OPTN

Thank you to everyone who attended the Region 9 Summer 2023 meeting. It was great seeing people 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. Comments from live discussion and electronic submissions are included in this summary.

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)

- No comments

Continuous Distribution of Hearts Concept Paper

OPTN Heart Transplantation Committee

- This was not discussed during the meeting, but attendees were able to submit comments with their sentiment. A member expressed support for this concept.

Deceased Donor Support Therapy Data Collection

OPTN Operations and Safety Committee

- Sentiment: **2 strongly support, 5 support, 4 neutral/abstain, 0 oppose, 0 strongly oppose**
- No comments

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

OPTN Disease Transmission Advisory Committee (Ad Hoc)

- Sentiment: **4 strongly support, 5 support, 3 neutral/abstain, 0 oppose, 0 strongly oppose**
- No comments

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

OPTN Histocompatibility Committee

- Sentiment: **4 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. A member stated that this form serves no good purpose and only makes the listing process more cumbersome.

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

- Sentiment: **2 strongly support, 5 support, 5 neutral/abstain, 0 oppose, 0 strongly oppose**
- No comments

Update HLA Equivalency Tables 2023
OPTN Histocompatibility Committee

- Sentiment: **5 strongly support, 5 support, 3 neutral/abstain, 0 oppose, 0 strongly oppose**
- 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. A member stated that since post-transplant survival is predictive and not a fact, it should not be included in the composite allocation score.

Discussion Agenda

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

- Comments: During the meeting the attendees participated in group discussion sessions and provided feedback on one of three questions:
    - Pancreas Medical Urgency
        - One group stated that there isn't a lot of information for this criteria to define whether it should be included, and they suggested engaging endocrinologists to better define pancreas medical urgency.
        - Another table shared that OPOs currently struggle with placing kidney/pancreas and isolated pancreas, so they're not confident that if they're already exhausting the list right now, what a medically urgent pancreas patient would gain. They also added they're not really sure what pancreas medical urgency means.
        - A member commented that there are very few pancreas candidates as it is, so the number who would qualify as medically urgent would be very small; therefore the impact of having a medically urgent classification would be minimal on the entire population, so they support pancreas medical urgency.

- Mandatory KP Shares Threshold
  - One table remarked that from an OPO perspective, defining criteria for mandatory kidney/pancreas shares is a good thing, but mandatory multi-organ shares policy overall needs to be clarified. There needs to be a definition of criteria of what patients take priority and specifics on where kidney/pancreas allocations fall with other multi-organ policies.
  - An attendee commented that the community is constantly trying to adjust the kidney/pancreas allocation, but there is an opportunity to use data to evaluate the benefits of simultaneous kidney/pancreas transplants.
- Dual Kidney
  - A group wondered if there was an opportunity to have two separate match runs, based on percentage or on cold ischemic time. A percentage of the match run is too broad due to the size of the match run, so maybe cold ischemic time would be a better option.
  - Another table said they think it should a combination of donor factors and a percentage of the match run. They also suggested looking at cold ischemia time and the size of the kidney; should also provide the tx center for recipient considerations.
  - An attendee commented that 50% of high KDPI kidneys are not used and suggested allocating all those kidneys as dual and let the center decide whether to keep them as dual or use them as single. The attendee thought this would lead to better outcomes and more transplants.

Amend Adult Heart Status 2 Mechanical Device Requirements

OPTN Heart Transplantation Committee

- Sentiment: **2 strongly support, 7 support, 3 neutral/abstain, 0 oppose, 0 strongly oppose**
- Comments: A member expressed support for the proposal and wondered if there are status 2 patients that should really be status 1. An attendee remarked that the review boards should follow existing guidelines. One member was concerned about patients with arrhythmias that cannot tolerate inotropes under this policy. An attendee was concerned that this proposal could undermine patient trust if physicians are not allowed to use their best judgment regarding the treatment of their patient. The member also was not sure if it makes sense to undertake this change now if the committee is already working on moving heart allocation into continuous distribution.

Require Reporting of Patient Safety Events

OPTN Membership & Professional Standards Committee

- Sentiment: **2 strongly support, 9 support, 2 neutral/abstain, 0 oppose, 0 strongly oppose**
- Comments: An attendee suggested having the system automatically flag when a prior living donor is listed for another organ. Many attendees were concerned with how “professional body” and “sanction” would be defined. One attendee suggested refining the definition to be more specific, like revocation of a medical license by the state medical board or termination

from a position based on clinical grounds. A member agreed with requiring reporting of living donors that are added to the wait list for any organ within 2 years of donation. One attendee commented that they were pleased to see this direction overall and hoped that the goal of this is to prioritize patient safety and improve care, rather than just penalize programs. Another attendee agreed, stating that programs may hesitate to report events if the focus is on penalties. For the timeframe for reporting, there was mixed feedback. A member stated support for the 24 hour reporting timeframe, while others felt that 48 hours or the next business day would be appropriate. A member expressed support for including the transportation events outlined in the proposal, with one attendee adding that travel and shipping errors should be included, even when the organ is used as they add cold time and could disadvantage the recipient. Another member suggested collaborating with NQF, AHQR, JCAHO & others in the patient safety community on this, rather than reinventing the wheel.

Modify Organ Offer Acceptance Limit

OPTN Organ Procurement Organization Committee

- Sentiment: **2 strongly support, 3 support, 5 neutral/abstain, 2 oppose, 1 strongly oppose**
- Comments: Several attendees disagreed with this proposal, saying that this potentially disadvantages patients. They do not believe this solves the problem of non-use of organs, and there needs to be a meaningful discussion between transplant programs and OPOs to ensure there are back up candidates waiting. Another attendee agreed with those points, and added that it is important for transplant centers and OPOs to communicate clearly and often. Several members agreed with the fact that communication is at the root of this issue. Several attendees stated support for an exception for high status liver candidates, high status lung candidates, and DCD donors, as this would still solve a good amount of the problem. One attendee remarked that not all back up offers and acceptances are created equal, and if there can be an agreed up and accepted process for back up offers, it will make the process smoother in the event of a late decline. A suggestion was made to provide a time limit on how long transplant centers can hold on to two offers at the same time. A member commented that all organ offers should be considered provisional and not accepted until a donor OR has been set, allowing centers to hold multiple offers for the same recipient until then. They added that it is impossible to determine the quality of a liver prior to recovery, especially for extended criteria and marginal donors, and this policy change would disadvantage patients and may limit the use of extended criteria livers.

Concepts for a Collaborative Approach to Living Donor Data Collection

OPTN Living Donor Committee

- Comments: A member commented that collecting data on potential living donor candidates is a great idea and that long term follow up of living donors is also very important. Another attendee thought that this is a value proposition, as everyone supports collecting more data to help patients, but how much time/effort/resources do we want to put towards it. The attendee suggested that if we want to collect more data up front for potential living donors that this be added to the cost report so centers would be able to adequately staff for this work. Also, the

attendee thought that "living donor candidate" needs to be more clearly defined because at their center, they had more than 200 living donor transplants with over 500 living donor "candidates". A member was concerned about sharing confidential information about living donor candidates, especially related to psychosocial turndowns. An attendee expressed concern about adding the additional data collection burden on a center, particularly during the intense period of evaluating a living donor. Another attendee said that identifying living donor candidates starting when their EMR is created is too soon, as their program creates an EMR when they do a blood draw. A suggestion was made that if in the future, programs will be required to submit pre-transplant or perioperative data, allowing for the electronic PDF/organ verification link that is enabled during a deceased donor transplant match to expedite this data submission would be helpful. A member expressed concern that there is not more emphasis on living donor long term follow up. An attendee strongly supported this concept and applauded it as a much-needed effort. A member commented that shifting data collection upstream to OPTN and transplant centers would result in onerous financial burden and perhaps the outreach to donors should incorporate the patient portal, as well as traditional means to gather data.

Ethical Analysis of Normothermic Regional Perfusion

OPTN Ethics Committee

- Sentiment: **4 strongly support, 4 support, 4 neutral/abstain, 1 oppose, 0 strongly oppose**
- Comments: A member was surprised that there is concern around NRP. An attendee appreciated the even approach taken by the paper and stated the that objection to NRP fails to respect the declaration of DCD. A member felt that information must be given to donor families, especially considering the historical distrust of the medical community by minorities. The member is concerned that that this could decrease the rate of donation among minorities, and also pointed to faith based resistance to organ donation needs to be considered as well. The member added that the idea of explaining to a donor family the need to recirculate blood after the heart has stopped would be challenging. Lastly, they wondered if the use of NRP would be standard practice nationally because if not, it could create disproportionate impacts in different regions and by proxy, patients. An attendee expressed support for NRP, as it honors the donor's wishes and that the restoration of circulation is not intended to, nor expected to, restore life to the donor.

Updates

Councillor Update

- No comments

OPTN Patient Affairs Committee Update

- Comments: A member commended the presenter and thanked her for the presentation.

OPTN Membership and Professional Standards Committee Update

- Comments: A member observed that there don't seem to be clear reasons driving out of sequence organ offers. An attendee commented on the metrics that include allocation of pancreata for research as contributing to OPO performance and how there is concern about whether it should be permissible.

Member Quality Update

- Comments: No comments

OPTN Executive Committee Update

- Comments: A member commented that their eGFR waitlist time modifications have been processed rapidly and all questions about the policy have been answered promptly. The member also stated their program is looking forward to the launch of mandatory kidney offer filters and recommended that when they do become mandatory that the data used to suggest filters is more current.

OPTN Strategic Planning Feedback Session

- During the meeting the attendees participated in group discussion sessions and provided feedback the strategic goals:
    - One table stated the biggest obstacles is lack of alignment among different types of OPTN members among goals. OPOs are being pressured to get as many organs procured, placed, and transplanted as possible, while transplant centers are being held to very high standards in terms of outcomes. These two goals are not aligned. One important question is whether the transplant community would support transplanting more patients, but with potentially slightly worse outcomes.
    - Several members agreed that there needs to be more shared decision making with patients.
    - Another group raised the issue, related to outcomes, that while the MPSC has relaxed some of its metrics, the insurance companies have not, so we need the insurance companies involved in these conversations.
    - A table suggested that perhaps the OPTN needs to help align the goals. They also added that the OPTN has lost some credibility with its members and patients, so there is a lot of rebuilding to do. They said that damage has been done and misinformation has been spread to patients, and the OPTN should be a trusted source of information for the public.
    - Virtual attendees ranked the goals in the following order: Improve allocation efficiency (14 votes), increase donors and available organs for use (11 votes), increase transplants (9 votes), maximize the value of organs and increase post-transplant quality of life (7 votes), increase patient engagement through education and transparency (3 votes).
    - An attendee commented that there needs to be more transparency and consistency with expedited placement of organs.
    - A participant commented that improving allocation efficiency will naturally help with all of the other identified goals
    - A member stated that there needs to be more emphasis on donor hospital cooperation and accountability.
    - An attendee suggested that to increase patient engagement, they would like to see a patient portal to see information related to their listing and any offers they receive.
    - A member recommended that the OPTN help drive advancement in immunosuppression and develop policies that reduce donor-recipient HLA class II mismatching.
    - An attendee asked that the OPTN have an improved platform for its online education resources.

Policy Oversight Committee Update

- No comments.