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**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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1 INTRODUCTION

2
3 This document provides ethical guidance that the Ethics Subcommittee of the Advisory
4 Committee to the Director, Centers for Disease Control and Prevention (CDC) proposes
5 as a foundation for decision making specific to allocation of mechanical ventilators
6 during a severe pandemic influenza. It is intended to supplement previous guidance
7 written by the Ethics Subcommittee, *Ethical Guidelines in Pandemic Influenza*, and
8 released by CDC in 2007 (1). The 2007 document was developed in response to a
9 request from CDC that the Ethics Subcommittee address ethical considerations in vaccine
10 and antiviral drug distribution prioritization and in the development of interventions that
11 would limit individual freedom and create social distancing (in discourse on pandemic
12 influenza, often referred to as non-pharmaceutical or community mitigation
13 interventions). After release of the initial ethics guidance document, numerous public
14 health stakeholders requested that CDC specifically address ethical issues for allocation
15 of mechanical ventilators. This current document is not intended to comprehensively
16 revisit all of the topics and issues promulgated in the 2007 document; instead, it is
17 intended to supplement the initial document. Circumstances and major issues specific to
18 allocation of mechanical ventilators as well as issues which require alternative ethical
19 guidance from that proposed in the original guidance form the basis for this supplemental
20 document.

21
22 Difficult decisions are made on a regular basis in both the practice of public health and
23 clinical medicine; however, the process for decision making, including the framework
24 and reasoning that support ethical choices, may not always be clearly articulated. We
25 appreciate that while ethical guidelines can articulate guidance and considerations that
26 need to be taken into account, policy decisions need to be set by responsible officials,
27 with input from scientists and the public. The intent of this document is to provide
28 decision makers at all levels—federal, tribal, territorial, state, and local—with guidance for
29 ethical points to consider when life-sustaining healthcare resources are limited due to a
30 severe pandemic influenza. This document highlights ethical principles relevant to
31 allocation of ventilators and discusses some of the advantages and disadvantages inherent
32 in different approaches to allocation. Some of the approaches are sufficiently
33 problematic that we suggest that they not be used to guide decisions. Other approaches
34 have positive and negative aspects that must be considered. In the interest of
35 encouraging broader public deliberation about ethically contentious matters, we refrain
36 from making specific recommendations and instead highlight these issues and
37 controversies. Although this guidance does not provide simple, direct recommendations,
38 we hope that it will encourage use of a fair and equitable process for making policy
39 choices.

40
41 This document addresses conditions during a severe pandemic. However, there is no
42 standard definition of a severe pandemic or list of features to distinguish it from a
43 pandemic. The term pandemic refers largely to a geographic development: an epidemic
44 that has spread beyond its original region to several countries or continents and that
45 effects a large portion of the population [because few people have pre-existing immunity](#)
46 [to the causative pathogen](#). Pandemics, although potentially serious public health events,

1 rarely call for the kind of emergency policies discussed here. In the context of this
2 document, a pandemic becomes severe when the demands for treating patients
3 significantly exceed the system’s capacity despite attempts to increase surge capacity.
4 This moment will vary by disease and by different communities or regions experiencing
5 the same disease.

6
7 The timeliness of this discussion of ethical issues in pandemic influenza is highlighted by
8 the emergence of pandemic (H1N1) 2009 influenza. As of September 2009, pandemic
9 (H1N1) 2009 virus is the predominant influenza virus in circulation worldwide. This
10 virus was officially declared by the World Health Organization as the cause of a
11 pandemic in June 2009. Disease severity appears to be generally similar to the severity
12 of recent seasonal influenza, although different age groups have been predominantly
13 affected, with most cases and most severe cases occurring in older children and adults
14 less than 65 years of age.¹ If the pandemic (H1N1) 2009 virus becomes more widespread
15 or more severe than during spring and summer 2009, it is possible that some communities
16 may experience shortages of mechanical ventilators for adult or pediatric use.

17
18 **KEY ASSUMPTIONS**

19
20 The guidance proposed in this document is based on a number of assumptions regarding
21 severity of illness and the availability of resources. It is intended only for circumstances
22 when people with severe acute respiratory failure far outnumber available and adequate
23 mechanical ventilator supply. For most U.S. communities, such extreme imbalances are
24 only anticipated in special circumstances (e.g., if pandemic (H1N1) 2009 influenza
25 becomes more widespread or more severe). Federal, tribal, territorial, state, local, and
26 private entities have undertaken extensive preparedness activities and supported rapid
27 advancement of vaccine and antiviral treatments to reduce the potential burden of a
28 severe pandemic influenza on communities. Advances have also been made in increasing
29 the supply of ventilators. Currently the American Association for Respiratory Care has
30 estimated that there are between 65,000-105,000 full-feature mechanical ventilators in the
31 United States.² Some states and other groups have purchased additional ventilators for
32 surge demand. In addition, there has been significant federal investment to procure and
33 stockpile additional ventilator assets. Despite these crucial activities, it is possible that in
34 the event of a severe pandemic influenza many hospitals and other healthcare facilities
35 will not have adequate numbers of ventilators to support a major disaster response.

36
37 During a severe pandemic influenza, many patients with respiratory failure who are able
38 to receive mechanical ventilation (and all associated supportive critical care components)
39 may survive, while patients with respiratory failure who do not receive mechanical
40 ventilation are likely to die. Thus, a major underlying assumption for this document is
41 that advanced critical care will save lives during a severe pandemic influenza. This
42 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 at <http://www.aarc.org/nvs/moreaboutnvs.asp>.

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

9
10 This guidance is also predicated on the assumption that cases of pandemic influenza
11 infection will occur in waves and most likely a well-matched vaccine will not be
12 available until the second wave. A pandemic wave is defined as a series of community
13 outbreaks that occur nearly simultaneously across the country. It is expected that
14 pandemic waves will occur in the spring, fall, or winter, and that more than one wave is
15 likely. In 1918-19, for example, there were three pandemic waves, and in 1957 and 1968
16 there were two waves. Periods between waves (typically measured in months) are
17 characterized by very little disease and can be a time of recovery and preparedness for a
18 subsequent wave. For example, following the initial wave of pandemic (H1N1) 2009
19 influenza in North America, public health authorities prepared guidance for patients,
20 clinicians, and other groups, and monitored first-wave influenza activity in the Southern
21 Hemisphere.³

22
23 During a severe pandemic influenza it is anticipated that resources will be overwhelmed
24 in the first or second wave of illness as the entire community will be at risk for illness.
25 Equipment for emergency respiratory care, including ventilators, may be in full use and
26 no longer available to additional patients by the first or second wave of a severe
27 pandemic influenza, depending on the geographical spread and timing of the waves, the
28 symptomatology of the disease, the availability of pandemic vaccine, and the local
29 effectiveness of community mitigation strategies. This guidance assumes that ventilators
30 may be in short supply in some communities as early as prior to or during the peak of the
31 first wave of a severe pandemic influenza.

32
33 The need to make difficult decisions during a severe pandemic influenza will most likely
34 occur in an environment of overall limited public health resources. Considerable costs
35 are associated with stockpiling, maintaining reserve ventilators, and funding training of
36 personnel needed to operate ventilators skillfully and safely. The decision by states,
37 regions, healthcare systems, or hospitals to augment mechanical ventilation capacity (and
38 all associated critical care elements) for emergency use during a severe pandemic
39 influenza should be made within the larger context of everyday public health and clinical
40 obligations, as well as broader community-based emergency preparedness and response
41 resource needs. This guidance assumes that individual communities will need to balance
42 pandemic-preparedness requirements with other healthcare and public health needs.

43
44 **ROUTINE VERSUS EMERGENCY PRACTICE**

45

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

1 The central ethical requirement of routine clinical practice is competence. Healthcare
2 professionals should be competent to perform the functions of their professional practice
3 and make continuing efforts to maintain their level of competence. In general, the
4 professional should not perform functions that lie outside the boundaries of his or her
5 specialty. Healthcare professionals also have a fiduciary duty to patients. This requires
6 undivided loyalty to the health interests of the patient. Any actual, potential or apparent
7 competing loyalty must be disclosed to the patient.

8
9 Public health emergencies have an impact on each of these ethical standards. During
10 severe pandemics it may be necessary to call upon health professionals and even non-
11 health professionals to temporarily perform tasks that lie outside the bounds of their
12 certification (or even competence). A public health emergency also has an impact on
13 healthcare professionals' fiduciary duty to patients. The central purpose of public health
14 practice is to maintain the health of populations. Because of the need to establish
15 priorities to maximize the health of the public during a public health emergency,
16 practicing physicians may be constrained in acting in the best interests of particular
17 patients. During public health emergencies physicians may also be required to act
18 contrary to the liberty interests of particular patients. For example, they may have to
19 report to authorities individuals who would be considered candidates for quarantine or
20 isolation. These constraints are not alien to usual medical practice. Healthcare providers
21 are accustomed to rules establishing priorities (e.g., rules pertaining to admitting patients
22 to intensive care units) and are obliged in many jurisdictions to report patients to
23 authorities in certain circumstances (e.g., in suspected cases of child or elder abuse or
24 when patients are a danger to themselves or others and need to be involuntarily
25 committed).

26
27 A public health emergency, such as a severe pandemic influenza, creates a need to
28 transition from individual patient-focused clinical care to a population-oriented public
29 health approach intended to provide the best possible outcomes for a large cohort of
30 critical care patients. The decision to begin the transition from usual critical care
31 procedures to emergency mass critical care should occur when there is a substantial
32 extreme mismatch between patient need and available resources, that is, when the
33 numbers of critically ill patients surpass the capability of traditional critical care capacity.

34
35 The term triage is commonly applied to the process of sorting, classifying, and assigning
36 priority to patients when available medical resources are not sufficient to provide care to
37 all who need it. Triage has been used in situations such as natural disasters, deadly
38 epidemics, and battlefield situations, where shortages are extreme and people die who
39 might be saved if they had access to the level of medical care available in ordinary
40 clinical circumstances. The decision to initiate triage plans is usually made by specific
41 governmental authority within local or state emergency management systems only after
42 all reasonable efforts to augment resources have been exhausted.

43
44 Devereaux and colleagues have recently published guidance regarding use of triage
45 during mass critical care emergency events when surge capacity has become
46 overwhelmed in a nation, state or region and resources are inadequate to meet patient

1 care needs (5). They recommend that triage plans be invoked after all attempts at
2 resource procurement have failed and when all area hospitals are facing a similar short-
3 fall. Triage plans should be based upon a graded response that matches the need resulting
4 from the public health emergency and that all impacted hospitals have a uniform response
5 for providing mass critical care. This would be considered the most extreme of situations
6 and the guiding principle is that the provision of usual critical care, when able to meet
7 demand, is always the preferred approach. Triage plans should remain in effect only until
8 the imbalance between need and resources is remedied and all hospitals are able to
9 provide safe critical care. Return to previous standards of care is warranted when critical
10 resources or infrastructure are augmented or when the need abates.

11
12 Devereaux and colleagues suggest that the following conditions be present to initiate the
13 triage process (5):

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

26
27 In September 2009 the Institute of Medicine (IOM) released *Guidance for Establishing*
28 *Crisis Standards of Care for Use in Disaster Situations* (6). This report provides
29 guidance for state and local public health officials, healthcare facilities, and professionals
30 on the development and implementation of policies for crisis standards of care in
31 disasters, both naturally occurring and manmade, in which resources are scarce. The
32 report identifies key elements that should be included in crisis standards of care protocols
33 and potential triggers for adopting these standards. The IOM recommends developing
34 consistent crisis standards of care protocols that are built on strong ethical and legal
35 underpinnings with input from community and provider stakeholders, and strong
36 coordination among federal, tribal, state and local health officials. This report addresses
37 a number of issues also considered in this guidance, including the importance of
38 establishing fair and equitable processes that are transparent, consistent in application
39 across populations and among individuals, and proportional to the emergency and degree
40 of scarce resources.

41 42 **ROUTINE VERSUS EMERGENCY PRACTICE: PRIORITIES FOR** 43 **VENTILATOR ALLOCATION**

44
45 Historically, during routine clinical practice the organizing principle for ventilator
46 distribution, as well as for the distribution of most therapeutic procedures and

1 interventions has been the minimization of adverse outcomes, including hospitalization
2 and death. Typically all patients who have a medical need for mechanical ventilation and
3 who consent to treatment (or have the concurrence of a surrogate) are provided this type
4 of care.

5
6 If a scarcity of ventilators occurs during a severe pandemic influenza, ventilators will
7 need to be allocated according to different guidelines than during usual clinical care (7).
8 During a public health emergency, there will be competing priorities for ventilator use
9 from patients whose need for a ventilator is unrelated to influenza, including the need for
10 chronic ventilator use. In addition, decisions will need to be made regarding whether
11 patients should be removed from a ventilator to make way for others who may have a
12 better chance of recovery, and whether there should be suspension of non-emergency
13 surgical procedures that might create a need for ventilator therapy.

14
15 The principle of *sickest first* is routinely employed to triage patients presenting for care in
16 the emergency department, where staff time is scarce but medical resources are not.
17 Other patients will still receive care, but they must wait. During a severe pandemic
18 influenza that creates a critical shortage of ventilators, however, this strategy may lead to
19 resources being used by patients who ultimately are too sick to survive.

20
21 *First-come, first-served* is used to allocate intensive care unit (ICU) beds during routine
22 clinical circumstances. Once a patient is in the ICU, they are generally not transferred
23 out of the ICU if they still need intensive care unless the patient or surrogate agrees to
24 forego life-sustaining interventions. That is, fiduciary duties to existing patients take
25 priority over potential benefits to other patients. During ordinary clinical care, the
26 healthcare system generally can accommodate patients with a very poor prognosis who
27 require an ICU bed for many days and who ultimately may not survive. Other patients
28 are still able to receive intensive care if needed. However, the situation would be
29 different if ventilators are in extremely short supply during a severe pandemic influenza;
30 other patients, who may have a much better prognosis if they receive intensive care, will
31 not have access to it. After a public health emergency is declared, individual autonomy
32 may be superseded by rules that favor the overall benefit to the population and society.

33
34 In order to use scarce resources most efficiently, in some clinical situations where there is
35 a severe shortage of life-saving medical resources, priority is given to those who are *most*
36 *likely to recover* after receiving them. When treating soldiers with life threatening
37 injuries, medics give priority to those who are most likely to survive with a relatively
38 small amount of scarce resources. Such triage is carried out without regard to rank.
39 Similarly during cholera epidemics in refugee camps, limited supplies of intravenous
40 fluid are given not to those with the most severe dehydration, but instead to those with
41 moderate dehydration who will likely recover with small amounts of fluid (8).

42
43 In the Ethics Subcommittee's previous ethics guidance document, *Ethical Guidelines in*
44 *Pandemic Influenza*, which addressed distribution of vaccines and antiviral medications,
45 the principle of preserving the functioning of society was given greater priority than
46 preventing serious complications (1). This is because vaccines and antiviral medications

1 are predominantly used to prevent or lessen illness and thus can be useful in maintaining
2 or restoring health for groups identified as essential for preserving the functioning of
3 society. However, decisions about priorities for ventilator distribution pose a different
4 situation. Ventilators are an essential life-saving intervention. Patients with severe
5 pandemic influenza-related respiratory failure who do not receive a ventilator are likely
6 to die, and those who receive one are likely to have a long recovery period if they
7 survive. Thus, prioritizing based on preserving the functioning of society is not as
8 relevant to decision making about distribution of ventilators as with vaccines and
9 antiviral medications. Those who are ill enough to require ventilator therapy are unlikely
10 to recover sufficient function to be able to contribute to the preservation of the
11 functioning of society—at least not during the ‘wave’ of the pandemic during which they
12 fell ill.

14 **WHAT PRINCIPLES SHOULD GUIDE VENTILATOR ALLOCATION?**

16 **Basic Biomedical Ethical Principles**

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

21 *Respect for Persons and their Autonomy*

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

34 *Beneficence*

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

43 *Justice*

44 The principle of justice during a severe pandemic has several dimensions. First,
45 physicians and public health officials should “steward resources during a period of true
46 scarcity (9).” Second, the distribution of benefits and burdens should be equitable;

1 allocation decisions should be applied consistently across people and across time.
2 Responses to a pandemic should not exacerbate existing disparities in health outcomes, as
3 unfortunately has occurred in some past public health emergencies (9). Indeed, during a
4 public health emergency the perception of fairness is essential for citizens to accept
5 mandatory public health measures (10).

6
7 Fair process or procedural justice is especially important during a public health
8 emergency because mandatory public health measures may be adopted. Fairness and
9 perceptions of fairness are essential for sustaining public trust and willingness to comply
10 with public health regulations. Fairness requires the absence of unjustified favoritism
11 and discrimination. Citizens may be more likely to subordinate their own personal self-
12 interest to the common good if they believe the same rules apply to all. Conversely, if
13 people believe that others are receiving special consideration, they may be less likely to
14 accept mandatory public health measures. Even the perception of favoritism may
15 undermine willingness to sacrifice for the sake of the greater good of the community.

16
17 As described in the Ethics Subcommittee’s prior pandemic influenza ethics guidance (1),
18 procedural justice requires the following:

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

32
33 Procedural justice is closely related to other procedural guidelines, such as transparency
34 and accountability, which help to establish the legitimacy of public health policies.
35 Transparency refers to making policies and their rationale available to the public.
36 Accountability refers to explaining and justifying policies and taking responsibility for
37 the consequences of actions and decisions. Prior to a pandemic influenza the public
38 needs to know how ventilators will be allocated in order to trust that allocation is fair. As
39 such, it is the responsibility of public health leaders to provide timely information
40 regarding the pandemic, even when there is uncertainty due to the lack of data.
41 Transparency will be enhanced if triage priorities and policies are explicit and if the
42 public has ready access to the triage guidelines, the data and reasoning underlying them,
43 and the process by which they were derived. Public input into the formulation of triage
44 guidelines is more feasible before a pandemic occurs than during it.

45

1 In order to promote transparency and accountability, there should be a retrospective
2 review process to ensure that triage guidelines are applied accurately, consistently, and
3 fairly. This review would also serve as a quality-improvement process. However,
4 because of the need for triage decisions to be made in a timely manner, it would be
5 impractical for the review process to function as an appeal process for real-time decisions
6 (9).

7
8 In addition, policies for allocation of resources during a pandemic should involve the
9 following:

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

24
25 **Specific Ethical Considerations**

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

30
31 *Maximizing Net Benefits*

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

38
39 Maximize the number of lives saved - The utilitarian rule of maximizing the number of
40 lives saved is widely accepted during a public health emergency (16). Prioritizing
41 individuals according to their chances for short-term survival also avoids ethically
42 irrelevant considerations, such as race or socioeconomic status. Finally, it is appealing
43 because it balances utilitarian claims for efficiency with egalitarian claims that because
44 all lives have equal value the goal should be to save the most lives.

1 Working groups in Ontario, Canada and New York State have proposed modifying a
2 relatively simple mortality prediction model—the Sequential Organ Failure Assessment
3 (SOFA) score—to determine an individual’s priority for access to a ventilator (15, 17).
4 No model can predict with perfect accuracy which patients will benefit from mechanical
5 ventilation during a severe pandemic influenza and which will not. When selecting a
6 predictive score model, physicians and policy makers need to take into account several
7 considerations, including feasibility, ease of use, accuracy, validity, objectivity, and
8 transparency. The predictive score model employed should be based on the best
9 available science; hence research needs to be carried out to validate and potentially
10 modify whatever predictive score model is employed.

11
12 Any predictive score model yields probabilities of outcomes, which may not accurately
13 predict the outcome for any one individual. This concern has limited the use of
14 probabilistic scoring systems to make treatment decisions during routine clinical practice.
15 However, the rationale for their use is stronger during a severe pandemic influenza, when
16 the goal is to maximize population-level outcomes. Such an objective approach during a
17 severe pandemic may also be viewed by the public as fairer than decisions based on more
18 subjective criteria.

19
20 Maximizing years of life saved - A broader conceptualization of maximizing net benefits
21 is to consider the *years of life* saved in addition to the *number of lives* saved. Assuming
22 equal chances of short term survival, giving priority to a 60-year old woman who is
23 otherwise healthy over a 60 year-old woman with a limited life expectancy from severe
24 co-morbidities will result in more “life years” gained. The justification for incorporating
25 this utilitarian claim is simply that, all other things being equal, it is better to save more
26 years of life than fewer.

27
28 The principle of maximizing years of life saved has been used in organ transplantation to
29 exclude as recipients persons with such severe co-morbidities that they have a very poor
30 prognosis for survival even if they receive a transplant. Furthermore, this principle has
31 also been invoked in some published guidelines regarding triage of ventilators during a
32 severe pandemic influenza to exclude certain poor-prognosis subgroups of patients from
33 access to ventilatory support. For example, one group advocates denying ventilatory
34 support to persons who are functionally dependent from a neurologic impairment (18).
35 Another group recommends excluding those older than 85 years of age and those with
36 New York Heart Association Class III or IV heart failure (5, 15). These
37 recommendations have been criticized because the criteria for exclusion (age, long-term
38 prognosis, and functional status) are selectively applied to some patients, rather than to
39 all patients who require life-sustaining interventions. Such selective application violates
40 the principle of justice because patients who are similar in ethically relevant ways are
41 treated differently. Categorical exclusion may also have the unintended negative effect
42 of implying that some groups are “not worth saving,” leading to perceptions of
43 unfairness. These concerns might be addressed by keeping as *eligible* all patients who
44 require mechanical ventilation but allowing the availability of ventilators to determine
45 how many eligible patients receive one.

1 Maximizing adjusted years of life saved - A still more nuanced utilitarian approach
2 would be to maximize years of life after adjusting for the quality of those years.
3 However, predicting quality-adjusted life years (QALYs) or disability-adjusted life years
4 (DALYs) for an individual patient requires considerable clinical information about an
5 individual and would not be feasible when making decisions regarding intubation and
6 mechanical ventilations in an emergency department or ambulance during a public health
7 crisis (19, 20).

8
9 Although the utilitarian goal of maximizing net benefits is an important public health
10 principle, we conclude that ethically, allocating scarce resources during a severe
11 pandemic by only considering chances of survival to hospital discharge is insufficient
12 because it omits other important ethical considerations.

13 *Social Worth*

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

17
18
19 Broad social value - Broad social value refers to one’s overall worth to society. It
20 involves summary judgments about whether an individual’s past and future contributions
21 to society’s goals merit prioritization for scarce resources (16). When dialysis was first
22 introduced, social value was a key consideration in allocating scarce dialysis machines.
23 Patients who were professionals, heads of families, and caregivers received priority over
24 others who were perceived as less worthy (21). The public firestorm in response to
25 revelations that social worth was a key factor in the Seattle Dialysis Committee’s
26 deliberations partly led Congress to authorize universal coverage for hemodialysis (22).

27
28 In our morally pluralistic society, there has been widespread rejection of the idea that one
29 individual is intrinsically more worthy of saving than another. Many writers advocate the
30 egalitarian view that all individuals have an equal moral claim to treatment regardless of
31 whether they can contribute measurably to broad social goals (23). As one philosopher
32 put it, one’s "dignity as a person...cannot be reduced to his past or future contribution to
33 society (24)."

34
35 Instrumental value: The multiplier effect - Instrumental value refers to an individual’s
36 ability to carry out a specific function that is viewed as essential to prevent social
37 disintegration or a great number of deaths during a time of crisis. It has also been
38 described as “narrow social utility (16)” and the “multiplier effect (14).” Federal
39 guidance on prioritization of pandemic vaccines adopted this principle by recommending
40 that priority be given to individuals essential to the pandemic response (including public
41 health and healthcare personnel) and to those who maintain essential community services
42 (25, 26). The ethical justification is that prioritizing certain key individuals will achieve a
43 “multiplier effect” through which more many lives are ultimately saved through their
44 work.

1 Instrumental value must be distinguished from judgments about broad social worth.
2 Individuals who have instrumental value for one type of public health disaster may not
3 have instrumental value during another type of crisis. For example, vaccine manufacturer
4 workers would not be prioritized during the public health response to a terrorist attack
5 with chemical or nuclear weapons. Individuals are prioritized not because they are
6 judged to hold more “intrinsic worth,” but because of their ability to perform a specific
7 task that is essential to society. In this sense, instrumental value is a derivative allocation
8 principle; it is desirable because it ensures an adequate workforce to achieve public
9 health goals. Even critics of allocation based on broad social value accept the use of
10 instrumental value in certain circumstances (23).

11
12 However as indicated previously, using instrumental value may be ethically problematic
13 for decision making about allocation of ventilators. In general, to justify a restrictive
14 public health measure, there must be good evidence that the measure is *necessary* and
15 will be *effective* (27). Most important, will individuals with respiratory failure who
16 receive priority for mechanical ventilation recover in time to re-enter the work force and
17 achieve their instrumental purposes during the pandemic wave? Because of the
18 uncertainty about which key personnel will be in short supply and whether they will
19 recover in time to achieve their instrumental value, this criterion would likely be highly
20 controversial.

21 22 *The Life Cycle Principle*

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

32
33 Empirical data suggest that when individuals are asked to consider situations of absolute
34 scarcity of life sustaining resources, most believe younger patients should be prioritized
35 over older (30). One advocate for a life cycle approach declares: “it is always a
36 misfortune to die...it is both a misfortune and a tragedy [for life] to be cut off prematurely
37 (31).”

38
39 Some critics contend that the life cycle principle unjustly discriminates against older
40 individuals. However, others respond that this principle is inherently egalitarian because
41 it seeks to give *all individuals* equal opportunity to live a normal life span. It applies the
42 notion of equality to individuals’ *whole lifetime experiences* rather than just to their
43 current situation (29). In their view, unlike prioritization based on gender or race,
44 everyone faces the prospect of aging and everyone hopes to move through all stages of
45 life (28). However, when public input was sought in Seattle-King County on values and
46 priorities for delivery of medical services during a severe pandemic influenza, most

1 participants agreed that the number of years a person would live if they survive should
2 only be a factor in the absence of other priority criteria (13).

3
4 *Fair Chances versus Maximization of Best Outcomes*

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

22
23 **Incorporating Multiple Principles**

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

43
44 **WHO SHOULD MAKE VENTILATOR ALLOCATION DECISIONS?**

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

8
9 Separating the roles of clinical care and triage allows physicians who are caring for
10 patients with ventilatory failure to continue to maintain loyalty to their patients and to act
11 in their best interests (37). This separation of roles will mean that treating physicians will
12 not need to make a decision to withhold mechanical ventilation from patients who still
13 desire it. Instead, a triage officer could make decisions impartially based on the overall
14 outcomes for the population according to pre-determined guidelines, while the treating
15 physician is free to act in the best interests of the individual patient, within the constraints
16 of the public health emergency. Constant communication with the treating provider and
17 establishment of prioritization of patients to receive a critical resource is necessary in the
18 event a ventilator or other scarce resource becomes available (5).

19
20 The role of the triage officer will need to be specified in some detail in advance of a
21 pandemic. Questions that need to be addressed include what training they will receive,
22 what decision support and consultation and emotional support will be available, what
23 appeals will be permitted, and how decisions will be reviewed for quality improvement.

24 25 **OTHER CONSIDERATIONS**

26 27 **Uniform Decision Criteria versus Local Flexibility**

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

1 criteria may help address the moral hazard that an institution may "free ride" upon others,
2 rather than sharing the burden of making appropriate plans in advance.

3
4 Healthcare professionals and community representatives should be actively engaged in
5 the development of uniform criteria for access to ventilators and the rationale supporting
6 the criteria should be clearly articulated in advance of a pandemic influenza. During an
7 event of long duration, it is important to demonstrate an ongoing commitment to
8 transparency by continuing to seek community input on the adequacy of the criteria and
9 whether the criteria are being applied consistently. Additionally, steps should be taken to
10 ensure that all patients reaching the highest priority group have equitable access to the
11 pool of ventilators. This assures that allocation does not exacerbate pre-existing
12 inequalities in access to health care or disproportionately impact vulnerable populations.
13 For example, health jurisdictions should work with institutions to address issues of
14 fairness recognizing that institutions with trauma centers and larger intensive care
15 services will bear a disproportionate burden.

16
17 It is important to recognize the need for flexibility and ongoing evaluation of whether a
18 coordinated decision making process and uniform criteria are indicated as there may be
19 instances where specific local needs should be taken into consideration. Institutions
20 should be allowed to opt out of coordinated ventilator distribution plans when there is no
21 evidence to support a belief that coordination of decision making will contribute
22 substantially to fairness of access to care. However, institutions should be able to make
23 their reasons for implementing different criteria transparent. In general, state and local
24 health departments are strongly encouraged to work with hospitals and with each other to
25 implement uniform triage processes for ventilator distribution. The presumption should
26 be to follow uniform guidelines in the interest of fairness, consistency, and coordination
27 of efforts. State and local laws may provide authority for public health officials to
28 control, restrict, and/or regulate the use of private property, such as ventilators, for the
29 general welfare and may vary from jurisdiction to jurisdiction. Officials should
30 understand the scope of their authority during emergencies.

31
32 **Obligations to Healthcare Professionals**

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

1 Preparedness Act (“PREP Act”) enacted as Division C of the Defense Appropriations Act
2 for fiscal year 2006, Pub. L. No. 109-148), and address whether health jurisdictions will
3 defend physicians practicing under altered standards.
4

5 During a severe influenza pandemic and declared public health emergency there may be a
6 severe shortage of healthcare professionals skilled in providing intensive care. In the
7 planning phase increasing the number of individuals trained or cross-trained to manage
8 ventilator-dependent patients should be a goal. These staff should also be trained to
9 utilize supplemental ventilators whose settings and controls differ from those typically at
10 use in the institution. Staff will need to be informed of existing triage plans and trained
11 regarding their specific roles in implementing the triage protocol.
12

13 State medical boards, nursing boards and other licensing and certifying agencies should
14 be partners in planning efforts to “adjust scopes of practice” and “alter licensure and
15 credentialing practices” during declared emergencies (6). The IOM report also urged state
16 and local governments to explicitly tie liability protections to crisis standards of care, so
17 that concerns about legal liability do not deter health care workers from providing needed
18 care to individual patients and to society during a declared public health emergency.
19

20 We have suggested in this guidance that prioritizing based on preserving the functioning
21 of society is not relevant to decision making about distribution of ventilators. However,
22 some may argue that the ethical principle of reciprocity may provide ethical justification
23 for giving priority to those who put themselves at risk during a severe pandemic (i.e.,
24 health care providers and emergency responders), especially prior to the availability of a
25 vaccine. The application of this principle for allocation of ventilators will depend on the
26 extent of the shortage and the extent to which an individual healthcare provider faces
27 additional risk when providing care to others. In situations where health care providers
28 or other essential workers may benefit from a ventilator, the fact that they may have
29 become ill as a consequence of their work may be a factor to be considered.
30

31 **Community Engagement**

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

- 46 • Centralized, consistent messages

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

6
7 Since activities designed to engage communities exist to varying degrees in federal, state,
8 and local health agencies and their partners, these existing efforts should be expanded. It
9 may be appropriate to re-direct previously implemented or ongoing community
10 engagement initiatives to focus on issues raised by a severe pandemic influenza.

11 12 **Provision of Palliative Care**

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

30 31 **Withdrawal of Patients from Ventilators**

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

43
44 In ordinary clinical practice, it is rare for patients not to receive beneficial critical care
45 because of resource scarcity (51). However, when the need for ventilators temporarily
46 exceeds the supply of ventilators or critical care unit beds, typically arrangements are

1 made to postpone elective surgery, try to wean recovering patients from ventilators,
2 utilize emergency department beds or post-operative recovery suites to treat patients on
3 ventilators, or transfer patients to another healthcare institution. Because there are few
4 precedents and policies in ordinary clinical care for denying the use of mechanical
5 ventilation to patients who would benefit from it and who would agree to it, it is essential
6 that careful policies be developed in advance for use of mechanical ventilation during a
7 severe pandemic influenza in which the need for mechanical ventilation far exceeds
8 capacity (7).

9
10 In order to achieve the public health goal of minimizing the number of preventable deaths
11 during a severe pandemic emergency, states and hospitals need to address the issue of
12 removing patients with respiratory failure whose prognosis has significantly worsened
13 from ventilators in order to provide access to patients with a better prognosis. During a
14 declared public health emergency, decisions about allocation of scarce resources may be
15 taken out of the hands of patients and the treating physicians, in accordance with
16 transparent, accountable, and fair public health directives. Policies for withdrawal of
17 patients from ventilators need to be the least restrictive possible - i.e., withdrawing of
18 ventilation without requiring assent of patient or surrogate continues only as long as the
19 shortage of ICU resources continues. The policy should be transparent, formed with
20 input from the public, and include explicit criteria for identifying patients from whom
21 ventilation will be withdrawn. There should also be procedural safeguards for
22 prioritizing patients to receive ventilatory support (e.g., triage officer, post-event review
23 of decisions for quality improvement; policy developed with public input). Patients who
24 are removed from mechanical ventilation and their families or surrogates, like patients
25 with respiratory failure who are not placed on mechanical ventilation, should be notified
26 this will occur, given a chance to say good-byes and complete religious rituals, and
27 provided compassionate palliative care.

28 29 **CONCLUSIONS**

30
31 The intent of this guidance to provide decision makers at all levels—federal, tribal,
32 territorial, state, and local—with ethical points to consider when life-sustaining healthcare
33 resources are limited due to a severe pandemic influenza. It is intended only for
34 circumstances when people with severe acute respiratory failure far outnumber available
35 and adequate mechanical ventilator availability and when a public health emergency has
36 been declared. If a scarcity of ventilators occurs during a severe pandemic influenza,
37 ventilators will need to be allocated according to different guidelines than during usual
38 clinical care. Unlike the allocation of pandemic vaccines and antiviral medications,
39 where the principle of preserving the functioning of society has a high priority, decisions
40 about allocation of ventilators pose a different situation. Individuals who require a
41 ventilator are unlikely to recover sufficient function to contribute to the preservation of
42 the functioning of society—at least not during the ‘wave’ of the pandemic during which
43 they fell ill. We present a number of general ethical principles that should guide
44 ventilator allocation decisions—respect for persons and their autonomy, beneficence, and
45 justice—and review several strategies for establishing priorities for who should receive a
46 ventilator when there are not enough for everyone. We suggest that a multi-principle

1 allocation system may best reflect the diverse moral considerations relevant to these
2 difficult decisions. Most importantly, triage models for allocation of scarce life-saving
3 resources should be evaluated based on the extent to which they result in fair processes
4 and should take into account the values and priorities of the community members who
5 will be impacted. We recommend that state and local health departments work with
6 hospitals and each other to implement uniform triage processes for ventilator distribution
7 in the interest of fairness, consistency, and coordination of efforts.

8
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