

as fast, and the results can be harder to interpret.<sup>4</sup> This problem can sometimes be overcome by comparing outcomes with early vaccination versus delayed vaccination, as in the “Ebola ça suffit!” trial. One possible way forward would be to test several vaccines simultaneously in an adaptive trial design using a single, shared control group, so that more participants would receive an active vaccine.<sup>5</sup> This approach has advantages but can be logistically and statistically complex, and developers often avoid trials that may generate head-to-head comparative data.

CEPI, as a relatively new organization, had not established financial mechanisms and instruments to support development of pandemic vaccines and will need to raise additional funds to see

 An audio interview with Dr. Lurie is available at NEJM.org

SARS-CoV-2 vaccines through the development and scale-up manufacturing processes. Although as many as several million vaccine doses may become available as a by-product of development, in a pandemic situation, once vaccine candidates are proved safe and effective, doses must be manufac-

tured in large quantities. Though some high-income countries may pay for development and manufacture with their own populations in mind, there's no global entity responsible for financing or ordering vaccine manufacture. Discussions with global stakeholders about organizing and financing large-scale vaccine manufacturing, procurement, and delivery are under way.

Finally, pandemics will generate simultaneous demand for vaccines around the world. Clinical and serologic studies will be needed to confirm which populations remain at highest risk once vaccines are available and could form the basis for establishing a globally fair vaccine-allocation system. Some Group of Seven countries have already called for such a global system, whose planning must start while vaccine development proceeds.

Though it's unlikely, if the pandemic appears to abruptly end before vaccines are ready, we should continue developing the most promising candidates to a point at which they can be stockpiled and ready for trials and emergency authorization should an outbreak recur. A global financ-

ing system that supports end-to-end development and large-scale manufacturing and deployment, ensures fair allocation, and protects private-sector partners from significant financial losses will be a critical component of future pandemic preparedness.

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## The Toughest Triage — Allocating Ventilators in a Pandemic

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The Covid-19 pandemic has led to severe shortages of many essential goods and services, from hand sanitizers and N95 masks to ICU beds and ventilators. Although rationing is not unprecedented, never before has the American public been faced with the prospect of having to ration

medical goods and services on this scale.

Of all the medical care that will have to be rationed, the most problematic will be mechanical ventilation. Several countries, but not the United States, have already experienced a shortage of ventilators. Acute care hospitals

in the United States currently have about 62,000 full-function ventilators and about 98,000 basic ventilators, with an additional 8900 in the Office of the Assistant Secretary for Preparedness and Response Strategic National Stockpile.<sup>1</sup> The Centers for Disease Control and Prevention estimates

that 2.4 million to 21 million Americans will require hospitalization during the pandemic, and the experience in Italy has been that about 10 to 25% of hospitalized patients will require ventilation, in some cases for several weeks.<sup>2</sup> On the basis of these estimates, the number of patients needing ventilation could range between 1.4 and 31 patients per ventilator. Whether it will be necessary to ration ventilators will depend on the pace of the pandemic and how many patients need ventilation at the same time, but many analysts warn that the risk is high.<sup>3</sup>

Although shortages of other goods and services may lead to deaths, in most cases it will be the combined effects of a variety of shortages that will result in worse outcomes. Mechanical ventilation is different. When patients' breathing deteriorates to the point that they need a ventilator, there is typically only a limited window during which they can be saved. And when the machine is withdrawn from patients who are fully ventilator-dependent, they will usually die within minutes. Unlike decisions regarding other forms of life-sustaining treatment, the decision about initiating or terminating mechanical ventilation is often truly a life-or-death choice.

Many states have developed strategies for rationing during pandemics. The New York Guidelines target saving the most lives, as defined by the patient's short-term likelihood of surviving the acute medical episode.<sup>4</sup> Rationing is performed by a triage officer or a triage committee composed of people who have no clinical responsibilities for the care of the patient. Triage pro-

ceeds in three steps: application of exclusion criteria, such as irreversible shock; assessment of mortality risk using the Sequential Organ Failure Assessment (SOFA) score, to determine priority for initiating ventilation; and repeat assessments over time, such that patients whose condition is not improving are removed from the ventilator to make it available for another patient.

Anticipating the need to allocate ventilators to the patients who are most likely to benefit, clinicians should proactively engage in discussions with patients and families regarding do-not-intubate orders for high-risk subgroups of patients before their health deteriorates. Once patients have already been placed on mechanical ventilation, decisions to withdraw it are especially fraught. Less than 50 years ago, physicians argued that withdrawing a ventilator was an act of killing, prohibited by both law and ethics. Today, withdrawal of ventilatory support is the most common proximate cause of death in ICU patients, and withdrawal of this support at the request of a patient or surrogate is considered an ethical and legal obligation. Withdrawal of a ventilator against the wishes of the patient or surrogate, however, is primarily done only in states and hospitals that permit physicians to unilaterally withdraw life support when treatment is determined to be futile.

Decisions to withdraw ventilators during a pandemic in order to make the resource available to another patient cannot be justified in either of these ways: it is not being done at the request of the patient or surrogate, nor can it be claimed that the treatment is futile. Even though the chances

of survival may be low, in the absence of the pandemic the treatment would be continued. Whereas this type of rationing may not be unusual in countries that tragically have a chronic shortage of essential ICU care, it is unprecedented for most physicians who practice in well-resourced countries. Reports from Italy describe physicians "weeping in the hospital hallways because of the choices they were going to have to make."<sup>5</sup>

The angst that clinicians may experience when asked to withdraw ventilators for reasons not related to the welfare of their patients should not be underestimated — it may lead to debilitating and disabling distress for some clinicians. One strategy for avoiding this tragic outcome is to use a triage committee to buffer clinicians from this potential harm. We believe that such a committee should be composed of volunteers who are respected clinicians and leaders among their peers and the medical community.

Advantages of this approach are that it allows the physicians and nurses caring for the patients to maintain their traditional roles as fiduciary advocates, including the opportunity to appeal the initial decision of the committee when appropriate. While working together to ensure consistent and unbiased decisions across patient groups, the committee also has the flexibility to consider factors that may be unique to a given situation. As circumstances change and the availability of ventilators increases or decreases, the committee can adjust its rationing criteria to produce the best outcomes. Finally, when a hospital is placed in the unavoidable but

tragic role of making decisions that may harm some patients, the use of a committee removes the weight of these choices from any one individual, spreading the burden among all members of the committee, whose broader responsibility is to save the most lives.

In addition to removing the responsibility for triage decisions from the bedside clinicians, committee members should also take on the task of communicating the decision to the family. The treating clinicians may be motivated to try to comfort the family by telling them that mechanical ventilation is not being provided because it would be futile and by reassuring them that everything possible has been done. Though well intentioned, such inaccurate representations could ultimately undermine public trust and confidence. Having the committee members communicate these decisions would ensure that the message is clear and accurate, helping to prevent confusion or misunderstandings.

Similarly, the physicians, nurses, or respiratory therapists who are caring for the patient should not be required to carry out the process of withdrawing mechan-

ical ventilation; they should be supported by a team that is willing to serve in this role and that has skills and expertise in palliative care and emotional support of patients and families. Pain and suffering at the end of life can be controlled, and these patients deserve the best that palliative care can provide.

In the weeks ahead, physicians in the United States may be asked to make decisions that they have never before had to face, and for which many of them will not be prepared. Though some people may denounce triage committees as “death panels,” in fact they would be just the opposite — their goal would be to save the most lives possible in a time of unprecedented crisis. Creation and use of triage committees, informed by experience in the current pandemic<sup>2</sup> and prior written recommendations,<sup>4</sup> can help mitigate the enormous emotional, spiritual, and existential burden to which caregivers may be exposed.

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## Leadership for the Social Climate

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More and more, we are seeing the effects of climate change up close in the form of large-scale, destructive flooding, rising sea levels, fires, storms, and prolonged and disabling heat, as well as agricultural and other economic disruptions. The Covid-19 pandemic is a taste of the level

of global disruption, system failures, ongoing unreadiness, and pervasive loss that large-scale ecologic change brings.<sup>1</sup>

As the reality of these facets of massive climate and ecologic change closes in, we can envision more clearly the steep climb that will be needed not only to

sustainably reengineer our hardware (energy and water sources, food production, public health and health care systems, buildings, and transportation) but also to bolster our software (the social and emotional resilience and involvement of people and communities).