

Thank you to everyone who attended the Region 6 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 <u>presentations and materials</u>

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. One attendee commented that they supported this proposal.

Continuous Distribution of Hearts Concept Paper, OPTN Heart Transplantation Committee

• Comments: One attendee commented that the committee should consider geographic equity as an attribute. They added that region 6 borders the ocean so using nautical miles and circles is problematic. They suggested possibly using population density as a proxy. Another attendee commented that the lung community has experienced logistical inefficiencies in lung continuous distribution given the volume of offers and recommended the committee consider that while developing their policy. One attendee added that logistical challenges, resource utilization and cost need to be considered to avoid late turndowns and non-utilization of organs. Another attendee recommended including concepts learned from the early experience in lung continuous distribution.

Deceased Donor Support Therapy Data Collection, OPTN Operations and Safety Committee

- Sentiment: 1 strongly support, 9 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. One attendee commented that this is a reasonable way to systematically improve data sharing between OPOs and accepting centers.

Recognizing Seasonal and Geographically Endemic Infections in Organ Donors: Considerations during Deceased and Living Donor Evaluation, OPTN *Disease Transmission Advisory Committee* (Ad Hoc)

- Sentiment: 0 strongly support, 8 support, 3 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 they supported this proposal.

Remove CPRA 99-100% Form for Highly Sensitized Kidney Candidates, *OPTN Histocompatibility Committee*

- Sentiment: 3 strongly support, 6 support, 3 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 supported the proposal commenting that the form is an extra administrative burden while adding little to clinical practice or patient safety.

Update Guidance on Optimizing VCA Recovery, *OPTN Vascularized Composite Allograft Transplantation Committee*

- Sentiment: 1 strongly support, 7 support, 3 neutral/abstain, 0 oppose, 0 strongly oppose
- Comments: No comments

Update HLA Equivalency Tables 2023, OPTN Histocompatibility Committee

- Sentiment: 3 strongly support, 9 support, 0 neutral/abstain, 0 oppose, 0 strongly oppose
- Comments: No comments

Update on Continuous Distribution of Livers and Intestines, *OPTN Liver & Intestinal Organ Transplantation Committee*

Comments: This was not discussed during the meeting, but attendees were able to submit
comments with their sentiment. One attendee questioned the impact of continuous
distribution on utilization and cost. Another attendee commented that there needs to be
modeling for regions in the corners of the country. They added that region 6 borders the ocean
and Canada and has a smaller population per capita and that given regional differences,
continuous distribution cannot be one-size-fits-all. One attendee commented that pediatric
candidates should not be disadvantaged.

Discussion Agenda

Efficiency and Utilization in Kidney and Pancreas Continuous Distribution Request for Feedback, OPTN Kidney & Pancreas Transplantation Committees

- Comments: One attendee recommended the committee monitor cost and non-utilization rate. During the meeting the attendees participated in group discussion sessions and provided feedback on one of three questions:
 - Pancreas Medical Urgency clinical guidance
 - One group commented that the lists are small and often exhausted without getting the pancreas placed. They supported whatever policy helps to get more pancreas transplanted should be prioritized.
 - One virtual attendee supported adding hypoglycemic unawareness as a medical urgency criterion for pancreas distribution.
 - Mandatory Kidney Pancreas Shares Threshold
 - No comments

- Dual Kidney Eligibility Requirements
 - Two groups commented that allocation should be prior to cross-clamp. They supported prioritizing dual allocation higher on the list and potentially including age and KDPI.
 - One group commented that selecting specific characteristics of donors in a particular setting is challenging. They added that cold ischemia time should serve as a threshold for OPOs to start offering organs. Dual offers with long cold times are generally undesirable. They also supported using a percentage of the waiting list prior to cross-clamp and then using cold ischemic time as a threshold.
 - One group commented that it is difficult to make a recommendation when we don't know what the lists will look like. They added that it could be a different threshold for different areas of the country.
 - One group commented that they recommended using high KDPI and age as a factor in determining how soon to move to dual allocation.
 - One group commented that placing dual kidneys is challenging and it will be important to make it clear on the list which centers will accept dual kidneys. This was echoed by a virtual attendee who commented that any change to the process should allow transplant centers to indicate interest in single or dual at the time of the initial offer so that OPOs can allocation duals without having to re-run the match.
 - One virtual attendee supported a mix of donor criteria and match run cutoffs to determine when to flip to dual kidney alone allocation. They added that the cutoff should be if the kidney isn't placed in the 100-250 NM range it should be given priority as dual kidney.

Amend Adult Heart Status 2 Mechanical Device Requirements, *OPTN Heart Transplantation Committee*

- Sentiment: 1 strongly support, 8 support, 3 neutral/abstain, 0 oppose, 0 strongly oppose
- Comments: One attendee commented that it would be helpful to have regional data about how many candidates are at status 2 with devices, versus being transplanted at status 3 or 4 with inotropic escalation. Another attendee supported the proposal but cautioned the committee on getting too prescriptive with doses and timing of medications. Several attendees supported the intent of the policy but had concerns about patients with arrhythmias and the requirements to maintain high inotropes with percutaneous mechanical circulatory support (pMCS). One attendee commented that the committee needed to make sure the inotrope does are supported within the committee with input from cardiology.

Require Reporting of Patient Safety Events, OPTN Membership & Professional Standards Committee

- Sentiment: 1 strongly support, 9 support, 2 neutral/abstain, 0 oppose, 0 strongly oppose
- Comments: Several attendees commented that there needs to be more clarification around different types of transportation issues and whether they resulted in non-utilization of organs. One concern raised was that transportation issues, despite their impact, are often beyond the control of OPOs and transplant centers. One attendee suggested involving industry partners when reporting on transportation events. One attendee recommended removing the requirement of reporting when a transportation issue results in the organ not being transplanted into the intended recipient. Another attendee commented that the 24-hour time limit may not be long enough to evaluate an event and determine if it is reportable. One attendee commented that the reporting system needs to be more user-friendly to allow OPOs and transplant hospitals to easily communicate. One attendee recommended extending the ABO typing error to any blood typing done during potential registration/evaluation because those values can be sued during verification. Several attendees were supportive of reporting these events and collecting data to increase patient safety.

Modify Organ Offer Acceptance Limit, OPTN Organ Procurement Organization Committee

- Sentiment: 3 strongly support, 2 support, 3 neutral/abstain, 3 oppose, 1 strongly oppose
- Comments: Several attendees did not support this proposal and were concerned about limiting acceptance for liver candidates, particularly those who are medically urgent. They went on to recommend improving communication between OPOs and Transplant Centers as a solution rather than limiting the number of acceptances. Another recommendation was to enhance DonorNet to allow centers and OPOs to see on the match if a candidate has simultaneous acceptances for more than one organ. This would allow OPOs and transplant centers to prepare with backup candidates. Another attendee recommended allowing two acceptances for DCD organs in the event of non-arrest. One attendee commented that due to the region being geographically isolated, they don't always have access to frequent liver offers for their high MELD candidates. Limiting the acceptances to one will be detrimental to these candidates who may not receive another offer in time. Another attendee commented that there are many things that contribute to holding two offers for a candidate that are not considered in the proposal. Often surgeons don't know until they are in the operating room if the liver will be right for their patient. One attendee was concerned that limiting the acceptances could place pressure on smaller volume programs to accept higher risk organs and could worsen outcomes. They added that the reasons for late declines should be explored in more detail. One attendee commented that late declines are very challenging for OPOs and often result in non-use of the organ.



Concepts for a Collaborative Approach to Living Donor Data Collection, *OPTN Living Donor Committee*

Comments: Several attendees commented that they supported this initiative. Some attendees
were concerned about consent from potential living donors and living donors. They added that
some potential living donors may not want to be monitored this closely over time. One
attendee was concerned about the administrative burden this may add to living donor
programs. They commented that there will need to be a balance between collecting data and
adding work for program staff.

Ethical Analysis of Normothermic Regional Perfusion, OPTN Ethics Committee

- Sentiment: 1 strongly support, 6 support, 2 neutral/abstain, 1 oppose, 0 strongly oppose
- Comments: During the discussion, some attendees recommended elevating the principle of respect for persons to equal or above the principle of non-maleficence via recognition of the "last gift" justification of respect for the intention of donors/donor family to proceed with donation. One attendee commented that it is unknown how first-person authorization through a driver's license and last directives would be affected if this information were included. Another attendee commented that families often don't want to know this level of detail, they just want to respect their loved one's decision to donate. One attendee recommended a distinction between abdominal NRP (A-NRP) and thoracoabdominal NRP (ta-NRP). Another attendee recommended a larger ethical discussion about how we qualify a patient as a donor, adding that there should be specific, prescribed, objective criteria. One attendee recommended that additional education be expanded to include potential recipients of NRP organs so that they understand the difference between organs recovered using NRP and those recovered using other procedures.

Updates

Councillor Update

Comments: None

OPTN Patient Affairs Committee Update

• Comments: During the discussion, several attendees commented that the transplant community should come up with a system to always get a letter to the donor family. One suggestion was for the recipient's surgeon/physician to write a letter to the donor family if the recipient was not ready to make that contact. Other attendees were interested in a process for donor families to update their contact information so that if a recipient wants to reach out, there is a current address. One attendee shared that they have workshops for recipients in their area to help them understand the perspective of the donor families. There was also a recommendation to share stories from donor families and recipients on social media.



OPTN Membership and Professional Standards Committee Update

Comments: During the discussion, one attendee shared concerns that continuous distribution
may be the cause of more out of sequence allocations. They also commented that MPSC should
align their OPO performance standards with AOPO data committee dashboards. Another
member commented that the committee should define what they are measuring and collect the
data across systems.

Member Quality Update

Comments: During the discussion one member noted that organ acceptance metrics could be a
really powerful tool, but currently does not differentiate between adult and pediatric programs
which makes it hard to compare offer acceptance rates. They added that there should be two
reports for each center, one for adults and one for pediatrics. Another attendee commented
that small volume centers may be disadvantaged by using filters due to receiving fewer offers
for their patients.

OPTN Executive Committee Update

• Comments: During the discussion, one attendee commented that the Efficiency Task Force needs to consider how different geographic areas are affected by changes in allocation policy. They went on to note that 150NM and 250NM circles in region 6 cover very little of the geography in the region. They added that the Task Force needs to consider different strategies to increase efficiency for different parts of the country based on geography. One attendee commented that the sample notification letters for eGFR need to be in plain language and also need to be translated into other languages.

OPTN Strategic Planning Feedback Session

- 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 should be the prioritized, which was the highest priority, and if there were any key themes missing.
 The ideas from the OPTN Board were to 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.
 - Several groups selected "improve allocation efficiency" as a priority. One group commented that continuous distribution may be able to increase efficiency. They also commented that cost, safety and decreasing non-use need to be considered. Another group said increasing efficiency will impact all of the other goals.
 - Several groups selected "increase donors and available organs for use" as a priority.
 They commented that exploring preservation and how it can be better used and standardizing donor management and sharing best practices would be part of this goal.
 - One group prioritized maximizing the value of organs and increasing post-transplant quality of life. They commented that volume does not always mean quality, and while we want to save as many lives as possible, we also want recipients to have a good quality of life. They also commented that pediatrics should be prioritized for transplant.
 - Several groups also prioritized "increase patient engagement through education and transparency".

- Virtual attendees also prioritized improving allocation efficiency, followed by increase transplants and increase donors and available organs for use. One virtual attendee prioritized increasing patient engagement through education and transparency given the drop in public trust with the donation/transplant system. They added that work in this area will be a necessary foundation for the donation and transplantation rates to improve.
- Attendees had several suggestions for missing themes. One recommendation was to increase education for OPO staff regarding cultural and other beliefs to support donation discussions with patient families. Another attendee commented that the biggest need was to be efficient and aligned with technology. They added that being prepared for artificial intelligence should be a goal. One attendee commented that the reduction of the non-use of organs should be one of the goals. Several attendees commented that equity in access should be a priority.

OPTN Policy Oversight Committee Update

• Comments: None