



March 17, 2021

Rochelle Walensky, MD, MPH Director, Centers for Disease Control and Prevention 1600 Clifton Road Atlanta, GA 30329

Dear Director Walensky:

On behalf of the Cystic Fibrosis Foundation, the International Society for Heart and Lung Transplantation, and the below signed members of the Cystic Fibrosis Lung Transplant Consortium, we write in response to the Centers for Disease Control and Prevention (CDC) Interim Public Health Recommendations for Fully Vaccinated People.¹

We urge the CDC to provide further clarity, specificity, and increased prominence in recommendations for vaccinated individuals who are immunocompromised. We appreciate the importance of this guidance in providing much-needed direction to those who are fully vaccinated on what public health measures can be eased at this time. However, we are deeply concerned that the guidance does not clearly reflect the unique circumstances of those who are immunocompromised and their greater risk of not mounting an adequate immune response to vaccination, including those who have received a solid organ transplant.

<u>Fully vaccinated individuals with immunocompromising conditions need clear guidance on the importance of continuing protective behaviors</u>

We appreciate that the CDC has included a recommendation that fully vaccinated individuals with immunocompromising conditions discuss their individual circumstances with their care provider. However, the statement provided in the CDC's recommendations fails to clearly and adequately reflect the importance of continued protective behaviors for these individuals in the absence of widespread COVID-19 vaccination and herd immunity. We are additionally concerned that this limited acknowledgement that individual circumstances may impact recommendations about public health measures is not given appropriate prominence in the CDC's recent guidance.

COVID-19 represents a serious threat for this population. Over 260 people with CF received transplants in 2019, the majority of which were lung transplants.² Results from a published global analysis of 181 COVID-19 cases among people with CF indicate that individuals who are post-lung transplantation may be at risk of severe outcomes including death.³ As such, COVID-19 vaccines are an important addition to

¹ https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated-guidance.html

² https://www.cff.org/Research/Researcher-Resources/Patient-Registry/2019-Patient-Registry-Annual-Data-Report.pdf

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

the protective measures needed to reduce the risk posed by the virus for transplant recipients and other immunocompromised individuals.

We know that individuals who are immunocompromised, including those who have received a solid organ transplant, do not tend to mount as robust a response to vaccines compared to those without such conditions. For example, the standard dose influenza vaccine elicits less of an immune response in transplant recipients compared to others. Data on immunogenicity of COVID-19 vaccines in immunocompromised individuals is still limited at this time. However, a recently published study of 436 transplant recipients found that the immune response following the first dose of an mRNA COVID-19 vaccine appears to be significantly dampened compared to those who participated in clinical trials for the FDA-authorized COVID-19 vaccines. Of note, individuals receiving antimetabolite maintenance immunosuppression therapy, which is commonly used in lung transplantation, were even less likely to mount an antibody response.

We believe it is necessary for the CDC to urge caution at this time for solid organ transplant recipients on immunosuppression given that currently available data and experience with other vaccines indicates that COVID-19 vaccines may not provide the same level of protection for these individuals. Clear guidance for immunocompromised patients should be featured prominently to ensure that information on appropriate protective behaviors reaches this vulnerable population.

Once again, we urge the CDC to further clarify, specify, and increase the prominence of recommendations for individuals with immunocompromising conditions. We thank you for your attention and consideration of transplant recipients as you tackle these difficult issues around evolving public health recommendations. We are happy to serve as a resource and stand ready to work alongside the CDC in this endeavor.

Sincerely,

Mary Dwight

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⁴ Natori, Yoichiro et al. "A double-blind, randomized trial of high-dose vs standard-dose influenza vaccine in adult solid-organ transplant recipients." *Clinical Infectious Diseases* (2018), 66(11), 1698-1704. doi: 10.1093/cid/cix1082

⁵ Boyarsky, Brian et al. "Immunogenicity of a single dose of SARS-CoV-2 messenger RNA vaccine in solid organ transplant recipients." *JAMA* (2021), Published online March 15, 2021. doi:10.1001/jama.2021.4385

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