Allocation of Scarce Medical Resources and Crisis Standards of Care

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SUMMARY. Potential shortages of medical resources and services related to COVID-19 present government officials and emergency planners with difficult choices. If resources become too scarce, health care professionals and institutions may need to implement triage protocols adopting crisis standards of care. COVID-19 patient surges tested the health care system in March and April 2020, and highlighted the need to prepare to accommodate larger patient capacity in the near future. As a primary consideration, governments and health care institutions should utilize existing powers and resources to avoid shortages and mitigate their severity. If shortages do occur, most states have begun to develop crisis standards of care protocols to assist in making decisions about allocating scarce resources. These protocols attempt to maximize the number of lives saved. Many protocols give priority access to health care and other essential workers. These protocols should be structured to facilitate fair and equitable access, although several have been found to be inconsistent with federal antidiscrimination law. Legal issues that may arise in this context include liability for health care professionals and institutions who decide to not allocate resources to patients who later suffer harm, and civil rights concerns over discrimination arising from the protocols or their implementation. Liability shields have been put in place by many states to protect health care professionals from lawsuits based on allocation decisions. Federal and state officials should support efforts to clarify and incorporate protections into crisis standards of care plans that prioritize antidiscrimination, fairness, and equity in allocation decision making.

Introduction

This chapter addresses the legal and ethical issues that may arise when shortages of medical resources and services occur during the response to the COVID-19 pandemic. Health care facilities in the hardest hit areas have had to adapt their patient care practices to respond to the influx of COVID-19 patients. During the initial months of the COVID-19 outbreak, many U.S. hospitals faced shortages of key resources such as ventilators, beds, medications, and personal protective equipment (PPE), and had to consider contingency plans for allocating these scarce resources (HHS, 2020). These shortages have the potential to lead to some of the most gut-wrenching decisions a health care professional would ever have to make: how to decide who gets a resource when there is not enough of it to provide to everyone who needs it?

New York City hospitals were stretched nearly to the breaking point in April 2020, and only avoided enacting triage protocols through significant systemic adaptations (unprecedented coordination of patient loads and supplies between hospitals, adapting space and altering treatment protocols—including ventilator sharing—to expand capacity) and social solidarity (the unprecedented physical distancing efforts across the population that bent the curve of COVID-19 infections downward). However, it is difficult to determine how many people may have been deterred from seeking care out of concern about the protocols being used to allocate medical resources and whether this contributed to higher mortality rates. Moreover, many health care or other essential workers were exposed to COVID-19 due to PPE shortages and have experienced high rates of infection (Nguyen et al., 2020). As hospitals, EMS, long-term care facilities, and public health departments in more areas experienced spikes in COVID-19 cases, it is vital to have plans in place that clearly outline protocols for avoiding scarcity. If scarcity does occur, including limited supplies of newly-developed treatments and vaccines, scarce medical resources and services must be allocated consistent with legal and ethical responsibilities that protect the most vulnerable persons through fair and equitable prioritization.

Avoiding Scarcity

A number of factors cause resource shortages during emergencies like the COVID-19 crisis. These include: inadequate planning and investment in surge capacity by governments and health care facilities; slow or insufficient reaction to novel public health risks that allows the case rate to grow to an unmanageable level; a lack of government leadership to coordinate distribution and sharing of necessary resources to facilities in need; and underlying economic incentives and systemic shortcomings inherent to the cost-centric, redundancy-averse, for-profit health care system in the United States. Notwithstanding, ethicists and prudent policymakers agree that avoiding scarcity of medical resources and services is much preferred to later invoking triage protocols out of necessity. Consequently, there is a duty to plan for surge capacity in the health care and public health settings to avoid the need to make tough allocation decisions (Hick et al., 2020; Berlinger et al. 2020).

Increased demand for medical resources and services are predictable during an epidemic, which is why emergency preparedness plans explicitly encourage health care and public health institutions to plan for and invest in surge capacity and capability. Most of these plans envision expanded capacity in three areas: space, staff, and supplies (IOM, 2012). A surge in patients can overtake the physical space in a healthcare facility. Many hospitals faced with an influx of COVID-19 patients in April 2020 reorganized their facilities to provide more intensive care beds, set up staging areas to evaluate patients in tents outside their facilities, and postponed elective medical procedures. In addition, state officials used executive orders to set up ad hoc spaces for medical care in convention centers in New York City, Detroit, Houston, and elsewhere. Staff capacity can be bolstered by lengthening shifts and increasing patient counts, waiving regulatory limitations to expand scope of practice, and bringing in additional health care professionals from other, less-affected areas. State law can be used to waive practice and staffing restrictions and to grant licensure reciprocity for health care professionals from other states. Indeed, state emergency powers laws often explicitly grant authority to governors or state officials to take these steps, as does the Emergency Management Assistance Compact. Access to supplies—the materials, medications, and medical devices needed to provide safe and effective care—has posed the most significant challenge during the initial stages of the COVID-19 epidemic. Shortages of PPE placed both health care workers and patients at higher risk of infection, while concerns about insufficient access to ventilators and medications raised the possibility that triage schemes could be needed to fairly and effectively deploy these resources. New York, facing the largest surge of COVID-19 cases in April 2020, took the unprecedented step of implementing a centralized management structure for staff and supplies under the state department of health, which was effective in coordinating surge capacity and resource use.

Federal, state, and local governments have emergency response plans in place that consider the need to address scarce resources during a public health emergency. Federal law provides resources, infrastructure, and support to specifically incentivize such planning through the National Disaster Medical System and the National Hospital Preparedness Program, among other programs. However, over the past decade, federal support for emergency preparedness in general, and crisis standards of care planning in particular, have been curtailed (Trust for America's Health, 2019). Resource reductions for public health emergency preparedness undermine the capacity of health care and public health systems to effectively respond to a pandemic threat like COVID-19. The federal government plays a vital role in funding programs to avoid resource scarcity due to its capacity to deficit spend, a luxury most states don't have.

The federal government possesses two additional tools for expanding capacity to meet medical needs during shortages. The Defense Production Act has been invoked during the COVID-19 response as a possible way to compel manufacturers to produce ventilators and PPE (see Chapter 23). The federal government also maintains the Strategic National Stockpile, which contains medications and medical equipment available for distribution to states. During the initial phase of the COVID-19 response, supplies—including N95 respirators, face masks, face shields, gowns, gloves, and ventilators—were distributed to state and local jurisdictions based on a population formula, but this approach was later modified to take the prevalence of COVID-19 infections and local need, as well as political considerations, into account. Widespread distribution of resources between March and May 2020, however, have left the SNS depleted, raising concerns about shortages in subsequent COVID-19 outbreaks and concerns about the reluctance of Trump administration officials to fully utilize appropriated resources. Finally, federal resources supported efforts to enhance capacity to treat patients by supporting alternative care sites in convention centers and military hospital ships. Although these overflow sites only saw limited use, this approach could be helpful in future stages of the epidemic.

State laws similarly grant authority to the governor or designated state officials to implement strategies to expand access to resources during a declared emergency, disaster, or public health emergency. While these provisions vary somewhat state-to-state, they generally provide state officials with great leeway to waive state law requirements that would limit efforts to procure additional supplies quickly, authorize alternative sites for providing medical care, or expand the public health or health care workforce.

Legal Responsibility for Allocating Scarce Medical Resources and Services

Crisis Standards of Care

An essential legal and ethical consideration in addressing the allocation of scarce medical resource is how scarcity affects the standard of care in health care settings. The National Academy of Sciences (NAS) (then the Institute of Medicine) published a series of influential reports addressing this issue and articulating standards and guidance for crisis standards of care (IOM, 2009; IOM, 2012; IOM, 2013). Crisis standards of care apply to situations where "a substantial change in usual healthcare operations and the level of care it is possible to deliver" occurs (IOM, 2009). This guidance further notes:

> This change in the level of care delivered is justified by specific circumstances and is formally declared by a state government, in recognition that crisis operations will be in effect for a sustained period. The formal declaration that crisis standards of care are in operation enables specific legal/regulatory powers and protections for healthcare providers in the necessary tasks of allocating and using scarce medical resources and implementing alternate care facility operations.

The NAS approach identifies fairness, duty to care, duty to steward resources, transparency, consistency, proportionality, and accountability as important ethical considerations in allocating scarce resources; outlines indicators and triggers for when surge capacity has reached crisis levels; and develops support tools to assist with triage decisions (IOM, 2009; IOM, 2012). At least 34 states have developed guidance to address allocation of scarce medical resources and/or crisis standards of care, and many of these guidance documents adopt the NAS approach. Most of these plans include protocols that seek to save the most people possible by prioritizing patients with the greatest likelihood of successful recovery from treatment; grant priority to essential health care workers; and promote fairness and equity by prohibiting prioritization based on race, gender, national origin, religious affiliation, citizenship, sexual orientation, ability to pay, or assessments of a person's social value.

Many jurisdictions have developed this nonbinding guidance, but few states have enacted statutory provisions granting state executive officials the legal authority to alter standards of care during a declared emergency. Rather, this authority can be implied as a component of broadly-worded state and local emergency declaration powers. State legislatures should enact statutory provisions outlining the process for imposing crisis standards of care, such as those found in Virginia law (Virginia Code, secs. 8.01-225.01, 8.01-225.02), to establish a clear process for when crisis standards of care are in place, who has the authority to impose altered standards of care, and the limitations of such authority.

Liability for Allocation Decisions

Tort law recognizes that health care professionals and institutions must adhere to the applicable standard of care, i.e. the standard of care that a professional would follow under the same or similar circumstances. Allocation decisions made and the level of care provided in the face of pandemic-induced shortages thus will be subject to different expectations under tort law than similar clinical decisions made under ordinary circumstances. It will likely be difficult for a plaintiff to persuade a jury that a health care professional or institution that followed state crisis standards of care guidance to allocate medical resources should be held civilly liable for any harm suffered due to not being offered access to that scarce resource, provided that a declared emergency, disaster, or public health emergency is in place. The plaintiff may have a stronger liability claim for a decision that reallocated a resource—such as a ventilator—away from a person using it to another person with a more favorable prognosis (Cohen et al., 2020; Truog et al, 2020).

Consequently, some states have gone further and implemented statutory protections for triage and scarce resource allocation decisions during declared emergencies. Maryland law, for example, provides health care providers with strong civil and criminal immunity for triage decisions, including removal and reallocation of a ventilator "if the health care provider acts in good faith" during a state-declared emergency (Maryland Code, Public Safety, sec. 14-3A-06; Cohen et al., 2020). Likewise, Virginia law protects health care providers from civil liability and criminal penalties during a state or local emergency where "the provider was unable to provide the requisite health care [as a result of the] response to the relevant disaster" or when "the emergency and subsequent conditions caused a lack of resources, attributable to the disaster, rendering the health care provider unable to provide the level or manner of care that otherwise would have been required in the absence of the emergency" (Virginia Code, secs. 8.01-225.01, 8.01-225.02).

COVID-19-specific liability shields for health care professionals—and in some cases health care facilities—have been adopted by executive order in over 20 states. Similarly, federal law grants liability protections for health care professionals providing COVID-19 treatments under the PREP Act and to volunteer health care professionals under the CARES Act and the Volunteer Protection Act (see Chapter 27).

Only a few states have specifically invoked crisis standards of care in executive orders protecting health care workers from liability for decisions about scarce resource allocation. For example, on June 29, 2020 the Arizona Department of Health Services formally authorized the state crisis standards of care, allowing hospitals to implement triage protocols if necessary. Virginia governor Ralph Northam issued Executive Order 60 on April 28, 2020, applying immunity from liability for health care providers for "insufficient availability of PPE, ventilators, or other drugs, blood products, supplies or equipment" and "implementation or execution of triage protocols or scarce resource allocation policies necessitated by healthcare provider declaration of crisis standards of care."

Despite these orders, it does not seem that health care providers or institutions actually implemented crisis standards of care in either state. Indeed, at this time, it remains unclear whether shortages requiring triage decisions have occurred in any jurisdiction; if such decisions are made, litigation will inevitably follow. It is appropriate for state law to provide liability protection for health care professionals making difficult decisions brought on by resource scarcity beyond their control. It is less clear that health care institutions should be held harmless for their failure to plan for predictable shortages during a pandemic, but they will likely face shortages exceeding their ability to prepare. It remains an ethical imperative that health care professionals and institutions, as well as public health officials, adhere to ethical and practical guidance from crisis standards of care protocols that are designed to mitigate the spread and harm of COVID-19 and maintain fair and equitable distribution of scarce resources (Emanuel et al., 2020).

Civil Rights Protections and Scarce Resource Allocation

Civil rights protections have particular importance in the context of scarce resource allocation decisions to insure such decisions do not discriminate, and are fair and equitable. Differential access to care and inequities in health outcomes exist in the United States even under normal circumstances and these disparities are exacerbated during the COVID-19 pandemic, especially for low-income communities, older people, people with disabilities, and communities that are primarily Black, Indigenous, and People of Color. People in these communities often face higher rates of serious illness, which could have the effect of reducing their priority to access scarce resources under scarce resource allocation models that favor patients with the highest likelihood of successful treatment (Shaw, 2020). Antidiscrimination provisions in federal and state law provide essential legal protections against discrimination in the context of scarce resource allocation decisions for members of these communities.

Most state crisis standards of care guidelines prohibit prioritization of access to resources based on demographic factors and factors related to social standing. However, since age and disability status could affect clinical assessments of medical prognosis and survivability, allocation protocols vary in their consideration of these factors. Problematically, a number of states' crisis standards of care plans explicitly deprioritize people with disabilities in decisions allocating critical care by categorically excluding people with certain physical or intellectual disabilities from receiving scarce resources or implicitly discriminating by basing triage decisions on long-term survivability or assessments of the patient's quality of life (Bagenstos, 2020).

Recognizing the potential for discrimination under the existing protocols in some states, disability rights advocates asked the U.S. Dept. of Health and Human Services Office for Civil Rights (OCR) to evaluate whether crisis standard of care policies in several states (Alabama, Connecticut, Delaware, Massachusetts, New York, Pennsylvania, Utah, Tennessee, and Washington) violated federal civil rights laws. OCR enforces the Rehabilitation Act of 1974, Title II of the Americans with Disabilities Act, and Section 1557 of the Affordable Care Act, all of which protect people with disabilities from discrimination in the health care setting (Mello et al., 2020). To date, OCR has resolved complaints against Alabama, Pennsylvania, and Tennessee, and these state have changed their crisis standards of care plans to remove discriminatory policies.

OCR also issued guidance stating that "no person should be denied medical care on the basis of stereotypes, assessments of quality of life, or judgments about a person's relative 'worth,' including judgments about a person's worth based on the presence or absence of disabilities or age." Michigan Governor Gretchen Whitmer adopted nearly identical language in Executive Order 2020-64, prohibiting discrimination based on disability status in resource allocation decisions in health care settings.

Thus it appears that prospective application of antidiscrimination law has already led to modifications to crisis standards of care protocols that make them more fair and equitable in some states. Other states should review their crisis standards of care plans to clarify necessary protections under federal and state antidiscrimination law. States also should pursue public input and engagement in the development of crisis standards of care protocols, including representation from communities that are most effected by the consequences of COVID-19 infections and most likely to be disadvantaged by crisis standards of care protocols. These approaches will ensure that patients receive the best possible care even when resources are limited while simultaneously protecting against discrimination and disparate treatment of individuals from historically-marginalized communities.

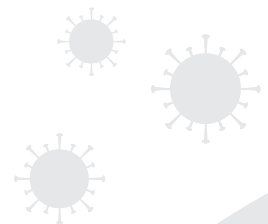
Recommendations for Action

Federal government:

- Congress should increase and maintain funding for public health emergency preparedness through a dedicated public health emergency fund, and should expand support for the National Hospital Preparedness Program and the Strategic National Stockpile.
- HHS OCR should develop, expand, and update guidance for the allocation of scarce resource and crisis standards of care consistent with federal antidiscrimination laws.

State governments:

- State legislatures or executive agencies should develop and approve protocols for crisis standards of care and allocation of scarce medical resources and services during declared emergencies, disasters, or public health emergencies and clear indicators and triggers for when crisis standards of care apply, including guidance for the distribution of new treatments and vaccines for COVID-19.
- State legislatures or executive agencies should pursue public input and engagement in the development of crisis standards of care protocols, including representation from communities that are most effected by the consequences of COVID-19 infections and most likely to be disadvantaged by crisis standards of care protocols.
- State legislatures should enact statutory provisions outlining the process for imposing crisis standards of care to establish a clear process for when crisis standards of care are in place, who has the authority to impose altered standards of care, and the limitations of such authority.
- State legislatures should review their crisis standards of care protocols to clarify necessary protections under federal and state antidiscrimination law.
- States should assess, and if necessary, enact the requisite legal authority for executive branch officials to avoid medical resource and service scarcity through means such as resource stockpiling, alternate care sites, and health care workforce expansion.
- State legislatures should adopt liability shields for health care professionals and institutions related to decisions allocating scarce medical resources and services in the health care setting, provided that health care professionals and institutions follow state-adopted and implemented crisis standards of care protocols in good faith.
- State laws should prohibit medical allocation decision-making based on social stigma or stereotypes regarding age, color, criminal history, disability, ethnicity, familial status, gender identity, height, homelessness, immigration status, incarceration status, marital status, mental illness, national origin, poverty, race, religion, sex, sexual orientation, socio-economic status, substance abuse disorder, use of government resources, veteran status, or weight.



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