



February 17, 2021

Scott Rivkees, MD
State Surgeon General
Florida Department of Health
4052 Bald Cypress Way
Tallahassee, Florida 32399

Dear Dr. Rivkees:

On behalf of the 1,650 people living with cystic fibrosis in Florida, we write today to urge the state to ensure people with high-risk medical conditions—including cystic fibrosis—are prioritized for early access to COVID-19 vaccines.¹ We recognize the monumentally difficult task public health officials face when creating allocation plans that are both equitable and actionable during this crisis, and we appreciate the immense effort state public health departments have put into creating plans to allocate limited supplies of COVID-19 vaccines.

Our comments below call on Florida to ensure those with CF are prioritized for access to COVID-19 vaccines with others with high-risk conditions in the state's prioritization plan.

Background on Cystic Fibrosis and COVID-19

The Cystic Fibrosis Foundation is a national organization actively engaged in the research and development of new therapies for cystic fibrosis – a rare, life-threatening genetic disease that affects more than 30,000 people in the United States. The buildup of thick, sticky mucus in the lungs characteristic of the disease makes people with CF particularly prone to chronic respiratory infections. These chronic infections are punctuated by pulmonary exacerbations, events that are a risk factor for an irreversible decline of lung function and associated with morbidity and mortality. A significant proportion of pulmonary exacerbations are triggered by respiratory viral infections. With continued progress of the disease, some individuals with CF and advanced lung disease pursue lung transplantation.

The absent or malfunctioning protein that causes CF is also associated with a wide range of disease manifestations beyond the lungs, including pancreatic insufficiency that can lead to malnutrition, gastrointestinal issues, biliary cirrhosis, and diabetes mellitus.

While we have seen incredible progress in recent decades for those living with cystic fibrosis, COVID-19 represents a serious threat for this population. The strongest evidence to date on the threat COVID-19 poses to those with CF comes from a global analysis of 181 COVID-19 cases among people with CF.²

¹ <https://floridahealthcovid19.gov/covid-19-vaccines-in-florida/>

² Cosgriff, Rebecca et al. "The global impact of SARS-CoV-2 in 181 people with cystic fibrosis." *Journal of Cystic Fibrosis* (2020), in press

From that analysis, it appears CF patients with advanced lung disease, those that are post-lung transplantation, and those with diabetes mellitus may be at risk of severe outcomes including death.

Due to the known risks posed by viral infections and multi-system manifestations of the disease described above, people with CF should be considered at increased risk of poor outcomes from COVID-19 infection, and the Centers for Disease Control and Prevention (CDC) has listed CF as a condition that may put individuals at increased risk for worse outcomes.³

Clear Communication on the Vaccination Process Is Needed to Support High-risk Patients

We urge Florida to bring increased transparency around vaccine eligibility and access so patients with high-risk conditions like CF can understand how and when they may receive a vaccine. This pandemic has been enormously taxing on many in the CF community, and for those living with CF and their families, prioritized access to a vaccine means regaining some sense of safety, normalcy, and ultimately a return to society.

Instead of seeing a light at the end of the tunnel now that vaccines are publicly available, many in our community feel anxious and frustrated by ongoing confusion about vaccine access. We have been hearing from a number of CF community members on the barriers they have faced in trying to access COVID-19 vaccines. One community member from Florida shared the following:

My daughter's hospital has opened up to severe illness for vaccines, but cystic fibrosis was not listed as a severe illness. Other local hospitals have the same issue. I am anxious for my daughter to be vaccinated before she goes off to college, but I am getting resistance everywhere I turn. COVID attacks the lungs, CF is a deadly lung disease. This is very frustrating.

People with underlying conditions, such as those with CF, remain confused as to whether they qualify for prioritized access to COVID-19 vaccines, how they will be notified when they become eligible, how they will be expected to demonstrate eligibility at the time of vaccination, and where they will need to go to get vaccinated. We urge the state to ensure more clarity is provided around which high-risk medical conditions are being prioritized for vaccine access, and more information on how patient communities like ours may navigate the process when their time comes to get vaccinated.

Individuals with Cystic Fibrosis Must Be Prioritized for Access to COVID-19 Vaccines

As the state defines further priority populations, we urge you to follow the allocation recommendations put forth by the CDC's Advisory Committee on Immunization Practices (ACIP). Additionally, we call on the state to heed further CDC guidance on the limitations of evidence for rare disease patients and the need for physician discretion in identifying individuals for early vaccine access in order to support prioritized vaccine access for people with CF.

The recommendations released by the ACIP are the result of months of careful deliberation by vaccine and public health experts and input from thousands of stakeholders. The ACIP and other decisionmakers sought to balance competing ethical principles and public health priorities, as well as the urgency of improving health equity in vaccine distribution plans. Importantly, the committee's process has included

³ <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html>

meaningful public engagement and transparency on how the committee weighed different considerations related to prioritized populations.

The ACIP recommendations are accompanied by important CDC guidance on the limitations of available evidence on COVID-19's impact for many disease groups, including rare diseases like CF. This CDC guidance recommends using clinical judgement in identifying patients whose individual risks factors warrant priority vaccine access but whose condition may not be on the CDC's list of high-risk conditions.^{4,5} Together, these recommendations support prioritized vaccine access for people with CF and other rare disease populations that, due to small population size, are unable to generate the same level of evidence on the risk of severe illness from COVID-19 as substantially larger disease populations.

We urge Florida to ensure people with CF and other rare diseases that may increase the risk of worse outcomes from COVID-19 infection can get vaccines alongside other patients with high-risk conditions under the state's plan. We ask that the state incorporate the additional CDC guidance into the state's allocation plan and ensure clinician discretion may be used in identifying additional individuals at high-risk for prioritization purposes.

Once again, we thank you for your attention and consideration of people with CF as you tackle these difficult issues. It is critical that all state COVID-19 vaccination plans ensure early vaccine access for vulnerable populations like those with CF. We look forward to working with you as the state continues to revise and develop further allocation recommendations for COVID-19 vaccines.

Sincerely,



Mary B. Dwight

Chief Policy and Advocacy Officer
Senior Vice President of Policy and Advocacy
Cystic Fibrosis Foundation

CC: The Honorable Ron DeSantis, Governor of Florida

⁴ <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html>

⁵ <https://www.cdc.gov/vaccines/covid-19/phased-implementation.html>