Rationing of Resources: Ethical Issues in Disasters and Epidemic Situations

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PTC = Pandemic Triage Committee
SOFA = Sequential Organ Failure Assessment

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Abstract

In an epidemic situation or large-scale disaster, medical and human resources may be stretched to the point of exhaustion. Appropriate planning must incorporate plans of action that minimize public health morbidity and mortality while maximizing the appropriate use of medical and human healthcare resources. While the current novel H1N1 influenza has spread throughout the world, the severity of this strain of influenza appears to be relatively less virulent and lethal compared to the 1918 influenza pandemic. However, the presence of this new influenza strain has reignited interest in pandemic planning.

Amongst other necessary resources needed to combat pandemic influenza, a major medical resource concern is the limited number of mechanical ventilators that would be available to be used to treat ill patients. Recent reported cases of avian influenza suggest that mechanical ventilation will be required for the successful recovery of many individuals ill with this strain of virus. However, should the need for ventilators exceed the number of available machines, how will care providers make the difficult ethical decisions as to who should be placed or who should remain on these machines as more influenza patients arrive in need of care?

This paper presents a decision-making model for clinicians that is based upon the bioethical principles of beneficence and justice. The model begins with the basic assumptions of triage and progresses into a useful algorithm based upon utilitarian principles. The model is intended to be used as a guide for clinicians in making decisions about the allocation of scarce resources in a just manner and to serve as an impetus for institutions to create or adapt plans to address resource allocation issues should the need arise.

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Introduction

During an epidemic or disaster, medical and human resources may be stretched to the point of exhaustion. The current concern of a pandemic influenza crisis has each country reviewing plans of action that would minimize public health morbidity and mortality, and maximize the appropriate use of medical and human healthcare resources.

A major limitation in an influenza epidemic would be the availability of mechanical ventilators. Recent cases of avian influenza suggest that mechanical ventilation will be required for the successful recovery of some individuals who are ill with this strain of virus. No one can predict accurately what the demand for advanced ventilatory care will be. Several models have estimated the need through computer simulation based on the current understanding of influenza and statistical data.[1,2]

In a 12 March 2006 *New York Times* article, Donald G. McNeil, Jr. reports that the United States has roughly 105,000 ventilators, and that during a typical influenza season, about 100,000 are in use.[3] It is estimated that if the US were to experience an influenza pandemic, as many as 742,500 ventilators would be needed. The federal government has a stockpile of 4,000–5,000 ventilators for such an emergency, well short of the projected need.

Should the need for ventilators exceed the number of available machines, healthcare providers will face difficult ethical decisions regarding who should be placed or who should remain on these machines as more influenza patients arrive in need of ventilatory support. Is there an ethical decision-making model that can assist providers in making difficult choices as resources become limited?

Methods

The development of an ethically based decision-making model for the allocation of scarce resources, specifically mechanical ventilators, was undertaken while developing the University of Illinois Medical Center at Chicago Pandemic Influenza Disaster Plan during the winter of 2005–2006. The authors conducted a literature review utilizing the following keywords: (1) triage; (2) resource allocation; (3) transplantation; (4) medical ethics; (5) critical care; and (6) disasters. In addition, several other plans were reviewed that had incorporated pandemic resource allocation.[4–7]

Utilizing the concepts and constructs extracted from the review of literature and data, a plan was presented to provide a clinical decision-making model for the hospital. While the proposed plan is institution-based, the authors emphasize the importance of the expansion or inclusion of this type of plan into larger citywide, statewide, or national efforts. No one institution can realistically accommodate the potential magnitude of need without the cooperation from larger entities.

Background on Ethical Principles

This model is based upon the bioethical principles of beneficence and justice. It begins with triage and progresses into an algorithm based upon utilitarian principles.

Beneficence

The ethical principle of beneficence implies that all actions are intended to benefit the patients. Often, this medical benefit falls within an individual context. However, in a large-scale disaster situation, such as an epidemic or a pandemic, the individual is treated in a public health context in which beneficence must balance between the individual and the group of individuals who also have been affected (group/community/public). This principle assumes that there is a moral obligation that providers act *for the benefit* of others.[8] During an epidemic/pandemic situation, providers act in a way that ultimately benefits all of the affected people. It is this principle that warrants the just allocation of scarce resources such as mechanical ventilators.

Justice

According to the *Principles of Biomedical Ethics*, justice may be defined as "fair, equitable, and appropriate treatment in light of what is due or owed to persons". More specifically, distributive justice "refers to fair, equitable, and appropriate distribution determined by justified norms that structure the terms of social cooperation".[8] It is the principle of distributive justice that would apply during a pandemic. With respect to healthcare services and equipment in a disaster, distributive justice can guide the decision-making process of providers. This creation of a decision model for the allocation of scarce medical resources based on defined clinical guidelines that also is transparent to the public, reflects this principle.

Utilitarian Theory and Triage

The general principles of triage draw from utilitarian principles, which simply entail the "greatest good to the greatest number". In essence, it is a policy in which all individuals are assessed with the overall goal of using the resources available for those who are most likely to benefit from the care. For example, under the guidance of utility, it would be acceptable to provide comfort care measures only to those victims who are assessed as unlikely to benefit from aggressive medical care. By doing so, scarce resources would be available for use by those who would benefit, thus allowing the greatest number to have the best chance for survival.

Triage provides the means to form an ethical framework to help make fair and just clinical decisions during difficult times. The term itself means "to set priorities of medical treatment to casualties on the basis of urgency or the chance for survival".[9] One of the best examples of the practice of utilitarian theory is the concept of mass-casualty disaster triage. "Disaster medical triage is a dynamic process occurring at several levels in the system to rapidly identify patients with critical injuries from the total number of presenting casualties. Traditionally, triage systems have attempted to sort victims into categories to determine treatment and transport priorities. Triage in a disaster is neither perfect nor democratic...however, triage improves outcome".[9]

Clinical Model for Decision-Making: Allocation of Mechanical Ventilators in a Disaster/Pandemic Situation

This clinical model is based on the two principles of bioethics described previously, beneficence and justice, and utilizes the concepts of triage. Because the severity of pandemic influenza potentially is devastating and non-discriminatory, this issue must be addressed in a way that is as fair and as consistent as is possible. Thus, the "fair process approach" from the [US] Centers for Disease Control and Prevention (CDC) was adopted in creating a model that adheres to procedural justice.[10] This model aims to enforce: (1) consistent application of guidelines, treating all cases alike and minimizing individual interpretation; (2) impartiality and neutrality of decision-makers; (3) incorporation of current accepted medical practice criteria; (4) respect and dignity in the treatment of all patients; (5) allowance of an appeal process; (6) transparency of the criteria/guidelines; and (7) a dynamic process that encourages constant review of practices and allows for adaptation as warranted by new information or technology. These parameters are reflected in the seven-component decision-making model (Table 1).

Formation of a Pandemic Triage Committee

The decision to initiate, continue, or remove mechanical support should not be made solely by the caring physician. The formation of a Pandemic Triage Committee would serve two purposes: (1) the committee would be a neutral and impartial entity serving as the supervising body when a medical center faces resource allocation decisions; and (2) the committee would regularly review current advances and decisions within state, federal, and international organiza-

1. Formation of a Pandemic Triage Committee
2. Phased allocation of resources
3. Clinical evaluation: Pandemic triage, also must include non-influenza patients
4. Checklist of clinical progress
5. Palliative care protocol
6. Appeals process
7. Early family involvement

Table 1—Seven components of the clinical decision-making model

Level 1	Firm exclusion criteria apply. **No** Relative exclusion criteria. Mechanical ventilators **not** exhausted.	SOFA score	Critical care color-coded triage tool** Assessments at: Initial 48 hour 120 hour
Level 2	Firm exclusion criteria apply. Relative exclusion criteria apply. Mechanical ventilators use **at** capacity.	SOFA score	Critical care color-coded triage tool** Assessments at: Initial 48 hour 120 hour
Level 3	Firm exclusion criteria apply. Relative exclusion criteria apply. Mechanical ventilators **over** capacity	SOFA score	Critical care color-coded triage tool** Assessments at: Initial 48 hour 120 hour

Table 2—Pandemic triage protocol
(D/C = discharge; SOFA = Sequential Organ Failure Assessment)

tions relating to limited resource allocation and care protocols, and recommend adaptations as warranted by new information. Ideally, this committee is comprised of members representing impacted clinical units, including representatives from respiratory services, critical care services, emergency care services, infectious disease, ethics, and pastoral care. When needed, the group would consult community members and politicians.

Phased Allocation of Resources

The rationale behind phased allocation of resources is to maximize the utility of hospital resources as dictated by the nature and severity of the situation. When facing an influx of patients requiring advanced ventilatory support, the first stage of addressing the increasing demand should be a review of the use of the current ventilators. A detailed review of all patients on ventilatory support and their need for ventilation or expected duration of ventilatory support should be implemented. Also, cancellation of elective procedures that would require or anticipate prolonged ventilatory support should be considered. At this point, an inventory of available ventilators within the medical center and from vendors should be performed to anticipate need and limitations.

Clinical Evaluation

Several triage protocols have been proposed that address the clinical evaluation of patients with influenza.[4–7] While there is some variation in the content of each of these protocols, they are similar in structure and reasoning and build upon each other. Several of their concepts and constructs are incorporated into the pandemic triage protocol. Clinical criteria concepts also were drawn from other existing sources, i.e., the critical care, military and mass-casualty triage, and transplantation literature.

Initiation of mechanical ventilation in light of a limited number of ventilators is difficult. However, the most difficult decision in addressing the allocation of mechanical ventilators is the decision to remove a patient from a ventilator in order use it for someone else that might benefit more from mechanical ventilation. The distinction between the two is not insignificant and can have great implications for family and care providers. In this protocol, an effort is made to try to maintain equivalent and parallel application between initiation and withdrawal of support.

The pandemic triage protocol has three levels that correspond to the degree of pandemic crisis: (1) *Level 1*—where a pandemic is present but resources are not exhausted; (2) *Level 2*—where a pandemic is present and resources are at capacity; and (3) *Level 3*—where a pandemic is present and resources are over capacity. Within each of these three levels, there are three sections: (1) inclusion criteria; (2) exclusion criteria; and (3) objective score criteria. Exclusion criteria are subdivided further into "firm" and "relative" exclusion criteria (Table 2).

Inclusion Criteria—Any patient with ventilatory failure requiring ventilatory support, regardless of the etiology, is

Cardiac: NYHA class III or IV
Renal: dialysis dependent
Neurological: poor prognosis
Immunocompromised state, i.e., advanced HIV/AIDS
Pulmonary: severe CLD FEV_1<25%
Hepatic: MELD score >20
Malignancy: poor prognosis

Table 3—Seven components of the clinical decision-making model (Adapted from Ontario Health Plan for an Influenza Pandemic (OHPIP) Guidelines) (CLD = chronic lung disease; FEV^1 = forced expiratory volume in one second; MELD = Model for End-Stage Liver Disease; NYHY = New York Heart Association)

considered in the protocol. Because non-influenza or infectious patients also may present at any time, they cannot be excluded from consideration for mechanical ventilation.

Exclusion Criteria—There are three basic categories of exclusion criteria:

1. Patients presenting with severe disease with poor prognosis and/or high mortality despite aggressive critical care treatment;
2. Patients with overwhelming care requirements that will exhaust the ability of the critical care unit during a pandemic situation; and
3. Patients with pre-existing, advanced medical illnesses with a poor prognosis and high short-term mortality despite the current, severe illness requiring critical care.

The first category is considered *firm* exclusion criteria. These patients are excluded from further intervention because their chance of survival is extremely poor despite any treatment. These are patients presenting with severe trauma, such as severe burns quantified as >40% body surface area and/or severe inhalation injury, cardiac arrest that either is unwitnessed or witnessed without any response or recurrent need for resuscitation; a calculated sequential organ failure assessment (SOFA) >11 (to be discussed), or failure of more than four organ systems.

The latter two categories are considered *relative* criteria. They are activated as the degree of a pandemic increases. Under normal circumstances, patients in these categories likely would receive critical care, but as resources become more limited, further scrutinization of patients is required. Pre-existing conditions that have implications for survival become a factor in deciding the best use of limited resources. These are defined by measures of organ function or associated prognosis of disease (Table 2).

Patients who may require exhaustive resources for treatment under normal circumstances would be excluded if the same amount of resources would be available to treat more people. For example, a patient requiring multiple transfusions might be excluded if the same amount of blood required to treat the one patient could treat 10 people that require fewer units of blood per person. This concept is drawn from a military practice called minimal qualifications for survival (MQS).[5] Age is not specifically incorporated within the exclusion criteria. Many of the co-morbidities are associated with increased age. However, age itself does not necessarily correlate to increased co-morbidities, and alone, does not firmly exclude someone from receiving advanced care.

Objective Score Criteria—The SOFA is an objective tool used by critical care specialists to predict outcome. It is calculated at defined intervals and can help to estimate mortality risk. It has been utilized in the aforementioned state health plans, and is incorporated here. A patient who has a SOFA score >11 on initial assessments has an associated mortality of >90%. Mean and highest SOFA scores particularly are useful predictors of outcome. Independent of the initial score, an increase in SOFA score during the first 48 hours in the intensive care unit predicts a mortality rate of at least 50%.[11]

The protocol is dynamic in that it is applied to track progress of each patient requiring ventilatory support on a recurring basis. A critical care, color-coded triage tool (adopted from the Ontario Health Plan for an Influenza Pandemic (OHPIP)) is used to summarize the data from exclusion criteria and SOFA scoring and used to determine the level of care provided. This tool is applied at regular intervals: initial, 48 hour, and 120 hour assessments (Table 4).[7]

Critical Care Assessment Checklist

A critical care assessment checklist is an easily accessible, one-page document placed in the front of a patient chart that allows decision-makers to view objective parameters and track the involvement of other key services, i.e., social work and patient care services. This document facilitates the monitoring of patients under critical care or ventilatory treatment primarily with respect to those with an infectious- or pandemic-related disease (Figure 1).

Palliative Care Protocol

Ethical obligation stipulates that healthcare providers must try to be of benefit and to provide just allocation of resources. When the application of mechanical ventilation becomes medically futile, the obligation to apply its use is replaced by an obligation to provide comfort and dignity to those dying.

The clinical decision model includes provisions for palliative care for those that initially do not qualify for critical care allocation and for those that no longer may qualify for any reason. This is an extremely sensitive component, as either scenario may invoke strong emotions from family members and loved ones. Respect and dignity of the patient are of utmost importance in this setting. Provision for sedation and pain control for those that do not fit into the critical care allocation is necessary. Selection of medications will depend upon existing pain and sedation protocols that already may exist in an institution.

Other considerations include the use of alternative means of ventilation or supplemental oxygen. Any of the above decisions are made in accordance with the wishes of the patient and/or family and knowledge of a palliative care protocol is introduced to the family early in the care of the patient.

Appeals Process

While the protocol is designed to eliminate individual variation of practice in determining who should or should not receive mechanical ventilation, the aforementioned Pandemic Triage Committee (PTC) can and should delib-

Critical Care Triage Tool (Initial Assessment)		
Color Code	*Criteria*	*Priority/Action*
Blue	Exclusion Criteria *OR* SOFA >11	Medical Management ±Palliative care and D/C
Red	SOFA ≤7 *OR* Single Organ Failure	Highest
Yellow	SOFA 8–11	Intermediate
Green	No significant organ failure	Defer or D/C, re-assess as needed

Critical Care Triage Tool (48-Hour Assessment)		
Color Code	*Criteria*	*Priority/Action*
Blue	Exclusion Criteria *OR* SOFA >11 *OR* SOFA 8–11 and no change	Medical Management and Palliative and D/C from ICU
Red	SOFA <11 and decreasing	Highest
Yellow	SOFA <8 and no change	Intermediate
Green	No longer ventilator dependent	D/C from ICU

Critical Care Triage Tool (120-Hour Assessment)		
Color Code	*Criteria*	*Priority/Action*
Blue	Exclusion Criteria *OR* SOFA >11 *OR* SOFA 8–11 and no change	Palliative care and D/C from ICU
Red	SOFA <11 and decreasing progressively	Highest
Yellow	SOFA <8 and no change (<3 point decrease in past 72 h)	Intermediate
Green	No longer ventilator dependent	D/C from ICU

Table 4—Critical Care Triage Tool (D/C = discharge; ICU = intensive care unit; SOFA = sequential organ failure assessment)

erate and allow for appeals if there are outstanding issues raised by family or clinical providers. Deviation from the guideline is not permitted. However, there may be some unforeseen conflict or issue that may arise that would enlist arbitration by the PTC. It is anticipated that most cases will be unique; hence, there is no formal written protocol. Once an appeal is filed, a few steps must be followed to ensure fairness: (1) obtain information from the patient's care providers and family through interviews; (2) review the existing written guidelines; (3) review the current treatment modalities and outcomes at both the institution and externally; and (4) reassess the patient's clinical health status. Only after these steps have been followed can the PTC make any determination about the initial decision to withhold or withdrawal mechanical ventilation.

Early Family Involvement

In the event of a pandemic, during which hospital resources are limited to a point requiring allocation, the family of a sick patient must be aware of the protocol that is in effect to minimize potential conflict or misinterpretation of the provision of care. Early family involvement engages the family into the clinical decision model from the beginning. The components of the decision model, including criteria, should be made available to family members in a written document on or soon after presentation or admission. Transparency of the criteria and guidelines is important, and regular discussion of care with family in a pandemic situation is essential to ensuring that patients and families understand the management constraints. To help to address concerns raised by the pandemic triage protocol, a chaplain and social workers are enlisted for proactive and early involvement.

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Patient name:
MR#:
Room/bed number:
Hospital day:
Days on ventilator:
Diagnosis:
Secondary Diagnoses:
Exisiting:
New:
SOFA score (0–24)
Respiratory (0–4):
Coagulation (0–4):
Hepatic (0–4):
Cardiovascular (0–4):
Neurological (0–4):
Renal (0–4):
Total:

Sequential Organ Failure Assessment (SOFA) Scale

Variable	*0*	*1*	*2*	*3*	*4*
PaO_2/F_iO_2 mmHg	>400	<400	<300	<200	<100
Plateletes, x $10^3/\mu L$ ($x10^6/L$)	>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
Creatine, ng/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] dose 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

Chaplin meeting:	☐ Yes	Date:	Comments:
Family meeting:	☐ Yes	Date:	Comments:
Palliative care protocol discussed?	☐ Yes:	Date:	Comments:
Palliative care protocol initiated?	☐ Yes:	Date:	Comments:

Figure 1—Critical care assessment checklist (MAB = mean arterial blood pressure; SOFA = sequential organ failure assessment)

The idea of transparency is essential to the ethical ideal of fidelity or trust. If the public is to trust that those who are caring for them in time of need are going to do so according to a well-prepared and just plan, the public must be informed of what the plan is, how the decision-making model was created, and how and when it is executed. Enlisting the aid of the government and the media is important.

Discussion

Today medicine practiced in the US is individualistic as opposed to looking at healthcare resources in the aggregate. The current system encourages using the most technology available for each individual patient, simply because there often is no reason not to. However, in order to plan for a pandemic situation, healthcare providers, as well as the

public, must understand that healthcare resources are limited and the health system may need to provide these resources in a systematic way to maximize overall good. The public must be fully aware of the issues in order to understand and accept the limitations of the healthcare system. While the need for public education and awareness about influenza or a pandemic situation has been identified, the general public was not specifically tested in the development of this model, except through input from several community members that serve on the institution's Ethics Committee. Education of the public is key in tempering panic that likely would ensue in a pandemic situation. Any action plan for limited resources must be transparent to the public and to healthcare providers. Education of healthcare providers and the public about the impact of pandemic influenza is a key component to the adoption of such an action plan.

Conclusions

This proposed clinical decision model is a starting point to serve as a template or guideline for further work and discussion. Through these efforts, discussion about the application of this plan among the Emergency Management Committee and leaders of the hospital should have been initiated by the hospital and extended to the healthcare planners in the surrounding medical community. There are many issues raised by the plan that cannot be addressed without further intensive research, thought, and search for the best possible scenarios, including not using any mechanical ventilators. Input is welcome. The use of this document to spark discussion and adaptation in other institutions is encouraged. No one institution can do this alone. Ultimately, any sound plan will require the cooperation from multiple levels and hospitals. The most important step is to start the dialogue in institutions and to expand this dialogue to a broader level, including the government stakeholders.

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Editorial Comments—Rationing of Resources: Ethical Issues in Disasters and Epidemic Situations

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The striking issues raised by Lin and Anderson-Shaw point the way to myriad legal questions facing the disaster medicine community. In international law, the closest we have come to explicit legal guidance on medical rationing comes from the Geneva Conventions of 1949. These treaties state that "Only urgent medical reasons will authorize priority in the order of treatment to be administered." These treaties only apply in wartime; thus, this guidance is of little value for practitioners in many of the situations in which (as described by the authors) "medical and human resources may be stretched to the point of exhaustion."

In situations of extreme stress—where services are provided in failing states, or disasters might destroy official coping mechanisms and institutions—practitioners could find that locally imposed constraints or guidance offer little help or insight. Healthcare professionals may have to rely entirely on their own ethical training, and procedures internal to their own organizations to arrive at satisfactory answers. When services are provided in states where resources have been overwhelmed, but legal and institutional authority remains intact, healthcare practitioners also must take local rules of professional conduct and liability into account. In short, there are no universal guidelines or rules for resource allocation during disasters.

A stark and realistic scenario is brought into focus in this article—How should mechanical ventilators be allocated during an influenza epidemic? Similar questions could be raised with other scenarios. The authors have performed a valuable service by raising questions and offering an ethical roadmap for decision-making. There is a need to address gaps, if not chasms, that may separate ethical decision-making standards from national and international legal norms for professional conduct and liability. This article is a starting point for dialogue, and an intellectual foundation on which the World Association for Disaster and Emergency Medicine can build to help meet the challenge.