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Existing Crisis Standards of Care Triage Protocols May Not Significantly Differentiate Between Patients With Coronavirus Disease 2019 Who Require Intensive Care

OBJECTIVES: To determine how several existing crisis standards of care triage protocols would have distinguished between patients with coronavirus disease 2019 requiring intensive care.

DESIGN: Retrospective cohort study.

SETTING: Single urban academic medical center.

PATIENTS: One-hundred twenty patients with coronavirus disease 2019 who required intensive care and mechanical ventilation.

INTERVENTIONS: None.

MEASUREMENTS AND MAIN RESULTS: The characteristics of each patient at the time of ICU triage were used to determine how patients would have been prioritized using four crisis standards of care protocols. The vast majority of patients in the cohort would have been in the highest priority group using a triage protocol focusing on Sequential Organ Failure Assessment alone. Prioritization based on Sequential Organ Failure Assessment and 1-year life expectancy would have resulted in only slightly more differentiation between patients. Prioritization based on Sequential Organ Failure Assessment and 5-year life expectancy would have added significant additional differentiation depending on how priority groups were defined.

CONCLUSIONS: There is considerable controversy regarding the use of criteria other than prognosis for short-term survival in initial allocation of critical care resources under crisis standards of care triage protocols. To the extent that initial triage protocols would not create sufficient differentiation between patients, effectively resulting in a first-come, first-served initial allocation of resources, it is important to focus on how resources would be reallocated in the event of ongoing scarcity.

KEY WORDS: crisis standards of care; disaster; ethics; intensive care unit triage

BACKGROUND

Crisis standards of care (CSC) protocols provide guidance to hospitals for allocation of critical care resources such as ventilators during a disaster or public health emergency such as the coronavirus disease 2019 (COVID-19) pandemic. Existing protocols provide frameworks for the initial allocation of critical care Emily B. Rubin, MD, JD, MS¹ Rachel S. Knipe, MD¹ Rebecca A. Israel, MD¹ Thomas H. McCoy, Jr, MD² Andrew M. Courtwright, MD PhD³

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resources and contemplate reevaluation of patients once they are receiving critical care with reallocation of resources where appropriate. The frameworks vary in their interpretation of maximizing overall benefit, with some focusing solely on saving the most lives by prioritizing those considered to have the highest likelihood of surviving the acute illness (1) and others including consideration of other factors, including near-term life expectancy or duration of benefit if a person survives the acute illness (2-4). All aim at some level to avoid allocation of scarce resources on an entirely first-come, first-served basis and to limit ad hoc decision-making in emergencies. It remains unclear, however, to what extent existing CSC protocols would meaningfully differentiate between patients if they were applied under conditions of scarcity. We evaluated how a cohort of patients admitted to ICUs during the COVID-19 pandemic would have been prioritized under four existing or previously proposed CSC protocols.

METHODS

The study was a retrospective cohort study involving 120 patients who were admitted to an ICU with COVID-19 and required mechanical ventilation between March 20, 2020, and May 4, 2020 at a large academic medical center. The cohort included the first 50 patients admitted to an ICU during this time period with a primary diagnosis of COVID-19 who required mechanical ventilation and were known to have died during the hospitalization, and 70 randomly selected patients admitted to an ICU during this time period with a primary diagnosis of COVID-19 who required mechanical ventilation and were either known to have been discharged alive or who were still in the hospital at the time of cohort selection. Of those 70, 15 patients died in the hospital after the cohort was selected, for a total of 65 of the 120 patients (54.2%). The age of the patients ranged from 27 to 89 years with a mean age of 64.1 years.

Critical care physicians retroactively calculated the Sequential Organ Failure Assessment (SOFA) score of each patient at the time the patient was triaged to the ICU and abstracted the medical record available at the time of ICU triage into a written synopsis for each patient. Four physicians provided prognostic estimates for each patient, indicating which of the following they thought was "most" likely based on the patient's underlying medical condition, "assuming the patient were to survive this episode of critical illness": 1) survival less than 1 year, 2) survival less than 5 years, 3) survival greater than 5 years. They were asked to rate their degree of confidence in the prognostic assessment on a Likert scale from 1 to 5 (with 1 being not very confident and 5 being completely confident).

Using the SOFA scores and the prognostic assessments, we calculated how patients would have been prioritized using four triage scoring systems: 1) New York, which uses SOFA score alone to divide patients into three priority groups-highest priority (SOFA score \leq 7), intermediate priority (SOFA score 8–11), and no ventilator (SOFA score > 11) (1); 2) Maryland, which uses SOFA score plus expected survival less than 1 year to assign priority scores from 1 to 7, with higher priority scores associated with lower priority for resources (2); 3) Pennsylvania, which uses SOFA score, expected survival less than 1 year and expected survival less than 5 years to assign priority scores from 1 to 8 with higher priority scores associated with lower priority for resources and then places patients into priority groups (priority score 1-3 = high priority; priority score 4-5 = intermediate priority; priority score 6-8 = 100 priority) (3); and 4) a prior version of the Massachusetts CSC guidance, which was similar to the Pennsylvania protocol but assigned high priority to those with priority score 1-2, intermediate priority to those with priority score 3-5, and low priority to those with priority score 6-8 (4). The Massachusetts guidance has since been revised to assign points only for expected survival less than 1 year (5).

For purposes of this exercise, we assigned points for likely less than 1-year survival to patients only where there was complete consensus with a mean confidence greater than or equal to 4 that the patient was likely to live less than 1 year (n = 7; 5.8%). We assigned points for less than 5-year survival to two groups of patients: 1) those for whom there was complete consensus that the patient was likely to live less than 5 years with a mean confidence greater than or equal to 4 (n = 4;3.3%) and 2) those for whom physicians were divided between the patient being likely to live less than 1 year and the patient being likely to live less than 5 years, provided that mean confidence was greater than or equal to 4 for less than 5-year assessments (n = 21;17.5%). CSC protocols do not routinely specify that multiple physician opinions are required to designate

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a patient as having limited near-term life expectancy. We assumed that triage physicians would act conservatively in making such designations in a real-world triage situation and, as such, only assigned points for limited near-term life expectancy if there was complete consensus with a high degree of confidence.

This project was undertaken as a quality improvement initiative and as such was not formally supervised by the Institutional Review Board per its policies.

RESULTS

Figure 1 depicts the distribution of SOFA scores by patient survival status. One-hundred four patients (86.7%) had a SOFA score of 6 or less, including 51 patients who died (78.5%). **Figure 2** depicts the distribution of priority categories or priority scores by patient survival status using the New York (Fig. 2*A*), Maryland (Fig. 2*B*), Pennsylvania (Fig. 2*C*), and Massachusetts (Fig. 2*D*) protocols. Under the New York protocol, 90.8% of all patients would have been in the highest priority group, including 84.6% of the patients who died. Under the Maryland protocol, 85% of patients would have received a priority score of 1 (the highest possible score), including 76.9% of

patients who died. Under the Pennsylvania protocol, 85% of patients would have been in the high priority group (including 75.4% of those who died); 14.2% would have been in the intermediate priority group; and 0.83% would have been in the low priority group. Under the Massachusetts protocol, 66.7% of patients would have been in the high priority group (including 47.7% of those who died); 32.5% would have been in the intermediate priority group; and 0.83% would have been in the high priority group (including 47.7% of those who died); 32.5% would have been in the intermediate priority group; and 0.83% would have been in the low priority group.

DISCUSSION

Analyses of patient data from the COVID-19 pandemic has called into question the utility of existing CSC protocols for fairly allocating scarce critical care resources, in terms of both adequately differentiating between patients and assigning lowest priority to those with the highest risk of mortality. Evidence has emerged that SOFA at the time of ICU triage, which is the most common rank tool in CSC protocols (6), performs poorly in predicting COVID-19 mortality (7). Furthermore, Wunsch et al (8) evaluated how two triage protocols would have performed in a large cohort of patients with COVID-19 requiring mechanical

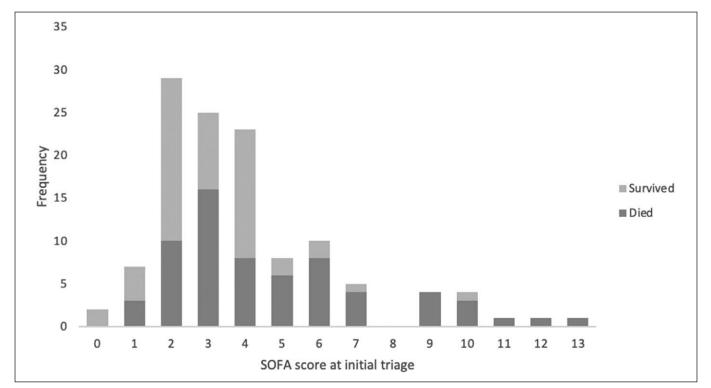


Figure 1. Distribution of Sequential Organ Failure Assessment (SOFA) scores by survival category. This figure shows distribution of SOFA scores among all patients in the cohort by survival status.

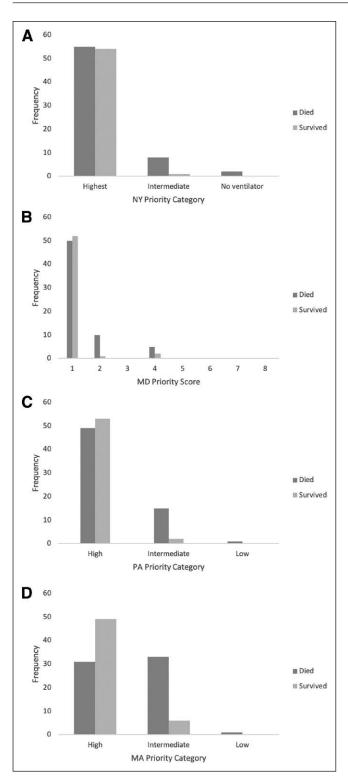


Figure 2. Distribution of priority category or priority score by survival status using New York (NY), Maryland (MD), Pennsylvania (PA), and Massachusetts (MA) crisis standard of care guidelines.
A, Depicts the distribution of patient priority category by survival status using the NY guidelines.
B, Depicts the distribution of patient priority category by survival status using the NY guidelines.
C, Depicts the distribution of patient priority category by survival status using the PA guidelines.
D, Depicts the distribution of patient priority category by survival status using the PA guidelines.

ventilation: the New York State protocol that focuses on lives saved and a model protocol from White and Lo (9) that takes into account both lives saved and lifeyears saved using specific comorbid conditions as potential indicators of limited life expectancy. They found that use of criteria from those two protocols would have identified one in between 10 and 25 admissions as being in the lowest priority group for ventilator allocation, with little agreement between the two protocols. A relatively large proportion of patients who would have been in the lowest priority group under one or both of the protocols (36% using New York State and 56% using White and Lo [9]) survived to hospital discharge.

Our analysis of how four-state CSC protocols would have performed in this cohort of 120 ICU patients with COVID-19 raises further questions about whether these protocols would accomplish their intended objectives if implemented. It also incorporates analysis of the impact of subjective determinations of life expectancy, which are relevant to several existing or proposed CSC protocols. In this analysis, SOFA scores at time of ICU admission did not appear to be reliably associated with short-term survival, consistent with analysis of other cohorts of critically ill patients with COVID-19 (7). 76.8% of all patients and 66.2% of patients who would die during the hospitalization had SOFA scores below 6 at the time of ICU triage, and SOFA scores alone would not have significantly differentiated between patients under the CSC prioritization schemes. Further, these data suggest that adding likely 1-year survival as a marker of duration of benefit may result in little differentiation between patients beyond that provided by SOFA scoring. In this cohort, there were few cases (n = 7, 5.8%) in which complete consensus could be reached on the likelihood of survival less than 1 year. Adding likelihood of survival less than 5 years added more differentiation in priority scores and priority groups in this cohort, particularly under the Massachusetts protocol in which only patients with priority score 1 or 2 were assigned high priority.

There remains significant disagreement about what combination of ethical principles ought to govern allocation of critical care resources in the event of scarcity. There are legitimate concerns about bias and disproportionate impact on those who have been historically disadvantaged with the use of criteria that involve any consideration of underlying life expectancy or duration of benefit (10). The premise of most existing CSC

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protocols, however, is that the default triage principle of first-come, first-served allocation is not optimal. These data suggest that, without some differentiating factor beyond SOFA scoring and likelihood of 1-year survival, the vast majority of critical care resources in an emergency would be allocated at least initially on a first-come, first-served basis.

In addition to concerns about unequal access to care favoring the most privileged, in the event of strict scarcity a largely first-come, first-served approach could result in what many might perceive as perverse outcomes, including patients at an extreme of age with multiple underlying medical problems portending significantly limited life expectancy receiving critical care resources, leaving none for young patients with recoverable illness who presented later. Given that patients typically present for intensive care sequentially as opposed to simultaneously, so-called "tie breakers" in CSC protocols (e.g., age) likely would have limited role in reducing the frequency of such outcomes. If implementation of a triage system was to lead to frequent outcomes that were perceived by those implementing the system as perverse or unfair, ad hoc decision-making and gaming the system could become common.

Given the ethical and logistical difficulties of applying triage protocols in emergency settings to distinguish between patients for initial receipt of critical care resources, it may be that a largely first-come, firstserved approach to initial triage with an emphasis on reevaluating patients quickly once in an ICU and reallocating resources when patients are declining or otherwise thought to have limited prospects for recovery would be a reasonable approach. If that would in effect be the upshot of many CSC protocols because of lack of upfront differentiation between patients, then concerted attention should be paid to developing iterative frameworks to predict survival in patients with COVID-19 requiring intensive care. Given the difficulty of withdrawing life-sustaining treatment without assent of the patient or surrogate, such decisions would ideally be as data driven as possible.

There are several limitations to our data. The sample is relatively small. The patients were from a single medical center and may not be representative of populations presenting for intensive care during COVID-19. The small number of patients triaged to the ICU who were thought by consensus to be most likely to survive less than 1 year may reflect affirmative efforts to incorporate palliative approaches to care for patients in our hospital who fall into that category. In addition, it is possible that triage physicians in actual triage situations would more liberally designate patients as having near-term life expectancy less than 1 year or less than 5 years than we did in this analysis, which would lead to increased differentiation between patients under those protocols allowing consideration of nearterm life expectancy. Finally, the selection of a cohort that was enriched for death and had patients with both known and unknown outcomes at the time of selection may limit the generalizability of the findings.

CONCLUSIONS

Given ongoing concerns about the ability of hospital systems to meet demands for critical care resources during the COVID-19 pandemic, and the likelihood of future events that will strain the capacity of hospitals to provide certain medical resources, it is important to critically evaluate the CSC protocols that are in place and to understand how they would perform in the event of true scarcity if implemented as written. Our data suggest that protocols that include only consideration of SOFA scores and/or 1-year survival when determining priority for initial triage may not provide significant differentiation between patients.

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