



April 28, 2020

Statewide Medical Response Systems Coordinator
Department of Emergency Preparedness and Response
Oklahoma State Department of Health

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Mr. Mike Alba,

On behalf of those living with cystic fibrosis in Oklahoma, we write to comment on the state's draft document entitled "Hospital Crisis Standards of Care."¹ We appreciate this opportunity to provide input on the state's draft guidelines and recognize the monumentally difficult task public health officials face when creating allocation guidelines that are both equitable and actionable during this crisis.

All human life is valuable, and we are heartbroken that clinicians and caretakers on the front lines of this pandemic may be forced to consider unthinkable choices as they care for their patients. While we recognize the importance of giving healthcare workers guidance during this crisis, it is critical that plans for allocating scarce medical resources ensure all patients are evaluated on a case-by-case basis and decisions about who receives treatment are based on current clinical presentation – regardless of underlying health conditions.

On March 28, the Office for Civil Rights (OCR) at the US Department of Health and Human Services issued a bulletin regarding Civil Rights, the Health Insurance Portability and Accountability Act, and COVID-19.² In the bulletin, OCR reminded federally-funded health programs and activities that Section 1557 of the Affordable Care Act and Section 504 of the Rehabilitation Act prohibit discrimination on the basis of disability, and that these civil rights laws are still in effect. OCR stated, "Decisions by covered entities concerning whether an individual is a candidate for treatment should be based on an individualized assessment of the patient based on the best available objective medical evidence."

We are encouraged to see that the state has decided to revise their allocation guidelines to address patient care during times of crisis. However, we are concerned that Oklahoma's draft guidelines, dated April 7, 2020, use the mere presence of existing health conditions – including preexisting lung disease – as a determining factor in deciding which patients receive ventilators in the event that there is an inadequate supply. The mechanical ventilation and external oxygenation allocation guidelines recommend assessing patient prognosis of long-term survival and list moderate and severe chronic lung disease as examples of comorbidities associated with significantly decreased long-term survival. Such decisions could result in the denial of life-saving care for patients with CF who seek treatment solely based on their underlying conditions – even though there is no evidence to suggest that people with CF cannot make a full recovery from COVID-19.

¹ <https://www.ok.gov/health2/documents/Hospital%20Crisis%20Standards%20of%20Care.pdf>

² <https://www.hhs.gov/sites/default/files/ocr-bulletin-3-28-20.pdf>

Preliminary data from the CF patient registry—which collects data from accredited CF care centers and includes 97 percent of CF patients in the US—shows that of the 20 confirmed cases of COVID-19 among people with CF, 19 made a full recovery. This includes 4 people with advanced lung disease, defined as those with a FEV₁ less than 40 percent predicted, and 3 patients post-lung transplantation. Only one person with CF has died from complications related to COVID-19.

While decisions about who receives treatment should never be based on underlying diagnoses, this criterion is also based on an inaccurate understanding of the current survival outcomes for the CF patient population and does not factor in the short- and long-term impact of disease-modifying therapy. The outlook has dramatically improved in recent years for patients living with cystic fibrosis, even those with low lung function, thanks to recent advances in care and treatment options.³ In fact, the median survival for patients with CF with an FEV₁ of less than 30 percent was shown to be 6.5 years.⁴ We expect that the introduction of new and transformational therapies like Trikafta™, which treats the underlying cause of the disease, will only further improve life expectancy. As such, every patient with CF must be evaluated and triaged for COVID-19 treatment on a case-by-case basis based on their clinical presentation.

We urge Oklahoma's Adapted Standards of Care Committee to revise the ventilator allocation guidelines included in the draft plan, being careful to avoid any language that unfairly disadvantages those with underlying conditions like cystic fibrosis. Guidelines for determining which patients receive scarce resources should be developed in consultation with relevant stakeholders, including patient representatives and disease-specific experts, to ensure that the resulting recommendations are equitable and based on the most recent data. Additionally, we urge the Committee to create guidelines that leverage available disease-specific experts on site to ensure assessments tied to allocation determinations include the best available objective medical evidence.

State triage plans that are transparent and ensure equitable access to scarce resources are an important tool for protecting both care providers and patients in this difficult time. We look forward to working with you as you continue to revise the crisis standards of care plan for your state.

Sincerely,

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³ <https://www.atsjournals.org/doi/pdf/10.1164/rccm.202004-0999LE>

⁴ <https://www.ncbi.nlm.nih.gov/pubmed/28115168>

Cc: Adapted Standards of Care Committee
Oklahoma Catastrophic Health Emergency Planning Task Force