Ethical Considerations for Decision Making Regarding Allocation of Mechanical Ventilators during a Severe Influenza Pandemic

Prepared by the Ventilator Guidance Workgroup for the Ethics Subcommittee of the Advisory Committee to the Director

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INTRODUCTION

This document provides ethical guidance that the Ethics Subcommittee of the Advisory Committee to the Director, Centers for Disease Control and Prevention (CDC) proposes as a foundation for decision making specific to allocation of mechanical ventilators during a severe pandemic influenza. It is intended to supplement previous guidance written by the Ethics Subcommittee, *Ethical Guidelines in Pandemic Influenza*, and released by CDC in 2007 (1). The 2007 document was developed in response to a request from CDC that the Ethics Subcommittee address ethical considerations in vaccine and antiviral drug distribution prioritization and in the development of interventions that would limit individual freedom and create social distancing (in discourse on pandemic influenza, often referred to as non-pharmaceutical or community mitigation interventions). After release of the initial ethics guidance document, numerous public health stakeholders requested that CDC specifically address ethical issues for allocation of mechanical ventilators. This current document is not intended to comprehensively revisit all of the topics and issues promulgated in the 2007 document; instead, it is intended to supplement the initial document. Circumstances and major issues specific to allocation of mechanical ventilators as well as issues which require alternative ethical guidance from that proposed in the original guidance form the basis for this supplemental document.

Difficult decisions are made on a regular basis in both the practice of public health and clinical medicine; however, the process for decision making, including the framework and reasoning that support ethical choices, may not always be clearly articulated. We appreciate that while ethical guidelines can articulate guidance and considerations that need to be taken into account, policy decisions need to be set by responsible officials, with input from scientists and the public. The intent of this document is to provide decision makers at all levels—federal, tribal, territorial, state, and local—with guidance for ethical points to consider when life-sustaining healthcare resources are limited due to a severe pandemic influenza. This document highlights ethical principles relevant to allocation of ventilators and discusses some of the advantages and disadvantages inherent in different approaches to allocation. Some of the approaches are sufficiently problematic that we suggest that they not be used to guide decisions. Other approaches have positive and negative aspects that must be considered. In the interest of encouraging broader public deliberation about ethically contentious matters, we refrain from making specific recommendations and instead highlight these issues and controversies. Although this guidance does not provide simple, direct recommendations, we hope that it will encourage use of a fair and equitable process for making policy choices.

This document addresses conditions during a severe pandemic. However, there is no standard definition of a severe pandemic or list of features to distinguish it from a pandemic. The term pandemic refers largely to a geographic development: an epidemic that has spread beyond its original region to several countries or continents and that effects a large portion of the population because few people have pre-existing immunity to the causative pathogen. Pandemics, although potentially serious public health events,
rarely call for the kind of emergency policies discussed here. In the context of this
document, a pandemic becomes severe when the demands for treating patients
significantly exceed the system’s capacity despite attempts to increase surge capacity.
This moment will vary by disease and by different communities or regions experiencing
the same disease.

The timeliness of this discussion of ethical issues in pandemic influenza is highlighted by
the emergence of pandemic (H1N1) 2009 influenza. As of September 2009, pandemic
(H1N1) 2009 virus is the predominant influenza virus in circulation worldwide. This
virus was officially declared by the World Health Organization as the cause of a
pandemic in June 2009. Disease severity appears to be generally similar to the severity
of recent seasonal influenza, although different age groups have been predominantly
affected, with most cases and most severe cases occurring in older children and adults
less than 65 years of age. ¹ If the pandemic (H1N1) 2009 virus becomes more widespread
or more severe than during spring and summer 2009, it is possible that some communities
may experience shortages of mechanical ventilators for adult or pediatric use.

KEY ASSUMPTIONS

The guidance proposed in this document is based on a number of assumptions regarding
severity of illness and the availability of resources. It is intended only for circumstances
when people with severe acute respiratory failure far outnumber available and adequate
mechanical ventilator supply. For most U.S. communities, such extreme imbalances are
only anticipated in special circumstances (e.g., if pandemic (H1N1) 2009 influenza
becomes more widespread or more severe). Federal, tribal, territorial, state, local, and
private entities have undertaken extensive preparedness activities and supported rapid
advancement of vaccine and antiviral treatments to reduce the potential burden of a
severe pandemic influenza on communities. Advances have also been made in increasing
the supply of ventilators. Currently the American Association for Respiratory Care has
estimated that there are between 65,000-105,000 full-feature mechanical ventilators in the
United States. ² Some states and other groups have purchased additional ventilators for
surge demand. In addition, there has been significant federal investment to procure and
stockpile additional ventilator assets. Despite these crucial activities, it is possible that in
the event of a severe pandemic influenza many hospitals and other healthcare facilities
will not have adequate numbers of ventilators to support a major disaster response.

During a severe pandemic influenza, many patients with respiratory failure who are able
to receive mechanical ventilation (and all associated supportive critical care components)
may survive, while patients with respiratory failure who do not receive mechanical
ventilation are likely to die. Thus, a major underlying assumption for this document is
that advanced critical care will save lives during a severe pandemic influenza. This
assumption is based on experience with avian H5N1 influenza virus, severe acute

¹ Information on cases of pandemic (H1N1) 2009 influenza is posted at http://www.cdc.gov/h1n1flu/.
² In August 2009, HHS and the American Association for Respiratory Care began a survey to obtain a more
precise count of the number of ventilators in U.S. hospitals. More information on the survey can be found
respiratory syndrome (SARS), and acute respiratory distress syndrome (ARDS).

Although the majority of patients infected with H5N1 influenza who received mechanical ventilation have not survived (2), many persons infected with SARS who received mechanical ventilation during the 2003 outbreak did survive (3). Moreover, 40-70% of patients with acute respiratory failure (including acute lung injuries and ARDS which is predominant in current H5N1 cases) survive in intensive care units in U.S. hospitals under non-pandemic circumstances (4). Most experts agree that the vast majority of people with ARDS who do not receive mechanical ventilation will likely die.

This guidance is also predicated on the assumption that cases of pandemic influenza infection will occur in waves and most likely a well-matched vaccine will not be available until the second wave. A pandemic wave is defined as a series of community outbreaks that occur nearly simultaneously across the country. It is expected that pandemic waves will occur in the spring, fall, or winter, and that more than one wave is likely. In 1918-19, for example, there were three pandemic waves, and in 1957 and 1968 there were two waves. Periods between waves (typically measured in months) are characterized by very little disease and can be a time of recovery and preparedness for a subsequent wave. For example, following the initial wave of pandemic (H1N1) 2009 influenza in North America, public health authorities prepared guidance for patients, clinicians, and other groups, and monitored first-wave influenza activity in the Southern Hemisphere.3

During a severe pandemic influenza it is anticipated that resources will be overwhelmed in the first or second wave of illness as the entire community will be at risk for illness. Equipment for emergency respiratory care, including ventilators, may be in full use and no longer available to additional patients by the first or second wave of a severe pandemic influenza, depending on the geographical spread and timing of the waves, the symptomatology of the disease, the availability of pandemic vaccine, and the local effectiveness of community mitigation strategies. This guidance assumes that ventilators may be in short supply in some communities as early as prior to or during the peak of the first wave of a severe pandemic influenza.

The need to make difficult decisions during a severe pandemic influenza will most likely occur in an environment of overall limited public health resources. Considerable costs are associated with stockpiling, maintaining reserve ventilators, and funding training of personnel needed to operate ventilators skillfully and safely. The decision by states, regions, healthcare systems, or hospitals to augment mechanical ventilation capacity (and all associated critical care elements) for emergency use during a severe pandemic influenza should be made within the larger context of everyday public health and clinical obligations, as well as broader community-based emergency preparedness and response resource needs. This guidance assumes that individual communities will need to balance pandemic-preparedness requirements with other healthcare and public health needs.

**ROUTINE VERSUS EMERGENCY PRACTICE**

3 See [http://www.cdc.gov/h1n1flu/](http://www.cdc.gov/h1n1flu/) for examples of guidance documents.
The central ethical requirement of routine clinical practice is competence. Healthcare professionals should be competent to perform the functions of their professional practice and make continuing efforts to maintain their level of competence. In general, the professional should not perform functions that lie outside the boundaries of his or her specialty. Healthcare professionals also have a fiduciary duty to patients. This requires undivided loyalty to the health interests of the patient. Any actual, potential or apparent competing loyalty must be disclosed to the patient.

Public health emergencies have an impact on each of these ethical standards. During severe pandemics it may be necessary to call upon health professionals and even non-health professionals to temporarily perform tasks that lie outside the bounds of their certification (or even competence). A public health emergency also has an impact on healthcare professionals’ fiduciary duty to patients. The central purpose of public health practice is to maintain the health of populations. Because of the need to establish priorities to maximize the health of the public during a public health emergency, practicing physicians may be constrained in acting in the best interests of particular patients. During public health emergencies physicians may also be required to act contrary to the liberty interests of particular patients. For example, they may have to report to authorities individuals who would be considered candidates for quarantine or isolation. These constraints are not alien to usual medical practice. Healthcare providers are accustomed to rules establishing priorities (e.g., rules pertaining to admitting patients to intensive care units) and are obliged in many jurisdictions to report patients to authorities in certain circumstances (e.g., in suspected cases of child or elder abuse or when patients are a danger to themselves or others and need to be involuntarily committed).

A public health emergency, such as a severe pandemic influenza, creates a need to transition from individual patient-focused clinical care to a population-oriented public health approach intended to provide the best possible outcomes for a large cohort of critical care patients. The decision to begin the transition from usual critical care procedures to emergency mass critical care should occur when there is a substantial extreme mismatch between patient need and available resources, that is, when the numbers of critically ill patients surpass the capability of traditional critical care capacity.

The term triage is commonly applied to the process of sorting, classifying, and assigning priority to patients when available medical resources are not sufficient to provide care to all who need it. Triage has been used in situations such as natural disasters, deadly epidemics, and battlefield situations, where shortages are extreme and people die who might be saved if they had access to the level of medical care available in ordinary clinical circumstances. The decision to initiate triage plans is usually made by specific governmental authority within local or state emergency management systems only after all reasonable efforts to augment resources have been exhausted.

Devereaux and colleagues have recently published guidance regarding use of triage during mass critical care emergency events when surge capacity has become overwhelmed in a nation, state or region and resources are inadequate to meet patient
care needs (5). They recommend that triage plans be invoked after all attempts at
resource procurement have failed and when all area hospitals are facing a similar short-
fall. Triage plans should be based upon a graded response that matches the need resulting
from the public health emergency and that all impacted hospitals have a uniform response
for providing mass critical care. This would be considered the most extreme of situations
and the guiding principle is that the provision of usual critical care, when able to meet
demand, is always the preferred approach. Triage plans should remain in effect only until
the imbalance between need and resources is remedied and all hospitals are able to
provide safe critical care. Return to previous standards of care is warranted when critical
resources or infrastructure are augmented or when the need abates.

Devereaux and colleagues suggest that the following conditions be present to initiate the
triage process (5):

- Declared state of emergency or incident of national significance
- Initiation of national disaster medical system and national mutual aid and resource
  management
- Surge capacity fully employed within healthcare facility
- Attempts at conservation, reutilization, adaption, and substitution are performed
  maximally
- Identification of critically limited resources (e.g., ventilators, antibiotics)
- Identification of limited infrastructure (e.g., isolation, staff, electrical power)
- Request for resources and infrastructure made to local and regional health
  officials
- Current attempt at regional, state, and federal level for resource or infrastructure
  allocation

In September 2009 the Institute of Medicine (IOM) released Guidance for Establishing
Crisis Standards of Care for Use in Disaster Situations (6). This report provides
guidance for state and local public health officials, healthcare facilities, and professionals
on the development and implementation of policies for crisis standards of care in
disasters, both naturally occurring and manmade, in which resources are scarce. The
report identifies key elements that should be included in crisis standards of care protocols
and potential triggers for adopting these standards. The IOM recommends developing
consistent crisis standards of care protocols that are built on strong ethical and legal
underpinnings with input from community and provider stakeholders, and strong
coordination among federal, tribal, state and local health officials. This report addresses
a number of issues also considered in this guidance, including the importance of
establishing fair and equitable processes that are transparent, consistent in application
across populations and among individuals, and proportional to the emergency and degree
of scarce resources.

**ROUTINE VERSUS EMERGENCY PRACTICE: PRIORITIES FOR
VENTILATOR ALLOCATION**

Historically, during routine clinical practice the organizing principle for ventilator
distribution, as well as for the distribution of most therapeutic procedures and
interventions has been the minimization of adverse outcomes, including hospitalization and death. Typically all patients who have a medical need for mechanical ventilation and who consent to treatment (or have the concurrence of a surrogate) are provided this type of care.

If a scarcity of ventilators occurs during a severe pandemic influenza, ventilators will need to be allocated according to different guidelines than during usual clinical care (7). During a public health emergency, there will be competing priorities for ventilator use from patients whose need for a ventilator is unrelated to influenza, including the need for chronic ventilator use. In addition, decisions will need to be made regarding whether patients should be removed from a ventilator to make way for others who may have a better chance of recovery, and whether there should be suspension of non-emergency surgical procedures that might create a need for ventilator therapy.

The principle of sickest first is routinely employed to triage patients presenting for care in the emergency department, where staff time is scarce but medical resources are not. Other patients will still receive care, but they must wait. During a severe pandemic influenza that creates a critical shortage of ventilators, however, this strategy may lead to resources being used by patients who ultimately are too sick to survive.

First-come, first-served is used to allocate intensive care unit (ICU) beds during routine clinical circumstances. Once a patient is in the ICU, they are generally not transferred out of the ICU if they still need intensive care unless the patient or surrogate agrees to forego life-sustaining interventions. That is, fiduciary duties to existing patients take priority over potential benefits to other patients. During ordinary clinical care, the healthcare system generally can accommodate patients with a very poor prognosis who require an ICU bed for many days and who ultimately may not survive. Other patients are still able to receive intensive care if needed. However, the situation would be different if ventilators are in extremely short supply during a severe pandemic influenza; other patients, who may have a much better prognosis if they receive intensive care, will not have access to it. After a public health emergency is declared, individual autonomy may be superseded by rules that favor the overall benefit to the population and society.

In order to use scarce resources most efficiently, in some clinical situations where there is a severe shortage of life-saving medical resources, priority is given to those who are most likely to recover after receiving them. When treating soldiers with life threatening injuries, medics give priority to those who are most likely to survive with a relatively small amount of scarce resources. Such triage is carried out without regard to rank. Similarly during cholera epidemics in refugee camps, limited supplies of intravenous fluid are given not to those with the most severe dehydration, but instead to those with moderate dehydration who will likely recover with small amounts of fluid (8).

In the Ethics Subcommittee’s previous ethics guidance document, Ethical Guidelines in Pandemic Influenza, which addressed distribution of vaccines and antiviral medications, the principle of preserving the functioning of society was given greater priority than preventing serious complications (1). This is because vaccines and antiviral medications
are predominantly used to prevent or lessen illness and thus can be useful in maintaining or restoring health for groups identified as essential for preserving the functioning of society. However, decisions about priorities for ventilator distribution pose a different situation. Ventilators are an essential life-saving intervention. Patients with severe pandemic influenza-related respiratory failure who do not receive a ventilator are likely to die, and those who receive one are likely to have a long recovery period if they survive. Thus, prioritizing based on preserving the functioning of society is not as relevant to decision making about distribution of ventilators as with vaccines and antiviral medications. Those who are ill enough to require ventilator therapy are unlikely to recover sufficient function to be able to contribute to the preservation of the functioning of society—at least not during the ‘wave’ of the pandemic during which they fell ill.

WHAT PRINCIPLES SHOULD GUIDE VENTILATOR ALLOCATION?

Basic Biomedical Ethical Principles
A consideration of the basic biomedical ethical principles is a useful starting place for decision making about ventilator allocation. These basic principles include respect for persons and their autonomy, beneficence, and justice.

Respect for Persons and their Autonomy
The principle of respect for persons and their autonomy requires physicians to obtain informed consent from patients and to respect their informed refusal. During ordinary clinical practice, it is highly unusual to discontinue or withhold mechanical ventilation without the consent or concurrence of the patient or surrogate. During a severe pandemic influenza, public health mandates may override patient autonomy. If a public health emergency is declared and emergency guidelines are triggered, treating physicians may be constrained by these guidelines. In addition, if there are severe shortages of ventilators, ICU beds, and staff, some patients with respiratory failure who desire mechanical ventilation will not receive it. Regardless, patients still must be treated with dignity and compassion. This will include the provision of palliative care, discussed in more detail later.

Beneficence
The principle of beneficence requires physicians to act in the best interests of their patients and to subordinate their personal and institutional interests to those of the patient. During a severe pandemic, however, physician decisions will be guided by benefits to the population as a whole, not to the individual patient. However, within the constraints of public health mandates, treating physicians will still have obligations to provide benefits to individual patients. These obligations include the provision of palliative care and non-abandonment.

Justice
The principle of justice during a severe pandemic has several dimensions. First, physicians and public health officials should “steward resources during a period of true scarcity (9).” Second, the distribution of benefits and burdens should be equitable;
allocation decisions should be applied consistently across people and across time.

Responses to a pandemic should not exacerbate existing disparities in health outcomes, as unfortunately has occurred in some past public health emergencies (9). Indeed, during a public health emergency the perception of fairness is essential for citizens to accept mandatory public health measures (10).

Fair process or procedural justice is especially important during a public health emergency because mandatory public health measures may be adopted. Fairness and perceptions of fairness are essential for sustaining public trust and willingness to comply with public health regulations. Fairness requires the absence of unjustified favoritism and discrimination. Citizens may be more likely to subordinate their own personal self-interest to the common good if they believe the same rules apply to all. Conversely, if people believe that others are receiving special consideration, they may be less likely to accept mandatory public health measures. Even the perception of favoritism may undermine willingness to sacrifice for the sake of the greater good of the community.

As described in the Ethics Subcommittee’s prior pandemic influenza ethics guidance (1), procedural justice requires the following:

- Consistency in applying standards across people and time (treating like cases alike)
- Decision makers who are impartial and neutral
- Ensuring that those affected by the decisions have a voice in decision making and agree in advance to the proposed process. This would require meaningful public engagement, as has been carried out with other aspects of pandemic planning (11-13). These public engagement exercises have moved beyond public education and soliciting input at public hearings to include balanced learning from credible sources on all sides of an issue, neutral facilitation, and opportunities for frank dialogue and genuine deliberation, and linkage to the government decision-making process. This process allowed both organized stakeholders and ordinary citizens to provide meaningful input into policy choices that involved tradeoffs among conflicting values.

Procedural justice is closely related to other procedural guidelines, such as transparency and accountability, which help to establish the legitimacy of public health policies. Transparency refers to making policies and their rationale available to the public. Accountability refers to explaining and justifying policies and taking responsibility for the consequences of actions and decisions. Prior to a pandemic influenza the public needs to know how ventilators will be allocated in order to trust that allocation is fair. As such, it is the responsibility of public health leaders to provide timely information regarding the pandemic, even when there is uncertainty due to the lack of data. Transparency will be enhanced if triage priorities and policies are explicit and if the public has ready access to the triage guidelines, the data and reasoning underlying them, and the process by which they were derived. Public input into the formulation of triage guidelines is more feasible before a pandemic occurs than during it.
In order to promote transparency and accountability, there should be a retrospective review process to ensure that triage guidelines are applied accurately, consistently, and fairly. This review would also serve as a quality-improvement process. However, because of the need for triage decisions to be made in a timely manner, it would be impractical for the review process to function as an appeal process for real-time decisions (9).

In addition, policies for allocation of resources during a pandemic should involve the following:

- Proactive planning. Public health officials should maximize preparedness in order to minimize the need to make allocation decisions later after a pandemic occurs.
- Ensuring that decisions are adequately reasoned and based on accurate information. This would require guidelines to be based on the best available evidence. Because adequate evidence to guide policy may not exist before a pandemic strikes, it is essential to carry out research during a pandemic to provide evidence to inform public health policies. Such research, of course, needs to be carried out in ways that minimize risks to participants, respect them as persons, and select participants equitably. Research should never conflict with the public health emergency response.
- Processes to revise, improve, or correct approaches as new information becomes available. For instance, this might involve retrospective review of allocation decisions in individual cases to adjust triage standards for future allocations.

Specific Ethical Considerations

In addition to the basic biomedical ethical principles discussed above, there are a number of more specific ethical considerations that will be useful in guiding decision making about allocation of ventilators. These considerations focus on differing approaches to maximizing and distributing benefits.

Maximizing Net Benefits

Historically, allocation decisions in public health have been driven by the utilitarian goal of maximizing net benefits (14). Although this broad principle can be specified in numerous ways (i.e., maximizing the number of lives saved, maximizing years of life saved, maximizing adjusted years of life saved), several recent guidelines for allocating life support during a public health emergency have specified it narrowly as “maximize the number of people who survive to hospital discharge (5, 9, 15).”

Maximize the number of lives saved - The utilitarian rule of maximizing the number of lives saved is widely accepted during a public health emergency (16). Prioritizing individuals according to their chances for short-term survival also avoids ethically irrelevant considerations, such as race or socioeconomic status. Finally, it is appealing because it balances utilitarian claims for efficiency with egalitarian claims that because all lives have equal value the goal should be to save the most lives.
Working groups in Ontario, Canada and New York State have proposed modifying a relatively simple mortality prediction model—the Sequential Organ Failure Assessment (SOFA) score—to determine an individual’s priority for access to a ventilator (15, 17). No model can predict with perfect accuracy which patients will benefit from mechanical ventilation during a severe pandemic influenza and which will not. When selecting a predictive score model, physicians and policy makers need to take into account several considerations, including feasibility, ease of use, accuracy, validity, objectivity, and transparency. The predictive score model employed should be based on the best available science; hence research needs to be carried out to validate and potentially modify whatever predictive score model is employed.

Any predictive score model yields probabilities of outcomes, which may not accurately predict the outcome for any one individual. This concern has limited the use of probabilistic scoring systems to make treatment decisions during routine clinical practice. However, the rationale for their use is stronger during a severe pandemic influenza, when the goal is to maximize population-level outcomes. Such an objective approach during a severe pandemic may also be viewed by the public as fairer than decisions based on more subjective criteria.

Maximizing years of life saved - A broader conceptualization of maximizing net benefits is to consider the years of life saved in addition to the number of lives saved. Assuming equal chances of short term survival, giving priority to a 60-year old woman who is otherwise healthy over a 60 year-old woman with a limited life expectancy from severe co-morbidities will result in more “life years” gained. The justification for incorporating this utilitarian claim is simply that, all other things being equal, it is better to save more years of life than fewer.

The principle of maximizing years of life saved has been used in organ transplantation to exclude as recipients persons with such severe co-morbidities that they have a very poor prognosis for survival even if they receive a transplant. Furthermore, this principle has also been invoked in some published guidelines regarding triage of ventilators during a severe pandemic influenza to exclude certain poor-prognosis subgroups of patients from access to ventilatory support. For example, one group advocates denying ventilatory support to persons who are functionally dependent from a neurologic impairment (18). Another group recommends excluding those older than 85 years of age and those with New York Heart Association Class III or IV heart failure (5, 15). These recommendations have been criticized because the criteria for exclusion (age, long-term prognosis, and functional status) are selectively applied to some patients, rather than to all patients who require life-sustaining interventions. Such selective application violates the principle of justice because patients who are similar in ethically relevant ways are treated differently. Categorical exclusion may also have the unintended negative effect of implying that some groups are “not worth saving,” leading to perceptions of unfairness. These concerns might be addressed by keeping as eligible all patients who require mechanical ventilation but allowing the availability of ventilators to determine how many eligible patients receive one.
Maximizing adjusted years of life saved - A still more nuanced utilitarian approach would be to maximize years of life after adjusting for the quality of those years. However, predicting quality-adjusted life years (QALYs) or disability-adjusted life years (DALYs) for an individual patient requires considerable clinical information about an individual and would not be feasible when making decisions regarding intubation and mechanical ventilations in an emergency department or ambulance during a public health crisis (19, 20).

Although the utilitarian goal of maximizing net benefits is an important public health principle, we conclude that ethically, allocating scarce resources during a severe pandemic by only considering chances of survival to hospital discharge is insufficient because it omits other important ethical considerations.

Social Worth
Additional principles that have been used to allocate scarce resource are concerned with the distribution of benefits among patients, rather than the aggregate level of benefit. This has included criteria based on social worth and instrumental value.

Broad social value - Broad social value refers to one’s overall worth to society. It involves summary judgments about whether an individual’s past and future contributions to society’s goals merit prioritization for scarce resources (16). When dialysis was first introduced, social value was a key consideration in allocating scarce dialysis machines. Patients who were professionals, heads of families, and caregivers received priority over others who were perceived as less worthy (21). The public firestorm in response to revelations that social worth was a key factor in the Seattle Dialysis Committee’s deliberations partly led Congress to authorize universal coverage for hemodialysis (22).

In our morally pluralistic society, there has been widespread rejection of the idea that one individual is intrinsically more worthy of saving than another. Many writers advocate the egalitarian view that all individuals have an equal moral claim to treatment regardless of whether they can contribute measurably to broad social goals (23). As one philosopher put it, one’s "dignity as a person...cannot be reduced to his past or future contribution to society (24)."

Instrumental value: The multiplier effect - Instrumental value refers to an individual’s ability to carry out a specific function that is viewed as essential to prevent social disintegration or a great number of deaths during a time of crisis. It has also been described as “narrow social utility (16)” and the “multiplier effect (14).” Federal guidance on prioritization of pandemic vaccines adopted this principle by recommending that priority be given to individuals essential to the pandemic response (including public health and healthcare personnel) and to those who maintain essential community services (25, 26). The ethical justification is that prioritizing certain key individuals will achieve a "multiplier effect" through which more many lives are ultimately saved through their work.
Instrumental value must be distinguished from judgments about broad social worth. Individuals who have instrumental value for one type of public health disaster may not have instrumental value during another type of crisis. For example, vaccine manufacturer workers would not be prioritized during the public health response to a terrorist attack with chemical or nuclear weapons. Individuals are prioritized not because they are judged to hold more “intrinsic worth,” but because of their ability to perform a specific task that is essential to society. In this sense, instrumental value is a derivative allocation principle; it is desirable because it ensures an adequate workforce to achieve public health goals. Even critics of allocation based on broad social value accept the use of instrumental value in certain circumstances (23).

However as indicated previously, using instrumental value may be ethically problematic for decision making about allocation of ventilators. In general, to justify a restrictive public health measure, there must be good evidence that the measure is necessary and will be effective (27). Most important, will individuals with respiratory failure who receive priority for mechanical ventilation recover in time to re-enter the work force and achieve their instrumental purposes during the pandemic wave? Because of the uncertainty about which key personnel will be in short supply and whether they will recover in time to achieve their instrumental value, this criterion would likely be highly controversial.

The Life Cycle Principle
The life cycle principle grants each individual equal opportunity to live through the various phases of life (28). This principle has also been called the “fair innings” argument and “intergenerational equity (29).” In practical terms, the life cycle principle gives relative priority to younger individuals over older individuals. The ethical justification of the life cycle principle is that it is a desirable as a matter of justice to give individuals equal opportunity to pass through the stages of life—childhood, young adulthood, middle age, and old age (28). The justification for this principle does not rely on considerations of one’s intrinsic worth or social utility. Rather, younger individuals receive priority because they have had the least opportunity to live through life’s stages.

Empirical data suggest that when individuals are asked to consider situations of absolute scarcity of life sustaining resources, most believe younger patients should be prioritized over older (30). One advocate for a life cycle approach declares: “it is always a misfortune to die...it is both a misfortune and a tragedy [for life] to be cut off prematurely (31).”

Some critics contend that the life cycle principle unjustly discriminates against older individuals. However, others respond that this principle is inherently egalitarian because it seeks to give all individuals equal opportunity to live a normal life span. It applies the notion of equality to individuals’ whole lifetime experiences rather than just to their current situation (29). In their view, unlike prioritization based on gender or race, everyone faces the prospect of aging and everyone hopes to move through all stages of life (28). However, when public input was sought in Seattle-King County on values and priorities for delivery of medical services during a severe pandemic influenza, most
participants agreed that the number of years a person would live if they survive should
only be a factor in the absence of other priority criteria (13).

Fair Chances versus Maximization of Best Outcomes
Traditionally, public health emergency response has focused on maximizing population
health, for example, through saving the most lives. However, some have challenged this
assumption and have suggested that fairness considerations be more explicitly included in
policy decisions, even if doing so does not maximize population health (32-34). Conflict
between providing “fair chances” and maximizing “best outcomes” arises when there are
relatively small differences in expected benefits that may be gained by people in different
prioritization groups. In the case of access to ventilators, if ventilators are provided only
to people with the highest probability of surviving and denied to those with a somewhat
less, but still significant chance of survival, then we may save more lives but we do so by
asking some individuals to give up all chance of survival. Some argue that this approach
is not fair to those who give up their chance of survival, even though more total lives are
saved. Some propose an alternative approach (e.g., a “weighted lottery”) to provide more
people with a fair chance at survival, even if it would not maximize the number of lives
saved (32, 33). Objections to the fair chances approach include: lack of clarity and
transparency about what criteria are being used to make choices and practical limitations
in applying a complex, weighted lottery in an emergency setting. A deliberative public
engagement process may be required to establish appropriate weights (35).

Incorporating Multiple Principles
Because several different considerations for allocating ventilators during a severe
pandemic influenza may be justified, some writers have proposed that several
principles—saving the most lives, saving the most life-years, and giving individuals
equal opportunity to live through life’s stages—be combined into a composite priority
score (7). Although more complex than a single principle allocation system, a multi-
principle allocation system may better reflect the diverse moral considerations relevant to
these difficult decisions. In addition, this approach avoids the need to categorically deny
treatment to certain groups, a problem that one legal scholar calls a “political and legal
minefield (36).” This multi-principle approach can take into account the degree of
scarcity—patients with lower priorities can receive ventilators until no more remain.
However, a multi-principle allocation approach that relies on a composite priority score
raises difficult questions regarding what principles should be represented in the
composite score and how to weight the various components that contribute to the score.
People may legitimately disagree about the weights. It will be important to have a broad
public deliberation about the various tradeoffs among the principles in order for such an
index to be accepted as legitimate. The criteria of fair process and procedural justice
criteria discussed previously need to be followed. Most importantly, the values and
priorities of community members who will be impacted by decisions about allocation of
scarce life-saving resources must be considered in the development of triage plans.

WHO SHOULD MAKE VENTILATOR ALLOCATION DECISIONS?
A lesson learned in routine medical practice is applicable for public health emergencies. Healthcare professionals will, in general, attempt to interpret priority rules in a way that favors the access of their own patients to scarce life-saving therapies such as organ transplants and placement in the ICU (with ventilator therapy). It is very helpful, in the interest of fair distribution of such therapies to have in advance well-formulated prioritization guidelines that are interpreted (in particular cases) by professionals who have no fiduciary commitment to the individual patient.

Separating the roles of clinical care and triage allows physicians who are caring for patients with ventilatory failure to continue to maintain loyalty to their patients and to act in their best interests (37). This separation of roles will mean that treating physicians will not need to make a decision to withhold mechanical ventilation from patients who still desire it. Instead, a triage officer could make decisions impartially based on the overall outcomes for the population according to pre-determined guidelines, while the treating physician is free to act in the best interests of the individual patient, within the constraints of the public health emergency. Constant communication with the treating provider and establishment of prioritization of patients to receive a critical resource is necessary in the event a ventilator or other scarce resource becomes available (5).

The role of the triage officer will need to be specified in some detail in advance of a pandemic. Questions that need to be addressed include what training they will receive, what decision support and consultation and emotional support will be available, what appeals will be permitted, and how decisions will be reviewed for quality improvement.

**OTHER CONSIDERATIONS**

**Uniform Decision Criteria versus Local Flexibility**

Effective emergency response requires coordination of various partners, including government authorities at the local, state, territorial, tribal, and federal levels, not-for-profit organizations, and public and private sectors. The need for coordination is strongest in an acute catastrophic emergency that overwhelms basic social systems for health and safety. Coordination of efforts is enhanced when there are uniform, consistent criteria for access to live-saving interventions in regions that represent functional medical referral areas. Such consistency across hospitals promotes fairness. Uniform criteria help ensure that cases that are similar in ethically and clinically relevant ways are treated similarly. In contrast, reliance upon a variety of criteria established at the local level has the potential to undermine the principle of fairness if individuals living in contiguous areas receive different treatment based on non-medical criteria. Making decisions about ventilator distribution and triage using a standard framework for incident management creates a clear hierarchy of accountability and responsibility, facilitates consistent communication, and helps minimize differential treatment of patients. Strongly encouraging all institutions within a region to adopt uniform triage plans for access to ventilators, and making this expectation clear in advance of an event, creates a common framework for providers and enhances public trust by minimizing the potential for conflicting decisions from different partners or jurisdictions. Also, uniform treatment
criteria may help address the moral hazard that an institution may "free ride" upon others, rather than sharing the burden of making appropriate plans in advance.

Healthcare professionals and community representatives should be actively engaged in the development of uniform criteria for access to ventilators and the rationale supporting the criteria should be clearly articulated in advance of a pandemic influenza. During an event of long duration, it is important to demonstrate an ongoing commitment to transparency by continuing to seek community input on the adequacy of the criteria and whether the criteria are being applied consistently. Additionally, steps should be taken to ensure that all patients reaching the highest priority group have equitable access to the pool of ventilators. This assures that allocation does not exacerbate pre-existing inequalities in access to health care or disproportionately impact vulnerable populations. For example, health jurisdictions should work with institutions to address issues of fairness recognizing that institutions with trauma centers and larger intensive care services will bear a disproportionate burden.

It is important to recognize the need for flexibility and ongoing evaluation of whether a coordinated decision making process and uniform criteria are indicated as there may be instances where specific local needs should be taken into consideration. Institutions should be allowed to opt out of coordinated ventilator distribution plans when there is no evidence to support a belief that coordination of decision making will contribute substantially to fairness of access to care. However, institutions should be able to make their reasons for implementing different criteria transparent. In general, state and local health departments are strongly encouraged to work with hospitals and with each other to implement uniform triage processes for ventilator distribution. The presumption should be to follow uniform guidelines in the interest of fairness, consistency, and coordination of efforts. State and local laws may provide authority for public health officials to control, restrict, and/or regulate the use of private property, such as ventilators, for the general welfare and may vary from jurisdiction to jurisdiction. Officials should understand the scope of their authority during emergencies.

**Obligations to Healthcare Professionals**

Clinicians and hospitals have a responsibility to prepare for emergencies, clarify expectations about the roles of physicians and staff during an emergency, and plan and provide for necessary support so clinicians may continue to provide care. Hospitals and area health jurisdictions should ensure clinicians have timely and accurate information, and ensure that any reluctance to provide care is not based on a misunderstanding, such as misunderstandings about liability during an emergency. The right to practice medicine is conveyed at the state level and standards of practice are enforced at the state level. To the extent that medical care during an emergency may be deficient compared with standard of care, health jurisdictions and boards of medicine should address concerns of physicians about immunity from liability and regulatory oversight when practicing under regionally or nationally required uniform criteria and processes. Hospitals and health jurisdictions should clarify their role in supporting legal protections for tort liability in the jurisdiction, and provide information about federal immunity from tort for some actions undertaken during a public health emergency (Public Readiness and Emergency

During a severe influenza pandemic and declared public health emergency there may be a severe shortage of healthcare professionals skilled in providing intensive care. In the planning phase increasing the number of individuals trained or cross-trained to manage ventilator-dependent patients should be a goal. These staff should also be trained to utilize supplemental ventilators whose settings and controls differ from those typically at use in the institution. Staff will need to be informed of existing triage plans and trained regarding their specific roles in implementing the triage protocol.

State medical boards, nursing boards and other licensing and certifying agencies should be partners in planning efforts to “adjust scopes of practice” and “alter licensure and credentialing practices” during declared emergencies (6). The IOM report also urged state and local governments to explicitly tie liability protections to crisis standards of care, so that concerns about legal liability do not deter health care workers from providing needed care to individual patients and to society during a declared public health emergency.

We have suggested in this guidance that prioritizing based on preserving the functioning of society is not relevant to decision making about distribution of ventilators. However, some may argue that the ethical principle of reciprocity may provide ethical justification for giving priority to those who put themselves at risk during a severe pandemic (i.e., health care providers and emergency responders), especially prior to the availability of a vaccine. The application of this principle for allocation of ventilators will depend on the extent of the shortage and the extent to which an individual healthcare provider faces additional risk when providing care to others. In situations where health care providers or other essential workers may benefit from a ventilator, the fact that they may have become ill as a consequence of their work may be a factor to be considered.

Community Engagement

Active involvement of the community in the planning and triage process, such as that done in Seattle-King County, is critical (13). Public health officials, as health professionals with ethical responsibilities to their communities, should collaborate with health care institutions and perhaps other government bodies, such as city or county councils, to ensure that a diverse and broad representation of community members are included in the planning and implementation of the triage process. Diverse and broad representation of citizens in multiple phases of the planning process will impact the quality and depth of decisions made. Concurrent with the planning phase, information about the planning process should be communicated widely in the community so that the public anticipates the outcome of the process. The principles and considerations that are utilized in determining triage protocols should be transparent and clearly communicated. The community should also participate in planning how the information about an impending pandemic will be communicated. Considerations for engaging the community include the following:

• Centralized, consistent messages
Particular attention to historically marginalized and potentially vulnerable groups
Consideration of spokespeople who might best be heard by communities or who can emphasize centrally communicated messages
Consideration of a variety of modes of communication that will best reach the whole community

Since activities designed to engage communities exist to varying degrees in federal, state, and local health agencies and their partners, these existing efforts should be expanded. It may be appropriate to re-direct previously implemented or ongoing community engagement initiatives to focus on issues raised by a severe pandemic influenza.

Provision of Palliative Care
During a severe pandemic influenza, patients with respiratory failure who do not receive mechanical ventilation are expected to die. They should receive respectful and compassionate palliative care to relieve the symptoms of respiratory failure (38). Doses of sedatives and analgesics that will cause unconsciousness are appropriate if lower doses fail to relieve symptoms (39). Although such palliative sedation has strong ethical and legal justification, health-care workers are often confused about the distinction between palliative sedation, which is intended to relieve suffering, and active euthanasia, which is intended to kill the patient. During a public health emergency, such misunderstandings may be particularly prominent (40). Thus, emergency-preparedness plans should include provisions for training physicians and nurses about palliative sedation, for providing emotional and spiritual support to patients, families, and health-care workers, and for addressing shortages of trained nurses to administer sedation and analgesia and shortages of medications caused by disruptions to hospital supply chains (37, 41). Plans also need to be put in place to address the possibility of a shortage of both ventilators and palliative medications. These plans should be based on sound scientific and ethical reasoning, be transparent and open to public input and scrutiny, and include steps for ensuring that disadvantaged and vulnerable populations have fair access to scarce resources.

Withdrawal of Patients from Ventilators
In the United States, there is ethical, legal, and professional consensus that mechanical ventilation may be withdrawn, and that there is no ethical or legal distinction between withdrawing mechanical ventilation and not starting it (42-48). During usual clinical practice, about 75% of deaths in critical care units occur after a conscious decision to withdraw or withhold life support. Mechanical ventilation may be withdrawn at the request of a competent, informed patient. For patients who lack decision-making capacity, mechanical ventilation may be withdrawn or withheld by a duly appointed surrogate, usually a family member, in accordance with the patient’s previously expressed wishes or best interests. More controversially, critical care physicians may withdraw life support from patients who lack decision-making capacity, have no surrogate, and have given no advance directives (49, 50).

In ordinary clinical practice, it is rare for patients not to receive beneficial critical care because of resource scarcity (51). However, when the need for ventilators temporarily exceeds the supply of ventilators or critical care unit beds, typically arrangements are
made to postpone elective surgery, try to wean recovering patients from ventilators, 
utilize emergency department beds or post-operative recovery suites to treat patients on 
ventilators, or transfer patients to another healthcare institution. Because there are few 
precedents and policies in ordinary clinical care for denying the use of mechanical 
ventilation to patients who would benefit from it and who would agree to it, it is essential 
that careful policies be developed in advance for use of mechanical ventilation during a 
severe pandemic influenza in which the need for mechanical ventilation far exceeds 
capacity (7).

In order to achieve the public health goal of minimizing the number of preventable deaths 
during a severe pandemic emergency, states and hospitals need to address the issue of 
removing patients with respiratory failure whose prognosis has significantly worsened 
from ventilators in order to provide access to patients with a better prognosis. During a 
declared public health emergency, decisions about allocation of scarce resources may be 
taken out of the hands of patients and the treating physicians, in accordance with 
transparent, accountable, and fair public health directives. Policies for withdrawal of 
patients from ventilators need to be the least restrictive possible - i.e., withdrawing of 
ventilation without requiring assent of patient or surrogate continues only as long as the 
shortage of ICU resources continues. The policy should be transparent, formed with 
input from the public, and include explicit criteria for identifying patients from whom 
ventilation will be withdrawn. There should also be procedural safeguards for 
prioritizing patients to receive ventilatory support (e.g., triage officer, post-event review 
of decisions for quality improvement; policy developed with public input). Patients who 
are removed from mechanical ventilation and their families or surrogates, like patients 
with respiratory failure who are not placed on mechanical ventilation, should be notified 
this will occur, given a chance to say good-byes and complete religious rituals, and 
provided compassionate palliative care.

CONCLUSIONS

The intent of this guidance to provide decision makers at all levels–federal, tribal, 
territorial, state, and local–with ethical points to consider when life-sustaining healthcare 
resources are limited due to a severe pandemic influenza. It is intended only for 
circumstances when people with severe acute respiratory failure far outnumber available 
and adequate mechanical ventilator availability and when a public health emergency has 
been declared. If a scarcity of ventilators occurs during a severe pandemic influenza, 
ventilators will need to be allocated according to different guidelines than during usual 
clinical care. Unlike the allocation of pandemic vaccines and antiviral medications, 
where the principle of preserving the functioning of society has a high priority, decisions 
about allocation of ventilators pose a different situation. Individuals who require a 
ventilator are unlikely to recover sufficient function to contribute to the preservation of 
the functioning of society—at least not during the ‘wave’ of the pandemic during which 
they fell ill. We present a number of general ethical principles that should guide 
ventilator allocation decisions—respect for persons and their autonomy, beneficence, and 
justice—and review several strategies for establishing priorities for who should receive a 
ventilator when there are not enough for everyone. We suggest that a multi-principle
allocation system may best reflect the diverse moral considerations relevant to these
difficult decisions. Most importantly, triage models for allocation of scarce life-saving
resources should be evaluated based on the extent to which they result in fair processes
and should take into account the values and priorities of the community members who
will be impacted. We recommend that state and local health departments work with
hospitals and each other to implement uniform triage processes for ventilator distribution
in the interest of fairness, consistency, and coordination of efforts.

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