OPTN

Thank you to everyone who attended the Region 10 Winter 2024 meeting. Your participation is critical to the OPTN policy development process.

Regional meeting presentations and materials

Public comment closes March 19! Submit your comments

Continuous Distribution – tell us what you value!
The Heart Transplantation Committee is seeking feedback from the community to inform the development of heart continuous distribution allocation. The community is invited to participate in a prioritization exercise through March 19. You do not need to be a clinician, heart transplant professional or heart patient to participate. Click here to complete the exercise and provide your feedback.

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

Non-Discussion Agenda

Update Post-Transplant Histocompatibility Data Collection

OPTN Histocompatibility Committee

- *Sentiment*: **8 strongly support, 13 support, 0 neutral/abstain, 0 oppose, 0 strongly oppose**
- *Comments*: None

Promote Efficiency of Lung Allocation

OPTN Lung Transplantation Committee

- *Sentiment*: **7 strongly support, 12 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 stated that there is a need to improve pediatric access to lung donors. Another attendee noted that offer filters should be implemented in order to decrease late offer declines that lead to non-transplantable organs. It was also noted that the addition of offer filters for lung transplant programs will assist in decreasing allocation time, so long as programs effectively utilize offer filters. It was suggested, that when implemented, it should be an opt out option based on previous acceptance behavior for the transplant programs.

Standardize Six Minute Walk for Lung Allocation

OPTN Lung Transplantation Committee

- *Sentiment*: **3 strongly support, 12 support, 5 neutral/abstain, 0 oppose, 0 strongly oppose**
- *Comments*: None

Clarifying Requirements for Pronouncement of Death

OPTN Organ Procurement Organization Committee

- *Sentiment*: **8 strongly support, 12 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. An attendee noted that there is a need for clarification for those who declare death to ensure that they do not have conflicts of interest due to their OPO relationship.

Discussion Agenda

Standardize the Patient Safety Contact and Reduce Duplicate Reporting

Ad Hoc Disease Transmission Advisory Committee

- *Sentiment*: **12 strongly support, 9 support, 0 neutral/abstain, 2 oppose, 0 strongly oppose**
- *Comments*: Member of the region were supportive of the proposal. One attendee noted that the requirement to verify the listed Patient Safety Contact every six months may be too infrequent. A few attendees expressed concerns with the requirement that Patient Safety Contacts must be employed by the institution and can no longer be third party contractors. One attendee added that it is critical to acknowledge that many transplant programs have established contracted relationships with third party contractors and these contractual relationships are tried-and-tested with seamless communication. Another attendee added that it is up to the centers to work with their third-party contractors to ensure they have access to the appropriate transplant center staff to pass along the information. If this is a problem with some safety notifications, those transplant centers should be held accountable. Do not penalize all centers using contracted services for the poor planning on the part of some centers. Lastly, an attendee noted that this will help the reporting process/timeline/data tracking tremendously from the OPO perspective. Trying to track down Patient Safety Contacts that don't answer, don't know what to do with the information, or directing that information to someone else increases unnecessary workload for the OPO and potentially puts the transplant patient at risk for delayed response/treatment due to this run around. Having it built directly into the system would prevent the burden OPOs currently experience by having to make multiple attempts to find the correct person to receive it and confirm the information that has been received. Instead, the OPO should be able to input the information into the OPTN computer system and the system should send automatic notifications to those programs that accepted the donor organs and require acknowledgement of that notification. The OPOs have performed the tests, received the results, and are ready to report them but are being held responsible when the transplant center is not prepared, which is not fair.

Concepts for Modifying Multi-Organ Policies

OPTN Ad Hoc Multi-Organ Transplantation Committee

- *Comments*: Overall, members of the region were appreciative of the chance to provide early feedback as the committee works towards a potential policy proposal. The discussions reflected a comprehensive exploration of the complexities and considerations in multi-organ transplantation policies, touching on equity, patient prioritization, and the need for standardized procedures. One attendee expressed contentment with the existing data which does not seem to be significant issues. The Simultaneous Liver Kidney (SLK) policy was noted, and there was a call for MOT-specific policies across all organs. Attendees touched on the exclusion of privileged groups, such as pediatric patients and those with high CPRA. Suggestions

were made to consider including certain groups, like high CPRA kidney-pancreas (KP) candidates and heart-kidney candidates. Many attendees agreed with prioritizing candidates with 100% CPRA, contingent on the availability of crossmatching. Concerns were raised about the lack of a standardized acuity score across organs. A suggestion emerged to categorize KP candidates as kidney candidates who also need a pancreas, emphasizing the need for clarity in distinguishing between different patient groups. Next, concerns were raised about the current system disadvantaging pediatric kidney candidates, leading to prolonged wait times for kidney offers. Suggestions included having at least one kidney allocated to a kidney-alone recipient and adjusting the allocation policies for pediatric donors and recipients. Participants called for clarification and standardization of multi-organ allocation policies. The idea of giving greater priority to specific groups, such as pediatric, high CPRA, medically urgent, and former living donors, was discussed. Some participants advocated for a system allowing simultaneous allocation of heart, lung, and liver from one match run to streamline the process and reduce delays in organ placement. The importance of addressing issues related to required shares and the timing of allocations was highlighted. Concerns were raised about the unequal distribution of kidneys based on KDPI, particularly affecting pediatric patients. Suggestions included offering kidneys to kidney-only patients when both kidneys are available and implementing criteria based on KDPI for MOT allocation. For example, donors with a KDPI less than 35% should be offered first to kidney alone candidates, specifically pediatric candidates, and donors with a KDPI greater than 35% could be offered to MOT candidates first.

Modify Effect of Acceptance Policy

OPTN Ad Hoc Multi-Organ Transplantation Committee

- *Sentiment*: **7 strongly support, 11 support, 2 neutral/abstain, 2 oppose, 0 strongly oppose**
- *Comments*: Members of the region are supportive of the proposal. Concerns were raised about the frequency of MOTs and their potential impact on patients, particularly in the pediatric population. There was a suggestion to review data from the past year to understand the prevalence of MOTs and whether there should be exceptions, such as carving out pediatric patients from these proposed changes. Another attendee acknowledged the challenges of handling MOT allocation on a case-by-case basis and emphasized the importance of time as a significant variable in allocation. There was a suggestion to define specific timeframes or match sequence number for determining allocation and holding single organs. Another attendee proposed modifications in the allocation of low Kidney Donor Profile Index (KDPI) kidneys to MOTs, with considerations for vulnerable populations like highly sensitized individuals, pediatrics, and prior living donors. Several attendees recommended protecting high CPRA patients and limiting MOT kidney placement to one MOT candidate per donor. The unequal distribution of kidneys based on KDPI categories, especially affecting vulnerable populations like pediatric patients, is a cause for concern. There's was also apprehension about the potential impact on liver/kidney or heart/kidney candidates if they are bypassed because the kidney is not available.

OPTN Strategic Plan 2024-2027

OPTN Executive Committee

- *Sentiment*: **3 strongly support, 16 support, 2 neutral/abstain, 0 oppose, 0 strongly oppose**
- *Comments*: Members of the region are supportive of the Strategic Plan. One attendee noted that with the OPTN Modernization Initiative it would be helpful to have insight from HRSA as to the future of the Strategic Plan and if changes will occur as part of the Modernization Initiative. Another attendee would like to see initiatives added to the Strategic Plan around living donation given the living donation numbers have stayed relatively the same while deceased donation continues to increase each year. Another attendee noted that efforts to improve organ non-use should primarily be focused on kidney allocation and distribution. The non-renal organs are improving with practice change and improved technology. The kidney need is the most substantial and optimizing kidney utilization should be a primary focus of OPTN efforts. Lastly, and attendee suggested focusing on the non-transplant parts of making the nation's transplant system work, such as support for transplant professionals, transplant hospitals, etc. Increasing the number of transplants is more than just can we have more organs recovered and distributed with equity to more programs/patients.

Update on Continuous Distribution of Hearts

OPTN Heart Transplantation Committee

- *Comments*: Overall, there was appreciation for the committee's efforts, and support for continuous distribution. Participants expressed interest in understanding specific variables under "medical urgency" and inquired about potential shifts away from the heavy reliance on mechanical devices in the current allocation system. There was acknowledgment of the pressure on OPOs to transplant more organs, with hopes that expedited placement will enhance efficiency without compromising equity. One attendee recommended incorporating commonly used "standard" exception requests as attributes to minimize the use of exceptions and potential inequities. Additionally, there was agreement on including Ventricular Assist Device (VAD) status as an attribute, with considerations for stability on VAD and measures to prevent manipulation of the system. Measurable indicators of end-organ perfusion may be useful, for example, to help define medical urgency. Lastly, there was consensus on monitoring the impact of the continuous distribution model on equity during implementation.

National Liver Review Board (NLRB) Updates Related to Transplant Oncology

OPTN Liver & Intestinal Organ Transplantation Committee

- *Sentiment*: **9 strongly support, 11 support, 2 neutral/abstain, 0 oppose, 0 strongly oppose**
- *Comments*: Members of the region are supportive of the proposal. Participants discussed various aspects of liver transplant allocation, focusing on specific medical conditions and exceptions. An attendee noted surprise that neuroendocrine tumors were not included in the discussion. Questions arose about the MELD score of MMaT minus 20 for colorectal cancer and whether a score of 15 would provide more exposure to open offers. The presenter acknowledged the discussion within the committee, emphasizing the challenges in capturing data for colorectal liver metastases patients and the considerations behind the MELD of 15. Some participants questioned the need for mathematical modeling and proposed using a

standard exception of 15 for colorectal liver metastases patients. The integration of these exceptions into the Continuous Distribution (CD) system was also considered, with uncertainty about how non-standard indications would fit into the CD framework. Additionally, concerns were raised about the potential increase in exception requests and the burden on the review board. Participants supported the standardization of exceptions for neuroendocrine tumors and emphasized the importance of monitoring the cases for review by the NLRB to ensure adequate expertise and timely responses. Additionally, there was a suggestion to consider liver disease and hepatocellular carcinoma (HCC) secondary to Fontan Heart, expanding the scope of conditions for discussion within the liver transplant allocation system.

Refit Kidney Donor Profile Index (KDPI) Without Race and Hepatitis C Virus
OPTN Minority Affairs Committee

- *Sentiment:* **11 strongly support, 8 support, 2 neutral/abstain, 2 oppose, 0 strongly oppose**
- *Comments*: Members of the region are supportive of the proposal. The discussion revolved around the Kidney Donor Profile Index (KDPI) and potential modifications to its components. Participants expressed concern over the significant placement of Black donors in higher KDPI categories, pointing out the need for awareness of this disparity. There is overall support for the proposed changes, particularly in relation to Hepatitis C (HCV) and the consideration of Apol-1 data. Concerns were raised about the proposal to remove the Hep C variable without sufficient data and the potential unintended consequences on non-utilization rates. Some participants suggest a broader reevaluation of the entire KDPI, proposing a "KDPI 2.0" to address modern data and potential psychological shifts in its interpretation. Another attendee noted the psychological impact of KDPI, the need for standardizing biopsy processes, and concerns about insurance coverage for HCV treatment post-transplant. The sentiment was generally supportive of revisiting and potentially redefining the KDPI calculation, with emphasis on incorporating modern data and avoiding artificial inflation of KDPI that may lead to organ non-utilization. There was also a call for standardized processing methods and interpretations of biopsies to ensure consistency.

Updates

Councillor Update

- *Comments*: None

OPTN Patient Affairs Committee Update

- *Comments*: None

OPTN Membership and Professional Standards Committee Update

- *Comments*: None

OPTN Executive Committee Update

- *Comments*: In response to the bold aim of sixty thousand transplants by 2026, one attendee noted that the goal may be too bold. Their hospital is short staffed, which is a common occurrence throughout the transplant community. Additionally, it is difficult to grow living donation transplants when deceased donation continues to grow. Another attendee echoed the

same sentiment that their program is struggling to grow their living donor program even though they tell kidney candidates that the best organ will come from a living donor. Another attendee added that for the bold aim of sixty thousand transplants, there is a massive infrastructure concern with rapidly increasing transplant numbers. Hospitals are seeing a continuous turnover of nurses and coordinators. It's important to address where the staff to take care of this increase in transplant recipients is going to come from, as there will be years of additional care for recipients. The OPTN needs to think about how we can carve out some of the money to support this endeavor.

Improving Organ Usage and Efficiency: Update from the Expeditious Task Force

- *Comments*: Discussions opened with the need for standardization in various aspects of organ procurement processes. Donor hospitals within a given Donation Service Area (DSA) were reported to have inconsistent practices regarding medications for comfort, donor management, and participation in DCD recovery. Participants highlighted the importance of establishing clear DCD policies to ensure uniformity. Concerns were raised about the significant role of OPO discretion in the allocation process, emphasizing the necessity for well-defined guiding policies. Timely OPO onsite responses to referrals and effective communication with attending physicians were identified as crucial elements for optimizing organ function. Participants expressed a desire for improved electronic tracking systems to monitor the timing of offer responses, from referral to recovery. In regard to kidney allocation, there was a call for standardizing the use of virtual crossmatches. Additionally, it was proposed that every OPO should have a dedicated stand-alone recovery center to streamline and enhance the organ procurement process. Overall, the discussions underscored the importance of consistency, clear policies, and streamlined communication in the organ procurement and allocation process. Next, participants emphasized the need for comprehensive and granular data collection. There was a suggestion to include specific details about each organ, such as photographs of unused organs, to enhance the quality and depth of data. Concerns were raised about the challenges of finding living donors. Some participants speculated that the success achieved in organ transplantation might contribute to a mindset where potential recipients anticipate a "better" organ becoming available in the future, impacting the willingness to accept living donors. In the field of heart and lung transplantation, there was a consensus that risk aversion remains prevalent. Despite advancements in outcomes, there is still a cautious approach, and participants noted that addressing this mindset is important for further progress. Logistical challenges in liver transplantation were discussed, with instances of having to turn down livers due to logistics issues. The suggestion was made to engage with CMS and other payers to consider billing and reimbursement for procurement and transport separately, acknowledging the need for specialized expertise in this area. Recognizing the significance of engaging hospital leadership, participants emphasized the importance of involving hospital c-suite executives in organ transplantation discussions. Building strong relationships with hospital leadership was identified as a key factor in overcoming challenges and fostering collaboration between OPOs and transplant centers. In regard to policy review, participants noted a shift in the allocation process from a simpler model involving a few transplant centers communicating with one OPO to a larger, more complex system. This expansion has led to a slowdown in the allocation process.

The difficulties in securing air transport emerged as a significant issue. Participants cited instances, especially in lung transplantation with the Continuous Distribution (CD) model, where receiving offers from distant locations on the West Coast posed challenges due to prohibitive costs associated with transportation. This has added complexity to decision-making processes. While changes in allocation were acknowledged to have enhanced equity, there was a recognition that they have also led to increased costs. The balance between achieving fairness in allocation and managing the associated financial implications was discussed, reflecting the ongoing need to optimize both aspects in the evolving landscape of organ transplantation. When discussing potential protocols for PDSAs, there was a suggestion to enhance the efficiency of organ allocation by incorporating a feature or filter in the system. This proposed feature would allow for the identification or exclusion of candidates requiring a crossmatch, streamlining the process, and aligning with the increasing use of virtual crossmatching. Lastly, the importance of programmatic considerations in organ allocation decisions was underscored. The criteria for candidate selection, specifically emphasizing factors such as proximity, emerged as a crucial consideration. This reflects the need for a balanced approach that takes into account both programmatic and logistical aspects to optimize the transplantation process.

HRSA Update

- *Comments*: In response to HRSA's data directive for OPO data collection, questions were raised regarding the potential impact on existing CMS metrics, and whether the new elements would replace or add to the current data collection process. The presenter indicated collaboration with CMS and emphasized that the new data elements would likely be additional, with efforts to minimize duplication. Another attendee added that the OPO community had a lot of collaboration with the MPSC to suggest new metrics to better define performance. That collaboration will result in a much better system, but the reality is the community is being judged by an unscientific performance metric with decisions being made on imperfect data. It would be prudent to look at how performance is judged. Concerns were expressed about potential disruptions to the system with the OPTN Modernization Initiative, and the community would like reassurances from HRSA that there will be no disruptions throughout the process, most importantly for patients. The presenter noted that steps have been taken to prevent disruptions and efforts will be made to ensure a smooth transition, but the community should submit these concerns to the federal contracting office. Lastly, there was a question about the fate of the Expeditious Task Force and the work of the committees, which it was clarified that the operations of the OPTN will continue.