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On behalf of the Cystic Fibrosis Foundation (CFF), we write in response to the OPTN/UNOS Public Comment Proposal, Modifications to the Distribution of Deceased Donor Lungs. CFF commends the OPTN/UNOS Executive Committee for addressing the issue of geographic disparity in lung allocation. The cystic fibrosis (CF) community feels a great sense of urgency around this issue on behalf of people with CF who are awaiting lung transplants.

First and foremost, 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.

Developing an allocation scheme that prioritizes the most appropriate recipient when an organ becomes available without substantially jeopardizing the viability of the organ or creating unacceptable barriers to getting the organ to the appropriate person is a challenging task. We offer a number of considerations below for UNOS to think about in developing its final policy.

Overall, we believe if these concerns are addressed thoughtfully, UNOS’ proposed expansion of the radius of initial distribution of donor lungs to 500 nautical miles (NM), based on the modeling that has been done so far, would provide the most benefit to the patients most in need and minimize waitlist mortality. We also propose a modification to the policy to a tiered LAS system which is described further below.

Identifying the most appropriate recipient of a donor lung
As an initial matter, a system to allocate donor lungs should start by identifying the most appropriate recipient. We believe the following factors should be considered in doing so:

1. The lung allocation score should accurately reflect mortality on the wait list (medical urgency) as well as longer term survival rather than one-year survival alone. We also ask that UNOS continue to monitor the present scoring system recognizing that it must continue to evolve in a timely fashion.
2. The allocation system should acknowledge the likelihood that a difference of one or two points in the lung allocation score is unlikely to yield significant differences in risk of waitlist mortality.
**Considerations for making geographic distribution equitable**

When addressing geographic distribution, several factors must be weighed including balancing medical urgency with the potential consequences of accepting organs that are an extended distance from the transplant center. These potential consequences include not only the impact on the graft and post-transplant outcomes, but also resource utilization and costs associated with sending teams out greater distances. In addition, not incorporating population density and the variability in the performance between OPOs into the equation may lead to inequities in distribution in some areas of the country.

To achieve the goal of providing more equity in access to transplantation regardless of a candidate’s geography, we request that the OPTN consider the following:

1. Candidates with highest risk of mortality on the waiting list should be prioritized—we believe that the proposal does this by prioritizing candidates with the highest LAS.
2. Provide priority for candidates with unique characteristics that may adversely impact their access to transplant (e.g., sensitized candidates, and dual organ candidates).
3. Preserving organ viability and minimizing discard rates—as noted above, if organs are routinely travelling longer distances to reach patients with a higher LAS, there may be an unintended consequence that fewer organs are viable and a higher number are discarded. We recommend that UNOS watch this issue carefully through interim monitoring of data under the current allocation system.
4. Population density—the present allocation system does not account for the unique circumstances of very low-population density and high-population density areas of the country. Consideration should be given to how to allocate organs equitably in these areas.
5. Variability between organ procurement organizations (OPO) in organ conversion rates—similar to population density, consideration should be given to the differences between OPO performance in designing the final system.
6. Efficient use of resources—while we support the wider geographic distribution of lungs, we must acknowledge that if donor organs are routinely being transported much greater distances, this will in turn increase the costs and time needed to send transplant recovery teams further distances to retrieve the organs. While considering a greater geographic distribution area, UNOS should also consider the additional resources that correspond to the proposed changes.

**Concerns about delisting**

A potential unintended consequence of the change in geographic distribution may be that candidates will routinely require higher LAS to be transplanted. How will transplant programs react? We know that there are many programs that already routinely transplant patients with a very high LAS, but we also know there are programs that are not as experienced with this higher risk population of patients. We request that UNOS monitor all programs for delisting rates (not including deaths while actively on the waitlist) and make this data, by center, available to the public.

**Proposal to use a tiered LAS system**

Acknowledging that the present scoring system is not perfect allows for a less rigid approach to the allocation and distribution of donor lungs so that patients with the greatest medical need are receiving
the care they deserve while not imposing undue risks or hardships to patients or to transplant resources.

We request that as the data from the current 250 NM approach are analyzed, UNOS and its Thoracic Committee model a system in which potential recipients, based on blood type and size, are stratified into LAS tiers. Under this model, organs would be allocated greater distances only when the difference in LAS meets a defined minimum threshold between a local recipient and a regional recipient. If this is done thoughtfully, an expansion to 500 NM, based on the modeling that has been done so far, would provide the most benefit to the patients most in need and minimize waitlist mortality.

**Conclusion**

In summary, we ask that the OPTN consider implementation of a tiered LAS coupled with a broader geographic system of distribution that takes into account population density and maintains organ viability while minimizing discard rates. We believe that such a model 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. We recognize that all policies have tradeoffs, but we believe that prioritizing the sickest individuals without risking patient outcomes is a best practice for the lung transplant community overall.

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

Sincerely,

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