

Allocating Medical Resources during Times of Scarcity

Lance Gable, JD, MPH, Wayne State University Law School

SUMMARY. Scarcity of medical resources and services during public health emergencies raises challenging legal and ethical questions. The COVID-19 pandemic has strained the capacity of health systems, and revealed some of the shortcomings of previous efforts to plan for and implement ethical and effective allocation protocols for scarce medical resources and services. Governments and health institutions have ample authority and expertise, but often lack the political and economic support needed to avoid shortages and mitigate their severity. Legal issues that may arise in this context include liability for health care professionals and institutions that must make allocation decisions when resources are scarce and civil rights concerns over discrimination in crisis standards of care protocols or their implementation. In the short term, federal and state officials must expand available resources to mitigate resource scarcity in the COVID-19 response. They must provide legal and practical guidance to health care and public health entities that may need to implement crisis standards of care, and ensure that scarce resources – including newly-developed treatments and vaccines – are allocated consistent with legal and ethical responsibilities that protect the most vulnerable persons through fair and equitable prioritization. In the longer term, 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 how legal and ethical considerations apply to situations of scarcity that may arise during the response to the COVID-19 pandemic and similar public health emergencies. Throughout the COVID-19 pandemic, health care facilities, EMS providers, public health departments, and long-term care facilities in the most-affected areas have had to consider adapting their patient care practices to account for potential shortages in medical resources and services. Severe shortages can result in the need to make challenging and tragic triage decisions, as health professionals are forced to determine who gets a scarce medical resource or service when there is not enough for everyone who needs it.

Chapter 24 in Volume I, *Assessing Allocation of Scarce Resources and Crisis Standards of Care*, examined the conditions under which pandemics can give rise to scarcity of medical resources and services, and the infrastructure in place to deal with resource allocation decisions under conditions of scarcity, including crisis standards of care guidance. That Chapter also analyzed the corresponding legal challenges that may arise under theories of civil liability or civil rights violations (Gable, 2020).

In the intervening seven months, concerns about medical resource shortages have become even more acute as the winter

2020-2021 wave of COVID-19 patients has stretched health care facilities to – and in some cases beyond – capacity. Despite the increased availability of COVID-19 testing and some supplies (like mechanical ventilators) compared with the spring 2020 COVID-19 patient surge, many U.S. health care providers have continued to experience shortages of medications, personal protective equipment (PPE), and most importantly, qualified staff to treat the influx of new patients. Mirroring conditions seen in Wuhan, China; Lombardy, Italy; and in New York City early in the pandemic, areas like Los Angeles experienced substantial surges in COVID-19 cases and hospitalizations in December 2020 and January 2021. In the absence of strong federal government leadership, national organizations urged state and local governments and private sector health leaders to take immediate action to implement crisis standards of care while ensuring equitable resource allocation (NAM, 2020).

The re-emergence of medical resource and service shortages affirms that many of the lessons that should have been learned early in the COVID-19 pandemic to avoid scarcity have not been heeded. This Chapter recommends a series of legal and policy proposals that will help avoid scarcity of medical resources and services, and ensure that when crisis standards of care must be implemented, such implementation occurs consistent with principles of equity.

Resource Scarcity and Allocation

Avoiding Scarcity

Ethicists and policymakers agree that preemptively avoiding scarcity of medical resources and services is a fundamental obligation of leaders in government and the private sector. These leaders also have an essential duty to plan for implementation of surge capacity and the development of effective and equitable scarce resource allocation protocols in settings where health services are provided, including health care and public health settings (Hick et al., 2020). Furthermore, since scarcity of medical resources and services and allocation protocols tend to exacerbate health disparities that disproportionately disadvantage people of color, people with disabilities, and other politically- and socially-marginalized populations, taking preemptive measures to avoid scarcity and to plan for equitable allocation protocols also advances equity in public health emergency responses.

The Volume I analysis of scarce resource allocation posited several factors contributing to scarcity during the COVID-19 pandemic. Inadequate planning and investment in surge capacity by governments and health care facilities prior to the pandemic undermined systemic resilience. Slow or insufficient reaction to the novel public health risks posed by COVID-19 allowed the case rate to grow to an unmanageable level. Government leaders failed to coordinate distribution, sharing, and use of necessary resources to facilities and patients in need. The cost-centric, redundancy-averse, for-profit health care system in the United States creates (and continues to perpetuate) underlying economic incentives and systemic shortcomings that render public health preparedness more difficult and less equitable (Gable, 2020).

As time passed and the second wave of supply and personnel shortages occurred, it became clear that many of these factors continue to undermine efforts to avoid shortages. Due to the efforts of the federal government and some state governments to downplay the seriousness of the COVID-19 outbreak, government entities and private institutions had fewer incentives and less support for expanding stockpiles of supplies and developing plans for crisis standards of care. While some regions took greater precautions after experiencing the narrow avoidance of overwhelmed hospitals in spring 2020, others paid insufficient heed to these experiences in their own areas. Further, while many hospitals had suspended non-essential procedures during the spring 2020 surge to conserve resources, most health care entities attempted to continue non-essential procedures during the winter 2020 surge, driven by both public health and economic goals.

Analyses of the early response efforts in New York City also highlighted that the existing crisis standards of care plans were insufficient to deal with the clinical decisions that arose in many health care facilities. Staff shortages were the most obvious and persistent challenge faced by many hospitals and health care facilities, yet most of the existing plans focused more on supply shortages. Further, most crisis standards of care plans focused on worst-case scenarios, such as removing a patient from a ventilator to re-allocate it, rather than more likely circumstances such as how to stretch scarce personnel and PPE over many months

(Toner et al., 2020). Indeed, the most challenging supply shortages during the winter 2020 surge were staff shortages. Overwhelmed hospitals in New York City were able to function during April and May 2020 due to an influx of trained health professionals from other parts of the country to supplement staffing shortages, but the nationwide spike in COVID-19 cases in December 2020 rendered similar personnel sharing impossible as all areas of the country experienced COVID-19 outbreaks simultaneously.

The most direct tools that can avert potential scarcity of medical supplies remain in the hands of the federal government. Congressional appropriations can directly support creating reserves of supplies likely to be needed in public health emergency responses and can incentivize the development of crisis standards of care planning. The Defense Production Act has the potential to be used to expand manufacturing capacity for needed supplies. Yet, the Trump administration used this authority sparingly and allowed resource shortages to persist. The Strategic National Stockpile (SNS) distributed supplies — including N95 respirators, face masks, face shields, gowns, gloves, and ventilators — to state and local jurisdictions early in the pandemic. However, the SNS cannot assist overwhelmed facilities with personnel shortages.

Implementation of Crisis Standards of Care and Liability Protections for Allocation Decisions

The concept of crisis standards of care has been widely adopted by emergency planners to apply to situations where “a substantial change in usual health care operations and the level of care it is possible to deliver” occurs (IOM, 2009). During the COVID-19 pandemic, many states have developed or updated non-binding guidance for implementing crisis standards of care, adopting a variety of standards and approaches (Manchanda et al., 2020). Importantly, however, few states have formally invoked legal provisions (statutory, regulatory, or executive orders) that would explicitly authorize an alteration in the standard of care to address resource shortages in health care or related settings. The Arizona Department of Health Services formally designated that state crisis standards of care were in effect in June 2020, allowing hospitals to implement triage protocols if necessary. New Mexico’s governor issued an executive order in December 2020 activating state crisis care standards, and relaxing state licensure and credentialing guidelines for health care professionals. Virginia also authorized health care providers to declare a crisis standard of care to execute triage protocols or scarce resource allocation policies in April 2020. California’s surge in cases in January 2021 did not result in a formal statewide order altering standards of care, but the California Department of Public Health required hospitals to publicize their scarce resource allocation plans and prepare to implement crisis standards of care. EMS providers in Los Angeles were instructed to conserve oxygen and to not transport adult patients to hospitals if they could not be resuscitated at the scene of the emergency (Evans & Mai-Duc, 2020).

Despite these state and local orders, there have been no explicitly documented cases in any of these jurisdictions of health care facilities formally implementing crisis standards of care protocols and making triage decisions based on them. By contrast, there

is ample anecdotal evidence of hospitals and EMS agencies in numerous locations taking informal, adaptive steps to stretch health care capacity to deal with COVID-19 patient surges, effectively changing the standard of care that patients receive (Toner et al., 2020; Evans et al., 2020).

The potential for tort liability related to resource allocation decisions looms over many discussions of crisis standards of care. The professional standard of care applicable to medical, nursing, or EMS treatment adapts with the circumstances, so a professional working under situations of scarcity need only provide the care that would be expected under those circumstances of scarcity to avoid liability in most cases. The legal position of the health provider will be even stronger if government officials have declared an emergency or disaster, or government officials or even private entities have recognized that a contingency or crisis standard of care is in effect.

Many health care professionals support more explicit liability shields to provide immunity for allocation decisions. States have taken steps to protect health care professionals – and in some cases health care and long-term care facilities – from liability for triage and scarce resource allocation decisions during declared emergencies. Maryland and Virginia, for example, both extend immunity from civil liability to health care providers who make good faith triage decisions due to medical resource scarcity during a declared emergency, with Maryland also granting immunity from criminal liability (Maryland Code, Public Safety, sec. 14-3A-06; Virginia Code, secs. 8.01-225.01, 8.01-225.02). At least 24 states have adopted COVID-19-specific liability shields for health care professionals by executive order or legislation, which would presumably cover resource allocation determinations related to COVID-19 care (see Chapter 31).

Ensuring Equity in Scarce Resource Allocation

The COVID-19 pandemic has exacerbated health disparities. Communities that primarily consist of Black people, Indigenous people, other people of color, older people, and people with disabilities have faced higher rates of illness and death related to COVID-19. The health disparities that produce higher rates of morbidity and mortality in these communities – both generally and specific to COVID-19 – can perniciously reduce the priority of patients from these communities to access scarce resources, since many scarce resource allocation plans favor patients with the highest likelihood of successful medical treatment (Shaw, 2020). While these plans appropriately place great ethical and practical importance on mitigating the spread and harm of COVID-19 through saving the most lives, protocols for allocating scarce resources also must maintain fair and equitable distribution of scarce resources. Maximizing lives saved and prioritizing equitable allocation may appear to be in tension in some situations, but an ethical public health response can, and must, balance both factors.

Equity can be better achieved during times of medical resources scarcity through the application of two strategies. First, scarce resource allocation protocols must explicitly recognize and incorporate equity as a fundamental goal of such protocols. Second, civil rights and anti-discrimination laws must be enforced

to 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.

Centering Equity in Crisis Standards of Care Plans

While allocation protocols in crisis standards of care plans vary from state to state, most of these plans base allocation decisions in significant part on an individual patient's medical prognosis. At least 10 states' plans apply criteria to categorically exclude people from accessing critical care resources such as ventilators, while many more states consider factors such as long-term comorbidities and algorithms, such as the Modified Sequential Organ Failure Assessment to determine priority to resources (Manchanda et al., 2020). Exclusion criteria often explicitly disfavor access to scarce resources for people with physical or intellectual disabilities, and have been legally challenged (see discussion below).

Most states also prohibit prioritization of access to scarce resources based on demographic factors (such as race, ethnicity, age, etc.) and factors related to social standing. While this type of facially neutral framework seems ethically appealing and can be important to prevent overt discrimination, it also can allow inequity to persist in resource allocation decisions since age and disability status, for example, can affect clinical assessments of medical prognosis, long-term survivability, and quality of life (Bagenstos, 2020). Officials in state government and leaders in private entities tasked with implementing crisis standards of care should counteract explicit and implicit structural inequities built into medical resource allocation plans by eliminating rigid exclusion criteria; incorporating tools to reduce disparities in allocation decisions such as the CDC's Social Vulnerability Index; and pursuing public input and engagement in the development of crisis standards of care protocols, including representation from communities that are most affected by the consequences of COVID-19 infections and most likely to be disadvantaged by crisis standards of care protocols.

Civil Rights Protections and Crisis Standards Of Care

Federal civil rights and antidiscrimination laws provide another avenue to achieve more equitable results in scarce resource allocation decisions in health care settings. For example, the Rehabilitation Act of 1974, Title II of the Americans with Disabilities Act, and Section 1557 of the Affordable Care Act, provide protection for people with disabilities from discrimination in health care settings. The U.S. Department of Health and Human Services Office for Civil Rights (OCR), which enforces these laws, has acted aggressively over the past year to resolve legal challenges to crisis standards of care policies from disability rights advocates (Mello et al., 2020). OCR has resolved complaints against Alabama, North Carolina, Pennsylvania, Tennessee, and Utah, and the North Texas Mass Critical Care Guidelines Task Force, the Southwest Texas Regional Advisory Council, and the Indian Health Service to remove categorical exclusions and discriminatory policies within crisis standards of care plans.

In January 2021, OCR issued technical assistance addressing age and disability in crisis standards of care plans. This guidance prohibits categorical exclusion criteria, as well as the use of criteria that account for a patient's long-term life expectancy or the resource-intensity and duration of need. The guidance also suggests modifications to ensure clinical instruments accurately assess the likelihood of short-term survival for people with disabilities. It includes protections against pressuring patients into agreeing to withdrawal or withhold life-sustaining treatments or use of blanket do not resuscitate orders, and prohibitions on reallocation of personal ventilators brought by a patient to an acute care facility to continue pre-existing personal use.

The Biden administration has stated that it will provide guidance and strengthen enforcement to ensure that crisis standards of care policies do not discriminate. These steps are important to ensure that equity in resource allocation is achieved. Likewise, states should review their crisis standards of care plans to clarify necessary protections under federal and state antidiscrimination law.

Allocation of COVID-19 Vaccines

One of the most prominent examples of the legal and ethical challenges created by resource scarcity involves the distribution and allocation of COVID-19 vaccines. In anticipation of COVID-19 vaccine approvals, the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP) and an ad hoc committee of the National Academies of Sciences, Engineering, and Medicine (NASEM) developed recommendations for equitable vaccine distribution. These allocation proposals seek to maximize public health benefits and minimize harm, uphold human dignity, and promote justice, while simultaneously mitigating health inequities (Dooling et al., 2021; National Academies, 2020). At the time of this writing, the Pfizer, Moderna, and Johnson & Johnson COVID-19 vaccines have been approved through FDA Emergency Use Authorization, but are only available in limited supply. While changes in manufacturing capacity and the approval of additional COVID-19 vaccines may expand access in the near future, shortages of vaccines are likely through at least summer 2021 and possibly longer in the United States. Worldwide, shortages are likely to last much longer. Thus, allocation protocols and their successful implementation are essential to target vaccinations where they will have the most public health benefit and can mitigate health inequities.

The ACIP and NASEM guidance have been influential, but actual allocation protocols are being determined and administered at the state and local levels, with varying levels of success. Most states have used private entities such as hospital systems and pharmacies to act as intermediaries to provide vaccinations to the first identified priority groups: front-line health care workers and long-term care facility residents and staff. Many states quickly expanded eligibility for vaccines beyond these groups, allowing other essential workers and adults older than age 75 — or in some states older than age 65 — to receive COVID-19 vaccines. These categories of people are so large and heterogeneous that disparities exist even with groups, so prioritization of these large categories alone will be insufficient to avoid disparities within priority groups (Artiga & Kates, 2020).

Early evidence suggests that the same disparities in access to health care resources that exist already in the United States are being perpetuated in the COVID-19 vaccine rollout, with members of racial and ethnic minority groups facing more obstacles to obtaining COVID-19 vaccinations than members of wealthy white communities, despite explicit plans to avoid such disparities (Goodnough & Hoffman, 2021). Structural and practical strategies — including more targeted vaccine distribution and allocation protocols and expansion of access options in more vulnerable communities — must be employed to combat these emerging disparities. Additionally, targeting limited vaccine supplies to communities most in need using tools such as the Social Vulnerability Index or Area Deprivation Index could reduce disparities in access (Schmidt et al. 2020).

The initial challenges in implementing equitable vaccine allocation processes demonstrate that having well-designed, ethically thoughtful plans is not enough to achieve equitable results. Federal, state, and local officials must take steps to affirmatively connect vulnerable populations with available vaccines through more deliberate outreach. The Biden administration's National Strategy for COVID-19 Response seeks a more coordinated, expansive, and well-funded vaccine distribution effort, with a focus on equity and reaching hard-to-reach populations. These efforts are key to saving lives and hastening the end of this pandemic. Successful and equitable administration of COVID-19 vaccines not only hastens the end of the pandemic through herd immunity but also greatly reduces the number of serious COVID-19 infections, which makes resource shortages and crisis standards of care much less likely to occur. Going forward, continuing to plan for and alleviate scarcity, and building a robust public health infrastructure can render the terrible possibility of triage exceedingly rare. 🌟

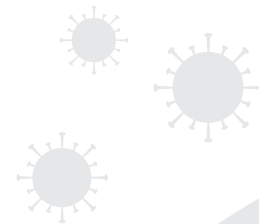
Recommendations for Action

Federal government:

- Congress should increase and maintain funding for public health emergency preparedness through a dedicated public health emergency fund; should expand support for the National Hospital Preparedness Program, the Strategic National Stockpile, and vaccine manufacturing capacity; and should fund state, local, and private sector efforts to expand COVID-19 vaccination capacity.
- OCR should develop, expand, and update best practices and guidance for the allocation of scarce resources 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.
- State legislatures or executive agencies should develop clear indicators and triggers for when crisis standards of care apply, including guidance for the distribution of new treatments and vaccines for COVID-19 that center both efficacy and equity.
- 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 affected 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 laws.



About the Author

Lance Gable, JD, MPH is an Associate Professor of Law at Wayne State University Law School. His research addresses the overlap among law, policy, ethics, health, and science. He has published journal articles on a diverse array of topics, including public health law, ethics and policy; international human rights; emergency preparedness; mental health; research ethics; and information privacy. He developed ethical guidelines for the allocation of scarce medical resources during public health emergencies for the state of Michigan and has worked with the World Health Organization and the Pan American Health Organization.

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