Factors Informing Clinical Decisions about Ventilator Use during Ventilator Shortages in an Infectious Disease Pandemic


During infectious disease pandemics, hospitals can become overwhelmed if many patients require life-saving measures. Ventilator shortages are common, and clinicians must make critical decisions regarding their use (i.e., who gets one, when to terminate care). Factors that may inform decision making during ventilator shortages include patient age, presence of comorbidities, expected survival, and existence of advanced directives. In this report, we examine the effectiveness of triage systems for identifying disease severity and mortality risk to inform decisions on scarce resource allocation during pandemics.

The Evidence Bar™

Evidence raises concerns

We identified 14 guidelines, 4 triage frameworks, and 10 disease-severity scoring systems intended to aid scarce resource allocation during pandemics. We reviewed nine studies evaluating the efficacy of scoring systems and frameworks using H1N1 patient cohorts. The available literature raises concerns that these systems may be inadequate for determining patient disease severity and mortality risk. Some scoring systems (e.g., Sequential Organ Failure Assessment [SOFA]), if used, would have prevented intensive care unit (ICU) admission for patients with high scores who survived with treatment.

Evidence limitations. Studies are at high risk of bias due to one or more of the following: retrospective design, small sample size, and single-center focus. All studies evaluating triage systems used patient cohorts from the H1N1 pandemic; therefore, triage effectiveness and the predictive values of risk factors may not generalize to pandemics of other pathogens, such as SARS CoV2. Three of the four triage officers in one study (Christian et al.) participated in drafting the triage protocols, and this model’s results (e.g., confidence in decisions) may not reflect outcomes in real-world triage settings.
Executive Summary

Findings

We assessed 9 studies evaluating efficacy of scoring systems and frameworks.

- 5 retrospective cohort studies (Shahpori et al., Adeniji and Cusack, Khan et al., Guest et al., and Christian et al.) reported that using SOFA score >11, a predictor of high mortality risk, to relegate patients to palliative care was ineffective for prioritizing care of survivors. Shahpori et al. (n = 10,204) reported patients with H1N1 with SOFA score >11 had only 31% mortality, and Guest et al. (n = 24) found 39% of patients who would have been excluded by SOFA survived.

- 1 case series (Estenssoro et al., n = 337) reported APACHE II score, lowest PaO2/FIO2 value (oxygen exchange), shock, hemodialysis, and prone positioning each independently predicted mortality in patients with H1N1 infections on mechanical ventilation (p <0.001).

Evidence

Search dates: We searched PubMed, EMBASE, and the Cochrane Library for studies published January 1, 2000, through April 2, 2020. We reviewed full text of 2 systematic reviews (SRs) and 10 studies.

- We assessed scoring systems used during the severe acute respiratory syndrome (SARS), Middle East Respiratory Syndrome (MERS), H1N1, and COVID-19 pandemics. We included studies that assessed the effectiveness of decision making based on disease severity scoring systems and studies that focused on survival predictors of patients on mechanical ventilation. We also included an SR on MERS risk factors and mortality predictors.

- 1 SR (Matsuyama et al. 2016; 25 studies, n = 2,081) examined clinical predictors of mortality in patients with MERS.

- 1 SR (Timbie et al. 2013; 23 of 74 studies) assessed the effectiveness of triage systems for allocating scarce resources during pandemics.

- 1 multicenter case series (Estenssoro et al. 2010; n = 337) of consecutive patients with pandemic H1N1 infections on mechanical ventilators reported on mortality predictors, including APACHE II scores, oxygen exchange measurements (PaO2/FiO2), hemodialysis, and coinfections.

- 1 retrospective, multicenter cohort study (Morton et al. 2015; n = 101) compared Ontario Health Plan for an Influenza Epidemic (OHPIP) triage protocol, Simple Triage Scoring System (STSS), and PaO2/FiO2 measurements for predicting the need for mechanical ventilation in patients with pandemic H1N1 infections.

- 1 retrospective, multicenter cohort study (Fujikura et al. 2014; n = 320) compared CURB-65 and A-DROP (age, dehydration, respiration, disorientation, and blood pressure) scoring systems for predicting mortality and severe pneumonia in patients with pandemic H1N1 infections.

- 1 retrospective, multicenter cohort study (Semple et al. 2013; n = 1,520) assessed community assessment tools for predicting severe outcomes in patients with pandemic H1N1 infections.

- 1 prospective, multicenter cohort study (Challen et al. 2012; n = 481) compared triage systems (CURB-65, PMEWS, and “swine-flu hospital pathway criteria”) for predicting serious illness or death in patients with pandemic H1N1 infections and reported on the sensitivity and specificity of scores at decision-making thresholds.

- 1 retrospective, multicenter cohort study (Shahpori et al. 2013; n = 10,204) assessed the association of mortality with high SOFA scores in patients with pandemic H1N1 infections.

- 1 retrospective, single-center cohort study (Adeniji et al. 2011; n = 62) compared the accuracy of STSS and SOFA for predicting patient outcomes and allocating resources, including ventilators.

- 1 retrospective, single-center cohort study (Khan et al. 2009; n = 8) assessed use of SOFA for predicting mortality of patients with pandemic H1N1 infections to inform allocation of scarce resources and reported on triage scoring and patient survival.
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1 retrospective, multicenter cohort study (Guest et al. 2009; n = 255) assessed SOFA scoring for predicting mortality to triage patients with pandemic H1N1 infections. Patients with SOFA >11 were triaged for palliative care.

1 retrospective, multicenter cohort study (Christian et al. 2009; n = 234) applied the OHIP draft triage protocol as a pilot to determine the framework's effectiveness. Triage officers assigned treatment priorities on the framework's criteria, including palliative care for patients with SOFA >11. Authors reported on survival rates for each triage group, number of ventilator and ICU days, and triage officers’ decision-making abilities.

Scoring Systems, Guidelines, Position and Consensus Statements


Scoring Systems: We identified 10 scoring systems.

- SOFA, APACHE II, Simplified Acute Physiology Score (SAPS II), Morbidity Probability Model II (MPM II), Charlson Comorbidity Index (CCI), CURB-65 (confusion, urea, respiratory rate, blood pressure, and age ≥65 years), A-DROP, Logistic Organ Dysfunction Score (LODS), STSS, and the Modified Early Warning (MEW).


- Guidelines: Italian Society of Anesthesia, Analgesics, Resuscitation, and Intensive Care; Swiss Academy of Medical Sciences; World Health Organization; U.K. Dept. of Health; U.S. Centers for Disease Control and Prevention (CDC); Veterans Health Administration Center for Ethics in Healthcare; Minnesota Dept. of Health; Colorado Dept. of Public Health and Environment; Oregon Health Authority; Tennessee Dept. of Health; New York Dept. of Health; Kansas Dept. of Health; Washington State Dept. of Health; Michigan Dept. of Community Health.

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Background

During infectious disease pandemics, hospitals can become overwhelmed if many patients require life-saving measures and ventilators are in short supply. In this scenario, clinicians must make critical decisions regarding ventilator access and use (i.e., who gets one, when to end care). Factors that may inform decision making include patient age, presence of comorbidities, expected survival, and patients’ advanced directives.

Pandemics

According to CDC, 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.” Disease pandemics caused by respiratory viruses that have occurred in the last few decades include severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), SARS, MERS, and H1N1 (i.e., swine flu).

COVID-19, a respiratory illness and ongoing pandemic (as of spring 2020) caused by SARS-CoV-2, was first identified during an investigation into an outbreak in Wuhan, China, in December 2019. Since then, the illness has spread throughout the world (see CDC Fact Sheet).

SARS, a respiratory illness caused by the SARS-associated coronavirus (SARS-CoV), was first reported in Asia in February 2003. The outbreak in countries in North America, South America, Europe, and Asia was contained in 2003 (see CDC fact sheet).

MERS, a viral respiratory illness caused by the Middle East Respiratory Syndrome coronavirus (MER-CoV), was first reported in Saudi Arabia in September 2012. So far, “all cases of MERS have been linked through travel to, or residence in, countries in and near the Arabian Peninsula” (see CDC MERS fact sheet).

H1N1, a respiratory illness caused by the H1N1pdm09 virus, originated in the United States in 2009 and spread throughout the world. The World Health Organization declared the H1N1 influenza pandemic over in August 2010 (see CDC 2009 H1N1 Pandemic).

Table 1. Pandemic Statistics on Incidence, Mortality, and Mortality Risk

<table>
<thead>
<tr>
<th>Pandemic</th>
<th>Number of Cases Worldwide</th>
<th>Ventilation/ ICU Requirement</th>
<th>Worldwide Mortality Rate</th>
<th>Mortality Risk Factors</th>
</tr>
</thead>
<tbody>
<tr>
<td>COVID-19</td>
<td>On the rise in 184 countries: 1,536,094 cases as of April 9, 2020 (Worldometer)</td>
<td>As of April 8, 2020, 48,079 cases (3%) were deemed “serious or critical” (Worldometer)</td>
<td>Estimate: 0.25% to 3.0%(1)</td>
<td>Individuals over age 80 years (&gt;14%) and those with coexisting conditions (10% for those with cardiovascular disease and 7% for those with diabetes)(1)</td>
</tr>
<tr>
<td>SARS</td>
<td>8,098 probable SARS cases in 29 countries were reported to the World Health Organization (CDC MMWR).</td>
<td>About 20% to 30% of patients required ICU admission; most of them required mechanical ventilation.(2)</td>
<td>9.6% (CDC MMWR)</td>
<td>Advanced age and coexisting illness (diabetes or heart disease)(2)</td>
</tr>
<tr>
<td>MERS</td>
<td>2,484 cases (CDC Emerging Infectious Diseases)</td>
<td>50% to 89% of patients required ICU admission(3)</td>
<td>34.5% (CDC Emerging Infectious Diseases)</td>
<td>Underlying medical condition (CDC Information Sheet)</td>
</tr>
</tbody>
</table>
# Factors Informing Clinical Decision about Ventilator Use during Ventilator Shortages in an Infectious Disease Pandemic

## Pandemic | Number of Cases Worldwide | Ventilation/ ICU Requirement | Worldwide Mortality Rate | Mortality Risk Factors
--- | --- | --- | --- | ---
H1N1 | Unknown | Median 90.2 (64.2 to 132.4) per 100,000 required ventilation(4) | Estimated deaths worldwide 151,700 to 575,400 (CDC 2009 H1N1 Pandemic) | Age younger than 65 (CDC 2009 H1N1 Pandemic) Infants <6 months of age, children with underlying neuromuscular disease, pulmonary disorders, or other comorbid conditions.(5)

### Ventilator Shortages during Pandemics

During pandemics, successfully ventilating critically ill patients depends on ventilator availability and “having sufficient numbers of suitably trained staff, needed supplies (e.g., drugs, reliable oxygen sources, suction apparatus, circuits, and monitoring equipment) and timely ability to match access to ventilators with critically ill cases.”(6) The need to ration available ventilators “depends on the pace of the pandemic and how many patients need ventilation at the same time.”(7)

At the start of the COVID-19 outbreak in the United States, the country had approximately 62,000 full-featured ventilators (the type needed to adequately treat the most severe complications), about 10,000 to 20,000 more on call in the CDC Strategic National Stockpile, and an estimated 98,000 ventilators without full features that could provide basic function in an emergency.(1) As the illness spread, ventilator demand rose as states prepared for potential shortages. States most affected by COVID-19 reported shortages of ventilators and ventilator-related medications. In addition, many healthcare workers contracted the disease, creating shortages of the skilled staff needed to care for many ventilated patients.

During ventilator shortages, healthcare providers may consider the following measures:

- **Use of non-FDA-cleared ventilators:** In the United States, mechanical ventilators are subject to FDA clearance through the 510(k) process. However, equivalent performance and controls are required for ventilators available with a CE mark in Europe and registered with the Australian Trade Goods Registrar. Some manufacturers, such as Medtronic (Dublin, Ireland), have also made their designs available for assembly by third parties, and open-source designs are also available. (For additional information, see the FDA Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices during the Coronavirus Disease 2019 [COVID-19] Public Health Emergency.)

- **Alternative devices:** Anesthesia gas machines and portable ventilators are not intended for extended use and may not provide all possible ventilator modes but may provide basic support to patients until a full ventilator is available. Bilevel and continuous positive airway pressure therapy and high-flow oxygen therapy devices are intended to improve oxygenation in patients with spontaneous breathing and may be used to delay ventilator use in such patients. Risks of airborne disease spread should be considered when using these devices for noninvasive ventilation during outbreaks. (For additional information, see the FDA Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices during the Coronavirus Disease 2019 [COVID-19] Public Health Emergency.)

- **Triage-based allocation:** Clinicians use scoring systems that predict mortality or triage frameworks to inform decisions to not ventilate or terminate ventilation in patients who are not expected to recover.
Ethical Concerns

Triage-based Allocation

Triage-based allocation of scarce potentially life-saving equipment during pandemics raises ethical concerns. Several papers have been published that address the ethical concerns, including those authored by Hick et al. (8) and White et al. (9)

Hick et al. emphasize that an ethical framework with the following components is necessary to support decision making when resources are scarce: (8)

- Fairness: The process is inherently just to all individuals, and the process itself treats all individuals equally who have equal needs.
- Duty to care: Physicians have a duty to care as best they can for all victims of the incident.
- Duty to steward resources: Physicians have a duty to attempt to obtain the best outcome for the greatest number of patients with the resources available (this does not specifically translate to “save the most lives” because a comfortable death may be a good outcome and thus appropriate to receive resources).
- Transparency: Though difficult in reactive triage decisions, the process and criteria should be as transparent as possible
- Consistency: The process should be applied in the same way to all presenting for care.
- Proportionality: The degree of resource restriction should be proportional to the demands.
- Accountability: Triage officers and others should be able to defend their decisions and be answerable for them. This may involve documentation and potential review of decisions by the institution and possibly outside agencies.

White et al. describe the following principles that should guide allocation of scarce resources: (9)

- Broad social value: one’s overall worth to society.
- Instrumental value: an individual’s ability to carry out a specific function that is essential to prevent social disintegration or a great number of deaths during a time of crisis.
- Maximizing life-years: a broader conceptualization of accomplishing the “greatest good” is to consider the years of life saved in addition to the number of lives saved.
- The life cycle principle: give relative priority to younger individuals over older individuals

Several triage frameworks have been developed to aid the allocation of resources during a pandemic, and numerous legal and ethical concerns are associated with planning and implementing resource rationing. Allocation strategies should be designed impartially and justly to best serve the afflicted, but the principles behind them vary. Potential triage approaches include “first come, first serve,” deciding based on “social worth,” and a utilitarian policy intended to do the most good for the most people possible (i.e., maximize lives saved). An SR of literature on ethical guidance for disaster response states: “Some scholars argue that a purely consequentialist viewpoint could lead to substantive unfairness or injustice.” (10)

Ethics Guidelines from the Centers for Disease Control and Prevention

In 2007, the CDC published Ethical Guidelines in Pandemic Influenza for decision making in preparing for and responding to influenza pandemics. CDC’s ethical considerations include the following:

- Public engagement and involvement are important to allow vulnerable or marginalized groups to know they are a part of the decision-making process and seen as partners with other experts.
- The responsibility to maximize preparedness requires proactive planning to reduce lag time for training staff, resource distribution, and production of prophylaxis, vaccines, antivirals, or other necessary resources.
- Basing guidelines on sound scientific evidence: “The current knowledge basis should serve as a foundation for ethical guidelines and a commitment to ongoing scientific and ethical evaluation of interventions should be made.”
Recognize the importance of working with and learning from preparedness efforts globally. Also recognize international connectedness and the impact decisions made in the United States can have on the rest of the world.

Diversity in ethical decision making. To avoid repeating historical mistreatment of people in the context of public good, “public health officials must adequately acknowledge and respond to strong currents of suspicion and distrust of the healthcare system… Diverse public voices should be involved in determining the need for restrictions and in articulating the ethical justification for these restrictions.”

Legal Concerns

Cohen et al. authored an article about withholding ventilators during the COVID-19 pandemic, stating that “clinicians who withhold or withdraw ventilators without patients’ consent become exposed to risks of criminal and civil liability. The odds that such liability will materialize in any given instance are likely low, especially if clinicians follow recommended guidelines and strategies when allocating ventilators.” (See full article for more details.)

Advanced Directives

Legal documents that allow patients to make end-of-life decisions ahead of time (i.e., advanced directives) also inform clinical decision making when life-saving resources are scarce. During the COVID-19 pandemic, clinicians were encouraged to “proactively engage in discussions with high-risk patients and their families regarding do-not-intubate orders before the need for a ventilator.”

Scoring Systems for Predicting Mortality Risk

Clinicians can use several scoring systems to predict mortality risk in intensive care settings. Scoring systems allow comparison of mortality risk between patients when life-saving equipment is scarce. We include descriptions of those that are most commonly mentioned in the literature on resource management during pandemics or listed in COVID-19 resource support documents.

Sequential Organ Failure Assessment

The SOFA score assesses the likelihood of sequential organ failure based on the degree of dysfunction of six organ systems (i.e., neurologic, blood, liver, renal, blood pressure/hemodynamics). Clinicians calculate a numeric score on a scale of 0-4 based on a few clinical and laboratory measurements (i.e., bilirubin, creatinine, platelet count) obtained on admission and every 24 hours until discharge using the worst parameters measured during the prior 24 hours. The higher the score, the higher the mortality risk.

The Modified SOFA score assesses the likelihood of sequential organ failure based on the degree of respiratory, liver, cardiovascular, and neurologic dysfunction. This score requires fewer laboratory tests because it “substitutes measurements of PaO2/FiO2 and serum bilirubin level with the SPO2/FiO2 ratio (obtained by dividing pulse oximeter saturation with a fraction of inspired oxygen) and clinical examination for jaundice.” (See article by Rapsang and Shyam.)

APACHE II

The APACHE II point score provides a general measure of disease severity based on 12 routine physiologic measurements (taken during the first 24 hours after admission), age, and previous health status. Clinicians calculate a score from 0 to 71 based on these measurements. Higher scores indicate a more severe disease and a higher mortality risk.

Simplified Acute Physiology Score

The SAPS II score is based on 12 physiologic variables, 3 disease-related variables, age, and admission type. This score captures the worst value of selected variables within the first 24 hours of admission. This score ranges from 0 to 163 points. Mortality risk is calculated using logistic regression.
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Morbidity Probability Model II

The MPM II model estimates hospital mortality risk directly based on chronic health status, acute diagnosis, a few physiologic variables, and other variables, including mechanical ventilation. Clinicians use 1 of 4 models (i.e., MPM II at admission, at 24 hours, at 48 hours, at 72 hours) to compute mortality risk using logistic regression.

Charlson Comorbidity Index

The CCI score is used to estimate 10-year survival in patients with multiple comorbidities. Scoring is based on age; history of definite or probable myocardial infarction; history of stroke or transient ischemic attack; and diagnosis of congestive heart failure, peripheral vascular disease, dementia, chronic obstructive pulmonary disease, connective tissue disease, peptic ulcer disease, liver disease, diabetes mellitus, hemiplegia, moderate to severe chronic kidney disease, solid tumor, leukemia, lymphoma, or AIDS. The lower the score, the higher the chance of survival.

CURB-65

The CURB-65 score estimates pneumonia severity based on a point for confusion, blood urea nitrogen levels >19 mg/dL (>7 mmol/L), respiratory rate ≥30, systolic blood pressure (BP) <90 mmHg or diastolic BP ≤60 mmHg, and age ≥65 years. The higher the score, the greater the mortality risk.

A-DROP

The A-DROP score is a modified version of the CURB-65 score that estimates pneumonia severity based on a point for age ≥70 years in males or ≥75 years in females, blood urea nitrogen ≥21 mg/dL or dehydration, oxyhemoglobin saturation measured by pulse oximetry ≤90% or partial oxygen pressure in arterial blood ≤60 mmHg, confusion, and systolic BP ≤90 mmHg. The higher the score, the greater the mortality risk.

Logistic Organ Dysfunction Score

The LODS is a point score that predicts mortality based on the degree of dysfunction in the neurologic, cardiovascular, renal, pulmonary, hematologic, and hepatic systems. The higher the score, the greater the mortality risk.

Simple Triage Scoring System

The STSS provides a numeric score that predicts mortality based on points for a respiratory rate >30 breaths per minute, shock index >1 (HR > BP), low oxygen saturation, altered mental state, age of 65 to 74 years, and age of at least 75 years. The higher the score, the greater the mortality risk.

Modified Early Warning

The MEW score provides a numeric score that predicts risk of deterioration in a busy clinical area based on points for abnormal BP, heart rate, respiratory rate, and temperature as well as consciousness level. The higher the score, the greater the risk.

For a more detailed discussion of mortality risk scoring, see the article by Rapsang and Shyam and information from MDCalc COVID-19 Resource Center.

Triage Frameworks

Clinicians can use triage frameworks to make allocation decisions when rationing scarce healthcare resources is necessary. Frameworks “incorporate multiple ethically relevant considerations, while allowing all patients in need to be eligible for access to critical care” (see article by DeBruin et al.) See Table 2 for examples of triage frameworks.
## Table 2. Examples of Triage Frameworks

<table>
<thead>
<tr>
<th>Author/Year</th>
<th>Framework Title</th>
<th>Resources Searched and Inclusion Criteria</th>
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<tbody>
<tr>
<td>University of Pittsburgh 2020</td>
<td><strong>Framework for Rationing Ventilators and Critical Care Beds During the COVID-19 Pandemic</strong> (11)</td>
<td>This framework includes a scoring system “intended to maximize benefit to populations of patients, specifically by maximizing survival to hospital discharge and beyond for as many patients as possible.” Using this framework, patients are “assigned a priority score using a 1 to 8 scale (lower scores indicate higher likelihood of benefit from critical care), based on (1) patients’ likelihood of surviving to hospital discharge, assessed with an objective measure of acute illness severity; and (2) patients’ likelihood of achieving longer-term survival based on the presence or absence of comorbid conditions that influence survival. In addition, individuals who perform tasks vital to the public health response are given heightened priority by subtracting points from their priority score. In the event that there are ties in priority scores between patients, life-cycle considerations are used as a tiebreaker, with priority going to younger patients, who have had less opportunity to live through life’s stages.” On March 23, 2020, the Commonwealth of Pennsylvania expressed support for use of this framework by all Pennsylvania hospitals during the COVID-19 outbreak. Many other U.S. hospitals also adopted this framework during that time.</td>
</tr>
<tr>
<td>Framework Advisory Council/Maryland State 2017</td>
<td><strong>Maryland Framework for the Allocation of Scarce Life-sustaining Medical Resources in a Catastrophic Public Health Emergency</strong></td>
<td>This framework includes “a scoring system intended to assist Maryland hospitals and public health agencies in their response to a declared catastrophic health emergency in which there has been an order to implement scarce resource allocation procedures.” The framework includes consideration of prognosis for short-term survival (SOFA score), prognosis for long-term survival (i.e., comorbid conditions), and life cycle consideration (i.e., age). “Individual scores (1-4 for short-term; 0 or 3 for long-term) are assigned for each consideration and then added together to produce a total triage score (minimum 1, maximum 7). Priority is given to those with the lowest total triage scores.” (12)</td>
</tr>
<tr>
<td>Minnesota Department of Health/Minnesota Center for Health Care Ethics and the University of Minnesota Center for Bioethics 2010</td>
<td><strong>Ethically Rationing Health Resources in Minnesota in a Severe Influenza Pandemic</strong></td>
<td>This document includes a detailed ethical framework for rationing ventilators.</td>
</tr>
<tr>
<td>Steering Committee of the Ontario Health Plan for an Influenza Pandemic 2006</td>
<td><strong>Ontario Health Plan for an Influenza Epidemic (OHPIP) Triage Protocol</strong></td>
<td>This protocol “is intended to provide guidance for making triage decisions during the initial days to weeks of an influenza pandemic if the critical care system becomes overwhelmed.” The protocol “uses the Sequential Organ Failure Assessment score and has 4 main components: inclusion criteria, exclusion criteria, minimum qualifications for survival and a prioritization tool.”</td>
</tr>
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Potential Pitfalls of Scoring Systems and Frameworks

Discussing preparation for future influenza pandemics, the Ethics Subcommittee of the Advisory Committee to the director of CDC stated in 2007 that the utilitarian approach “is not a morally adequate platform for pandemic influenza planning. We recommend an approach to ethical justification, that, like utilitarianism, evaluates the rightness or wrongness of actions or policies primarily by their consequences, but, we further recommend that planning should take into account other checks (‘side constraints’) grounded in the ethical principles of respect for persons, nonmaleficence, and justice.” The recommendations describe additional principles that may temper patient and community suffering compared with a strictly utilitarian policy:

- Refrain from harming or injuring individuals and communities.
- Equal opportunity to access resources should be assured to those within agreed upon priority groups.
- Respect for individual autonomy by, for example, employment of the least restrictive interventions that are likely to be effective.

The subcommittee further expressed that “first come, first served” policies may disservice disadvantaged populations (e.g., people who are less informed or lack transportation) and that “the distribution criterion, ‘to each according to his or her social worth,’ is not morally acceptable. However, in planning for a pandemic where the primary objective is to preserve the function of society, it is necessary to identify certain individuals and groups of persons as ‘key’ to the preservation of society and to accord to them a high priority for the distribution of certain goods such as vaccines and antiviral drugs... Care must be taken to avoid extension of the evaluation of social worth to other attributes that are not morally relevant.”

Scoring systems, such as SOFA and STSS, are included frameworks to help determine which patients are more likely to survive and are therefore better candidates for ICU admission, mechanical ventilation, or other resources in the event of shortages. SOFA scores greater than 11 have been associated with a >90% mortality risk (Cabré et al., and Ferreira et al.), but Shahpori et al. reported that mortality rate was only 31% among patients with H1N1 and SOFA >11.13 The authors discuss that change in SOFA score may be more valuable than an individual score, but such retrospective outcomes are not known at the time of triage.

Morton et al.(14) compared scoring systems retrospectively, using patient cohorts from the H1N1 pandemic, and found they were less effective than a single outcome measuring pulmonary function (PaO2 /FIO) for predicting survival. A retrospective pilot study of the Ontario Health triage protocol found that although the system succeeded in reducing ICU admission of patients who would have died, one-fourth of the excluded patients ended up surviving until they were discharged.(15) Even in a simulated event, triage officers frequently disagreed, requiring arbitration, and their reported confidence levels for decision making fell well below the 90% goal.
Guidelines, Position and Consensus Statements

Searches of PubMed, EMBASE, ECRI Guidelines Trust, and other web-based resources identified 14 relevant guidance documents (i.e., global guidelines, examples of U.S. regional guidelines, standards and disaster plans not intended to be all-inclusive) published between January 1, 2010, and April 2, 2020. See Table 3 and Table 4 for summaries.

Table 3. Guidelines

<table>
<thead>
<tr>
<th>Author/Year</th>
<th>Title</th>
<th>Summary</th>
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| Italian Society of Anesthesia, Analgesia, Resuscitation, and Intensive Care 2020 | **Clinical Ethics Recommendations for the Allocation of Intensive Care Treatments, in Exceptional Resource-Limited Circumstances** | This guidance includes the following recommendations:
  - “An age limit for the admission to the ICU [intensive care unit] may ultimately need to be set. The underlying principle would be to save limited resources which may become extremely scarce for those who have a much greater probability of survival and life expectancy, in order to maximize the benefits for the largest number of people. In the worst-case scenario of complete saturation of ICU resources, keeping a ‘first come, first served’ criterion would ultimately result in withholding ICU care by limiting ICU admission for any subsequently presenting patient.”
  - Together with age, “the comorbidities and functional status of any critically ill patient presenting in these exceptional circumstances should carefully be evaluated. A longer and, hence, more ‘resource consuming’ clinical course may be anticipated in frail elderly patients with severe comorbidities, as compared to a relatively shorter, and potentially more benign course in healthy young subjects.”
  - “The presence of advance healthcare directives or advance care planning should be carefully evaluated, especially for patients affected by severe chronic illnesses. These plans should be shared as much as possible between the patient, their proxies and all the healthcare staff involved in patient care.” |

| Swiss Academy of Medical Sciences 2020 | **COVID-19 Pandemic: Triage for Intensive-care Treatment under Resource Scarcity** | This guidance emphasizes that “four widely recognized principles of medical ethics (beneficence, non-maleficence, respect for autonomy and equity) are crucial under conditions of resource scarcity.”
  - “If ICU capacity is exhausted and not all patients who require intensive care can be admitted, the short-term prognosis is decisive for purposes of triage. For ICU admission, highest priority is to be accorded to those patients whose prognosis with regard to hospital discharge is good with intensive care, but poor without it – i.e. the patients who will benefit most from intensive care.
  - Age in itself is not to be applied as a criterion, as this would be to accord less value to older than to younger people, thus infringing the constitutional prohibition on discrimination. Age is, however, indirectly taken into account under the main criterion “short-term prognosis”, since older people more frequently suffer from comorbidity. In connection with COVID-19, age is a risk factor for mortality and must therefore be taken into account.
  - Consideration of additional criteria. In the literature, additional criteria are discussed, such as lotteries, ‘first come, first served’ and prioritisation according to social usefulness. These criteria are not to be applied.” |
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<th>Author/Year</th>
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<td>World Health Organization 2016</td>
<td>Guidance for Managing Ethical Issues in Infectious Disease Outbreaks</td>
<td>“Resource allocation decisions should be guided by the ethical principles of utility and equity. The principle of utility requires allocating resources to maximize benefits and minimize burdens, while the principle of equity requires attention to the fair distribution of benefits and burdens. In some cases, an equal distribution of benefits and burdens may be considered fair, but in others, it may be fairer to give preference to groups that are worse off, such as the poor, the sick, or the vulnerable. It is not always be possible to achieve fully both utility and equity.”</td>
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<tr>
<td>U.K. Department of Health 2011</td>
<td>UK Influenza Pandemic Preparedness Strategy 2011</td>
<td>“National and local preparations for an influenza pandemic should be based on widely held ethical values, and the choices that may become necessary should be discussed openly as plans are developed, so that they reflect what most people will accept as proportionate and fair. At the request of the Department of Health, an independent committee with cross-UK representation has developed an ethical framework to inform the development and implementation of response policy both in the health and social care sector and more widely. The systematic use of the principles it contains can act as a checklist to ensure that all the ethical aspects have been considered at all levels.”</td>
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<tr>
<td>U.S. Centers for Disease Control and Prevention 2011</td>
<td>Ethical Considerations for Decision Making Regarding Allocation of Mechanical Ventilators during a Severe Influenza Pandemic or Other Public Health Emergency</td>
<td>“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.”</td>
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Factors Informing Clinical Decision about Ventilator Use during Ventilator Shortages in an Infectious Disease Pandemic

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<tr>
<td>Veterans Health Administration.</td>
<td>Meeting the Challenge of Pandemic Influenza: Ethical Guidance for Leaders and Health Care Professionals in the Veterans Health Administration</td>
<td>This guidance includes exclusion criteria for access to scarce life-saving resources as follows: Confirmed presence of any advanced disease with average life expectancy of 6 months or fewer (e.g., advanced cancer or end-stage organ failure with fewer than 6 months average survival). Recent cardiac arrest: unwitnessed arrest, recurrent arrest, arrest unresponsive to standard measures, trauma-related arrest. Confirmed severe irreversible cognitive impairment (e.g., Persistent Vegetative State or advanced dementia).</td>
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Table 4. Examples of U.S. Regional Guidelines, Standards, and Disaster Plans

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<tr>
<td>Minnesota Department of Health</td>
<td>Patient Care Strategies for Scarce Resource Situations</td>
<td>This guidance includes a list of strategies that can be employed when ventilators are scarce.</td>
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| Colorado Department of Public Health and Environment (CPDHE) | CDPHE All Hazards Internal Emergency Response and Recovery Plan. Annex B: Colorado Crisis Standards of Care Plan | “Allocation of limited resources should support achieving the greatest measurable benefit for the greatest possible number of persons over the long run. During an incident with scarce resources, all therapies that might usually be available may not be appropriate for some patients, yet other curative and/or comfort care treatments should still be provided. There is also an ethical duty to maximize preparedness efforts and adopt prevention strategies that will minimize the scarcity of resources and the need to ration resources at a later time during a disaster. These Crisis Standards of Care are based upon several ethical principles that have been recognized as central to a just process for allocating limited resources during catastrophic disasters.  
  ─ Fairness - Every healthcare provider should attempt to be fair to all those who are affected by the disaster, without regard to factors such as race, ethnicity, socioeconomic status, disability or region that are not medically relevant.  
  ─ Proportionality - any reduction in the quality of care provided should be commensurate with the degree of emergency and the degree of scarcity of resources.  
  ─ Solidarity - when limited available resources are unable to meet everyone’s needs, all people should consider the greater good of the entire community.  
  ─ Participatory - planners and decision-makers should engage the community, healthcare providers, and emergency management agencies during the development of CSC, which can encourage greater understanding, clarity, and trust when CSC implementation is required.” |
## CLINICAL EVIDENCE ASSESSMENT

Factors Informing Clinical Decision about Ventilator Use during Ventilator Shortages in an Infectious Disease Pandemic

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<tr>
<td>Oregon Health Authority 2018</td>
<td><em>Oregon Crisis Care Guidance Critical Care Triage Card</em></td>
<td>This guidance includes a triage tool that “bases resource allocation decisions on: 1) Likelihood of death, based on best information, if presenting patient doesn’t receive critical care services, 2) Likelihood of survival and recovery from acute condition if critical care services provided. 3) Scope and magnitude of resources needed to care for this patient and the scarcity of those resources 4) Underlying medical conditions and expected impact on long-term prognosis. For Pregnant women - critical care allocation decisions based primarily on woman’s clinical condition and chance of survival. If, based on assessment and resources available, there is high likelihood of unborn infant’s survival, this could be considered in resource allocation. Modified Sequential Organ Failure Assessment Higher score suggests worse prognosis despite receipt of critical care resources. Could be used to guide allocation decisions, but only as tie-breaker when patients meeting critical care criteria outnumber critical care beds.”</td>
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<tr>
<td>Tennessee Department of Health, the Tennessee Hospital Association, and other industry experts 2016</td>
<td><em>Guidance for the Ethical Allocation of Scarce Resources during a Community-Wide Public Health Emergency as Declared by the Governor of Tennessee</em></td>
<td>This standard states, “Principles to guide decision makers through community-wide public health emergency planning and response include duty to plan, duty to care, reciprocity, stewardship of resources, respect for human dignity, and communication.”</td>
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<td>New York Department of Health/New York State Task Force on Life and the Law 2015</td>
<td><em>Ventilator Allocation Guidelines</em></td>
<td>The primary goal of these guidelines is “to save the most lives in an influenza pandemic where there are a limited number of available ventilators. To accomplish this goal, patients for whom ventilator therapy would most likely be lifesaving are prioritized. The guidelines define survival by examining a patient’s short-term likelihood of surviving the acute medical episode and not by focusing on whether the patient may survive a given illness or disease in the long-term (e.g., years after the pandemic). Patients with the highest probability of mortality without medical intervention, along with patients with the smallest probability of mortality with medical intervention, have the lowest level of access to ventilator therapy.”</td>
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| Kansas Department of Health     | Guidelines for the Use of Modified Health Care Protocols in Acute Care Hospitals During Public Health Emergencies | “As a public health emergency spreads, hospitals should limit the non-critical use of ventilators. Elective procedures that may require the use of ventilators should be canceled or postponed during the period of emergency. For an emergency that stretches from days to weeks, such as a pandemic, facilities will need a review system for procedures that decrease morbidity or mortality, but are not of an emergency nature.

The ideal interval for re-assessing patients in need of critical care and ventilators has not been well defined. Critical care experts point out that many patients will not show signs of improvement for several days after they start receiving intensive care resources such as ventilators; therefore a reassessment schedule should allow for sufficient time to pass from when a patient first receives the resources, so that clinical improvement can become evident. Other experts point out that the greatest impact on survival is often made by aggressive action in the first hours of presentation, and a reassessment schedule that is conducted using long intervals may not identify early enough patients who fail to improve (and whose critical care resources should therefore be re-allocated). These are factors that should be kept in mind when determining a re-assessment schedule. The decision should be based on the clinical characteristics of the emergency and on how acute the need for the re-allocation of resources is. The expert panel believes that hospitals should reassess this allocation every 24 hours.” |
| Washington State Department of Health/Northwest Healthcare Response Network | Scarce Resource Management & Crisis Standards of Care | “Strategies for scarce availability of mechanical ventilation include the following: decrease demand for ventilators, re-use ventilator circuits, use alternative respiratory support technologies.” |
Factors Informing Clinical Decision about Ventilator Use during Ventilator Shortages in an Infectious Disease Pandemic

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<td>Michigan Department of Community Health, Office of Public Health Preparedness 2012</td>
<td>Guidelines for Ethical Allocation of Scarce Medical Resources and Services During Public Health Emergencies in Michigan</td>
<td>These guidelines contain “two general criteria considered acceptable for guiding allocation decisions: medical prognosis and essential social functions. Medical prognosis should be used to determine priority of access to scarce medical resources and services during public health emergencies. Decision-makers should consider the patient’s medical condition, the likelihood of a positive medical response, the relative risk of harm posed by not treating the patient, and other indicia of survivability and favorable medical outcomes. Treating patients according to their medical prognosis directly supports the goal of reducing morbidity and mortality. It is consistent with ethical principles of beneficence, utility, and stewardship. Workers who perform essential social functions, i.e., those deemed critical for the ongoing functioning of society, should receive priority access to scarce medical resources and services. The Committee agreed that workers who fall into these categories of people would be given priority because preserving their socially-useful functions will facilitate two of our overall goals: maintaining the social fabric and reducing morbidity and mortality. Essential personnel may include: • health care workers who are directly treating patients affected by the public health emergency (doctors, nurses, behavioral and mental health professionals, etc.); • personnel key to responding to the public health emergency (first responders, public health scientists, etc.); • personnel key to public safety (police, fire, military, etc.); and • personnel key to critical infrastructure (energy grid, telecommunications etc.).”</td>
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*List not intended to be all-inclusive

Response during COVID-19 Outbreak

Actions taken in March 2020 and April 2020 in response to the 2019-2020 COVID-19 outbreak and potential ventilator shortage include the following:

- The U.S. Department of Health and Human Services issued a bulletin “to ensure that entities covered by civil rights authorities keep in mind their obligations under laws and regulations that prohibit discrimination on the basis of race, color, national origin, disability, age, sex, and exercise of conscience and religion in HHS-funded programs, including in the provision of health care services during COVID-19.”
- The Hastings Center published an ethical framework for healthcare institutions and guidelines for institutional ethics services responding to the coronavirus.
- The National Academy of Medicine published an article that includes strategies for scarce resource situations.
- The provincial government of Ontario developed a triage protocol for doctors to use “to make ethically fraught decisions over how to ration critical care beds and ventilators.”
- The Washington Post and other news outlets reported Ford and General Motors would build ventilators after shutting down car production.
- The Wall Street Journal reported that New York State’s Department of Health drafted hospital guidance to inform decision making about possible ventilator rationing.
- According to StatNews, “some critical care physicians question the widespread use of ventilators for COVID-19 patients, saying that large numbers of patients could instead be treated with less intensive respiratory support.”

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Clinical Literature
We searched PubMed, EMBASE, the Cochrane Library, and selected web-based resources for clinical studies published between January 1, 2000, and April 2, 2020, that reported on predictors of patient survival as well as resource allocation strategies during pandemics. Our searches included relevant topics from the SARS, MERS, H1N1, and COVID-19 pandemics. We included studies that assessed the effectiveness of decision making based on disease severity scoring systems, as well as other studies that focused specifically on survival predictors of patients on mechanical ventilation. We also included an SR on risk factors and mortality predictors for MERS. We identified and reviewed full text of two SRs, nine triage tool assessment studies, and one case series, as follows:

Systematic Reviews
- 1 SR (25 studies, n = 2,081) examined clinical predictors of mortality in patients with MERS.(16)
- 1 SR (23 of 74 studies) assessed the effectiveness of triage systems for allocating scarce resources during pandemics.(17)

Table 5 provides summaries of the SRs we reviewed.

Clinical Studies
- 1 multicenter case series (n = 337) of consecutive patients with pandemic H1N1 infections on mechanical ventilators reported on mortality predictors, including APACHE II scores, oxygen exchange measurements (PaO2/FiO2), hemodialysis, and coinfections.(18)
- 1 retrospective, multicenter cohort study (n = 101) compared OHPIP triage protocol, STSS, and PaO2/FiO2 measurements for predicting the need for mechanical ventilation in patients with pandemic H1N1 infections.(14)
- 1 retrospective, multicenter cohort study (n = 320) compared CURB-65 and A-DROP (age, dehydration, respiration, disorientation, and blood pressure) scoring systems for predicting mortality and severe pneumonia in patients with pandemic H1N1 infections.(19)
- 1 retrospective, multicenter cohort study (n = 1,520) assessed community assessment tools for predicting severe outcomes in patients with pandemic H1N1 infections.(20)
- 1 prospective, multicenter cohort study (n = 481) compared triage systems (CURB-65, PMEWS, and “swine-flu hospital pathway criteria”) for predicting serious illness or death in patients with pandemic H1N1 infections and reported on the sensitivity and specificity of scores at decision-making thresholds.(21)
- 1 retrospective, multicenter cohort study (n = 10,204) assessed the association of mortality with high SOFA scores in patients with pandemic H1N1 infections.(13)
- 1 retrospective, single-center cohort study (n = 62) compared the accuracy of STSS and SOFA for predicting patient outcomes and allocating resources, including ventilators.(22)
- 1 retrospective, single-center cohort study (n = 8) assessed use of SOFA for predicting mortality of patients with pandemic H1N1 infections to inform allocation of scarce resources and reported on triage scoring and patient survival.(23)
- 1 retrospective, multicenter cohort study (n = 255) assessed SOFA scoring for predicting mortality to triage patients with pandemic H1N1 infections. Patients with SOFA >11 were triaged blue for palliative care.(24)
- 1 retrospective, multicenter cohort study (n = 234) applied the OHPIP draft triage protocol as a pilot to determine the framework’s effectiveness. Triage officers assigned treatment priorities on the framework’s criteria, including palliative care for patients with SOFA >11. Authors reported on survival rates for each triage group, number of ventilator and ICU days, and triage officers’ decision-making abilities.(15)

Table 6 provides a summary of clinical studies we reviewed.

Evidence limitations: Studies are at high risk of bias due to one or more of the following: retrospective design, small sample size, and single-center focus. Because all studies evaluating triage systems used patient cohorts from the H1N1 pandemic, triage effectiveness and the predictive values of risk factors may not generalize to pandemics of other pathogens. Three of the four triage officers in one study (Christian et al.) participated in drafting the triage...
protocols, and this model’s results (e.g., confidence in decisions) may not reflect outcomes in real-world triage settings.

Table 5. Systematic Reviews

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<thead>
<tr>
<th>Author/Year</th>
<th>Purpose</th>
<th>Resources Searched and Inclusion Criteria</th>
<th>Findings Reported By Authors</th>
<th>Authors’ Conclusions</th>
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<tr>
<td>Matsuyama et al. 2016(16)</td>
<td>Review factors associated with risk of death, intensive care unit (ICU) admission, and mechanical ventilation for Middle East respiratory syndrome (MERS).</td>
<td>PubMed and Web of Science were searched for studies reporting clinical outcomes of MERS published between April 2012 and June 2016.</td>
<td>“A total of 25 eligible articles were identified. The case fatality risk ranged from 14.5 to 100%, with the pooled estimate at 39.1%. The risks of ICU admission and mechanical ventilation ranged from 44.4 to 100% and from 25.0 to 100%, with pooled estimates at 78.2 and 73.0%, respectively. These risks showed a substantial heterogeneity among the identified studies, and appeared to be the highest in case studies focusing on ICU cases. We identified older age, male sex and underlying medical conditions, including diabetes mellitus, renal disease, respiratory disease, heart disease and hypertension, as clinical predictors of death associated with MERS. In ICU case studies, the expected odds ratios (OR) of death among patients with underlying heart disease or renal disease to patients without such comorbidities were 0.6 (95% Confidence Interval (CI): 0.1, 4.3) and 0.6 (95% CI: 0.0, 2.1), respectively, while the ORs were 3.8 (95% CI: 3.4, 4.2) and 2.4 (95% CI: 2.0, 2.9), respectively, in studies with other types of designs.”</td>
<td>“The heterogeneity for the risk of death and severe manifestations was substantially high among the studies, and varying study designs was one of the underlying reasons for this heterogeneity. A statistical estimation of the risk of MERS death and identification of risk factors must be conducted, particularly considering the study design and potential biases associated with case detection and diagnosis.”</td>
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<tr>
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<td>Timbie et al. 2013(17)</td>
<td>Assess the effectiveness of resource allocation and triage systems during mass casualty events (MCEs) (including pandemics).</td>
<td>“Medline, Scopus, Embase, Cumulative Index to Nursing and Allied Health Literature, Global Health, Web of Science®, and the Cochrane Database of Systematic Reviews, from 1990 through late 2011.” Included studies assessed strategies during actual events, drills, or simulations. Studies compared multiple interventions or interventions with established benchmarks.</td>
<td>“[23 of 74 included] studies focused on biological threats, including pandemic influenza (13), anthrax (7), smallpox (2), and SARS (1).” “…as a strategy to optimize use of existing resources, commonly used field triage systems do not perform consistently during actual MCEs. The number of high-quality studies addressing other strategies was insufficient to support conclusions about their effectiveness because of differences in study context, comparison groups, and outcome measures.”</td>
<td>“The current evidence base is inadequate to inform providers and policymakers about the most effective strategies for managing or allocating scarce resources during mass casualty events. Consensus on methodological standards that encompass a range of study designs is needed to guide future research and strengthen the evidence base. Evidentiary standards should be developed to promote consensus interpretations of the evidence supporting individual strategies.”</td>
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### Table 6. Clinical Studies

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<tr>
<th>Author/Year</th>
<th>Study Type and Patients</th>
<th>Intervention</th>
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<tr>
<td><strong>Case Series</strong></td>
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<tr>
<td>Estenssoro et al., 2010(18)</td>
<td>Multicenter case series (n = 337) of patients with pandemic H1N1 infections and on ventilators</td>
<td>Mechanical ventilation</td>
<td>“APACHE II was 18 +/- 7; age 47 +/- 17 years; 56% were male; and 64% had underlying conditions, with obesity (24%), chronic obstructive respiratory disease (18%), and immunosuppression (15%) being the most common. Seven percent were pregnant. On admission, patients had severe hypoxemia (Pa(O2)/Fi(O2) 140 [87-200]), extensive lung radiologic infiltrates (2.87 +/- 1.03 quadrants) and bacterial coinfection, (25%; mostly with Streptococcus pneumoniae). Use of adjuvants such as recruitment maneuvers (40%) and prone positioning (13%), and shock (72%) and acute kidney injury requiring hemodialysis (17%), were frequent. Mortality was 46%, and was similar across all ages. APACHE II, lowest Pa(O2)/Fi(O2), shock, hemodialysis, prone positioning, and S. pneumoniae coinfection independently predicted death.”</td>
<td>“Patients with 2009 influenza A (H1N1) requiring mechanical ventilation were mostly middle-aged adults, often with comorbidities, and frequently developed severe acute respiratory distress syndrome and multiorgan failure requiring advanced organ support. Case fatality rate was accordingly high.”</td>
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<td><strong>Triage Tool Evaluation Studies</strong></td>
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<td>Morton et al., 2015(14)</td>
<td>Retrospective multicenter cohort study (n = 101) of patients with pandemic H1N1 infections to assess triage tools for predicting the need for mechanical ventilation</td>
<td>Ontario Health Plan for an Influenza Epidemic (OHPIP) Triage Protocol vs. Simple Triage Scoring System (STSS) vs. Oxygen exchange (P/F)</td>
<td>“One hundred and one patients were included, 29 were admitted to critical care and 23 required mechanical ventilation. The P/F ratio predicted the need for mechanical ventilation with a receiver operating characteristic area under the curve (ROC AUC) of 0.885 (CI 0.817-0.952). Predictive ability was not reduced when the P/F ratio had to be estimated using the Pandharipande tool. The STSS score predicted the need for mechanical ventilation [ROC AUC 0.798 (CI 0.704-0.891)]. The reverse triage component of the OHPIP tool was a poor predictor of patient outcome.”</td>
<td>“The P/F ratio was a better predictor of need for mechanical ventilation than STSS. The P/F ratio is a simple and accepted determinant of hypoxaemia and should be used if secondary triaging becomes necessary during future influenza pandemics.”</td>
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### Clinical Evidence Assessment
Factors Informing Clinical Decision about Ventilator Use during Ventilator Shortages in an Infectious Disease Pandemic

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<tr>
<td>Fujikura et al. 2014(19)</td>
<td>Retrospective multicenter cohort study (n = 320) of patients with pandemic H1N1 infections, to assess potential triage methods for predicting severe pneumonia or death</td>
<td>CURB-65 (confusion, urea, respiratory rate, blood pressure, and age≥65 years) vs. A-DROP (age, dehydration, respiration, disorientation, and blood pressure)</td>
<td>“Although all routine prediction models showed that higher mortality tended to be associated with a higher risk class/grade, the actual mortality rates were higher than predicted. The risk class of mortality calculated by the PSI was influenced by pneumonia patterns. Although pneumonia severity was similarly predicted, the types of pneumonia also affected severity in all prediction models. A-DROP showed the highest accuracy on receiver operating characteristic analysis for both mortality and severity.”</td>
<td>“CURB-65 and A-DROP are fair predictors of mortality regardless of pneumonia patterns. However, the current pneumonia prediction models may underestimate the severity and appropriate site of care for patients with influenza pneumonia.”</td>
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| Semple et al. 2013(20) | Retrospective multicenter cohort study (n = 1,520) of patients with pandemic H1N1 infections to assess the predictive power of community assessment tools (CATs) for predicting patient outcomes | CATs:  
- Severe respiratory distress  
- Increased respiratory rate  
- Oxygen saturation ≤92%  
- Respiratory exhaustion  
- Severe clinical dehydration  
- Altered consciousness  
- Causing other clinical concern | “Each CATs criterion independently identified both use of clinical interventions that would in normal circumstances only be provided in hospital and patient outcome measures. "Peripheral oxygen saturation #92% breathing air, or being on oxygen" performed well in predicting use of resources and outcomes for both adults and children; supporting routine measurement of peripheral oxygen saturation when assessing severity of disease. In multivariable analyses the single subjective criterion in CATs ‘other cause for clinical concern’ independently predicted death in children and in adults predicted length of stay, mechanical ventilation and ‘severe outcome’; supporting the role of clinical acumen as an important independent predictor of serious illness.” | “This study shows that CATs are potentially useful predictors of both use of hospital-based interventions and severe patient outcomes during an influenza pandemic. Each of the CATs criteria had a role in predicting a given outcome and none are redundant. It is also notable and novel that both paediatric and adults CATs were developed upon a common framework of assessment. Importantly this confers an element of equity in a situation where children and adults may have to compete for access to a limited common resource such as mechanical ventilators.” |
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<tr>
<td>Goodacre et al. 2012(21)</td>
<td>Prospective multicenter cohort study (n = 481) of patients with pandemic H1N1 infections to assess potential triage tools for predicting serious illness or death. 437 pediatric patients and 44 adult patients</td>
<td>Triage tools: CURB-65 vs. PMEWS vs. Swine-flu hospital pathway criteria</td>
<td>“There were five poor outcomes: two deaths and three survivors who required respiratory support. The five patients with poor outcomes had CURB-65 scores of zero, one (three cases) and two, and PMEWS scores of one, five, six, seven and eight. The swine flu hospital pathway was positive in three out of five cases. The C-statistic for each method was CURB-65 0.78 [95% confidence interval (CI) 0.58 to 0.99], PMEWS 0.77 (95% CI 0.55 to 0.99) and the swine flu hospital pathway 0.70 (95% CI 0.45 to 0.96). Patients with a higher CURB-65 score were more likely to be admitted (p &lt; 0.001): 25 out of 101 (25%) with a score of zero, 11 out of 24 (46%) with a score of one, 7 out of 8 (88%) with a score of two, and the patient with a score of three were admitted. Admitted patients had a higher mean PMEWS score (4.6 vs 2.0, p &lt; 0.001). The C-statistics for CURB-65, PMEWS and the swine flu hospital pathway in adults in terms of discriminating between those admitted and discharged were 0.65 (95% CI 0.54 to 0.76), 0.76 (95% CI 0.66 to 0.86) and 0.62 (95% CI 0.51 to 0.72) respectively.”</td>
<td>“Potential concerns were raised about the use of existing triage methods for patients with suspected pandemic influenza, as these methods may fail to discriminate between patients who will have an adverse outcome and those with a benign course. Clinicians in the study did not generally appear to admit or discharge on the basis of these methods, despite their recommended use. Further research is required to evaluate existing triage methods and develop new triage tools for suspected pandemic influenza.”</td>
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## CLINICAL EVIDENCE ASSESSMENT

**Factors Informing Clinical Decision about Ventilator Use during Ventilator Shortages in an Infectious Disease Pandemic**

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<tr>
<td>Shahpori et al. 2011(13)</td>
<td>Retrospective multicenter cohort study (n = 10,204) of patients with pandemic H1N1 infections to assess the association of Sequential Organ Failure Assessment (SOFA) scores with mortality rates</td>
<td>Reported on surviving patients who would have been excluded from critical care if SOFA scoring criteria had been used.</td>
<td>“Mortality in patients with an initial Sequential Organ Failure Assessment score of &gt;11 was 59% (95% confidence interval: 56%, 62%). The mortality associated with an initial [SOFA] &gt;11 across diagnostic categories varied from 29% for poisoning to 67% for neurologic patients. Hospital mortality exceeded 90% only when initial [SOFA] was &gt;20 (0.2% of patients). H1N1 patients were younger, had a longer intensive care unit length of stay, and more commonly had a respiratory admission diagnosis than the non-H1N1 cohort. Hospital mortality in H1N1 patients with an initial [SOFA] score of &gt;11 was 31% (95% confidence interval: 5%, 56%).”</td>
<td>“A [SOFA] score of &gt;11 was not associated with a hospital mortality of &gt;90% at any time during intensive care unit stay. Only a small proportion of patients have the extreme initial [SOFA] values associated with a hospital mortality of &gt;90% limiting the usefulness of [SOFA] as a triage instrument for pandemic planning. Application of a [SOFA] threshold of &gt;11 to the recent H1N1 pandemic would have excluded patients with a markedly lower mortality than seen in a large regional cohort of intensive care unit patients.”</td>
</tr>
<tr>
<td>Adeniji and Cusack 2011(22)</td>
<td>Retrospective single-center cohort study (n = 62) of patients with pandemic H1N1 infections to assess the use of Simple Triage Scoring System (STSS) and SOFA for determining mortality and ventilator need</td>
<td>Triage methods: SOFA vs. STSS for predicting patient outcomes to assist resource decision making</td>
<td>“Over an 8 month period, 62 patients with confirmed H1N1 were admitted. Forty (65%) had documented comorbidities and 27 (44%) had pneumonia changes on their admission CXR. Nineteen (31%) were admitted to the intensive care unit where 5 (26%) required mechanical ventilation (MV). There were 3 deaths. The STSS group categorization demonstrated a better discriminating accuracy in predicting critical care resource usage with a receiver operating characteristic area under the curve (95% confidence interval) for ICU admission of 0.88 (0.78-0.98) and need for MV of 0.91 (0.83-0.99). This compared to the staged SOFA score of 0.77 (0.65-0.89) and 0.87 (0.72-1.00) respectively. Low mortality rates limited analysis on survival predictions.”</td>
<td>“The STSS accurately risk stratified patients in this cohort according to their risk of death and predicted the likelihood of admission to critical care and the requirement for MV. Its single point in time, accuracy and easily collected component variables commend it as an alternative reproducible system to facilitate the triage and treatment of patients in any future influenza pandemic.”</td>
</tr>
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### Clinical Evidence Assessment

Factors Informing Clinical Decision about Ventilator Use during Ventilator Shortages in an Infectious Disease Pandemic

<table>
<thead>
<tr>
<th>Author/Year</th>
<th>Study Type and Patients</th>
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<th>Findings Reported by Authors</th>
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<tbody>
<tr>
<td>Khan et al. 2009(23) United Kingdom</td>
<td>Retrospective single-center cohort study (n = 8) of patients with pandemic H1N1 infection to assess SOFA’s use for predicting mortality and informing resource allocation decisions</td>
<td>Reported on surviving patients who would have been excluded from critical care if SOFA scoring criteria had been used.</td>
<td>“Eight critically ill patients with influenza A H1N1 were admitted to the intensive care unit. Their mean (range) age was 39 (26–52) years with a length of stay of 11 (3–17) days. All patients met SOFA score based triage admission criteria with a modal SOFA score of five. Five patients required invasive ventilation for a mean (range) of 5 (4–11) days. Five patients would have been considered for withdrawal of treatment using SOFA scoring guidelines at 48 h. All patients survived.”</td>
<td>“We conclude that SOFA score based triage could lead to withdrawal of life support in critically ill patients who could survive with an acceptably low length of stay in the intensive care unit.”</td>
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<tr>
<td>Guest et al. 2009(24) United Kingdom</td>
<td>Retrospective multicenter cohort study (n = 255) of patients with pandemic H1N1 infections to assess the effectiveness of using SOFA scores for patient triage</td>
<td>SOFA: patients with scores &gt;11 were triaged for palliative care in the model</td>
<td>“We found that applying the triage criteria to a current case-mix would result in 116 of the 255 patients (46%) admitted during the study period being denied intensive care treatment they would have otherwise received, of which 45 (39%) survived to hospital discharge. In turn, 69% of those categorised as too ill to warrant admission according to the criteria survived. The sensitivity and specificity of the triage category at ICU admission predicting mortality was 0.29 and 0.84, respectively. If the need for intensive care beds is estimated to be 275 patients per week, the triage criteria would not exclude enough patients to prevent the need for further rationing.”</td>
<td>“We conclude that the proposed triage tool failed adequately to prioritise patients who would benefit from intensive care.”</td>
</tr>
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<td>Christian et al 2009(15)</td>
<td>Retrospective multicenter cohort study (n = 234) of ICU patients with pandemic H1N1 infections. Pilot study to assess triage framework effectiveness.</td>
<td>OHPIP triage protocol SOFA: patients with scores $&gt;$11 were triaged for palliative care in the model.</td>
<td>“Overall, triage officers were either confident or very confident in 68.4% of their scores; arbitration was required in 54.9% of cases. Application of the triage protocol would potentially decrease the number of required ventilator days by 49.3% (568 days) and decrease the total ICU days by 52.6% (895 days). On the triage protocol at ICU admission the survival rate in the red (93.7%) and yellow (62.5%) categories were significantly higher than that of the blue category (24.6%) with associated $P$ values of $&lt; 0.0001$ and 0.0003 respectively. Further, the survival rate of the red group was significantly higher than the overall survival rate of 70.9% observed in the cohort ($P &lt; 0.0001$). At 48 and 120 hours, survival rates in the blue group increased but remained lower than the red or yellow groups.”</td>
<td>“Refinement of the triage protocol and implementation is required prior to future study, including improved training of triage officers, and protocol modification to minimize the exclusion from critical care of patients who may in fact benefit. However, our results suggest that the triage protocol can help to direct resources to patients who are most likely to benefit, and help to decrease the demands on critical care resources, thereby making available more resources to treat other critically ill patients.”</td>
</tr>
</tbody>
</table>

Selected Resources and Reference

**ECRI Institute Resources searched January 1, 2000, through April 2, 2020**

Search Strategy: Crisis standards of care, disaster planning, duty of care, ethical decision making, ventilators


Results: We identified seven related reports.


Search Strategy:

Factors Informing Clinical Decision about Ventilator Use during Ventilator Shortages in an Infectious Disease Pandemic

Results: We identified 176 records.


Search Strategy:

Results: We identified eight records.

Guidelines and Standards [searched January 1, 2000, through April 2, 2020]

Search Strategy: crisis care, disaster, epidemic, ethics, pandemic, resource allocation, ventilator

Results:

Selected Standards and Guidelines

United States


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Other Countries


United Kingdom


United States Regional Guidance (Examples-not meant to be all-inclusive)

Colorado Department of Public Health & Environment (CPDHE). [cited 2020 Apr 3].


Minnesota Department of Health. [cited 2020 Apr 2].


Oregon Health Authority. Oregon Crisis Care Guidance Critical Care Triage Card. 2018.


Selected Web Resources. [searched April 2, 2020]

Additional United States Regional Guidance (Examples-not meant to be all inclusive)


Arizona Department of Health Services. [cited 2020 Apr 3].


Minnesota Department of Health. [cited 2020 Apr 2].
  - Implementing Ethical Frameworks for Rationing Scarce Health Resources in Minnesota During Severe Influenza Pandemic. 2010.
  - Minnesota Crisis Standards of Care Framework. Ethical Guidance. [updated 2020 Jan 10].


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Other Web Resources

- American Medical Association (AMA). [cited 2020 Apr 3].
  - Allocating Limited Health Care Resources. [cited 2020 Apr 3].
  - AMA Code of Medical Ethics: Guidance in a pandemic. [cited 2020 Apr 3].
  - Crisis standards of care: Guidance from the AMA Code of Medical Ethics. [cited 2020 Apr 3].
  - Fair access to limited critical care resources. [cited 2020 Apr 3].

- Centers for Disease Control and Prevention (CDC). [cited 2020 Apr 2].
  - Information about Middle East Respiratory Syndrome (MERS). [revised 2015 Dec].
  - Pandemic Influenza Plan, 2017.
  - Revised U.S. Surveillance Case Definition for Severe Acute Respiratory Syndrome (SARS) and Update on SARS Cases --- United States and Worldwide, December 2003. 2013 Dec.

- Hastings Center. [cited 2020 Apr 3].
  - Confronting Disability Discrimination During the Pandemic. [2020 Apr 2].
  - Ethical Framework for Health Care Institutions & Guidelines for Institutional Ethics Services Responding to the Coronavirus Pandemic. 2020 Mar 16.

- Institute of Medicine (US). [cited 2020 Apr 3].
  - Crisis Standards of Care: A Toolkit for Indicators and Triggers, 2013.


  - Hard choices at the frontline. 2020 Mar 27.

  - Topic Collection: Crisis Standards of Care. [cited 2020 Apr 2].


- World Health Organization (WHO) [cited 2020 Apr 2].
  - Ethical considerations in developing a public health response to pandemic influenza. 2007.
  - Ethical standards for research during public health emergencies: Distilling existing guidance to support COVID-19 R&D. [cited 2020 Apr 2].
  - Ethics in epidemics, emergencies and disasters: Research, surveillance and patient care. 2015.
  - Global health ethics. [cited 2020 Apr 2].
  - Institutional Repository for Information Sharing (IRIS). Note: to view additional related materials enter pandemic ethics in the search box.
Factors Informing Clinical Decision about Ventilator Use during Ventilator Shortages in an Infectious Disease Pandemic

References Reviewed (PubMed search dates were January 1, 2000, through April 2, 2020)

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The Evidence Bar™

ECRI developed The Evidence Bar™ to provide a visualization of our judgment about the balance of benefits and harms of the technology after assessing the available published clinical evidence in light of key outcomes and comparisons of interest. The Evidence Bar™ rubric shows five possible choices for our expert judgment. After review and analysis of evidence identified through literature searches conducted by master’s-level medical librarians, ECRI research analysts, extensively trained in methods of evidence assessment, weigh potential benefits and harms of a technology to arrive at their expert judgment.

- Balance of evidence unfavorable
- Balance of evidence raises concerns
- Balance of evidence inconclusive because of no available evidence, mixed results, or too few data
- Balance of evidence somewhat favorable
- Balance of evidence very favorable

Policy Statement

The information presented in this Clinical Evidence Assessment is highly perishable and reflects the state of the literature on this topic at the time at which searches were conducted and the Clinical Evidence Assessment was prepared. Clinical Evidence Assessments provide a guide to the published clinical literature and other information about a topic on which we received a client inquiry. The scope is customized to address the specific information needs of the requestor. The content reflects the information identified from searches of the available, published, peer-reviewed scientific literature, gray literature, and websites at the time the searches were conducted. Publications referenced in this Clinical Evidence Assessment are generally limited to the English language. Clinical Evidence Assessments are developed by a multidisciplinary staff of doctoral level research analysts, clinicians, and medical librarian information specialists. For quality assurance, all reports are subject to review within ECRI before publication. Neither ECRI nor its employees accept gifts, grants, or contributions from, or consult for medical device or pharmaceutical manufacturers. The Clinical Evidence Assessment may be based on review of abstracts of published articles as well as full text articles. Abstracts do not always accurately reflect the methods and findings of full-length articles and limit full interpretation of published data. This Clinical Evidence Assessment is not intended to provide specific guidance for the care of individual patients. ECRI implies no warranty and assumes no liability for the information contained in the Clinical Evidence Assessment.

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