October 15, 2020

Alyson Capp, PhD  Rajiv Naik, MD
Co-Chair, Ethics Subcommittee  Co-Chair, Ethics Subcommittee
State Disaster Medical Advisory Committee  State Disaster Medical Advisory Committee
Wisconsin Department of Health Services  Wisconsin Department of Health Services
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Submitted electronically at: DHSSDMAC@dhs.wisconsin.gov

Re: DRAFT Ethical Framework to Guide the Allocation of COVID-19 Therapeutics and Vaccines

Dear Drs. Capp and Naik,

On behalf of those living with cystic fibrosis in Wisconsin, I write to comment on the Draft Ethical Framework to Guide the Allocation of COVID-19 Therapeutics and Vaccines.¹ We recognize the monumentally difficult task public health officials face when creating allocation guidelines that are both equitable and actionable during this crisis, and we appreciate that the state of Wisconsin has taken steps toward creating principles for allocating COVID-19 vaccines and therapeutics that will aid decisionmakers and care providers during the current COVID-19 pandemic.

Our comments below call on the State Disaster Medical Advisory Committee Ethics Subcommittee to ensure individuals with serious underlying health conditions are prioritized for access to COVID-19 vaccines – including those living with cystic fibrosis; to encourage dedicating resources for gathering data on specific populations with underlying conditions to guide allocation and vaccination decisions; and to leverage 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 approximately 35,000 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

¹ https://publicmeetings.wi.gov/download-attachment/3e667bb6-731c-4c8a-aea7-9e060c610728
found that sixty-five percent of pulmonary exacerbations among people with CF were associated with viral infections.\(^2\)

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, 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**

We appreciate that the subcommittee 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 vaccines, and we urge the committee to take into account the work of the Centers for Disease Control and Prevention (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.\(^3\) 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. 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.

**Public Health Agencies Should Collect Disease Specific Data on COVID-19 Vaccine Safety and Benefits**

We were pleased to see the subcommittee recommend dedicating resources to ensure that data needed to make resource allocation decisions is made available and updated regularly, and we encourage the subcommittee to go further and specify that data on specific populations with underlying health conditions should be made available to allocation decisionmakers as well as the public. 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 COVID-19 vaccine approval. Therefore, it is critical that decisionmakers have access to the most up-to-date data on different populations as allocation decisions are being made, and that such information is also made available to the public to guide clinician and patient decisions.

**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. Under this framework,

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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.

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State COVID-19 therapeutic and vaccine allocation guidelines that are transparent and ensure equitable access to scarce resources are an important tool for supporting patients and care providers in this difficult time, and we appreciate Wisconsin’s commitment to equity and fairness in this allocation framework. We look forward to working with you as the state continues to revise and develop further allocation recommendations for COVID-19 vaccines and treatments.

Sincerely,

[Signature]

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