



March 1, 2021

José Romero, MD
Chair, Advisory Committee on Immunization Practices (ACIP)
1600 Clifton Road, NE
Mailstop A27
Atlanta, GA 30329

Re: CDC-2021-0021, Advisory Committee on Immunization Practices (ACIP) Emergency Meeting,
February 28 – March 1, 2021

Filed electronically at [regulations.gov](https://www.regulations.gov)

Dear Dr. Romero:

On behalf of the Cystic Fibrosis Foundation, thank you for this opportunity to provide comments for the Advisory Committee on Immunization Practices (ACIP) meeting on February 28th and March 1st. We are aware of how challenging it has been for the ACIP and other decisionmakers to balance competing ethical principles and public health priorities, as well as the urgency of improving health equity in vaccine distribution plans, and we thank committee members for the many thoughtful discussions regarding COVID-19 vaccine allocation.

Our comments below urge the committee to ensure that allocation recommendations to states clearly reflect the need for early vaccine access for high-risk rare disease populations, including those with CF. We have also included some firsthand experiences of navigating the vaccine process from people living with CF, which underscore the fear and confusion in our community.

We hope you will consider these comments and stories as the committee continues efforts related to COVID-19 vaccine development, distribution, and allocation planning.

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 intractable bacterial infections. These chronic airway 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 as well. Continued progression of the disease can result in advanced lung disease so severe that lung transplantation may be the only life extending option.

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 people with CF comes from a published global analysis of 181 COVID-19 cases among people with CF made possible through an international collaboration of 19 countries including the US.¹ 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 risks posed by viral infections described above and multi-system manifestations of the disease, people with CF may be at increased risk of poor outcomes from COVID-19 infection. However, despite being identified by the Centers for Disease Control and Prevention (CDC) as a condition that might put individuals at increased risk for worse outcomes,² not all states are prioritizing people with CF for COVID-19 vaccines.

Age-based vaccine distribution deprioritizes those with high-risk medical conditions

We are deeply concerned by the emerging trend of age-based vaccine distribution plans in states across the US, which deprioritize younger individuals with high-risk conditions such as CF. We thank the members of the committee for acknowledging that prioritizing vaccine distribution by age alone will significantly impact equitable vaccine access during the March 1st meeting. We urge the ACIP to provide further guidance upholding the interim vaccine allocation recommendations finalized by the committee in December and discouraging states from moving to a strictly age-based distribution scheme.

In 2019, the median age at death for those living with CF was 32 years of age. Over 260 people with CF received a solid organ transplant that same year, and 77 percent of those receiving a transplant were under the age of 40.³ Using age-based distribution alone to define prioritized populations will put people with CF who are most vulnerable to worse outcomes with COVID-19 after older, healthier adults for vaccine access simply because those with CF have a shorter life expectancy. People with CF and others with high-risk conditions must not be deprioritized in vaccination efforts.

These allocation schemes abandon the carefully crafted recommendations finalized by the ACIP in December. These recommendations are the result of months of careful deliberation by vaccine and public health experts and input from thousands of stakeholders. We recognize that the ACIP and other decisionmakers have worked diligently 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 meaningful public engagement and transparency on how the committee weighed different considerations related to prioritized populations.

¹ Cosgriff, Rebecca et al. "The global impact of SARS-CoV-2 in 181 people with cystic fibrosis." *Journal of Cystic Fibrosis* (2020), in press

² <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html>

³ <https://www.cff.org/Research/Researcher-Resources/Patient-Registry/2019-Patient-Registry-Annual-Data-Report.pdf>

The ACIP must signal the importance of upholding the committee’s existing interim vaccine allocation recommendations to states, which balance important objectives such as minimizing harm to those most at risk for worse outcomes, increasing access to disadvantaged populations, and ensuring a transparent process. We recognize that states are contending with overwhelming demand for vaccine access in the absence of adequate resources to carry out efficient mass vaccination efforts. However, the desire for simplicity must not come at the expense of those who are most vulnerable to the consequences of COVID-19 infection. We encourage the ACIP and CDC to issue further guidance to states to ensure vaccination efforts are carried out equitably and in accordance with the ACIP’s existing recommendations.

Clear guidance on allocation recommendations is needed to support high-risk rare disease patients

We urge the ACIP to provide clarifying language and guidance on phase 1c allocation recommendations for rare diseases that might be at increased risk for serious complications from COVID-19 infection to ensure high-risk patients like those with CF are able to gain early access to COVID-19 vaccines alongside others with high-risk conditions.

We are seeing a wide range of interpretations of ACIP’s recommendations among states and localities, which is resulting in confusion and concern within patient communities like ours. Unfortunately, some states have not included people with CF and other rare diseases on their list of prioritized populations. Some states also established allocation plans that limit vaccine access to the CDC’s list of conditions known to increase risk of worse outcomes with no allowance for physician discretion. In these instances, people with CF are denied the ability to access COVID-19 vaccines alongside others with high-risk conditions despite ACIP guidance.

We were pleased that the ACIP included persons aged 16 to 64 years with high-risk medical conditions in final recommendations for phase 1c. Additionally, we appreciate that the committee’s recommendations are accompanied by language from the CDC about using individual clinical judgement to identify patients whose risks factors warrant priority vaccine access and new language on the CDC’s website recognizing the limitations of available evidence on COVID-19’s impact for many disease groups, including rare diseases like CF. This language is important for ensuring people with CF and other rare disease populations at increased risk for worse outcomes with COVID-19 are not excluded from prioritized vaccine access.

We urge the ACIP to build on the CDC’s language about clinical discretion in identifying high-risk patients and lack of evidence for rare disease populations and provide clarifying language on phase 1c recommendations. It is critical that guidance on ACIP allocation recommendations clearly reflect the needs of both diseases with large populations capable of generating clear evidence of risk of severe COVID-19 illness and other rare disease populations too small to generate similar evidence. We ask ACIP to clarify the need for a broad definition of high-risk medical conditions based on the CDC’s list and allow for clinician discretion in identifying additional high-risk individuals so vulnerable patient populations are able to access COVID-19 vaccines as early as is feasible.

Once again, we thank you for your attention and consideration of people with cystic fibrosis as you tackle these difficult issues. These are important opportunities for collaboration and discussion regarding the ACIP's work to support public access to safe and effective COVID-19 vaccines, and we stand ready to work alongside the committee in this endeavor.

Sincerely,

A handwritten signature in black ink, appearing to read "Mary B. Dwight". The signature is fluid and cursive, with a large initial "M" and "D".

Mary B. Dwight

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

Attachment: CF community experiences with COVID-19 vaccine access

The following anecdotes were gathered from people with CF and their caregivers on experiences navigating the COVID-19 vaccine process in their state.

Adult with CF in Pennsylvania

As someone with advanced stage disease who does not benefit from a CFTR (cystic fibrosis transmembrane conductance regulator) modulator, I'm at high risk for a bad outcome from COVID. As a result, I've been on strict quarantine in my house since March 2020. I haven't stepped foot in a public place since then. I have been putting off critical health care appointments and testing, living in fear of needing medical care for my advanced CF, and put in the unthinkable position of having to weigh the costs/benefits of seeking emergency care with potential exposure to COVID. In fact, just the other week, I had to forego imaging for a suspected partial lung collapse because my doctor felt it wasn't worth the risk of COVID exposure. These are decisions that nobody should have to make.

I am not trying to get vaccinated so I can go out to restaurants to eat or attend a social gathering or even go to the grocery store. I'm trying to get vaccinated so I can get critical health care for my advanced stage disease, which resists negotiation and control even under the best of circumstances. For many of us with advanced stage disease or who are living post-transplant, a vaccine now versus in a few weeks or months may be the difference between life and death.

Adult with CF in Colorado

I'm not sure the Governor truly appreciate the reality many people with chronic health needs face: scarce resources that make sheltering in place and paying extra for delivery charges unattainable, living alone without assistance, and just the extreme anxiety around even a trip to our hospitals/care centers or pharmacies when we are so vulnerable the virus is so widespread. It is striking to me how we as a society acknowledge that employment may force people to interact with the public (and properly prioritize based on that exposure) but fail to recognize that people with chronic health needs MUST enter high-risk areas like health care settings and pharmacies on a very regular basis. This is emphasized to me every time I hear someone argue that the most vulnerable can "just stay home" when of course I can't get chest x-rays or CT scans or skin cancer checks from home, all of which are extremely necessary to maintain my overall health. I know I'm not alone in feeling upset at this misconception, nor with feeling the frustration that vaccine priority hasn't properly addressed this concern.

Caregiver of a child with CF in Florida

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.

Adult with CF in Ohio

Although, I am eligible for the vaccine as of January 25th as a person with CF in Ohio, I have not able to get any appointments. I signed up for several waiting lists including both major hospitals, county health departments, pharmacies as well. I am on the staff of a high school football team so I reached out to the head football coach to see if he could get me on a list through the school and after some negotiations with those in charge of vaccine distribution at the school- I was added to the list. I got a call the next day that an appointment had been scheduled for me. I think it is crazy that I was able to get a vaccine as an outside part time football coach before I was able to get one as a person with CF, but I am so grateful that I was able to get one.