OPTN

Thank you to everyone who attended the Region 11 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:* **7 strongly support, 10 support, 0 neutral/abstain, 1 oppose, 0 strongly oppose**
- *Comments:* This proposal was not discussed during the meeting, but attendees were able to submit comments. The region supports this proposal. A member suggested modifying the proposed "Original Typing Confirmed Correct" to say "This HLA Typing Result was Accepted as Correct" because it could be misleading if the correct results were determined by the receiving center and not the originating OPO laboratory.

Promote Efficiency of Lung Allocation
OPTN Lung Transplantation Committee

- *Sentiment:* **6 strongly support, 4 support, 8 neutral/abstain, 0 oppose, 0 strongly oppose**
- *Comments:* None

Standardize Six Minute Walk for Lung Allocation
OPTN Lung Transplantation Committee

- *Sentiment:* **3 strongly support, 3 support, 11 neutral/abstain, 1 oppose, 0 strongly oppose**
- *Comments:* None

Clarifying Requirements for Pronouncement of DCD Donor Death
OPTN Organ Procurement Organization Committee

- *Sentiment:* **6 strongly support, 11 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. The region supports this proposal. A member pointed out the need to emphasize that this proposal does not change the existing definitions of death but is a

clarification on the role of the individual who pronounces death. An attendee strongly supported the proposal because of the importance of aligning policy with the current practices of health care providers and OPOs.

Discussion Agenda

Standardize the Patient Safety Contact and Duplicate Reporting

Ad Hoc Disease Transmission Advisory Committee

- *Sentiment:* **10 strongly support, 7 support, 1 neutral/abstain, 0 oppose, 0 strongly oppose**
- *Comments:* The region supports this proposal. Two members expressed specific support for the proposal and that the patient safety contact should work for a third party vendor. One attendee suggested that if changes are made to patient safety contacts during the six months between audits, there should be a required timeframe for updating that information. One member stated opposition to the proposal because it is unclear whether the OPTN has the authority to determine how a transplant center staffs its operations.

Concepts for Modifying Multi-Organ Policies

OPTN Ad Hoc Multi-Organ Transplantation Committee

- *Comments:* An attendee stated it is crucial to determine how multi-organ candidates appear on a match. The attendee agreed with priority for highly sensitized candidates, pediatric candidates, and candidates with a high risk of mortality without a multi-organ transplant. A member was reassured to see that a high percentage of low KDPI kidneys go to kidney-alone recipients, but was concerned that since pediatric candidates, those with a high CPRA, and 0-ABDR mismatch candidates get priority for those kidney alone offers, young adult kidney alone candidates face severely prolonged wait times if they don't find a living donor. The member would like to see some priority for young adult kidney alone candidates for low KDPI kidneys. One attendee commented that they would support one kidney going to a kidney alone candidate and one kidney going to a multi-organ recipient. They added that the greatest utility is for kidneys to go to candidates on dialysis rather than those with decreased function. One person suggested having a cutoff time before reallocating the organ. Another member remarked that allocation is often driven by the timing of the collection of required and requested data for each individual organ, and dictating by policy how organs are allocated could have the unintended consequence of delaying allocation of organs when you have information for some, but not all of them. An attendee suggested that consistent application of allocation policies for OPOs is important because they do not feel that occurs right now. They recommended including a time frame in the allocation so that when changes happen during allocation, multi-organ candidates are not needlessly excluded and late primary allocation can occur to the candidate that was intended to be the recipient, but not so late that logistical issues result in the organ going to a backup candidate. A member stated that organ offers need to be clear prior to procurement. Another attendee supports multi-organ recipients receiving priority over kidney-alone candidates, as heart, lung, and liver candidates typically do not have the ability to receive life extending treatments that kidney-alone candidates do, such as dialysis and diabetic management protocols.

Modify Effect of Acceptance

OPTN Ad Hoc Multi-Organ Transplantation Committee

- *Sentiment:* **4 strongly support, 13 support, 1 neutral/abstain, 0 oppose, 0 strongly oppose**
- *Comments:* The region supports this proposal. Several members expressed support for including specific timeframes in the policy. One member said without specific timeframes, there will be inequity and inconsistency in implementation, and that multi-organ candidates should not be disadvantaged. Another attendee suggested establishing timelines based on data that balance the need for earliest allocation as possible of single organs, while minimizing the disadvantage to multi-organ candidates who tend to have a limitations to access and make up a minority of allocations. A member recommended that kidneys be offered four hours before procurement. Another attendee supported the idea of kidney allocation being done before procurement, possibly after other organs are placed or the list is exhausted, to save unnecessary work and expense. A member commented that an easy option is for OPOs currently is to not offer the kidney as primary until after procurement and instead offer as a back up.

OPTN Strategic Plan 2024-2027

OPTN Executive Committee

- *Sentiment:* **2 strongly support, 12 support, 3 neutral/abstain, 0 oppose, 1 strongly oppose**
- Comments: The region overall supports this proposal. One attendee commented that in their professional experience, objectives may not always be aligned with vision. A member stated that offer acceptance should be removed as a metric because that would allow centers to decline an offer, versus putting in a provisional yes just to see if the organ gets accepted by a center ahead of them. The member believes that by removing offer acceptance, allocation will speed up and increase utilization because offers will go to centers that will accept them. An attendee remarked that with the significant focus on offer acceptance, the OPTN should have a similar focus on fixing issues with allocation and system inefficiencies. Another member suggested that long term outcomes of transplants is important, and that doing transplants but not being able to provide care of these organs is not a good practice. They added that there are significant work force issues in transplant, especially with transplant nephrology, that need attention. One attendee recommended that the OPTN provide feedback to transplant centers that turn down donors with the organ offer refusal code “DCD donor neurological function/not expected to arrest” so they know when there are instances where the donor did progress.

Update on Continuous Distribution of Hearts

OPTN Heart Transplantation Committee

- *Comments:* An attendee strongly encouraged the committee to consider including long term outcomes in continuous distribution. One member expressed support for the consideration of VAD patients. Another attendee stated that OPTN data collection is antiquated and needs to be modernized. A member strongly supports the continuous distribution of hearts project, as many patients do not fit the current status hierarchy, and a score would allow for other factors that are important to be considered. One attendee urged the committee to consider the scale for potential recipients developed in Europe.

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

OPTN Liver & Intestinal Organ Transplantation Committee

- *Sentiment:* **2 strongly support, 8 support, 8 neutral/abstain, 0 oppose, 0 strongly oppose**
- *Comments:* The region supports the proposal. An attendee shared support for the oncology review board and that intrahepatic cholangiocarcinoma recurrence survival needs to be considered as it is different than first time occurrence. A member requested that the committee clarify that percutaneous biopsy does not exclude intrahepatic cholangiocarcinoma from transplant consideration.

Refit Kidney Donor Profile Index (KDPI) Without Race and Hepatitis C

OPTN Minority Affairs Committee

- *Sentiment:* **7 strongly support, 9 support, 1 neutral/abstain, 1 oppose, 0 strongly oppose**
- *Comments:* The region supports the proposal. A member expressed support for the proposal and questioned whether KDPI still meets the community's needs, as there are misconceptions about what the numbers really mean. An attendee agreed that Black race is an imperfect proxy for a genetic variant causing worse graft outcomes but suggested the OPTN consider requiring APOL1 testing for all deceased donors. Three other attendees agreed that APOL1 testing should be considered. One member remarked that it is okay to acknowledge that racism is why only Black race was factored into these calculations, especially as we make these improvements. One member did not support removing race or Hepatitis C status from the calculation.

Updates

Councillor Update

- *Comments:* Two members expressed support for continuing to have Region 11 meetings in Charlotte

OPTN Patient Affairs Committee Update

- *Comments:* None

OPTN Membership and Professional Standards Committee Update

- *Comments:* An attendee suggested that the MPSC look at the reasons for out of sequence allocations because of the substantial increase because they need to make sure we're not furthering more inequities in access. Another attendee echoed the need for the MPSC to figure out this issue. A member recommended that the MPSC provide feedback and data to the Expeditious Taskforce so they can act if necessary. The member also added that there is an opportunity to use predictive analytics to prevent out of sequence allocations. Another attendee stated that the MPSC needs to look at cases to determine the definition of late decline. A member who is on the MPSC shared that all allocations out of sequence are reviewed and agreed that defining late decline is important. The member added that there is no percentage of out of sequence allocations that the MPSC believes to be acceptable, because they do not want it to be seen as a target. One attendee commented that while allocation reviews are important, getting organs allocated is also important, and that avoiding non utilization of organs is more important than reviewing every out of sequence allocation. Another member agreed and said

placing more organs means more access to transplant. The member also stated it is important to have clear definitions of things, such as organs at risk of decline, before policy is established. An attendee wondered if there has been any thought to the idea that less patients could be getting listed for transplant because programs are concerned about being flagged for pre-transplant mortality rates.

OPTN Executive Committee Update

- *Comments:* An attendee expressed support for continued development of more advanced methods of data collection, outside of programs manually filling out forms. A member stated that the OPTN needs to do more to address non-utilization and organs at risk of not being utilized.

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

- *Comments:* During the discussion, there were several comments made by attendees on how to improve organ usage and efficiency:
    - Remove barriers to growth, utilization, and efficiency
        - Multi-organ allocation policy and the lack of uniformity among OPOs. The attendee commented that OPOs should not be waiting until the last second to allocate kidneys
        - Electronic methods for donor referral
        - Surgeon fatigue and transplants occurring late in the night
        - Finding transportation
        - Handling last minute offers
        - The use of provisional yes for offers
        - Using artificial intelligence for more efficient allocation
        - Increasing the use of OPO donor care units
        - Increasing the use of kidneys with a KDPI of 85% or above
        - Resolving the ethics of TA-NRP on a national basis
        - Donor testing – what is required and the timing of these tests
        - Donors being required to have FDA-cleared screening tests, which are typically done by labs, when hospitals have almost identical tests
        - Removing KDPI and post-transplant outcomes monitoring – programs should do a better job guiding patients wisely on the risks and benefits of transplanting certain organs. Right now, programs do not know what patients think, so they make the decision for them
        - More and continued communication and education for patients regarding high KDPI kidneys – this cannot be a one-time conversation because it is a complicated topic and a patient's risk tolerance can change based on things like time on dialysis, health status, or general changes in their life.

- Rescue pathway protocols
  - Create a tool ("kidney wizard") to quickly identify recipients once a certain amount of cold ischemic time has been reached
  - Create a filter to opt in or out for specific characteristics to get to the right recipient more quickly
  - Define who a program will use rescue kidneys for upfront
  - More deliberative use of preservation techniques will increase the quality and length of time to allocate
- Community forum planning
  - Hold conferences on NRP with the public and hospitals
  - Hold conferences on the benefits of donor care centers
  - More national public education and messaging on the donation process for both living donation and deceased donor families
  - Work with end-of-life providers and end of life protocols
  - Work with dialysis centers on educating their patients
  - Meet with hospital executives and explain donor care units and the value it provides to the hospital
- Non-use study
  - Consider a workforce survey of transplant programs to help understand what resources and personnel successful programs have – this could help small and medium programs understand what is needed for success and be able to justify it to hospital executives

HRSA Update

- Comments: A member commented that data is needed on donor hospital behavior and that accountability is essential in the discussion about pre-waitlist data. An attendee emphasized that HRSA needs to be transparent with the reality of the short timeline they are operating on with the end of the current contract and needing to ensure there are no disruptions to services during this process. The attendee also stressed that the use of electronic health records for the pre-waitlist data collection would be less burdensome and generate better data.