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Operationalizing Ethical Guidance for Ventilator Allocation in Minnesota: Saving the Most Lives or Exacerbating Health Disparities?

OBJECTIVES: A statewide working group in Minnesota created a ventilator allocation scoring system in anticipation of functioning under a Crisis Standards of Care declaration. The scoring system was intended for patients with and without coronavirus disease 2019. There was disagreement about whether the scoring system might exacerbate health disparities and about whether the score should include age. We measured the relationship of ventilator scores to in-hospital and 3-month mortality. We analyzed our findings in the context of ethical and legal guidance for the triage of scarce resources.

DESIGN: Retrospective cohort study.

SETTING: Multihospital within a single healthcare system.

PATIENTS: Five-hundred four patients emergently intubated and admitted to the ICU.

INTERVENTIONS: None.

MEASUREMENTS AND MAIN RESULTS: The Ventilator Allocation Score was positively associated with higher mortality (p < 0.0001). The 3-month mortality rate for patients with a score of 6 or higher was 96% (42/44 patients). Age was positively associated with mortality. The 3-month mortality rate for patients 80 and older with scores of 4 or greater was 93% (40/43 patients). Of patients assigned a score of 5, those with end stage renal disease had lower mortality than patients without end stage renal disease although the difference did not achieve statistical significance (n = 27; 25% vs 58%; p = 0.2).

CONCLUSIONS: The Ventilator Allocation Score can accurately identify patients with high rates of short-term mortality. However, these high mortality patients only represent 27% of all the patients who died, limiting the utility of the score for allocation of scarce resources. The score may unfairly prioritize older patients and inadvertently exacerbate racial health disparities through the inclusion of specific comorbidities such as end stage renal disease. Triage frameworks that include age should be considered. Purposeful efforts must be taken to ensure that triage protocols do not perpetuate or exacerbate prevailing inequities. Further work on the allocation of scarce resources in critical care settings would benefit from consensus on the primary ethical objective.

KEY WORDS: bioethics; coronavirus disease 2019; disaster medicine; healthcare disparities; healthcare rationing; triage

BACKGROUND/RATIONALE

Only 3 months after the first case of coronavirus was reported in Wuhan to the World Health Organization (1), healthcare systems in Italy (2) and New York City (3) were forced to do ad hoc rationing of critical resources including ventilators and medications (4). Models projected that many states, Sarah M. Kesler, MD Joel T. Wu, JD, MPH Krystina R. Kalland, BS Logan G. Peter, BS Jillian K. Wothe, BS Jennifer K. Needle, MD Qi Wang, MD Craig R. Weinert, MD, MPH

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including Minnesota, would be forced to operate under Crisis Standards of Care (CSC) during the spring of 2020 (5, 6).

The Minnesota Department of Health enlisted the Minnesota Coronavirus Disease Ethics Collaborative (MCEC), a multidisciplinary group of ethicists and other professionals, to create ethical guidance for how to approach ICU and ventilator rationing under CSC conditions. MCEC's effort built on Minnesota Department of Health (MDH) guidance created during the 2009 Influenza pandemic (7). The Minnesota Critical Care Workgroup, which included physicians from all major healthcare systems in the state of Minnesota, was tasked with operationalizing the MCEC guidance through a ventilator allocation scoring system that would be used for patients with all diagnoses. The intent was to create a triage system that would maximize population level benefit, or save the most lives, as is commonly accepted as a primary objective of using a triage process under CSC (8-10). The group used guidance for managing scarce medical resources created by MDH during the 2009 Influenza pandemic (11), prior academic and institutional work (12-16), and data that were available at the time on outcomes for coronavirus disease 2019 (COVID-19) patients with critical illness (17, 18). Starting in March, the group met three times weekly.

The group used Sequential Organ Failure Assessment (SOFA) as the foundation of the scoring system but was aware of the limitations of SOFA from prior studies (19, 20). This led to the inclusion of two additional factors: comorbidities anticipated to impact a patient's chance of surviving their hospitalization and anticipated use of ventilator. Comorbidities that were severe and/or were associated with life expectancy of less than 6 months were assigned 4 points. If patients had no severe comorbidities but one or more comorbidities that were advanced and expected to impact the probability of surviving a hospital admission, they were assigned 2 points. A list of comorbidities included in the scoring system is shown in **Supplemental Table 1** (http:// links.lww.com/CCX/A665).

Patients were assigned 0 points if they were anticipated to need mechanical ventilation for 3 days or less. They were assigned 1 point if their estimated need for mechanical ventilation was more than 3 days. The group created a specific list of diagnoses for which patients were predicted to need the ventilator for 3 days or less. The list of diagnoses is shown in **Supplemental Table 2** (http://links.lww.com/CCX/A666).

These discussions produced an 8-point Minnesota Ventilator Allocation Score (VAS). The VAS was intended to apply to patients with all diagnoses needing ventilatory support. Patients with a score of 1 were assumed to have the lowest in-hospital mortality and thus be the highest priority for accessing ventilators. Patients with a score of 8 were predicted to have the highest in-hospital mortality and therefore be of lowest priority. The 8-score levels were then placed into four colored priority tiers. Patients with scores of 1 were placed into the green tier and were of highest priority. Patients with scores of 2-4 were placed into the yellow tier and were second priority. Patients with scores of 5 or 6 were placed into the red tier and were third priority. Patients with scores of 7 or 8 were placed into the blue tier and were lowest priority. The Minnesota VAS is shown in Figure 1.

The majority of the working group felt it was appropriate to incorporate age into the VAS, given the preliminary data about the relatively poor prognosis of older patients with COVID-19 and cute respiratory distress syndrome (18, 21). A proposal was made to assign 1 point to patients between the ages of 65 and 79 and 3 points to patients who were 80 and older. However, a vocal minority of the group expressed concerns about age discrimination, and age was not included. There was also concern among members of the group that the VAS might deprioritize Black, indigenous and other people of color (BIPOC). During its deliberations, the group noted that most of the work it used as a basis for its VAS was based on expert consensus.

OBJECTIVES

The objective was to investigate how accurately the VAS grouped patients into priority tiers, how many patients fell into each priority tier, and whether there was evidence of bias against any demographic group with the overall purpose of predicting mortality, saving the most life years, and fairly allocating resources. The group planned to adjust the score if necessary.

METHODS

The Minnesota VAS was evaluated via a retrospective cohort study on 504 adult patients who were emergently

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Figure 1. Four-step method to calculate patient Ventilator Allocation Score using the range of Sequential Organ Failure Assessment (SOFA) score, presence of comorbidities, and anticipated length of ventilator use.

intubated between March 10, and September 24, 2020, and cared for in the MHealth Fairview healthcare system. March 10 was the date of intubation of the first patient with COVID-19 in the healthcare system. The MHealth Fairview healthcare system is made up of 11 hospitals although most patients were cared for in one of five hospitals: an academic medical center, three community hospitals, and one hospital specifically devoted to patients with COVID-19.

The University of Minnesota Institutional Review Board (IRB) approved the study involved as not greater than minimal risk, and patient consent was not needed for data abstraction (IRB number 00010831). Patients were excluded if they had not provided information on race or ethnicity (7% of patients). Six-hundred fortythree patients were eligible. Sixty-nine patients were excluded because they died in the emergency department, and 70 patients were excluded because they were transferred to another hospital.

Charts were reviewed by trained medical students and one faculty member (S.M.K.). Patients were assigned a score using data available within 6 hours of intubation. An automated SOFA score was created in the electronic health record (EHR). Automated SOFA

scores for intubated patients assumed patients to have a Glasgow Coma Scale (GCS) score of 15. GCS and respiratory sub scores could be manually overridden to adjust the SOFA score. Charts were reviewed to assess for the presence of relevant comorbidities and to assess the reason for intubation as determined at the time of intubation. Faculty secondary review was conducted for all patients who died, lacked an automated SOFA score, had significant comorbidities, or were intubated for a neurologic condition. Secondary review was also carried out if requested by a medical student. Information was collected on each patient's vital status at the time of discharge and 3 months after discharge through the Minnesota Department of Health Department of Vital Records. Mortality rates were calculated for all patients and by group (with/ without COVID-19, age group, and race group). The Cochrane-Armitage test for trend was conducted to examine the association between mortality and VAS and age group. For each VAS, a chi-square test (or Fisher exact test for cell counts of 5 or less) was performed to compare mortality rates between those with COVID-19 and those without COVID-19. Statistical analyses were performed using SAS software, Version 9.4 (SAS Institute, Cary, NC).

MEASUREMENTS AND MAIN RESULTS

Patients

Of the 504 patients, 149 patients had COVID-19, and 355 patients had an alternate diagnosis. In-hospital and 3-month mortality rates for all patients were 27% and 33%. The cohort of patients with COVID-19 was 34.2% White. The cohort of patients without COVID-19 was 84.6% White. The racial makeup of patients without COVID was similar to the state in general, which was estimated to be 83.5% White as of July 1, 2019 (22). Mean age was similar for COVID-19–positive (61.1 yr) and COVID-19–negative (60.8 yr) patients. These data are shown in **Supplemental Table 3** (http://links. lww.com/CCX/A667).

Score and Mortality Association

The relationship between score and mortality was significant and similar for COVID-19–positive patients (p = 0.02) and COVID-19–negative patients

(p < 0.0001). The mortality rate of patients with scores of 6 or higher was 96%, but only 46 of 171 deaths occurred in patients with scores of 6 or higher. No COVID-19– positive patients were given a score of 1, because all patients intubated for COVID-19 had an anticipated duration of mechanical ventilation of more than 3 days. Of patients with COVID-19, 71% scored a 2.

The system did not accurately group patients into the same tiers. For example, COVID-19–negative patients who scored 5 and 6 were placed together in the red tier and had mortality rates of 50% and 95.8%, respectively. These results are similar to those reported by Wunch (23). These data are shown in **Table 1** and **Figure 2**.

Age, Race, and Comorbidity-Associated Results

Patients who died were older than patients who survived (mean age 70.9 vs 56.1 yr). Age was associated with mortality with scores of 2, 3, and 4, as shown in **Figure 3**. Patients who were 80 and older with scores of 4 or above had a 93% mortality rate.

There were no statistically significant differences in mortality rates in any score between patients who identified as White and patients of other ethnic and racial backgrounds. Numbers were too small to assess mortality differences by individual racial or ethnic groups.

Despite a trend toward higher mortality rates for increasing scores, the mortality rate of patients with a score of 5 was lower (48%) than for patients with a

TABLE 1. Ventilator Allocation Score Distribution

Allocation Score	All Patients, n (%)		COVID-19 Negative, <i>n</i> (%)
1	78 (15.5)	0 (0)	72 (20.3)
2	207 (41.1)	107 (71.8)	106 (29.9)
3	71 (14.1)	17 (11.4)	54 (15.2)
4	73 (14.5)	14 (9.4)	59 (16.6)
5	27 (5.4)	5 (3.4)	22 (6.2)
6	28 (5.6)	4 (2.7)	24 (6.8)
7	11 (2.2)	1 (< 1)	10 (2.8)
8	9 (1.8)	1 (< 1)	8 (2.3)

COVID-19 = coronavirus disease 2019.



Figure 2. Mortality rate per Ventilator Allocation Score (VAS) by coronavirus disease 2019 (COVID-19) status. The colors in the figure correspond with the four tiers of priority designated in the original VAS. Increasing scores correlated with increasing 3 mo mortality rates in patients with COVID-19 (p = 0.02) and without COVID-19 (p < 0.0001). The 3 mo mortality rate of patients with scores of 5 was lower than patients with scores of 4 for patients with COVID-19 (71% vs 40%) and without COVID-19 (56% vs 50%). Patients with scores of 6, 7, and 8 had 3 mo mortality rates ranging from 90% to 100%.

score of 4 (59%). The intent of the study was not to look for associations between specific comorbidity and mortality. However, after examining patients with scores of 5 more closely, it was noted that eight of the 18 patients with end stage renal disease (ESRD) were assigned a score of 5. The mortality rate for patients with ESRD and a score of 5 was 25%. The mortality rate for patients without ESRD and a score of 5 was 58%. The difference in mortality rate did not achieve statistical significance (p = 0.2), possibly because of the small sample size. For patients with scores of 5, patients with ESRD were less likely to be White (50% White) than patients without ESRD (79% White).

DISCUSSION

These data demonstrate that the VAS was able to identify patients with very high rates of short-term mortality. However, it was not able to distinguish between

patients with lower scores and did not group patients into appropriate priority tiers, which reduces its utility as a triage tool. Our results suggest that despite the groups' adherence to ethical and legal guidance with the intent of treating people fairly and saving the most lives, the scoring system we created may not have achieved either of these objectives. The data strongly suggest the score was biased against younger people. The data also raise the possibility that the score may have been biased against BIPOC patients. Three example patients are considered below in Table 2.

Patient A and patient B are assigned the same scores and given similar priority. However, in this patient population, the mortality rate of COVID-19–negative

patients younger than 65 with scores of 4, such as patient A was 36%, whereas the mortality rate of patients COVID-19-negative patients 80 and older with scores of 4, such as patient B, was 95%. Patient C would have been given a score of 5 (due to the comorbidity of ESRD) and grouped with patients who had mortality rates of up to 95%. If triage had been necessary, the patient with the best prognosis may have been given the lowest priority. These results illustrate the difficulty of operationalizing an ethical framework that must balance conflicting ethical principles. These results also provide an example of the unintended consequences created by striving to avoid discrimination on the bases of certain criteria or vulnerable classes of persons and the importance of monitoring the implementation of triage protocols in real time to identify unanticipated effects that may create or exacerbate inequity.

Under normal conditions, the primary ethical consideration for treating patients is the individual



Figure 3. Three-month mortality rate per Ventilator Allocation Score by age group: All patients. Age was associated with mortality with scores of 2 (p < 0.0001), 3 (p = 0.054), and 4 (p = 0.0002).

patient's interests. However, as scarcity increases, and particularly when operating under CSC, consideration of justice and population level utility increase in relative importance. According to the state of Minnesota ethical guidance for operating under CSC; "In the COVID-19 pandemic, as in other public health emergencies, response must focus on the overall benefit to the population, to try to save the most lives possible, while also respecting individual rights and promoting fairness across our population" (8). However, no guidance or precedence specifies that the duty to save the most lives is more important than the duty to respect individual rights and fairness, even during CSC conditions. In theory, these obligations can be balanced. However, our experience suggests that in a critical care setting during a real crisis, the affirmation of individual rights and interests may still carry significant weight relative to justice considerations. Future work on resource allocation will benefit from consensus on which duty should be of highest priority.

These results raise the possibility that attempting to operationalize equity concerns in a critical care setting may actually deepen existing inequities. At the time the working group was deliberating about its triage protocol, the ethical and legal guidance with respect to avoiding age discrimination in triage protocols was very clear. Some ethicists and physician groups have argued during this pandemic that the concept of life years is relevant when designing ventilator allocation frameworks (24, 25). However, in the wake of reports that some triage protocols might discriminate against older people and those with disabilities, The Office of Civil Rights made a statement on the importance of not discriminating on the basis of age, race, color, national origin, sex, religion, or disability, and further stated that only predictions of in-hospital mortality should be considered (26, 27). This resulted in a number of states revising initial CSC guidance (28, 29).

As said earlier, the majority of the group felt that age should be part of the triage algorithm. However, when the group presented their proposal along with data on age and outcomes from COVID-19 to MCEC, advocates against age discrimination presented data that suggested functional status and frailty were equally important considerations (30–32). When it became clear that age would not be included, many members of the group felt anticipatory moral distress about the prospect of giving an older person with a poor prognosis a ventilator instead of a younger patient with a better prognosis. These data suggest that many such instances would have occurred if the original VAS had been used. Age-blinded triage protocols are particularly problematic for patients with COVID-19. Data have shown that hospitalized White patients with COVID-19 are older than non-White patients in Minnesota (unpublished data, Minnesota Department of Health) and other locations nationwide (33, 34). Triage systems that are blinded to age run the risk of prioritizing older White patients at the expense of younger BIPOC patients.

The possibility that patients with ESRD may have been systematically deprioritized by the VAS highlights the importance of monitoring implementation of triage algorithms in real time. The VAS assigned patients with ESRD 2 points for the comorbidity. Patients with ESRD also had SOFA scores that overestimated their severity of illness. Per capita rates of dialysis are higher for patients who are non-White, have lower educational attainment, and have lower incomes (35). Since systemic inequities contribute to poor health outcomes like dialysis dependence, including ESRD as a comorbidity may run the risk of exacerbating the effects of inequities based on race and income. Patients who are already disadvantaged on the basis of race and income may be penalized both by the conditions that increase risk for dialysis dependence and then again by a score that relies on ESRD for calculating priority. In our patient population, two of the three surviving patients who were 80 and older and had scores of 4 or higher had ESRD.

It is known that the COVID-19 pandemic disproportionately affects BIPOC and those with low

TABLE 2.Example Patients

Patients	A: 22-yr-Old With Septic Shock and Pneumonia	B: 81-yr-Old With Pneumonia	C: 44-yr-Old With Pneumonia
Past medical history	None	O ₂ -dependent chronic obstruc- tive pulmonary disease	End stage renal disease from hypertension
Vital sign data	92 Sao ₂ % on 80% Fio_2	92 ${\rm Sao_2\%}$ on 80% ${\rm Fio_2}$	92 Sao ₂ % on 80% Fio_2
	On norepinephrine and vasopressin	Other vital signs normal	Other vital signs normal
	Other vital signs normal		
Laboratories	Creatinine 2.1	All laboratories normal	Creatinine 5.
	Platelets: 98		All other laboratories
	Other laboratories normal		normal
SOFA	13	4	8
SOFA score	3	1	2
Comorbidity score	0	2	2
Score for length of use of ventilator	1	1	1
Score (color code)	4 (yellow)	4 (yellow)	5 (red)
Estimated mortality based on study data, %	36	93	28

Sao₂ = arterial O₂ saturation, SOFA = Sequential Organ Failure Assessment.

socioeconomic status (36, 37). Additionally, concerns have been raised that ventilator scoring systems might exacerbate health inequities and systematically deprioritize BIPOC patients or people with lower socioeconomic status (37, 38). Given this reality, some ethicists and clinicians have advocated for incorporating equity more intentionally into triage protocols (39, 40). Our data suggest concerns about bias in triage scoring systems are well founded. The exclusion of consideration of categories like race and age may actually obscure practices or procedures that tend to perpetuate or re-express systemic inequity. In the future, specific consideration of age and the construct of race may be necessary to account for systemic racism or other similar kinds of systemic societal inequity.

After reviewing these results, the working group removed ESRD from the list of advanced comorbidities and now calculates SOFA scores for patients with ESRD using their actual renal function. For most patients this will bring their total score down by 2 points. This allows systems to use the automated her-generated SOFA score. It also lessens the chance of penalizing patients with ESRD and may function as a practical way to "give back" as suggested by Sederstrom (41). The group is gathering more information and has not yet determined how age might be included in future triage algorithms.

Our conclusions are limited by a small sample size, the changing approach to treating COVID-19 during the period of our study, and the varying levels of stress over time in Minnesota during the period of observation. Our conclusions are also limited by the discrepancy in the racial identities between patients with and without COVID-19, as well as the changing racial demographics over time in Minnesota for patients with COVID-19.

CONCLUSIONS

The Minnesota VAS is able to identify patients with very low short-term survival rates. The data show that incorporation of age into the VAS and elimination of ESRD as a comorbidity would more accurately predict those patients expected to survive. The data demonstrate the challenges of implementing ethical frameworks aimed at balancing utility and fairness. Tools like triage protocols alone cannot rectify the problem of systemic inequity and racism; however, purposeful efforts must be taken to ensure that triage protocols do not perpetuate or exacerbate prevailing inequities.

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Dr. Kesler had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. All authors contributed substantially to the study design, data analysis and interpretation, and the writing of the article.

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