OPTN

Thank you to everyone who attended the Region 7 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. An attendee noted that proving an HIV test was a false positive takes multiple confirmatory tests that not all OPOs have the ability to get in a timely fashion. The attendee does not support allowing match runs to be generated as HIV negative when there is no certainty that the test was a false positive. Another attendee added they would be in favor of clarifying how to classify donors as being false positive for HIV. They currently use a test that screens in bulk for HBV, HCV, and HIV. There are instances when that bulk test comes back positive, so they then perform individual test for each infectious disease and all three come back negative. To err on the side of caution they will proceed with the donor as positive for all three infectious diseases, which decreases utilization.

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. An attendee suggested Continuous Distribution should include detailed analysis and consideration of the efficiency and logistics impacts. As has been seen with lungs, there is a need to look at this from a system standpoint, not just an individual committee standpoint. Another attendee noted concerns with various aspects like distance, size match, and ventricular assist devices. Continuous Distribution needs to be continuously monitored to see if it can be improved. Another attended suggested evaluating the weight given to proximity due to inconsistent use of machine perfusion. Lastly, an attendee noted that Continuous Distribution may add ongoing barriers to progress.

Deceased Donor Support Therapy Data Collection

OPTN Operations and Safety Committee

- *Sentiment*: **7 strongly support, 4 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. It was noted that this is emerging as a very important issue, with one attendee adding that it can be challenging to find this information in an organ offer and it should be highlighted. Another attendee stated that having the Donor Support Therapy fields in DonorNet will help streamline the allocation process for both OPOs and transplant 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*: **4 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. An attendee noted that decreasing donor derived infection is important and guidance from DTAC is vital since it has the expertise of infectious disease physicians and epidemiologists. Another attendee added that if implemented correctly it should streamline the screening process. Lastly, the committee must assess the availability of infectious disease testing, including NAT, to ensure that there are no delays in deceased organ procurement.

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

OPTN Histocompatibility Committee

- *Sentiment*: **7 strongly support, 5 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 stated that administrative burdens should be removed if they do not add any benefit to the process. Another attendee added that the current form is unnecessary and seems to add delays to patient access. Lastly, it was noted that current efforts are trying to increase priority for these difficult to transplant candidates.

Update Guidance on Optimizing VCA Recovery

OPTN Vascularized Composite Allograft Transplantation Committee

- *Sentiment*: **1 strongly support, 7 support, 8 neutral/abstain, 0 oppose, 0 strongly oppose**
- *Comments*: None

Update HLA Equivalency Tables 2023

OPTN Histocompatibility Committee

- *Sentiment*: **1 strongly support, 9 support, 5 neutral/abstain, 0 oppose, 0 strongly oppose**
- *Comments*: None

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. An attendee noted that geographic equity is now complicated by machine perfusion and the transplant community needs to decide if machine perfusion should play a part in allocation models.

Discussion Agenda

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

OPTN Kidney & Pancreas Transplantation Committees

- *Comments*: An attendee suggested that the committees wait on releasing a final proposal for public comment until a detailed analysis of efficiency and logistical impacts on the system can be performed. This analysis needs to be considered on a system level, not an individual committee level. For dual kidney allocation, another attendee expressed minimal interest in making offers through a percentage of single kidney candidates, but strongly favored allowing OPOs to maintain discretion in establishing donor criteria. They added that pancreas transplant providers are the best resource to determine the plan for medically urgent pancreas candidates. For mandatory kidney/pancreas (KP) shares they agree with required KP allocation through a point, but without details of the attributes, or composite allocation score, it is difficult to recommend a stopping point before kidneys would be available for the kidney match. Another attendee noted that offer filters should be mandatory, requiring transplant centers to have a minimum of 3 filters for inside the 250NM circle and 3 filters for outside their 250NM circle. Additionally, OPOs should be allowed to perform national allocation. However, for dual kidney allocation should not be at the discretion of the OPOs as they are unaware if a transplant center would choose to accept a single or dual for their candidate with that donor's kidneys. There should be minimum donor criteria (such as percentage of glomerulosclerosis) that triggers an integrated dual list where the kidneys are immediately offered as dual, but the transplant center has the discretion to accept as a single or dual.

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

  - Mandatory Kidney/Pancreas Share Threshold
    - One group noted that for candidate characteristics the committees need to define which characteristics are important for required KP shares. For example, high waitlist mortality due to hypoglycemia awareness.
    - The next group questioned if expanding mandatory KP shares is necessary. It would be helpful to review data on the distance between the donor hospital and the recipient.

- Another group added that highly sensitized kidney patients warrant priority over KP shares. These patients rarely receive offers and the current allocation algorithm disadvantages high sensitized kidney patients.

- Pancreas Medical Urgency
  - One group felt that pancreas medical urgency is not a priority since most pancreas candidates have less than a year of waiting time.
  - The next group noted that they would like to see what are the true clinical values that define a pancreas medical urgent candidate.
  - Online attendees favored the inclusion of an exception-based medical urgency attribute for pancreas with one attendee noting that previous transplant outcome should be included in qualifying criteria.

- Dual Kidney
  - One group noted that there needs to be certain defined criteria that warrants dual kidney allocation, if certain criteria are met OPOs should go straight to dual kidney allocation. Their recommendation was to identify a certain kidney biopsy threshold as part of the potential criteria.
  - The next group added that it should be the discretion of OPOs for when to allocate dual kidneys. Additionally, allow transplant programs the discretion to accept an offer as either single or dual kidney instead of having a specific dual kidney match run.
  - Another group noted that in order to reduce non-utilization it would be beneficial to define the criteria that transplant programs use when accepting a dual kidney versus a single kidney offer. Additionally, it may help with allocation efficiency to create a list of dual kidney candidates prior to the OR so that OPOs can switch to dual kidney allocation quickly.
  - The next group suggested establishing best practices for dual kidney allocation based on the transplant programs that are currently accepting dual kidneys.
  - Another group suggested that the committee need to determine the societal value of allocating dual kidneys and weigh these considerations before making policy.
  - The majority of online participants felt that the policy definition of when an OPO may begin allocating kidneys as dual should be based on a combination of donor criteria and offering the kidney as single first. The majority also felt that if a donor's kidneys are being declined then OPOs should offer to less than 50% of the match run before the OPO can move to dual kidney allocation.

Amend Adult Heart Status 2 Mechanical Device Requirements

OPTN Heart Transplantation Committee

- *Sentiment*: **1 strongly support, 7 support, 5 neutral/abstain, 1 oppose, 3 strongly oppose**
- *Comments*: Attendees expressed concern that adding more criteria for determining Status 2 eligibility might result in more exception requests, complicating the allocation process further. They raised the issue of high inotrope levels, which they felt could limit physician flexibility and potentially run counter to the policy's intent. Additionally, the addition of more parameters and criteria could lead to an increase in exception requests, particularly for patients with a history of ventricular tachycardia (VT). In regard to handling current Status 2 candidate, an attendee questioned how the proposed policy changes would affect candidates who are currently listed as status 2 but may not meet the new criteria. There was discussion about the use of inotropes and intra-aortic balloon pumps (IABP) in managing heart transplant candidates, with some attendees questioning the evidence supporting the use of high-dose inotropes and the benefits of IABP, suggesting that the effectiveness of these interventions should be considered. An attendee noted that comparing waitlist mortality between Status 2 and Status 3 candidates is not entirely accurate, and the focus should be on specific subgroups within Status 2. In particular, candidates with surgically implanted non-endovascular LVAD devices should move to Status 1. An attendee raised concerns about the potential risks associated with the proposed parameters, especially in terms of weaning inotrope support, which could put patients at increased risk. The attendee emphasized the importance of patient safety and avoiding undue risk. Additionally, attendees proposed alternative approaches, such as requiring patients to meet Status 4 criteria before becoming eligible for Status 2 IABP criteria, to prevent patients from being upgraded from Status 6 directly to Status 2. An attendee noted concern over the complexity of the proposed changes and the potential increased administrative burden, including the need for more frequent status renewals. Lastly, and attendee suggested that the focus should be on understanding and addressing the reasons for the high number of exception requests, rather than adding more layers and barriers to Status 2 eligibility.

Require Reporting of Patient Safety Events

OPTN Membership & Professional Standards Committee

- *Sentiment:* **6 strongly support, 7 support, 2 neutral/abstain, 1 oppose, 0 strongly oppose**
- *Comments*: Overall, there was strong support for reporting specific safety events, with recommendations for streamlining the reporting process and providing guidance documents to assist in reporting. Attendees suggested modernizing the reporting system to streamline the process and reduce redundancy, making it easier for centers and organizations to report safety events. An attendee recommended treating wrong HLA typing similarly to ABO errors, as incorrect HLA typing could lead to the transplantation of the wrong organ, particularly in highly immunized candidates. Another attendee noted the importance of technological solutions for situations like when living donors are later placed on a waiting list. There was an interest in enhancing the computer system, especially regarding Social Security Number registration. Attendees agreed on the definition of a near miss and discussed the information that should be gathered when a near miss is reported to prevent future incidents from recurring. Questions about missing information were mentioned, suggesting that the reporting system should prompt for necessary details. Attendees discussed ways to encourage reporting and stressed the

importance of sharing information and lessons learned from near misses with the transplant community to benefit everyone. Some participants emphasized the importance of reporting any time a living donor is placed on the waitlist, not just within the first two years. This data is seen as crucial for long-term living donor outcomes. There were differing opinions on the timeline for reporting patient safety events with some participants suggested extending the required time frame from 24 hours to 72 hours or eliminating it altogether to avoid punitive measures. Additionally, the tracking of transportation events, particularly involving third-party vendors responsible for organ transportation, was considered important. Concerns were raised about whether punitive measures would be applied to member institutions when errors occurred due to third party vendors. Lastly, maintaining public confidence through enhanced transparency regarding safety events was seen as critical.

Modify Organ Offer Acceptance Limit

OPTN Organ Procurement Organization Committee

- *Sentiment:* **5 strongly support, 6 support, 2 neutral/abstain, 1 oppose, 2 strongly oppose**
- *Comments*: Overall, the need to improve efficiency and reduce the non-use of organs was emphasized, and several attendees strongly supported the proposal to limit accepted offers from two to one. However, it was noted that this change might not necessarily decrease the number of late turndowns, and there should be an exception for Status 1A liver candidates. One attendee noted that there is delicate balance between organ non-use, allocation out of sequence, and the potential impact on waitlist mortality. The committee needs to determine the threshold for how many out-of-sequence allocations could be deemed equivalent to waitlist mortality. Another attendee suggested that this change might align with Continuous Distribution (CD) and could be incorporated into future allocation models. Concerns were voiced about potential unintended behaviors that might arise if the change is implemented and how transplant centers might adapt to it. Another attendee added that the reasons behind liver declines and the specific codes used to indicate these reasons are important data to consider before making any changes. It was noted that having the ability to maintain a provisional yes could be valuable. In support of the proposal, an attendee emphasized the importance of timeliness in organ acceptance decisions, particularly leading up to the operating room (OR) time. Another attendee noted that programs may need to hold onto more than one organ offer if they are waiting on cross match results. They also suggested establishing timelines from organ offers to OR times to encourage communication between OPOs and transplant programs. Lastly, from a patient's perspective, the desire to have the flexibility to choose between organs in real-time was acknowledged. However, there was a consensus that this desire should not hinder the chances of someone else receiving a life-saving organ.

Concepts for a Collaborative Approach to Living Donor Data Collection

OPTN Living Donor Committee

- *Comments*: Overall, attendees were supportive of collecting data related to living donors and their experiences, but there were concerns about the potential burden on transplant centers and the need to carefully design data collection methods to ensure their value and effectiveness. An attendee noted there being a benefit of informing potential donors about the long-term outcomes of living donation, suggesting that this information could serve as an

incentive for more individuals to consider living donation. Several attendees raised concerns about the impact of increased administrative requirements on living donation rates. Attendees questioned how the data would be collected and expressed worries that additional data burdens might discourage centers from engaging in living donor evaluations. Another attendee noted that there needs to be a better understanding of the barriers to living donation, particularly for individuals who want to become living donors but encounter obstacles in the process. There was a recommendation for the OPTN to provide a secure portal for patients to self-report their experiences, potentially reducing the burden on transplant centers. Another attendee noted their support for collecting living donor data but raised concerns about the practical implementation. They stressed the importance of carefully selecting the data to collect and avoiding overburdening transplant programs. Additionally, there was strong support for a national registration for living donors and for lifelong tracking of organ donors. There was a suggestion of a voluntary system with automatic reminders for donors to input data. Lastly, it was suggested that for individuals who undergo evaluations but ultimately choose not to donate there should be a voluntary survey available for these individuals to provide feedback on their decision.

Ethical Analysis of Normothermic Regional Perfusion

OPTN Ethics Committee

- *Sentiment*: **2 strongly support, 10 support, 2 neutral/abstain, 1 oppose, 0 strongly oppose**
- *Comments*: Members of the region are supportive of the white paper and highlighted the need for careful consideration of the ethical, communication, and transparency aspects surrounding NRP as the technology becomes more prevalent in organ transplantation. Attendees emphasized the need for a well-defined strategy and path forward regarding the adoption of NRP. It was emphasized that the burden of understanding and consenting to these procedures should not fall on the grieving families at the bedside. It was recognized that clarifying the process and providing appropriate information to families is crucial. However, there were differing opinions on the extent and depth of information that should be disclosed to families during their time of grief. An attendee noted the necessity of standardized language to inform the public about the NRP process. One attendee shared there have been instances where they received organs encountered unexpected delays due to NRP, leading additional communication with the OPO. They recommended including a data field in DonorNet that provides easy access to detailed information about the procedures involved. Another attendee noted that ethical concerns regarding NRP are on the rise, and some hospitals that initially agreed to its use have changed their stance after experiencing the process. They also noted that some hospitals are instead opting for traditional DCD and ex vivo perfusion.

Updates

Councillor Update

- *Comments:* None

OPTN Patient Affairs Committee Update

- *Comments:* None

OPTN Membership and Professional Standards Committee Update

- *Comments*: It was noted that as the SRTR starts to publish transplant center offer and acceptance rate data, it would be helpful if they develop a baseline threshold as to what is acceptable or ideal for transplant centers.

Member Quality Update

- *Comments:* None

OPTN Executive Committee Update

- *Comments*: None

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.
    - The first group chose Improve allocation efficiency, Increase transplants, and Increase patient engagement through education and transparency as their top three strategic initiatives. Ensuring patients have the resources they need to advocate for themselves could potentially lead to an increase in transplantation.
    - The next group chose Improve allocation efficiency as their top priority. The OPTN needs to develop processes for efficiency. There is also a need to ensure transparency with the algorithms to have open evaluations moving forward in order to identify apparent flaws in the system. Their second priority was Maximizing the value of organs and increase post-transplant quality of life. The OPTN should focus on policies that foster and engage new innovations for transplant from a therapeutic standpoint. Additionally, there should be a plan to engage with the government along with other transplant organizations.
    - The next group also chose Improve allocation efficiency as their top priority. Additionally, by increasing donors and available organs for use it can help lead to increasing the number of transplants. The group felt that a key theme missing from the priorities is equity in organ allocation; there is much work left to be done in this area.
    - The last group also chose Improve allocation efficiency as their top priority. They agreed that the focus should be on organs that are available for use. One way to help maximize the value of organs is by standardizing OPO practices. This will also help impact post-transplant outcomes.

- Online participants chose Improve allocation efficiency, Increase transplants, and Increase donors and available organs for use as their top three priorities. The group agreed that a key missing theme is equity in organ allocation along with improving IT infrastructure. In regard to Increase patient engagement through education and transparency, one attendee noted that the more informed a patient is, the more efficient that allocation process can be.

OPTN Policy Oversight Committee Update

- *Comments:* None