![Cystic Fibrosis Foundation logo]

October 1, 2020

Erika Lease, MD
Chair, Lung Transplantation Committee
Organ Procurement and Transplantation Network
United Network for Organ Sharing
700 N 4th Street
Richmond, VA 23219

RE: Update on the Continuous Distribution of Organs Project

Submitted electronically at optn.transplant.hrsa.gov.

Dear Dr. Lease:

On behalf of the Cystic Fibrosis Foundation and the below signed individuals of the CF Lung Transplant Consortium, we write in response to the OPTN/UNOS Public Comment Proposal, *Update on the Continuous Distribution of Organs Project*.

UNOS Must Revise the Benefit Component
One-year survival rate alone does not accurately reflect how beneficial a transplant is for any given patient. It is unlikely that people undergo lung transplantation with the aim of only surviving for one year. Instead, we should be using endpoints that are more reflective of transplant success and patient wishes. It is critical that the inputs used in the continuous distribution algorithm are as appropriately reflective as possible in measuring the factors they are designed to assess. We therefore urge UNOS to move away from use of one-year survival to either three- or five-year survival at this time.

We recognize that using long-term survival measures in place of one-year survival introduces more uncertainty in the model given that predictability of survival decreases the further out a patient is from the time of transplant. UNOS should therefore consider whether incorporating age as a predictor for transplant outcomes can be used as a proxy for long-term survival. The data demonstrating that post-transplant survival decreases with older age is compelling.[1] Providing a similar benefit score to individuals where long-term survival is likely similar based on age may provide a more reliable measure for the benefit an individual is likely to receive from a transplant. This measure could be used in concert with other measures of survival.

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[1] Lehr, Carli J. et al. " Extremes of Age Decrease Survival in Adults After Lung Transplant." *CHEST* (2019), Vol. 157: 907-915.

Long-term Survival Should Be Given the Most Weight in a Composite Score
Finally, in terms of weighting different categories of attributes based on importance, we believe long-term post-transplant survival is of highest importance in determining allocation of donor organs. As stated above, we believe that long-term post-transplant survival is a stronger measure for transplant benefit compared with one-year survival and urge UNOS to pursue this change in conjunction with the move to continuous distribution. Long-term survival additionally supports the goal of ensuring fair innings for transplant candidates. Following long-term survival, candidate biology and patient access should be considered given the importance of improving access for otherwise difficult-to-match patients. Placement efficiency should have the least bearing on a person's prioritization for a given donor organ.

Continuous Distribution Has the Potential to Improve Patient Access
We are supportive of UNOS's aim to move to a continuous distribution framework for organ allocation, and we believe the strength of this model lies in its flexibility. With the shift to continuous distribution, UNOS has the opportunity to improve upon accommodations for individuals who are medically harder to match or have other special considerations with bearing on access. The challenge with this model will be successfully identifying appropriate factors and their weights for inclusion in the final allocation system.

We feel the categories of attributes identified by UNOS included the most recent update to the continuous distribution project are appropriate. In particular, we are pleased to see that UNOS has included sensitization and candidate height as attributes for candidate biology in order to address certain patient access challenges. We additionally appreciate that UNOS has ruled out the use of ischemic time as an attribute for placement efficiency. While we believe it is reasonable to include a placement efficiency score as a component of the model, ischemic time is not a valuable measure for efficiency of organ placement.

UNOS should further consider adding multi-organ transplant as an attribute under the candidate biology category in order to improve access to needed donor organs for this vulnerable patient population. The present allocation system has failed to adequately address the needs of this population, and UNOS should take this opportunity to improve access to multi-organ transplants. We are aware that UNOS is working on a project to look at the needs of multi-organ transplant candidates at this time, and we look forward to seeing this work reflected in future iterations of the continuous distribution project.

Background on Cystic Fibrosis and the Foundation
Cystic fibrosis (CF) is a rare genetic disease that affects over 30,000 people in the United States. In people with CF, a defective gene causes a thick buildup of mucus in the lungs, pancreas and other organs. In the lungs, the mucus obstructs the airways and traps bacteria leading to infections, extensive lung damage and eventually, respiratory failure. Over 280 people with CF received transplants in 2018, the majority of which were lung transplants. However, some people with CF also may require liver or kidney transplants due to the disease.

In order to address the needs of people with CF living with advanced lung disease, as well as those considering transplant, the CF Foundation launched the Lung Transplant Initiative in 2016. Through this initiative, the Foundation is working to improve and standardize the care received by people with CF for whom transplant is an option and to find solutions to barriers that may adversely impact a person with CF's chance of receiving a donor organ.

Conclusion

We believe the continuous distribution framework has the potential to best address the need to appropriately weigh meaningful factors in organ allocation as proposed, and we are pleased to see UNOS moving forward with this model. We hope to see UNOS be receptive and adaptable in responding to data and making necessary changes in the future in order to get the most benefit out of the shift to continuous distribution.

We are happy to serve as a resource and look forward to working alongside OPTN/UNOS in the future on this issue.

Sincerely,

Albert Faro, MD
Vice President, Clinical Affairs
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