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BIOETHICS: Ethical Considerations of Ventilator Triage During a Pandemic

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BIOETHICS

Ethical Considerations of Ventilator Triage During a Pandemic: Formulation and Implementation of Ventilator Triage and Other Scarce Resource Allocation Guidelines for Use During COVID-19

CODE SECTIONS:	29 U.S.C. § 794; 42 U.S.C. §§ 6101, 6102, 6103, 12132, 18116
SUMMARY:	In the midst of the COVID-19 pandemic, hospitals across the country faced unprecedented volumes of patients seeking treatment related to the respiratory complications of the virus. As a result, states were forced to reassess existing scarce resource allocation guidelines to appropriately accommodate the high demand. This *Peach Sheet* analyzes the ethical considerations implicated in enacting and following these guidelines when treating patients, specifically in the context of ventilator triage in response to the COVID-19 pandemic.

Introduction

In early 2020, COVID-19 swept across the world, affecting every corner of the globe from New Zealand to the United States on a scale not seen since at least the Hong Kong flu of the late 1960s, and likely the infamous Spanish flu of the 1920s.[1] The U.S. federal government declared a public health emergency in response to the growing threat posed by COVID-19 in late January.[2] The United States recorded its first COVID-19-related death a month later in late February, and the

1. Tim Newman, *Comparing COVID-19 with Previous Pandemics*, MED. NEWS TODAY (Apr. 19, 2020), https://www.medicalnewstoday.com/articles/comparing-covid-19-with-previous-pandemics [https://perma.cc/SWQ2-TCZD].

2. Proclamation No. 9994, 55 Fed. Reg. 15337 (Mar. 18, 2020).

situation rapidly deteriorated from there.[3] Per data available from the Centers for Disease Control and Prevention (CDC), as of October 10, 2020, the United States had reported over 7.5 million cases of COVID-19 and over 200,000 COVID-19-related deaths.[4] At that time, the United States ranked ninth in the world, with 653.98 deaths per million inhabitants, according to German statistics from Statista.[5] Throughout the 2020 summer, many states, including Texas, Arizona, Alabama, and both Carolinas, reported increased rates of COVID-19 transmissions and hospitalizations, casting some doubt that the rise in cases was solely due to increased testing availability.[6] The American response faced heavy scrutiny due to several factors, including the severity and prolonged nature of the pandemic in the United States, as well as the seemingly inconsistent and conflicting nature of expert recommendations and guidelines.[7] Chief among these concerns was the revival of ethical concerns surrounding scarce resource allocation guidelines, more colloquially referred to as ventilator triage policies.[8]

To prevent the hospital overcrowding seen in other COVID-19 hotbeds, most American states and municipalities instituted fairly

3. Nicole Acevedo & Minyvonne Burke, *Washington State Man Becomes First U.S. Death from Coronavirus*, NBC NEWS, https://www.nbcnews.com/news/us-news/1st-coronavirus-death-u-s-officials-say-n1145931 [https://perma.cc/C8KB-LKBN] (Feb. 29, 2020, 5:38 PM); *COVID-19 Situation 'Worsening' Worldwide, Says WHO Chief; Protests in US, EU Spark Fears of a Second Wave*, FIRSTPOST (June 9, 2020, 1:12 PM), https://www.firstpost.com/health/covid-19-situation-worsening-worldwide-says-who-chief-protests-in-us-eu-spark-fears-of-a-second-wave-8463371.html [https://perma.cc/RR8F-4Z75].

4. United States COVID-19 Cases and Deaths by State of *CDC COVID Data Tracker*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://covid.cdc.gov/covid-data-tracker/?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fcases-updates%2Fcases-in-us.html#cases_casesinlast7days [https://perma.cc/6XPG-8AMD].

5. Raynor de Best, *COVID-19 Deaths Worldwide per One Million Population in 2020, by Country*, STATISTA, https://www.statista.com/statistics/1104709/coronavirus-deaths-worldwide-per-million-inhabitants/ [https://perma.cc/U5FT-3URZ].

6. Andrew Joseph, *Rising Covid-19 Cases and Hospitalizations Underscore the Long Road Ahead*, STAT (June 17, 2020), https://www.statnews.com/2020/06/17/rising-covid-19-cases-hospitalization-long-road/ [https://perma.cc/93RW-X8E2].

7. Allan Smith, *'I'm looking for the truth': States Face Criticism for COVID-19 Data Cover-ups*, NBC NEWS (May 25, 2020, 6:00 AM), https://www.nbcnews.com/politics/politics-news/i-m-looking-truth-states-face-criticism-covid-19-data-n1202086 [https://perma.cc/C7DN-ZV6K].

8. Connor Sheets, *Alabama Disavows Plan to Limit Ventilators for Disabled During Shortages*, AL.COM (Apr. 8, 2020), https://www.al.com/news/2020/04/alabama-disavows-plan-to-limit-ventilators-for-disabled-during-shortages.html [https://perma.cc/T2SM-FSXX].

strict lockdown measures.[9] Additionally, many states and healthcare organizations proactively published scarce resource allocation guidelines for the COVID-19 pandemic.[10] Typically, these guidelines were not legally binding and were meant to be used as a tool for hospitals when formulating their own guidelines.[11] However, critics claimed these guidelines "neglect[ed] human values in favor of unconscionable ranking by economic and identifiable considerations."[12] These concerns and others were echoed by bioethicists and legal scholars for at least a decade and raised a myriad of questions around the state's role in the current healthcare system, the legal implications of following state-recommended guidelines, and the formulation of legitimate and accepted guidelines based on well-recognized bioethical principles.[13]

Background

The history of United States bioethics reaches back to the Anglo-Saxon common law notion of necessity, showcased by the mid-nineteenth century landmark case *United States v. Holmes*.[14] The reasoning articulated in *Holmes* had a profound impact on bioethics in both the United States and Western Europe, and is still taught in bioethics classes around the country.[15]

9. Kara Gavin, *Flattening the Curve for COVID-19: What Does It Mean and How Can You Help*, MICH. MED.: MICH. HEALTH (Mar. 11, 2020, 1:47 PM), https://healthblog.uofmhealth.org/wellness-prevention/flattening-curve-for-covid-19-what-does-it-mean-and-how-can-you-help [https://perma.cc/JEP4-FQ64].

10. *See* Liz Essley Whyte, *State Policies May Send People With Disabilities to the Back of the Line for Ventilators*, CTR. FOR PUB. INTEGRITY, https://publicintegrity.org/health/coronavirus-and-inequality/state-policies-may-send-people-with-disabilities-to-the-back-of-the-line-for-ventilators/ [https://perma.cc/9W64-SZKT] (Apr. 13, 2020, 1:05 PM).

11. Gina M. Piscitello et al., *Variation in Ventilator Allocation Guidelines by State During the Coronavirus Disease 2019 Pandemic: A Systemic Review*, JAMA NETWORK OPEN, June 19, 2020, at 1, 9, https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2767360 [https://perma.cc/8DCP-R3QQ].

12. Opinion, *Editorial: Who Do We Save from Coronavirus and Who Do We Let Die? Take Wealth, Race and Disability out of that Brutal Equation*, L.A. TIMES (Apr. 25, 2020, 3:00 AM) [hereinafter *Who Do We Save?*], https://www.latimes.com/opinion/story/2020-04-25/triage-rules-priority-ventilators [https://perma.cc/P9UX-E563].

13. *See generally* Daniel T. O'Laughlin & John L Hick, *Ethical Issues in Resource Triage*, 53 RESPIRATORY CARE 190 (2008).

14. *See* United States v. Holmes, 26 F. Cas. 360 (C.C.E.D. Pa. 1842) (No. 15,383).

15. Telephone Interview with Dr. Paul Lombardo, Regents' Professor & Bobby Lee Cook Professor

In *Holmes*, a passenger ship hit an iceberg and left thirty-odd crew members and passengers in a longboat waiting for rescue.[16] The longboat encountered rough seas, sprung multiple leaks, and began taking on water and sinking.[17] On the order of the highest-ranking officer aboard the ship, the crew members aboard the longboat tossed fourteen passengers, including two women, into the sea.[18] Upon arrival in the United States, a surviving passenger filed a complaint.[19] The only member of the crew who could be located, Alexander Holmes, was initially charged with murder, though the charge was downgraded to manslaughter after a grand jury failed to indict Holmes on the murder charge.[20] The *Holmes* court articulated that there may be times when it is necessary to sacrifice the life of the passengers to ensure there are "a sufficient number of seamen to navigate the boat" because without those navigators, the ship would not survive its journey.[21] The court carefully avoided condoning the actions of Holmes and his fellow crewman, noting that only the absolute minimum number of men needed to pilot the ship should have been given preference: "But if there be more seamen than are necessary to manage the boat, the supernumerary sailors have no right . . . to sacrifice the passengers."[22] Further, the court went on to say that in situations where someone's skill set does not help avoid the current situation, such as when marooned with no food, the individuals must resort to "the fairest mode" of selection: "selection . . . by lots."[23]

These principles remained primarily theoretical for bioethicists in the United States until the early 1960s when the first kidney dialysis machines were put into practice in a Seattle hospital.[24] In 1962, the nonprofit Seattle Artificial Kidney Center located at the University

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of L., Ga. State Univ. Coll. of L. (May 28, 2020) (on file with the Georgia State University Law Review) [hereinafter Lombardo Interview].

16. *Holmes*, 26 F. Cas. at 366.
17. *Id.*
18. *Id.* at 365.
19. *Id.*
20. *Id.* at 368.
21. *Id.* at 367.
22. *Holmes*, 26 F. Cas. at 369.
23. *Id.*
24. Shana Alexander, *They Decide Who Lives, Who Dies*, LIFE MAG., Nov. 9, 1962, at 102, 102–25.

Hospital developed three kidney dialysis machines, which were capable of treating nine patients per year at the cost of $20,000 per patient.[25] After a year of providing dialysis treatments, the University Hospital forced the center to relocate to the Swedish Hospital in Seattle due to a lack of funding.[26] The Swedish Hospital then offered to fund the center's research and operation of the dialysis machines.[27] However, it quickly became apparent that the need for dialysis treatment far exceeded the availability of machines, forcing the Swedish Hospital to determine how to adequately allocate the use of such machines.[28] What happened next drew little attention at the time but has been judged much more harshly in hindsight. With the help of the local medical society, the hospital formed a committee, made up of local citizens, to address the issue of appropriately allocating the available dialysis machines to those patients in need.[29] The committee, which became known as the "God Committee," individually processed each potential patient's eligibility for dialysis treatment and granted access to the machines based on recommendations from kidney doctors—the committee chose who received treatment and who did not.[30] First, the committee categorically barred all children and those over the age of forty-five from receiving access to the machines.[31] Next, the committee drew up a list of factors that should be weighed for the remaining applicant pool.[32] The factors included "sex, marital status, number of dependents, income, net worth, emotional stability, educational background, occupation, past performance, future potential, and references."[33] Rather than weigh these factors and recommendations free from biases, the committee ultimately made arbitrary decisions

25. Carol M. Ostrom, *The Dialysis Dilemma: Urgent Need vs. Overtaxed System*, SEATTLE TIMES, https://www.seattletimes.com/pacific-nw-magazine/the-dialysis-dilemma-urgent-need-vs-overtaxed-system/ [https://perma.cc/8LMD-PSUP] (Jan. 18, 2013, 2:01 PM).

26. *Id.*

27. *Id.*

28. *Id.*

29. Alexander, *supra* note 24, at 106.

30. Carol Levine, *The Seattle 'God Committee': A Cautionary Tale*, HEALTH AFFS. BLOG (Nov. 30, 2009), https://www.healthaffairs.org/do/10.1377/hblog20091130.002998/full/ [https://perma.cc/9Q7E-9TFE].

31. *Id.*

32. *Id.*

33. *Id.*

based on their own personal values of worth to the community—a result that gave the embryonic American bioethics community a case study still examined today.[34] Shana Alexander from LIFE Magazine observed the committee's work for six months and published a particularly shocking conversation in her article that brought to light the ethical issues with such committees:

> HOUSEWIFE: If we are still looking for the men with the highest potential of service to society, I think we must consider that the chemist and the accountant have the finest educational backgrounds of all five candidates.
> SURGEON: How do the rest of you feel about Number Three—the small businessman with three children? I am impressed that his doctor took special pains to mention this man is active in church work. This is an indication to me of character and moral strength.
> HOUSEWIFE: Which certainly would help him conform to the demands of the treatment . . . .
> LAWYER: It would also help him to endure a lingering death . . . .
> STATE OFFICIAL: But that would seem to be placing a penalty on the very people who perhaps have the most provident . . . .
> MINISTER: And both these families have three children too.
> LABOR LEADER: For the children's sake, we've got to reckon with the surviving parents [sic] opportunity to remarry, and a woman with three children has a better chance to find a new husband than a very young widow with six children.
> SURGEON: How can we possibly be sure of that?[35]

Thankfully, this ethical dilemma was quickly solved as Congress made dialysis publicly funded through a Medicare supplement after

34. *See* Lombardo Interview, *supra* note 15.
35. Alexander, *supra* note 24, at 110.

more machines became available.[36] However, the takeaway from the "God Committee" for the American bioethics community was clear: The principles of *Holmes*' were no longer merely theoretical topics of discussions on ethical allocation of healthcare. It was imperative to give hospitals the tools they needed to avoid another situation where the "bourgeoisie spared the bourgeoisie" through "prejudices and mindless clichés."[37]

At the turn of the century, the need for resource allocation guidelines shifted from medical equipment for diseases such as kidney failure to medical equipment for infectious diseases.[38] As several foreign diseases affecting the respiratory system spread across the United States during the 2000s, it became easy to envision a pandemic that could cause a shortage of vital respiratory equipment such as ventilators.[39] Recognizing this danger, the CDC formed the Ethics Subcommittee of the Advisory Committee to the Director in 2011 (CDC Ethics Subcommittee) to address some of the common ethical considerations that arise during triage—the process of determining the priority of patients' treatments by the severity of their condition—and to formulate model guidelines for jurisdictions to consult when adopting their own guidelines.[40] Several states' departments of health also issued their own official recommendations for use during the COVID-19 pandemic, tailoring the CDC Ethics Subcommittee's model guidelines to their own perceived needs.[41] However, the COVID-19 pandemic and the accompanying threat of

36. *See NFK Commemorates 35th Anniversary of Medicare ESRD Program*, NAT'L KIDNEY FOUND., https://www.kidney.org/news/ekidney/july08/MedicareBill_july08 [https://perma.cc/G34Y-N625].

37. David Sanders & Jesse Dukeminier, *Medical Advance and Legal Lag: Hemodialysis and Kidney Transplantation*, 15 UCLA L. REV. 357, 377–78 (1968).

38. *See* Lombardo Interview, *supra* note 15.

39. *Id.* These outbreaks include Severe Acute Respiratory Syndrome (SARS), Influenza A Virus subtype H1N1 (H1N1), and others. *Id.*

40. *See generally* CTRS. FOR DISEASE CONTROL & PREVENTION, ETHICAL CONSIDERATIONS FOR DECISION MAKING REGARDING ALLOCATION OF MECHANICAL VENTILATORS DURING A SEVERE INFLUENZA PANDEMIC OR OTHER PUBLIC HEALTH EMERGENCY (2011) [hereinafter ETHICAL CONSIDERATIONS FOR VENTILATOR ALLOCATION].

41. Telephone Interview with Leslie Wolf, Interim Dean, Distinguished Univ. Professor & Professor of L., Ga. State Univ. Coll. of L. (May 28, 2020) (on file with the Georgia State University Law Review) [hereinafter Wolf Interview].

ventilator shortage shed unprecedented public light on these guidelines and the ethical principles behind them.[42]

Bioethics Recommendations

Due to a ventilator shortage that arose during the COVID-19 pandemic, states across the country suddenly faced an allocation dilemma in hospitals that became overrun with patients. Several states used old influenza plans, but what might work in allocating scarce resources for one disease may not always be right for a different disease.[43] Other states developed new guidelines, while some released no guidelines at all and left allocation decisions up to hospitals.[44] Whether using a new or old plan, bioethics principles were a common source that many states and hospitals turned to when making allocation decisions because the principles help determine how to *fairly* allocate the medical resources.[45] As the nation faced the COVID-19 pandemic, the ethics behind scarce resource allocation guidelines once again became a topic of national discussion.[46]

Though several commonly agreed-upon ethical principles can help guide difficult allocation decisions, variation can arise when determining how to properly implement those principles into practice.[47] Generally, four ethical values are used to guide rationing decisions.[48] These include "maximizing the benefits produced by scarce resources, treating people equally, promoting and rewarding instrumental value, and giving priority to the worst off."[49] But even

42. *See generally* Kevin McCoy & Dennis Wagner, *Which Coronavirus Patients Will Get Life Saving Ventilators? Guidelines Show How Hospitals in NYC, US Will Decide*, USA TODAY, https://www.usatoday.com/story/news/2020/04/04/coronavirus-ventilator-shortages-may-force-tough-ethical-questions-nyc-hospitals/5108498002/ [https://perma.cc/5W7K-72WR] (Apr. 4, 2020, 2:17 PM).

43. McCoy & Wagner, *supra* note 42 (noting that states such as Colorado, Arizona, and Alabama used existing influenza crisis plans during the COVID-19 pandemic); Wolf Interview, *supra* note 41.

44. McCoy & Wagner, *supra* note 42.

45. Ezekiel J. Emanuel et al., *Fair Allocation of Scarce Medical Resources in the Time of Covid-19*, 382 NEW ENG. J. MED. 2049, 2049 (2020).

46. *See generally* Tyler Foggatt, *Who Gets a Ventilator?*, NEW YORKER (Apr. 11, 2020), https://www.newyorker.com/magazine/2020/04/20/who-gets-a-ventilator [https://perma.cc/H4WQ-ND54]; *Who Do We Save?*, *supra* note 12; McCoy & Wagner, *supra* note 42.

47. *See* Wolf Interview, *supra* note 41.

48. Emanuel et al., *supra* note 45, at 2051.

49. *Id.*

though the values themselves may be agreed-upon, what they mean remains a topic of debate.[50]

First, the maximization of benefits can be interpreted in two different ways.[51] One interpretation focuses on saving the most individual lives, while another focuses on saving the most years of life, giving higher priority to those who have the best prognosis for survival post-treatment.[52] Both interpretations have been viewed as possibly the most important ethical values to consider.[53] These ideas align with the utilitarian ethical perspective, which seeks to maximize population outcome—by giving a ventilator to someone who will benefit—while also balancing the nonutilitarian perspective, which values each life.[54]

Second, treating people equally in the context of triage can be accomplished in two ways.[55] The first involves the use of a lottery system of random selection.[56] Because of the blind nature of random selection, a lottery system equates to fairer decision-making, but still, no one principle alone should be used to make determinations.[57] One recommendation is to use random selection only among patients with similar prognoses to account for more than just a single ethical principle.[58] A first-come, first-served approach also attempts to promote equal treatment, but in reality, it benefits those who live closest to the hospital.[59] If a hospital has only one bed left and two people are rushing to the hospital seeking treatment, the individual closer to the hospital has an advantage under the first-come, first-served principle, thus preventing true equal treatment.[60]

Third is the principle of rewarding instrumental value.[61] The basic principles in *Holmes* involved the idea of maximizing benefits by

50. *Id.*; *see also* Wolf Interview, *supra* note 41.
51. Emanuel et al., *supra* note 45, at 2051–52.
52. *Id.*
53. *Id.*
54. *Id.* at 2052; *see also* Wolf Interview, *supra* note 41.
55. Emanuel et al., *supra* note 45, at 2051.
56. *Id.* at 2053.
57. *Id.*
58. *Id.*; ETHICAL CONSIDERATIONS FOR VENTILATOR ALLOCATION, *supra* note 40, at 16.
59. Emanuel et al., *supra* note 45, at 2053.
60. *Id.*; *see also* Lombardo Interview, *supra* note 15.
61. Emanuel et al., *supra* note 45, at 2051.

keeping the best sailors on board because, practically, they were the best resource.[62] In turn, one could reason that healthcare workers were essential in responding to a pandemic; therefore, there would be greater mortality overall if they were not given priority to receive medical treatment over non-healthcare workers.[63]

Finally, giving priority to the worst-off can either mean helping the sickest first or the youngest, who will be worse off because they will have lived such a short life.[64] Giving priority to the youngest best aligns with the principle of maximizing benefits because those who are younger are not only more likely to recover but also have more life years that would otherwise be lost.[65] At the same time, this principle discriminates against the elderly, thus contradicting the idea that all lives are equal.[66]

In addition, the 2011 CDC Ethics Subcommittee Report recommended saving the most lives by prioritizing those most likely to survive post-discharge as opposed to those in the worst condition because prioritizing the latter could lead to ventilators being allocated to those too sick survive at all.[67] The Report recommended that hospitals use the Sequential Organ Failure Assessment (SOFA) model to determine which patients are most likely to survive.[68] The SOFA model, typically used in organ transplant determinations, assigns patients a mortality score to determine their priority.[69] Physician familiarity with the SOFA model suggested that the model would be helpful during the COVID-19 pandemic.[70] The Report also noted that other score models could be used so long as they were based on the appropriate research and took into consideration factors such as the population for which it was being considered, the disease, feasibility, ease, accuracy, validity, objectivity, and transparency.[71] However, the Report recognized that the "life years" model to

62. *See* Lombardo Interview, *supra* note 15.
63. Emanuel et al., *supra* note 45, at 2053.
64. *Id.* at 2051.
65. *Id.* at 2052.
66. ETHICAL CONSIDERATIONS FOR VENTILATOR ALLOCATION, *supra* note 40, at 15.
67. *Id.* at 9, 12.
68. *Id.* at 12.
69. *Id.*
70. *See* Wolf Interview, *supra* note 41.
71. ETHICAL CONSIDERATIONS FOR VENTILATOR ALLOCATION, *supra* note 40, at 12.

maximizing benefits, as opposed to the "most lives" model, often leads to discriminatory exclusion criteria despite its justification under the utilitarian model.[72]

These bioethics principles acted as some of the few sources of guidance for hospitals preparing to make decisions regarding scarce resource allocation in the midst of the COVID-19 pandemic. Even though the allocation of scarce resources continued to be a national issue throughout the COVID-19 pandemic, no new federal guidance regarding allocation decisions had emerged for the states to follow as of early fall 2020.[73] Although the CDC may seem ideally-suited to issue such recommendations, it has very limited authority.[74] The 2011 recommendations by the CDC Ethics Subcommittee were never meant to be implemented as true guidance.[75] The idea behind the 2011 recommendations was that states might review the issues presented to better recognize some of the significant ethical principles in play and to use the recommendations to create their own guidelines before finding themselves in the midst of a pandemic.[76]

Analysis

An Analysis of Select Triage Plans

During the early stages of the COVID-19 pandemic, thirty states disclosed plans meant to provide hospitals with guidance on rationing scarce resources, such as ventilators.[77] Of these thirty states, the Center for Public Integrity categorized twenty-five, including California, Texas, and New York, as "problematic" because they included "provisions of the sort advocates fear [would] send people with disabilities to the back of the line for life-saving treatment."[78] The remaining five states with guidelines not considered problematic—Nevada, Arizona, New Mexico, Missouri, and West

72. *Id.* at 13.
73. *See* Wolf Interview, *supra* note 41.
74. *Id.*
75. *Id.*
76. *Id.*
77. Whyte, *supra* note 10.
78. *Id.*

Virginia—proposed guidelines that either presented no disability problems or were too vague to include such specific language.[79] The other twenty states, including Georgia, had not provided public guidelines.[80] This *Peach Sheet* analyzes the plans from California and New York, two of the most populous states that provided guidelines deemed "problematic," though in different ways. This *Peach Sheet* also discusses the regionalized Santa Clara, California guidelines as an example of what a county plan can look like in a state with broad guidelines.

The California Plan

California's Department of Public Health (CDPH) authored a comprehensive emergency plan in a 263-page document to guide hospitals through several different types of emergencies, including pandemics and other national incidents that necessitate a medical response.[81] However, the language specifically regarding triage more closely resembles remarkably broad goals, rather than clearly-defined guidelines.[82] Described in the subsection "Transitioning from Individual Care to Population-Based Care," the CDPH lists both appropriate and inappropriate criteria for resource allocation, listing factors such as "[l]ikelihood of survival, change in quality of life, duration of benefit, urgency of need, and amount of resources required" under "Appropriate Criteria for Resource Allocation."[83] Under the "Inappropriate Criteria for Resource Allocation," on the other hand, the CDPH lists "[a]bility to pay, provider's perception of social worth, patient contribution to disease, and past use of resources."[84] Such language suggests that California incorporated the lessons learned during the kidney dialysis trials, discussed *supra*, especially with its inclusion of the "provider's perception of social worth" in the inappropriate criteria section. However, disability rights

79. *See id.*
80. *Id.*
81. *See generally* CAL. DEP'T OF PUB. HEALTH, STANDARDS AND GUIDELINES FOR HEALTHCARE SURGE DURING EMERGENCIES (2008).
82. *See id.*
83. *Id.* at 14.
84. *Id.*

advocates expressed concerns that the vague language of the "appropriate criteria" still left room for unacceptable and possibly illegal discrimination.[85]

Further, the California plan included a more general description of the state's expectations for shifts in care during a pandemic.[86] The plan stated:

> Triage efforts . . . will need to focus on maximizing the number of lives saved. Instead of treating the sickest or the most critically injured first, triage would focus on identifying and reserving immediate treatment for individuals who have a critical need for treatment and are likely to survive. The goal would be to allocate resources in order to maximize the number of lives saved. Complicating conditions, such as underlying chronic disease, may have an impact on an individual's ability to survive.[87]

Disability rights advocates were especially concerned with the last sentence, which could be read as a license to deny care to individuals with disabilities such as Down Syndrome or Asperger Syndrome.[88] However, California's plan aimed for a fairly compassionate ultimate goal, emphasizing that the overall goal of triaging scarce resources was to "focus on maximizing the number of lives saved."[89] This could be a source of comfort for disability rights advocates because it values saving lives, regardless of their perceived social worth.

A potential benefit of the broad reach of the California plan—California being the most populous state and third-largest state by area—is that it allowed its localities, such as Santa Clara County, to introduce more detailed guidelines that took more specific, regional needs into account.[90] However, this also allowed localities to

85. Whyte, *supra* note 10; Wolf Interview, *supra* note 41.

86. CAL. DEP'T OF PUB. HEALTH, *supra* note 81, at 15.

87. *Id.*

88. Whyte, *supra* note 10; Wolf Interview, *supra* note 41; *see also* Wendy F. Hensel & Leslie E. Wolf, *Playing God: The Legality of Plans Denying Scarce Resources to People with Disabilities in Public Health Emergencies*, 63 FLA. L. REV. 719, 741 (2011).

89. CAL. DEP'T OF PUB. HEALTH, *supra* note 81, at 15.

90. *See generally* SANTA CLARA CNTY. PUB. HEALTH DEP'T, SANTA CLARA CLINICAL TRIAGE

introduce equally problematic plans.[91] In contrast to the more generalized list of criteria provided by California, Santa Clara County relied on a SOFA-like scoring system, admitting only patients who scored a fifty or greater based on values assigned to a specific list of items that "pandemic flu triage" protocols must consider: ten points for "highest risk age groups, significant co-morbid illness"; and twenty points for respirations, systolic blood pressure, pulse, and room air pulse oximetry.[92] Additionally, hospitals were allowed to consider the "toxic appearance or rapid decompensation" of the prospective patient and whether the prospective patient showed signs of "significant hypoxia," which occurs when there is less than 88% oxygen saturation in room air.[93] The SOFA scoring system used in the Santa Clara plan has been criticized by experts for excluding large portions of the population based on metrics that are inherently biased against disabled individuals.[94] However, because the Santa Clara plan aggregated points and required a certain score before admitting patients into the hospital, the scoring system still functioned in a non-discriminatory, pro-disability rights fashion.[95]

The New York Plan

Although New York endured heavy criticism for its COVID-19 response and protocols, the New York State Department of Health recognized the threat that a flu-like pandemic presented and developed ventilator triage protocols in November 2015.[96] New York's plan also presented a detailed look into the plan's development process with its "Executive Summary."[97] As noted by Leslie Wolf, Interim Dean of the Georgia State University College of Law, these plans ideally represent the result of close communication

GUIDELINES DURING PANDEMIC CRITICAL RESOURCE STAGE (2007).

91. *See id.*

92. *Id.* at 3

93. *Id.*

94. *See* Hensel, *supra* note 88, at 759–60.

95. SANTA CLARA CNTY. PUB. HEALTH DEP'T, *supra* note 90.

96. *See generally* Howard A. Zucker, *Letter from the Commissioner of Health* in N.Y. STATE DEP'T OF HEALTH, VENTILATOR ALLOCATION GUIDELINES (2015).

97. *See id.*

and feedback from the communities that the plan will cover.[98] The development of the New York plan fit within those ideals.[99] First, it was developed by experts from the medical and ethics fields.[100] Then, the New York Task Force on Life and the Law "oversaw a public engagement project" to garner the type of real-world pragmatism that was essential for these plans to be implemented.[101] Further, New York formed a separate legal subcommittee in 2008 to review past guidelines and help shape the development of the new guidelines in a way that would help the new guidelines avoid legal criticism.[102] Finally, New York included a statement indicating that because "research and data on this topic are constantly evolving, the guidelines are a living document intended to be updated and revised in line with . . . societal norms."[103] This flexibility and willingness to update was critical to the implementation of the guidelines.[104]

Like the California plan, the New York plan stated that the goal of the guidelines was to "save the most lives."[105] However, New York's guidelines, unlike California's, provide a stricter framework for hospitals to operate under during a pandemic.[106] The plan enumerated three steps applicable to adults for ventilator triage.[107] First, the prospective patient must be screened for exclusion criteria.[108] If a prospective patient possesses a medical condition enumerated in the exclusion criteria list, they are essentially denied a ventilator.[109] The exclusion criteria is limited to conditions that fundamentally alter a prospective patient's ability to survive the procedure and the immediate recovery.[110] These include "cardiac arrest, irreversible age-specific hypotension unresponsive to fluid resuscitation, traumatic brain injury with no motor response to painful stimulus,

98. Wolf Interview, *supra* note 41.
99. N.Y. STATE DEP'T OF HEALTH, VENTILATOR ALLOCATION GUIDELINES 1–3 (2015).
100. *Id.* at 2.
101. *Id.*
102. *Id.*
103. *Id.* at 3.
104. *See* Whyte, *supra* note 10; Wolf Interview, *supra* note 41.
105. N.Y. STATE DEP'T OF HEALTH, *supra* note 99, at 11.
106. *See generally id.*; CAL. DEP'T OF PUB. HEALTH, *supra* note 81.
107. N.Y. STATE DEP'T OF HEALTH, *supra* note 99, at 53.
108. *Id.* at 54.
109. *See id.*
110. *Id.*

and severe burns where predicted survival is less than 10% even with unlimited aggressive therapy."[111] Once the prospective patient has been screened for exclusion criteria, their mortality risk is assessed using SOFA.[112] The patient's SOFA score is assessed against the chart below.

Figure 1: Step 2 SOFA Assessment[113]

Step 2 – Mortality Risk Assessment Using SOFA[1]	
Color Code and Level of Access	**Assessment of Mortality Risk/ Organ Failure**
Blue No ventilator provided. Use alternative forms of medical intervention and/or palliative care or discharge. Reassess if ventilators become available.	Exclusion criterion OR SOFA > 11
Red Highest Use ventilators as available	SOFA < 7 OR Single organ failure[2]
Yellow Intermediate Use ventilators as available	SOFA 8 – 11
Green Use alternative forms of medical intervention or defer or discharge. Reassess as needed.	No significant organ failure AND/OR No requirement for lifesaving resources

The guidelines make clear that a triage committee must not compare patients in the same color code and that a lottery system should be used instead if a decision must be made between individuals in the same color code.[114] Finally, once a patient has been selected, the patient must undergo periodic clinical assessments at 48 hours, 120 hours, and every subsequent 48 hours, to reassess the patient's progress and the utility of continuing to provide that patient

111. *Id.* at 54.
112. *Id.* at 56.
113. N.Y. STATE DEP'T OF HEALTH, *supra* note 99, at 59.
114. *Id.* at 60.

with a ventilator, as calculated by using SOFA.[115] These assessments, known as time trials, are governed by their own separate charts, as seen below.[116]

Figure 2: 48 Hour SOFA Assessment[117]

Step 3 - Ventilator Time Trials (48 Hour Assessment)[1]	
Color Code and Level of Access	**Assessment of Mortality Risk/ Organ Failure**
Blue No ventilator provided.[2] Use alternative forms of medical intervention and/or palliative care or discharge. Reassess if resources become available.	Exclusion criterion OR SOFA > 11 OR SOFA 8 – 11 and No Change in SOFA Score Compared to the Initial Assessment[3]
Red Highest Use lifesaving resources as available.	SOFA < 7 and Decrease in SOFA Score Compared to the Initial Assessment[4] OR SOFA < 11 and Decrease in SOFA Score Compared to the Initial Assessment[5]
Yellow Intermediate Use lifesaving resources as available.	SOFA < 7 and No Change in SOFA Score Compared to the Initial Assessment
Green Use alternative forms of medical intervention or defer or discharge. Reassess as needed.	No longer ventilator dependent / Actively weaning from ventilator

Again, the guidelines make clear that patients in the same color code should never be compared and that a random lottery system should be used for discontinuing ventilator use for patients within the same color code.[118]

The New York plan also addressed using a lower standard of care and advocated for alternative forms of medical intervention during a pandemic.[119] Though taking a more hands-off approach, similar to

115. *Id.*
116. *Id.*
117. *Id.* at 64.
118. *Id.* at 68.
119. N.Y. STATE DEP'T OF HEALTH, *supra* note 99, at 69–70.

the California plan, the New York plan allowed healthcare providers to explore less proven, more experimental respiratory relief procedures, such as "nasal cannula, oxygen face masks, bilevel positive airway pressure (BiPAP), continuous positive airway pressure (CPAP), transtracheal catheters, or other supplements to breathing" if appropriate.[120] Providing a framework to lower the standard of care and allowing for these kinds of procedures served a vital role in furthering the goal of the guidelines: to save as many lives as possible. The guidelines provided a legal and regulatory framework for hospitals to serve as many people as they could, rather than deny health care to someone, out of fear of litigation, who failed to qualify for a ventilator.[121]

Legal Ramifications

In an ideal world, states would create and implement their own guidelines regarding scarce resource allocation after gathering different perspectives from across their communities.[122] Engaging not only physicians and nurses, but also religious leaders, civil rights leaders, lawyers, and representatives from different communities could help to ensure different perspectives are accounted for and align with what the ethical principles promote: fairness.[123] In reality, few states prepared ventilator triage policies prior to the COVID-19 pandemic.[124] The lack of preparation in turn led to the creation of guidelines that involved a variety of legal ramifications.

120. *Id.* at 75.
121. *See id.*
122. *See* Wolf Interview, *supra* note 41.
123. *See id.*
124. Armand H. Matheny Antommaria et al., *Ventilator Triage Policies During the COVID-19 Pandemic at U.S. Hospitals Associated with Members of the Association of Bioethics Program Directors*, 173 ANNALS INTERNAL MED. 188, 188 (2020), https://www.acpjournals.org/doi/pdf/10.7326/M20-1738# [https://perma.cc/8QDL-3TGP]; *Who Do We Save?*, *supra* note 12.

Medical Malpractice

Although the ethics of saving the most lives is widely accepted, one major legal concern that emerged during the COVID-19 pandemic was the potential ramifications that could occur from a hospital's withholding or withdrawing a ventilator.[125] A physician and a hospital could be sued for negligence for either withholding a ventilator or withdrawing a ventilator from a patient.[126] If proper guidelines were not set in place ahead of the crisis, physicians and hospitals could find themselves in trouble.[127] It is important to implement guidelines ahead of time so that physicians are not trying to follow the guidelines for the very first time during a crisis.[128] Otherwise, physicians could find themselves making less-informed choices—such as the implementing the less ethical first-come, first-served model—that could lead to a lawsuit, rather than following a well-thought-out set of guidelines.[129] Additionally, established guidelines are important because they create transparency and buy-in with the community.[130] A physician needs to feel supported by the community, and there is a greater chance that guidelines will not be followed if a physician's decisions are influenced by the fear of a lawsuit.[131]

Overall, though the chance of a malpractice lawsuit succeeding decreases when proper nondiscriminatory guidelines are established and followed, the chance exists nonetheless.[132] In a crisis there is a shift in normal standards of care that, if breached, would otherwise result in a negligence lawsuit.[133] During a pandemic, such as COVID-19, a "crisis standards of care" should apply in cases of

125. Glenn Cohen et al., *Potential Legal Liability for Withdrawing or Withholding Ventilators During COVID-19*, 323 JAMA 1901, 1901 (2020), https://jamanetwork.com/journals/jama/fullarticle/2764239 [https://perma.cc/3NWA-4M86].
126. *Id.*
127. *See* Wolf Interview, *supra* note 41.
128. *Id.*
129. *Id.*; Cohen et al., *supra* note 125.
130. Wolf Interview, *supra* note 41.
131. Cohen et al., *supra* note 125.
132. *Id.*
133. Wolf Interview, *supra* note 41.

negligence.[134] When the healthcare system is overrun, the crisis standards of care represent "a substantial change in usual healthcare operations and the level of care [that] it is possible to deliver, which is made necessary by a pervasive (e.g., pandemic influenza) or catastrophic (e.g., earthquake, hurricane) disaster."[135] This shift helps protect physicians when making scarce resource allocation decisions, such as determining which patients receive a ventilator.[136] Although the standard of care shifts during a crisis, legislation that limits malpractice liability for physicians during a crisis could also make physicians and hospitals feel more supported, leading them to make better decisions.[137]

Discrimination

Another major legal concern surrounding ventilator triage policies involves issues of discrimination based on disabilities, age, and race.[138] Without gathering adequate community input on potential ethical and legal implications, several states issued COVID-19 triage guidance that discriminated against patients with disabilities by creating allocation guidelines that excluded physically or mentally disabled individuals in violation of federal laws.[139] The State of Alabama released guidance in 2010 after the H1N1 pandemic that allowed for the exclusion of individuals with intellectual disabilities such as "profound mental retardation" and severe dementia.[140] Similarly, Tennessee used its "Guidance for the Ethical Use of

134. CLARE STROUD ET AL., CRISIS STANDARDS OF CARE: SUMMARY OF A WORKSHOP SERIES 69 (2010), https://www.ncbi.nlm.nih.gov/books/NBK32748/ [https://perma.cc/2SZG-L4UL].

135. *Id.* at 70.

136. *Id.*

137. Wolf Interview, *supra* note 41.

138. *See generally OCR Reaches Early Case Resolution with Alabama After It Removes Discriminatory Ventilator Triaging Guidelines*, HHS.GOV (Apr. 8, 2020) [hereinafter *OCR Case Resolution*], https://www.hhs.gov/about/news/2020/04/08/ocr-reaches-early-case-resolution-alabama-after-it-removes-discriminatory-ventilator-triaging.html [https://perma.cc/TB9U-EKHX]; Nathan Chomilo et al., *The Harm of a Colorblind Allocation of Scarce Resources*, HEALTH AFFS. BLOG (Apr. 30, 2020), https://www.healthaffairs.org/do/10.1377/hblog20200428.904804/full/ [https://perma.cc/55BH-W7GZ]; Wolf Interview, *supra* note 41.

139. *OCR Case Resolution*, *supra* note 138.

140. *Id.*; *Alabama Resolves Complaint over Old Ventilator Guidelines*, AP NEWS (Apr. 9, 2020), https://apnews.com/4f699ae5b1a8fd31c0a2367312cd6d93.

Scarce Resources during a Health Emergency" from 2016, which excluded those who need assistance in daily living—including people with cancer, dementia, and traumatic brain injuries—from accessing ventilators.[141] This type of categorical exclusion could potentially violate section 504 of the Rehabilitation Act of 1973 and Title II of the Americans with Disabilities Act (ADA).[142] Section 504 of the Rehabilitation Act of 1973 prohibits discrimination against people with disabilities in programs that receive federal financial aid, while Title II of the ADA prohibits discrimination against people with disabilities in programs and activities of state and local governments.[143] Because public hospitals and health services are run by the state government, they are covered under both of these statutes.[144] Accordingly, the government may not set guidance which precludes individuals from services at a public hospital based on an individual's disability because this discriminates against certain people.[145] This kind of guidance that discriminates on the basis of disabilities, in addition to being unethical, violates federal law under both the ADA and section 504 of the Rehabilitation Act because a state program is prohibiting an individual from receiving their services based on a disability.[146]

Additionally, questions of race discrimination arose as states rushed to release ventilator triage guidance during COVID-19.[147] According to the CDC, "[l]ong-standing systemic health and social inequities . . . put some members of racial and ethnic minority groups at increased risk of getting COVID-19 or experiencing severe illness, regardless of age."[148] Because of this higher risk in racial and ethnic

141. *TN COVID Treatment Rationing Plan Triggers Disability Discrimination Complaint*, DISABILITY RTS. TN (Mar. 28, 2020) [hereinafter *TN COVID Treatment*], https://www.disabilityrightstn.org/resources/news/march-2020/tn-covid-treatment-rationing-triggers-disability-d [https://perma.cc/3N97-8C6M].

142. *OCR Case Resolution*, *supra* note 138.

143. 29 U.S.C. § 794; 42 U.S.C. § 12132.

144. Hensel & Wolf, *supra* note 88, at 733–34.

145. *Id.*

146. *Id.*; *TN COVID Treatment*, *supra* note 141.

147. *See generally* Chomilo et al., *supra* note 138; Ayodola Adigun, *As Pandemic Endures, COVID-Associated Discrimination Towards Minorities Persists, Study Shows*, ABC NEWS (July 17, 2020, 6:02 AM), https://abcnews.go.com/Health/pandemic-endures-covid-discrimination-minorities-persists-study-shows/story?id=71778497 [https://perma.cc/3YUY-VSGB].

148. COVID-19 in Racial and Ethnic Minority Groups of *Coronavirus Disease 2019 (COVID-19)*,

minority groups, colorblind ventilator triage may have led to a disparate impact based on race.[149] For example, allocating ventilators based on the life years model would not account for the fact that white males have a life expectancy that is four-and-a-half years longer than that of black males.[150] Additionally, guidelines that place those with certain comorbidities—such as asthma, heart disease, and obesity—at a lower priority could have a disparate impact because black Americans and American Indians are both more likely to have these conditions.[151] All of these situations could violate section 1557 of the Affordable Care Act (ACA), which prohibits discrimination based on race, color, national origin, sex, age, or disabilities in programs receiving federal funding.[152] Because most hospitals receive federal funding in the form of public payer insurance payments, such as Medicare, they are prohibited from making decisions which would discriminate against an individual based on their race.

Finally, the problem of age discrimination often arises in scarce resource allocation guidelines.[153] Age is often used as a factor, or rather a cut-off, in triage policies.[154] Triage guidelines that use age as criteria to determine who will or will not receive a ventilator may run afoul the Age Discrimination Act of 1975.[155] The Act prohibits "discrimination on the basis of age in programs or activities receiving federal financial assistance."[156] This again encompasses hospitals because, in addition to Medicare, many hospitals also received federal COVID-19 aid.[157] Under the Act, an individual is

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CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/racial-ethnic-minorities.html [https://perma.cc/B4QS-RUVD] (June 25, 2020).

149. Chomilo et al., *supra* note 138.

150. Elizabeth Arias & Jiaquan Xu, *United States Life Tables, 2017*, NAT'L VITAL STAT. REP., June 24, 2019, at 1, 3.

151. Chomilo et al., *supra* note 138.

152. *OCR Case Resolution*, *supra* note 138; 42 U.S.C. § 18116.

153. Wolf Interview, *supra* note 41.

154. *Id.*

155. *OCR Case Resolution*, *supra* note 138.

156. 42 U.S.C. § 6101.

157. Ayla Ellison, *How Much Federal COVID-19 Aid Are Hospitals Getting? A State-by-State Analysis*, BECKER'S HOSP. REV.: HOSP. CFO REP. (May 4, 2020), https://www.beckershospitalreview.com/finance/how-much-federal-covid-19-aid-are-hospitals-getting-a-state-by-state-analysis.html [https://perma.cc/R7KZ-TGM9].

discriminated against if they are excluded or denied benefits from a program or activity based on their age.[158] If the determination for the denial of the benefit is ultimately made based on a factor other than age, the Act is not violated.[159] Allocation criteria that uses age as a determination factor alone would deny people access to treatment solely based on their age. Therefore, a hospital that uses age as a basis for denying someone a ventilator could end up violating the Age Discrimination Act if no other factors were used in making the allocation determination.

The easiest solution to avoiding these potential discrimination claims is to create guidelines before a crisis arises so that there is time to receive community input, as discussed *supra*.[160] Community input first helps to gather different perspectives from the representatives of different groups that might face adverse consequences based on certain guidelines.[161] This practice can help in recognizing potentially problematic criteria or criteria that was not included before.[162] Additionally, having to explain the guidelines will not only bring to light problems but will add transparency to the process.[163] If the community buys into the guidelines, there will be less disagreement overall surrounding the allocation decisions being made, resolving many of the potential legal implications of such decisions before the issues even arise.[164]

Conclusion

States are ideally situated to gather a broad range of different perspectives from all the communities that will be affected by triage guidelines.[165] Georgia was one of the many states that did not issue any ventilator triage guidance during the COVID-19 pandemic.[166]

158. 42 U.S.C. § 6102.
159. *Id.* § 6103(b)(1)(A).
160. Wolf Interview, *supra* note 41.
161. *Id.*
162. *Id.*
163. *Id.*
164. *Id.*
165. *Id.*
166. Whyte, *supra* note 10.

This decision left all scarce resource allocation decisions—from ventilators to personal protective equipment, such as masks and gloves—up to individual hospitals and physicians within the state. Though generally accepted ethical principles exist, a transparent discussion surrounding these principles and the ultimate decisions to be made would provide the best solution for the issue of how to properly allocate scare resources during a crisis.[167] The COVID-19 pandemic presented many states, whether they had already implemented a crisis standards of care plan or not, with an opportunity to evaluate the ethical and legal implications that their guidelines could have on their population and to consider issuing well-rounded guidance in preparation for the worst.

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167. *See* discussion *supra* Section *Legal Ramifications.*