OPTN

Thank you to everyone who attended the Region 7 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. <u>Click here to complete the exercise and provide your feedback</u>.

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: 5 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 noted that this extra data collection is absolutely required.

Promote Efficiency of Lung Allocation, OPTN Lung Transplantation Committee

- Sentiment: 4 strongly support, 8 support, 5 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 of the proposal stating that this will be a great tool for lung programs and will increase efficiency. Another attendee suggested that the data should be analyzed at a later point to confirm that the requirements are not too onerous. Another attendee added that the proposal does not go far enough and there needs to be more data fields and the ability to combine filter parameters for individual candidates, not just program specific filters. Lastly, another attendee noted that lung allocation can be a time-consuming process given the unique clinical needs of lung donors such as ventilator settings, ABGs, and imaging; applying offer filters will help with lung allocation efficiency.

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

- Sentiment: 6 strongly support, 4 support, 7 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 suggested that the committee should look to see if other organizations, such as AST or ASTS, have similar standards and the OPTN standards should mirror those standards. Another attendee noted that the oxygen dose test will be a



considerable burden for lung programs. Lastly, another attendee added that such standardization may be helpful for abdominal organs too.

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

- Sentiment: 7 strongly support, 7 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 their strong support for the clear language in the proposal. Another attendee added that this policy will help maintain public trust with the transplantation community. The proposal does acknowledge the issue and requires transplant programs and OPOs to address the issue.

Discussion Agenda

Standardize the Patient Safety Contact and Reduce Duplicate Reporting, Ad Hoc Disease

Transmission Advisory Committee

- Sentiment: 8 strongly support, 7 support, 1 neutral/abstain, 0 oppose, 0 strongly oppose
- *Comments*: Members of the region are supportive of the proposal. One attendee noted strong support of standardizing the patient safety contact as it will improve communication on potential disease transmissions.

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

Committee

• *Comments*: The discussion revolved around the classification of kidney-pancreas (KP) transplants as multi-organ transplants (MOT) and its potential impact on organ allocation and utilization. Several participants expressed concerns that categorizing KP transplants as MOT could diminish access to pancreas transplantation and lead to decreased utilization of pancreata from donors. Arguments were made for treating KP transplants as single organs with kidney-only status to ensure that pancreas utilization is maximized. Participants highlighted the complexities involved in organ allocation, especially when considering the needs of different patient groups and the limitations of current allocation systems. There was consensus that while some priority may be warranted for MOTs, there should be careful consideration to avoid disadvantaging certain patient populations or hindering organ allocation efficiency. If the OPTN develops strict allocation policy for MOT candidates, given the relatively small number of MOT transplants, could negatively impact overall allocation efficiency. Suggestions were made for a universal match system across all organs that prioritizes the most medically urgent patients for organ allocation, regardless of transplant type. Overall, there's a shared sentiment against including KP transplants in MOT groups, with concerns centered around potential negative implications for pancreas utilization and transplantation rates in the United States.

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

- Sentiment: 4 strongly support, 9 support, 2 neutral/abstain, 1 oppose, 0 strongly oppose
- *Comments*: Overall, members of the region are supportive of the proposal. The discussion centered on the challenges of kidney acceptance and allocation, particularly regarding the



emotional impact on patients and the logistical complexities faced by organ procurement organizations (OPOs). Participants expressed concerns about retracting kidney offers and suggested a potential solution, such as involving the Membership and Professional Standards Committee (MPSC) to review such cases. There was a debate about when kidneys should be considered accepted, with questions raised about the timing in relation to the donor recovery. Suggestions were made to establish clearer guidelines and timeframes for kidney acceptance, with considerations for provisional acceptance and the implications for multi-organ transplant recipients. Attendees emphasized the need for clarity on what constitutes acceptance and advocated for policies that prioritize accepted kidneys over multi-organ shares. They highlighted the importance of providing OPOs with appropriate guidance to streamline the allocation process while ensuring equitable access to organs for all patients.

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

- Sentiment: 2 strongly support, 9 support, 1 neutral/abstain, 2 oppose, 0 strongly oppose
- Comments: Overall, members of the region are supportive of the proposed strategic plan, but • with some opposition. One attendee noted that the plan has great large goals with are in line with the Patient Affairs Committee priorities. There is a need to tie measures of performance and measures of effectiveness that are quantifiable and are reviewed at pre-determined points in time, perhaps quarterly, to determine success. Another attendee noted that there needs to be clarification on how the community will be evaluated on the strategic plan initiatives. Another attendee agreed with including the proposed metrics as it is a great way to focus the discussion and shorten the Observe, Orient, Decide, and Act loop. Another attendee suggested that in addition to the business, operations and efficiency on the allocation and pre-transplant side, the OPTN should develop a strategic plan on what framework and infrastructure is needed to help improve the clinical outcomes and transplant longevity. Another attendee noted that increasing acceptance rates could be achieved by decreasing donor offers instead of increasing transplants, but this would be detrimental to the transplant community. Another attendee suggested that future iterations of the strategic plan needs to address recipient outcome data and initiatives. An attendee noted their concern with the strategic plan as they feel it does not contain a clear plan. Lastly, one attendee suggested that before educating patients on organ acceptance rates, patients need to have an introductory education on the transplant process. As there is a large knowledge gap amongst patients, starting with organ acceptance rates may be overwhelming and confusing.

Update on Continuous Distribution of Hearts, OPTN Heart Transplantation Committee

• Comments: One attendee expressed their full support for Continuous Distribution of hearts and encouraged the OPTN to get to implementation as soon as possible. Another attendee representing the pediatric heart community echoed that sentiment and raised concerns about the OPTN Modernization Initiative causing delays to Continuous Distribution implementation. They also encouraged the OPTN to more broadly publicize the Values Prioritization Exercise as there are professional and patient groups that are unaware of the exercise. They also suggested that with the changes to ABO incompatible allocation for pediatric heart candidates, the committee should consider possible re-transplantation for those patients as they enter adulthood. Lastly, another attendee noted that with the adult heart allocation changes in 2018,



heart programs have been entering a large amount of data for their candidate's risk stratification data with each listing and status update. This has become a very heavy burden on transplant programs, and they would like to see this data used in some way, or help alleviate the burden by cutting back on the required data.

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

- Sentiment: 5 strongly support, 7 support, 5 neutral/abstain, 0 oppose, 0 strongly oppose
- *Comments*: Members of the region are supportive of the proposal. One attendee noted concern that the MELD of 15 would limit patients to only receiving living donor transplants, it is unlikely they would receive deceased donor offers with this MELD. The committee may want to consider increasing the MELD to 20 with a more reasonable MELD score for DCD organ offers. Another attendee suggested that there needs to be clarity on the definition for unresectable as this definition varies across programs. Another attendee noted support in recognizing diseases that do not fit well into the current MELD model, but the proposal does not indicate any data related to the expected increase, so it is difficult to speculate what the impacts will be for transplant programs. Lastly, one attendee questioned the validity of MMAT minus 20 as the standard for these exception requests.

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

- Sentiment: 8 strongly support, 7 support, 1 neutral/abstain, 0 oppose, 1 strongly oppose
- *Comments*: Members of the region are supportive of the proposal overall, but there were some concerns raised about the removal of Hepatitis C (HCV) as a factor in the KDPI calculation. One attendee acknowledged the need to move past using KDPI as an absolute rule out and to incorporate offer filters for decision making, such as DCD high KDPI, to potentially increase kidney utilization and cut down on cold ischemia time (CIT). Concerns were raised about the impact of race and HCV on allocation, with a call for more data to assess the effects on pediatric kidney allocation and ensure appropriate decision-making. Overall, there is consensus that the proposed changes are overdue and necessary, particularly the removal of race as a factor in allocation decisions. However, there are reservations regarding the HCV component, indicating a need for further evaluation before full support can be given. Since the KDPI calculation is determined by the donor pool and ranks them by a percentage of those donors, there needs to be detailed analysis of how the calculation will change when those two factors are removed from the calculation.

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: One attendee noted concern with long term effects of adding more bureaucracy to the transplant network, will that ultimately be a deterrent for future professionals to pursue a career in transplantation. Another attendee expressed concerns with ensuring the work of the OPTN continues throughout the OPTN Modernization Initiative. There should be reassurances that opportunities to improve the OPTN and increase opportunities for patients will go unimpeded despite contract negotiations and Board of Director separations. There is a lot of good going on in the community and we do not want to lose that momentum. Lastly, another attendee noted that the OPTN Strategic Plan lacks details about transplant outcomes. There is a lot of focus on pre-transplant metrics and there should be a focus on improving transplant outcomes.

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

Comments: The discussion started off with the topic of Forum ideas with one group suggesting an OPO best practices publication and a transplant program strategy publication. Programs may have different strategies so letting the public understand those strategies would be helpful. They raised concerns about patient information and communication as part of the transplant process, what medium can the community use to share that information. Another idea would be how to generate interest in pursuing a career in transplantation. Another group highlighted that offer filters are a good start but basic and there needs to be more advanced filters, ideally patient specific. Another idea is to utilize artificial intelligence to improve organ offer efficiency and rescue pathways instead of OPOs contacting specific surgeons. In regard to kidney non-use, the discussion addressed various challenges and opportunities in organ transplantation, particularly focusing on transportation issues, acceptance practices among surgeons and programs, and utilizing data to optimize allocation and utilization. Transportation challenges, particularly at night, hinder timely transplantation, highlighting the need for improved logistics and access to flights. Understanding the variability in acceptance practices among surgeons and programs is crucial, with a call for data-driven approaches to identify bottlenecks in allocation processes. Attendees emphasized the importance of effective communication strategies, especially when presenting aggressive offers to patients. There's a call for better evaluation strategies over time, considering factors like creatinine changes, and revising rescue protocols to incentivize informed decision-making without penalizing patients. Concerns were raised about the significant number of kidneys that remain unused annually, prompting a discussion on the need to identify which kidneys are truly transplantable to address this issue effectively. Leveraging data to assess transplantability and improve decision-making processes is essential. Lastly, the success of educational workshops aimed at increasing the utilization of higher KDPI kidneys was noted, suggesting potential strategies such as allowing centers to apply for high-risk KDPI kidneys and receive credit for their utilization, thus encouraging broader acceptance and transplantation of organs. Next the group discussed Policy Review and the limitations and potential improvements of current metrics and allocation practices in organ transplantation. Attendees reflected on the long-standing use of KDPI and questioned its effectiveness in ranking kidneys relative to each other. There was a suggestion to shift to an absolute score system to evaluate kidney quality objectively based on factual data rather than comparative rankings. Concerns were raised about the exclusion of certain qualitative factors such as quality of care and recipient risk from current metrics, highlighting the need for a comprehensive approach to assessing donor and recipient factors to improve outcomes. Regarding allocation, there was an

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idea to base it on patient urgency rather than donor characteristics, which could potentially lead to a more equitable distribution of organs. From the OPO perspective, there was recognition of the manual nature of the allocation process and the need for technological advancements to enhance efficiency. There's a suggestion to explore AI-driven decision-making to streamline the allocation process and potentially make it fairer and more efficient. The conversation also touched upon the idea of allowing transplant programs more discretion in organ acceptance, drawing from the policy in the UK where hearts were offered directly to programs. However, there are concerns about community perception and the potential for bias. Again, the possibility of using AI databases to make allocation decisions more quickly and fairly was discussed. In regard to transportation, it was noted that there is trouble with transportation and acceptance of kidneys. Especially when trying to allocate in the evenings there are fewer options for flights, and it is difficult to get the organs to more aggressive programs that are further away. Another attendee highlighted that in the past overnight freight flights used to be an options, but now are confined to passenger flights that largely operate during the day. Lastly, the discussion focused on geographical disparities in organ shipping and the potential use of technology to address them while maintaining equity in allocation. Participants noted that while there are significant disparities in shipping livers over long distances, overall disparities are not as pronounced. There's a suggestion to leverage AI or similar technologies to prioritize and level out organ shipping, ensuring equity without unnecessary transportation. There is differentiation between organs based on their suitability for long-distance transportation. Marginal hearts may not need to be flown across the country, while high-quality kidneys should be flown all over the country for patients with high CPRA. There was consensus on the need to standardize definitions to ensure clarity and consistency in discussions and practices. The conversation extended beyond aggressive organs to include average kidneys, emphasizing the importance of sending the necessary kidneys to recipients without delays. Lastly, attendees noted appreciation for the flexibility provided by expeditious means, allowing for learning from various Plan-Do-Study-Act (PDSA) cycles to continually improve organ allocation and transportation practices.

HRSA Update

Comments: The discussion delved into several key concerns and queries regarding the management and transition of the OPTN Board of Directors and OPTN operations, as well as funding and future plans. Participants expressed apprehension regarding potential negative consequences of proposals aimed at utilizing more organs, emphasizing the need for countermetrics to prevent unintended outcomes. Additionally, there was a call for assurance to taxpayers regarding the utilization of the allocated \$36 million to improve the system, with concerns raised about moving forward without a clear plan for fund dispersal. Questions were posed about the frequency of HRSA reporting to the community and the stability of the OPTN Board during its separation from the current contractor. Continuity of the system emerged as a central concern, with participants urging HRSA to ensure transparency and stability during the transition period. Moreover, there was a desire for more comprehensive education on modernization efforts and continuity of the OPTN, particularly to address patient concerns. Concerns were also raised about the exclusion of certain groups, especially donor families, from the planning and change management processes. Participants expressed confusion and a lack of clarity regarding the next steps in the process, urging HRSA to provide more detailed information and transparency. There were also queries about the fate of committees and the Expeditious Task Force during the transition period, with assurances sought regarding continued



support through separate contracts. Furthermore, concerns about the funding of OPTN operations post-separation from the current contractor were articulated, with questions raised about how funding will be managed without additional sources. HRSA was pressed for details on its plans for funding the OPTN if the current contractor is no longer utilized, with emphasis placed on the importance of maintaining current funding mechanisms to support OPTN activities.