



September 4, 2020

National Academies of Sciences, Engineering, and Medicine
Committee on Equitable Allocation of Vaccine for the Novel Coronavirus
500 Fifth St., N.W.
Washington, D.C. 20001

Re: Discussion Draft of the Preliminary Framework for Equitable Allocation of COVID-19 Vaccine

Dear committee members:

On behalf of the Cystic Fibrosis Foundation, thank you for the opportunity to comment on your *Discussion Draft of the Preliminary Framework for Equitable Allocation of COVID-19 Vaccine*. We appreciate the committee's recommendation to prioritize access for high-risk populations, including those with cystic fibrosis. However, because of the multi-system manifestations of this genetic disease and risks associated with respiratory infections, we urge the committee to include people with cystic fibrosis in phase 1b. We also recommend removing the requirement to have two or more comorbid conditions for phase 1b to ensure early vaccine access for immunosuppressed post-transplant patients. We share these and other comments below, and hope to partner with the committee as work continues 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 approximately 35,000 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, and people with CF should be considered at increased risk of poor outcomes from COVID-19 infection.

People with Cystic Fibrosis Should be Included in Phase 1B

We appreciate that the committee’s framework prioritizes people at increased risk of severe disease from COVID-19 for early access to a vaccine; however, we urge the committee to revise its recommendations to include people with cystic fibrosis in phase 1b.

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 forthcoming global analysis of 181 COVID-19 cases among people with CF. From that analysis, it appears CF patients with advanced lung disease, those that are post-lung transplantation, and those with diabetes mellitus are at risk of severe outcomes, including death. We recognize the committee used the CDC’s designations as the basis of its allocation scheme and in the case of cystic fibrosis, we believe this designation may mischaracterize the true risk for some people living with the disease.

Instead, we recommend the committee include people with cystic fibrosis in phase 1b, along with those at significantly higher-risk of severe disease due to COVID-19. 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.¹ 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.² Moreover, as a multi-system condition, cystic fibrosis itself can represent 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 significant risk.

People with One High-Risk Condition Should be Included in Phase 1b

We recommend the committee give equal priority to anyone with a condition that puts them at high-risk for severe disease from COVID-19 in phase 1b. We recognize the committee proposes including people with two or more comorbid conditions in this phase because of concerns about the number of people included in the CDC’s list. However, a focus on multiple conditions neglects other indications of disease severity or vulnerability. 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. However, under the scheme proposed by this committee, such individuals would 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 removing the criteria related to multiple conditions.

¹ 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.

² 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.

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

While we were pleased to see the committee’s discussion about the need for ongoing data collection and public communication on safety and efficacy, it is important to collect this information for specific disease states. 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 a vaccine approval. Therefore, as the committee notes in its report, 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 committee 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 committee to emphasize the need for transparent and accessible pre-clinical and clinical trial data for any COVID-19 vaccine so health care providers can understand the risks and benefits for their patients at the time of 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 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 discussion about the importance of clear, consistent public communications and urge the committee to specify the importance of publicly available pre-clinical and clinical trial data.

Vaccine Distribution Programs Should Leverage Specialized Provider Networks

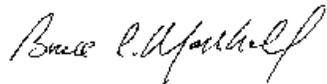
Specialty providers, such as the CF care center network, can help overcome some of the onerous implementation challenges associated with the committee’s allocation plan. Under this framework, individuals will need to prove the existence of a qualifying medical condition, place of employment, or living situation—among other criteria that would make them eligible for early vaccine access. Operationalizing this plan is 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 them to leverage specialty providers to help ensure that vaccines get to the right people at the right time.

COVID-19 Vaccines Must Be Affordable for All

We appreciate the discussion about the importance of providing vaccines without cost-sharing. 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 health plans and public programs provide access to approved COVID-19 vaccines without cost-sharing.

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 committee'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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