Ventilator Allocation Protocols: *Sophisticated Bioethics for an Unworkable Strategy*

by ROBERT D. TRUOG

In the early weeks of the Covid-19 pandemic, as the U.S. Centers for Disease Control and Prevention predicted that hospitals might soon not have enough ventilators to treat all patients in need, states recognized that they must urgently develop crisis standards of care (CSC), including algorithms for determining who would be offered this resource under conditions of scarcity. The first priority in all these protocols was to do everything possible to avoid or mitigate the scarcity in the first place. But given the predictions that such shortages were likely, states also recognized that it would be irresponsible not to have plans in place for prioritizing patients if a time came when the need for ventilators exceeded the supply.

As states grappled with how to design these allocation protocols, they considered a long list of factors that could be relevant to making these decisions. To my knowledge, all the protocols that were developed included some measure of the probability of survival from the acute illness. Beyond that, however, the protocols varied widely. One of the key questions has been whether the duration of the benefit should matter (measured, for example, in terms of life-years saved or the probability of survival for a certain period, such as one year or five years). Other questions included whether age should matter (as, for example, by setting strict age cutoffs or using a "fair-innings" approach), whether priority should be given to essential workers (and if so, how they should be defined), whether pregnant women should be given priority, and whether protocols should address issues of structural racism and social inequity, for instance, by including measures such as the Social Vulnerability Index. The two featured articles in this issue of the *Hastings Center Report* discuss the ethical relevance of these factors and the process for how decisions about them should be made.[1]

I was a member of the Massachusetts advisory working group that wrote the Commonwealth's CSC guidance,[2] and I was proud of the work we did, thinking carefully about each of the issues listed above. But as a critical care physician, I have come to the conclusion that, no matter how sophisticated the ethical analysis, the fundamental approach we proposed was flawed and virtually impossible to implement.

All the existing protocols are based on the assumption that clinicians will be faced with the task of selecting which patients will be offered a ventilator from among a population of patients who are each in need of one. The allocation protocols then assign patients a priority category (typically color coded, with red for the highest priority, orange for the next highest, and yellow for the lowest), and the protocols specify "tie-breaking" criteria to be used when necessary. The problem with this approach for ventilator allocation is that it has no relationship whatsoever to what happens in the real world. Let me explain.

Patients do not arrive at hospitals in groups. They do not arrive simultaneously, but sequentially. Suppose a patient arrives in a hospital emergency department and the physician believes that they are at risk of imminent death if not placed on a ventilator. Suppose the physician uses the algorithm and determines that the patient is in the orange category. If the patient is placed on a ventilator, then that ventilator will not be available for other patients with a higher priority who may arrive at the hospital within the next hours or even days. Following the algorithm, the physician should therefore keep the ventilator unused and in reserve so that it is available when and if a higher-priority patient should arrive.

But what if, in fact, no other patients with a higher priority actually arrive and the first patient dies, even though a ventilator is physically available?

Despite the fact that the algorithm would have been applied exactly as it is designed to be, this outcome would likely cause many clinicians and family members considerable emotional and psychological distress. The reluctance of clinicians to allow a patient to die when a potential means of saving their life is immediately available is understandably and appropriately very powerful in motivating clinicians to intervene.

To my knowledge, no data have been published about how physicians actually responded to these situations. More specifically, I am not aware of any data about whether or how the algorithms were actually used. One study examined how a ventilator allocation protocol would have performed if implemented on a retrospective database, but again, this study treated the database as representing a population of patients that could be evaluated simultaneously and did not reflect the real world, where patients present sequentially.[3]

From conversations I have had with a number of intensive care unit clinicians, my impression is that the algorithms were not used, and that when faced with patients who were expected to die imminently without me-

Robert D. Truog, "Ventilator Allocation Protocols: Sophisticated Bioethics for an Unworkable Strategy," *Hastings Center Report* 51, no. 5 (2021): 56-57. DOI: 10.1002/hast.1289

chanical ventilation, clinicians resorted to the principle of first come, first served. In other words, patients who were at imminent risk of death were offered a ventilator if one was available, regardless of their priority status.

A first-come, first-served approach has been described as a "natural lottery," which is a reasonable description when we can assume that the order in which patients become ill and arrive at the hospital is random. When this condition is met, first come, first served is a good strategy for treating people equally, which is why having people "queue up" or "get in line" is so often considered the best way to ensure the fairest distribution of social goods. But many consider it the worst principle to use in the allocation of potentially life-saving medical interventions when it is reasonable to believe that there are identifiable differences between patients that should matter in deciding who should receive treatment. This is the concept of triage, which was developed by military surgeons in the nineteenth century to "focus on those patients who need immediate treatment and for whom treatment is likely to be successful."[4]

In short, in situations where patients present sequentially rather than simultaneously, allocation strategies that are designed to hold a potentially life-saving resource in reserve even when a patient is in imminent need are likely to be untenable for the clinicians who must implement them, as well as intolerable for the patients and families who must accept them. In these situations, clinicians are strongly motivated to offer ventilators on a first-come, first-served basis, despite the fact that this principle may not optimize the desired outcome.

If we assume that this is not the last pandemic that the world will face, then we should examine the practices used during this pandemic and ask if they can be improved before the next one. I propose that a better approach to allocating ventilators would be to adopt a practice that is often used in the routine practice of clinical care, which is to offer patients a "time-limited trial" of therapy.[5]

Using this approach, patients are offered critical care treatments, including ventilation, for a defined period, with the understanding that if certain clinical milestones are not met within that time frame, then the treatment will be withdrawn, and the patients will be provided with palliative care.

This common clinical practice could be modified to help manage a shortage of ventilators during a pandemic. Using this strategy, allocation protocols could be written to create a very low threshold for offering ventilation to patients at risk of imminent death. But they would be offered using the framework of a time-limited trial, such that if certain clinical parameters were not met within that time frame, the ventilator would be withdrawn to make it available for another. This approach would avoid the problem of holding ventilators in reserve while preserving the triage goal of using them for those patients who are most likely to survive.

An important difference between the use of time-limited trials in a routine clinical context as opposed to their use during a pandemic is that the former occurs with the agreement and cooperation of the patient and family, whereas the latter could often result in ventilator withdrawal against the wishes of the patient or family. For guidelines allowing such use of CSC to be effective, there would need to be strong legal support for this use so that clinicians implementing the standards in this way would be protected against professional accusations of abandonment or malpractice. This may turn out to be a significant hurdle for the next pandemic, given that state governors were very resistant to implementing and legally authorizing the CSC guidelines that their own advisors had created.[6]

To be fair, the prioritization algorithms that have been developed by states during the pandemic could be effective for therapies other than mechanical ventilation. Unlike in the situation with ventilators, where death is often imminent if the machine is not immediately available, the effectiveness of other treatments for Covid-19 (such as antiviral agents or monoclonal antibodies) is not as time sensitive. For treatments like these, the names of patients who need and could benefit from a therapy could be collected once or twice a day, and then patients from this group could be selected for treatment based on their priority score.

While it is still too early to say that the Covid-19 pandemic is behind us, it is not too early for us to begin an inventory of what worked and what did not. Crisis standards of care will always be a necessary component of pandemic preparedness. Future iterations of these standards will need to include a better strategy for the allocation of ventilators if they are to be both ethical and effective.

1. M. Gaurke et al., "Life-Years and Rationing in the Covid-19 Pandemic: A Critical Analysis," and A. Rajczi et al., "The University of California Crisis Standards of Care: Public Reasoning for Socially Responsible Medicine," both in *Hastings Center Report* 51, no. 5 (2021): 18-29 and 30-41, respectively.

2. See the October 6, 2020, draft guidance of "Crisis Standards of Care Planning Guidance for the Covid-19 Pandemic," from the Commonwealth of Massachusetts's Department of Public Health. A version of this document was originally published by the Commonwealth in April 2020; the October draft, a revision of the earlier guidance, was offered for public comment. As of August 30, 2021, this draft can be found online by using the search term "MA CSC Draft October 6, 2020."

3. H. B. Gershengorn et al., "Assessment of Disparities Associated with a Crisis Standards of Care Resource Allocation Algorithm for Patients in 2 US Hospitals during the COVID-19 Pandemic," *JAMA Network Open* 4, no. 3 (2021): e214149.

4. J. C. Moskop and K. V. Iserson, "Triage in Medicine, Part I: Concept, History, and Types," *Annals of Emergency Medicine* 49, no. 3 (2007): 275-81, at 277.

5. E. E. Vink et al., "Time-Limited Trial of Intensive Care Treatment: An Overview of Current Literature," *Intensive Care Medicine* 44, no. 9 (2018): 1369-77.

6. T. Powell and E. Chuang, "COVID in NYC: What We Could Do Better," *American Journal of Bioethics* 20, no. 7 (2020): 62-66.