

Ventilator Allocation In A Pandemic: Discussion And A Model For Rationing Restricted Resources

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Article ID: WMC001258

Article Type: Original Articles

Submitted on: 01-Dec-2010, 04:31:31 PM GMT **Published on:** 03-Dec-2010, 05:37:57 PM GMT

Article URL: http://www.webmedcentral.com/article_view/1258

Subject Categories: Medical Ethics

Keywords: ethics, resource allocation, pandemic, critical care, emergency medicine, ventilator

How to cite the article: Howes D, Tsai E. Ventilator Allocation In A Pandemic: Discussion And A Model For Rationing Restricted Resources . WebmedCentral Medical Ethics 2010;1(12):WMC001258

Source(s) of Funding:

No funding was required for the completion of this manuscript.

Competing Interests:

Neither Author has any competing interests

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Abstract

In a state of emergency, increased demands for limited resources force a shift in the standards of care. With preparation and thoughtful deliberation, we can ensure that these changes in care continue to be consistent with our ethical principles.

In a respiratory infectious disease outbreak or other disaster, the demand for ventilators may outstrip the supply. Once efforts to shift demand or increase supply have been exhausted, clinicians may be put in the very difficult position of rationing this life-sustaining resource. The values and principles of these situations have been well outlined in the work of the University of Toronto Joint Centre for Bioethics (JCB) in their document *Stand on Guard for Thee - Ethical considerations in preparedness planning for pandemic influenza*, but it has been challenging to develop a practical method of implementing the values they describe.

We build on the values outlined by the JCB with addition of the very practical value of expediency. We outline also a protocol to maximize benefit from a limited resource during a crisis (ventilators in a flu pandemic) with a discussion that focuses on ethical and practical implementation.

Introduction

During an infectious disease outbreak or disaster, clinicians may find themselves in the difficult position of having to choose who among multiple patients in their care will be allocated a limited resource^{[[i]]}. This may put them in a real or perceived conflict of interest. Protocols for this decision-making process can help assure the public that resource allocation is fair both in terms of procedure and outcome, while providing a reasonable, attainable standard for decision-makers.

In 2010 the European Society of Intensive Care Medicine's task force for ICU Triage during an Influenza Epidemic or Mass Disaster^{[[ii]]} provided recommendations for these situations. Their recommendations include the implementation of an

executive control group with authority over resource allocation; they note that usual care standards may be impossible to achieve, and that some treatments may have to be withheld or withdrawn resulting in patient death. They recommend that decisions be made by a triage officer using a protocol that is objective, ethical, transparent and equitably applied, but they were unable to conclude whether triage should be based on a 'first come, first served' basis or in a manner to provide the most benefit.

In Canada a number of provincial pandemic and emergency plans address the issue of resource allocation and decision-making with general guidelines. Most of these are based on the principles outlined in the work of the University of Toronto Joint Centre for Bioethics (JCB) in their document *Stand on Guard for Thee - Ethical considerations in preparedness planning for pandemic influenza*^{[[iii]]}. They identify four substantive values and five procedural values that are most applicable to situations of rationing (table 1). Attempts to recommend procedures based on these values has resulted in inclusive but impractical decision-making recommendations^{[[iv]]}

Christian et al^{[[v]]} and Tia et al^{[[vi]]} have proposed the use of a triage-scoring tool for allocating ventilator resources during a pandemic. Triage tools are consistent in how they are applied and how decisions are made over time. They involve stakeholders, can be used quickly, and release clinicians from some of the psychological burden of making difficult choices. The disadvantage of static triage tools is that they do not adjust to the variations in resource availability, and may not represent the values of the community. Frolic et al. ^{[[vii]]} found significant gaps in the recommendations when they tried to implement these tools, in that they lack precision, haven't been validated, and don't consider a number of non-clinical variables.

We propose a process where an individual triage officer uses a dynamic triage tool that is kept current and supported by a two-tiered committee. The tool includes triage-scoring information for patients already on ventilators as well as direction on how to deal with nonclinical issues. The goals of the protocol are to meet the nine values outlined by the JCB with the additional value of expediency, and to be practical

enough for urgent implementation during a crisis.

Discussion

Principles and Values:

The European ICU triage guidelines [2] were unable to come to consensus whether the limited resource should be allocated to those who will benefit most or a 'first-in-line' basis. We functioned under the premise that publicly owned or supported health care resources (such as ventilators) are shared by all members of the supporting society, and that the goal of access to shared resources is to improve health. For that reason, the overriding principle is a utilitarian ethic, that the allocation of resources should produce the greatest health benefit. This material principle is chosen over a predominant alternative, which is allocation on a first-come, first-served basis.

The first-in-line alternative is tempting for its potential to free decision-makers of emotional stress. After some consideration, however, it seemed unlikely that an otherwise healthy patient with a high likelihood of successful treatment would be palliated as another patient with poor baseline health and a small chance of survival continues their treatment. Adoption of this alternative seemed to conflict with societal goals and risk putting decision-makers at odds with the protocol. The values used to develop the protocol guideline are listed in Table 1. As noted in the introduction, the values are derived from the JCB recommendations [3] with the addition of the procedural value of expediency. One of the additional challenges in the allocation of critical care resources such as ventilators is that the decision must almost always be made quickly. If the protocol cannot function at the speed that clinician needs the decision, it is of limited value in this environment. The clinician will remain trapped in a conflict of interest that the guideline was meant to mitigate, and will be unable to adhere to a recommended yet unattainable standard, increasing the stress of an already very difficult situation.

Protocol Activation:

The protocol should only come into effect when resources are unable to meet the demand. Prior to invoking the protocol, the institution or regional health authority should make all reasonable efforts to secure additional resources and redistribute the demand.

Decisions covered under the protocol:

While the protocol is in effect, all decisions about ventilator use should be made using the ventilator allocation protocol. The protocol should specify the ventilator pool covered by the protocol. Ideally the decision-making should be centralized for a given

resource pool; for example, if for a given region there is the ability to move patients between centers or to move ventilators between locations, decisions should be made centrally to minimize variations in care between hospitals.

Decision makers:

Physicians providing patient care should not be the decision makers. Their role of patient advocate for all of the patients competing for the resource puts them in a position of perceived conflict. Other groups [[i], [ii]] have advocated for decision by committee to help minimize the burden of decision. We felt that this process would interfere with our value of expediency, and that the experienced Critical Care physician might be better equipped to deal with the emotional burden than committee members taken from other stakeholder groups.

We propose a solution with a three-tiered approach. Time-sensitive decisions are made by a "triage officer," an intensivist on-call for a 24-hour period. The decisions are assisted by a dynamic triage tool and reviewed by a three person administrative committee, with oversight and guidance from a broader stakeholder based protocol committee who creates Hard and Soft Guidelines.

The triage officer is an attending critical care physician who does not have any patient care responsibilities during their on-call period. During their 24-hour on-call period the triage officer makes all decisions about ventilator allocation for the resource pool.

The administrative committee is a group of three clinicians who rotate on-call duties as triage officer. The committee meets daily to review the decisions for the last 24 hours and to review the current status and create a ranking of the ventilated patients using a tool such as the modified SOFA score described by Christian et al[[iii]].

The decision-making values, triage tool, and documentation templates are developed, reviewed and maintained by the protocol committee. The protocol committee is composed of relevant stakeholders, including caregivers and members of the public and is responsible for protocol development and oversight of the administrative committee.

Decision-Making Process:

A narrative of the decision process is outlined in Appendix II.

The decision to offer, withhold or remove ventilatory support is a complex one. Standardization of the process using scoring tools has the advantage of transparency and reproducibility and mitigates invisible rationing. It also helps protect the decision-maker from some of the emotional and potential legal burden of the responsibility.

Unfortunately, there is no scoring system currently available that is able to incorporate all of the variables that should be considered in these types of decisions. The triage officer is guided by patient information that includes past medical history, severity of illness scores and indicators, an understanding of the current ventilator supply and demand, and the severity of illness of patients currently being ventilated. The decision is also guided by the ethical principles and values detailed by the protocol committee.

The Protocol committee's values and principles are communicated as Hard Guidelines and Soft Guidelines. Hard Guidelines include the Substantive values of the protocol (Equity, Trust, Solidarity and Stewardship) and human rights law (e.g.: decisions not be made on the basis of gender, sexual-orientation, race, religion, or age.)

The soft guidelines direct the triage officer around ethical issues that they are likely to encounter based on the discussions of the protocol committee at their inception. The committee will determine its position on issues like: prioritization of healthcare workers, prioritization of caregivers, fair-innings/life-cycle principle, heroism, and populations at risk[[iv]].

Reallocation of resources

In our protocol, we decided that allocation of a ventilator does not confer a guarantee that the patient will continue to have access to the resource. This position is important to the ongoing decision-making process. If resource allocation is committed for the duration of the patient's illness, triage officers will have to anticipate future demands and predict the illness course of each patient. Neither of these is likely to be accurate, and decision-makers might be put in significant moral distress.

The decision to withdraw the resource should trigger a procedure that provides palliation for the patient as well as support for the family.

Appeal of decisions

Due to the urgency of these decisions, an appeal process that defers the decision is not practical. If the clinician disagrees with the triage officer's decision and there is a reasonable way to temporize the patient without removing a resource from another patient, the administrative committee could be assembled to hear the appeal. If there is disagreement and the conditions for hearing the appeal outlined above are not possible, the decision of the triage officer will be final, and be reviewed at a later date by the administrative committee.

Families and personal representatives of the patient should not be allowed to directly appeal to the administrative committee. Such an appeal would most likely be for presenting information that should be

specifically excluded from the decision-making process (e.g., social status, worthiness).

It is important to ensure that the triage officer and administrative committee members are not unduly influenced by emotional appeals, physical or legal threats.

Communication

During a disaster situation, it will be important for institutions to provide information to patients and their families about the increased demand and lack of sufficient resources. It will be particularly important that patients and families are aware of the unpleasant possibility that the patient may have to be removed from the ventilator under certain circumstances. The nature of the protocol, the decision-making process, as well as the values on which the protocol is based should be transparent and well communicated.

Conclusion(s)

In a state of emergency, increased demands for limited resources compel a shift in the standards of care. With preparation and thoughtful deliberation, we can ensure our decisions continue to be consistent with our ethical principles. Efforts to guarantee fairness must be tempered with practical considerations. Decision-makers should be well supported and given guidance, but ultimately the system will have to trust them to do their best in a difficult situation.

Abbreviation(s)

JCB - Toronto Joint Centre for Bioethics

Authors Contribution(s)

Dr. Howes created the original draft of the manuscript. Both authors reviewed and edited the manuscript as well as the protocol.

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Illustrations

Illustration 1

Table 1: Ethical values for consideration during protocol development

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<u>Substantive Values</u>	<u>Procedural Values</u>
<p>Equity* All patients have an equal claim to receive the health care they need under normal conditions. During a pandemic, difficult decisions will need to be made about which health services to maintain and which to defer. Depending on the severity of the health crisis, this could curtail not only elective surgeries, but could also limit the provision of emergency or necessary services.</p> <p>Trust * Trust is an essential component of the relationships among clinicians and patients, staff and their organizations, the public and health care providers or organizations, and among organizations within a health system. Decision makers will be confronted with the challenge of maintaining stakeholder trust while simultaneously implementing various control measures during an evolving health crisis. Upholding such process values as transparency enhances trust.</p> <p>Solidarity* A pandemic influenza outbreak will require a new vision of global solidarity and a vision of solidarity among nations. A pandemic can challenge conventional ideas of national sovereignty, security or territoriality. It also requires solidarity within and among health care institutions. It calls for collaborative approaches that set aside traditional values of self-interest or territoriality among health care professionals, services, or institutions.</p> <p>Stewardship* Those entrusted with governance roles should be guided by the notion of stewardship. Inherent in stewardship are the notions of trust, ethical behaviour, and good decision-making. This implies that decisions regarding resources are intended to achieve the best patient health and public health outcomes given the unique circumstances of the influenza crisis.</p>	<p>Reasonable* Decisions should be based on reasons (i.e., evidence, principles, and values) that stakeholders can agree are relevant to meeting health needs in a pandemic influenza crisis. People who are credible and accountable should make the decisions.</p> <p>Open and transparent* The process by which decisions are made must be open to scrutiny, and the basis upon which decisions are made should be publicly accessible.</p> <p>Inclusive* Decisions should be made explicitly with stakeholder views in mind, and there should be opportunities to engage stakeholders in the decision-making process.</p> <p>Responsive* There should be opportunities to revisit and revise decisions as new information emerges throughout the crisis. There should be mechanisms to address disputes and complaints.</p> <p>Accountable* There should be mechanisms in place to ensure that decision makers are answerable for their actions and inactions. Defense of actions and inactions should be grounded in the other ethical values proposed.</p> <p>Expedient ** The process should facilitate a decision in the timeframe dictated by the clinical situation. Critically ill patients are particularly vulnerable to harm if decisions are delayed.</p>

* Adapted from *Stand on guard for thee – ethical considerations in preparedness planning for pandemic influenza* ². **Additional procedural value.

Illustration 2

Appendix I - Sample protocol:

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Draft Pandemic Ventilator Assignment Protocol

Preamble:

The purpose of this protocol is to outline the decision-making process for allocating ventilators to patients in a situation where the demand for ventilators far outstrips the number of available ventilators.

The protocol attempts to assign the ventilators to patients in a way that maximizes the health benefit derived from the ventilator use. The protocol is in place to ensure that the process is fair and unbiased, transparent, responsible, and practical.

Protocol:

1. Activation of the protocol: This protocol may be activated in a situation where the demand for ventilators outstrips the supply. Before activation, every reasonable effort must be made to shift demand to locations with excess resources and improve the supply of staffed ventilator beds.
 - i. This protocol may be activated by:
 - A. The Program Director in a situation where the demand for ventilator resources is expected to outstrip the supply
 - B. An attending physician working in the intensive care unit who is in a situation where the demand for ventilators is about to be outstripped by the supply
 - ii. To activate the protocol the Program Director or designate is contacted. The Program Director will populate the administrative committee as outlined below and will notify the hospital CEO who will appoint a chair of the Protocol Committee
 - A. If a ventilator allocation decision is required immediately, the Program Director may render a decision as outlined below, functioning as the triage officer on-call.
 - B. If the Program Director is acting in a clinical capacity, he/she will contact an alternate to function as the acting program director in his/her capacity for this protocol.
2. Authority of the protocol: When in effect, this protocol will be used for all ventilator resources within decision-making control. Initially this will be hospital, but may be expanded to the Local Health Region.
3. Ventilator Allocation Administrative Committee:
 - A. Composition:

- i. The administrative committee is made-up of three critical care physicians appointed by the Chair, who is the Critical Care Program Director or designate.
 - ii. The administrative committee members will not be participating in the care of patients who are or may require ventilator support while serving on the committee
 - iii. Members are appointed to the administrative committee at the discretion of the Program Director. It is expected that the members of the team will have to shift regularly as clinicians take-on or come off clinical duty.
- B. Responsibilities:
- A. Administrative Committee Chair:
 - i. The chair will be responsible for maintaining a record of administrative team meetings and decisions.
 - ii. The chair is responsible for making every reasonable effort to ensure that the supply of ventilator support is maximized. This might include, but is not limited to:
 - a. Reallocation and sharing of ventilators within the Local Health Integration Network
 - b. Application for provincial resource support
 - c. Application for federal resource support
 - d. Use of alternative ventilatory supports, including those designed for temporary prehospital ventilatory support, veterinary or research use.
 - iii. The chair will report to the Protocol Committee biweekly, or as requested by the chair of the Protocol Committee.
 - B. Triage Officers – the membership of the Administrative Committee:
 - i. Critical care physicians on the administrative committee will populate a call roster. One member (the Triage Officer) will be on call for ventilator decisions at all times.
 - ii. When the protocol is active, the triage officer will make all decisions on the use of ventilators within the resource pool.
 - iii. When on-call, it is the responsibility of the triage officer to be immediately available by phone at all times.
 - iv. The triage officer will use the documentation tool to outline the factors considered in the decision to provide, refuse, or withdraw the resource.
 - v. The triage officer on-call is not to provide consultative collaboration or recommendations on the care of patients. The role of the triage officer is strictly resource allocation. This condition is to ensure the arms-length nature of decision-making based on the protocol is maintained.
 - vi. If the triage officer is ever put into a situation where there is conflict of interest or perceived conflict of interest (e.g.: family

- member is the patient) the physician will make every reasonable effort to find a substitute for the decision process.
- vii. All team members will meet daily at the discretion of the Chair for situation updates and to review decisions made by the triage officer on-call.
Team members remain current in their knowledge of ventilator supply, demand, as well as the pathophysiology, treatment and prognosis of the infectious disease process initiating the disaster.
- viii. The administrative committee will remain current of the progress of all patients using or requiring ventilator resources to ensure that the allocation of ventilators continues to follow the overriding principle of maximizing health outcomes.
- ix. The committee will maintain a rank-order for ventilated patients to assist the triage officer in decisions of ventilator withdrawal and reallocation.
4. Foundation for decision-making: The decision to allocate ventilator resources is to be based on the following, known as the 'hard guidelines':
- a. The scarce resource of the ventilator will be allocated to the patient who is most likely to benefit from the resource.
 - i. The protocol committee will review the literature for adoption of available critical care triaging tools. (e.g.: Christian et al. Development of a triage protocol for critical care during an influenza pandemic. *CMAJ* 2006;175(11):1377-81.)
 - b. The decision to allocate the ventilator may not be made on the basis of race, religious affiliation, age, sex, sexual orientation, or any other personal characteristic that does not directly impact their prognosis or health status.
 - c. The decision should be consistent with the ethical values of the protocol:
 - i. **Equity:** All patients have an equal claim to receive the health care they need under normal conditions. During a pandemic, difficult decisions will need to be made about which health services to maintain and which to defer. Depending on the severity of the health crisis, this could curtail not only elective surgeries, but could also limit the provision of emergency or necessary services.
 - ii. **Trust:** Trust is an essential component of the relationships among clinicians and patients, staff and their organizations, the public and health care providers or organizations, and among organizations within a health system. Decision makers will be confronted with the challenge of maintaining stakeholder trust while simultaneously implementing various control measures during an evolving health crisis. Upholding such process values as transparency enhances trust.
 - iii. **Solidarity:** A pandemic influenza outbreak will require a new vision of global solidarity and a vision of solidarity among nations. A pandemic can challenge conventional ideas of national sovereignty, security or territoriality. It also requires solidarity within and among health care institutions. It calls for collaborative approaches that set aside traditional values of self-interest or territoriality among health care professionals, services, or institutions.
 - iv. **Stewardship:** Those entrusted with governance roles should be guided by the notion of stewardship. Inherent in stewardship are the notions of trust, ethical behaviour, and good decision-making. This implies that decisions regarding

resources are intended to achieve the best patient health and public health outcomes given the unique circumstances of the influenza crisis.

- v. **Reasonable:** Decisions should be based on reasons (i.e., evidence, principles, and values) that stakeholders can agree are relevant to meeting health needs in a pandemic influenza crisis. People who are credible and accountable should make the decisions.
- vi. **Open and transparent:** The process by which decisions are made must be open to scrutiny, and the basis upon which decisions are made should be publicly accessible.
- vii. **Inclusive:** Decisions should be made explicitly with stakeholder views in mind, and there should be opportunities to engage stakeholders in the decision-making process.
- viii. **Responsive:** There should be opportunities to revisit and revise decisions as new information emerges throughout the crisis. There should be mechanisms to address disputes and complaints.
- ix. **Expedient:** The process should facilitate a decision in the timeframe dictated by the clinical situation. Critically ill patients are particularly vulnerable to harm if decisions are delayed.
- x. **Accountable:** There should be mechanisms in place to ensure that decision makers are answerable for their actions and inactions. Defense of actions and inactions should be grounded in the other ethical values proposed.

- d. If the patient is known to the administrative team member in such a way that there would be a perceived conflict, either in favor or against the patient, the member will excuse them self from the decision. If the member cannot be replaced quickly enough, or if it is not practical to find a team member who is not familiar to the patient (e.g.: the patient is well-known to all members of the team), the administrative team member should make every effort to provide a decision free of bias. When possible, the entire administrative committee may be assembled for such decisions.
 - e. Long-term anticipation of future demand for ventilator resources need not be factored in to the decision because of the Reallocation of Applied Resources policy below.
 - f. **Soft Guidelines:** The Ventilator Allocation Protocol Committee will address anticipated ethical issues and provide guidance to the triage officers. These issues include but are not limited to: prioritization of healthcare workers, prioritization of caregivers, fair-innings/life-cycle principle, heroism, and populations at risk.
5. Reallocation of resources
- i. Allocation of a ventilator to a patient does not convey a commitment of the resource to the patient for the duration of their disease.
 - ii. If there is a change in demand for the resource, a change in the patient's condition resulting in a change in need for ventilation or a change in the patient's prognosis, the ventilator may be removed from the patient at the discretion of the administrative committee.
 - iii. The protocol committee will ensure that there is a procedure in place that provides appropriate palliation and family support.
6. Requests for ventilator resources:

- i. Clinicians caring for patients who require ventilator support when the protocol is active will contact the triage officer on-call through the hospital switchboard.
 - ii. For patients with an immediate need, the clinician may intubate and ventilate with bag-valve device at their discretion while contacting the triage officer on-call.
 - iii. If there are no ventilator resources available to the patient and no other treatment options, the clinician will provide palliative care to the patient.
7. Appeals of decisions: Due to the urgency of these decisions, which may often have to be made in only a few minutes, an appeal process that defers the decision is not practical and might endanger other patients.
 - i. If the clinician disagrees with the triage officer's decision and there is a reasonable way to temporize the patient without removing a resource from another patient, an appeal can be made for a meeting of the entire administrative committee.
 - ii. The appeal is made to the Chair of the administrative committee, who will call the meeting to take place as soon as is feasible.
 - iii. If there is disagreement between the clinician and the triage officer and the conditions for appeal outlined above are not possible, the decision of the triage officer will stand.
8. Anyone who feels that the administrative committee is functioning in a way that is not in keeping with the principles outlined in this protocol should immediately request a review from the protocol committee through the protocol committee chair. The protocol committee may choose to disband and repopulate the administrative committee.
9. Responsibilities of clinicians when the Ventilator Allocation Protocol is in effect: The purpose of this protocol is to allow the clinician to function in their role as patient advocate in a situation where they might otherwise be placed in conflict of interest.
 - i. Clinicians caring for patients who require ventilatory resources must contact the triage officer on-call as soon as possible for allocation of the resource.
 - ii. The clinician is responsible for providing the triage officer with a fair and accurate assessment of the patient's current condition and relevant medical history.
 - iii. The clinician will continue to be the patient's physician. The triage officer will not function as a consultant in the care of the patient.
 - iv. The clinician will provide medical care to the best of his/her ability with the resources made available. He/She will provide all communication to the patients and their families.
10. Deactivation of the protocol and administrative committee disbandment:
 - i. Deactivation of the protocol and disbandment of the Administrative Team is at the discretion of the Program Director, when the demand for ventilators can be met by the supply.

The Program Director may choose to maintain an administrative committee but deactivate the protocol if there is adequate ventilator supply but concern of threatening demand. In this situation clinicians may allocate ventilator resources, but the administrative

committee will continue to meet at the discretion of the Chair to monitor status of the resource.

Illustration 3

Appendix II - Narrative of process in action:

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Doctor X is working in the emergency department during an outbreak of H1N1 that has resulted in a large demand for ventilators. The normal 24 bed ICU has been expanded to 42 beds by annexing the outpatient procedure unit and a portion of the recovery room. The hospital's ventilator supply has been expanded by accessing the provincial pandemic stockpile and with support from the National Emergency Stockpile. No additional resources are available in the foreseeable future.

At 11:30 pm a 27-year-old male arrives in the emergency department with a severe head injury and multiple fractures after a car crash. Shortly thereafter, a 58-year-old female arrives in severe congestive heart failure with an ECG showing a large anterior myocardial infarction. Appropriate care is initiated for both patients, but it rapidly becomes evident that both will require intubation and ventilation.

Dr. X contacts the triage officer on-call through the switchboard. Dr. A responds within a few minutes, and hears the details of the patients' conditions and their relevant medical histories. Dr. A is aware that, due to a patient death earlier in the evening, there is one ventilator available in the hospital. Considering the scores of the patients on the triage tool as well as the Hard and Soft Criteria, Dr. A makes the decision to allocate the ventilator to the 58-year-old female. She is intubated, ventilated, and transported to the cardiac catheterization lab. The 27-year-old male is palliated, succumbing to his injuries 3 hours later.

Two hours later, a 28 year-old mother of two arrives with respiratory compromise and presumed H1N1 requiring ventilatory support. Based on her single organ system failure and SOFA score the triage tool codes her as "Red", as are the majority of the patients currently on the ventilator. During the daily review of ventilated patients by the administrative committee earlier that day, the patient ranked lowest is an 87 year-old gentleman who also has single system respiratory failure due to COPD. Based on the 'soft' principles outlined by the protocol committee related to caregivers and fair-innings, his ventilator is reallocated to the new patient while he is palliated.

The next day, the administrative committee meets to review the current status of the ventilator supply, as well as the medical status of the ventilated patients. They discuss each of Dr. A's decisions and provide feedback and thoughts. Later in the week, the chair of the administrative committee is scheduled to meet with the Protocol Committee to review ongoing issues and anticipated problems.

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