OPTN

Thank you to everyone who attended the Region 6 Summer 2024 meeting. Your participation is critical to the OPTN policy development process.

Regional meeting presentations and materials

Public comment closes September 24th! Submit your comments

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

Revise Conditions for Access to the OPTN Computer System

Network Operations Oversight Committee

Sentiment: 3 strongly support, 8 support, 0 neutral/abstain, 0 oppose, 0 strongly oppose

Comments: Region 6 supported the proposal. During the discussion, one attendee commented that if businesses become members of the OPTN, there could be an expectation that in addition to being held accountable for network security policies, they could also be held accountable for other aspects of policies. Another attendee raised questions about what types of businesses could be members, if there would be categories of membership, how much oversight the OPTN will have over these members, and what data they could access. One attendee supported the requirement for a data use agreement but commented that the proposal needs to clarify and communicate to the community the eligibility or criteria for membership. Another attendee commented that giving access to the OPTN computer system to a broader group may add more risk.

Promote Efficiency of Lung Donor Testing

Lung Transplantation Committee

Sentiment: 3 strongly support, 8 support, 0 neutral/abstain, 0 oppose, 0 strongly oppose

Comments: Region 6 supported the proposal. During the discussion, an OPO attendee expressed they had no concerns about the changes but noted that some donor hospitals might face challenges with right heart catheterization and the timeliness of CT scans. One attendee recommended making CT scans mandatory. Another attendee did not provide feedback on the proposal but expressed interest in the one-year monitoring update for continuous distribution, specifically how well the modeling predicted organ utilization.

Require Reporting of HLA Critical Discrepancies and Crossmatching Event to the OPTN

Histocompatibility Committee

Sentiment: 2 strongly support, 9 support, 0 neutral/abstain, 0 oppose, 0 strongly oppose

Comments: Following the presentation, one attendee commented that the 24-hour time frame for reporting should be 24 business hours. Another attendee commented that from a clinical standpoint, a 24-hour reporting deadline is ideal for ensuring patient care and improving transplant outcomes. They added that this requirement may place a significant burden on HLA labs, so it is essential to consider the impact on their ability to meet this deadline. Overall, there was agreement on the 24-hour reporting rule after the discovery of a discrepancy, though not necessarily requiring a full corrective action plan within that time frame. The 24-hour window allows for re-testing if necessary, which enhances patient safety.

Another attendee commented that one area needing clarification is the last row of Table 18-6, which mentions an "incorrect candidate HLA antibody test analyzed for a virtual crossmatch." They requested more details on the timing requirements, specifically whether reporting is required even if the issue was discovered pre-allocation and didn't impact allocation timing. Additionally, it is unclear if this reporting is necessary for all virtual crossmatch assessments, including those that didn't lead to a transplant or were declined for other reasons. One attendee expressed concerns that 24 hours may be too short of a timeframe for reporting.

Update Histocompatibility Bylaws

Histocompatibility Committee
Sentiment: 3 strongly support, 8 support, 0 neutral/abstain, 0 oppose, 0 strongly oppose
Comments: No comments

Continuous Distribution Updates

Continuous Distribution of Hearts Update, Summer 2024

Comments: During the meeting, in-person attendees participated in group discussions and commented that they generally agreed with the VPE (Value Prioritization Exercise) priorities, noting that the identification of prior living donor was interesting, as it offers a way to give back to the community that donates. They also commented that candidates with prolonged waiting times, especially those with durable LVADs, could be at a disadvantage if waiting time is given low priority. They added that the committee will need to determine how to prioritize those on long-term LVAD support. There was also feedback on the relatively low prioritization of the proximity efficiency attribute suggested by the VPE results and noted that proximity efficiency involves the cost and equipment needed to procure distant hearts and brings in quality considerations for transplant centers. Another attendee pointed out that lessons learned from lung continuous distribution indicate that logistical and financial constraints will affect transplant centers. They added that small programs, in particular, are vulnerable, which could lead to closures or behavioral changes. Since over 50% of heart transplant centers fall into the low and mid categories, many could be impacted. One attendee questioned why outcomes after transplant was weighted so low. They went on to comment that there should be a standard weighting for futility across all organs.

Virtual attendees also provided feedback on key questions. One attendee commented that the priority of the attributes in the VPE results seem reasonable, but since a majority of the respondents were transplant clinicians, the results may not reflect the values of the patients, families and members of the public. They went on to comment that they supported the low priority that proximity efficiency received in the VPE results if travel costs are not a consideration, and the only goal is maximizing the number of transplants.

Continuous Distribution of Kidneys Update, Summer 2024

Comments: During the meeting, in-person attendees participated in group discussions. The kidney group suggested that a six-hour threshold for cold ischemic time (CIT) would be reasonable for defining "hard-to-place" kidneys. They noted that CIT can vary depending on procurement timing and flight availability. The group also discussed anatomical factors that could contribute to a kidney being harder to place or at risk of non-use, agreeing that multiple arteries, surgical damage, cysts, infarctions, and aortic plaque should be considered. Additionally, when using allocation thresholds to assess kidneys, the group supported using sequence data, specifically citing sequence 200 as a potential threshold. They emphasized that patient declines, rather than transplant center declines, should be used.

Virtual attendees also provided feedback on key questions. Some attendees supported cold ischemic time as the only threshold to use when defining a “hard to place” kidney, while others commented that location should also be considered. One attendee commented that cold ischemic time, as a result of late turndowns of higher quality kidneys, should not result in expedited placement. There was also feedback on specific anatomy characteristics that should be included in a definition of a “hard to place” kidney. Suggestions included: multiple vessels, enbloc, hard plaque, petechiae, poor flush and significant sclerosis. Another question focused on the number of candidate or program declines at which an organ could be considered harder to place or at risk of non-use. Attendees supported using a sequence number for the threshold, rather than number of center declines.

Continuous Distribution of Livers and Intestines Update, Summer 2024

Comments: During the meeting, in-person attendees participated in group discussions. The liver and intestine group commented that the threshold for when teams fly rather than drive for organ procurement is 120 miles. They also agreed that the definition of a medically complex liver offer should include DCD donors and donors over the age of 70. They added that split livers should also be included in the definition to enhance utilization efficiency. They commented that some of the priorities and weights for travel efficiency and medically complex donors may decrease with the event of normothermic perfusion. The group also discussed exceptions and commented that more work is needed on specific conditions based on post-transplant outcomes. They went on to comment that an important consideration for pediatric patients is the overall mortality on the waiting list (WL). It was noted that 70% of pediatric patients are not transplanted based on their PELD (Pediatric End-Stage Liver Disease) score but through exceptions. Therefore, when reviewing adult exceptions, it is crucial to also consider pediatric exceptions to ensure fair and appropriate allocation for children.

Virtual attendees also provided feedback on key questions. Some attendees commented that the threshold for when teams fly rather than drive for organ procurement is around 120-150 miles. One attendee commented that flying versus driving is impacted as much by location, particular geography and transportation infrastructure in the country as distance.

Continuous Distribution of Pancreata Update, Summer 2024

Comments: During the meeting, in-person attendees participated in group discussions. The pancreas group discussed innovation strategies for fellowship training. While no specific recommendations were provided, it was noted that increased pancreas procurement experience could lead to better facilities and not every surgeon trains at a transplant center with pancreas transplant or procurement. They also encouraged transplant centers to have pancreas medical and surgical directors separate from kidney to

focus on specific organ needs and requirements to grow the program. The discussion also highlighted the positive impact of having a dedicated pancreas procurement team at Organ Procurement Organizations (OPOs). It was suggested that encouraging all OPOs to adopt this practice would be beneficial.

Virtual attendees also provided feedback on key questions. One attendee commented that having individuals that are exclusively on call for pancreas transplantation could be helpful. There was also feedback that while encouraging OPOs to have procurement teams for pancreas would likely increase pancreas procurement, it may also be a burden to bring multiple teams to distant recoveries.

Updates

Councillor Update

- **Comments:** No questions or comments

OPTN Patient Affairs Committee Update

- **Comments:** No questions or comments

OPTN Executive Committee Update

- **Comments:** No questions or comments

Update from the Expeditious Task Force

- **Comments:** Following the presentation, one attendee commented that the Task Force needs to involve payors as stakeholders in their efforts to increase transplantation and reduce organ non-use due to associated costs. It was also suggested that the Task Force should collaborate with the Scientific Registry of Transplant Recipients (SRTR) to offer leeway to transplant centers using hard-to-place organs. Concerns were raised that high SRTR performance metrics might discourage centers from using these organs, ultimately disadvantaging the community and patients. One attendee supported the goal of achieving 60,000 transplants but emphasized the importance of focusing on extending organ longevity. Additional comments focused on the utilization rate of kidneys with a Kidney Donor Profile Index (KDPI) over 75%. There was concern that 25% of kidneys are not being utilized because they fall into this percentile, and questions were raised about whether patients are aware they are being offered kidneys in this range. It was noted that consent is only required for kidneys with a KDPI of 85% or greater, but a KDPI of 75% may still be suitable for the right patient. The tension between turn-down decisions and concerns about outcome reporting was highlighted, particularly regarding the potential penalties centers face from insurers and SRTR if their outcomes fall below thresholds. There was also discussion about whether replacing KDPI with raw Kidney Donor Risk Index (KDRI) data could provide more granular insights.

HRSA Update

- **Comments:** Following the presentation, one attendee raised questions about the OPTN Board election process, including how voting would work, who would vote on Board members, and how the contractor would ensure regional and stakeholder representation. Other concerns were voiced about the complexity of the contracting process, including the number of vendors, bid reviews, the timeline, and opportunities for public input. Additional comments focused on the new data collection forms, with concerns about the administrative burden they would place on some transplant centers. It was pointed out that there would be no funding provided to hire additional staff to complete these forms. Questions also arose regarding future MPSC (Membership and Professional Standards Committee) metrics, particularly around referral acceptance rates once referral data collection is implemented. Lastly, one attendee inquired about how CMS (Centers for Medicare & Medicaid Services) and the OTAG group plan to evaluate Organ Procurement Organizations (OPOs).