

Thank you to everyone who attended the Region 11 Summer 2025 meeting. Your participation is critical to the OPTN policy development process.

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

Public comment closes October 1st! Submit your comments

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

Non-Discussion Agenda

Modify Guidance for Pediatric Heart Exception Requests to Address Temporary Mechanical Circulatory Support Equipment Shortage

Heart Transplantation Committee

Sentiment: 10 strongly support, 7 support, 8 neutral/abstain, 0 oppose, 0 strongly oppose

Comments: This was not discussed during the meeting, but attendees were able to submit comments with their sentiment. A member strongly supports the OPTN Board's emergency policy change allowing Status 1A exceptions for pediatric heart transplant candidates with dilated cardiomyopathy due to a shortage of mechanical support devices. The policy ensures critically ill children receive appropriate transplant priority and reflects a swift, patient-centered response to a serious safety issue. The member urges that this guidance remain in place for as long as the shortage continues, to protect the most vulnerable patients.

2025 Histocompatibility HLA Table Update

Histocompatibility Committee

Sentiment: 3 strongly support, 15 support, 7 neutral/abstain, 0 oppose, 0 strongly oppose Comments: No comments.

Discussion Agenda

Require West Nile Virus Seasonal Testing for All Donors,

Ad Hoc Disease Transmission Advisory Committee

Sentiment: 2 strongly support, 10 support, 10 neutral/abstain, 3 oppose, 0 strongly oppose

Comments: A member requested the committee consider any potential risks of non-use of an organ for which West Nile Virus (WNV) testing has not come back in time, particularly when it comes to DCD cases. An attendee stated that the turnaround time from LabCorp makes it not feasible at most transplant programs, and another member agreed. An attendee suggested that symptom review with living donors could replace another required NAT test, noting rising transplant costs without reimbursement changes. A member felt there was not enough data or information presented to answer

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questions about the need and noted insufficient discussion of the OPO burden. An attendee recommended excluding very small pediatric donors or those hospitalized over 21 days from the requirement, or adjusting the timeframe, citing concerns about blood volume loss in neonates due to multiple mandated tests. A member expressed that too many unanswered questions remained after the regional meeting and felt the proposal was not fully thought out. An attendee commented that the timelines for the requirement seem unrealistic for both living and deceased donors, especially at smaller centers/OPOs, and questioned the effectiveness of screening based on past WNV cluster data. A member supported West Nile virus testing for donors but not as currently proposed, citing concerns about turnaround times and potential loss of donor organs. An attendee stated that WNV serology is reasonable for expedited placement and should not prevent OPOs from utilizing kidneys. A member emphasized the need for feasible and quick turnaround and questioned the impact of delayed results on donor organ availability. An attendee opposed the proposal based on the presentation and unanswered questions, requesting more comprehensive data and clarity on timelines and actions for positive results.

Update and Improve Efficiency in Living Donor Data Collection

Living Donor Committee

Sentiment: 2 strongly support, 12 support, 4 neutral/abstain, 7 oppose, 0 strongly oppose

Comments: A member expressed concern that their center receives a lot of potential living donors, who do not end up moving forward in the process for a variety of reasons, and this proposal could potentially add burden to transplant programs or disrupt workflow. An attendee noted that the two year follow up conducted by transplant programs helps them learn and that removing this requirement might negatively impact future donors because programs may not continue to follow them. A member stated they do not favor additional forms but understand the rationale and suggested implementing the process for a specific time period followed by reevaluation. An attendee emphasized that two-year follow-up is essential for donor health and noted this change would place additional demands on coordinators and divert nursing time from other responsibilities. A member expressed concern about using the first in-person appointment as the start of data collection, recommending instead the first appointment with the pre-transplant team due to remote evaluations. An attendee acknowledged the value of comprehensive data collection but raised several concerns: operational burden from expanded data collection, uncertainty about center-specific versus national reporting, variability in testing practices, and unclear cost responsibility. A member recommended that the 90-day living donor form submission for those who do not proceed should be based on the evaluation closure date, not the first clinic visit. An attendee supported making the second-year follow-up voluntary and conducted by SRTR, but did not support collecting data on donors who decide not to donate, citing privacy concerns and limited actionable value. A member supported the initiative but noted the increased data collection burden for evaluations that do not proceed and emphasized that long-term follow-up response rates may be lower if conducted by an unfamiliar organization.



Require Patient Notification for Waitlist Status Changes

Transplant Coordinators Committee

Sentiment: 6 strongly support, 10 support, 2 neutral/abstain, 1 oppose, 4 strongly oppose

Comments: A member noted that a standardized communication form with reasons for change of status would increase administrative burden and require approved funding, and recommended each center create a QAPI process to avoid confusing messaging. An attendee shared that their center already performs this communication and finds it useful for patients. A member requested guidance on whether notification should be via phone call or letter. An attendee did not support requiring written notification to candidates, citing clinical and logistical challenges, and advocated for individualized, patient-centered communication documented in the medical record. A member expressed support for formalizing this in OPTN policy. An attendee shared that lack of communication about waitlist status impacted their family and recommended electronic and written communication to both patients and caregivers. A member supported notifications, with detail when warranted, but raised concerns about lack of flexibility in EMR use and reliance on paper, especially during unusual circumstances, such as the pandemic, for example. An attendee strongly supported the policy as a transplant recipient family member but did not believe a mailed letter was necessary if outreach was documented, and suggested future inclusion of offer filter notifications. A member supported notifying patients of status changes as part of current practice but opposed requiring formal letters for every change, citing increased workload and the temporary nature of some changes. An attendee agreed candidates should be informed of listing status but recommended modifications to include notifying legal next of kin and allowing phone calls with documentation to meet the requirement. They added that if a candidate had multiple changes in status every week, receiving multiple letters could be extremely confusing to the patient. A member expressed concern that most patients do not understand the waitlist and that the policy could increase workload for transplant centers. An attendee emphasized the need to clarify what counts as notification, noting that not all patients have portal access and that letters may be confusing with frequent status changes. A member encouraged a system that informs patients and their families, but that having more than one channel of notification may be most effective.

Establish Comprehensive Multi-Organ Allocation Policy

Ad Hoc Multi-Organ Transplantation Committee

Sentiment: 3 strongly support, 15 support, 5 neutral/abstain, 1 oppose, 0 strongly oppose

Comments: An attendee asked the committee to consider how the policy would apply in expedited allocation scenarios. An attendee noted significant concern about the impact on kidney and kidney-pancreas lists, citing worse graft outcomes in multi-organ recipients. A member asked that the pediatric population be kept in mind during policy development. An attendee stated that pediatric candidates listed before age 18 are not adequately prioritized and should be placed ahead of SPK candidates, and requested that single organ match runs indicate when a donor is part of a multi-organ allocation plan to improve awareness for pediatric kidney teams. A member requested guidelines for cases where a center accepts multiple organs but transplants only one, asking how this would be monitored and whether reallocation would be possible. An attendee suggested that when two organs are placed, one kidney should go to the kidney or KP match run and the second to multi-organ and expressed appreciation for the 500nm allocation. A member recommended post-implementation monitoring of transplant rates for highly sensitized candidates and asked the committee to consider situations where organ usability



changes during donor management, and how OPOs should handle allocation timing. An attendee supported the policy but was disheartened by the lack of prioritization for pediatric candidates and emphasized the need to prepare for impacts on expedited DCD allocation. A member supported a standardized process but stressed the importance of maintaining options for donors with limited allocation time and preserving the benefits of safety net policies. An attendee supported the work behind the policy and emphasized the need for thoughtful implementation and education, expressing concern about increased multi-organ transplants that could bypass the safety net, while also recognizing the need for improved transparency and access for multi-organ candidates.

Updates

Councillor Update
Comments: None

OPTN Patient Affairs Committee Update

Comments: Several attendees acknowledged the presenter for her selfless gift and service on the OPTN Patient Affairs Committee.

OPTN Executive Update

Comments: A member asked about what expenses the increased registration fee will cover and how the increased fees will impact smaller transplant programs. The presenter clarified that the fees pay for OPTN policy development and implementation, and that the more work that is identified as necessary, the more funding the OPTN will need. The Board is paying close attention to the budget and is having meetings to prioritize which policies are most important to develop and implement. Regarding the fee impact on smaller programs, the more patients a program has, the more expensive it will be overall. Attendees were encouraged to reach out to the Region 11 Councillor, Dr. Vincent Casingal, with any concerns or questions, so that he may bring them to the Board. The Board is committed to developing more effective policies and implementing them in a timely fashion. An attendee commented appreciation for the presentation and for the engagement of the meeting attendees.

HRSA Update

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