

Thank you to everyone who attended the Region 8 Winter 2025 meeting. Your participation is critical to the OPTN policy development process.

Regional meeting presentations and materials

## Public comment closes March 19th! Submit your comments

The sentiment and comments will be shared with the sponsoring committees and posted to the OPTN website.

#### Clarify Requirements for Reporting a Potential Disease Transmission

Disease Transmission Advisory Committee

Sentiment: 4 strongly support, 9 support, 0 neutral/abstain, 1 oppose, 0 strongly oppose Comments: Several attendees suggested the committee consider changing the word "sick" to "symptomatic" or using the terms "colonized" versus "infected". Several attendees agreed that it is necessary to establish a specific timeframe to determine when an infection should be considered donor-derived. Another expressed concern that this proposal could lead to potential lung donor rule-outs due to confusion.

#### Escalation of Status for Time on Left Ventricular Assist Device

## **Heart Committee**

Sentiment: 0 strongly support, 8 support, 5 neutral/abstain, 1 oppose, 0 strongly oppose Comments: Regarding implementation time frame, an attendee though it would be reasonable to have it roll out automatically but also monitor data in the interim; in favor of this because the LVADs really are stuck. A member suggested simulated status 2 and 3 numbers – specifically, if there's an escape pathway there might be fewer status 2's done. There was discussion of whether to move these candidates to status 3. And explained it's a balance of not disadvantaging higher risk patients at higher statuses with this policy change, but this has been part of the discussion, and the goal of the monitoring period will be to make sure we don't disadvantage those at higher risk. An attendee pointed out that another aspect of this situation is the candidate's quality of life on an LVAD. They encouraged other to think about whether the device is helping the candidate live the lifestyle the candidate had prior. They explained there are several activities the candidate can't do with a device that they could do with a transplant. Another attendee supported this comment. Another agreed that LVAD patients are likely the most likely to benefit from the transplant, and less time on LVAD is likely best. Several attendees recommended a shorter timeframe for prioritization to status 2/3 for LVAD patients. For status 3, 3-5 years seems reasonable and status 2 closer to 5 years. A member said they are in favor of any changes that will get more people transplanted. The devices were never intended to be a destination for any and all patients.

## **Modify Lung Donor Data Collection**

Lung Committee

Sentiment: 1 strongly support, 7 support, 6 neutral/abstain, 0 oppose, 0 strongly oppose

# **OPTN**

Comments: The region supported this proposal and offered the following feedback. A member explained that as a recipient and doctor they would want to know whether the donor's cigarette use was greater than 20 pack years as that may increase risk of certain cancers. They thought 20 pack years was an acceptable threshold for decision making. An attendee recommended the committee evaluate whether any other data elements can be removed from data collection with this modification request. Others agreed with providing additional information about testing and creating a status that reflects whether it was ordered/pending versus not able to be completed. Another thought it would be interesting to survey lung transplant programs to understand if additional data would be useful in organ acceptance decisions. Lastly, it was pointed out that the efficacy of it would be dependent on if the recipient centers are also using this metric because the comparison cannot be made if they are not. There would also be a concern for human error in the use of the mathematical equations but noted calculator availability via medical education websites.

#### Establish Comprehensive Multi-Organ Allocation Policy

### Ad Hoc Multi-Organ Transplantation Committee

Comments: The region supports the committee's hard work and acknowledged what a complex and tough topic this is. From an OPO perspective, an attendee explained the most important thing is to make sure the final proposal is very clear on who gets the offer over others. And, what happens when an OPO begins allocation, then another organ becomes available that wasn't initially thought to be viable for transplant, and how to incorporate the newly available organ into the allocation. Another member pointed out that he suspects OPOs amount of time they are actively allocating the organs will increase. Others thought this is important work and needs to be implemented as soon as possible. They acknowledge that OPOs are always in the middle of these type of allocations and it's an uncomfortable situation for them be in. A member institution explained this is a very complex solution for a system that already relies on too many human factors to determine methodology for organ allocation. They support a more standardized approach and suggest the committee build a system that eliminates as many human factors as possible and optimizes performance of the allocation process by utilizing technology and machine learning. An attendee commented that they thought it was reasonable to standardize multi organ allocation, with the intention of prioritizing pediatrics, status 1 heart and liver. Another said that standardization of multi-organ allocation is desirable and the framework of the tables presented is transparent.

#### <u>Barriers Related to the Evaluation and Follow-Up of International Living Donors</u>

#### Ad Hoc International Relations Committee

Sentiment: 1 strongly support, 8 support, 4 neutral/abstain, 1 oppose, 0 strongly oppose Comments: The region appreciated the guidance and recommended the committee consider a different approach regarding follow-up for international donors. Specifically, they recommended the committee investigate an approach that decreases the compliance percentage requirements for this population.

#### Monitor Ongoing eGFR Modification Policy Requirements

Minority Affairs Committee

Sentiment: 4 strongly support, 9 support, 1 neutral/abstain, 0 oppose, 0 strongly oppose



Comments: The region supported this proposal and thought it was important to continue and refine the committee's work on this. An attendee asked the committee to re-evaluate the date of January 4, 2024, for notification of all patients added to the waitlist. They requested clarity on whether the transplant centers just need to retroactively notify any patient added to the waitlist since January 4, 2024, that is still on the waitlist; or whether it would be more efficient to set an effective future date. A center explained that while they support this proposal's intent, they have concerns about the growing burden on the transplant programs.

## <u>Updates to National Liver Review Board Guidance and Further Alignment with LI-RADS</u>

Liver & Intestinal Organ Transplantation Committee

Sentiment: 1 strongly support, 11 support, 0 neutral/abstain, 2 oppose, 0 strongly oppose

Comments: No comments

## **Continuous Distribution Updates**

### Continuous Distribution of Kidneys, Winter 2025

Kidney Transplantation Committee

Comments: The region appreciated the update and was supportive of the committee's progress. A member recommended the committee to focus on expedited placement policy prior to moving forward with continuous distribution. They explained the system is increasing the burden on transplant programs to sustain operations in light of increases to costs in travel/transportation, perfusion and preservation devices, and decreases to reimbursement across the system. Additionally, there are major capacity constraints in the health system challenging our ability to increase access for patients requiring end stage disease management and possible organ transplantation. They encouraged the committee to consider lessons learned from lung CAS to determine what changes are needed prior to implementation in other organs. A member thought the data driven definition of hard-to-place kidneys is reasonable and supported it. They also supported prior behavior to determine eligibility in expedited placement, with an option for a program to request an opt-in (i.e. a new surgeon or resources may justify participation without historical behavior).

## Continuous Distribution of Pancreata, Winter 2025

Pancreas Transplantation Committee

Comments: No comments

## **Updates**

#### **Councillor Update**

Comments: No comments

## **OPTN Patient Affairs Committee Update**

 Comments: The region appreciates all the committee does on behalf of patients and donor families.



## **Executive Update**

• Comments: The region appreciated the update and inquired about whether public comment will still be available going forward. It was explained that OPTN public comment is separate from federal agencies' public comment processes.

## **MPSC Update**

Comments: The region appreciated the update and discussed whether the number of
investigations is increasing, associated data for flagging programs, whether this type of analysis
has been performed for the wait list mortality metric, and the timeline for when MPSC future
proposals will be available for public comment.

#### **Feedback Session on OPTN Modernization**

• Comments: Attendees provided feedback to HRSA's Division of Transplantation during this session