



March 5, 2021

Dannette Smith
Chief Executive Officer
Nebraska Department of Health and Human Services
301 Centennial Mall South,
Lincoln, Nebraska 68509

Dear Dannette Smith:

On behalf of the approximately 270 people living with cystic fibrosis in Nebraska, 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. 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. However, we are deeply concerned by the state's decision to move to age-based distribution, which deprioritizes people with CF and others with high-risk medical conditions and conflicts with the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) recommendations on vaccine allocation.¹

Our comments below urge the state to immediately revise its vaccine prioritization plan to ensure those with CF and other high-risk medical conditions are prioritized for access to COVID-19 vaccines in accordance with the CDC's recommendations.

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. 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.

¹ <https://dhhs.ne.gov/Pages/COVID-19-Vaccine-Information.aspx>

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 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 CDC has listed CF as a condition that may put individuals at increased risk for worse outcomes.³

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

We are deeply concerned by the state’s decision to move to age-based vaccine distribution, which deprioritizes younger individuals with high-risk conditions such as CF. We urge you not to override the allocation recommendations put forth by the ACIP,⁴ which call for prioritizing individuals with high-risk conditions, such as those with CF, for early vaccine access.

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 40.⁵ Using age-based distribution alone to define prioritized populations will result in people with CF who are vulnerable to worse outcomes from COVID-19 getting vaccinated after older, healthier adults simply because those with CF have a shorter life expectancy.

The state’s age-based vaccine allocation plan abandons the carefully crafted recommendations finalized by the ACIP in December, which the committee reaffirmed earlier this week. These recommendations are the result of months of thoughtful deliberation by vaccine and public health experts and input from thousands of stakeholders. 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 ACIP’s process has included 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.⁶ 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.⁷ Together, these recommendations support prioritized vaccine access for people with CF and

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

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

⁴ <https://www.cdc.gov/vaccines/covid-19/phased-implementation.html>

⁵ <https://www.cff.org/Research/Researcher-Resources/Patient-Registry/2019-Patient-Registry-Annual-Data-Report.pdf>

⁶ <https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html>

⁷ <https://www.cdc.gov/vaccines/covid-19/phased-implementation.html>

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 the state to follow the ACIP's vaccine allocation recommendations, 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. The state's COVID-19 vaccine prioritization plan should be revised to ensure people with CF and other high-risk conditions at increased risk of worse outcomes from COVID-19 infection are able to get vaccinated as early as possible.

Once again, we thank you for your attention and consideration of people with CF as you tackle these difficult issues. 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

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CC: The Honorable Pete Ricketts, Governor of Nebraska