OPTN

Thank you to everyone who attended the Region 6 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: 3 strongly support, 10 support, 1 neutral/abstain, 0 oppose, 0 strongly oppose
- Comments: This proposal was not discussed during the meeting, but attendees were able to submit comments. One attendee commented that this would significantly impact post-transplant outcomes and morbidity.

Promote Efficiency of Lung Allocation, *OPTN Lung Transplantation Committee*

- Sentiment: 2 strongly support, 8 support, 3 neutral/abstain, 0 oppose, 0 strongly oppose
- Comments: This proposal was not discussed during the meeting, but attendees were able to submit comments. One attendee commented that they supported giving programs the option to opt-in for offers from geographically isolated areas (Hawaii, Alaska, Puerto Rico). They went on to comment that they supported allowing OPOs allocating a single lung, the option to bypass candidates who need a double lung transplant.

Standardize Six Minute Walk for Lung Allocation, *OPTN Lung Transplantation Committee*

- Sentiment: 1 strongly support, 7 support, 5 neutral/abstain, 0 oppose, 0 strongly oppose
- Comments: This proposal was not discussed during the meeting, but attendees were able to submit comments. One attendee commented that there should be consideration for standardizing the six-minute walk for any organs that use this value.

Clarifying Requirements for Pronouncement of Death, *OPTN Organ Procurement Organization Committee*

- Sentiment: 2 strongly support, 11 support, 0 neutral/abstain, 0 oppose, 0 strongly oppose
- Comments: This proposal was not discussed during the meeting, but attendees were able to submit comments. One attendee commented that this is an opportunity to review current

policy and provide updates re: utilizing family readiness assessments and the importance of providing information to families during the end-of-life decision making process that meets their individual needs.

Discussion Agenda

Standardize the Patient Safety Contact and Reduce Duplicate Reporting, *Ad Hoc Disease Transmission Advisory Committee*

- Sentiment: 3 strongly support, 10 support, 0 neutral/abstain, 0 oppose, 0 strongly oppose
- Comments: Region 6 supported this proposal. One attendee commented that they support any process that streamlines communication if guidelines and expectations are clear. Another attendee commented that this would lead to improved safety for patients and standardize center requirements. One attendee commented that many programs are using 3rd party vendors and requiring the contact to be at the transplant program may cause burden on the programs. They added that eliminating OPO duplicate reporting is a good idea.

Concepts for Modifying Multi-Organ Policies, *OPTN Ad Hoc Multi-Organ Transplantation Committee*

- Comments: Several attendees commented that kidney-pancreas (KP) candidates should be considered as kidney candidates. One added that most pancreas are allocated with kidneys, and they shouldn't compete with multi-organ transplant (MOT) combinations that aren't always transplanted together. They went on to comment that this would help to avoid scenarios where the pancreas remains unused, potentially increasing non-utilization rates. Another attendee recommended adding non-use to the metrics. One attendee supported limiting multi-organ placement to one kidney per donor and establishing a specific time point prior to going to the operating room, to finalize isolated kidney offers. They added that pediatric candidates are often affected by delayed offers of ideal, low KDPI (Kidney Donor Profile Index) kidneys due to OPOs delaying placement to accommodate backup multi-organ candidates on match runs. This delay increases the risk of ischemia time for kidney recipients unnecessarily. They also recommended implementing a metric to monitor the non-utilization of KDPI 1-34% kidneys. One attendee supported pediatric priority above MOT.

Modify Effect of Acceptance Policy, *OPTN Ad Hoc Multi-Organ Transplantation Committee*

- Sentiment: 1 strongly support, 8 support, 3 neutral/abstain, 1 oppose, 0 strongly oppose
- Comments: Overall, attendees were supportive of the proposal, but with some opposition. Many attendees commented that there needs to be a time frame to guide allocation of multi-organ and single organ earlier in the process. They went on to comment that adding more structure to multi-organ allocation will improve efficiency of placement, allow transplant centers to better prepare their patients, and decrease risk for non-utilization of donor kidneys due to late allocation. One attendee commented that this change will particularly benefit kidney alone candidates in remote geographic areas, allowing them more opportunities to receive kidneys with shorter cold ischemic time.

OPTN Strategic Plan 2024-2027, *OPTN Executive Committee*

- Sentiment: 1 strongly support, 7 support, 4 neutral/abstain, 1 oppose, 0 strongly oppose
- Comments: Several attendees commented that the goals are too narrow and do not incorporate enough of the necessary work of the OPTN. They added that while some universal goals can be part of the organization's vision and not listed as strategic goals, some need to be explicit. There was also concern from several commenters that equity is not included in the plan, especially for vulnerable populations such as children. There was also concern that living donation was not included and the plan provides minimal opportunity for Living Donor Committee project prioritization. One attendee recommended that the committee consider a plan for the potential mass decertification of OPOs.

Update on Continuous Distribution of Hearts, *OPTN Heart Transplantation Committee*

- Comments: The feedback from attendees emphasizes the importance of considering unique geographic differences/constraints, particularly in regions like region 6, where prioritizing location can disadvantage large patient populations. Geographic differences, including distance, population density, and the number of transplant programs, should be heavily weighted in allocation decisions. The actual attribute for efficiency should not be based on physical distance in miles for the whole US because of the differences in population density, density of candidates and density of centers in the US. A different variable should be used. Suggestions include using population density to normalize criteria across different regions and considering placement efficiency and travel logistics, especially for areas without access to normothermic pumps. Concerns were raised about the economic barriers and decreased access to transplants for patients in regions with long travel times, such as Region 6. Specific issues highlighted include the economic barriers posed by using organ preservation technologies like OCS, as well as logistical challenges such as plane availability and ECMO capacity. The impact on sparsely populated regions must be carefully considered, and any changes should be followed by assessments of their impact on utilization rates.

National Liver Review Board (NLRB) Updates Related to Transplant Oncology, *OPTN Liver & Intestinal Organ Transplantation Committee*

- Sentiment: 2 strongly support, 5 support, 4 neutral/abstain, 0 oppose, 0 strongly oppose
- Comments: Overall, there is strong support for providing additional guidance, consistency, and access to transplant, but concerns were raised regarding specific criteria, scoring systems, and their impact on different patient populations. While there was wide support for the change to an Adult Oncology Board, one attendee commented that there may be a need to recruit more reviewers if the volume of cases increases. Another attendee added that centers will need to look at their payers related to any new diagnosis for transplant. There were several comments specific to each of the proposed diagnosis:
    - Intrahepatic Cholangiocarcinoma (iCCA)- There was concern raised regarding the poor outcomes for these recipients. Some commented that the score was too high. One attendee recommended doing these transplants as part of a research protocol. There was also concern around the lack of guidance for assessing if the iCCA is resectable. One attendee commented that the primary treatment evaluated for these patients should be resection, with transplant considered only for unresectable cases. They also recommended including the reason for why the iCCA is unresectable in the exception

request and noting the treatments used prior to transplant to understand how the treatments affect outcomes. There was also a recommendation to explicitly state in the requirements that this is a single lesion. One attendee was opposed to transplant for iCCA due to the high recurrence rates, adding that more research is necessary. There was also concern about the impact on pediatric patients with lower MELD scores and the consistency of scores approved by the pediatric NLRB as compared to the oncology NLRB.

- Colorectal Liver Metastases (CRLM)-One attendee raised concern about the guidance for colorectal liver metastases given the high recurrence rates. They commented that in the current environment of organ scarcity, the concern is the use of liver grafts with worse outcomes than for other indications, and to grant exception points with worse outcomes. They did support these patients being transplanted at selected centers under research protocols (similar to how transplants for HIV + patients were started). They added that living donor transplants for metastatic CRLM is another way to continue to investigate and determine consistent inclusion and exclusion criteria and consistent chemoRx regimens and molecular typing to improve the current high recurrence rates seen in liver transplant for metastatic CRC. They also recommended that the expertise required to assess centers' protocols for metastatic CRC should include medical oncologists at the cutting edge of current treatment - immunoRx, systemic chemoRX and should be expanded. They commented that they did not support all centers performing transplants for metastatic CRC given that transplant for this disease is not curative at this stage. They added that data collection to truly learn from this experience is missing as this is guidance and not policy so unless these transplants are studied in a multicenter fashion we won't learn from the national experience. They recommended templated narratives for NLRB applications and commented that molecular typing of the tumors should be part of the selection process including BRAF mutations and microsatellite instability.

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

- Sentiment: 2 strongly support, 3 support, 8 neutral/abstain, 0 oppose, 0 strongly oppose
- Comments: Many attendees commented that this proposal does not go far enough and that the entire KDPI calculator needs to be re-examined. Several attendees raised concerns about the impact of removing HCV-related variables on pediatric candidates as HCV positive donors will now be in the 0-34% KDPI sequence. They went on to comment that there is a lack of data to guide management or predict outcomes for use of HCV kidneys in children and most pediatric kidney transplant programs do not have protocols for management of an HCV positive donor kidney. They added that HCV treatment medications are also not FDA approved for use in children under 3 years of age. Some attendees supported removing race from the variable, but not HCV. One attendee supported more APL1 research. One attendee commented that this proposal should not impact how transplant professionals are assessing offers but added that there is a need to look at KDPI and KDRI together when investigating non-use. One attendee offered this reference document: https://www.srtr.org/media/1668/miller-ajt-2023-impacts-of-removing-race-from-the-calculation-of-kdpi.pdf.

Updates

Councillor Update

- No comments

OPTN Membership and Professional Standards Committee Update

- Comments: One attendee commented that some of these metrics feel at odds with the goals of the Expeditious Task Force, adding that these two things should work in tandem.

OPTN Executive Update

- Comments: There was recognition and appreciation for the OPTN President's service to the OPTN and the patients. Some attendees commented that the OPTN needed to have more of a commitment to living donation.

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

- Comments: The discussion started off with ideas for decreasing organ non-utilization. One group recommended removing KDPI and looking at KDRI as a metric. They wanted to encourage the use of hard-to-place organs so that when centers take risks there's a way to re-list and prioritize those patients. They also commented that there is a need for additional resources (modern standard of care) for higher risk transplants. Another group commented that there is a disconnect between the cost of dialysis vs. the benefit of transplant and that more data is needed to find out which kidneys are not being used. They added that we need to leverage doing more DCD donors (effective practices). A third group commented that decline codes needed to be more granular to help identify the number of truly unusable organs. They recommended reporting in real-time about the non-use to track performance. Another group recommended allowing OPOs to develop their own rescue/expedited placement protocols for approval and study these for best practices.

HRSA Update

- Comments: One attendee commented that there needs to be better alignment between the different regulatory bodies that transplant programs and OPOs are accountable to. Another attendee applauded the improvement effort but commented that the scope should be broader and focus on access to transplant. There were several questions about the modernization plan and the state of the OPTN contractor and Board at the end of the current contract. There was a suggestion that there should be a pathway for the transplant community to provide feedback to HRSA on the performance of the vendors selected for the OPTN contract.