Emergency Services: Some patients arrive in the emergency department with endotracheal tubes already inserted. Participants disagreed about whether EMS personnel should continue to intubate patients before arrival at the hospital. Workgroup members express concern that EMS personnel might not have sufficient data to apply allocation criteria in the field. However, participants concurred that emergency department staff may reassess patients upon arrival and extubate as necessary those patients who do not meet criteria for ICU admission and ventilator use.

Time Trials: Continued use of the ventilator will be reviewed and reassessed at intervals of 48 and 120 hours. Patients who continue to meet criteria for benefit or improvement would continue until the next assessment, while those who no longer met these criteria would lose access to mechanical ventilation. Access for a specific single period of time was considered but rejected as excessively arbitrary.

Time trials for ventilator use should reflect the expected duration of beneficial treatment for acute respiratory distress syndrome (ARDS) or other likely complications of severe influenza. Too brief a trial, for instance of only a few hours, might not provide any significant benefit to patients, including those who might survive with a limited but longer trial. Excessively brief trials might permit use of ventilators by more patients, but without decreasing overall mortality. Moreover, very short trials would raise the option of terminal extubation for large numbers of patients, a circumstance that the guidelines should attempt to minimize if possible.

Exclusion Criteria: Clinicians will assess patients for exclusion criteria both to determine the appropriateness of 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 would objectively define those patients with a high risk of mortality even with ventilator support, but would not rely on subjective judgments of quality of life. Exclusion criteria should focus primarily on current organ function, rather than on specific disease entities. A revised set of exclusion criteria, drawing upon the work of OHPIP and incorporating suggestions from workgroup members and additional critical care experts, is presented below.

Exclusion Criteria for Ventilator Access*

- Cardiac arrest: unwitnessed arrest, recurrent arrest, arrest unresponsive to standard measures; Trauma-related arrest
- Metastatic malignancy with poor prognosis
- Severe burn: body surface area >40%, severe inhalation injury
- End-stage organ failure:
  - o Cardiac: NY Heart Association class III or IV
  - o Pulmonary: severe chronic lung disease with FEV_1** < 25%
  - o Hepatic: MELD*** score > 20
  - o Renal: dialysis dependent
  - o Neurologic: severe, irreversible neurologic event/condition with high expected mortality

*Adapted from OHPIP guidelines
** Forced Expiratory Volume in 1 second, a measure of lung function
*** Model of End-stage Liver Disease

5. Triage decision-makers

The primary clinicians treating a patient would have neither the main nor the sole responsibility for deciding to remove a ventilator from the patient. The clinicians directly caring for the patient would assess the patient's condition and note the emergence of any exclusion criteria; a triage review officer, the supervising clinician in charge of intensive care patients (either in the unit or in its overflow areas), would make triage decisions based on the allocation protocol.

This approach is consistent with the recommendations of the Working Group on Emergency Mass Critical Care, a distinguished group of experts that produced a 2005 guidance document for improving surge capacity in public health disasters. [17] That document directs senior clinicians to take on a role of supervising those with less critical care experience. An epidemic will create shortages of personnel for intensive care, both because the need will increase and because fewer personnel may be available. Clinicians providing direct care for patients in the intensive care unit during a pandemic may be far less experienced with critical care than would ordinarily be the case. Second, primary clinicians could fulfill their obligation to care for their individual patients without facing a conflict of interest; they could advocate for their patients and would not also be responsible for deciding to end treatment. Third, staff with the best information on the current balance of need versus resources would make triage decisions, and would be most likely to make the decisions consistently within a group of patients. The triage officer will be a supervising clinician with better access to information about the number and nature of patients awaiting admission to the unit, and can set triage goals accordingly. Fourth, this form of role sequestration would enhance the capacity for maintaining professionalism. The pandemic will have a finite duration. Guidelines for triage should minimize the erosion of the clinicians' duty to care for individual patients. Role sequestration may help decrease burnout and stress for clinicians providing critical care during the epidemic, and help sustain their integrity as healers.

6. Palliative care

Patients who fail to meet rationing criteria have poor prognoses and will be taken off ventilators. Clinicians should then endeavor to follow existing facility protocols for withdrawing and withholding life-sustaining care. Palliative care should be offered to patients who fail to meet rationing standards for continued ventilator support. Typically, terminal weaning in response to patient preferences can include sedation, so that the patient need not suffer from air hunger. Patients who are extubated against their wishes may be offered sedation, but may choose to decline. Clinicians should clearly document the rationale and decision regarding sedation with extubation; transparency is a crucial element in adhering to ethical standards. Facility protocols for terminal extubation may offer guidance for appropriate dosing and procedures. In addition, facilities should prepare for a significant increase in demand for palliative care expertise. Extubated patients could receive nasal cannula oxygen if available, or other supplements to breathing. Facilities will need to address whether family or community members will be allowed to supplement ventilation, perhaps after transfer out of the ICU, with hand-held devices such as ambu-bags.

7. Appeals process

Triage decisions will engender controversy and objections. Workgroup participants disagreed about whether a real-time or retrospective form of review would better serve the goal of providing a just and workable triage system. Some review process is needed to assure consistency and justice in the application of the criteria.

OHPIP and others call for a system in which on-going triage decisions may be appealed. [18] Ideally, even under conditions of limited staffing, personnel involved in the

appeals process would differ from those who made the initial triage determination, and if possible, the review should be made by several persons rather than an individual. These persons should also be experienced in conflict mediation and have clinical expertise; drawing upon members of the ethics committee, the patient representative service, retired clinicians, and the chaplaincy may be ways to provide an appeals process even during the period of limited staffing. This system offers the benefit of review for individual cases, but also creates potentially unworkable delays in implementing triage decision during the public health emergency.

Some argue that a real-time appeals process could invite explosive debate during a time of scarce manpower and other resources. An alternate to a real-time appeals process could involve daily retrospective review of all triage decisions. The review would assure that standards are followed consistently and correctly, and would present an opportunity for correcting the guidelines or their implementation as needed. Such retrospective review would provide oversight and accountability for triage decisions, but would not permit intervention for individual decisions regarding access to ventilators.

8. Communication about triage

Initiation of each phase of treatment, but especially of ventilator support, will require clear communication about goals and options. Even before a patient comes to the hospital, political leaders and health officials will have to emphasize publicly that pandemic flu is potentially fatal, that clinicians are doing all they can with the available resources, and that everyone will need to adjust to a different way of providing and receiving health care than is customary. Patients and families must be informed

immediately that ventilator support represents a trial of therapy that may not improve the 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 such time trials. Communication should be clear upon hospital admission and ICU admission, as well as upon initiation of ventilator treatment.

VI. LEGAL ISSUES

The law must inform any ethical and clinical recommendations of the workgroup. In devising a rationing scheme for ventilators, the state should examine various current health laws, regulations, and policies. The best resolution for the challenging issue of liability and/or indemnification for providers and facilities during a public health emergency is as yet unclear; various options, including new legislation, merit consideration.

Emergency Powers

A pandemic could meet the criteria of a "disaster" needed to trigger the emergency powers of the Governor and local officials enumerated in New York's Executive Law. In a disaster, the Governor may temporarily suspend "any statute, local law, ordinance, or orders, rules or regulations." 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." Suspensions are limited to 30 days, but can be renewed. [19] Prudence compels consideration of which laws should be suspended by the Governor in a pandemic.

DNR Orders: Ventilator triage in a public health emergency will change the context in which decisions are made to attempt resuscitation. If pandemic triage guidelines endorse the removal of ventilators from patients in certain circumstances, physicians cannot then resuscitate such patients by reintubation. Article 29-B of the Public Health Law presumes that a patient consents to cardiopulmonary resuscitation

unless there is consent for a Do Not Resuscitate (DNR) Orders. [20] Thus, the protocol described in these ventilator allocation guidelines appears to conflict with the DNR statute.

In a disaster emergency the Governor might suspend provisions of the DNR law that conflict with these ventilator guidelines. Specifically, patients who lose access to ventilator support under rationing criteria will also require DNR orders, and these cannot depend upon the consent of patients and surrogates. The specific provisions requiring suspension would be those sections of Article 29-B that establish presumed consent for cardiopulmonary resuscitation and require consent to issuance of a DNR order.

As noted above, any suspension of law by the Governor in an emergency is subject to the requirements of the federal and state constitutions, as well as federal law. Whether the emergency suspension of the DNR law (or portions thereof) to support emergency ventilator allocation would be viewed as running afoul of these requirements cannot be predicted with certainty.

DNR orders in other contexts, for instance for hospice patients and others for whom ventilator use is not an issue, should continue to rely upon consent from patients or surrogates, even during the public health emergency.

Brain death: Evaluations of brain death in New York follow voluntary guidelines issued by NYSDOH. As such, they can be revised or amended by NYSDOH before or during an emergency without invocation of the Governor's emergency powers. These guidelines call for two separate assessments of brain stem reflexes separated by a six-hour interval. Revised guidelines for brain death evaluations for use during a public health emergency should be reviewed as part of pandemic planning, so that they may be

promulgated quickly if an emergency is declared. Criteria for removal of ventilator support during a pandemic might include an abbreviated assessment for brain death, relying upon only one assessment of brain stem reflexes and the elimination of various confounding factors such as substance overdose.

Liability: Among the most challenging legal questions related to the pandemic is the issue of liability protection for clinicians and facilities that adhere to rationing criteria in a public health crisis. Patient consent, the mainstay of ordinary medical care, will not be the determining factor in allocating ventilators. These emergency allocation guidelines represent a significant departure from standard non-emergency practice and will generate distress for clinicians and patients. Threatened and actual legal actions are reasonable concerns in response to any emergency rationing scheme.

NYSDOH takes the view that voluntary guidelines issued by DOH for ventilator allocation would provide strong evidence for an acceptable standard of care during the dire circumstances of a pandemic. But while the guidelines offer the prospect of liability protection for providers and facilities, NYSDOH cannot promise in advance that a court would accept its view. Further, New York State law does not clearly empower the Governor to offer legal immunity to providers, even in a state of emergency.

In regard to potential lawsuits related to ventilator allocation, legislation is the only avenue certain to provide robust protection for providers who adhere to the guidelines. Protections should extend to facilities and a wide range of clinicians, including doctors, nurses, respiratory technicians, emergency medical personnel and others. Such legislation could offer immunity to health care providers engaged in ventilator allocation, or alternatively, could guarantee defense and/or indemnification to providers. One statute

that may prove useful in this regard is section 17 of the Public Officers Law, which provides for indemnification and defense of state employees. "Employee" is given broad meaning in the statute by numerous subsections of section 17(1). [21] It may be appropriate to recommend legislation adding to this list of indemnified "employees" those persons who engage in conduct pursuant to NYSDOH-issued ventilator allocation guidelines.

Another indemnification option worth exploring is the "volunteer" provision of section 17, which includes among indemnified persons "volunteer[s] expressly authorized to participate in a state-sponsored volunteer program." [22] It may be possible to design a state-sponsored volunteer program including those providers who participate in a ventilator allocation triage process, thereby offering them defense and indemnification under the Public Officers Law. Providers who act in good faith by adhering to the voluntary guidelines could be offered defense and indemnification by statute, even if the ventilator guidelines themselves remained voluntary and non-statutory. Such a statute would need to clarify that "volunteers" defined for this purpose include paid health care providers who comply with ventilator allocation guidelines.

Form of Recommendations

NYSDOH will present this planning document for ventilator allocation for public review and then incorporate any appropriate revisions. NYSDOH will then issue recommendations for allocating ventilators in an avian influenza pandemic as voluntary guidelines. NYSDOH is empowered to issue voluntary, non-binding guidelines for health care workers and facilities; such guidelines could be readily published and would provide hospitals with an ethical and clinical framework for decision-making. Some question

whether voluntary guidelines offer a sufficient guarantee of state-wide consistency. However, facility representatives stress that they are eager to follow state-level guidance, and do not seek wide latitude in devising their own policies. The complex legal issues raised by altered standards of care in a public health emergency create vulnerabilities for facilities. Hospitals perceive greater safety in accepting state guidance than in drafting their own policies. Moreover, designing a link between liability protection and compliance would increase adherence to the voluntary guidelines.

NYSDOH is also empowered to issue binding regulations for hospitals that would apply to standards of care during a pandemic. However, statutory law precludes NYSDOH from regulating physician practice. [23] Moreover, these rationing recommendations remain untested in actual circumstances; issuing them as binding regulations may produce unforeseen consequences. Creating regulations for the provision of medical care, especially in the absence of direct experience, poses significant problems and may produce negative unforeseen consequences. A ventilator allocation system must be designed with flexibility to adjust to changing clinical information; even if a pandemic arrives it may only occur some years from now, when technological advances may demand revisions in the guidelines. The static nature of regulation could make it an awkward mode for clinically detailed recommendations.

Finally, NYSDOH could request that recommendations for rationing be drafted as new legislation. Setting recommendations into law would reflect support from elected leaders, yet would face significant difficulties. Rationing recommendations must include flexibility for revision; as with regulation, legislation that permits such flexibility is challenging to draft. In addition, the timing and pace of a pandemic is inherently

unpredictable. Should the pandemic occur, the legislature will face numerous challenging issues, and health care providers may require guidance long before appropriate measures can become legislative realities.

VII. REVIEW AND IMPLEMENTATION

This document presents recommendations for an ethically and medically sound system for allocating ventilators in a pandemic. These recommendations should now be publicly presented in a variety of settings, with the explicit goal of requesting review and improvement. This public review is an important component in fulfilling the ethical obligation to promote transparency and develop just guidelines. Appropriate forums for presentation include medical facilities, professional associations, and citizen groups. Table-top exercises designed to test the guidelines are a useful way to reveal strengths and liabilities of the current proposal. In addition, after an initial opportunity for public review and revision, the guidelines could be published to increase their accessibility.

After appropriate review and revision, NYSDOH will present the results as voluntary guidelines for acute care facilities for ventilator allocation in a pandemic. Legislation that provides legal protection for facilities and providers who conform to the voluntary guidelines should also be pursued. [24]

Clear state-level guidance and the consistent policies that result will provide the best possible care for New York's patients if a pandemic occurs. Policies for rationing ventilators in an emergency will not have credibility if issued by individual facilities; rather, guidelines issued by the State are more likely to be viewed as appropriately grounded in concern for public health.

With luck, an 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 the impact. These recommendations for allocating ventilators in a pandemic rely upon both ethical and clinical standards in an effort to offer the best possible care under gravely compromised conditions.

Appendix I. Sequential Organ Failure Assessment (SOFA) score

SOFA Scale

Variable	0	1	2	3	4
PaO2/FiO2 mmHg	>400	< 400	< 300	< 200	< 100
Platelets, x $10^3/\mu L$ ($\times 10^6$/L)	> 150 (>150)	< 150 (< 150)	< 100 (< 100)	<50 (<50)	< 20 (< 20)
Bilirubin, mg/dL (μmol/L)	<1.2 (<20)	1.2-1.9 (20 – 32)	2.0-5.9 (33 – 100)	6.0-11.9 (101 – 203)	>12 (> 203)
Hypotension	None	MABP < 70 mmHg	Dop < 5	Dop > 5, Epi < 0.1, Norepi < 0.1 6-9	Dop > 15, Epi > 0.1, Norepi >0.1 <6
Glasgow Coma Score	15	13 - 14	10 - 12	3.5-4.9	>5
Creatinine, mg/dL (μmol/L)	< 1.2 (<106)	1.2-1.9 (106 – 168)	2.0-3.4 (169 - 300)	(301 – 433)	(> 434)

Dopamine [Dop], epinephrine [Epi], norepinephrine [Norepi] doses in ug/kg/min
SI units in brackets

Adapted from:
Ferreira FI, Bota DP, Bross A, Melot C, Vincent JL. Serial evaluation of the SOFA score to predict outcome in critically ill patients. JAMA 2001; 286(14): 1754-1758.

Explanation of variables:
PaO2/FiO2 indicates the level of oxygen in the 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 score is a standardized measure that indicates neurologic function; low score indicates poorer function.
Creatinine is measured by a blood test and indicates kidney function.

Appendix II. Adapted OHPIP Triage Tool

Critical Care Triage Tool (Initial Assessment)		
Color Code	Criteria • Exclusion Criteria*	Priority/Action
Blue	or • SOFA > 11*	Medical Mgmt +/- Palliate & d/c
Red	• SOFA < 7 or • Single Organ Failure	Highest
Yellow	• SOFA 8 - 11	Intermediate
Green	• No significant organ failure	Defer or d/c, reassess as needed

*If exclusion criteria or SOFA > 11 occurs at any time from the initial assessment to 48 hours change triage code to Blue and palliate.
d/c = discharge

Critical Care Triage Tool (48 Hour Assessment)		
Color Code	Criteria • Exclusion Criteria	Priority/Action
Blue	• SOFA $\frac{\text{at}}{\text{admit}}$ > 11 $\frac{\text{or}}{\text{}}$ • SOFA 8 → 11 no Δ	**Palliate & d/c from CC**
Red	• SOFA < 11 and decreasing	Highest
Yellow	• SOFA < 8 no Δ	Intermediate
Green	• No longer ventilator dependant	d/c from CC

Δ = change
CC = critical care
d/c = discharge

Critical Care Triage Tool (120 Hour Assessment)		
Color Code	Criteria • Exclusion Criteria*	Priority/Action
Blue	or • SOFA > 11* • SOFA < 8 no A	**Palliate & d/c from CC**
Red	• SOFA score < 11 and decreasing progressively	Highest
Yellow	• SOFA < 8 minimal decrease (< 3 point decrease in past 72h)	Intermediate
Green	• No longer ventilator dependant	d/c from CC

* If exclusion criteria or SOFA > 11 occurs at anytime from 48 – 120 hours change triage code to Blue and palliate.
CC = critical care
d/c = discharge

Appendix III. Workgroup Members
Ethical Issues in Ventilator Allocation in an Influenza Pandemic

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[2]Merriam-Webster's Collegiate Dictionary, 10th ed. (Massachusetts: Merriam-Webster, Incorporated, 1993), 838.
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