



October 3, 2018

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On behalf of the Cystic Fibrosis Foundation (CFF), we write in response to the OPTN/UNOS Public Comment Proposal, *Frameworks for Organ Distribution*.

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 an appropriate geographic framework that minimizes the impact of arbitrary barriers while maintaining donor organ viability and reasonable resource use is critical to ensuring an equitable allocation policy. We offer a number of issues below for UNOS to consider as it continues to assess geographic frameworks appropriate for all organ types.

Overall, we believe if these concerns are addressed thoughtfully, UNOS' proposed continuous distribution framework will best address appropriate use of geographic consideration in organ allocation while honoring the intent of the OPTN Final Rule.

Benefits of Selecting the Continuous Distribution Framework

The continuous distribution framework appears to be the best candidate for eliminating the use of arbitrary boundaries in determining appropriate recipients for available organs. This framework has the best potential to balance the use of proximity with medical urgency in order to minimize the role of geography in determining transplant recipients. It is critical that this model be built to account for the fact that transport time plays a role in the viability of the donor organ and the safety of the transplant procedure.

A strong reason for our preference for the continuous distribution framework is that among the proposed models, it is the most flexible option. In looking for a geographic framework that can be used across organ types, it is important to identify a framework nimble enough to accommodate special considerations for different organ types such as different medical urgency scoring systems, factors like cold ischemic time, and the need for modifications to the framework as technology or patient populations change over time. The continuous distribution framework can be adjusted by changing the factors included in the allocation assessment as well as the weighting of those factors.

Assessing Factors Used in the Continuous Distribution Framework

The design details of the adopted geographic framework are incredibly important, especially in the continuous distribution framework where the inappropriate weighting of factors may adversely impact donor organ allocations and recipient outcomes. Robust modeling is required to fully evaluate how allocation outcomes may change and whether those changes reflect overall improvements to the system.

Measuring proximity between donor and recipient

UNOS should carefully consider how it will measure proximity between donor organ and recipient. We ask that UNOS consider the benefits and feasibility of using travel time versus travel distance as a factor in the continuous distribution framework. Travel time may more accurately account for natural barriers, transportation infrastructure, population density, etc. in determining the resources and time needed to transport a donor organ to a recipient. We request that UNOS assess the feasibility and benefits of different measures of proximity as they continue to assess geographic distribution frameworks.

Considerations Regarding Clinically Similar Medical Urgency Scores and Proximity

We applaud the Committee's consideration of the issues raised by geographic "cliffs" in the zone model for individuals with the same medical urgency score as it is presented on page six of the proposal. This is an important equity issue that optimally will be addressed by the Committee's chosen geographic framework. However, we believe the Committee also needs to consider a related problem: addressing cases where individuals with clinically similar medical urgency scores have vastly different proximities to the donor organ.

In response to the OPTN/UNOS Public Comment Proposal, *Modifications to the Distribution of Deceased Donor Lungs*, we proposed the creation of a tiered allocation scoring system for transplant recipients in an effort to reduce undervaluing of geographic location. We believe it is important to ensure that organs are allocated at greater distances only when the difference in medical urgency score meets a defined minimum threshold between a local recipient and a regional recipient to utilize available organs and other resources in an efficient and equitable manner.

For example, under the current lung allocation system a patient with a lung allocation score (LAS) of 51 located 249 miles away from the donor organ would be prioritized over a patient with an LAS of 50 who is located in the same hospital as the donor. Small differences in LAS do not necessarily reflect a substantive difference in medical urgency between patients. An equitable allocation system should strive to reduce discard rates and resource use in cases such as the example mentioned above.

Conclusion

We believe the continuous distribution framework has the potential to best address the need to appropriately weigh geographic considerations in organ allocation. This framework is consistent with the OPTN's Final Rule, which requires the implementation of policies that prioritize medically urgent cases over as broad a geographic area as feasible. It can achieve this goal by weighing geographic location in balance with medical urgency without using arbitrary borders to determine a patient's location. However, we believe further assessment of the continuous distribution framework is needed.

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, M.D.

Handwritten signature of Albert Faro in black ink, featuring a stylized 'A' and 'F'.

Senior Director of Clinical Affairs
Cystic Fibrosis Foundation

Mary Dwight

Handwritten signature of Mary Dwight in black ink, featuring a stylized 'M' and 'D'.

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