

October 2, 2019

Submitted electronically at <https://optn.transplant.hrsa.gov/>

On behalf of the Cystic Fibrosis Foundation (CFF) and the below signed individuals of the CF Lung Transplant Consortium, we write in response to the OPTN/UNOS Public Comment Proposal, *Continuous Distribution of Lungs Concept Paper*.

Cystic fibrosis (CF) is a rare genetic disease that affects over 30,000 people in the United States. Over 250 people with CF received transplants in 2017, the majority of which were lung transplants. However, some people with CF also may require liver or kidney transplants due to the disease.

As we have previously stated, we ask that UNOS and all transplant providers remain focused on what matters most: the people on the waitlist. They deserve an allocation scheme that aspires to reduce waitlist mortality to zero, transplants the most medically urgent, minimizes the risk of post-transplant complications, and does so in a resource efficient manner.

Determining the appropriate measures and weights for a continuous distribution framework is critical to ensuring an equitable allocation policy. We offer a number of thoughts below for UNOS to consider as it continues to assess the continuous distribution framework approach and works towards creating a model appropriate for all organ types.

Overall, we believe if these concerns are addressed thoughtfully, UNOS' proposed move from a classification-based system with hard boundaries and inflexible rules to a point-based system using a continuous distribution framework has the potential to improve organ allocation while honoring the intent of the OPTN Final Rule.

Benefits of Selecting the Continuous Distribution Framework

We were pleased to see that UNOS chose to move forward with the continuous distribution model for all organ types. A continuous distribution scheme has the best potential to balance the use of proximity with medical urgency along with additional factors in order to minimize the role of geography in determining transplant recipients. The strength of this model lies in its flexibility, and it should be capable of accommodating special considerations for different organ types. The challenge with this model will be successfully identifying appropriate factors and their weights for inclusion in the final allocation system.

UNOS will need to be flexible as the organization advances continuous distribution in lung allocation. As new information on the application and impacts of different metrics become available, UNOS will need to revise the scheme to improve the system to best serve patients in need of a transplant. Additionally, UNOS should be mindful that modifications to the framework will also likely be needed in the future as technology (for example ex vivo lung perfusion) or patient populations change over time. We would like to see UNOS be far more

receptive and adaptable in responding to data and making necessary changes than the organization has historically been.

Flaws in the Lung Allocation Score (LAS) Must Be Addressed

It is critical that all inputs used in the allocation algorithm are reflective of the outcomes we aim to achieve. Medical priority is a key variable in the allocation process – how urgent a patient’s condition is and how likely they are to benefit from a transplant should be the primary considerations for any organ allocation scheme.

As transplant allocation shifts towards an individualized approach where pertinent details about a patients’ circumstances are accounted for, medical urgency scores – including the Lung Allocation Score (LAS) – should shift with it. Medical priority scores that are more attuned to a patient’s specific circumstances will give more accurate predictions of urgency and waitlist mortality.

Therefore, we strongly believe that revisions to the LAS should be made in conjunction with the development of the new model. With reasonable updates, the LAS would be better situated to predict the risk of mortality on the waitlist, which would in turn would make the model a more useful tool and accomplish the goals set out in the Final Rule.

We understand that the Committee’s priority at this time is devising an allocation scheme that removes the use of arbitrary measures like geographic boundaries. However, the LAS is so critical to the organ allocation process that the Committee would be remiss in not making some necessary updates to it if it is to be used as a core measure in this new model.

UNOS in the past has promised to be flexible with the LAS and adapt to new information. However, LAS reforms remain minimal despite evidence that further adjustments are needed to decrease waitlist mortality and reduce arbitrary biases in the existing scoring system.

Recently, a paper published using merged data from the Scientific Registry of Transplant Recipients and the CF Foundation’s patient registry demonstrated that the LAS fails to account for critical variables reflecting waitlist mortality for individuals with CF and COPD.¹ This data demonstrates that the LAS, as it stands, does not identify those most likely to benefit from transplant.

If UNOS fails to address flaws in the existing LAS, it will do a great disservice to those patients who are dying unnecessarily while awaiting transplant. Decreasing waitlist mortality should not be sacrificed in the name of expedited geographic distribution reform; UNOS should take the time to devise a new allocation system that addresses the needs of *all* patients on the waitlist.

¹ <https://www.ncbi.nlm.nih.gov/pubmed/31199166> accessed 9/27/2019.

Further Factors to Consider

As the Thoracic Committee proceeds with evaluation of the continuous distribution model, there are several considerations we would like to share on potential factors being considered for a revised allocation system.

Placement Efficiency Score

We believe it is reasonable to include a placement efficiency score as a component of the model. Our opinion is that ischemic time is not a valuable measure for efficiency of organ placement. Instead, the committee will need to carefully consider what measures best serve as proxies for placement efficiency. Both the time and method of transportation are important factors for efficiency of placement. While cost should never be the foremost driver for match decisions, we cannot ignore the reality that transportation methods come with different costs. Resource use is inherently tied to the sustainability of the organ transplant system as a whole. UNOS must carefully weigh all options for efficiency measures and be exceptionally thoughtful in considering the value of efficiency scores in the overall model.

Revised Benefit Component

One-year survival rate alone does not accurately reflect the benefit of transplantation for any given patient. It is unlikely that people undergo lung transplantation with the aim of only surviving for one year. Instead, important benefits such as disease burden, quality of life and long-term survival should be better reflected in any measure of benefit used in a revised allocation system. We suggest UNOS consider additional measures, including three- or five-year outcomes, as endpoints that are more reflective of success and patient wishes. Additionally, UNOS should consider how the revised system can serve to collect additional relevant data on patient benefit, such as Patient Reported Outcome (PRO) scores or number of hospitalizations, to help develop a more robust understanding of meaningful measures of patient benefit.

Including Factors that Impact Access

Measures that reflect patient access to transplant should be considered. In particular, special measures to help transplant candidates who may face more barriers to matching in the current system, such as those who are highly sensitized or individuals with short stature, should be devised and assessed.

More information is needed to better characterize the highly sensitized lung transplant recipient. The committee should consider methods to collect more granular data on these patients. We could similarly benefit from more robust data collection on the impact of short stature on access to transplant. While there is evidence to support that short stature reduces an individual's chance to match, more information is needed to assess what measures could be included to counteract the disadvantages experienced by these individuals during the match process.

The committee should also begin to think about how continuous distribution for all organ systems will impact a person's ability to receive a multi-organ transplant. The present allocation

system has failed to adequately address the needs of this vulnerable patient population. UNOS should take this opportunity to fully address this issue.

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. However, we are concerned that maintaining a singular focus on this model without simultaneously addressing arbitrary measures and biases in the LAS will be a major disservice to patients on the waitlist.

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
Senior Director, Clinical Affairs
Cystic Fibrosis Foundation

CF Lung Transplant Consortium Members

Jason Christie, MD, MS
Penn Medicine

Joseph Pilewski, MD
University of Pittsburgh Medical Center

Elliott Dasenbrook, MD, MHS
Cleveland Clinic

Kathleen Ramos, MD, MSc
University of Washington, Seattle

Joshua Diamond, MD, MSCE
Hospital of the University of Pennsylvania

Pali Shah, MD
Johns Hopkins

Ramsey Hachem, MD
Washington University School of Medicine

Laurie Snyder, MD, MHS
Duke University School of Medicine

Marshall Hertz, MD
University of Minnesota

Stuart Sweet, MD, PhD
*Washington University School of Medicine
in St. Louis*

Erin Lowery, MD, MS
Loyola University Medical Center