OPTN

Thank you to everyone who attended the Region 2 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:* **6 strongly support, 16 support, 2 neutral/abstain, 0 oppose, 0 strongly oppose**
- *Comments*: None

Promote Efficiency of Lung Allocation

OPTN Lung Transplantation Committee

- *Sentiment*: **6 strongly support, 13 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 expressed support for increasing efficiency of lung allocation as long as the committee monitors transplant outcomes. Another attendee noted that moving forward it is important to consider policies on DCD guidelines for how decisions can be made about use of organs without NRP when programs do not agree on the need for NRP. Lastly, another attendee is encouraged by the potential benefit to the community with this proposal. They urge early transparency before implementation in how a center's use of offer filters will impact reported and publicly available donor acceptance rates, in terms of MPSC quality review. Additionally, they suggested the consideration of inclusion of broader filter availability, such as potentially significant years of smoking history and DCD brainstem reflexes being maintained.

Standardize Six Minute Walk for Lung Allocation

OPTN Lung Transplantation Committee

- *Sentiment*: **4 strongly support, 15 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 that standardization should always be a

common goal. Another attendee added that the proposal needs to be more specific about the requirements inherent in performing the oxygen titration study.

Clarifying Requirements for Pronouncement of Death

OPTN Organ Procurement Organization Committee

- *Sentiment*: **7 strongly support, 12 support, 3 neutral/abstain, 0 oppose, 0 strongly oppose**
- *Comments*: None

Discussion Agenda

Standardize the Patient Safety Contact and Reduce Duplicate Reporting

Ad Hoc Disease Transmission Advisory Committee

- *Sentiment*: **10 strongly support, 11 support, 0 neutral/abstain, 0 oppose, 0 strongly oppose**
- *Comments*: Members of the region were supportive of the proposal, with several OPO attendees noting their strong support as the current patient safety contact process can be time consuming and inefficient. One attendee stated that this is a needed update as there are significant deficits in the current reporting system. It was also noted that by improving the reporting efficiency it may lead to decreased costs. Another attendee added that while this will streamline communications, with any new system there needs to be a review of the process to make sure it is meeting the project's goals. They would encourage the OPTN to continue to monitor this process in order to improve efficiency. Another attendee added that there is a need for an assessment of the communication portal to ensure that all is streamlined and efficient. It was also noted that there needs to be more information about the notification process, the timing to acknowledge a patient safety event, and the escalation process if a notification is not acknowledged. Another attendee suggested that technology programming should allow for alternate coverage to account for staffing changes or when a patient safety contact is out on leave. In addition to the yearly attestation from patient safety contacts, there should be quarterly notifications to the patient safety contacts to ensure accurate and timely reporting. In regard to using third parties as patient safety contacts, there was mixed feedback from the region. One attendee noted support for using third party contractors, while another attendee stated that patient safety contacts should be employed at the institution and not a third-party vendor. There was also a suggestion to allow for the OPTN to be simultaneously notified when OPOs reach out to transplant programs.

Concepts for Modifying Multi-Organ Policies

OPTN Ad Hoc Multi-Organ Transplantation Committee

- *Comments*: For the question, "How should MOT candidates be prioritized when there is only one kidney available?", an attendee advocated for a more comprehensive approach in determining organ transplant priorities. Instead of arbitrary factors, focus on anticipated waitlist survival. The suggestion was to link decision-making to a standardized measure, allowing for a consistent and defensible approach across different scenarios. Another attendee noted the effectiveness of the safety net policies, particularly in liver-kidney combinations. However, concerns were raised about the potential alteration of decision-making when it comes to heart-

kidney and lung-kidney combinations. Another attendee highlighted the significant variability in the decision to list MOT candidate across different transplant centers and providers. The absence of uniform criteria for MOT across various domains and organs highlights the need for a standardized bar to determine the necessity of kidney inclusion in combination with other organs. Another attendee noted perceived flaws in using the Kidney Donor Profile Index (KDPI) as a sole criterion for organ acceptance. There are times when a high KDPI kidney would be suitable for kidney-liver recipients. Kidney-liver allocation should assess KDPI similarly to kidney-alone cases. Another attendee added that the primary need in MOT allocation is more organs. One solution would be to increase organ availability through living donation and encouraging voluntary donations to address the critical shortage. It was also noted that the higher mortality rates associated with multi-organ candidates, such as heart-kidney transplants should not be considered as a factor to deprioritize heart-kidney allocation. In regard to the question "Should kidney-pancreas (KP) candidates be considered multi-organ candidates and be prioritized among other multi-organ combinations?", attendees largely felt that KP candidates should be considered MOT candidates and should be prioritized among other multi-organ combinations and should have priority over kidney alone candidates. When both kidneys are available from a donor with a kidney donor profile index (KDPI) between 0-34 percent, there was support for allocating one kidney to kidney alone candidates and the other kidney should be offered to multi-organ candidates. An attendee emphasized that too many kidney candidates are waiting for a very long time to get a transplant. In regard to policy guidance for OPOs, attendees emphasized the significance of additional policy and system considerations for OPOs. There was a call for a policy to define which patients are at highest risk of graft failure, as well as a policy to provide clarity and standardization for out-of-sequence allocation. OPOs currently decide on the aggressive allocation of organs, and different OPOs may have varying criteria for out-of-sequence allocation. Another attendee noted that in the near future similar considerations will be needed for liver transplants involving liver-heart and liver-lung scenarios. The need for objective criteria was emphasized, with a suggestion to consider waitlist mortality as a relevant factor. However, concerns were raised about potential disadvantages for kidneys if waitlist mortality is the sole criterion. It was suggested to have one kidney allocated to kidney alone and the other kidney to multi-organ candidates with waitlist mortality as the deciding factor. Another attendee added that there is an arbitrary priority granted to pediatric and prior living donor candidates, while the greater concern should be for high CPRA candidates. They emphasized the importance of prioritizing those least likely to receive an organ over those with a higher likelihood. The principles of benefit and justice in ethical considerations underline the need to prioritize those with a lower likelihood of receiving an organ in the near future.

Modify Effect of Acceptance Policy

OPTN Ad Hoc Multi-Organ Transplantation Committee

- *Sentiment*: **6 strongly support, 12 support, 2 neutral/abstain, 0 oppose, 0 strongly oppose**
- *Comments*: Overall, members of the region are supportive of the proposal. Several attendees noted experiences when they had been primary for a kidney offer only to have the kidney offer rescinded so that the kidney could be offered to a multi-organ candidate. This proposal is especially beneficial to 100% CPRA candidates, as they rarely receive kidney offers. Having a kidney offer rescinded for a 100% CPRA candidate can be a life-or-death situation. Many attendees noted that the proposal should help to improve allocation efficiency. While

supportive of the proposal, the OPTN should continue to consider the risk of increased waiting time for multi-organ transplant candidates. Additionally, there is a need to assess differences in safety net access for candidates with high pre-transplant mortality.

OPTN Strategic Plan 2024-2027

OPTN Executive Committee

- *Sentiment*: **4 strongly support, 13 support, 3 neutral/abstain, 1 oppose, 0 strongly oppose**
- *Comments*: Members of the region support the proposed strategic plan. It was noted that the plan has identified great areas of focus. While there was support for increasing the number of transplants over the coming years, one attendee highlighted the need for increased infrastructure outside of the OPTN's purview to support this goal. In order to achieve more transplants, there will need to be more hospital beds, ancillary services, ease of access to medications, and combating medication shortages, to name a few. Another attendee noted their support of the plan, but there is a need to define the ethical responsibility to have discussions with transplant candidates when accepting marginal organs. Additionally, there needs to be an OPO standard to provide basic required testing in order for transplant programs to make informed decisions. One attendee did note their opposition to the proposed strategic plan as there is a poor balance between equity and utility.

Update on Continuous Distribution of Hearts

OPTN Heart Transplantation Committee

- *Comments*: An attendee inquired about the committee's decision not to include post-transplant survival in Continuous Distribution (CD). The reasons cited included logistical challenges, lack of available data, and concerns about program decision-making for candidate selection. Despite considerable public interest, it was deemed acceptable for the first iteration of the system to omit post-transplant survival measures. The attendee suggested that the committee revisit and possibly include post-transplant survival after a few years under the new system, allowing for more data collection and modeling. Concerns were raised about the absence of detailed information and data on post-transplant outcomes, emphasizing the importance of considering outcomes in transplantation decisions. One attendee added that this issue should be addressed before implementing any further changes to the allocation system. There was a call for simulations to contrast pre- and post-CD allocation to guard against unexpected disadvantages. Another attendee expressed the need to rapidly develop a system for assessing potential post-transplant survival metrics to strike a balance between medical urgency and post-transplant survival, especially given the inadequate number of organs for listed patients. Among the attendees there were varying opinions on the prioritization of patients with Ventricular Assist Devices (VADs), with suggestions to prioritize them based on complications such as right ventricular failure or infection. The overall sentiment was a recognition of the need for continuous improvement in transplantation allocation systems, a focus on data collection, and the inclusion of post-transplant outcomes in future iterations. Additionally, there was a suggestion to explore opportunities to utilize more hearts from DCD donors.

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

OPTN Liver & Intestinal Organ Transplantation Committee

- *Sentiment*: **3 strongly support, 13 support, 4 neutral/abstain, 1 oppose, 0 strongly oppose**
- *Comments*: Overall, members of the region support the proposal. The discussion revolved around consolidating oncology diagnoses in the context of liver transplantation. Concerns were raised about the impact on the waitlist mortality and the appropriateness of the Model for End-Stage Liver Disease (MELD) score for these cases. The committee acknowledges the complexity, especially for intrahepatic cholangiocarcinoma, but the current goal is getting these candidates into consideration with the focus on providing opportunities for candidates with a MELD score of 15 or higher. Another attendee noted the potential handicapping of results by setting MELD exceptions for colorectal metastases too low. They suggested creating a subcommittee within the transplant oncology review board with true expertise in cholangiocarcinoma and colorectal cancers. Enriching the review board with experts in these specific areas is essential, recognizing the limited number of specialists in the U.S. In regard to pediatric oncology there was a suggestion to involve the Pediatric Transplantation Committee and consider pediatric representation on the Liver and Intestinal Organ Transplantation Committee. The need for committee members with expertise in pediatric surgery and various cancers beyond hepatocellular carcinoma (HCC) was emphasized. There were concerns regarding access to experts with sufficient knowledge to guide decisions related to specific cancers, and there is a need for consistency in review board decisions. The importance of ensuring specialty knowledge in non-HCC cancers and monitoring equity in exception requests is essential. Overall, the discussion highlighted the complexity of consolidating oncology diagnoses in transplantation and the need for thorough consideration of various factors, including expertise, equity, and consistency in decision-making.

Refit Kidney Donor Profile Index Without Race and Hepatitis C Virus

OPTN Minority Affairs Committee

- *Sentiment*: **7 strongly support, 10 support, 3 neutral/abstain, 1 oppose, 0 strongly oppose**
- *Comments*: Members of the region are supportive of the proposal. Attendees acknowledged the well-reasoned nature of the proposal, but there was a noted concern about the KDPI shifting over time and its potential impact on organ quality. There was a suggestion to remove race from the KDPI calculation but retain Hepatitis C (HCV) as a separate factor due to the specific treatment requirements and lack of reliable options for pediatric patients. While supporting the removal of race, there were calls to carefully examine the impact on pediatric kidney recipients. Concerns are raised about the acceptance of HCV positive donors for pediatric patients, as many antiviral drugs are not approved for those below age 12. An attendee suggested modeling the impact and considering changes in how pediatric donors are classified, possibly excluding children under 18 from the KDPI calculator. Another attendee noted the potential impact on minority individuals especially those with blood type B. By improving the KDPI and moving kidneys into categories that are more likely to be accepted, there is the possibility of enhancing access for minority members with blood type B. Lastly, an attendee encouraged kidney allocation to follow a similar approach to liver allocation by utilizing more HCV positive kidneys to help alleviate the shortage of available organs. The discussion reflected a nuanced

consideration of the proposed changes, with a focus on both improving organ allocation and addressing specific concerns related to pediatric recipients and HCV positive donors.

Updates

Councillor Update

- *Comments*: An attendee inquired about the committee member selection process and why there is a need to apply each year. They also noted that the committees would benefit from having more patient and donor family representatives, as this group provides a very unique perspective to the organ donation and transplant system outside of the expertise of the medical professionals on the committees. In response to the need to apply each year for committee service, it was noted that updated applications help the nominating committees identify those applicants that are still interested in serving on a committee as well as highlight any personal or professional changes that may have occurred within the previous year.

OPTN Patient Affairs Committee Update

- *Comments*: None

OPTN Membership and Professional Standards Committee Update

- *Comments*: An attendee expressed a need for an electronic means to report out of sequence allocation. Right now, OPOs have to write letters to the OPTN to explain each out of sequence allocation, which is very time consuming. While the OPTN is taking steps to address out of sequence allocation, in the meantime, it would be helpful for OPOs to have a more efficient means to report out of sequence allocation, potentially through an online form.

OPTN Executive Committee Update

- *Comments*: The conversation touched on several concerns. Firstly, there was unease about the process of obtaining attestations for IT security. The release of proprietary information as part of the attestation is alarming. Revealing institutional vulnerabilities could put institutions at risk of cyber-attacks. Another attendee noted that the OPTN should be responsible for their system's security, and individual institutions should not have to undergo separate audits for IT security, advocating for a responsibility shift to OPTN. It was noted that there are challenges associated with the growth in the number of transplantation targets, particularly due to limitations in current resources such as nursing, bed availability, and longitudinal care required for successful outcomes. The prospect of increasing transplants by 40% without a corresponding increase in the ability to provide adequate care will be highly challenging. Another attendee noted that the eGFR wait time modification project was commendable, but there concerns about non-Black patients also experiencing late access to transplantation. There is a need to address equity across the system for all potential transplant candidates. Next, an attendee encouraged the OPTN to continue conversations with CMS in regard to financial considerations related to non-use and the desire to push programs to do more transplants. Specifically in relation to the cost implications of pumping livers as it is a very expensive practice. Lastly, the impact of an organ collaboration was mentioned, with concerns arising as donors become more marginal thus affecting outcomes. The accountability for organ acceptance rates was

highlighted, and the challenge of defending decisions made before transplantation if outcomes are impacted was raised.

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

- *Comments*: Meeting attendees were appreciative of the opportunity to discuss and participate in the Expeditious Task Force conversations. One attendee noted concern about the composition of the Expeditious Task Force, specifically regarding low patient representation. There is a need to ensure a more comprehensive and inclusive perspective in the Task Force. Some participants express dissatisfaction with the current use of the Kidney Donor Profile Index (KDPI) and its impact on decision-making. Issues include inaccurate information being provided to patients by community nephrologists based on KDPI scores. There is a call for a more efficient system and a reevaluation of the reliance on KDPI, emphasizing the need for patient and community nephrologist education and trust-building within the transplant community. Another attendee underscored the idea that the primary focus for the Task Force should be on achieving an efficient organ allocation system, as it serves as the foundation for addressing other challenges in transplantation. The discussion expanded to considering patients who receive organs that do not function properly, proposing the development of a system to prioritize rescuing such patients. Going further, there was a suggestion to address futility in organ offers and identify organs that may never work and implement a safety net for such cases. Addressing futility has the potential to impact patient outcomes and prevent the allocation of organs that are unlikely to be successful. Additionally, standardizing the way OPOs handle donor management could help with efficiency. While recognizing the uniqueness of each donor, there was a call for more consistency in donor management approaches across different the OPOs. Another attendee highlighted the importance of patient education, suggesting the creation of a standardized, OPTN-generated educational slide deck for each organ that programs can share with each transplant candidate. Emphasis was placed on creating educational materials that are inclusive of different languages and cultures. Another attendee stressed the importance of involving commercial payers in Task Force discussions, as their cooperation is deemed crucial for potential initiatives related to outcomes assessment and monitoring. Next, attendees suggested leveraging technology, similar to KDPI algorithms, to include post-cross clamp data. Then an algorithm could be built that would create an opt-in system for centers interested in specific kidney offers and an auto-decline for those not on the list. Additionally, there was a suggestion to use AI to match donors with recipients, considering individual center performance and exploring ways to make the process more efficient. To help address organ non-use allocation could move from a national to a regional allocation system for marginal kidneys/livers, taking into account the history of centers in accepting such organs. Lastly, an attendee suggested the potential utilization of ideal livers by encouraging pairing of candidates with low MELD scores to receive split livers as a way to expand organ utilization.

HRSA Update

- *Comments*: The discussion revolved around HRSA's modernization initiative. Concerns were raised about maintaining morale and momentum, especially during potential transitions in contractors. HRSA noted their intention to minimize disruptions, emphasizing that the current contractor has the opportunity to bid on contracts. An attendee inquired about HRSA's workforce dedicated to the project, with the answer detailing a division of 20 people solely dedicated to the OPTN, along with additional staff across various levels. HRSA's focus is on addressing current duties while planning for the future. Additionally, questions arose about the negotiation timeline for future OPTN contracts. The intention is to have a 60-90 day window for contract bids. Once a contractor is selected for a particular task, there will be thorough testing of that particular task before implementing it in the system. It was acknowledged that the overall process could take several years to fully implement. The budget for the project was also discussed, with acknowledgment of requesting an additional $36 million from the President's budget. The final appropriation is pending, subject to decisions by the legislative branch. The inclusion of pre-waitlist data, concerns about workforce shortages, and the need for sustainability initiatives were brought up. The emphasis is on addressing workforce challenges and ensuring initiatives are feasible and supported through reimbursement and incentives. The importance of considering access to care for referring physicians and stakeholders beyond dialysis was highlighted. The conversation also touched on HRSA's commitment to adhering to OPTN's strategic goals during the modernization initiative, aiming to fortify and bolster the existing framework. Concerns about for-profit companies vying for contracts in the transplant sphere prompted discussion on safeguards. The response emphasizes government rules, oversight, and conflict of interest provisions in contracts to monitor performance and prevent profiteering. The overall sentiment is a commitment to a smooth transition, accountability, and ensuring the success of the OPTN modernization initiative.