## Sequential organ failure assessment, ventilator rationing and evolving triage guidance: new evidence underlines the need to recognise and revise, unjust allocation frameworks

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## **ABSTRACT**

We respond to recent comments on our proposal to improve justice in ventilator triage, in which we used as an example New Jersey's (NJ) publicly available and legally binding Directive Number 2020-03. We agree with Bernard Lo and Doug White that equity implications of triage frameworks should be continually reassessed, which is why we offered six concrete options for improvement, and called for monitoring the consequences of adopted triage models. We disagree with their assessment that we mis-characterised their Model Guidance, as included in the NJ Directive, in ways that undermine our conclusions. They suggest we erroneously described their model as a two-criterion allocation framework; that recognising other operant criterion reveals it 'likely mitigate[s] rather than exacerbate[s] racial disparities during triage', and allege that concerns about inequitable outcomes are 'without evidence'. We highlight two major studies robustly demonstrating why concerns about disparate outcomes are justified. We also show that White and Lo seek to retrospectively—and counterfactually—correct the version of the Model Guideline included in the NJ Directive. However, as our facsimile reproductions show, neither the alleged four-criteria form, nor other key changes, such as dropping the Sequential Organ Failure Assessment score, are found in the Directive. These points matter because (1) our conclusions hence stand, (2) because the public version of the Model Guidance had not been updated to reduce the risk of inequitable outcomes until June 2021 and (3) NJ's Directive still does not reflect these revisions, and, hence, represents a less equitable version, as acknowledged by its authors. We comment on broader policy implications and call for ways of ensuring accurate, transparent and timely updates for users of high-stakes guidelines.

We respond here to recent comments on our proposal to improve justice in ventilator triage. We used a public and legally binding standard, New Jersey's (NJ) Directive Number 2020-03 (valid as of this writing, henceforth: Directive) and noted that such frameworks compound prior unfair structural disadvantage for many black patients. Chiefly, this is due to the way scores such as the Sequential Organ Failure Assessment (SOFA) and life expectancy are integrated. Focussing on the role of SOFA and its capture of kidney function, we offered six possible policy options towards a more just approach: improving diversity in decision processes, adjusting creatinine scores, dropping creatinine, finding alternative measures, adding equity weights and dropping measures such as SOFA.1

Doug White and Bernard Lo comment as authors of the Model Guidance adopted in the Directive.<sup>2</sup> They suggest we wrongly characterised this model in our background description of SOFA's function as a two-criterion framework; that recognising other criteria reveals it 'likely mitigate[s] rather than exacerbate[s] racial disparities during triage', and allege that our concerns about inequitable outcomes are 'without evidence'.<sup>2</sup> While we share White's and Lo's aim to promote equity, we disagree on all three points. The disagreement is not one of opinions, but of hard data.

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Correspondence to Dr Harald Schmidt, Medical Ethics and Health Policy, University of Pennsylvania Perelman School of Medicine, Philadelphia, PA 19104, USA; schmidth@upenn.edu First, and most importantly, is the evidence on inequitable outcomes. On submitting our initial paper, we were not aware of any robust published data, although one of us (NDE) was a coauthor of a study assessing SOFA's performance among different racial groups. Our patient vignettes that illustrated the Directive's harmful consequences were directly informed by this work—ongoing at the time, published since<sup>3</sup>—and align closely with similar recent research.<sup>45</sup>

Specifically, Deepshikha Ashana and colleagues analysed data of 113 158 black and white patients admitted for sepsis or acute respiratory failure at 27 US hospitals. The team calculated in-hospital mortality of SOFA and another score, 'including categorical SOFA groups recommended in a popular crisis standard of care, and a SOFA score without creatinine to reduce the influence of race'. The standard referred to is the same Model Guidance included in the Directive that we drew on. The authors urge that more equitable mortality prediction scores be developed, since:

81.6% of Black patients [were] included in lower priority crisis standard of care categories, and 9.4% of all Black patients, were erroneously excluded from receiving the highest prioritization. The SOFA score without creatinine reduced racial miscalibration.<sup>3</sup>

In practice, under severe crisis conditions, these results suggest that the Model Policy would lead to the deaths of large numbers of black patients by inappropriately denying them ICU care despite good prognoses.

It is unclear on what grounds White and Lo can argue that their model—as embedded in the Directive—tends to reduce, rather than increase racial inequities. It is also unclear why they failed to take account of this study, and instead cite Gershengorn and colleagues' less robust one, 6 that was published within days of Ashana and colleagues', but is focused on a single location, and comprises 10-fold fewer patients. 2

Further work strongly supports the findings of harm to black patients. William Miller and colleagues analysed data of 95 549 patients admitted to 233 US ICUs in 118 hospitals. They, too, found that the SOFA score overestimated the mortality of black patients and restricts their access to the top priority tier of the Model Guidance. Under severe shortage conditions,

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where only the top priority tier would receive treatment, 15.6% of black patients were misclassified from the highest to the second priority.4

Second, White and Lo claim that our conclusions are at best limited, due to a perceived erroneous description of their model. For example:

'Although it is plausible-but uncertainthat using the two-criterion framework they inaccurately described as the NJ framework may worsen disparities the actual four-criterion framework developed is unlikely to worsen disparities and would probably mitigate them'.

Above evidence aside, we reject this charge and are surprised that White and Lo seek to retrospectively-and counterfactually-correct and disown the version of the Model Guideline included in NJ's Directive (even though we agree that the direction of change is the right one).

The 11 April 2020 version of the multiprinciple strategy included in the Directive (that we already reproduced facsimile in the analysis that White and Lo respond to) calculates points based on SOFA (or similar) score and life expectancy. Unlike in later versions, no further criteria are included. Expressly, the text underneath the point score table states: 'These points are then added together to produce a total priority score which ranges from 1 to 8'.7 Life cycle and essential worker status are only introduced in the following paragraph in a secondary way as 'other scoring considerations'. It is suggested that 'heightened priority' might be given to them. But no specific points are assigned to either criterion.

By contrast, White and Lo do include these criteria directly in table 1 of their response with specific point weights. They also remove SOFA. They write that this depiction shows 'a summary of the four criteria in the NJ framework'2—only, this table differs substantially from the one in the NJ's Directive.

Moreover, neither the version of the multiprinciple strategy shown in White's and Lo's response,<sup>2</sup> nor later adjustments proposed to reduce the risk of inequitable outcomes-including reducing the life expectancy requirement, and adding Area Deprivation Index equity weights,8 as per a subsequent version, published in December 2020<sup>9</sup>—are found in NJ's Directive. And the version on the University of Pittsburgh's dedicated Model Guidance web was updated to reflect these changes only on 14 June 2021 (even though the date shown on the guideline itself is stated as '9 April 2021'). The previous guideline version, dated 15 April 2020 and available until 13 June 2021, was directly parallel to the version included in the Directive (archived copies of all documents available from the authors).

To clarify this discrepancy, we show below side-by-side facsimile reproductions of the multiprinciple strategy included in the NJ Directive, and in White's and Lo's response.<sup>2</sup> Asserting that the version included in the Directive integrated four criteria with points as suggested in White's and Lo's depiction included in their response conflicts with the record and creates distraction and confusion. In the same vein, it is incorrect to suggest that the SOFA score—which was the principal subject of the paper White and Lo respond to-was already omitted in the version integrated in the NJ Directive.

Finally, even if the version presented in the White's and Lo's response were found in the Directive, these changes would be of little comfort to those black patients who do not happen to qualify for possible extra points based on essential worker and life cycle status.

We, therefore accurately characterised the multiprinciple strategy and its consequences, and more robust (including broadly concurrent) data than presented by White and Lo show that the Model Guidance as integrated into the NJ Directive indeed exacerbates black patients' disadvantage.3-5

In a broader perspective, this situation raises critical questions about the obligations of authors of high-stake guidelines to inform users about important updates in an accurate, transparent and timely manner as well as regarding other structures that avoid triage decisions being based on outdated frameworks.

According to the description on the Model Guidance website available until 13 June 2021, the Model Guidance dated 15 April 2020 had been adopted 'by several hundred hospitals across the United States' and several states. 10 White and Lo indicate their commitment to equity in their

Facsimile versions of the Pittsburgh Model Policy's multi-principle strategy/point score system (as included in NJ's Directive Number 2020-03, dated 11 April 2020, and as presented by White and Lo,<sup>2</sup> purporting to show the status as of April 2020)

White's and Lo's presentation purporting to show the operant criteria in the point score system status April 2020 (left hand side) differs substantially from the version included in Directive Number 2020-03 (already reproduced facsimile, ie, exactly as shown below, in our initial analysis that White and Lo respond to, 1 right hand side). In particular, and counter to White's and Lo's writing, the 11 April 2020 version from Directive Number 2020-03 includes neither essential workers nor life-cycle considerations, with assigned points. Note also that the 11 April 2020 version from Directive Number. 2020-03 does include SOFA, including points for each of the SOFA scale increments—omitted from the version supposedly showing the status April 2020. The full text of the April 11 version is also available, as of this writing, on the New Jersey Attorney General's website listing currently active, revised and repealed Directives: https://www.njoag.

Table 1 of White/Lo response, 2 purporting to show the status April 2020 (conflicting with the Table 1, included in Directive Number 2020-03, part of the embedded Model Policy dated 11 version in Directive Number 2020-03, to the right here)

Principle	Criterion	Point system					
		+1	+2	+3	+4		
Promote population health outcomes	Prognosis for hospital survival (using a risk prediction score score)	Quartile 1 lowest risk of death (ie, risk of death <25%)	Quartile 2 (ie, risk of death 25%-49%)	Quartile 3 (ie, risk of death 50%-75%)	Quartile 4 highest risk of death (ie, risk of death >75%)		
	Prognosis for near-term survival (individualised clinical judgment)	-	Death expected in 1–5 years	-	Death expected within 1 year from end stage condition		
Promote justice/equity	Priority to frontline essential workers	Subtract one point from Triage Priority Score if the patient is an essential worker in a high-risk occupation.*					
	Priority to those who have had the least chance to live through life's stages	<b>Tiebreaker</b> : In the event that two patients have identical Triage Priority Scores, give priority to the younger patient when a significant age difference exists.					
	Equal chances	Second tiebreaker: In the event that two patients have identical Triage Priority Scores and are of similar ages,					

<sup>\*</sup>This equity-focused criterion could also be operationalized as a tiebre:

April 2020 (reproduced exactly as included already in our paper, to which White/Lo respond)

Table 1. Multi-principle Strategy to Allocate Critical Care During a Public Health Emergency

Principle	Specification	Point System*				
		1	2	3	4	
Save lives	Prognosis for short-term survival (SOFA score*)	SOFA score < 6	SOFA score 6-8	SOFA score 9-11	SOFA score ≥12	
Save life- years	Prognosis for longer-term survival (medical assessment of prospects for survival after hospital discharge)	***	Life expectancy < 5 years despite successful treatment of acute condition	•••	Death likely within 1 year despite successful treatment of acute condition	

that predicts in-hospital mortality, such as LAPS2 score, could be used in place of SOFA, but should similarly be divided into 4 ranges.

response to us and acknowledged in the December 2020 revision 'important equity problems' with triage protocols, including their own<sup>9</sup>: in process terms, while it is unclear which Guidance versions adopters used, and whether they used full versions or sections of it, it would be helpful if Guidance adopters were contacted to ensure that they are aware of the latest version. On a more general note, thought should be given to automating update notifications. While this clearly requires further planning, one simple option would be to require those downloading a guidance copy to provide a contact email, so that, at a minimum, major updates can be passed on automatically.

Given the stakes, a more comprehensive alternative might be to establish a central repository, by requiring all hospitals with ICU facilities to register with the US Department of Health and Human Services, (1) whether or not they have triage guidelines and (2) if so, to provide copies of all iterations in a timely manner. The same could be required for any state-level triage guidance. Developers of Model Guidance could likewise be actively encouraged to share their frameworks in this way. A central repository, whether accessible publicly or only to relevant health officials and hospital leaders, would provide an incentive to establish and review guidance and offer significantly improved transparency about adopted rules. 11-13

Alex James Miller Tate comments on another aspect in the background description of our analysis, regarding the risk that unweighted lotteries tend to compound past health injustice for most black patients.8 He points out that prior work defending such lotteries has insufficiently addressed this problem and suggests that a more appropriate characterisation of the normative problem would be to say that unweighted lotteries 'fail to satisfy healthcare providers' duty to prevent unjust health outcomes'. Much here depends on the understanding of what it means to compound disadvantage, but we welcome the unfolding of important nuances that comport with the overall direction of our argument and offer a broader basis for why frameworks based on supposedly objective medical knowledge alone are normatively inadequate.

During the pandemic's peak, many commentators felt it was the wrong time to re-examine the principles underpinning ventilator triage. Eventually, considerable variation, and a multitude of different types of frameworks and revisions emerged. 11-13 The risk now is that a plethora of models with inequitable outcomes—including ones not reflecting key updates—is archived, to be at hand for the next pandemic. The injustice enshrined in these models should not stand. When we wrote our initial analysis, regrettably, there was no federal guidance on Crisis Standards of Care. Encouragingly, the US' National Covid Strategy charged the Covid Health Equity Task Force with developing such guidance. Hopefully, this will help ensure that, in substance and process, triage frameworks in future pandemics will more uniformly reflect equity and the views of those who have most to lose.14

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