OPTN

Thank you to everyone who attended the Region 10 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. One attendee noted that further clarification would be helpful to programs. Another member added that clinical guidance would be imperative in trying to increase the recipient pool for these situations with a positive donor HIV result. Lastly, another attendee stated that it is difficult to understand the scope of the issue. It would be helpful to see data on the incidence of positive HIV results and organs not used due to the positive HIV result.

Continuous Distribution of Hearts Concept Paper

OPTN Heart Transplantation Committee

- *Comments*: It was noted that the move to Continuous Distribution (CD) will create a more equitable waitlist for heart transplant candidates. Another attendee suggested the right ventricular failure that precludes consideration of LVAD should be added as an attribute for CD. Someone else added that it is unclear how proximity should be weighted in CD for heart transplantation, especially in the era of DCD utilization, normothermic regional perfusion, and machine perfusion. Another attendee noted that the OPTN needs to develop a plan on how to handle programs submitting exception requests in CD. There should be some level of holding programs accountable so that the system is not overrun with exceptions. Lastly, an attendee suggested that multi-organ candidates with congenital diagnoses or smaller candidates be considered as their own attribute. It is also an opportunity for the Heart Transplantation Committee to work with the Multi-Organ Transplantation Committee on the best path forward for multi-organ candidates in CD.

Deceased Donor Support Therapy Data Collection

OPTN Operations and Safety Committee

- *Sentiment:* **1 strongly support, 11 support, 2 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 their support as this information is necessary to increase the number of organs transplanted as well as improve transplant outcomes.

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

OPTN *Disease Transmission Advisory Committee (Ad Hoc)*

- *Sentiment:* **3 strongly support, 10 support, 2 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 encourages the committee to make sure this policy change does not negatively impact organ transplant rates. Another attendee noted their support of the proposal adding that programs and OPOs often base their infectious disease testing on their particular geography and do not often perform specific infectious disease testing if they are in a low-risk area. Lastly, another attendee suggested that the screening for these particular infectious diseases needs to be better highlighted in DonorNet, perhaps within its own section or box adjacent to the infectious disease testing data. Currently, it is often hard to find within the DonorNet attachments.

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

OPTN Histocompatibility Committee

- *Sentiment:* **8 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 noted that this change will save transplant programs time when adding patients to the waitlist.

Update Guidance on Optimizing VCA Recovery

OPTN Vascularized Composite Allograft Transplantation Committee

- *Sentiment:* **1 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. An attendee noted that this proposal is necessary to increase the number of VCA transplants.

Update HLA Equivalency Tables 2023

OPTN Histocompatibility Committee

- *Sentiment:* **4 strongly support, 8 support, 4 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 stated that this update is needed in order to alleviate waitlist issues in the current process and decrease required communication of OPO HLA representatives with transplant program HLA representatives.

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*: Overall, participants expressed appreciation for the committee's efforts to enhance organ allocation efficiency. However, there was a shared belief that addressing all aspects requires active input from front-line coordinators in both OPOs and transplant programs. Such input was seen as crucial for identifying barriers that hinder optimal efficiency in the organ offer process. There was mixed feedback about how to define Pancreas Medical Urgency with one attendee saying that there does not need to be a category for pancreas medical urgency. However, another attendee suggested using a scale rather than a binary distinction. Another attendee added that there needs to be clear criteria similar to those seen in the strict cholangitis exception criteria for liver transplantation. For dual kidney allocation, attendees emphasized the importance of applying very strict criteria to avoid denying single kidney offers to unique candidates for whom those kidneys might be the sole option. Another attendee suggested considering the time aspect due to increasing cold ischemic time and decreasing acceptance rates. Additionally, it was recommended that donor eligibility should factor in age and the type of donation, DCD versus brain death. Another attendee noted that OPOs should be allowed to switch to dual kidney allocation after 20 transplant programs decline a single kidney offer from a donor.

  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 generally they support the concept of pancreas medical urgency, with the caveat that the Pancreas Transplantation and/or the Kidney Transplantation committees should work to establish objective criteria to define urgency and leave little room for ambiguity particularly in thinking about allocation. In defining that urgency, whichever criteria is established, it would be helpful to further define the directive and order of multi-visceral allocation. Currently, a lot of discretion is left to OPOs, and further clarification would be very helpful to increase allocation efficiency.
    - Another group felt that too many pancreata are getting turned down by programs already and there is too much room for gaming the system. They do not see a reason for having pancreas medical urgency.

- Another group disagreed and felt that there is a need for pancreas medical urgency. Patients who have multiple readmissions for hypoglycemia or those with multiple motor vehicle crashes would be considered medically urgent. Most of these patients have medically difficult to manage diabetes, making small changes in insulin can lead to wide swings to blood sugars.
- Another group discussed establishing a medical review board, as there is lots of experience in the heart and lung community. Certainly, there are challenges and difficulties, but it can help the system be more practical and efficient. It's going to take a lot of understanding from the community, and there will be a lot of requests which can burden a review board. The lung community suggests having examples and guidance documents on how to write an exception available to the community.
- Online attendees support the inclusion of an exception-based medical urgency attribute for pancreas. One attendee commented that the criteria should include if a candidate has tried a failed medical treatment for pancreas and has experienced fainting as well as a creatinine over 3mg/dL.

o Dual Kidney

- The first group discussed how should post cross clamp data be considered, which is the trickiest part. After some debate, for the purposes of allocation, post cross clamp data should not be considered. Set donor criteria to include Age, DCD, history and lab values, warm ischemic time in the case of DCD, and have criteria similar to split liver criteria. Kidneys that meet that dual kidney allocation would allocate first to dual kidney list and centers would have the opportunity to accept. If only one kidney is transplantable, the kidney is going to trickle down the list anyway to a program looking for a kidney like that. Defining donor criteria is the trickiest part of this.
- Another group agreed with the first comment about criteria in general and dual kidney match run first. If allocation starts with single, programs should have the option to decline the single kidney offer, but be able to indicate that they are interested in a dual kidney offer. This would help with allocation efficiency as an OPO starts with dual kidney allocation.
- The next group suggested that instead of offering to a certain percentage of the single kidney allocation match run, the threshold should be by region and number of centers or patients that declined the single kidney offer. They suggested that the threshold should be declines from twenty programs
- Another group noted the high volume of offers and complexity of allocating donated organs and agreed that it will be difficult to establish dual kidney allocation. However, if accomplished it would greatly improve allocation efficiency.
- The last group suggested adding dual kidney usage to current data reports. It would be helpful to see who is accepting dual kidneys and establish patterns.
- A majority of online attendees voted for a combination of donor criteria and offering the kidney as single first. The majority also favored a match run offer threshold of 50-75% before the OPO can offer the kidneys as dual.

- Mandatory Kidney/Pancreas Share Threshold
  - No comments

Amend Adult Heart Status 2 Mechanical Device Requirements

OPTN Heart Transplantation Committee

- *Sentiment:* **0 strongly support, 8 support, 6 neutral/abstain, 1 oppose, 0 strongly oppose**
- *Comments:* Members of the region support the proposed changes to adult heart status 2 mechanical device requirements, but raised concerns in regard to issues with contraindications, weaning processes, and the need for more thorough guidelines. Attendees noted the need for change due to the increasing number of patients at Status 2 with balloon pumps and the identified inequities in terms of mortality. Concerns were raised about the impact of arrhythmias, a common issue for patients in cardiogenic shock on inotropes, on appeals based on inotrope-driven arrhythmias. An attendee highlighted practical challenges, such as patients arriving at transplant hospitals already on devices and the potential need for a weaning attempt to apply for Status 2. Questions were posed about the definition of contraindications to inotropic therapy and the potential for numerous exception requests in the absence of clear guidelines. There was concern over the minimum time requirement for treatment with inotropes prior to assessment with hemodynamics, along with the potential for patients transferred to transplant hospitals while already on mechanical circulatory support (MCS) to face delays in listing due to the requirement for weaning. Lastly, an attendee expressed concern about the thoroughness of the proposal, suggesting that it might be rushed without adequately addressing known concerns. The need for careful and comprehensive policy development, rather than addressing issues as they arise, was emphasized.

Require Reporting of Patient Safety Events

OPTN Membership & Professional Standards Committee

- *Sentiment:* **3 strongly support, 9 support, 2 neutral/abstain, 2 oppose, 0 strongly oppose**
- *Comments*: Members of the region support the proposal. The general consensus was in favor of timely reporting of patient safety events, but there was a shared sentiment that the committee should re-evaluate the urgency requirement for reporting instances that may not immediately jeopardize patient safety. Furthermore, consideration should be given to potential data duplication if similar information is already being reported through other channels. One attendee emphasized the critical nature of near misses in HLA typing errors, suggesting that the committee should consider a requirement in the TIEDI system for the completion of the Donor Histocompatibility Form (DHF) within two months after an event. Others recommended minimizing the workload on programs for reporting while maintaining clear and strict definitions. There was a call for more detailed clarification on the term "sanction taken by a state medical board or other professional body" to ensure that instances involving professionals losing medical licenses or clinical privileges are reported. The suggestion to create a specific list of acceptable reasons for submitting a Patient Safety Report was put forth to enhance the efficiency of the reporting process and time management. While supporting the reporting of patient safety events, an attendee expressed uncertainty about the necessity of reporting all events within a 24-hour window, extending this period to 48 hours seems reasonable. Lastly, a

point of contention was raised regarding the addition of living donors to the transplant waitlist within two years of donation as a patient safety event. The attendee did not see this as aligned with the concept of patient safety events.

Modify Organ Offer Acceptance Limit

OPTN Organ Procurement Organization Committee

- *Sentiment:* **5 strongly support, 5 support, 3 neutral/abstain, 3 oppose, 0 strongly oppose**
- *Comments*: Overall, the region is supportive of the proposal, but several attendees offered suggestions for instances when two acceptances are still appropriate. An attendee expressed support for the proposal's spirit but highlighted a concern that organ acceptance might not always align with quality due to logistical factors. They suggested exceptions for Status 1 liver candidates. Additionally, significance of timing in DCD cases was emphasized, with a second acceptance option seen as crucial for recipient assurance. Another attendee noted that managing multiple acceptances is challenging from an allocation standpoint, and the proposed policy is anticipated to reduce last-minute turndowns and organ non-utilization. Others suggested considerations for high MELD patients in addition to DCD donors. Another attendee suggested adding exceptions for Status 1 Liver or hepatic artery MELD 40 exception candidates who require the first available offer due to critical conditions. Acknowledgment was given to the necessity of exceptions for more seriously ill patients. Despite statistics indicating minimal concurrent DCD liver acceptances, there was a suggestion to allow for two liver acceptances when one is for a DCD offer. This could result in a rise in DCD liver acceptance rates. Another attendee noted that more data on DCD offer acceptances is needed. Lastly, an attendee suggested introducing a time limit for accepting subsequent organs for the same patient.

Concepts for a Collaborative Approach to Living Donor Data Collection

OPTN Living Donor Committee

- *Comments*: Members of the region voiced some support for data collection, the prevailing sentiment among the comments was caution and concern regarding the increased burden on transplant centers and the potential impact on patient care. There was acknowledgment of the challenge of motivating living donors to participate in follow-up, with the sentiment that willing donors would comply while others would decline regardless. The distinction between voluntary and mandatory follow-up was noted, with a caution that starting with voluntary follow-up would lead to mandatory. Standardizing the education provided to potential donors who have been turned down was suggested, emphasizing the right to seek evaluation at another center. While the goal of understanding long-term outcomes for living donors was appreciated, an attendee noted that may not be practical. Larger centers, with high donor volumes, questioned the responsibility of caring for thousands of donors over the long term. The project's impact on center burden and the need for clear definitions and data were highlighted. Concerns were raised about the practicality of data collection, especially for pre-donation potential candidates. Some advocated for evidence-based acceptance criteria and collaboration with professional organizations. Support for the project was expressed, but the administrative burden and potential for punitive actions were concerning. Lastly, resource allocation for data collection and follow-up was questioned, particularly given the challenges in achieving even the current 2-year

follow-up. The burden on transplant resources and the potential impact on living donor transplant opportunities were major considerations.

Ethical Analysis of Normothermic Regional Perfusion

OPTN Ethics Committee

- *Sentiment:* **0 strongly support, 9 support, 6 neutral/abstain, 1 oppose, 0 strongly oppose**
- *Comments*: Members of the region are supportive of the white paper. Attendees noted the use of NRP as an ethical procedure to enhance donation processes, while others raised concerns about disclosing techniques to families or requiring their approval. The need for balanced education, representation, and further study was emphasized throughout the comments. Some attendees expressed their experiences and observations, pointing out the need for broader engagement beyond the transplant community. The absence of input from lawyers or laypersons was noted, and it was suggested that including individuals with diverse perspectives, such as those not directly involved in medicine or transplantation, could provide valuable insights. The thoughtful balance of the white paper was acknowledged, yet some attendees felt that it didn't delve deeply into the potential harm caused by not honoring the decision to donate organs. The harm to donor families and the potential loss of organ utilization due to not implementing NRP were raised as important considerations. Additionally, education and clear communication were emphasized as crucial aspects of engaging the public and donor families in discussions about donation and NRP. The inclusion of the American College of Physicians and donor families in the conversation was recommended to enhance transparency and understanding. Concerns were expressed about the disclosure of procurement techniques to donor families, with some attendees advocating for transparency while others were cautious about potential confusion and unintended consequences. There were calls for more study and data on this matter. Lastly, the role of declaring physicians and the difficulty they face in their role was highlighted, along with the necessity of educating families about the issues involved. The importance of distinguishing between the decision to donate and the specific techniques of recovery was stressed by some attendees, who argued against requiring families' approval of procedural details.

Updates

Councillor Update

- *Comments*: None

OPTN Patient Affairs Committee Update

- *Comments*: None

OPTN Membership and Professional Standards Committee Update

- *Comments:* Overall, attendees expressed a strong desire for improved collaboration, consistency, and alignment between OPOs and transplant centers in order to address the challenges related to organ procurement, management, and allocation more effectively. Attendees noted the need to address donor management and allocation policies, highlighting the importance of achieving successful organ utilization through improved processes.

Additionally, the roles of OPOs and transplant centers were delineated, with a focus on the areas of donor management, preservation, and procurement, which were deemed to be common challenges. The potential for alignment of metrics for OPOs and transplant centers was noted as an opportunity, particularly in areas where both entities face challenges. An attendee stressed the complexity of approaching donor families and the need for appropriate donor family interaction, alongside considerations about case duration and optimal donor management practices. Several attendees expressed concerns with the variability in pursuing out of sequence allocation and aggressive offer across different OPOs. The potential for OPOs to work together, synchronize processes, and share data was highlighted as a way to enhance consistency. Next, concerns were raised about incomplete offers and the need for common technology and data standards to improve organ placement efficiency. An attendee noted the discrepancy between the number of organs procured and those transplanted was recognized as a significant issue. The MPSC's focus on measuring OPO performance was appreciated, but the attendee stressed the need to address the challenge of getting organs to the right recipients. With recent allocation changes and the increase in out of sequence allocation, this prompts questions about the quality of donors pursued and the need for consistency in decision-making. Lastly, the importance of dynamic and common technology was emphasized to improve the speed and efficiency of the allocation process, and the need for consistent data and definitions across OPOs was highlighted to ensure accurate analysis and comparison.

Member Quality Update

- *Comments*: It was noted that the data used for the performance monitoring reports will be retrospective and will be transferred to a dashboard for members.

OPTN Executive Committee Update

- *Comments*: As the OPTN works with the FAA to improve organ transportation, one attendee noted the importance of making sure all air carriers participate in any changes made to organ transport. The OPTN should encourage the FAA to make that happen. In response to the update on the wait time modifications for those negatively impacted by the use of a race-inclusive eGFR, one attendee noted that there have been instances where an African American's eGFR record has been redacted from earlier lab panels. As a result, those affected are unable to obtain the necessary data needed to update their waiting time.

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 focused on what we as a community can control – increase the number of transplants, increase organ donors, and improve efficiency. In regard to organ non-utilization over time, has there been a change in the percentage of organs not utilized, or has that percentage stayed the same? As a community we have done more transplants than before, and we want to continue to see an increase in organ transplants.
- The next group focused on transparency in patient education. It is important that patients and donor families have more education on what happens with transplants and how that process works. Additionally, what do programs expect from patients, and do the patients have resources available to them. Another discussion point was on insurance providers and what information is provided by those providers.
- Another group highlighted the white paper by the Ethics Committee and the Lung Committee patient webinars on how patients can compare programs. There needs to be a repository that patients can access when deciding on a particular program. This should be an easy task for all transplant programs to contribute to.
- The next group mostly focused on increasing transplants as the biggest priority and the rest of the priorities can feed into that. The other was improving allocation efficiency. There was much discussion about the challenge of being all things to the whole community of donation and transplant and how challenging that creates. Perhaps in the future if organizations and whoever holds the OPTN contract are allowed to be more singularly focused, that would be better. The group discussed whether it's the OPTN's responsibility to increase patient engagement and what role play in that. The SRTR is working on their Task 5 Initiative which came from their HRSA. They held a conference last July where they pulled together stakeholders and are developing a place where patients can go, at an understandable level, to compare transplant programs.
- The next group focused on what was possible, not just what would be good for the OPTN. There is a huge opportunity for improving allocation efficiency. OPOs and transplant programs are using gaps to maximize opportunities and find recipients for marginal organs. There are opportunities for enhancement to increase opportunities for placement. OPOs are not typically involved but there could be more visibility for groups that could refer patients for transplant, particularly in underserved areas. Currently, a gap exists for OPOs and donor hospitals. A best practice from Region 5 is a collaborative that invites hospital partners to join these conversations in a more controlled environment.
- Another group agreed that increasing transplants is our first and highest priority. We need to focus on what is missing, especially alignment between both CMS and OPTN. There is an opportunity for alignment of metrics between OPOs, transplant programs, and an ability to get alignment with Donor Hospitals. The other missing piece, and this may take some time, but there is not a lot of consistency on education in terms of donation or registration options. That's not taken up at a national level and would love to see that included in the next OPTN Strategic Plan.
- The last group talked about the priority of educating patients about transplantation in general, ensuring that potential candidates are referred appropriately, and know their resources, especially in communities with limited access to healthcare.

- Virtual attendees selected the following as their top three strategic plan priorities: Improve Allocation Efficiency, Maximize the Value of Organs and Increase Post-Transplant Quality of Life, and Increase Transplants. One attendee added that the business of organs flying commercially and then being trapped in cargo holds should be addressed. This should be impressed upon the policy makers that regardless of how efficiency the OPTN makes available viable kidneys for transplant, organs sitting in cargo hold for 12 hours definitely impacts the decision making of the transplant program. Another attendee stated that stopgaps need to be added to UNet in order to prevent organ offers when necessary information is not available. Another attendee added that in order to Improve allocation efficiency, Maximize the value of organs and increase post-transplant quality of life and Increase transplants. you have to engage the patients more and improve earlier education and make more transparent the flow of the transplant process to the patients/caregivers-families. In regard to Increase Donors and Available Organs for Use an attendee noted this can place tremendous strain on donor hospitals and can erode public trust and favorable relationship with organ donation if done in too aggressive of manner - please be aware of and sensitive to this.
- Attendees suggested two additional priorities that should be considered. First, improve access to vulnerable populations like minorities and children who do not have powerful advocates. Second, accept better than dialysis kidneys and not always seek the "perfect" organ. This will require discussion with regulatory bodies, but also a shift in transplant culture.

OPTN Policy Oversight Committee Update

- *Comments*: An attendee wanted to highlight the lung placement matching efficiency project that a subcommittee of the Lung Transplantation Committee is working on as a result of moving to Continuous Distribution. Lung programs have seen the number of organ offers increase since the implementation of Continuous Distribution which has created inefficiencies for lung transplant programs, preventing timely response to offer. The subcommittee is looking at ways to increase efficiency in lung offers so that programs can respond in a timely manner, thus helping OPOs as they allocate lungs.