

Ethical Considerations for Decision Making Regarding Allocation of Mechanical Ventilators during a Severe Influenza Pandemic or Other Public Health Emergency

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PREAMBLE

This document provides ethical considerations that the Ethics Subcommittee of the Advisory Committee to the Director, Centers for Disease Control and Prevention (CDC) proposes to aid in the decision making specific to allocation of mechanical ventilators during a severe influenza pandemic. This document supplements a previous document 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 HHS/CDC that the Ethics Subcommittee address ethical considerations in vaccine and antiviral drug distribution prioritization and in the development of interventions that create social distancing (in discourse on pandemic influenza, often referred to as non-pharmaceutical or community mitigation interventions). After release of the initial ethics document, numerous public health stakeholders requested that HHS/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 considerations from that proposed in the original document form the basis for this supplemental document.

The intent of this document is to provide decision makers at all levels—federal, tribal, territorial, state, and local—with an overview of the complex ethical landscape associated with decision making about allocation of scarce life-sustaining healthcare resources. This document is not meant to serve as detailed guidance about allocation decisions. Rather it is intended to serve as a conceptual framework to assist the planning process. Planning will need to occur at the state, local, and institutional level to develop specific operational details and implementation steps. Thus, this document will not address how to approach specific allocation decisions, but will instead highlight ethical standards and principles relevant to allocation of ventilators during a severe pandemic or other public health emergency and discusses some of the advantages and disadvantages inherent in different approaches to allocation. Some of the approaches are sufficiently and obviously 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 contested matters, we refrain from making specific recommendations and instead highlight these issues and controversies.

Although this document does not provide simple, direct recommendations, our intent is for the document to promote and enhance use of a fair and equitable process for making policy choices. We believe it is important that state and local health departments and federal agencies work with hospitals and each other to implement fair, consistent, and coordinated triage processes for ventilator distribution using the ethical considerations discussed in this document as a framework for decision making. Development of triage plans will require input from a variety of stakeholders, including public health, medical and other health care professionals, ethics and legal experts, and representatives of patients and the public who will be impacted by the plans. An important first step is to engage the stakeholders in a discussion about how to weigh the various ethical principles, values, and approaches reviewed in this document. In addition to preparing for how to fairly distribute limited resources, health officials should be taking appropriate steps to maximize health systems' capabilities to safely deliver appropriate

mechanical ventilation, in order to reduce the need to make these difficult allocation decisions in the future, keeping in mind that allocation of limited resources for ventilators to be used in an emergency will involve tradeoffs with other public health and health care priorities.

INTRODUCTION

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. This document addresses conditions during an influenza pandemic that causes severe illness in sufficient numbers of people to overwhelm routine clinical services. 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 are always potentially serious public health events. However, in order to call for the kind of emergency policies discussed in this document, they have to cause severe illness in large numbers and thereby create demands significantly exceeding the system's capacity for treating patients despite attempts to increase surge capacity. Depending on the capacity and flexibility of the healthcare system, a pandemic's impact may vary from one region or country to another and the point at which a pandemic will become severe and overwhelm resources may vary by disease and by different communities or regions experiencing the same disease.

The timeliness of this discussion of ethical issues in pandemic influenza was highlighted by the emergence of 2009 pandemic influenza A (H1N1). This virus was officially declared by the World Health Organization as the cause of a pandemic in June 2009. The profound level of respiratory failure experienced by those who developed 2009 H1N1 associated critical illness, especially in older children and young adults, raised much concern that shortages of mechanical ventilators or alternative therapies for very severe critical illness could occur during the fall and winter 2009-2010. While hospitals were challenged by the resource intensity of care these patients required, fortunately the overall proportion of people who developed severe illness was no greater than in recent years with seasonal influenza epidemics, and in the United States there were sufficient mechanical ventilators to meet the response need.² Although the 2009 H1N1 influenza pandemic did not produce a situation that would have required the use of this document, its emergence should serve as a reminder of the importance of being prepared for a situation if the demands for treating patients significantly exceed our health system's capacity.

KEY ASSUMPTIONS

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.,

² Information on cases of pandemic (H1N1) 2009 influenza is posted at <http://www.cdc.gov/h1n1flu/>.

an influenza pandemic that is both widespread and 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 influenza pandemic on communities. Advances have also been made in increasing the supply of ventilators. Currently the National Ventilator Inventory undertaken by the Office of the Assistant Secretary for Preparedness and Response together with the American Association for Respiratory Care has revealed that there are approximately 62,000 full-feature mechanical ventilators in the United States (2). Almost half (46%) of these full-feature devices were capable for use with pediatric and neonatal patients. In addition, there are approximately an additional 100,000 devices across a range of categories of respiratory equipment (not including anesthesia machines) at U.S. acute care hospitals which might be used for surge capacity. Almost half of the 100,000 additional devices have enough features to be useful for anticipated surge capacity events. Furthermore, some states and other groups have purchased additional ventilators, not included in the above counts of devices, for surge demand. There has also been significant federal investment to procure and stockpile additional ventilator assets. Despite these crucial activities, it is possible that in the event of a particularly virulent pandemic influenza virus, many hospitals and other healthcare facilities will not have adequate numbers of ventilators to support a major disaster response.

During a severe influenza pandemic, 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 influenza pandemic. This assumption is based on everyday experience with acute respiratory distress syndrome (ARDS), recent experience with 2009 pandemic influenza A (H1N1), and past experience with avian H5N1 influenza virus and severe acute respiratory syndrome (SARS). For 2009 pandemic influenza A (H1N1), 60-95% of critically ill patients required mechanical ventilation, and the mortality in these patients was lower than 40% and less than 20% in some countries. The level of respiratory failure in many of these patients was very severe, yet numerous patients who clearly would have died without mechanical ventilation and resource-intensive critical care survived (3-6). Although the majority of patients infected with H5N1 influenza who received mechanical ventilation have not survived (7), many persons infected with SARS who received mechanical ventilation during the 2003 outbreak did survive (8). Moreover, 40-70% of patients with acute respiratory failure (including acute lung injuries and ARDS which is predominant in current H1N1 and H5N1 cases) survive in intensive care units in U.S. hospitals under non-pandemic circumstances (9).

Another of the assumptions of this document is 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. This was the experience with 2009 pandemic influenza A (H1N1). A pandemic wave is defined as a series of community outbreaks that occur nearly simultaneously across the country. Pandemic waves typically occur in the spring, fall, or winter and more than one wave is likely; however waves may occur during any season. In 1918-1919, 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 2009 pandemic

influenza A (H1N1) 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 influenza pandemic it is anticipated that resources will be overwhelmed in the first or second wave of illness because 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 influenza pandemic, depending on the geographical spread and timing of the waves, the symptoms of the disease, the availability of pandemic vaccine, and the local effectiveness of community mitigation strategies. This document 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 influenza pandemic.

The need to make difficult decisions during a severe influenza pandemic or other public health emergency will most likely occur in an environment of overall limited public health resources. Considerable costs are associated with stockpiling, maintaining reserve ventilators, and funding the training of personnel needed to operate and maintain 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 influenza pandemic 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 document assumes that individual communities will need to balance pandemic-preparedness requirements with other healthcare and public health needs.

ROUTINE VERSUS EMERGENCY PRACTICE

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 and occasionally 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 on occasion be constrained in acting in the best interests of particular patients. In addition, they may have to

³ See <http://www.cdc.gov/h1n1flu/> for examples of guidance documents.

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 and the need to address how to best use limited resources (e.g., rules pertaining to admitting patients to intensive care units). Healthcare providers are also familiar with the obligation in many jurisdictions to notify 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 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 trigger for 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.

Triage is the process of sorting, classifying, and assigning priority to patients, especially when available medical resources are insufficient to provide care to all who need it. Triage is commonly 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 immediate access to medical care available in ordinary clinical circumstances. The decision to initiate triage plans is usually made by specific authority within local or state emergency management systems only after all reasonable efforts to augment resources have been exhausted⁴.

Considerable progress has been made by federal agencies, state and local health departments, professional societies, and other institutions on the development of pandemic preparedness plans and guidance about crisis standards of care, including plans for allocation of scarce resources. The Task Force for Mass Critical Care has 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 (10). 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. The Task Force suggested that 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. The Task Force recommended that triage plans 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.

The Task Force for Mass Critical Care suggested that the following conditions be present to initiate the triage process (10):

- Surge capacity fully employed within healthcare facility

⁴ This should also include exploring resources which may be available from Department of Veterans Affairs and Department of Defense treatment facilities,

- 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, regional, and state 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* (11). 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. The IOM 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.

As many healthcare providers may be unaccustomed to approaching healthcare decision making from a population perspective, it is crucial that individual providers be informed about and provided training on the implementation of crisis standards of care and triage protocols prior to the need to institute these procedures; this will facilitate the smooth transition to crisis care. It is also crucial for the guidance and training to provide clear information about when and how the transition back to usual standards of care will occur.

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 and can benefit from mechanical ventilation and who consent to treatment (or have the concurrence of a surrogate) are provided this type of care. However, during a severe pandemic when there is a shortage of health care resources, it may be necessary to re-evaluate the ethical considerations that govern the usual provision of care (12). In this and in the next two sections, we explore how the usual ethical considerations that govern allocation to ventilators may need to be modified during a severe influenza pandemic or other public health emergency when there might not be enough ventilators for all who need one.

During a public health emergency, there will be competing priorities for ventilator use from patients whose need for a ventilator is unrelated to influenza. In addition, decisions will need to be made regarding whether patients should be removed from ventilators if this is needed to free up ventilators for others who may have a much 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 influenza pandemic 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 influenza pandemic; 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, rules that favor the overall benefit to the population and society may have to be considered.

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 (13). During a declared public health emergency, prudent stewardship of scarce resources is an important ethical consideration.

In the Ethics Subcommittee's previous 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. Moreover, the vast majority of patients who required mechanical ventilation due to illness caused by 2009 pandemic influenza A (H1N1) had ARDS. While published data regarding systematic post ICU follow-up of these patients has been limited, patients with ARDS due to bacterial pneumonia and sepsis take a median of one week to recover from requiring mechanical

ventilation and then frequently have prolonged recoveries with long-term reduction of quality of life. Therefore, 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. 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.

WHAT PRINCIPLES SHOULD GUIDE VENTILATOR ALLOCATION?

Basic Biomedical Ethical Principles

A consideration of the basic biomedical ethical principles should be the cornerstone for decision making about ventilator allocation. These basic principles include respect for persons and their autonomy, beneficence (which includes nonmaleficence), 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 influenza pandemic, 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, not all patients with respiratory failure will be able to receive these resources. 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 only 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. Beneficence is closely related to nonmaleficence, which requires physicians to not harm patients and to try to prevent harm.

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 (14).” 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 (14). Fair process or procedural justice is especially important during a public health emergency to sustain public trust (15).

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 document (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 (16-20). 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 an influenza pandemic, the public need to have input on ventilator allocation decisions and 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 rather than during a pandemic.

In order to promote transparency and accountability, there should be interim and retrospective review processes to ensure that triage guidelines are applied accurately, consistently, and fairly. These reviews would also serve as a quality-improvement process. However, because of the need for triage decisions to be made in a timely manner, it may be impractical for the review process to function as an appeal process for real-time decisions (14). The reviews of triage decisions should be conducted by a different group of people than those involved in the initial triage decisions.

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.

- Adequately reasoned decisions 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 (21). 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 (10, 14, 22).”

Maximize the number of lives saved - The utilitarian rule of maximizing the number of lives saved is widely accepted during a public health emergency (23). Some non-consequentialist views also favor maximizing the number of lives saved, not because this approach produces the most good; but, because each life has an equal claim on being saved. 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.

Various groups have been developing models for allocating ventilators. Several groups 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 (22, 24-26). No model can predict with perfect accuracy which patients will benefit from mechanical ventilation during a severe influenza pandemic and which will not. When selecting a predictive score model, physicians and policy makers need to take into account several considerations, including whether the scoring system is validated in the populations for which it is being considered (e.g. pediatrics, non-influenza patients who will be triaged together with patients with influenza-related critical illness), whether it is a disease-specific or general score, if the score can be used at multiple time points in disease course in addition to 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 influenza pandemic, 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. However, if valid scoring systems are not available (as for example in the case of infants and children, explicit criteria based on expert opinion may be the most feasible option. No matter which scoring system is utilized within a triage schema, the performance of the score must be reviewed to assess its accuracy and to minimize misclassification of people's predicted outcomes. Ideally this reevaluation should be ongoing during the event, and data collection systems must be planned for and implemented during an event.

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 influenza pandemic to exclude certain poor-prognosis subgroups of patients from access to ventilator support. For example, one group advocates denying ventilator support to persons who are functionally dependent from a neurologic impairment (27). Another group recommends excluding those older than 85 years of age and those with New York Heart Association Class III or IV heart failure (10, 22). 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.

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 (28, 29). Another limitation of basing decisions on QALYs or DALYs is their potential to create invidious distinctions between people based on arbitrary judgments regarding quality of life.

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 resources 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 (23). 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 (30). 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 (31).

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 (32). As one philosopher put it, one's "dignity as a person...cannot be reduced to his past or future contribution to society (33)."

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" and the "multiplier effect (21, 23)." 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 (34, 35). 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 (32).

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* (36). 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 (37). Similar ideas have been based on the “fair innings” argument and “intergenerational equity (38).” 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 (37). 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 (39). 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 (40).” Prioritization based on the life cycle approach is not a simple linear function of a persons’ age (that is, the claim of priority does not decrease bit by bit as one ages year by year). Instead, this approach appeals to significant age differences rather than small differences of a few years.

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 (38). 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 (37). However, when public input was sought in Seattle-King County on values and priorities for delivery of medical services during a severe influenza pandemic, 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 (19).

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 (41-43). 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 (41, 42). 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 (44).

Incorporating Multiple Principles

Because several different considerations for allocating ventilators during a severe influenza pandemic may be justified, some writers have proposed that several principles be combined into a composite priority score (12). Although a multi-principle allocation system may be more complex to implement in a timely and practical manner than a single principle allocation system, it 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 (45).” 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 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 respiratory failure to continue to maintain loyalty to their patients and to act in their best interests (46). 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 expert 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 (10).

The role of the triage expert will need to be specified in some detail in advance of a pandemic. Details that will need to be specified include identification of qualifications for the triage expert and establishment of training requirements, establishment of procedures for providing support to the triage expert (both decisional support and emotional support), agreement of whether an appeals process will be permitted, and establishment of a mechanism to review triage decisions for quality improvement purposes. Devereaux and colleagues have pointed to the need for triage experts to have “exceptional clinical expertise, outstanding leadership ability, and effective communication skills (10).” The triage expert should be a senior-level provider within the institution with the experience, respect, and authority to carry out the function. When possible, it is desirable to establish a triage team composed of at least three members rather than relying upon a single triage expert. The team approach allows for consultation, multiple professional perspectives, and a broader base of support from clinical/community stakeholders. The suggested professional makeup of a triage team would include at least a critical care nurse, a respiratory care professional, and a physician. It is also desirable to have an ethicist on the triage team if available. Additionally, if the hospital has an ethics team, this team can serve as a valuable resource to the triage team. All team members must be fully licensed or certified and credentialed to engage in their profession. All triage experts, whether individuals or members of a team, should be chosen by the institution based on a past record of trustworthiness, integrity, compassion, competency in making consistent and difficult choices, and competency in clinical skills (especially in critical care medicine).

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 life-saving interventions in functional medical referral areas. Such consistency across hospitals promotes fairness. Uniform criteria would 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 functional medical referral area 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 an influenza pandemic. 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, public health officials 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, because 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 make their reasons for implementing different criteria transparent. In general, state and local health departments and federal agencies 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 resources, such as ventilators, for the general welfare and may vary from jurisdiction to jurisdiction. Officials should understand the scope of their authority during emergencies.

Community Engagement

Active involvement of the community in the planning and triage process is critical. 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:

- Consistent messages
- Particular attention to historically marginalized and potentially vulnerable groups

- Engagement of spokespeople who might best be heard by communities or who can emphasize centrally communicated messages
- Use 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 influenza pandemic.

We acknowledge that the public engagement process can be difficult to implement. It requires resources and can be time consuming; it may be difficult to identify the appropriate spokespersons who accurately reflect the sentiments of the community; and the discussions may raise political challenges due to sensitive nature of the issues which involve life and death decisions. However, despite these challenges, it is crucial that decision making about allocation of scarce life-saving resources reflect the value choices of the community thus necessitating the active involvement of the community in the planning and triage process. There are a number of excellent examples of public engagement for pandemic planning that can serve as useful models (16-20).

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 should clarify their role in supporting legal protections for tort liability in the jurisdiction, and provide information about immunity from tort for actions undertaken during a public health 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 (11). 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 document 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.

Provision of Palliative Care

During a severe influenza pandemic, patients with respiratory failure who do not receive mechanical ventilation should receive respectful and compassionate palliative care to relieve the symptoms of respiratory failure (47). Doses of sedatives and analgesics that will cause unconsciousness are appropriate if lower doses fail to relieve symptoms (48). 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 (49). 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 (46, 50). 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 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 consensus that mechanical ventilation may be withheld or withdrawn as requested by an informed patient or a qualified surrogate, and courts have consistently ruled that there is no distinction between discontinuing such medical interventions and not initiating them (51-57). 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 (58, 59).

In ordinary clinical practice, it is rare for patients not to receive beneficial critical care because of resource scarcity (60). 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 influenza pandemic in which the need for mechanical ventilation far exceeds capacity (12).

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 from ventilators patients with respiratory failure whose prognosis has significantly worsened in order to provide access to patients with a better prognosis. During a declared public health emergency, decisions about allocation of scarce resources must be made 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., withdrawal 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 ventilator support (e.g., triage expert, 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.

Special Considerations Relating to Children

Children make up a significant percentage of the population for whom there are special considerations in an influenza pandemic. Dependent on the strain of influenza, children may have greater susceptibility to disease and a disproportionate need for ventilation. However, not all ventilator equipment is customized to children or infants, and emergency services and hospitals may not have adequate age- appropriate equipment or supplies, or staff trained to provide ventilation to children. When making emergency preparations and in constituting triage teams, the special needs of children should be taken into account. State and local disaster planning should include assessment of the capacity of pediatric facilities as well as the capacity of all hospitals to treat children. The implications for keeping children and parents or other family members together during treatment should be considered. A number of important efforts have been made to address treatment of children during a disaster, including work by the National Commission on Children and Disasters which provides recommendations regarding addressing considerations for pediatric populations in disaster planning (61). CDC has also collaborated with various stakeholders and is preparing recommendations regarding pediatric emergency mass critical care (62, 63).

CONCLUSIONS

The intent of this document is 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 influenza pandemic. It is intended only for circumstances when people with severe acute respiratory failure far outnumber adequate mechanical ventilator availability and when a public health emergency has been declared. Fortunately, the 2009 H1N1 pandemic did not produce a situation requiring the use of this document. However, it is imperative that health officials be prepared for the future possibility of the emergence of a severe pandemic.

If a scarcity of ventilators occurs during a severe influenza pandemic, ventilators will need to be allocated according to different guidelines than during usual clinical care. In the allocation of vaccines and antiviral medications during a pandemic, the principle of preserving the functioning of society has a high priority. Such a priority does not apply to allocation of ventilators. 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. In this document, we present a number of general ethical principles that should serve as a conceptual framework for guiding 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.

While ethics guidance can articulate considerations that need to be taken into account, policy decisions need to be set and implemented by the responsible public health officials. In the interest of fairness, consistency, and coordination of efforts, we suggest that state and local health departments and federal agencies work with hospitals and each other to implement uniform triage processes for ventilator distribution using the ethical considerations described in this document as a framework for decision making. Development of these plans will require input from a variety of stakeholders, including public health, medical, ethics and legal experts and representatives from those who will be impacted by the plans. While preparing for how to fairly distribute limited resources, health officials may want to consider taking appropriate steps to increase supplies, and to conserve and make adaptations in current usage in order to reduce the need to make these difficult allocation decisions in the future.

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