OPTN

Thank you to everyone who attended the Region 4 Summer 2025 meeting. Your participation is critical to the OPTN policy development process.

Regional meeting presentations and materials

Public comment closes today, 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: 2 strongly support, 10 support, 11 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. One attendee commented that adding exceptions has the potential to decrease equity. Another attendee commented that there are alternatives to the Berlin Heart device and introducing additional exceptions to this population has the potential to increase inequities based on different approaches to the treatment of the same patients.

2025 Histocompatibility HLA Table Update

Histocompatibility Committee

Sentiment: 2 strongly support, 16 support, 5 neutral/abstain, 0 oppose, 0 strongly oppose
Comments: None

Discussion Agenda

Require West Nile Virus Seasonal Testing for All Donors

Ad Hoc Disease Transmission Advisory Committee

Sentiment: 1 strongly support, 10 support, 9 neutral/abstain, 3 oppose, 0 strongly oppose
Comments: During the discussion, several attendees raised concerns about how testing requirements would affect living donors, noting that additional testing could create different workflows and costs for transplant centers. They emphasized the importance of understanding whether living donor transmission has ever been documented and called for more clarity on this issue. Attendees discussed the need for additional data on test sensitivity and the rate of false positives, since these factors would impact the potential for unnecessary organ discards. They noted that while NAT assays are highly specific, false positive, though rare, remain possible, and the full impact of such results on discard rates was not fully addressed in the meeting. Data on transmission risk by organ type and overall prevalence of West Nile Virus were also identified as important to better assess the proposal.

Some attendees highlighted that the proposed approach, which involves testing blood samples, may not be the most accurate method for detecting West Nile Virus, since CNS fluid or tissues are more reliable sample sources. Given the complexity of collecting those types of samples, it was suggested that further consideration be given before moving forward with the current proposal. There were also comments about ensuring testing timelines are practical for both deceased and living donors. Specifically, the seven-day turnaround for living donor testing was seen as potentially challenging for donors who travel from a distance, and the impact on access to rapid DCD organs. One attendee noted that their OPO currently tests all donors and has not encountered false positives, with positive results being very rare.

Update and Improve Efficiency in Living Donor Data Collection

Living Donor Committee

Sentiment: 2 strongly support, 7 support, 4 neutral/abstain, 9 oppose, 1 strongly oppose

Comments: During the discussion, one attendee commented that the OPTN Data Advisory Committee declined to endorse the proposed data collection changes, citing excessive data burden, particularly with the Living Donor Non-Donation Form that would require significant manual entry. While the committee supported the overall goal of better understanding barriers to living donation, they raised concerns that the proposal goes beyond what is necessary to address the barriers to donation. They added that the DAC recommended that the Living Donor Committee re-present the proposal after the public comment period. Another attendee raised concerns about autonomy for non-donors, the potential harm in revisiting sensitive decisions, and the questionable clinical or scientific utility of the information. One attendee suggested that efforts to contact non-donors should count toward compliance, even if data are incomplete. Another attendee commented that more data is needed on living donor outcomes, especially considering recent reports of increased mortality from non-donation-related issues such as suicide. Several attendees raised concerns about collecting data from individuals who choose not to donate, noting the sensitive interpersonal issues involved and the limited benefit to those participants. They questioned who ultimately benefits from such data collection, whether the effort would meaningfully advance clinical improvement, and what knowledge gaps still need to be addressed. One attendee recalled that prior attempts at long-term donor follow-up failed due to lack of donor participation and expressed skepticism about expanding data collection to non-donors given the significant manual burden it would place on programs. One attendee recommended separating this proposal into two policies, one addressing data collection from prospective donors (including non-donors) and another focused on long-term donor follow-up. Participants stressed that if long-term data collection is to be successful, the burden on centers must be minimized, with SRTR taking responsibility for much of the follow-up. One attendee suggested a pilot study to evaluate feasibility and benefit before broader implementation. Several attendees emphasized that future efforts should balance the need for more comprehensive data with the realities of program capacity and the ethical considerations of involving individuals who ultimately choose not to donate.

Require Patient Notification for Waitlist Status Changes

Transplant Coordinators Committee

Sentiment: 8 strongly support, 11 support, 2 neutral/abstain, 2 oppose, 0 strongly oppose

Comments: During the discussion, attendees expressed support for the proposal's intent to keep patients informed of waitlist status changes, while raising concerns about requiring written notification.

One attendee noted that patients who are critically ill may move frequently between active and inactive status, and that sending letters in these situations could result in outdated or confusing communication for both patients and families. Another attendee highlighted that for patients temporarily living away from home, such as in a Ronald McDonald House, mailed letters may be ineffective, and that phone or electronic communication would be more practical. Several attendees suggested that centers should have flexibility to notify patients via phone calls, email with read receipts, or a patient portal, rather than being limited to written letters. Several attendees emphasized the importance of including the reason for a status change, along with guidance on what, if anything, a patient can do to return to active status. Some recommended a timeline-based approach to defining inactive status (e.g., less than 10 days, 11–29 days, 30–89 days, 90–180 days) to standardize reporting and communication. Multiple attendees noted that some centers do not use Epic or other EMR portals, making flexibility in the method of communication critical, and highlighted the need to account for patients with limited internet access or low health literacy. Many attendees supported documenting communication in the patient's chart as sufficient to meet the requirement, with written letters reserved only when patients cannot be reached by phone or electronically. Some noted that centers already use combined approaches, such as calling patients first and following up with letters for transparency. Several attendees commented that a UNOS patient portal could provide a centralized, transparent way for patients to track status changes, though considerations for accessibility and comprehension remain important. One attendee recommended quarterly notification, adding that explaining short-term inactivation can be confusing and cause patients and family's undue concern.

Establish Comprehensive Multi-Organ Allocation Policy

Ad Hoc Multi-Organ Transplantation Committee

Sentiment: 2 strongly support, 16 support, 2 neutral/abstain, 3 oppose, 0 strongly oppose
Comments: During the discussion, several attendees expressed concerns regarding the placement of pediatric kidney candidates in the proposed multi-organ allocation system, particularly for DBD donors aged 18–69 with KDPI 0–34, which represents most pediatric kidney donors. They noted that pediatric candidates remain at a significant disadvantage compared with adult kidney/pancreas candidates and emphasized that post-implementation monitoring will be essential to ensure fairness for single-organ candidates, especially pediatric and pancreas patients. One attendee commented that the proposal does not fully account for the complexities of multi-organ transplantation, particularly heart-liver and heart-kidney combinations, which are becoming more common in certain populations. They recommended that the committee reassess prioritization either prior to implementation or shortly after, to limit eligibility for kidneys with secondary organs. They also recommended giving higher priority to previous living donors. Additionally, they commented that it would be beneficial to allow centers to see where their candidates are prioritized within the multi-organ plan. Another attendee recommended that transplant centers have access to the seven allocation tables, and one called for a transparent data analysis of the policy's impact, particularly on pediatric allocation. They also requested additional education on heart-liver multiorgan transplants, which are becoming more common than heart-kidney transplants in their population, especially regarding Status 3 adult and Status 1A pediatric heart candidates. Another attendee commented that there is a need for standardized processes across OPOs. They also raised concern about potential disadvantages for kidney/pancreas recipients under the new system. Attendees also noted that while the new system-generated plan represents an improvement, challenges remain in handling late declines, rapid cases, and media scrutiny surrounding allocation decisions. One attendee commented that continuous distribution may allow better comparison across

organs, but current policy often prioritizes multi-organ recipients at the expense of maximizing the benefit to multiple single-organ recipients. One attendee commented on the specific disadvantages to pediatric kidney recipients, adding that the left kidney is often allocated to multi-organ recipients, leaving high-risk options or no offers for pediatric recipients. Attendees recommended careful post-implementation monitoring and ongoing work to adjust allocation policies to ensure equity and optimize outcomes for both pediatric and adult single-organ recipients. One attendee commented that there aree operational challenges with the policy including how the system handles late declines, rapid cases, and the growing scrutiny from media and external groups around Allocation Outside of System (AOOS) decisions. They added that while the system-generated plan is an improvement, they are concerned that the punitive tone surrounding AOOS could lead to increased scrutiny from HRSA, CMS, and OPTN. The need for standardized processes across OPOs was also raised to ensure consistency and fairness. One attendee noted that the current allocation system does not fully account for the broader impact of multi-organ transplants, which provide multiple organs to a single recipient rather than maximizing benefit across multiple single-organ recipients. They added that it is difficult to do this within the current allocation system, but continuous distribution may enable better comparison across organs.

Updates

Councillor Update

- **Comments:** None

OPTN Patient Affairs Committee Update

- **Comments:** Attendees thanked the presenter for sharing her story and the patient perspective.

OPTN Executive Update

- **Comments:** One attendee commented that since KAS 250, transplants have decreased and non-use has increased. They are concerned that if we wait too long to change the policy, this trend will continue. Another attendee commented that they would like to see more work on addressing rural patients with limited access to transplant center. These patients often lose out on kidneys due to distance of travel for last minute offers due to the difficulty to transport to rural centers. They added that AOOS disadvantages these patients, and they encourage having a metric to level the playing field. Two attendees asked about the plan to continue working on continuous distribution (CD). One added that there are many patients not being served by the current allocation sequence, including high antibody patients and that CD is critical to making things more equitable.

HRSA OPTN Modernization Update

- **Comments:** Attendees provided feedback to HRSA’s Division of Transplantation during this session.