Allocation of Ventilators in an Influenza Pandemic: Planning Document

NYS Workgroup on Ventilator Allocation in an Influenza Pandemic
NYS DOH/ NYS Task Force on Life & the Law

Executive Summary:

A powerful strain of avian influenza has generated concern about a possible pandemic, though scientists do not know with certainty whether or when a pandemic will occur. However, the better-prepared New York State is, the greater its chances of reducing morbidity, mortality and economic consequences. In a pandemic, many more patients could require the use of mechanical ventilators than can be accommodated with current supplies. A federal ventilator stockpile exists, and New York State plans to buy additional ventilators that would meet the needs of patients in a moderately severe pandemic. In a disaster on the scale of the 1918 influenza pandemic, however, stockpiles would not be sufficient to meet need. Even if the vast number of ventilators needed for a disaster of that scale 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 confront the rationing of ventilators.

An ethical framework must guide recommendations for allocating ventilators in a pandemic. Key ethical concepts are the duty to care for patients and the duty to use scarce resources wisely. Maintaining a balance between these two sometimes competing ethical obligations represents the core challenge in designing a just system for allocating ventilators.

The workgroup recommends an ethically and clinically sound system for allocating ventilators in a pandemic, containing the following elements:

1) Pre-triage requirements: Facilities must reduce the need for ventilators and expand resources before instituting ventilator triage procedures.
2) Patient categories for triage: All patients in acute care facilities will be equally subject to triage guidelines, regardless of their disease category or role in the community.
3) Implications of triage for facilities: State-wide consistency will prevent inequities; chronic care facilities will maintain different standards from acute care facilities.
4) Clinical evaluation: Clinicians will evaluate patients based on universally applied objective criteria, and offer time-based trials of ventilator support.
5) Triage decision-makers: Supervising physicians will take responsibility for triage decisions. Primary care clinicians will care for patients and will not determine ventilator allocation.
6) Palliative care: Palliative care will play a crucial role in providing comfort to patients, including those who do not receive ventilator treatment.
7) Appeals process: Physicians and patients require a means of requesting review for triage decisions; ethics committee members and others should be prepared to assist in the appeals process.
8) Communication about triage: Government and clinicians need to provide clear, accurate and consistent communication about triage guidelines. Data gathering and public comment can help improve the triage system.

The workgroup recommends that these guidelines be reviewed in public settings, including medical centers and community forums, with the explicit goals of encouraging education, comment and revision. After such public review, NYSDOH should incorporate improvements to these recommendations, and issue the revised document as a set of voluntary guidelines for acute care facilities.

NYSDOH is empowered to issue voluntary, non-binding guidelines for health care workers and facilities; such guidelines are readily implemented and would provide hospitals with an ethical and clinical framework for decision-making. The workgroup expects that compliance with voluntary guidelines would be extremely high. The complex legal issues raised by altered standards of care in a public health emergency create vulnerabilities for individual facilities as they draft policies. Facilities have requested

detailed procedural advice from the state, and do not seek wide latitude in devising their own policies.

NYSDOH is also empowered to issue binding regulations for hospitals that would apply to standards of care during a pandemic. However, these rationing recommendations remain untested in actual circumstances; issuing them as binding regulations may produce unforeseen consequences. A ventilator allocation system must be designed with sufficient flexibility to adjust to changing clinical information. The static nature of regulation could make it an awkward mode for clinically detailed recommendations.

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. Voluntary guidelines issued by NYSDOH for ventilator allocation provide strong evidence for an acceptable standard of care during the dire circumstances of a pandemic. However, there is no guarantee that a court would accept adherence to the guidelines as a defense against liability should lawsuits arise.

Legislation is the only avenue certain to provide robust protection for providers who adhere to the guidelines. Such legislation could offer immunity to health care providers who follow guidelines for ventilator allocation, or alternatively, could guarantee defense and/or indemnification to providers. The combination of voluntary guidelines based on sound ethical and clinical principles, paired with legislation that protects providers who comply with the guidelines, offers the best possible balance of clarity, flexibility, and confidence in designing public health policy for allocating ventilators in a pandemic.

I. INTRODUCTION

The U.S. Department of Homeland Security "views pandemic influenza as both the most likely and most lethal of all threats facing the United States."[1] Scientists and policymakers cannot know with certainty whether an influenza pandemic will occur. However, the better-prepared New York State is, the greater its chances of reducing morbidity, mortality and economic consequences.

Both federal and state governments have drafted plans for a possible pandemic. The federal Department of Health and Human Services (DHHS) released a pandemic influenza plan that offers an assessment of public health and medical preparedness, and guidance to state and local health departments. The New York State Department of Health (NYSDOH) released its draft preparedness plan for pandemic influenza in February, 2006. The state plan includes a review of actions to be taken by health officials, emergency responders and care providers at different phases of the pandemic. The healthcare planning section deals with hospital surge capacity issues and addresses the roles of triage centers and home care. Finally, the communications section discusses effective strategies for conveying to the public risks and steps to cope with them.

In March 2006, the New York State Task Force on Life and the Law, at the request of NYSDOH, convened a workgroup to consider clinical and ethical issues in the allocation of mechanical ventilators in an influenza pandemic. The group brought together experts in law, medicine, policymaking and ethics with representatives from medical facilities and city, county, and state government to address necessary alterations in the standard of care in an emergency. The efforts of the workgroup will inform

NYSDOH plans for coping with the large number of critically ill patients thrust upon the medical care system during a pandemic. Pandemic planning must address potential shortfalls in many resources, including staff, protective equipment, and medications, including oxygen. The goal of the workgroup was to develop recommendations for healthcare institutions specifically for the allocation of ventilators in a public health emergency. The recommendations presented here are intended to guide health professionals and others to act in a manner consistent with ethical principles while preserving as many lives as possible. These guidelines should be publicly reviewed with the explicit goals of achieving publicity and transparency, inviting comment and ensuring that they reflect the values of New Yorkers. After such public review, NYSDOH should incorporate improvements to these recommendations, and issue the revised document as a set of voluntary guidelines for acute care facilities.

This document draws upon the expertise of the workgroup, literature review, and the incorporation of extensive commentary on earlier drafts. NYSDOH and the Task Force wish to thank the workgroup members for their exceptional efforts in helping develop the recommendations through their presentations, their comments, and the generous donation of their time and wisdom. A full list of workgroup members is in Appendix III.

II. BACKGROUND

Influenza viruses can be designated as A, B, or C, with influenza A viruses being the most dangerous. Because influenza A viruses mutate and spread rapidly, and can affect various species, they are often responsible for seasonal influenza epidemics and rarer pandemics.

Influenza

Seasonal Influenza: Despite the availability of vaccines and immunity present in the population, each year seasonal influenza kills 250,000-500,000 people worldwide. In the United States, seasonal influenza causes an annual average of 36,000 deaths, 200,000 hospitalizations and 37 billion dollars in economic costs. Peak influenza season runs from November through March. Pandemic influenza is not the same as seasonal influenza; depending on its virulence, pandemic influenza has the potential to kill far greater numbers of people across the world.

Pandemic Influenza: A pandemic is defined as an illness "occurring over a wide geographic area and affecting an exceptionally high proportion of the population."[2] 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.[3] Because such a virus would be new and there would be no available vaccine, efficient transmission could have a devastating global impact.

There were three 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.[4] The influenza

pandemics of 1957 and 1968 were less severe, causing an estimated 2 million and 1 million deaths respectively. All three pandemics likely resulted from a mixture of genetic material from human and avian influenza viruses.[5]

Avian Influenza: 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."[6] The highly pathogenic avian influenza (HPAI) subtype H5N1, which emerged in 1997 and has spread throughout the Eastern Hemisphere, is one of few HPAI viruses that has crossed the species barrier to infect humans.

H5N1 virus is highly contagious in wild waterfowl and can easily infect domestic poultry. The virus is also known to have infected other animals including mice, cats, and tigers. Bird-to-human transmission has occurred, mostly via direct human contact with the secretions and/or excretions of infected poultry. The effect on migratory birds is not fully established. Human-to-human transmission is inefficient and rare. Evidence suggests that spread beyond first generation close contacts occurred in Indonesia, though without significant viral mutations.[7]

Presently, there is no H5N1-specific vaccine licensed and available to the public. The vaccines produced to thwart yearly seasonal influenza outbreaks will be ineffective in the event of a human avian influenza pandemic.

Rapid onset, severe illness, and a high mortality rate characterize H5N1. Of the first 18 human cases that were reported in Hong Kong in 1997, six patients died. Since the second outbreak began in 2003, the WHO has confirmed 278 human cases resulting in 168 deaths (See Table 1).

Table 1: Cumulative Number of Confirmed Human Cases of Avian Influenza A/(H5N1) Reported to WHO as of March 12, 2007.

Country	2003		2004		2005		2006		2007		Total	
	cases	deaths	cases	deaths	cases	deaths	cases	deaths	cases	deaths	**cases**	**deaths**
Azerbaijan	0	0	0	0	0	0	8	5	0	0	**8**	**5**
Cambodia	0	0	0	0	4	4	2	2	0	0	**6**	**6**
China	1	1	0	0	8	5	13	8	1	0	**23**	**14**
Djibouti	0	0	0	0	0	0	1	0	0	0	**1**	**0**
Egypt	0	0	0	0	0	0	18	10	6	3	**24**	**13**
Indonesia	0	0	0	0	19	12	56	46	6	5	**81**	**63**
Iraq	0	0	0	0	0	0	3	2	0	0	**3**	**2**
Lao People's Democratic Republic	0	0	0	0	0	0	0	0	1	1	**1**	**1**
Nigeria	0	0	0	0	0	0	0	0	1	1	**1**	**1**
Thailand	0	0	17	12	5	2	3	3	0	0	**25**	**17**
Turkey	0	0	0	0	0	0	12	4	0	0	**12**	**4**
Viet Nam	3	3	29	20	61	19	0	0	0	0	**93**	**42**
Total	**4**	**4**	**46**	**32**	**97**	**42**	**116**	**80**	**15**	**10**	**278**	**168**

Total number of cases includes number of deaths. WHO reports only laboratory-confirmed cases. All dates refer to onset of illness. (Source: The World Health Organization, http://www.who.int/csr/disease/avian_influenza/country/cases_table_2007_03_12/en/index.html)

A true infection rate and death rate are impossible to determine because of the unknown number of people with less severe or subclinical illness who do not seek medical care. For this reason, although the measured death rate has been high (>60%), this is likely an overestimation.

The clinical course of H5N1 infection in humans is not fully understood, but is thought to be highly aggressive. In recent experience, onset of disease occurred within a median of 3-4 days post exposure; the time from disease onset to hospitalization was a median of 3-8 days, and the time from disease onset to death ranged from 4-30 days.[8]

Unlike seasonal influenza, H5N1 influenza disproportionately affects young, previously healthy children and adolescents. Most patients are critically ill, commonly presenting symptoms such as high fever, lower respiratory tract infection, abdominal pain, diarrhea, and vomiting. Pneumonia caused by secondary bacterial infection is a common complication of seasonal influenza. In H5N1 influenza patients, primary viral

pneumonia can occur without secondary bacterial infection; in seasonal influenza patients, primary viral pneumonia is relatively rare in adults.

Acute renal failure is estimated to occur in approximately 10-29% of avian influenza cases, with multi-organ failure occurring in almost all fatalities. To date, the majority of avian influenza patients have required a ventilator within 48 hours of hospitalization.[9] Acute respiratory distress syndrome (ARDS) occurs frequently, with respiratory failure expected in more than half of hospitalized patients.

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

NYSDOH officials have used several outbreak scenarios to estimate the potential impact of pandemic influenza on New York. Officials relied upon the following baseline assumptions in crafting two possible scenarios:

- a specific H5N1 vaccine will not be available for at least 6 months, and will be in short supply thereafter; antiviral medications may be ineffective and in short supply
- the attack rate (percentage of people with pandemic flu out of the total population at risk) will vary, but may be as high as 35%
- the population of New York State is approximately 19 million,
- there are currently 3,981 adult and pediatric ICU beds staffed,
- 15% of the admitted patients with pandemic influenza will require intensive care,
- 7.5% of the admitted patients with pandemic influenza will require ventilators,
- there are currently 6,100 ventilators in acute care settings in New York State,
- at any given time, 85% of the ventilators in acute care settings are in use, and
- 70% of deaths related to pandemic influenza are projected to occur in a hospital.

The two outbreak scenarios are the DHHS moderate scenario, based on the 1957 and 1968 influenza pandemics, and the DHHS severe scenario, based on the 1918 influenza pandemic. The following estimates were calculated using the Centers for Disease Control and Prevention software programs FluAid2.0 and FluSurge2.0.

1. *The DHHS moderate scenario* with a 35% attack rate (percentage of population infected) and 6-week outbreak duration. Using New York State figures, there could be more than 93,753 total influenza-related hospital admissions with nearly 14,062 total influenza patients requiring intensive care unit (ICU) beds (*See Table 2*). More than 7,000 cumulative influenza patients would require ventilator support during at least part of the outbreak's duration, with over 2,171 patients needing them simultaneously during peak weeks. Those 2,171 ventilators represent 36% of the New York State capacity, which is critical considering the baseline assumption that 85% of the ventilators in acute care settings are in use during any given week. When this 85% normal utilization rate is considered, there is a projected shortfall of 1,256 ventilators. 18,650 total influenza-related deaths could be anticipated.

2. The *DHHS severe scenario* with a 35% attack rate during a 6-week outbreak. Though the attack rate is the same as the HHS moderate scenario, the impact will be far greater in this severe scenario; it assumes a more aggressive illness with a higher demand for intensive care and a much greater fatality rate. New York could expect over 770,000 hospital admissions with 115,500 influenza patients requiring ICU beds. During peak weeks, 35,000 patients—nearly 9 times current capacity—would require ICU care. Approximately 58,000 influenza patients would require ventilators during the 6-week outbreak, with 17,844 needing them in peak weeks. This is almost 3 times New York State's current ventilator capacity. The State could anticipate almost 153,000 total deaths over the duration of the outbreak; more than 107,000 deaths will occur in the hospital.

Table 2

	DHHS Moderate Scenario	DHHS Severe Scenario
Attack Rate	35%	35%
Total Admissions	93,753	770,640
Total Deaths	18,650	153,301

Deaths in Hospital	13,055	107,311
Total ICU Beds Needed	14,062	115,596
Peek Week Ventilator Need	2,171	17,844
Total Ventilators Needed	7,031	57,798
Ventilators Available (15%)	915	915
Projected Ventilator Shortfall	1,256	16,929
2006 NYS Ventilator Purchase	850	850
Amended Ventilator Availability	-406	-16,079

(Adapted from Bruce Fage, "Health Care Planning for New York State Pandemic Influenza," presentation at March 2, 2006 meeting)

NYSDOH pandemic planning includes careful consideration of the potential shortage of ventilators, based on the estimates discussed above and on federal plans. 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 if many regions need them at once.

New York State plans to buy ventilators to help avoid rationing in the face of the DHHS moderate scenario; there are no current plans to buy enough ventilators for the most severe DHHS model. This plan balances the need to prepare for a potential pandemic against the need to maintain adequate funding for current and ongoing health care expenses. Moreover, severe staffing shortages are anticipated; purchasing additional ventilators beyond a certain level will not save additional lives, since there would not be sufficient personnel to operate them. In the event of an overwhelming burden on the healthcare 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 confront the rationing of ventilators and other scarce resources.

A number of technical considerations will guide the purchase and use of these supplemental ventilators. Since a pandemic supposes excess numbers of patients requiring critical care, the extra ventilators should be portable so that they can be used

outside of typical ICU settings. Ventilators should have settings that adjust for volume and pressure, important in caring for patients with the severe respiratory symptoms of patients with H5N1-related pneumonia. Supplemental oxygen may be in short supply, so ventilators that are relatively oxygen-sparing are preferable. Staffing will be severely limited; ventilators should therefore be easy to use, since less experienced staff may need to manage patients on ventilators. This type of ventilator should be introduced as soon as possible into regular use in hospitals, for instance when transporting patients, so that many workers will be competent in their use.

III. ETHICAL FRAMEWORK FOR ALLOCATING VENTILATORS

An ethical framework must serve as the starting point for a plan that proposes to allocate ventilators fairly. A just rationing plan cannot evolve from technical considerations alone, such as survival probabilities and resource estimates, then have ethics applied as an afterthought, and hope to withstand ethical scrutiny. Discourse in medical ethics has generated various sets of principles and values. Different ethical considerations have greater or lesser weight in the process of resolving any particular dilemma; a number of authors have addressed ethical principles for decision-making in public health crises.[10]

The workgroup has articulated the following ethical framework in support of this specific effort to allocate ventilators in a pandemic:

Ethical Framework for Allocating Ventilators

- Duty to care
- Duty to steward resources
- Duty to plan
- Distributive Justice
- Transparency

Duty to Care: First and most importantly, an ethical rationing scheme must respect the fundamental obligation of health care professionals to care for patients. Indeed, in a pandemic, clinicians will try to care for as many patients and save the lives

of as many patients as is possible. However, doctors, nurses, and other health professionals offer care at the bedside to individual patients, not to populations. An ethically sound rationing 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 are not eligible to receive mechanical ventilation will receive other forms of curative and/or palliative treatment.

In day-to-day health care in the U.S., 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 a rationing system for ventilators in a pandemic; more patients will want ventilators than can be accommodated. A public health disaster such as a pandemic, by virtue of severe resource scarcity, will impose harsh limits on decision-making autonomy for patients and providers. Allocation guidelines must reflect those limits. Nonetheless, a just rationing scheme must endeavor to support autonomy, when possible, in ways that also honor the duties of care and stewardship. Guidelines must stress the provision of care that is possible when ventilation is not. An ethically sound triage system will include other treatment or palliative measures for patients denied access to ventilators.

Duty to Steward Resources: The second element in the ethical framework is the obligation for government and health care providers to steward 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 a rationing system. Even under ordinary circumstances, critical care providers question whether the estimated benefit of an intervention merits the use of scarce resources.

Providers struggle to decide whether a unit of platelets (or antibiotics, or surgical intervention) is appropriate or justified for a particular patient, given that the quantity of a particular resource is limited. Yet a disaster on the scale of a severe pandemic will force providers to confront limits far more starkly than they now do. Patients who might survive under ordinary circumstances cannot be given the ordinary level of resources, or numerous other patients will die without any resources at all. Clinicians will 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 increases, accommodating these two goals will require more and more difficult decisions.

Duty to Plan: A motivating force in designing a triage system is the knowledge that planning is an obligation. An absence of guidelines leaves allocation decisions to exhausted, over-taxed, front-line providers, who already bear a disproportionate burden in a disaster. A failure to produce acceptable guidelines for a foreseeable crisis amounts to a failure of responsibility toward both patients and providers. Health care providers are aware that some who served in the aftermath of Hurricane Katrina have been accused of serious crimes. Appropriate guidelines may help prevent both the actuality and the fear of similar consequences for those who provide care in a future emergency.

Though plans are obligatory, any guidelines the group devises will be imperfect, both ethically and medically. Ethically, current access to health care is unequal; no rationing system for a crisis can resolve inequities in pre-existing health status resulting from unequal access. Medically, the clinical parameters of a pandemic are as yet uncertain, increasing the difficulty of predicting survival or duration of critical symptoms. Nonetheless, the workgroup accepts the importance of creating guidelines

under conditions of uncertainty, including plans for allocating ventilators for this foreseeable public health emergency.

Distributive Justice: A just system of allocation must be applied broadly in order to be fair. The same allocation system should be in use across the state, and the decision to implement rationing must be authorized by the state. The timing and content of just rationing systems cannot be hospital-based, but must be coordinated within the community, among communities, and between the local communities and the State. A just or equitable healthcare 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 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 disaster must not exacerbate disparities in access to care. Rather, planners must designate appropriate resources for the most vulnerable, who are most likely to suffer the greatest impact in any disaster.

Transparency: Transparency is the next element in the ethical framework. Any just system of allocating ventilators will require robust efforts to promote transparency, by seeking broad input in the design of the system, and educating the public about the evolving plan. The state should publicize proposed guidelines, translate them into different languages as necessary, and share them with health care leaders and the community, including historically underserved communities. After assessing comments, revisions that will assure a just allocation process should be incorporated.

Pitfalls: In building an ethical framework, there are pitfalls that an allocation system must avoid. Disaster planning must not serve as a covert means to resolve long-standing problems in health care. For instance, a rationing system does not alleviate the need to provide adequate resources. In a resource-constrained environment, rationing may lead to the acceptance of a lack of resources without challenging the problem of scarcity. A just system will seek to avoid rationing by first implementing less drastic means of limiting and deferring the use of scarce resources. Prior appropriate steps will include the purchase and use of supplemental ventilators, cancellation of elective surgeries, and altered standards of care for staffing ratios. Triage should not be lightly invoked, but must be reserved for situations of true scarcity.

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

Taking into account this ethical framework, parameters for an allocation system for ventilators emerge. The workgroup accepted the idea of removing patients with the highest probability of mortality from ventilators in order to benefit patients with a high likelihood of survival. However, they struggled with the notion of removing less ill patients from ventilators, particularly those who might recover with continued mechanical ventilation. Guidelines should reflect this tension by minimizing circumstances that

require patient extubation, the most ethically and emotionally challenging aspect of any ventilator rationing system.

Clinicians and family members will be reluctant to withdraw ventilators from patients. Guidelines that rely heavily on withdrawal of ventilators will generate great concern and controversy and may be set aside in an emergency. Further, the experience of withdrawing ventilation and observing the subsequent demise of patients will be traumatic for all concerned, including clinicians. 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; again, appropriate guidelines will limit instances of tragic choices.

IV. MEDICAL FACTORS IN TRIAGE SYSTEM DESIGN

In order to design a perfect critical care triage system, clinicians would need a method that accurately differentiates in advance those patients who will survive without critical care, those who will survive only with critical care, and those who will die despite treatment. There are a number of proposed systems for estimating critical care mortality, but none is specifically designed to demonstrate the most efficient use of scarce resources. Some systems require resource-intensive tests that might be scarce during an epidemic; others focus on trauma patients and so are less applicable for an influenza pandemic.[11] 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. Our limited ability to assess survival capacity except in broad categories has critical implications for the design of a ventilator rationing system. These guidelines incorporate features of existing triage systems, yet the workgroup finds that the result remains imperfect. The workgroup urges critical care and emergency physicians to pursue the goal of perfecting a clinical scoring system appropriate to an influenza pandemic.

Scoring systems may help determine which patients will benefit from interventions; a well-designed triage plan will also focus on the limited number of critical care interventions likely to have the greatest impact**.** For a febrile illness likely to cause respiratory failure, mechanical ventilation will be one of the most important interventions.

One way in which an epidemic in the 21st century differs from that of 1918 is the increased ability to collect and analyze data quickly. Guidelines must incorporate new data as they become available, based either on resource availability or clinical circumstances. Systems set up in advance, as part of the planning process, could support the collection of information on symptoms, disease course, treatments, and survival.

Existing Triage Protocols

Hick and O'Laughlin: Very few authors have explicitly addressed the problem of allocating ventilators in a pandemic. Drs. John Hick and Daniel O'Laughlin propose guidelines that would 1) be implemented on a regional, not an institutional basis; 2) provide liability protections for providers and institutions; and 3) provide tiers so that as patients increase and resources are depleted, the criteria become more stringent. [12]

Hick and O'Laughlin devised three tiers of criteria; the first tier would eliminate access to ventilators for patients with the highest probability of mortality, including ventilator-dependent patients with persistent hypotension, and/or failure of greater than four organ systems. If resources continue to fall short, Hick and O'Laughlin propose a second tier that would be denied access to ventilators, containing patients with respiratory failure as well as high use of additional resources. This tier includes patients who have a pre-existing illness with a poor prognosis, including: severe congestive heart failure; acute renal failure requiring hemodialysis; severe chronic lung disease; AIDS with a low CD4 count; active malignancy with a poor potential for survival; cirrhosis with ascites; hepatic failure; and irreversible neurologic impairment, including persistent vegetative

state. In sum, this tier includes patients with respiratory failure and other chronic or potentially fatal conditions.

The third tier in this system is left intentionally vague. The authors suggest that a guideline development committee examine survival data in real time, and add categories of patients who would not have access to ventilators in an overwhelming disaster.

Hick and O'Laughlin propose 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."[13] Thus, patient A's continued use of the ventilator appears to depend not only on the estimated survival probability of patient A, but also upon that of newly arriving patient B, whose better health status leads to the extubation and probable death of A, and the intubation of B (at least until C arrives).

The 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 rationing. However, the workgroup expressed significant reservations about the plan to extubate a patient because a newly arriving patient had a better health assessment. First, patients require a sufficient trial on the ventilator in order to determine its benefit. More importantly, though, patients expect that doctors will provide treatment, to the extent possible, based on assessments of their health as individuals. If ventilator use is primarily determined by the health of *other* potential users of the ventilator, clinicians must abandon their obligation to advocate for individual patients. This proposal evokes an ICU war of all against all that ignores deeply felt professional obligations to advocate and care for individual patients. Though Hick and O'Laughlin offer many useful insights on the design of a triage system, workgroup members rejected

this aspect of the proposal upon ethical grounds. Participants also believed that clinicians would resist implementing guidelines based upon these premises.

Ontario Health Plan for an Influenza Pandemic (OHPIP): An additional pandemic triage protocol that merits consideration was proposed in April 2006 by the OHPIP Working Group on Adult Critical Care Admission, Discharge and Triage Criteria. Finding that no triage system has been developed for use in critical care or medical illnesses, the OHPIP authors present a new critical care triage tool based in part on the Sepsis-related Organ Failure Assessment (SOFA) score.[14] The SOFA score adds points based on objective measures of function in six key organs and systems: lungs, liver, brain, kidneys, blood clotting, and blood pressure. 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 components of SOFA scoring are listed in Appendix I.

The OHPIP triage protocol is based on three evaluative components: inclusion criteria, exclusion criteria, and minimum qualifications for survival (MQS). Inclusion criteria focus on respiratory failure and refractory hypotension, and identify patients who will benefit from admission to critical care. Exclusion criteria include a list of severe ailments. These exclusion criteria focus on illnesses that draw extensively upon resources. MQS, a term taken from military triage, refers to limits placed on resources used for any individual patient. The authors recognize this concept is "very foreign to western medical systems," but suggest such ceilings would be essential to optimizing resource allocation in a pandemic.

Patients are initially assessed for inclusion and exclusion criteria; if inclusion criteria are present and exclusion criteria are absent, patients are then evaluated with a SOFA score. Patients are reevaluated at 48 and 120 hours and either continue with similar levels of care or are re-assigned to a different category, based on SOFA scores and other objective criteria. In the OHPIP protocol, patients may lose access to ventilators and other critical care resources if their SOFA score increases. They may also lose access if SOFA scores fail to improve within the allocated period; OHPIP experts argue that failure to improve during the designated interval is associated with a high probability of mortality and thus these patients should be assigned to a different treatment category. Tables describing the protocol are presented in Appendix II. The overview of the protocol is as follows, with colors corresponding to triage categories:

- *Blue:* High probability of mortality; should be discharged from critical care and should receive medical management and palliative care as appropriate;.
  - Initial: Exclusion criteria *or* SOFA > 11
  - 48 hours: Exclusion criteria *or* SOFA > 11 *or* SOFA 8-11 unchanged
  - 120 hours: Exclusion criteria *or* SOFA > 11 *or* SOFA < 8 unchanged
- *Red:* Highest priority for critical care
  - Initial: SOFA ≤ 7 *or* single organ failure
  - 48 hours: SOFA < 11 and decreasing
  - 120 hours: SOFA < 11 and decreasing progressively
- *Yellow:* Intermediate priority for critical care
  - Initial: SOFA 8-11
  - 48 hours: SOFA < 8 unchanged
  - 120 hours: SOFA < 8 with minimal decrease (< 3 point decrease in 72 hours)
- *Green:* Low probability of mortality; defer admission/ discharge from critical care
  - Initial: no significant organ failure
  - 48 hours: no longer ventilator dependent
  - 120 hours: no longer ventilator dependent

Appeals: OHPIP also proposes a Central Triage Committee to perform ongoing modifications of the triage protocol as the pandemic progresses, and to consider appeals

and/or exemptions requested by clinicians. For example, the committee could be consulted if a triage officer or clinician thinks a patient is inappropriately designated "blue" under the protocol. OHPIP contemplates a 48-hour trial for such a patient, followed by re-triage at 120 hours.

The OHPIP proposal presents an ethically promising approach to triage. Appropriately, the patient's access to the ventilator depends on the patient's own clinical status, as objectively measured, rather than on a direct competition with other patients presenting for care. Nonetheless, patients will be re-assessed and those who do not benefit over time will lose access to ventilators; this system thus honors the ethical principles of caring for patients while stewarding resources wisely. This proposal suggests a form of appeals process. Workgroup participants were divided about the practicality of permitting appeals to the allocation protocol.

The OHPIP proposal has many excellent features yet does reveal some technical limitations. The list of exclusion criteria requires additional refinement as well as simplification for use in an emergency. The workgroup wished to exclude factors that reflect quality of life judgments rather than estimates of mortality. In addition, the SOFA score upon which the OHPIP proposal partly relies is a technically complex measure. Although some components of the score require only simple laboratory tests such as bilirubin and creatinine, the blood pressure measure depends upon invasive monitoring and pharmacologic therapy available in the intensive care unit. Thus, SOFA scores may prove more useful in determining continued use of ICU resources, rather than initial entrance to this level of care. The workgroup revised these exclusion criteria, based on the work of OHPIP and the SOFA criteria; see chart on page 33.

V. RECOMMENDED PROCESS FOR ALLOCATING VENTILATORS IN AN INFLUENZA PANDEMIC

The workgroup proposes the following ethically acceptable process for allocating ventilators in a public health emergency. These recommendations should be publicly presented, with the explicit goal of inviting comment and revision. The system includes the following components:

1) Pre-triage requirements
2) Patient categories for triage
3) Implications of triage for facilities
4) Clinical evaluation
5) Triage decision-makers
6) Palliative care
7) Appeals process
8) Communication about triage

1) Pre-triage Requirements

Limiting Need: 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, the state may wish to limit outpatient procedures that require a back-up option of hospital admission and ventilator support if complications arise.

Securing Resources: Before rationing procedures are implemented, facilities should institute all available means of creating "surge capacity." Staffing issues are critical, for personnel are the most valuable resource in any healthcare facility. Staff members will fall ill, will leave work to care for family, or may decline to serve from fear of contagion, while the number of infected patients reaches unprecedented levels. The

stockpiling of protective 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 disaster. Alternate levels of staffing should be permitted during the pandemic emergency, and systems for extending the skills of available staff must be utilized.

Facility, state, and federal ventilator stockpiles should be assessed, and additional ventilators should be brought into the system as rapidly as possible. Systems for sharing information about the number and severity of cases, equipment availability, and staffing shortages could be activated throughout hospital systems and regional networks. For instance, not all facilities may be equipped to care for infants who need ventilatory support; clinicians and families need rapid access to information about where such support is available. Federal and NYSDOH pandemic plans address these and related issues.

2. Patient categories for triage

A just rationing system must be applied to all hospitalized patients, and not only to patients with influenza. As a practical matter, clinicians 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.

Workgroup members debated whether various characteristics should factor into assessments of access to ventilators, including age. Age factors indirectly into any

criteria that assess overall health, since chronic disease generally increases with age. Existing triage proposals vary on this issue; some decline to refer to age overtly, while others list age as an exclusionary factor, but do so at a range that varies from 65 to 85. These recommendations do not include age as an exclusion criterion. Social worth, such as being the parent of many children or an important community member, was also rejected as a factor in determining access.

Health Care Workers and First Responders: Participants debated with great concern the question of offering enhanced access to ventilators to health care providers, first responders, or other special groups. Many participants argued that patients should be assessed on medical factors only, regardless of their work role, for various reasons. First, health care workers sick enough to require ventilators are unlikely to regain health and return to service during the pandemic. The predicted period of recovery will be at a minimum several weeks; the worst phase of the pandemic will likely end before a stricken individual can return to work. 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 and is not a health care worker. Part-time volunteers staff ambulances in some communities; 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 providers win access to ventilators in certain communities. All other community members, including all

children, would be denied access; this plan was unacceptable to the workgroup. Participants also objected strongly to the appearance of favoritism, in which those who devised the rationing system appeared to reserve special access for themselves. Participants ultimately found that access to ventilators should depend on clinical factors only. Of note, the allocation of other scarce resources, such as vaccine or anti-viral medications, as well as personal protective equipment, may well favor health care providers based on differing ethical and clinical considerations.[15]

3. Implications of triage for facilities

Statewide Application: It is in the nature of an epidemic that some facilities will be hit harder, or sooner, than others; one facility may run out of critical supplies, including ventilators, while other facilities still have capacity. Participants considered a number of options for balancing need and resources. One suggestion was for the transfer of patients to facilities with available resources, although the transfer of large numbers of critically ill and highly infectious patients is not easily, or perhaps wisely, undertaken. During the pandemic, leadership of facilities within a region should be encouraged to work out voluntary plans for loans of equipment and staff in a crisis. Hospital associations might play a role in convening such planning meetings. State and federal assets, including ventilator stockpiles, should be allocated to areas with the greatest discrepancy between population and resources.

Statewide policies are crucial; large variations among facilities will lead to inequities. Equitable rationing systems, particularly ones that contemplate limiting access to life-saving treatment, must assure that the same resources are available and in use at similarly situated facilities, i.e., all facilities in one city gripped by the pandemic.

Participants found morally unacceptable a rationing system that allowed terminal extubation at one hospital, while patients with similar symptoms survived by virtue of being in a neighboring hospital. Hospitals in less affluent neighborhoods typically serve a far larger population base. Thus, a system of rationing that permits wide variation between hospitals in different areas will likely result in excess mortality for the poor.

Acute and Chronic Care Facilities: Distinctions should be maintained between acute and chronic care facilities once triage begins, permitting chronic care facilities to maintain their specific mission. Patients using ventilators in chronic care facilities would not be subjected to acute care triage guidelines. If, however, such patients required transfer to an acute care facility, they would be assessed by the same criteria as all other patients, and might fail to meet criteria for continued ventilator use. Chronically ill patients will be vulnerable to the pandemic; chronic care facilities will have to provide more intensive care on site as part of the general process of expanding care beyond standard locations. Barriers to transfer are appropriate and likely during a phase in which acute care hospitals are overwhelmed.

An alternative approach would require assessing all intubated patients, whether in acute or chronic care facilities, by the same set of clinical criteria. Depending on the design of these criteria, the result might be the sudden and fatal extubation of stable, long-term ventilator dependent patients in chronic care facilities. The proposed justification for such a strategy would be that more patients could ultimately survive if these ventilators were used by the previously healthy victims of the flu epidemic. This strategy would, however, make victims of the disabled. More patients might survive, but they would also be different survivors. It is hard to avoid the conclusion that such a

strategy relies heavily upon ethically unsound judgments based on third-party assessments of quality of life.

Applying acute care triage guidelines to chronic care facilities fails to adhere to the ethical principle of providing care for each patient, including the most vulnerable. The second principle of using resources wisely must also be considered. Setting aside the small number of ventilators in chronic care facilities for use by the chronically ill, who likely will have severely limited access to ventilators in acute care facilities, offers an appropriate balance between the duties to care and to allocate wisely.

Small but increasing numbers of persons who depend on mechanical ventilators reside in the community, rather than in institutions. Workgroup participants concurred that community-dwelling persons should not be denied access to their ventilators. The rationing scheme must take into account the needs of this group of patients.

Finances and Special Centers: Financial factors will significantly affect the ability of hospitals to provide adequate care. Hospitals with more limited resources might not be able to buy or rent supplemental ventilators either before or during the crisis. State pandemic plans should assess how to balance the differences among facilities in their ability to pay for and provide surge capacity.

The creation of "special centers of excellence" to care exclusively for influenza patients is controversial, since such a plan could prove financially burdensome to selected hospitals. Elective surgeries would be canceled, and patients with other illnesses would stay away. In contrast, non-designated hospitals would perform a greater share of well-compensated procedural work not related to influenza. This dilemma affected the delivery of care for SARS patients in Toronto during the outbreak in 2003. Ultimately, four

hospitals in Toronto were designated centers for SARS patients; such an arrangement may be easier under Canada's single payer system than it would be in the U.S.

Centers of excellence for pediatric, as opposed to adult, influenza patients may be more appropriate, since the requisite expertise will not be widely distributed. Planning assumptions must adequately reflect the needs of infants and children. Special expertise, likely to be in short supply, is needed to care for this population, who may also be especially vulnerable to morbidity and mortality in a pandemic. Stockpiled ventilators accommodate patients weighing as little as 10 kilograms; these ventilators will not support infants. NYSDOH pandemic planning for pediatric patients is assessing these issues.

4. Clinical evaluation

A clinical evaluation system based on the OHPIP protocol and on the SOFA score is adapted for use in these guidelines.[16] Incoming patients who meet the inclusion criterion of pulmonary failure will be assessed for exclusion criteria and will then be placed in categories based on a variation of the OHPIP system (see Appendix II). Patients on ventilators when triage begins will also be assessed to see whether they meet criteria for continued use. Candidates for extubation during a pandemic would include patients with the highest probability of mortality. These include patients like those in Hick and O'Laughlin's first tier, or those described in the OHPIP blue category. When a ventilator becomes available and many potential patients are waiting, clinicians may choose the patient with pulmonary failure who has the best chance of survival with ventilatory support, based on objective clinical criteria.

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:
  - Cardiac: NY Heart Association class III or IV
  - Pulmonary: severe chronic lung disease with FEV_{1}** < 25%
  - Hepatic: MELD*** score > 20
  - Renal: dialysis dependent
  - 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

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 $10^3/\mu L$ (x $10^6/L$)	> 150 (>150)	≤ 150 (≤ 150)	≤ 100 (≤ 100)	≤50 (≤50)	≤ 20 (≤ 20)
Bilirubin, mg/dL (µmol/L)	<1.2 (<20)	1.2-1.9 (20 – 32)	2.0-5.9 (33 – 100)	6.0-11.9 (101 – 203)	>12 (> 203)
Hypotension	None	MABP < 70 mmHg	Dop ≤ 5	Dop > 5, Epi ≤ 0.1, Norepi ≤ 0.1	Dop > 15, Epi > 0.1, Norepi >0.1
Glasgow Coma Score	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)

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

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

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	Priority/Action
Blue	• Exclusion Criteria* <u>or</u> • SOFA > 11*	Medical Mgmt +/- Palliate & d/c
Red	• SOFA ≤ 7 <u>or</u> • 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	Priority/Action
Blue	• Exclusion Criteria or • SOFA > 11 or • 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	Priority/Action
Blue	• Exclusion Criteria* or • SOFA > 11* • SOFA < 8 no Δ	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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[16] Ontario Health Plan for an Influenza Pandemic (OHPIP) Working Group on Adult Critical Care Admission, Discharge, and Triage Criteria, "Critical Care During a Pandemic," April 2006. See also F. L. Ferreira, et al.

[17] L. Rubinson, et al.

[18] OHPIP.

[19] Executive Law 2-B § 29-a.

[20] A physician may issue a DNR for a patient without that patient's consent in specific circumstances described in Article 29-B.

[21] Public Officers Law § 17(1)(a)-(s).

[22] Public Officers Law § 17(1)(a).

[23] Education Law § 6532.