

Thank you to everyone who attended the Region 10 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: 5 strongly support, 8 support, 6 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 noted that they do not have concerns with the proposal, but that it needs to happen urgently.

2025 Histocompatibility HLA Table Update

Histocompatibility Committee

Sentiment: 5 strongly support, 9 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: 3 strongly support, 10 support, 2 neutral/abstain, 3 oppose, 1 strongly oppose

• Comments: An attendee expressed concern at the risk of false positives. Even a single false positive could result in two or more organs not being utilized, which might outweigh the benefit given the very low incidence of mortality from WNV transmission. While some in attendance reported extensive experience testing for WNV since 2016 without false positives, participants pointed out that other infectious disease tests have shown false positive rates of 4–5%. The question of how many false positives might realistically occur in a year was seen as critical. Accessibility and availability of WNV testing was also a concern. An attendee asked how many labs currently offer the test, whether labs are able to meet OPO demand in a timely manner, and whether this would be feasible across wide geographic regions such as the Pacific Northwest. The logic of testing donors rather than recipients was also questioned. Living donor testing was a particular focus of concern. Mandating WNV NAT for living donors was seen as

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potentially burdensome and could discourage donation. It was noted that many living donors travel significant distances for donation, sometimes from out of state, and often schedule donation surgery close to their travel. This makes it difficult to complete testing within a short time frame, particularly when some hospitals rely on "send-out" labs with long turnaround times. Additionally, living donors often plan vacations or other travel shortly before surgery, further complicating logistics. As such, attendees urged that the required testing window for living donors be extended from 10 days to at least 14 days, or that testing be reserved for symptomatic donors only. Without such flexibility, there was concern that living donor kidney and liver programs would be unduly burdened. Operational considerations included whether the OPTN computer system would be updated to show WNV testing as a required field, and how the costs of this testing would be funded or prioritized among OPTN projects. Attendees also highlighted that while WNV infection carries high morbidity, widespread mandatory testing without sufficient lab access and turnaround capability could paradoxically reduce organ utilization by delaying allocation or leading to organ discard.

<u>Update and Improve Efficiency in Living Donor Data Collection</u> *Living Donor Committee*

Sentiment: 1 strongly support, 8 support, 5 neutral/abstain, 2 oppose, 2 strongly oppose

Comments: Attendees agreed on the importance of collecting long-term data on living donors, both to improve counseling for future potential donors and to ensure the donor perspective remains a central focus in transplantation. However, there were concerns about how this would be operationalized and the administrative burden it may impose on transplant programs. One recurring point of confusion was the definition of an "in-person" visit. Attendees asked whether this would include orientations, lab draws, or meetings with healthcare providers, noting that the policy as written seemed unclear. Questions were also raised about how the SRTR would collect follow-up data after one year, particularly since many donors do not have primary care providers. Concerns were expressed about the feasibility of collecting reliable, voluntary followup data and whether responses would be sporadic. Some noted that SRTR has already begun reaching out to donors several years post-donation, and programs questioned how this process would be scaled and standardized. Others emphasized that details about SRTR's methods are not fully worked out but that ongoing discussions are exploring new approaches. The proposal to collect data on individuals who do not proceed with donation—whether because they were declined or chose not to donate—was flagged as a significant administrative challenge. Programs worried about having to follow up with patients who did not move forward, many of whom are unresponsive, and felt this would add considerable workload. Several suggested that if non-donor data is needed, it should be collected in aggregate form rather than on an individual basis. Some attendees questioned whether SRTR is the right entity to manage longterm donor follow-up, particularly in cases where living donors lack established healthcare providers. Others felt strongly that collecting both donor and non-donor data is essential, with the latter serving as a control group. Operational questions included how recovery hospitals would be notified if donors chose to participate in voluntary follow-up, whether those hospitals would have access to the responses, and how donor hospitals would integrate that information.



Require Patient Notification for Waitlist Status Changes

Transplant Coordinators Committee

Sentiment: 2 strongly support, 8 support, 5 neutral/abstain, 4 oppose, 0 strongly oppose

Comments: Attendees agreed that notification of waitlist status changes is essential for candidates but expressed strong concerns about mandating written letters as the only form of communication. Many emphasized that status changes can occur quickly, and written letters may arrive too late, be received out of order, or discourage programs from making timely updates. Some noted that patients often mistake hospital letters for bills and do not open them, further undermining the effectiveness of this approach. The majority supported permitting electronic medical record (EMR) documentation, patient portals, phone calls, and emails as valid alternatives to letters, provided that communication is properly documented in the patient's record. These methods were described as more immediate, reliable, and less burdensome. Several attendees underscored the administrative challenge of letters: based on one estimate, a center with 1,000 candidates could generate 18,000 letters annually if required for every status change. A recurring theme was patient empowerment and clarity. Attendees suggested capturing patient communication preferences at intake, steering patients toward portals, and creating a centralized way for candidates to access their status, possibly through the OPTN computer system. This would reduce confusion, as patients often struggle to understand their current status. While most argued against mandatory written letters, some attendees supported a hybrid approach. They suggested that written notification should follow electronic or phone communication, particularly in cases of inactivity, so that patients have a physical record of the change. However, others cautioned that this would still create extra burden and might cause delays or confusion if letters arrived out of sequence. The prevailing view was that programs should retain flexibility. Properly documented communication by phone, portal, EMR, or email should be sufficient in most circumstances, while written letters should be used at the program's discretion rather than as a blanket requirement.

Establish Comprehensive Multi-Organ Allocation Policy

Ad Hoc Multi-Organ Transplantation Committee

Sentiment: 4 strongly support, 13 support, 2 neutral/abstain, 0 oppose, 0 strongly oppose

• Comments: An attendee from the pediatric community noted that standard kidney-pancreas (KP) candidates continue to be prioritized above standard pediatric kidney-alone candidates, which disadvantages children, particularly when programs are located near large adult centers. This was identified as a significant pain point that the proposal aims to address. Concerns were also raised about how MOT allocation is managed when family or organ constraints exist, including how late declines should be handled and whether allocation decisions would be based on offers available at the beginning or end of the process. OPO representatives expressed that without a single match run integrating all organs, flipping between separate match runs is confusing and increases the risk of errors. Questions were raised about the robustness of the data informing prioritization sequences, including whether waitlist mortality, post-transplant survival, or utility were factors. Attendees also asked how feasible it would be to align this policy with future transitions to continuous distribution (CD). Related to thoracic safety nets, concerns were voiced that kidney function after simultaneous heart-kidney transplants often lags, leading

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to questions about whether allocating the heart alone and relying on the safety net might be more effective. There was broad agreement on the importance of standardization across OPOs, but also recognition of the operational and programming challenges. Attendees stressed that policy implementation should not move forward without clear system functionality to support allocation staff, warning that manual implementation would be impractical. Specific requests included system-generated tables, logic integrated into the OPTN computer system to guide real-time decision-making, and clarity on whether OPOs could override warnings in clinically appropriate cases. Several attendees emphasized that the complexity of the written policy underscored the need for integrated system support. Discussion also touched on how to handle expedited placements, late or in-process declines, and whether OPOs would be expected to rerun lists in time-sensitive scenarios. Concerns were raised about the impact on pancreas versus pediatric kidney prioritization, with calls to ensure pancreas candidates do not drop lower than their current position. Some argued that pediatric candidates should be prioritized above standard KP candidates in certain donor scenarios, particularly given that most pediatric kidney recipients receive kidneys from adult, not pediatric, donors. There were suggestions to consider higher priority for certain pediatric candidates, such as those with longer wait times or elevated but not maximum cPRA, to help address disparities. Several attendees highlighted the broader context, noting that CD had been paused partly due to funding limitations, and questioned whether this MOT policy could realistically be implemented given the significant programming required. Many reiterated that proceeding without adequate system support would undermine consistency and transparency. Overall, there was support for developing a formal and reproducible MOT allocation policy, coupled with recognition that numerous clinical, operational, and technical details remain unresolved. Attendees emphasized the need for a robust post-implementation monitoring plan, ongoing data collection, and careful attention to the impacts on pediatric, pancreas, and highly sensitized candidates.

Updates

Councillor Update

• Comments: No comments

OPTN Patient Affairs Committee Update

• **Comments:** An attendee expressed appreciation for the individual's story and acknowledged the work they contribute through their involvement with the Patient Affairs Committee.

OPTN Executive Update

• Comments: Attendees sought clarification on the structure and decision-making process for Allocation Out of Sequence (AOOS). The presenter explained that this work originated from a HRSA directive and is overseen by the OPTN Board. A workgroup chair was selected based on leadership qualities, and additional members were solicited from existing OPTN committees. The AOOS effort involves three committees, with significant oversight from the Board and active participation of Board officers. The process will include a regular cadence of work and defined deliverables, with recognition that adjustments may be necessary over time based on results and feedback. Questions were also raised about the balance between virtual and in-person meetings. While virtual meetings have supported high attendance, they limit opportunities for

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networking and informal information exchange. The presenter acknowledged this challenge and noted the value of in-person interaction, though budget constraints remain a barrier. Attendees noted interest in potentially including at least one in-person meeting to restore some of these benefits. Continuous Distribution (CD) was another topic of concern. An attendee noted prior effort invested and asked about its status. The presenter confirmed that CD is currently paused, primarily due to challenges related to technology, resource limitations, and concerns that it could increase AOOS. While CD is recognized as an important policy for fairness and improved outcomes, its reintroduction will depend on conditions that ensure feasibility and avoid unintended inefficiencies. The presenter suggested CD could be revisited within a year, but not immediately. Finally, the Board reiterated its commitment to the public-private partnership that underpins the OPTN, particularly the contributions of volunteers. This partnership was emphasized as essential and irreplaceable to advancing the system's mission.

HRSA OPTN Modernization Update

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