

Thank you to everyone who attended the Region 2 Summer 2023 meeting. It was great being back in person and still having an option for you to join virtually. We plan to continue providing both options.

Regional meeting [presentations and materials](#)

Public comment closes September 19! [Submit your comments](#)

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

Non-Discussion Agenda

Clarification of OPO and Living Donor Hospital Requirements for Organ Donors with HIV Positive Test Results

OPTN Disease Transmission Advisory Committee (Ad Hoc)

- *Comments:* This was not discussed during the meeting, but attendees were able to submit comments with their sentiment. It was noted that false positive HIV donors should be more generally allocated. Another member added that having precise protocols and definitions for ensuring a donor is truly negative is key. Additionally, ensuring there is precise follow up of recipients to demonstrate no transmission is also necessary.

Continuous Distribution of Hearts Concept Paper

OPTN Heart Transplantation Committee

- *Comments:* This was not discussed during the meeting, but attendees were able to submit comments with their sentiment. One member noted excitement in reviewing and recognizing increased utilization of organ distribution. Another member expressed supporting the hypertrophic cardiomyopathy and congenital populations. Continuous distribution could be especially beneficial for those patients. Continuous may not be as beneficial for Ventricular Assist Device (VAD) patients, as this therapy has gotten much better with regard to long-term outcomes. However, there should be higher listing statuses for VAD complications or VAD intolerance, like bleeding or infection. The other patient population that could benefit from continuous distribution would be patients with end stage coronary disease with intractable angina. Currently, it has been a struggle with trying to get these patients upgraded and transplanted.

Deceased Donor Support Therapy Data Collection

OPTN Operations and Safety Committee

- *Sentiment:* **10 strongly support, 10 support, 1 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. It was noted that this practice needs to be standardized across all OPOs.

Recognizing Seasonal and Geographically Endemic Infections in Organ Donors: Considerations during Deceased and Living Donor Evaluation

OPTN Disease Transmission Advisory Committee (Ad Hoc)

- *Sentiment:* **6 strongly support, 7 support, 5 neutral/abstain, 2 oppose, 0 strongly oppose**
- *Comments:* This was not discussed during the meeting, but attendees were able to submit comments with their sentiment. A member expressed concern that the additional criteria suggested is near impossible to find out during standard medical/social questioning and is often unreliable. If testing is going to be required, it should be across the board. The member urges the committee to investigate test availability, cost on the testing lab to add equipment and reagents, and the time it takes to purchase, validate, hire and train staff in labs to accommodate these additional tests.

Remove CPRA 99-100% Form for Highly Sensitized Kidney Candidates

OPTN Histocompatibility Committee

- *Sentiment:* **11 strongly support, 6 support, 2 neutral/abstain, 1 oppose, 0 strongly oppose**
- *Comments:* This was not discussed during the meeting, but attendees were able to submit comments with their sentiment. Members expressed support, adding that this change should have happened long ago. Additionally, it will help avoid delays with activating candidates.

Update Guidance on Optimizing VCA Recovery

OPTN Vascularized Composite Allograft Transplantation Committee

- *Sentiment:* **4 strongly support, 11 support, 5 neutral/abstain, 0 oppose, 0 strongly oppose**
- *Comments:* None

Update HLA Equivalency Tables 2023

OPTN Histocompatibility Committee

- *Sentiment:* **8 strongly support, 7 support, 5 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. It was noted that this update is needed for high resolution results.

Update on Continuous Distribution of Livers and Intestines

OPTN Liver & Intestinal Organ Transplantation Committee

- *Comments:* None

Discussion Agenda

Efficiency and Utilization in Kidney and Pancreas Continuous Distribution Request for Feedback

OPTN Kidney & Pancreas Transplantation Committees

- *Comments:* Multiple attendees suggested making offer filters more dynamic and mandatory based on transplant program historical transplant data and not allow the option to disengage the filters. The filters should be reevaluated on a three-year rolling cycle. Another attendee noted that for dual kidney allocation a combination of cold ischemic time, biopsy, anatomy, and match run considerations should be considered. Another attendee added that for dual kidney allocation if kidneys meet certain criteria, such as >30% sclerotic glomeruli, then the OPO should be allowed to go directly to dual kidney allocation.

During the meeting the attendees participated in group discussion sessions and provided feedback on one of three questions:

- Dual Kidney Eligibility Requirements
 - An attendee noted that biopsy results should come into play before deciding to allocate as dual. Poor biopsy results should allow for immediate dual kidney allocation.
 - Another attendee stated that the current system fails at trying to place hard-to-place kidneys. There needs to be a whole new one to maximize efficiency, and there should be the flexibility to allocate any kidneys as duals but with the option to place kidneys singly if someone is willing.
 - Another attendee noted their support for allocating single kidneys first and then moving to dual if that is not successful. The focus should be on improving single kidney allocation methods.
 - Another attendee stated that mandatory offer filters are the only way to increase single kidney allocation efficiency. It takes too long to wait for centers to evaluate all of their organ offers.
 - Lastly, another attendee highlighted the need for firm criteria that define candidates as “hard to place” with the data to support it. Currently, offer filters are not suitable since they aren’t mandatory.
 - Online attendees voted for a combination of donor criteria and offering as single first. The majority also favored a match run offer threshold of less than 50% before the OPO can offer the kidneys as dual.
- Pancreas Medical Urgency
 - One attendee noted that it is important to make sure that nothing in the policy further restricts access to patients needing multi-visceral and liver transplants. Additionally, there is concern that intestines cannot be procured because of pancreas allocation. This is especially a concern for pediatric candidates.
 - Another attendee stated that pancreas medical urgency should be based more on kidney criteria.
 - Another attendee expressed support for including two to three instances of hypoglycemic unawareness as part of the definition.

- Online attendees supported exception-based medical urgency attribute. One attendee noted that hypoglycemia unawareness is a factor, but concern is how data will be captured and periodically reviewed for accuracy.
- Mandatory Kidney/Pancreas Share Threshold
 - No comments

Amend Adult Heart Status 2 Mechanical Device Requirements

OPTN Heart Transplantation Committee

- **Sentiment: 2 strongly support, 6 support, 10 neutral/abstain, 1 oppose, 1 strongly oppose**
- **Comments:** Overall, members of the region support the proposal, but there was some opposition. An attendee highlighted that while some data suggests inotrope use is riskier than early use of Intra-Aortic Balloon Pumps (IABPs), their institution has achieved positive outcomes with IABPs. They emphasized that correlation does not imply causation and emphasized the importance of gathering more data from both sides before making changes to policy. They do not agree with the proposal. Another attendee expressed support for re-stratifying Status 2 patients to identify those who are sicker. A question was raised regarding the specific clinical parameters that would classify someone as sicker while on inotropes. Another attendee noted concerns about the potential impact of the change on patients. The concern was that the proposed criteria might not address the problem of gaming the system by using IABPs to increase status. There was a suggestion that patients on IABPs might not have comparable outcomes as those on inotropes, and better analytics like propensity matching were recommended to provide a clearer comparison. Lastly, there was support for better risk stratification of patients who receive temporary mechanical circulatory support (MCS) and fall into the Status 2 category with reservations. The concern was that certain issues like inotrope toxicity, ventricular arrhythmia, and deteriorating end organ function might not be captured by the proposed criteria. It was suggested that these issues could justify Status 2 without meeting the criteria. Additionally, potential impacts on waitlist mortality and outcomes post-surgery were highlighted.

Require Reporting of Patient Safety Events

OPTN Membership & Professional Standards Committee

- **Sentiment: 7 strongly support, 11 support, 1 neutral/abstain, 2 oppose, 0 strongly oppose**
- **Comments:** Members of the region are supportive of the proposal. An attendee suggested automating the reporting of prior living donors who subsequently get listed for an organ transplant. This approach would alleviate the burden of reporting from the transplant programs, shifting the responsibility to an automated system. An attendee noted no concerns with the "near miss" definition in the proposal. Reporting transportation events are valuable in providing clarification regarding instances where an organ did not arrive on time. The attendee also agreed with reporting of ABO typing errors or discrepancies. Several other attendees also noted their support of reporting transportation events that lead to delays in transplantation or organ non-use.

Modify Organ Offer Acceptance Limit

OPTN Organ Procurement Organization Committee

- **Sentiment: 11 strongly support, 8 support, 3 neutral/abstain, 0 oppose, 0 strongly oppose**
- **Comments:** Overall members of the region are supportive of this proposal. Attendees noted concern with OPOs facing late declines just prior to the surgery, resulting in out-of-sequence allocation or non-utilization. There was agreement that establishing mandatory guidelines could contribute to a smoother processes and better outcomes. One attendee did express concern for the need to understand the definitive reasons behind the non-utilization rates discussed in the proposal. The committee should ensure that non-utilization was not based on factors such as biopsies or other considerations that might not have been taken into account initially. Another attendee also noted the necessity of still allowing two acceptances for high panel reactive antibody (PRA) patients. It was suggested that these patients might need to be given special consideration given their specific medical needs.

Concepts for a Collaborative Approach to Living Donor Data Collection

OPTN Living Donor Committee

- **Comments:** Attendees expressed support for the project goals but acknowledged challenges in collecting meaningful long-term data on living donor candidates. An attendee voiced support for the project as it stands out for its randomized approach of comparing living donors to those who end up not donating. However, they noted challenges currently with obtaining data from living donors, so it seems that it would be even more difficult to collect similar longitudinal data from non-donors. The need for long-term follow-up of living donors was emphasized, while a critical stance was taken toward subjecting non-donors to the same level of follow-up. Protecting non-donors' anonymity and their ability to withdraw without giving a reason was deemed crucial due to potential discomfort, privacy concerns, and data breaches. A few attendees did express opposition to the project, describing it as unnecessary, costly, and burdensome for patients who don't proceed to donation. It was suggested that the evaluation process should be excluded from the project's requirements, and patients should have the option to remain in the study for life instead of being mandated to follow-up for two years. Lastly, there was a suggestion for an independent registry, separate from the transplant program, as a way to potentially increase willingness among donors to share information. Additionally, direct contact with living donors and exploring data collection from big data/insurance claims based on donor diagnoses were proposed as potential strategies.

Ethical Analysis of Normothermic Regional Perfusion

OPTN Ethics Committee

- **Sentiment: 4 strongly support, 12 support, 4 neutral/abstain, 0 oppose, 0 strongly oppose**
- **Comments:** Members of the region are supportive of the white paper and are supportive of disclosing information about the NRP process to donor families while also acknowledging the need for thoughtful consideration of the extent of information provided. An attendee noted concern with the extensive information proposed to be disclosed to families prior to NRP. The potential restoration of cerebral circulation was deemed not fully justified by current data, potentially impacting donor family willingness to participate. It was suggested that more nuanced information should be included if the proposal persists. Another attendee stated that

NRP could be defined as a perfusion technique after death pronouncement similar to in situ kidney perfusion. Currently, in situ kidney perfusion does not require additional donor family consent, so requiring NRP consent could lead to additional consent requirements on all procedures. Another attendee stated that informing family members about ligation and the possibility of circulation as part of informed consent was necessary. The intention behind the act of ligation was considered important, with the notion that fulfilling the deceased donor's wishes and allowing a peaceful passing might take precedence over the dead donor rule. Another attendee noted there needs to be transparency around which hospitals are willing to allow NRP recovery. Additionally, donor families should be allowed to opt out of NRP recovery due to the principle of respect for persons. Lastly, standardization of protocols for donor and donor family conversations and adherence to the dead donor rule during NRP were emphasized. The importance of feedback from donor families and clarification on the utilization of the analysis were noted.

Updates

Councillor Update

- *Comments:* None

OPTN Patient Affairs Committee Update

- *Comments:* None

OPTN Membership and Professional Standards Committee Update

- *Comments:* An attendee requested further clarification regarding the purpose of the newly introduced metrics and how Organ Procurement Organizations (OPOs) will be evaluated based on these metrics. The presenter noted that the proposed approach involves the creation of a concept paper that outlines precise data characteristics for OPOs. These characteristics will serve as a basis for identifying OPOs that might require assistance in adapting to the upcoming changes.

Member Quality Update

- *Comments:* An attendee expressed their support of Member Quality's Individual Member Focus Improvement (IMFI) program. They added that it is a free service that offers expertise and collaboration in a safe environment.

OPTN Executive Committee Update

- *Comments:* Attendee comments focused on the future of the OPTN contract and the HRSA modernization initiative. One attendee noted their concern with allowing for-profit institutions to bid on potential future contracts. They expressed the need to anticipate the areas of the contract that might be appealing to for-profit institutions and consider building a defensive strategy to safeguard these targeted segments. Another attendee expressed concern with engaging and reassuring potential volunteers who might have reservations about the ongoing modernization initiative and the future of the OPTN contract. The presenter emphasized that

despite the modernization, the OPTN would continue to exist, along with its committees. There was agreement that highlighting the fact that the OPTN is mandated by law would be a reassuring message to potential volunteers. A notable concern raised by another attendee was the potential breakdown of communication between different contractors if the contract were to be divided. This apprehension underlined the importance of maintaining effective communication channels and collaborative efforts, even in the face of changes or challenges. Lastly, another attendee expressed hope that the collaborative and inclusive approach of the OPTN would remain a central focus moving forward. This approach aims to ensure that the OPTN makes the most of its resources while promoting collaboration among different stakeholders.

OPTN Strategic Planning Feedback Session

- *Comments:* During the meeting the attendees participated in a group discussion session and provided feedback on which of the ideas for strategic plan goals generated by the OPTN Board of Directors should be the prioritized, which was the highest priority, and if there were any key themes missing. The ideas from the OPTN Board of Directors were: Increase patient engagement through education and transparency, Increase transplants, Increase donors and available organs for use, Maximize the value of organs and increase post-transplant quality of life, and Improve allocation efficiency.
 - One group noted their support for Increasing transplants as the highest priority theme.
 - Another group stated that the system needs to be fair to everyone, in addition to increasing donors and available organs for use.
 - Another group agreed that increased engagement leads to increased donors and increased transplants.
 - The next group noted that their top three priorities were Increase donor and available organs for use, increase transplant, improve allocation efficiency. Transplant programs should not be punished for outcomes of transplanting risky patients, also finances need to improve.
 - Another group noted that rural transplant centers and OPO's have issues with access, so Improve allocation efficiency was their highest priority.
 - Another group picked Improve allocation efficiency, Increase donors and available donors for use, and Increase engagement through education and transparency as their top three priorities.
 - Another group noted that Improving allocation efficiency will increase transplants and will maximize post-transplant quality of life.
 - The next group noted that Increase transplants seem too vague to be a strategic priority. Their top three priorities were to maximize the value of organs, longevity of organs improves quality of life for pediatric patients, next was increasing donors and organs for use, including those procured through NRP, and lastly improve allocation efficiency, mostly as a reduction in organ non-utilization.
 - The last group chose improving allocation efficiency as their top priority. Doing so would maximize current gifts by maximizing donated organs. Additionally, the community needs to make sure we have the capacity to do that through having enough surgeons, etc.

- Those attending virtually selected Increase donors and available organs for use, Increase transplants, and Improve allocation efficiency as their top three strategic priorities. One attendee noted that in regard to Increase donors and available organs to use it would be helpful to understand more about barriers to organ donation that exists in larger cities specific to pediatric donors. Another attendee stated that for Improve allocation efficiency there is a need to evaluate in detail with appropriate stakeholders (ethicists, OPO professionals, transplant professionals, recipients - past, current candidates, donor families, etc.) the value of equity vs utility as it pertains to "following the list;" especially with regard to hard-to-place organs in order to determine a unified, standardized, efficient, and effective method of organ allocation. Doing so, while using objective data will allow a realistic, time-sensitize approach that will hopefully maximize the gift and improve outcomes. Another attendee noted that for Increase patient engagement through education and transparency that there has been a lack of transparency and communication with those who have been transplanted. This became most apparent during the pandemic when transplant patients had no one to turn to for answers. Unfortunately, this may not be the last pandemic, so we must be prepared to have access and engagement between transplant patients and the transplant hospitals.
- Several attendees noted missing potential strategic priorities including improving equity in broader sharing, graft longevity, living donation, and patients and donors being the ultimate priority in any strategic initiative. It was also noted that there needs to be more policy for post-transplant recipients. The current rules and regulations are mostly dedicated to those prior to transplant. Lastly, the turnaround time for minor software modifications that can make a big difference in the system also needs to be addressed. While we are focusing on major policy changes, we can also be making small changes in real time to facilitate the development of existing process and increase efficiency.

OPTN Policy Oversight Committee Update

- *Comments:* An attendee noted concern over basing decisions on moving a project forward only on meeting a certain score. Disadvantaging a project that is not focused on vulnerable populations may be detrimental to the entire community. The presenter clarified that the project score is for comparing various projects and is not meant to be a determining factor for advancing new projects.