

Concept of Operations for Triage of Mechanical Ventilation in an Epidemic

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Abstract

The recent outbreak of severe acute respiratory syndrome and the growing potential of an influenza pandemic force us to consider the fact that despite great advances in critical care medicine, we lack the capacity to provide intensive care to the large number of patients that may be generated in an epidemic or multisite bioterrorism event. Because many epidemic and bioterrorist agent illnesses involve respiratory failure, mechanical ventilation is a frequently required intervention but one that is in limited supply. In advance of such an event, we must develop triage criteria that depend on clinical indicators of survivability and resource utilization to allocate scarce health care resources to those who are most likely to benefit. These criteria must be tiered, flexible, and implemented regionally, rather than institutionally, with the backing of public health agencies and relief of liability. This report provides a sample concept of operations for triage of mechanical ventilation in epidemic situations and discusses some of the ethical principles and pitfalls of such systems.

ACADEMIC EMERGENCY MEDICINE 2006; ■:■ ■-■ ■ © 2006 by the Society for Academic Emergency Medicine

Keywords: disaster, triage, ventilators, epidemics

The risk of epidemics continues to increase due to many factors, among them the threat of bioterrorism, the growing mobility of the world’s population, and many viruses, including influenza, that represent a threat to the population at large. The outbreak of severe acute respiratory syndrome that began in 2002 and the recent human cases of avian influenza, including the recently reported probable person-to-person transmission of avian influenza identified in Thailand,¹⁻⁷ are potent reminders that the population at large is vulnerable to agents both known and unknown.

Although advances in medical care since the last influenza pandemic in 1968–1969⁸ have improved infectious disease patient outcomes, there has been a significant and ongoing contraction of inpatient beds. Inpatient capacity decreased by 38,000 beds (4.4%) nationwide between 1996 and 2000.⁹ Emergency department (ED) overcrowding was reported by 91% of ED directors in

a recent national survey.¹⁰ Intensive care unit (ICU) bed capacity contracted by 20% nationally between 1995 and 2001.¹¹ Often, beds may be available but are unstaffed due to a shortage of qualified nurses. This staffing shortage is expected to worsen over the next few years.¹² Despite great advances in the technology and science of critical care, the amount of “surge capacity” (resources in excess of those used on a daily basis) is minimal.

In a disaster involving traumatic or chemical injuries, at least some victims die at the scene, and historically only a minor percentage of the survivors are critically ill. However, victims of epidemics and biologic attacks do not die instantly, and deaths usually occur following hospitalization and critical care interventions. The time course for stabilization and recovery from infections is also prolonged as compared with that from trauma or chemical injury. The average ICU stay of a patient with severe acute respiratory syndrome in Toronto hospitals was 10.5 days¹³ and the overall hospital length of stay in Singapore was 18 days.¹⁴ Further, the inhalational anthrax cases of 2001 demonstrate that modern critical care can save lives previously regarded as “unsalvageable.” Before this experience, it was believed that symptomatic inhalational anthrax was fatal despite treatment, yet more than half of the victims survived with appropriate critical care.¹⁵

The combination of the efficacy of intensive care and decreased resources has placed us in a difficult situation. Although intensive care has greatly improved survival in recent decades, the overall lack of resources may mean that many patients of a modern pandemic may receive medical care similar to that provided to patients during the 1918 pandemic.¹⁶⁻¹⁸

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Received April 28, 2005; revision received July 10, 2005; accepted July 18, 2005.

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In no area are our limitations more concrete than the availability of mechanical ventilation. Should an epidemic or bioterrorism event occur that is confined to one area, augmentation of ventilators (and other health care supplies and staffing) from regional and federal resources is probable within 12–24 hours. The Centers for Disease Control and Prevention maintains a stockpile of ventilators for such contingencies. The National Disaster Medical System provides medical support for disasters, including movement of patients from a medically overwhelmed area to areas of the nation with adequate resources. Patient evacuation (particularly of uninfected patients) via the National Disaster Medical System could be an important tool in managing a local or regional event.^{19,20} It is anticipated that while awaiting additional resources or patient movement, bag-valve-mask, bilevel pressure support, and other methods of ventilation could temporarily be used. Although any type of large-scale chemical, biologic, or conventional disaster may overwhelm these resources, it is more likely that an epidemic will be the event that forces widespread, systematic triage of resources.

If the epidemic is multisite, national, or international (e.g., pandemic influenza), it is unlikely that supplemental resources would be available. In this situation, triage of resources would be required to offer the “greatest good to the greatest number.” Although use of family members to manually ventilate intubated patients with a bag-valve system could be considered in select situations, this type of support would have limited utility unless the duration of intubation was relatively short. Although off-site care facilities have been proposed²¹ to augment hospital care when the health care system is overwhelmed, even the provision of oxygen in these facilities is difficult, and mechanical ventilation for more than a few patients is impractical, if not impossible.²²

In a recent drill, our 27-hospital regional compact (which maintains 4,857 beds, including 480 ICU beds) experienced a rapid and critical shortfall in ventilators when challenged with just more than 400 pneumonic plague cases. Despite a surge capacity between 2,500 and 3,500 beds in the area, there were only 16 ventilators available from vendors in our regional system. Modeling for a pandemic event involving 10% of our metropolitan population provides confirmation that our health care system will be pushed well beyond its usual boundaries (Table 1). Although all casualties in an epidemic will not present at once, the 1918 pandemic experience suggests that the initial wave of illness can be extremely rapid, over days

to a few weeks,¹⁸ and it is unlikely that those in the hospital will recover rapidly and be discharged, creating bottlenecks, particularly in the ICU and ED. Due to this drill experience, a concept of operations for allocation of scarce resources and a tiered framework for restricting mechanical ventilation were developed.

DEVELOPMENT OF CONCEPT OF OPERATIONS FOR ALLOCATION OF SCARCE RESOURCES

A concept of operations was developed at the regional/state level for adjusting standards of care during a disaster in which patient care resources are exceeded without potential for obtaining outside assistance in a timely manner (e.g., vaccines, treatments such as botulinum antitoxin, or ventilators).

1. Prior to an event occurring, the Minnesota Department of Health (DOH) convenes guideline development and guideline review groups to agree on a baseline framework for limiting care or adjusting standards of care to those appropriate for the scope of the disaster.
2. An event occurs, and the DOH recognizes that available health care resources are inadequate to allow usual standards of patient care.
3. The DOH requests a state declaration of emergency from the governor.
4. All available resources are used to mitigate stress on the health care system, including patient redistribution, with triage and adjusting standards of care considered as a last resort when no further resources can be obtained.
5. The DOH reconvenes the predetermined guideline development group to assess the situation and refine triage and treatment criteria based on the organism involved and its historical responses to interventions (medications, mechanical ventilation, and so on). This may occur in person or by telephone, depending on the urgency of the situation (Table 2).
6. The group modifies baseline triage criteria based on the specific event and recommends a new standard of care appropriate to the resources available.
7. The DOH convenes the guideline review group to assess the guidelines and provide feedback, modifications, and assent (Table 3).
8. The DOH assesses the need for off-site care facilities based on the event and the staff and supplies available.
9. The DOH meets with the governor's office to review the recommendations.
10. The governor issues an emergency order recommending standards of care based on the situation and ideally making those following this guidance “agents of the state,” providing them legal protections as if they were a state employee responding to a disaster. The governor also permits the establishment of off-site care facilities as needed.
11. The guideline development group continues to meet and update its recommendations based on the scope of the event and evolving knowledge of the pathogen and its response to medical management.

This could be accomplished within a short (hours to day) time frame, provided the groups have been convened previously and understand their mission.

Table 1
Effects of Pandemic Influenza on a Metropolitan Health Care System

Metropolitan-area population	2,600,000 persons
Ten percent affected by pandemic influenza	260,000 persons
Twenty percent of those affected too sick to care for selves	52,000 persons
Twenty percent of those too sick to care for selves lack family or friends to provide care, or require hospitalization for complications	10,400 patients
Optimal surge capacity in current system (without accounting for staff absences and illness)	2,500–3,500 beds

Table 2
Suggested Guideline Development Group Members

Department of Health commissioner or designee Department of Health state epidemiologist Department of Health Emergency Response/Office of Emergency Preparedness Infectious disease physicians (2)* Critical care physicians (2)* Emergency physicians (2)* Family practice physician Pediatric infectious disease physician Pediatric critical care physician
* Should include the chapter representative or designee from the state specialty society.

The guideline development group is focused on developing evidence-based recommendations for clinical care relative to resources available. We had no other models to use in determining the composition of the group, but we desired a small group focused on critical care, emergency care, and infectious disease with representation of primary care and pediatric considerations. Further research may be needed to determine the optimum composition of these groups, but we have found that the size and membership of our group promotes discussion and consideration of many points of view. If other resources require rationing, a different composition of the group might be needed (e.g., botulinum antitoxin, vaccines). Mechanical ventilation was the first limited resource that our group considered.

The recommendations advanced by the development group were vetted by a wider group of both clinical and nonclinical members in the guideline review group. This review group should be focused on the practical implementation of the clinical guidelines, yet be balanced enough by citizen and elected members to ensure community views are represented and avoid a "tyranny of experts."²³ Decisions of the group should be made public and the functions and initial concept of operations discussed in advance of an incident. The Minnesota guideline review group, whose membership is still being modified, is composed in large part of members of the

Table 3
Suggested Guideline Review Group Members

Additional members in the categories noted under guideline development group Respiratory therapists Ethicists State Attorney General and governor's legal counsel State hospital association State medical association State nursing association Hospital administrators, urban and rural Local public health Public safety and emergency management Emergency medical services Lay public members Faith-based community members Special interest groups: pediatrics, mental health, physical impairments groups Political positions: select mayors, county commissioners, council members
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Minnesota DOH Terrorism Task Force. The reception of the group to the concept of operations has been very positive. Our work with the groups, the DOH, the attorney general's office, and the governor's office is ongoing to further operationalize our conceptual model.

DEVELOPMENT OF CRITERIA FOR RESTRICTION OF MECHANICAL VENTILATION

Development of triage criteria must reflect basic medical ethics principles. However, in a resource-poor environment, the traditional bioethical focus on patient autonomy (which assumes respect for the individuals' freedom to make decisions) shifts to a utilitarian or "distributive justice" model that attempts to do the "greatest good for the greatest number" with the resources available.²⁴⁻²⁶

We attempted to develop a tiered, scalable framework for restricting mechanical ventilation. Ideal attributes were determined from our drill experiences.

1. They should assist the individual physician by providing a guideline and policy basis for determining criteria for resource allocation or withdrawal, which will reduce the potential for each physician to have to design and defend individual strategies for individual cases and improve consistency.
2. They should be implemented on a regional, not institutional basis, with a government agency providing policy support for implementation.
3. Appropriate liability protections for providers and institutions cooperating with the public health directives should be assured in advance, or as part of an emergency order.
4. Aside from disease-specific criteria, restrictions should apply equally to all patients (e.g., both those infected and those who are hospitalized for other reasons).
5. Criteria should be implemented in a tiered or stepwise fashion, so that as resources are exhausted, another (stricter) tier of exclusion criteria is implemented in an attempt to provide the best care possible to those with the best chance of survival.
6. Whenever possible, tiers should be based on objective determinations of effectiveness of care affecting survival, and of resource utilization, rather than subjective determinations regarding the value of either the intervention or the value of the patient's life.²⁷
7. The final tier should ideally provide a numeric assessment of survival probability. This figure may be then compared within and between institutions and regionally to allow resources to be shifted to equalize the care provided and also provide a "sliding scale" of care guidelines that may be adjusted depending on the demand on the resources (e.g., unable to provide mechanical ventilation to patients with score > X, tomorrow may change to score > Y).
8. The numeric scoring system should rely on as many clinical variables (rather than laboratory) as possible. It should be easily correlated with survival. It should be available in the public domain (e.g., nonproprietary). It should be easily adapted to Internet or personal digital assistant calculation programs. Ideally, it should involve simple calculations and few variables.

To define existing work in this area, Ovid MEDLINE searches for available articles since 1966 were performed (to October 2004) utilizing combinations of the following search terms and key words: ventilation-mechanical, triage, critical care, disaster, emergency medical services, resource utilization and allocation, ethics, intensive care unit, distributive justice, emergency medicine, severity of illness index, and multiple organ dysfunction score. Searches were limited to human subjects and English-language articles. Citations of relevance were reviewed by the authors. Review of applicable article references and bibliographies was also conducted. Standard textbooks in critical care medicine were reviewed.

Although select papers have discussed triage in disaster settings, including those of terrorist origin,²⁸⁻³² to date no triage discussions have proposed objective methods to triage inpatient resources. The literature has also been silent on the operational withdrawal of resources from some patients to allow their application to patients with a higher survival probability during a disaster. Although there is no pure ethical difference between the withdrawal of treatment and withholding treatment, the emotional distress for the provider, the patient, and family members will be significantly greater when previously provided (and desired) treatments are withheld.³³ We found no formal constructs to apply to our triage criteria. Substantial critical care and prognostic literature was reviewed.

Three tiers of criteria were developed (Table 4). The first tier is solely related to respiratory failure with shock and multiple organ dysfunction. Second-tier criteria are related to high potential for death, prolonged ventilation, and high levels of resource utilization. These tier 2 criteria are invoked when tier 1 restrictions are inadequate to meet resource demands. The first and second tiers require no familiarity with scoring systems and depend mainly on respiratory failure and poor prognosis based on current and underlying disease. Third-tier criteria may involve additional restrictions or a numeric score and are invoked when determined necessary to maintain consistent standards of patient care and further restrict demand on resources. Any of the tiers may be modified during the event to account for disease-specific prognostic information.

The use of a predictive survival instrument in the final tier standardizes assessments and allows numeric comparisons of patients both within the institution and between institutions. This allows more efficient allocation of available resources to institutions in greatest need and provides as consistent a level of care (as possible) across the community and region. It also provides the physician with guidance for clinical care that is rational and quantitative rather than qualitative.

The standard of care that is applied in the setting of a large-scale disaster is a sliding scale of care appropriate

Table 4
Three Tiers of Criteria

<p>Tier 1: Do not offer AND withdraw ventilatory support for patients with any one of the following:</p> <ol style="list-style-type: none"> 1. Respiratory failure requiring intubation <i>with</i> persistent hypotension (systolic blood pressure <90 mm Hg for adults) unresponsive to adequate fluid resuscitation after 6–12 hours of therapy <i>and</i> signs of additional end-organ dysfunction (e.g., oliguria, mental status changes, cardiac ischemia) 2. Failure to respond to mechanical ventilation (no improvement in oxygenation or lung compliance) and antibiotics after 72 hours of treatment for a bacterial pathogen (timeline may be modified based on organism-specific data) 3. Laboratory or clinical evidence of ≥ 4 organ systems failing <ol style="list-style-type: none"> a. Pulmonary (adult respiratory distress syndrome, ventilatory failure, refractory hypoxemia) b. Cardiovascular (left ventricular dysfunction, hypotension, new ischemia) c. Renal (hyperkalemia, diminished urine output despite adequate fluid resuscitation, increasing creatinine level) d. Hepatic (transaminase greater than two times normal upper limit, increasing bilirubin or ammonia levels) e. Neurologic (altered mental status not related to volume status, metabolic, or hypoxic source, stroke) f. Hematologic (clinical or laboratory evidence of disseminated intravascular coagulation) <p>Tier 2: Do not offer AND withdraw ventilatory support from patients with respiratory failure requiring intubation with the following conditions (in addition to those in tier 1):</p> <p>Patients with pre-existing system compromise or failure including:</p> <ol style="list-style-type: none"> 1. Known congestive heart failure with ejection fraction <25% (or persistent ischemia unresponsive to therapy and pulmonary edema) 2. Acute renal failure requiring hemodialysis (related to illness) 3. Severe chronic lung disease including pulmonary fibrosis, cystic fibrosis, obstructive or restrictive diseases requiring continuous home oxygen use before onset of acute illness 4. Acquired immunodeficiency syndrome (AIDS), other immunodeficiency syndromes at stage of disease susceptible to opportunistic pathogens (e.g., CD4 <200 for AIDS) with respiratory failure requiring intubation 5. Active malignancy with poor potential for survival (e.g., metastatic malignancy, pancreatic cancer) 6. Cirrhosis with ascites, history of variceal bleeding, fixed coagulopathy, or encephalopathy 7. Acute hepatic failure with hyperammonemia 8. Irreversible neurologic impairment that makes patient dependent for personal cares (e.g., severe stroke, congenital syndrome, persistent vegetative state) <p>Tier 3: Specific protocols to be agreed upon by guideline development committee. Possibilities include:</p> <ol style="list-style-type: none"> 1. Restriction of treatment based on disease-specific epidemiology and survival data for patient subgroups (may include age-based criteria) 2. Expansion of preexisting disease classes that will not be offered ventilatory support 3. Applying Sequential Organ Failure Assessment scoring to the triage process and establishing a cutoff score above which mechanical ventilation will not be offered
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to the resource demands of the event. A hospital attempting to manage a large influx of patients who require ventilator support during an epidemic may have to further ration resources in the face of increasing demand. This could potentially result in withdrawal of resources from an individual who might be stable, or even improving, but whose objective assessment indicates a worse prognosis than other patients who require the same resource (e.g., tier 3 criteria, where a score of X today might warrant a ventilator but, in the face of worsening shortages, might not be sufficient to justify continued ventilatory management tomorrow, or a patient who is already hospitalized when a disaster occurs, and whose resources are reapplied to a patient with a higher potential for a good outcome).

Many scoring systems have been developed to predict mortality in intensive care environments.³⁴ These scoring systems offer an ability to compare critical illness between patients and to numerically compare illness severity between ICUs (and thus across or between institutions or regions). None of these systems are applicable to all patient populations, and none were developed as a triage tool; thus, their ability to predict mortality across populations does not translate into accuracy for individual patients, discouraging their use for day-to-day triage of ICU resources. However, disasters require different measures, and we believe that scoring systems allow a validated, objective approach to compare mortality predictions and thus, in a disaster, should be strongly considered despite their limitations.^{35,36}

Some systems are proprietary (e.g., Acute Physiology and Chronic Health Evaluation III [APACHE III]), and many rely on complex variables and mathematical computations (Simplified Acute Physiology Score [SAPS], Logistic Organ Dysfunction [LOD] score, Modified Organ Dysfunction Score [MODS], and Morbidity Probability Model II [MPM II]).³⁷⁻⁴⁶ Of the scoring systems that are currently available, the Sequential Organ Failure Assessment (SOFA) seems to be the most useful of the systems, generating a numeric score that offers good predictive accuracy based on a few clinical and simple (bilirubin, creatinine, platelet count) laboratory observations (Table 5).³⁷⁻⁴¹ SOFA scores can also be used over time to evaluate prognosis and response to therapy.^{37,38,40,41}

Notably, SOFA (unlike MPM II) does not incorporate age-based criteria. Daniels would argue that the right of an individual to have the opportunity to reach the end of a natural life span would mean preferential triage of resources to the young rather than to those that had achieved a "natural life span."⁴⁷ However, what constitutes a natural life span is open to discussion.

Although elders in general have lower survival rates and fewer quality-adjusted years of life than younger patients, there are marked differences in chronologic age versus biologic age. Surveys have found that neither the public⁴⁸ nor ICU practitioners⁴⁹ favor withholding care based on age alone. For those 13% of ICU practitioners who did favor an age limit, 85 years was the median age selected.³⁶ To the degree that biologically aged persons are more fragile and prone to developing organ system failure, these frailties will be reflected in their organ dysfunction scores.

Aside from tier 2, item number 10, no assessment of functional independence is made. This is likely to be the most difficult of factors affecting triage, because it relates to the demands that an individual would place on society after recovery. How performance of activities of daily living⁵⁰ or dependence scores⁵¹ could be incorporated logically or ethically with physiologic scoring systems is an area that requires future discussion and research.

Finally, although use of a predictive framework is consistent with the view of ICU practitioners that social worth is of minimal consideration in decisions regarding ICU care, it fails to take into account quality of life, which was ranked as the most important factor affecting provision of ICU care. However, quality of life is very difficult to assess, because provider and patient interpretations of their condition may differ widely.⁴⁹

DISCUSSION

With the limitations present in our health care system today, we believe discussion of adjusting standards of care proportionate to the demands of a disaster or epidemic is critical. In developing and communicating our concept of operations and triage criteria, we do not believe that we have arrived at anything in our state besides a starting

Table 5
Sequential Organ Failure Assessment³⁹

Reprinted with kind permission from Springer Science and Business Media and the author, Dr. Vincent (Vincent JL, Moreno R, Takala J, et al. The SOFA [sepsis-related organ failure assessment] score to describe organ dysfunction/failure. *Intensive Care Med.* 1996;22:707-10).

NOTE. This table will not be available online but does appear in the February 2006 print issue of *AEM*.

* Adrenergic agents are expressed as $\mu\text{g}/\text{kg}/\text{min}$ for at least one hour.

point that needs further discussion, study, and refinement. We have thus far only looked at triage of ventilators, but this concept of operations theoretically can be applied to any resource in short supply. Mechanical ventilation and critical care are concrete resources that serve as good starting points for discussion, because there is at least some evidence to suggest which patients are likely to benefit and which are not, although the evidence is, at best, only indirectly related to triage applications.

The triage criteria must be regarded as guidelines, not standards. Individual clinicians have expressed the concern that they must have the ability to make decisions based on other criteria (e.g., preexisting functional capacity, prior wishes of patient regarding life-sustaining therapies, and so on) should they believe there is a need to deviate from the guidance in individual cases. We agree, although we believe that it would be unusual for a practitioner to decide to deviate substantially or systematically from a published emergency guideline, particularly one that could provide liability protection in what will certainly be a highly charged environment.

More important than the specifics of any tool (which will require modification based on the event) is the establishment of a process for making decisions to limit care so that in a time of crisis, a mechanism is in place to apply as much science as possible to these decisions and the persons involved are prepared for their roles.

According to the Society of Critical Care Medicine Ethics Committee, "triage policies should be disclosed in advance to the general public and, when feasible, to patients and surrogates on admission."³⁶ It cannot be anticipated that the families will agree with the decisions made; however, their disagreement and anger may be tempered by the fact that they viewed the underlying process as fair and understood it in advance, the so-called "fair process effect."⁵²

It is difficult to acknowledge and discuss restrictions of care and the limitations of our health care system, but we have been gratified by the acceptance and careful consideration with which these issues have been received by our state groups and look forward to opening broader discussions and generating more public awareness of the issues. We hope that with some preliminary attention being paid to this issue at the federal level,³¹ better definition of local, state, and federal roles and responsibilities will occur and operational planning will follow. Regardless of the federal role, there must be local discussions and understanding of resource limitations before an event. We hope that this report will serve as a stimulus for discussion and planning.

CONCLUSIONS

As physicians and health care providers, we owe it to ourselves and to our patients to develop thoughtful and fair triage strategies in conjunction with members of the community before a crisis. Only in this way can we acknowledge our system limitations and develop contingency plans that can be practiced in advance of an incident, so that we may be trusted to do the greatest good for the greatest number with what we have to offer when disaster strikes.

The authors thank the members of the Minnesota Terrorism Task Force Clinical Care Workgroup and the Minnesota Department of Health Adjusted Standard of Care Science Advisory Team for their assistance with the modification of the tiers and criteria and the Minnesota Department of Health Office of Emergency Preparedness and Section of Acute Disease Investigation and Control.

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