

Allocating Mechanical Ventilators During Mass Respiratory Failure: Kudos to New York State, but More Work to Be Done

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In this issue of *Disaster Medicine and Public Health Preparedness*, Powell et al¹ summarize the efforts of the New York State Workgroup on Allocation in an Influenza Pandemic to develop guidance for allocation of scarce mechanical ventilators during a severe influenza pandemic. In the United States, a core societal expectation is nearly limitless provision of critical care to those who want it and who have acute organ failure.^{2–5} Provision of usual critical care for the many additional patients anticipated during disasters such as a severe influenza pandemic poses an insurmountable challenge for most communities.⁶ When efforts to augment critical care are insufficient to meet need, and there is no fair and just system to allocate scarce life-sustaining interventions, then community trust in the broader health care delivery system may cease, thereby compromising the entire medical and public health response.

At first glance, it may seem absurd to focus on critical care delivery for an event with such a severe mismatch of patient need and medical resources. Indeed, critical care preparedness and response should not divert so many resources that core public health efforts cannot be accomplished (eg, community continuity of operations, community mitigation, pharmacological prevention, early treatment). At the same time, the plausible widespread transmission of a virulent pathogen, uncertain effectiveness and timely availability of vaccine and antimicrobials,^{7–10} and the existing large proportions of the population with comorbidities and social vulnerabilities increase the likelihood of mass critical illness even in communities with excellent public health services. Of those critically ill, many who receive critical care may survive, just as the majority of patients survive every day with similar serious syndromes (eg, acute respiratory distress syndrome and severe sepsis).^{11–16} It is unfortunate that individuals who are unable to access essential critical care services are likely to die.

In the United States, intensive care unit (ICU) beds frequently are a scarce commodity, and published guidance already exists for equitable access.^{17,18} Under usual conditions, all of the patients with clear need for critical care interventions and considerable likelihood of surviving are

admitted to ICUs. “ICU triage” usually is used to divert patients too healthy or too ill to benefit from critical care. Even with the usual ICU triage, everyday access to critical care is based largely on critically ill patients’ desire for aggressive treatment rather than their likelihood to benefit or the resource needs of other critically ill patients. Because everyday triage and rationing methods would be insufficient to handle the dramatic mismatches between patient need and available resources, the New York State Workgroup had to develop a new paradigm for allocation of scarce critical care resources. The New York State Workgroup focused on allocation of mechanical ventilators during a severe influenza pandemic. Their process is intended to be used for any catastrophe in which patients with respiratory failure far outnumber critical care capability. Their guidance for allocating mechanical ventilators should not be interpreted as limited solely to the ventilator machines, but more broadly. One must consider all of the resources necessary for ventilation: ventilator, ancillary equipment such as circuits, adequately skilled staff, and so forth. Their guidance rationally can be applied to other key life-sustaining interventions when triaging critically ill patients; for instance, renal replacement therapy for mass crush syndrome after an earthquake.

The authors anticipate that most patients with critical illness due to influenza will have respiratory failure; positive pressure ventilation (PPV) is the current standard for respiratory failure, and mechanical ventilators are most commonly used for sustained PPV.¹¹ Patients with severe acute respiratory failure unable to receive adequate PPV almost assuredly will die. Still, mechanical ventilation is not a guarantee of survival, and some people will still die despite access to PPV.

To best use scarce resources, managing medical catastrophes requires deliberate transition from individual-centered to population-focused critical care. In the United States, the federal government provides neither permission nor definitive guidance for such modifications in care delivery. Although the federal government has oversight for practices related to health care–relevant federal statutes (eg, the Health Insurance Portability and Accountability Act, the

Emergency Medical Treatment and Active Labor Act, and Centers for Medicare and Medicaid Services obligations by health care institutions) and civil rights protections, most health professionals' clinical activities are overseen by states. In recognition of the states' role, the New York State Workgroup developed a process to fairly and justly transition to population-focused care.

The authors focus on 3 major elements: an ethical framework to direct development and implementation of the ventilator allocation guidance, a physiologically based schema to prioritize patients (the "clinical protocol"), and an operational structure for triage implementation and evaluation. The "duty to steward resources" and "distributive justice" ethical constructs are notably dissimilar from the everyday practice of the majority of US health care professionals. Ordinarily, resources allocated to individual patients are based on the individual patient-clinician relationship. Similarly, single hospital practices are rarely influenced by regional resource availability. The ethical framework proposed by the workgroup argues for a different way of operating during a catastrophe. As stewards of the public's health, clinicians are responsible for ensuring that resources are most appropriately used for the entire community, not solely the patient in front of them. The workgroup also believes that hospitals cannot opt out of the triage process. They are concerned that some hospitals may continue to do "business as usual," while others ration resources, leaving the communities at the latter hospitals to shoulder a disproportionate risk of harm. The New York State proposal, as a statewide effort, intends for all state acute care hospitals to uniformly implement the allocation schema, thereby ensuring shared risk and benefit of the triage effort. Given that all acute care hospitals and relevant health professionals are expected to drastically modify usual care, they must be promised protection from civil and criminal liability if they adhere to the guidance in good faith.

In the wake of the response to Hurricane Katrina, the postevent lawsuits and prosecutions have become a significant concern for health care professionals for future disasters. A major advantage of a statewide effort rather than isolated local planning is the greater possibility for protection from criminal and civil liability for health professionals and institutions that implement the guidance. The statewide guidance may help define a community standard, thus increasing the likelihood of successful legal defense of clinicians who adhere to it. The true protection afforded by this strategy unfortunately will only be known after a catastrophe. Perhaps more

important, a statewide triage proposal can be a catalyst for passing state emergency powers or legislation intended to protect health professionals. At the same time, health professionals who use triage for events not serious enough to warrant it, or implement triage in an egregious manner, should be held fully accountable. If legal protection of health professionals, controlled at the state level, is tied to strict adherence to statewide guidance, then uniform implementation of triage across many hospitals is more likely than if plans without health professional protections are developed in isolation by local communities. Hence, statewide efforts are encouraged across the nation to afford the best protection to community members as well as health professionals.

The New York State Clinical Protocol is intended to assist with prioritization of patients. A central tenet is that all acutely, critically ill patients requiring mechanical ventilation should be evaluated, including those who do not have an influenza-related condition. All of the patients who require a mechanical ventilator as defined by the protocol's inclusion

criteria and who do not have one of the conditions listed as an exclusion criterion, will be assessed for physiological derangement. Those deemed most likely to benefit by the Sequential Organ Function Assessment (SOFA¹⁹) will be prioritized for mechanical ventilation. There has not been a severe influenza pandemic since modern critical care became available. Thus, there is no influenza-specific score available, and a score intended for medical critical care populations seems a reasonable al-

ternative until a pandemic occurs. The New York State Workgroup did not advocate use of triage algorithms developed for triage of traumatic injuries (eg, Simple Triage and Rapid Treatment Protocol) because they likely have limited accuracy for predicting ICU or hospital outcome for medical critically ill patients. Use of physiological scoring systems such as SOFA is appealing because they are intended for critically ill patients. Such systems allow for objective scoring, and the New York group believes that they will reduce bias in allocation decisions. Because the workgroup wanted the physiological scoring system to be applicable to all of the patients requiring mechanical ventilation, SOFA also is appealing because it has been validated for trauma patients as well as medically critically ill patients.²⁰ This scoring system is applicable to several plausible mass respiratory failure events beyond influenza pandemics (eg, large-scale anthrax or pneumonic plague outbreak, toxic inhalation).²¹

Caution is advised when using any of the ICU outcome prediction scores for allocation decisions regarding individual

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patients. The scores were originally developed to describe the severity of illness of a population (for use in research studies and for benchmark comparisons among ICUs). There is imperfection inherent in prospectively predicting an individual patient's outcome, most prominently early in the disease course when ICU admission usually takes place. Such deficiencies limit the application of physiological scores for most everyday allocation decisions. During an overwhelming disaster, nevertheless, scores such as SOFA can provide a means of objective prioritization of patients when resources are overwhelmed and there is no adequate alternate measure. There are a number of physiological scores from which to choose, but most of them require many additional laboratory values, are intended for use only at ICU admission and may need 24 hours of information to be most predictive, or are not validated for longitudinal measurements to use changes in the score to predict outcome. In addition, SOFA has been reasonably assessed to be predictive at ICU admission as a means to objectively reassess the likelihood of benefit after a trial of ICU care.²² The disadvantages of SOFA include the following: some of the variables were not designed for or are equally predictive for all populations (eg, Glasgow Coma Scale, creatinine), other variables can be modified by clinician actions without necessarily improving survival (eg, PaO₂/FiO₂), it is not validated for pediatric populations, and it is uncertain whether the cutoffs are truly as discriminating as their intended use warrants. The benefits of SOFA made it the choice of a group of Ontario experts as well as the New York State Workgroup.

There is no perfect physiological schema to prioritize patients and, until the next severe influenza pandemic occurs, the scores will not be derived from disease-specific evidence. For this reason, much attention should be paid to development of the operational structure to implement the triage program rather than expending excessive energies toward development of the unobtainable perfect scoring system.^{23,24} The New York State group mentions some of the structural features necessary for implementation (eg, development of the triage team and institutional triage review committee), but much more needs to be done in this domain. Responsibilities of decision-making groups at various levels (clinical ward, hospital, regional, state, interstate, federal, and international) need to be defined in detail. After experience with a new disease is gleaned, a better triage schema can be conceived. Communication plans must therefore be developed to ensure that implementation remains uniform even after schema revisions are issued. Much of the guidance needs to be done at the state level, with the implementation at the intrastate regional and local levels; equally

as important is that contiguous states figure out how to coordinate with their neighbors.

The New York State process is a great step forward in tackling a difficult issue, and this article will be a crucial resource for other jurisdictions' efforts. However, much remains to be done:

1. The exclusion criteria suggested by the New York State group may not stand up to scrutiny by other healthcare professionals or advocacy groups.
2. The group did not address how pediatrics fit in to the schema. Deliberate consideration of which community outcome should guide the triage process is crucial to future planning efforts. If survival is chosen, then age may be less important for decision making than if life-years saved is the key goal. No matter what the outcome goal, a prioritization schema for pediatric populations needs to be explicitly defined.
3. A broader group of health professionals needs to review the New York State guidance and offer recommendations for revision. Health professionals also will need to be educated in the process and undergo periodic retraining, which will be logistically difficult.
4. The New York State group was composed of professionals, and much communication with the rest of the public, which is acknowledged by the authors, is necessary to have the guidance ultimately accepted by communities.

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