



**CYSTIC FIBROSIS
FOUNDATION®**

December 15, 2020

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

Re: CDC-2020-0124-0003, Advisory Committee on Immunization Practices (ACIP) December 18 and 20

Filed electronically at 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 taking place on December 19th and December 20th. Our comments below call on the committee to ensure that allocation recommendations prioritize high-risk populations for early access, including those with CF. We additionally urge the committee to recommend ongoing data collection on the risks and benefits of different COVID-19 vaccines for specific disease states; continued transparency of vaccine safety and efficacy data to help inform clinicians and patients; use of specialized provider networks for vaccine distribution; and availability of COVID-19 vaccines without cost-sharing for Americans.

We share these and other comments below, and we look forward to working with the committee as efforts continue 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 cystic fibrosis 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. 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. Due to the risks posed by viral infections described above

and multi-system manifestations of the disease, people with CF should be considered at increased risk of poor outcomes from COVID-19 infection.

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

We are encouraged by the ACIP's most recent allocation proposal, which would include individuals with high-risk medical conditions in Phase 1c. We urge the committee to finalize allocation recommendations that include prioritized access for individuals with conditions that put them at high risk for worse outcomes due to COVID-19, including those living with CF.

The Centers for Disease Control and Prevention's (CDC) designation of cystic fibrosis as a condition that may increase the risk of severe disease from COVID-19 is due, in part, to a lack of evidence—which is unavoidable for a rare disease. As a small patient population, the CF Foundation has struggled to gain a clear picture about how COVID-19 affects people with cystic fibrosis. While we have been tracking and analyzing data through our own patient registry, the strongest evidence to date may come from a recently 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. We recognize that the ACIP is reviewing several COVID-19 vaccine allocation frameworks, including the framework put forward by the National Academy of Medicine, that use the CDC's risk designations as the basis of its allocation scheme. In the case of cystic fibrosis, we believe this designation may mischaracterize the true risk for some people living with the disease. We urge the ACIP to consider information beyond that provided by the CDC to inform prioritization, especially when considering the needs of rare disease populations like CF.

We recommend the ACIP include people with cystic fibrosis in the same allocation phase as those considered at high risk under the CDC list. In addition to the forthcoming data mentioned above, we know that respiratory viruses can be devastating for people with CF. One study found that sixty-five percent of pulmonary exacerbations among people with CF were associated viral infections.² Another study demonstrated that viral associated pulmonary exacerbations in adults with CF are associated with more severe pulmonary involvement and respond less well to standard treatment.³ Moreover, as a multi-system condition, cystic fibrosis itself typically encompasses multiple comorbidities, including chronic pancreatic insufficiency, malnutrition, diabetes mellitus, liver disease, bone disease, and others—further increasing this population's vulnerability to complications from COVID-19. Many people with CF have bronchiectasis associated with chronic obstructive pulmonary disease as well. As such, we believe it is appropriate to include people with cystic fibrosis with other patients for whom COVID-19 poses a high risk.

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 Wark, Peter A.B. et al. "Viral infections trigger exacerbations of cystic fibrosis in adults and children." *European Respiratory Journal* (2012), Vol. 40: 510-512.

³ Etherington, C et al. "The role of respiratory viruses in adult patients with cystic fibrosis receiving intravenous antibiotics for a pulmonary exacerbation." *Journal of Cystic Fibrosis* (2014), Vol. 13: 49-55.

People with One High-Risk Condition Should be Prioritized for Access to COVID-19 Vaccines

We appreciate that the ACIP's most recent allocation proposal includes all patients with relevant underlying conditions under Phase 1c rather than recommending to first prioritize people with multiple comorbid conditions for access to a vaccine. We recognize the need for sub-group prioritization due to potentially large demand for early vaccine supplies. However, a focus on multiple conditions neglects other indications of disease severity and vulnerability. We believe that scenario inappropriately disadvantages someone who should be prioritized for early access to a vaccine, including patients with CF with advanced disease or post-transplant.

For instance, someone with cystic fibrosis who received a double lung transplant is especially vulnerable to complications from COVID-19, as they are taking medication to suppress their immune system. Those with advanced disease or CF-related diabetes may also be particularly vulnerable. However, under an allocation scheme prioritizing those with two or more high-risk comorbid conditions according to the CDC, such individuals may receive a vaccine after someone with a body mass index above 30 and COPD. We believe that scenario inappropriately disadvantages someone who should be prioritized for early access to a vaccine, and we recommend avoiding any criteria related to multiple conditions in the ACIP's allocation recommendations.

Public Health Agencies Should Collect Data on Vaccine Safety Issues and Benefits in Specific Disease Populations

Ongoing data collection and public communication on safety and efficacy will be critical for COVID-19 vaccination efforts, including data collection for specific disease populations. Especially for people with rare diseases, it is unlikely there will be data on the specific risks or benefits for them at the time of authorization or approval for any given COVID-19 vaccine candidate. Therefore, it is critical that public health agencies have ongoing monitoring and regular communication about adverse events and efficacy so clinicians and patients can understand the risks and benefits of a vaccine for different populations. We urge the ACIP to recommend that CDC and the Food and Drug Administration track this information for specific disease groups, including rare diseases, so patients can have the most accurate picture possible about the relative safety and efficacy of a COVID-19 vaccine for people with their condition.

All Vaccine Development Data Should be Transparent and Accessible

We encourage the ACIP to emphasize the need for regularly updated transparent and accessible vaccine safety and efficacy data for any COVID-19 vaccine so health care providers can understand the risks and benefits for their patients at the time of authorization or approval. Clinical experts and trusted public health sources will be expected to communicate information on available COVID-19 vaccines and make recommendations to unique patient communities on appropriate use and risks. For clinicians to understand and communicate the full scope of benefits and risks associated with any early COVID-19 vaccine candidate, data from pre-clinical and clinical testing as well as ongoing safety surveillance must be made available to the public in a timely manner. It is also important to note that peer review can help ensure data quality and increase public confidence in COVID-19 vaccine candidates. We appreciate the committee's extensive discussions about the importance of clear, consistent public communications and urge the committee to specify the importance of continuing efforts to make updated data on vaccine safety and efficacy publicly available.

Vaccine Distribution Programs Should Leverage Specialized Provider Networks

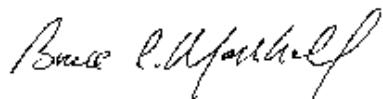
Specialty providers, such as the CF care center network, can help overcome some of the onerous implementation challenges associated with COVID-19 allocation plans. Under the allocation prioritization proposal being considered by the committee, individuals will need to prove the existence of a qualifying medical condition, place of employment, or living situation—among other criteria that would make them eligible for early vaccine access. Operationalizing an allocation plan will be immensely challenging, and we recognize the nearly impossible task that was assigned to this committee. As this committee and other decisionmakers consider how to implement a vaccine allocation plan that prioritizes certain populations, we encourage leveraging specialty providers to help ensure that vaccines get to the right people at the right time.

COVID-19 Vaccines Must Be Affordable for All

Finally, it is essential that decisionmakers ensure health plans and public programs provide access to approved COVID-19 vaccines without cost-sharing to patients. Ensuring access to COVID-19 vaccines will be critical for encouraging vaccine uptake and ultimately halting the COVID-19 pandemic. As we continue to press forward with development of multiple vaccine candidates, it is essential that decisionmakers engage with payors early and often to ensure costs do not serve as a barrier to COVID-19 vaccination efforts.

Once again, we thank you for your attention and consideration of people with cystic fibrosis as you tackle these critical 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,



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