e., blue, red, yellow, or green), which determines the patient's level of access to ventilator therapy. Patients with the red color code have the highest level of access to a ventilator because they are most likely to recover with treatment (and not likely to recover without it) and have a moderate risk of mortality. If resources are available, patients in the yellow category also have access to ventilator treatment. Those assigned the blue code are patients who potentially have the worst outlook for survival, even with ventilator therapy, and therefore have lowest access. The green category represents patients who are most likely to survive without ventilator therapy or are eligible for ventilator weaning. If resources become available, patients in the blue color category, or those with exclusion criteria, are reassessed and may become eligible for ventilator therapy.

Finally, a triage officer/committee must determine how to define what the cutoffs should be for highest, high/uncertain, moderate, and low risk of mortality risk categories because there are no evidence-based data early in a pandemic. Given the potential constraints associated with an influenza pandemic, mortality risk predictions should be based on the best clinical evidence available. However, the basic principle is that the more severe a patient's health condition is based on the clinical factors delineated above, the less likely s/he survives, even with ventilator therapy.

Triage Chart for Step 2

A triage officer/committee allocates ventilators according to the color code assigned.

Step 2 - Mortality Risk Assessment Using Physician Clinical Judgment ¹	
Color Code and Level of Access	Assessment of Mortality Risk/Organ Failure
<p>Blue</p> <p>No ventilator provided.</p> <p>Use alternative forms of medical intervention and/or palliative care or discharge.</p> <p>Reassess if ventilators become available.</p>	<p>Exclusion criterion</p> <p>OR</p> <p>HIGHEST risk of mortality associated with acute illness/injury (including epidemiology of the disease, if known) and</p> <p>Presence of SEVERE chronic comorbidity likely to worsen mortality risk or duration of ventilator treatment beyond that typical for the acute illness/injury</p>
<p>Red</p> <p>Highest</p> <p>Use ventilators as available</p>	<p>MODERATE risk of mortality, such as single organ failure,² associated with acute illness/injury (including epidemiology of the disease, if known) and</p> <p>NO severe chronic comorbidity likely to worsen mortality risk or duration of ventilator treatment beyond that typical for the acute illness/injury</p>
<p>Yellow</p> <p>Intermediate</p> <p>Use ventilators as available</p>	<p>HIGH/UNCERTAIN risk of mortality associated with acute illness/injury (including epidemiology of the disease, if known) and</p> <p>Presence of MODERATE chronic comorbidity likely to worsen mortality risk or duration of ventilator treatment beyond that typical for the acute illness/injury</p>
<p>Green</p> <p>Use alternative forms of medical intervention or defer or discharge.</p> <p>Reassess as needed.</p>	<p>LOW risk of mortality associated with acute illness/injury (including epidemiology of the disease, if known) and</p> <p>NO chronic comorbidity likely to worsen mortality risk or duration of ventilator treatment beyond that typical for the acute illness/injury</p>

¹ If a patient develops a condition on the exclusion criteria list at any time from the initial assessment to the 48 hour assessment, change color code to blue. Remove the patient from the ventilator and provide alternative forms of medical intervention and/or palliative care.

² Intubation for control of the airway (without lung disease) is not considered lung failure.

Decision-Making Process for Selecting an Eligible Patient for a Ventilator

At Step 2, a triage officer/committee may encounter a situation where there are several patients in the red color code,⁵ who are equally eligible for ventilator therapy and must select a patient for the ventilator. It is not appropriate for a triage officer/committee to compare patients within the same color category. If all the eligible patients are neonatal patients, a random process (e.g., lottery) should be used to choose a neonatal patient for ventilator therapy when there are more eligible neonatal patients than ventilators available. In addition, a random selection method is conducted each time a ventilator becomes available. Patients waiting for ventilator therapy wait in an eligible patient pool and receive alternative forms of medical intervention and/or palliative care until a ventilator becomes available.

3. Step 3: Periodic Assessments for Continued Ventilator Use (Time Trials)

Periodic clinical assessments at 48 and 120 hours using physician clinical judgment are conducted on a patient who has begun ventilator therapy to evaluate whether s/he continues with the treatment. The patient's attending physician examines three variables, (1) hypotension, (2) oxygenation index (OI) /arterial oxygen saturation, and (3) serum creatinine, using a scale of best, intermediate, and worst. These variables determine the severity of a patient's overall health and whether the patient's health condition was improving, deteriorating, or experiencing no change. The results of the time trial clinical assessments are provided to a triage officer/committee.

No single factor independently represents a patient's overall health trajectory and a triage officer/committee should never base a triage decision on a single clinical variable. Instead, a triage decision should examine all clinical variables so that an *overall* health assessment of a patient can be made. Furthermore, the first two variables – hypotension and OI/arterial oxygen saturation – are more important for a triage officer/committee to consider, compared to serum creatinine.⁶ While a triage decision to discontinue ventilator therapy may rely heavily on the assessments from the hypotension and OI/arterial oxygen saturation, such a decision should *never* be made based *solely* on a patient's serum creatinine.⁷ The latter variable may be more useful when deciding whether a patient eligible for continued ventilator therapy should be placed into the red or yellow color categories.

The clinical parameters appear below. The bold line separates the “primary” clinical variables from the “secondary” factor.

⁵ While the yellow category may also have eligible patients waiting for ventilator therapy, all red code patients must be attended to first. If there are no red code patients, and only yellow code patients, then the same decision-making process applies.

⁶ Depending on the extent of staff and equipment shortages, it may not be possible to obtain the necessary lab work for serum creatinine. Thus, this factor may only play a role in the triage decision if the appropriate data are available.

⁷ It is possible that a patient may exhibit better outcomes in some clinical variables, but not in others. In this situation, a triage officer/committee should place more weight on the health data trends from the OI/arterial oxygen saturation percentages and hypotension factors.

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}	<p>< 20 (Best) 20 – 40 (Intermediate) > 40 (Worst)</p> <p>OR</p> <p>> 88% (Best) 80 – 88% (Intermediate) < 80% (Worst)</p>
Hypotension	<p>Adequate circulation, with <u>no</u> vasoactive drugs (Best) Adequate circulation, with vasoactive drugs (Intermediate) Hypotension, with vasoactive drugs (Worst)</p>
Serum Creatinine (mg/dL)	<p>< 1 (Best) 1 < 3 (Intermediate) > 3 (Worst)</p>

¹ OI = mean airway pressure (MAP) x fraction of inspired oxygen (FiO₂) x 100 / partial pressure of oxygen in arterial blood (PaO₂). (PaO₂ 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.

Using the results of these three variables, a triage officer/ committee assigns a color code (blue, red, yellow, or green) to the patient. The color code assigned is dependent on ongoing clinical measures and data trends of the patient’s health condition, consisting of: (1) the overall prognosis estimated by the patient’s clinical indicators, which is indicative of mortality risk by revealing the presence (or likelihood), severity, and number of acute organ failure(s), and (2) the magnitude of improvement or deterioration of overall health, which provides additional information about the likelihood of survival with ventilator therapy. These results are compared to the results from the previous official clinical assessment. The decision whether to continue ventilator therapy for a patient is dependent on the trend of the health data.

The guiding principle for the triage decision is that the more severe a patient’s health condition (i.e., presence (or likelihood), number, and severity of acute organ failure) and the extent of deterioration, the less likely the patient continues with ventilator therapy. Conversely, the less severe a patient’s health condition (i.e., little risk of acute organ failure) and demonstration of improvement with ventilator therapy (i.e., lower mortality risk), the higher the likelihood the patient continues with this form of treatment. Thus, the extent of change in the three variables indicates whether a patient is improving, worsening, or experiencing no change in health status.

At 48 hours, a patient must exhibit a pattern of significant improvement to be placed in the red color code. After 120 hours, a patient must demonstrate a pattern of *further* significant improvement in health to be placed in the red color code.

After the 120 hour clinical assessment, a patient who continues with ventilator therapy is reassessed every 48 hours using the same parameters used in the previous assessments.⁸ A triage officer/committee determines whether a patient continues with ventilator therapy based on the extent of change in the three clinical variables.

When assigning a patient a color code, a triage officer/committee must determine how to define what the cutoffs should be for highest, high/uncertain, moderate, and low risk of mortality risk categories because there are no evidence-based data early in a pandemic. Given the potential constraints associated with an influenza pandemic, mortality risk predictions should be based on the best clinical evidence available. However, the basic principle is that the more severe a patient's health condition is based on the clinical factors delineated above, the less likely s/he survives, even with ventilator therapy.

In addition, a triage officer/committee must determine how to define a "pattern of significant improvement/deterioration." Because patients are not competing against each other for ventilator treatment, a triage officer/committee is not comparing a patient's level of improvement to another patient. Instead, the extent of improvement (or deterioration) is evaluated based on a patient's previous official assessment. A patient is only "competing" against him/herself and must demonstrate improvement to continue with the treatment.

The official assessments only occur after 48 and 120 hours (and subsequent 48 hours) of ventilator therapy. No formal triage decision or action may be taken until a patient's official assessment. However, at any point during the time trial, even before an official assessment occurs, if a patient develops a condition on the exclusion criteria list and there is an eligible patient waiting, then the ventilator is reallocated. Patients removed from the ventilator are provided with alternative forms of medical intervention and/or palliative care.⁹

Triage Charts for Step 3

Criteria for each color code at the 48 and 120 hour assessments are presented below.

⁸ Other considerations may include the known progression of the disease, updated data on the pandemic viral strain, availability of alternative treatments, current supply and demand data at the facility (e.g., number of available or soon to be available ventilators and incoming patients requiring ventilator therapy), alternative sites of health care, and whether there are any patients waiting for a ventilator therapy trial.

⁹ If no eligible patients are waiting for ventilator treatment, a patient who does not meet the time trial criteria would continue with the treatment and be evaluated again at the next official assessment.

48 Hour Clinical Assessment Chart

Step 3 - Ventilator Time Trials (48 Hour Assessment) ¹	
Color Code and Level of Access	Assessment of Mortality Risk/Organ Failure (Examining Three Clinical Variables)
<p style="text-align: center;">Blue</p> <p style="text-align: center;">No ventilator provided.² Use alternative forms of medical intervention and/or palliative care or discharge. Reassess if resources become available.</p>	<p style="text-align: center;">Exclusion criterion OR HIGHEST risk of mortality and Pattern of significant deterioration (or no change³) of overall health compared to the initial assessment</p>
<p style="text-align: center;">Red Highest</p> <p style="text-align: center;">Use lifesaving resources as available.</p>	<p style="text-align: center;">MODERATE risk of mortality and Pattern of significant improvement of overall health compared to the initial assessment</p>
<p style="text-align: center;">Yellow Intermediate</p> <p style="text-align: center;">Use lifesaving resources as available.</p>	<p style="text-align: center;">HIGH / UNCERTAIN risk of mortality and No significant change or slight deterioration in overall health compared to the initial assessment</p>
<p style="text-align: center;">Green</p> <p style="text-align: center;">Use alternative forms of medical intervention or defer or discharge. Reassess as needed.</p>	<p style="text-align: center;">LOW risk of mortality and No longer ventilator dependent / Actively weaning from ventilator</p>

¹ If a patient develops a condition on the exclusion criteria list at any time from the initial assessment to the 48 hour assessment, change color code to blue. Remove the patient from the ventilator and provide alternative forms of medical intervention and/or palliative care.

² A patient assigned a blue color code is removed from the ventilator and alternative forms of medical intervention and/or palliative care are provided.

³ The patient remains significantly ill.

120 Hour Clinical Assessment Chart

Step 3 - Ventilator Time Trials (120 Hour Assessment)¹	
Color Code and Level of Access	Assessment of Mortality Risk/Organ Failure (Examining Three Clinical Variables)
Blue No ventilator provided. ² Use alternative forms of medical intervention and/or palliative care or discharge. Reassess if resources become available.	Exclusion criterion OR HIGHEST risk of mortality and Pattern of significant deterioration (or no change ³) of overall health compared to the previous assessment
Red Highest Use lifesaving resources as available.	MODERATE risk of mortality and Pattern of <i>further</i> significant improvement of overall health compared to the previous assessment
Yellow Intermediate Use lifesaving resources as available.	HIGH / UNCERTAIN risk of mortality and No significant change in overall health compared to the previous assessment
Green Use alternative forms of medical intervention or defer or discharge. Reassess as needed.	LOW risk of mortality and No longer ventilator dependent / Actively weaning from ventilator

¹ If a patient develops a condition on the exclusion criteria list at any time from the 48 hour assessment to the 120 hour assessment, change color code to blue. Remove the patient from the ventilator and provide alternative forms of medical intervention and/or palliative care.

² A patient assigned a blue color code is removed from the ventilator and alternative forms of medical intervention and/or palliative care are provided.

³ The patient remains significantly ill.

Decision-Making Process for Removing a Patient from a Ventilator

There may be a scenario where there is an incoming red code patient(s)¹⁰ eligible for ventilator treatment and a triage officer/committee must remove a ventilator from a patient

¹⁰ While there may be yellow color code patients waiting for ventilator therapy, all red code patients must be attended to first. In limited circumstances, where incoming patients are only yellow code, these patients may only receive ventilator therapy if there are any blue code patients currently receiving ventilator treatment. Already ventilated yellow code patients would *not* be removed from the ventilator with the arrival of an incoming yellow code patients since both of these patients have equivalent likelihoods of survival (i.e., both are in the same color category).

whose health is not improving at the 48, 120, or subsequent 48 hour time trial assessments, so that the red code patient receives ventilator treatment. A triage officer/committee follows these steps to determine which patient should be removed from the ventilator.

First, a blue code patient(s) is the first patient(s) eligible for ventilator removal. If there are no patients in the blue category, then a triage officer/ committee proceeds to the yellow code patients. If there are several patients in the blue (or yellow) category, a triage officer/committee is not permitted to compare the health of patients within the same color category. Instead, a randomization process such as a lottery is used to select which patient is removed. A patient may only be removed from a ventilator after an official clinical assessment has occurred or where the patient develops a medical condition on the exclusion criteria list.

If all ventilated patients at the 48, 120, and subsequent 48 hour time trial assessments receive a red color code, then none of these patients discontinue ventilator therapy. The incoming red code patient(s) remains in an eligible patient pool and receives alternative forms of medical intervention and/or palliative care until a ventilator becomes available.

Interface between Neonatal and Pediatric Patients

In an influenza pandemic, the same triage officer/committee may need to allocate ventilators to both neonatal and pediatric patients. When either selecting or removing a patient in a patient pool that consists of both neonatal and pediatric patients, a triage officer/committee is not permitted to compare the health of patients. A triage officer/committee must assume that all patients in a color category have substantially equal likelihoods of survival because no other evidence-based clinical tools are available to further differentiate a patient's mortality risk. Because the patient pool consists of only children, young age would not be a consideration. Instead, a random process should be used to choose the patient for ventilator therapy when there are more patients than ventilators available. In addition, a random selection method is conducted each time a ventilator becomes available.

Alternative Forms of Medical Intervention and Palliative Care

Palliative care and/or alternative forms of medical intervention are provided to those who are waiting for or are not eligible for a ventilator. Palliative care is provided to all patients throughout the triage process, regardless of prognosis.

Conclusion

The triage process requires regular reassessments of the status of the pandemic, available resources, and of all patients. As new data and information about the pandemic viral strain become available during a pandemic, the neonatal clinical ventilator allocation protocol may be revised accordingly to ensure that triage decisions are made commensurate with updated clinical criteria.