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Too Many Patients…A Framework to Guide Statewide Allocation of Scarce Mechanical Ventilation During Disasters

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The threat of a catastrophic public health emergency causing life-threatening illness or injury on a massive scale has prompted extensive federal, state, and local preparedness efforts. Modeling studies suggest that an influenza pandemic similar to that of 1918 would require ICU and mechanical ventilation capacity that is significantly greater than what is available. Several groups have published recommendations for allocating life-support measures during a public health emergency. Because there are multiple ethically permissible approaches to allocating scarce life-sustaining resources and because the public will bear the consequences of these decisions, knowledge of public perspectives and moral points of reference on these issues is critical. Here we describe a critical care disaster resource allocation framework developed following a statewide community engagement process in Maryland. It is intended to assist hospitals and public health agencies in their independent and coordinated response to an officially declared catastrophic health emergency in which demand for mechanical ventilators exceeds the capabilities of all surge response efforts and in which there has been an executive order to implement scarce resource allocation procedures. The framework, built on a basic scoring system with modifications for specific considerations, also creates an opportunity for the legal community to review existing laws and liability protections in light of a specific disaster response process.

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The threat of a catastrophic public health emergency such as a severe influenza pandemic or other sudden crisis causing life-threatening illness or injury on a massive scale has prompted extensive federal, state, and local preparedness efforts. Although the United States health care system is large, its surge capacity (capacity to rapidly absorb additional patients) and surge capabilities (the availability of adequate medical supplies and appropriate staff) are limited, especially for critical care. Modeling studies suggest that an influenza pandemic similar to that of 1918 would require ICU and mechanical

ABBREVIATIONS: PELOD-2 = Pediatric Logistic Organ Dysfunction 2; SOFA = Sequential Organ Failure Assessment

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ventilation capacity that is significantly greater than what is available.[1,2]

Several groups have published recommendations for allocating life-support measures during a public health emergency based on a variety of considerations, including ethical ones. Existing guidelines differ substantially, however, regarding which ethical criteria should be determinative, whether some groups of patients should be categorically denied access to life support (exclusion criteria), and whether it is permissible to withdraw a resource from one patient to provide it to another who is more likely to benefit.[3-6] Ethical principles that form the foundation of published guidelines include saving the most lives, saving the most life-years, and the lifecycle principle, which uses stage of life as a criterion. Because there are multiple ethically permissible approaches to allocating scarce life-sustaining resources and because the public will bear the consequences of these decisions, knowledge of public perspectives and moral points of reference on these issues is critical. A successful allocation effort will require public trust and cooperation, both of which are more likely if the process for developing allocation guidance has been transparent and inclusive. Moreover, advance discussion and planning are essential because in-depth deliberations will not be feasible during a public health crisis.

To better characterize community values related to allocation of scarce lifesaving resources and gain the understanding needed to build an allocation framework for Maryland, a community engagement effort using Deliberative Democracy methodology was conducted among members of the general public as well as local health care and disaster professionals. This methodology required citizen participation in open and informed conversations, bringing multiple perspectives into the dialog.[7] Details of the community engagement process are provided elsewhere.[8] In brief, community engagement forums were conducted across the State over a 2-year period (2012-2014). At least one forum was held for the general public and one for health care and disaster workers in each of Maryland's five emergency management regions. The discussions were framed around ethical principles that have been proposed in existing guidance. Primary data sources used to inform the development of the framework described here included pre- and postdeliberation surveys and notes on small group deliberations. A total of 15 forums were conducted with 324 participants.

After compiling preliminary results, the project team scheduled and convened two expert working group meetings that were held in January and March 2015 that included practitioners, ethicists, public health lawyers, and communication specialists. The purpose of these working group sessions was to elicit expert input on the interpretation of emerging themes and to translate the findings into recommendations. Finally, following the publication of those recommendations,[8] the project team assembled a core advisory group to develop a framework built on the feedback received from Maryland citizens. That advisory group included an intensivist, an emergency medicine physician, a nurse, two ethicists, and two legal experts.

Here we describe the allocation framework developed from this process. It is intended to assist hospitals and public health agencies in their independent and coordinated response to a declared catastrophic health emergency in which demand for ventilators exceeds the capabilities of all surge response efforts and in which there has been an executive order from state authorities to implement scarce resource allocation procedures. The framework, built on a basic scoring system with modifications for specific considerations, also creates an opportunity for the legal community to review existing laws and liability protections in light of a specific disaster response process. The implementation of a guideline such as this should occur across the entire region for which it was written in as uniform a way as is possible.

Framework

The framework of this program is based first on a scoring system that primarily takes into account the two ethical considerations that are both most commonly used in existing guidance and also were of greatest importance to those who participated in the Maryland community engagement project: (1) likelihood of short-term survival (with the support of the scarce resource in question and other intensive care services) and (2) likelihood of long-term survival (based on presence of comorbid conditions). 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; Table 1). Priority is given to those with the lowest total triage scores. In the event that there is a "tie," life stage may be considered as a secondary criterion. The scoring system and overall framework presume a certain operational environment, including decision-making bodies at hospital and state levels that can apply, oversee, and adapt the framework

TABLE 1] Proposed Strategy for Ventilator Allocation in Epidemics of Novel Respiratory Pathogens

Principle	Specification	Point System			
		1	2	3	4
Prognosis for short-term survival	Adults (SOFA) or pediatrics (PELOD-2)	SOFA score ≤ 8 PELOD-2 ≤ 12	SOFA score 9-11 PELOD-2 12-13	SOFA score 12-14 PELOD-2 14-16	SOFA score > 14 PELOD-2 ≥ 17
Prognosis for long-term survival	Prognosis for long-term survival (assessment of comorbid conditions)	…	…	Severe comorbid conditions; death likely within 1 y	…
Secondary consideration					
Lifecycle considerations	Prioritize those who have had the lease chance to live through life's stages (age)	Age 0-49 y	Age 50-69 y	Age 70-84 y	Age ≥ 85 y

Examples of severe comorbid conditions with associated life expectancy < 1 year are listed. This list is meant as a guideline and is not exhaustive. Patients meeting the criteria of < 1 y predicted survival based on what of the listed or other similar conditions should be assigned a score of 3. NYHA = New York Heart Association.

1. NYHA class IV heart failure.
2. Advanced lung disease with FEV_1 < 25% predicted, total lung capacity < 60% predicted, or baseline P_{AO_2} < 55 mm Hg.
3. Primary pulmonary hypertension with NYHA class III or IV heart failure.
4. Chronic liver disease with Child-Pugh score > 7.
5. Severe trauma.
6. Advanced untreatable neuromuscular disease.
7. Metastatic malignant disease or high-grade primary brain tumors.

to a dynamic and multifaceted crisis. When a directive is issued to use the triage framework, its implementation should be considered mandatory, because doing so will provide the most legal protection for providers making triage decisions. Along with this mandatory designation, there should be a limited appeal process to meet the constitutional requirement of due process.

Guiding Ethical Principles and Special Considerations

Prospects for Short-Term Survival

The most straightforward measure of whether a patient will benefit from intensive care is whether that patient survives as a consequence of this care. Patients who are more likely to survive with intensive care are therefore given a higher priority when resources are scarce. The Sequential Organ Failure Assessment (SOFA) score and the Pediatric Logistic Organ Dysfunction 2 (PELOD-2) score are systems developed to predict mortality over the short term. The scoring quartiles for SOFA/PELOD-2 scores used here are based on in-hospital mortality from previous literature.[9,10]

Prospects for Long-Term Survival

Also related to how much benefit intensive care produces is the patient's prospects for survival after discharge. Some patients suffer from medical conditions that are likely to shorten their life spans (compared with healthy, age-matched individuals) even if the immediate medical problems that required intensive care are successfully treated. Although important, placing too great a priority on the criterion of long-term survival may, in certain circumstances, further disadvantage people who already face systematic disadvantages; poor people and people of color are more likely than other groups to have multiple and serious comorbidities because of factors including poorer access to medical care and the direct debilitating effects of poverty on health. To address concerns about compounding injustices associated with systematic disadvantage and the arbitrariness of comorbidities, and unlike other approaches that have been proposed for ICU triage in a disaster, the scoring system described here affects patients whose comorbidities are so serious that they are expected to live no more than 12 months even with successful ICU treatment. These patients are assigned a long-term survival score of 3. Those without a known comorbidity associated with survival < 12 months would receive a score of 0 for this portion of the scoring system.

Stage of Life-Related (Life-cycle) Considerations

Whether stage of life should be taken into account in the allocation of health care resources is an ethically challenging issue. Although most do not consider stage of life an appropriate criterion in determining who receives basic medical care during normal circumstances, different conclusions can be ethically justified[5] when confronted with a severe shortage of life-sustaining resources. Under such constrained circumstances and if chance of survival and long-term positive outcome are equivalent overall, it may be reasonable to give priority based on different stages of life. Although, arguably, all people stand to lose the same thing should they die—the rest of their lives—younger people have had less of an opportunity to experience different stages of life. Also, although social worth or contribution should not be considered in the allocation of scarce medical resources, prioritizing children over the generation on whom they are directly dependent for their basic welfare raises practical challenges. Additionally, feedback from the Maryland engagement process clearly suggested that, although age should be neither the primary nor sole criterion for resource allocation in disaster contexts, there are circumstances in which it may be appropriate to consider stage of life in decision-making. For these reasons, in the event that other criteria result in equivalent priority scores, equal and highest priority in this system is given to children and to adults age 49, whose death is most likely to impose hardship on other people whose well-being depends directly on their support (children, elderly relatives). Adults who have not yet lived a full life (age 50-69) are given next priority, followed by those who are approaching or have reached the high end of average life expectancy (age 70-84). Lowest priority is given to patients 85 and older.

Pregnancy

Pregnancy is a unique state in which medical decisions have a direct effect on the health and prospects for survival of not only the pregnant patient, but also the fetus she is carrying. The scoring system cannot take into account the complex moral and medical considerations that this unique relationship poses; however, the major consideration in this context is the possibility of saving the life of the fetus in addition to that of the mother. If it is determined that there is reasonable probability of supporting the pregnant patient and her child to a point where the child could survive without requiring excessive clinical resources, prioritizing that patient to receive a ventilator would be an ethically sound approach. Because we cannot perfectly predict which fetuses will survive, we are forced to rely on existing outcomes data. Pregnant patients will be assigned a priority score based on the same framework used for nonpregnant patients. If a pregnant patient presents in respiratory failure requiring mechanical ventilation, obstetrical evaluation of fetal heart tones should be performed urgently. Those individuals with a healthy fetus based on this evaluation will be given a 1-point "credit" (reduction) on their priority score, thus giving them higher priority. The triage team will operate under the general presumption that the pregnant patient's baseline priority score should not be modified if the prospects of survival for the fetus are poor.

Fair Chance

After the criteria above (long and short-term prognosis, age and pregnancy) have been applied it is likely that there will be some (perhaps many) patients who have the same priority score. In these cases, consistent with the input received in most community meetings across Maryland, the ventilator should be allocated based on chance in a maximally fair and transparent way. This might mean first-come, first-served or some form of lottery.

Exclusion Criteria

In the event of a declared catastrophic public health emergency resulting in a severe resource shortage in a constrained environment, certain conditions would make an individual ineligible for the life-sustaining critical resource in question. Those conditions include the following.

1. Cardiac arrest: unwitnessed, recurrent, or unresponsive to defibrillation or pacing
2. Advanced and irreversible neurologic event or condition
3. Severe burns in patient with both of the following
   a. Age $>$ 60 years
   b. 50% of total body surface area affected[11]

Assignment of Priority Score

For the purpose of allocating scarce ventilators during a disaster, each patient with demonstrated need for mechanical ventilator support would first be assessed for the previously outlined exclusion criteria. In the absence of any of these clearly defined criteria, each patient would then be assigned an initial priority score based on short- and long-term survival, as outlined in Table 1.

Once an initial priority score is assigned, credit of a single point should be deducted from the score of any pregnant patient found to have normal fetal heart tones, as described previously. If these scores do not adequately differentiate the group needing ventilators, points should be assigned for lifecycle considerations within the group that is "tied." Additionally, given the importance of demonstrated response to therapy,[12] those with increasing scores on this triage scale at 24, 48, or 120 hours will have an additional point added to their total score. Finally, those with scores that remain unchanged at 120 hours will also have an additional point added to their score. Example cases are outlined in Table 2.

Discussion of Operational Conditions and Assumptions

The operational conditions and assumptions surrounding the implementation of a framework such as this one are central to its ability to contribute both to continuity of operations and associated community stability.

Triage Team Authorization, Staffing, and Oversight

A triage officer, distinguished by established clinical expertise, leadership ability, and effective communication skills, should have ultimate responsibility for making decisions regarding which patients will receive priority for receiving critical care. Consistent with recommendations from the disaster literature,[13] the triage officer should share information about these decisions with the clinical team and then inform affected patients and family members. Teaming with the triage officer should be an experienced critical care nurse, another clinician with expertise relevant to the particular resource (eg, a respiratory therapist), a representative from hospital administration to serve as liaison with incident management staff and the ethics committee, and a nonclinical person for data gathering and documentation. Additional triage provisions include shifts that balance staff respite with the triage function; at least daily application of the allocation framework with an assessment of clinical improvement or worsening for patients already being supported by the scarce resource; and a limited appeals process in resource withdrawal cases. In the latter circumstance, a triage review committee comprising the following individuals can render a decision: chief medical officer, chief nursing officer, legal counsel, risk management, ethics committee chair, and a designated off-duty triage officer.

TABLE 2] Example Allocation Scores

Patients	History	Score Based on Table 1	Priority Based on Table 1 and Additional Considerations
Case 1			
Patient A	24 y of age, SOFA score 13, and no severe comorbid conditions	3	Patient B is prioritized via the framework
Patient B	52 y of age, SOFA score 10, and no severe comorbid conditions	2	
Case 2			
Patient A	20 y of age, SOFA score 7, and no severe comorbid conditions	1	Each receives 1 point for lifecycle considerations, giving both a total score of 2 The resource would then be allocated based on chance in a fair and transparent way (eg, lottery)
Patient B	39 y of age, SOFA score 8, and no severe comorbid conditions	1	
Case 3			
Patient A	45 y of age, SOFA score 15, and no severe comorbid conditions	4	For life-cycle considerations, Patient A receives 1 additional point and Patient B receives 3 additional points, yielding final scores of 5 and 7, respectively. Therefore, Patient A is prioritized.
Patient B	74 y of age, SOFA score 7, and metastatic cancer with death likely in 1 y	4	

SOFA = Sequential Organ Failure Assessment.

Central Monitoring of Crisis Conditions and Opportunity to Modify Triage Protocols

Consistent with the recommendations of the American College of Chest Physicians Task Force for Mass Critical Care, the accumulated data of all hospital triage decisions should be subject to review by a central triage committee for the State of Maryland.[13] This committee should not review any appeal determinations by the hospital triage review committee. Rather, the central triage committee should engage in bidirectional communication with local hospital triage review committees, assess triage decision-making on a statewide level, maintain situational awareness, and perform research to modify allocation algorithms as needed. This committee should consist of members appointed by the governor, including the following: the state health officer or designee, a representative of the state emergency management agency, a county public health officer, an epidemiologist, a representative of the state hospital association, a senior critical care nurse, a social worker, an ethicist, a triage officer representative, and three of the following: internal medicine critical care/pulmonary physician, anesthesia critical care physician, surgical critical care physician, pediatric critical care physician, and emergency medicine physician.

Scarce Resource Allocation Independent of Initial Indication

The scoring system may apply to allocation and reallocation of life-sustaining medical resources that are in critically short supply, regardless of initial indication for the resource. For example, in the setting of a severe pandemic, patients with respiratory failure resulting from influenza will be scored on the same scale as those needing a ventilator for another reason. Further, all patients who are allocated a ventilator will be allowed a minimum therapeutic trial of a duration to be determined by the central triage committee based on epidemiologic pattern of the disease. In the case of a novel respiratory pathogen, if all patients who survive require at least 4 days on a ventilator, then a trial period would be set at a minimum of 4 days. This minimum trial would be allowed unless a precipitous decline in clinical status over a shorter period indicates to the triage team that prognosis is exceptionally poor. Time-limited therapeutic trials would apply to many, but not all, conceivable life-sustaining resources, including mechanical ventilators; the duration of the therapeutic trial may vary for the same resource between the patients with different underlying conditions. Such a time-limited trial could be expected to supplant the 120-hour assessment previously outlined. For example, the appropriate duration of mechanical ventilation for patients having undergone emergency surgery may not necessarily be the same as for influenza patients or those with a novel respiratory infection. Such judgments will need to be made by the triage team.

Stabilization of Patients Awaiting Triage

First responders and ER and bedside clinicians should perform the immediate stabilization of any patient in need of critical care as they would under normal circumstances (up to and including intubation for those in respiratory distress, in the event that the crisis involved a respiratory illness). Along with stabilization, temporary support may be offered (eg, bag valve mask for ventilation) until the triage officer can assess the patient for critical resource allocation. Every effort should be made to complete the initial triage assessment within 90 minutes of the recognition of the need for the resource.

Limitations

It is unlikely that those tasked with allocation will face a simple case of determining which of two patients should receive a single ventilator. By definition, the sorts of disasters that trigger the need an allocation framework will result in many patients, arriving in a continuing stream, with shortages of not only ventilators, but also related necessary equipment and trained personnel. The high likelihood of difficult, chaotic conditions further reinforces the need for preparing an accessible framework in advance; it also emphasizes the importance of having a framework that is suitably constructed to allow users to anticipate and adapt to these inevitable complexities and challenges.

Current prognostic capacity is often more limited than is ideal. Anticipating this, this framework may be expected to operate in a manner that results in an overabundance of ties that will need to be resolved. Although a framework that resulted in fewer ties would be easier to implement, ties are preferable to a result that is inconsistent with the intended guiding principle (eg, a framework that led to selections that did not actually save the most lives or life-years).

Technologies will change. Any reliable results indicating changes in the relationship between SOFA and PELOD-2 scores and outcomes should lead to updates in their use in the framework. Scales or technologies that yield enhanced prognostic capacities in relevant areas

should be considered for adoption in place of SOFA and PELOD-2 as soon as practical. Additionally, although the use of SOFA and PELOD-2 provides a standardized approach that can help mitigate the influence of subjective bias, their use raises at least two challenges. First, the use of these scoring systems cannot eliminate bias entirely, and it is imperative that health care and disaster response professionals maintain an awareness of this possibility and consider alternative solutions as they become available. Second, their use will not be generalizable to resource-limited settings, where necessary laboratory results are not available. As noted previously, the central triage committee may, through a transparent, accountable real-time process, change allocation guidelines as new information and research data arise. With this flexibility, the Maryland guidelines retain the unique ability to adapt and change to maximize ethical results in any given emergency.

The boundaries between stages of the lifecycle are necessarily somewhat arbitrary, and there is a risk that it may result in difficult outcomes (eg, prioritizing a 49 year old over a 50 year old, with all else being equal). This is an unfortunate possibility, with harms that can be partially mitigated through transparent and effective advance communication about the underlying principle and the goals for its use in the framework.

Finally, although lottery or "fair chance" is not a primary consideration in the framework we have outlined, it was espoused as potentially appropriate in circumstances when other criteria do not adequately distinguish the priority that should be given to specific patients. There is further work to be done to address the logistical challenges that incorporating a lottery system will entail.

Conclusion

All would hope that this framework will never be needed, either because we are lucky enough never to experience such a severe disaster or because our preparedness and response efforts keep a disaster from becoming a catastrophe. If a catastrophic shortage of life-sustaining medical resources cannot be averted, however, we have provided an allocation scheme that is informed by the values of the people of Maryland and is consistent with the general consensus of experts. This must be a living document, because medical technologies will evolve and new research may improve our ability to determine prognosis in critically ill or injured patients. Although the framework we describe here has not yet been formally adopted and incorporated into Maryland's preparedness plans, work is ongoing. Additionally, validation of the predictive and discriminatory capability of the outlined framework is ongoing and will be reported as it becomes available. As that work continues, we believe this framework may serve as a model for other states or jurisdictions both in process and content.

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