

Thank you to everyone who attended the Region 7 Summer 2024 meeting. Your participation is critical to the OPTN policy development process.

Regional meeting <u>presentations and materials</u>

Public comment closes September 24th! Submit your comments

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

Revise Conditions for Access to the OPTN Computer System

Network Operations Oversight Committee

- Sentiment: 3 strongly support, 9 support, 0 neutral/abstain, 0 oppose, 0 strongly oppose
- Comments: Members of the region are supportive of the proposal. A concern was raised about the need to ensure compliance with new federal government policies on reporting cybersecurity breaches, with government agencies actively reviewing to ensure adherence to federal rules. The Data Use Agreement has undergone scrutiny by multiple government agencies, coordinated by HRSA, and OPTN members have been asked to complete security surveys. Another concern was expressed about the potential impact on smaller entities. A suggestion was made to monitor the implementation to ensure that barriers to entry are not disproportionately burdensome for smaller organizations compared to larger ones. There was also a call for implementing these changes in a way that does not create undue obstacles to system access and usage, particularly for smaller entities in the organ donation and transplantation community.

Promote Efficiency of Lung Donor Testing

Lung Transplantation Committee

- Sentiment: 0 strongly support, 7 support, 5 neutral/abstain, 0 oppose, 0 strongly oppose
- Comments: Members of the region expressed concerns about the required testing for DCD (donation after circulatory death) donors, particularly regarding invasive procedures. Several attendees highlighted the difficulties in performing mandatory tests on DCD donors, with specific mention of echocardiograms and right heart catheters. There was a consensus that the policy should be more flexible for DCD cases, with suggestions to either change the requirements to guidance or include language such as "if performed" to allow for exceptions when necessary. There was also discussion on issues related to OPO capabilities and donor hospital limitations. Attendees pointed out that smaller donor hospitals might struggle to meet all the proposed requirements, especially for DCD donors or when there's no clear clinical indication for certain tests. There was a suggestion to clarify the policy on chest X-rays, proposing that the first X-ray should be taken at the start of allocation rather than at the time of offer, with subsequent X-rays every 24 hours. Concerns were raised about the ability of smaller donor hospitals to obtain timely testing, particularly heart catheterizations for DCD donors. An attendee asked that considerations for the varied capabilities of different healthcare facilities be



made when implementing the policy. Another attendee noted that the proposed changes seemed to have the potential to reduce wait times and improve allocation efficiency.

Require Reporting of HLA Critical Discrepancies and Crossmatching Event to the OPTN

Histocompatibility Committee

- Sentiment: 2 strongly support, 7 support, 2 neutral/abstain, 0 oppose, 0 strongly oppose
- Comments: Members were supportive of this proposal. One attendee voiced support for more
 collaboration between the OPTN and accreditation organizations to ensure regulatory
 compliance and quality practices of HLA laboratories.

Update Histocompatibility Bylaws

Histocompatibility Committee

- Sentiment: 1 strongly support, 9 support, 0 neutral/abstain, 1 oppose, 0 strongly oppose
- Comments: Overall, the region is supportive of this proposal. One attendee commented that the
 OPTN having a separate approval process for HLA lab directors is redundant, and recommended
 collaboration with accreditation organizations for this process.

Continuous Distribution Updates

Continuous Distribution of Hearts Update, Summer 2024

Heart Transplantation Committee

Comments: Attendees generally agreed with the priorities identified by the Values Prioritization Exercise (VPE) results. However, some specific points were raised. Medical need was emphasized as the most important attribute. A virtual attendee stated they were surprised at the high value placed on prior living donor status. Another virtual attendee suggested increasing the weight for proximity efficiency, potentially by reducing the weight for access and urgency attributes slightly. A virtual attendee also noted that new technologies allow programs to consider greater distances without compromising donor quality.

During the meeting, attendees participated in group discussions and provided the following feedback:

- Participants agreed with medical urgency being the highest rated attribute.
- Participants also agreed that pediatric candidates should receive high priority.
- Participants questioned why proximity efficiency is rated so low.
- Participants discussed appropriate level of priority for prior living donors and Heart Committee representative will report back to the Committee.

Continuous Distribution of Kidneys Update, Summer 2024

Kidney Transplantation Committee

Comments: Attendees discussed the complexities in defining and managing hard-to-place kidneys, focusing on factors such as multiple declines during allocation, specific anatomical challenges like infarcts and renal artery plaque, and donor characteristics like age and health. There was general

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agreement that cold ischemic time alone should not be the sole criterion for determining a hard-toplace kidney; attendees suggested a combination of factors including donor risk profiles, kidney anomalies, and biopsy results should be considered along with cold ischemic time. Additionally, attendees raised concerns about transplant centers prioritizing "perfect" kidneys while there are patients who would accept organs that are more high risk.

During the meeting, attendees participated in group discussions and provided the following feedback:

- Participants agreed that cold ischemic time alone shouldn't qualify a kidney as "hard to place."
- In defining hard to place kidneys, multiple factors should be considered, including inability to pump, sever plaques, surgical damage, and DCD status (in addition to CIT).
- Difficult to determine a sequence number that should qualify a kidney as hard to place.

Continuous Distribution of Livers and Intestines Update, Summer 2024

Liver and Intestinal Organ Transplantation Committee

Comments: A virtual attendee commented their center begins to fly rather than drive for an organ if the drive time is greater than two hours, while another virtual attendee commented their threshold is greater than 90 minutes. In relation to proximity efficiency, attendees noted changing practices influenced by technologies. One attendee suggested that the Committee should consider utilization of expensive modes of transport. In relation to utilization efficiency, the attendee noted changing practices around DCD donors.

Continuous Distribution of Pancreata Update, Summer 2024

Pancreas Transplantation Committee

Comments: Virtual attendees emphasized several strategies to enhance pancreas transplantation. One virtual attendee suggested expert-supervised procurement training and programs to educate about the pancreas's importance, especially for people with diabetes. Another virtual attendee noted that encouraging OPOs to have procurement teams for all abdominal organs could prevent unnecessary declines, improve logistics, and reduce the number of teams needed. There was also support for having dedicated pancreas directors separate from kidney programs, as this could ensure more focused attention on pancreas transplants and better organ utilization. One virtual attendee stressed that pancreas transplantation requires intentional effort and time, and separating offer and procurement activities from kidney call could be beneficial.

During the meeting, attendees participated in group discussions and provided the following feedback:

 Participants discussed time to procure pancreata and reliance on other teams. Suggested strengthening pancreas recovery skill sets among OPOs through training.

Updates

Councillor Update

Comments: An attendee expressed concern that some health insurance companies refuse to allow small programs to transplant kidney patients because they are not considered Centers of Excellence. They



expressed concern that Centers of Excellence designation is based on number of transplants, not quality of outcomes.

OPTN Patient Affairs Committee Update

Comments: Regarding the PAC's potential inactive status project, an attendee noted that this is the third time a project on patient awareness of listing status has been attempted. Emphasized importance of project. The attendee shared that a relative's status was impacted by insurance issue, but he was unaware. Expressed concern that this effort may not progress. Another attendee thanked PAC for advancing work on patient awareness of listing status. The suggested first step should be ensuring patients are aware of their status. Another attendee experienced both active and inactive statuses. They suggested that centers should be required to advise patients in a standardized way.

OPTN Executive Committee Update

Comments: An attendee expressed concern about a new contracting model where HRSA would coordinate contractors, potentially increasing risks. The attendee thanked current and former OPTN Presidents for their efforts during a challenging period. The attendee expressed concern about potential changes to the Board of Directors (BOD) election process, it was noted that significant changes would likely require law reform which is subject to community input. An attendee expressed concern about the impact of the AOOS (Allocation Out Of Sequence) on smaller transplant centers being bypassed for organ offers. The discussion touched on the challenges of balancing competing responsibilities in organ allocation and placement. Another attendee expressed concern about losing experienced members and emphasized the talent within the community.

Update from the Expeditious Task Force

Comments: The discussion emphasized several key points regarding transplantation practices, focusing particularly on the use of higher Kidney Donor Profile Index (KDPI) kidneys and the allocation of resources for improving patient outcomes. An attendee suggested adjusting patient outcome metrics as there is an increase in the utilization of higher KDPI kidneys, noting that programs using these kidneys tend to have better-adjusted outcomes. An attendee noted there was also a need to better define successful transplants involving higher KDPI kidneys. An attendee asked for clarification about collaboration with the CMS on the IOTA model, and it was confirmed that there had been no collaboration. An attendee inquired about the resources available to the Taskforce, to which it was affirmed that while resources are available, progress has been slower than desired due to certain challenges facing the community.

HRSA Update

Comments: An attendee expressed appreciation for the goal of the new forms but questioned the resources transplant centers would need to complete them. In response, it was acknowledged that resources would be required and suggested expressing concerns via public comment, mentioning plans to consider automated data collection as the system modernizes. Another attendee encouraged collecting data on donor hospital support. Another attendee inquired about automation versus manual data entry. In response, it explained that HRSA will release forms for community input, with data collection focusing on referrals and evaluation progress, aiming to identify process improvements. An attendee referenced an upcoming Congressional hearing, asked if HRSA was prepared to address

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comments that may be made during the hearing. In response, it was noted HRSA could not speak to the issue at that time but would monitor the hearing and respond accordingly.