CYSTIC FIBROSIS FOUNDATION®

April 24, 2020

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To whom it may concern:

On behalf of those living with cystic fibrosis in Utah, I write to comment on the state's crisis standards of care guidelines. We recognize the monumentally difficult task public health officials face when creating allocation guidelines that are both equitable and actionable during this crisis and appreciate the state's timely release of the "Utah Crisis Standards of Care Guidelines – COVID-19 Annex."[1]

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 care protocol outlined in the COVID-19 Annex recommends that all patients are evaluated and triaged based on their acute clinical presentation. However, we are concerned that another state resource – "Utah Crisis Standards of Care – Base Guidance," dated June 2018 – provides conflicting information.[3] The plan, as currently written, states that CF patients with post-bronchodilator FEV_1 less than 30 percent or baseline PaO_2 less than 55 mm Hg may be excluded from admission or transfer to critical care in the event of inadequate capacity. Such decisions could result in the denial of life-saving care for patients with CF who seek treatment solely based on their underlying condition – even though there is no evidence to suggest that people with CF cannot make a full recovery from COVID-19.

[1] https://coronavirus-download.utah.gov/Health-provider/Final%20COVID19%20CSC%20Annex%20April%2015%202020%20(1).pdf
[2] https://www.hhs.gov/sites/default/files/ocr-bulletin-3-28-20.pdf
[3] https://coronavirus.utah.gov/wp-content/uploads/Final_Utah_Crisis_Standards_of_Care_011719-1.pdf

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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 FEV_1 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, these criteria are 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.[4] In fact, the median survival for patients with CF with an FEV_1 of less than 30 percent was shown to be 6.5 years.[5] 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 recognize that the COVID-19 Annex is intended to supplement existing standards of care guidelines, including the base document from 2018. Given that both documents remain active among the suite of emergency response resources, we ask that you remove any language that unfairly disadvantages those with underlying conditions like cystic fibrosis from the 2018 guidelines. If the 2018 Crisis Standards of Care guidelines are not intended to be utilized by providers and decisionmakers at this time, we ask that you remove it from your list of resources so as not to cause confusion.

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. Additionally, state guidelines should encourage the use of available disease-specific experts on site to ensure assessments tied to allocation determinations include the best available objective medical evidence. 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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[4] https://www.atsjournals.org/doi/pdf/10.1164/rccm.202004-0999LE
[5] https://www.ncbi.nlm.nih.gov/pubmed/28115168