



December 11, 2020

Ms. Shiela Hogan
Director, Montana Department of Public Health and Human Services

Sent electronically to: sheilahogan@mt.gov

Dear Director Hogan,

On behalf of the approximately 130 people living with cystic fibrosis in Montana we write today to comment on the state's plans to allocate and distribute COVID-19 vaccines. 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 that the Montana Department of Public Health and Human Services (DPHHS) has taken steps toward creating plans for allocating limited supplies of COVID-19 vaccines to Montana residents.

Our comments below call on the Department to ensure individuals with serious underlying health conditions are prioritized for access to COVID-19 vaccines, including those living with cystic fibrosis, and encourage the use of specialty providers to help ensure that vaccines get to the right people at the right time.

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; one study found that sixty-five percent of pulmonary exacerbations among people with CF were associated with viral infections.¹

With continued progression 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.

Individuals with High-Risk Conditions Must Be Prioritized for Access to COVID-19 Vaccines

A number of stakeholders at the national level, including the National Academy of Medicine and the Centers for Disease Control and Prevention (CDC) Advisory Committee on Immunization Practices, have identified those at higher risk for severe morbidity and mortality due to COVID-19 as needing to be considered for prioritized access to COVID-19

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.

vaccines. We urge Montana DPHHS to take into account the work of the CDC in identifying those likely to be at increased risk of COVID-19 – including those living with CF.

Due to the heightened life-long risk of infections described above, the CDC has included cystic fibrosis on the list of conditions that may cause people to be at increased risk for severe illness from COVID-19.² 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. Certain patients with CF, such as those living with advanced disease or who are post-transplant, may be especially vulnerable.³ Any COVID-19 vaccine allocation guideline should ensure that vulnerable patient populations with high-risk conditions, such as those living with CF, receive prioritized access to COVID-19 vaccines.

COVID-19 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 vaccine allocation plans. Individuals will likely 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. As decisionmakers in the state 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.

State COVID-19 vaccine allocation plans that are transparent and ensure equitable access to vaccines are an important tool for supporting vulnerable patient populations and care providers in this difficult time. 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: Governor Steve Bullock

² https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fneed-extra-precautions%2Fgroups-at-higher-risk.html

³ Cosgriff, Rebecca et al. “The global impact of SARS-CoV-2 in 181 people with cystic fibrosis.” *Journal of Cystic Fibrosis* (2020), in press.