Thank you to everyone who attended the Region 1 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: 1 strongly support, 9 support, 2 neutral/abstain, 1 oppose, 0 strongly oppose
- Comments: This proposal was not discussed during the meeting, but attendees were able to submit comments. A member suggested it would be helpful to review long term outcomes of post-transplant patients with issues related to histocompatibility and that his shared information could better guide the care of patients with negative post-transplant histocompatibility outcomes across the transplant community. Another member indicated support of the policy but noted it will likely increase the workload on their tissue typing lab as many workflows are manual.

Promote Efficiency of Lung Allocation, OPTN Lung Transplantation Committee

- Sentiment: 2 strongly support, 7 support, 4 neutral/abstain, 0 oppose, 0 strongly oppose
- No comments

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

- Sentiment: 2 strongly support, 7 support, 4 neutral/abstain, 0 oppose, 0 strongly oppose
- Comments: This proposal was not discussed during the meeting, but attendees were able to submit comments. A member commented that frailty testing needs to be standardized to be useful.

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

- Sentiment: 3 strongly support, 8 support, 2 neutral/abstain, 0 oppose, 0 strongly oppose
- Comments: This proposal was not discussed during the meeting, but attendees were able to submit comments. A member noted the proposal does not address the circumstance of an OPO Medical Director advising an OPO on donor screening and/or management of a donor and also

being the physician declaring death. This is not prohibited by the Uniform Anatomical Gift Act and is not a direct conflict but could be perceived as a potential conflict of interest. Another member shared that their hospital's cardiac intensive care nursing staff did not have the requirements of DCD pronouncement of death readily available to them at the time of a patient's DCD organ donation. The member strongly endorses clarifying these requirements and enhancing accessibility to staff who are exposed to the pronouncement of death for donors.

Discussion Agenda

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

- Sentiment: 2 strongly support, 9 support, 0 neutral/abstain, 2 oppose, 0 strongly oppose
- Comments: A member expressed support for the ability to have a group email serve as the secondary contact, as their center uses a group email for these types of incidents. An attendee expressed some concern with the requirement to confirm receipt in 24 hours, as 80% or more of these reports do not result in any change in clinical practice. They suggested a 72 hour requirement instead. A member stated that centers should be able to change the primary and secondary contact for this the same way it is done for primary and secondary contact for organ offers. Two attendees suggested there must be a more streamlined way to approach this workflow than what the committee is proposing. A member asked for more consideration of the reporting of donor cultures, as there are multiple notifications for the same donor with preliminary results and final culture reports.

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

Comments: A member noted that pancreas alone candidates were missing from the
presentation. An attendee commented that we should consider post-transplant survival when
considering how to allocate kidneys and that because kidney post-transplant survival is so high,
high KDPI kidneys should be going to single-organ transplants. Another member commented
that the safety net policy has provided options for patients and that sometimes when a
candidate receives a good heart transplant, they do not need the kidney or can wait a bit longer.
The member added they support additional review of the data to help drive this policy. Another
attendee agreed that whatever decision is made should be data driven. A member stated their
support for one kidney being allocated to hard to match candidates, like those with blood type B
or a high PRA. An attendee expressed concern that multi-organ candidates have too much
priority and there is not enough oversight over these transplants. Several members shared they
do not believe that kidney-pancreas candidates should be grouped with multi-organ candidates
because they are driven by the need for the kidney.

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

- Sentiment: 3 strongly support, 9 support, 1 neutral/abstain, 0 oppose, 0 strongly oppose
- Comments: A member suggested clarifying that transplant centers are putting in a provisional yes, not an acceptance. An attendee stated that heart-lung transplants are challenging under

current policy because the heart is driving the match, and if there is enough time, the OPO should finish going through the match run. The attendee also recommended setting a cutoff time or a trigger, such as cross clamp, but that otherwise the process should be to continue to go down the match. A member proposed that since policy uses nautical miles, perhaps that could be used to build in travel time. An attendee asked that the community not spend a lot of time on policies that impact so few cases. A member commented that multi-organ delays allocation.

OPTN Strategic Plan 2024-2027, OPTN Executive Committee

- Sentiment: 0 strongly support, 9 support, 2 neutral/abstain, 1 oppose, 0 strongly oppose
- Comments: A member noted the absence of a specific goal around equity, especially with the findings of the National Academies of Sciences, Engineering, and Medicine (NASEM) report. The member was also concerned at the omission of the work around continuous distribution, as this is currently a very large OPTN project that aims to provide more equitable organ allocation. The member stated that combining these components with the goals already in the plan would make it more complete. An attendee commented that the plan is missing any mention around living donation opportunities, which is important due to the current OPTN Living Donor Committee work in addressing long-term follow up and the collection of pre-referral data. A member agreed with the plan overall, but did stress that equity needs to be included. Two members agreed that equity must be included. An attendee suggested that the OPTN should be doing more with education of patients around listing and allocation, as many patients are confused with the allocation process and how the waiting list works. A member stated that it is challenging to review the strategic plan without the additional context of HRSA's OPTN modernization initiative and how that might impact it.

Update on Continuous Distribution of Hearts, OPTN Heart Transplantation Committee

Comments: Attendees discussed a comparison of how continuous distribution of lungs has been working since implementation and how the OPTN Heart Transplantation Committee could learn from their work. A member noted that for lung allocation it has been very successful especially for Region 1, as they now have expanded access to donors and can get harder to match candidates transplanted faster. While has meant additional travel, perfusion technology makes it feasible. Also the new allocation system is more responsive, for example when an issue with the amount of points for blood type was discovered, it could be fixed quickly. An attendee asked that the committee keep an eye on out of sequence allocation and extended allocation times impacting overall utilization rates. A member said they do not support including time on LVAD in the calculation. An attendee endorsed the closer review of continuous distribution of hearts regarding allocation for transplant recipients with LVADs, with increased sensitization, and nautical mileage constrictions. A member requested the committee monitor the effect of continuous distribution on multi-organ allocation. Another attendee commented that continuous distribution makes sense for hearts, but not for kidneys because it is overly complex.

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

- Sentiment: 3 strongly support, 8 support, 1 neutral/abstain, 0 oppose, 1 strongly oppose
- Comments: A member stated that a MELD of 15 may limit access for this group of patients. An attendee commented that the data is inconsistent at best.

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

- Sentiment: 6 strongly support, 7 support, 0 neutral/abstain, 0 oppose, 0 strongly oppose
- Comments: A member applauded this proposal and suggested including testing donors for APOL1. An attendee suggested also removing the question about ethnicity from the calculation. They added that the committee should consider the impact on data analysis and scientific research with the plan to retroactively recalculate KDPI. A member asked the committee to consider donors with treated HCV versus donors with active HCV and how insurance protocols might impact the ability to treat recipients of these donors. Another attendee expressed strong support for the removal of HCV status.

Updates

Councillor Update

• Comments: No comments

OPTN Patient Affairs Committee Update

• No comments.

OPTN Membership and Professional Standards Committee Update

 Comments: A member commented that with some policy rollouts, such as the HBV vaccine policy, all of the information needed to guide members is not available in one single source. The member suggested that the implementation guidelines include all of the necessary details. They also added that they do not feel that programs have all of the tools needed to achieve metrics for things like offer acceptance. An attendee advocated for having policy implementations on a more regular cadence. A member wondered if the upcoming changes to the OPTN Board of Directors will have implications for the MPSC. An attendee asked about the status of the updated kidney offer filters project.

OPTN Executive Committee Update

• Comments: A member requested any information that could be shared regarding the rollout of the independent OPTN Board of Directors. An attendee mentioned an increase in donors due to the opioid use epidemic and wondered if society was able to find a solution to this epidemic, does the OPTN have a plan to continue increasing donation and transplant. Another member responded to this citing data that shows that while overdose deaths are contributing to the increase in donors, they are not driving the increase. A member asked for an update on the percentage increase in transplants for African Americans related to the eGFR waiting time

modification policy. An attendee asked if the HRSA pre-listing data directive will be looking at other organs and diseases. Also regarding the pre-listing data directive, a member stated that a lot of this data exists in the healthcare system outside of transplant and suggested that the OPTN should work with CMS to get this information.

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:
 - Early engagement for offers before you are primary perhaps a dashboard showing you potential upcoming offers to allow programs to be proactive
 - Suggested a dashboard that is informed by data showing how far down a match an offer is predicted to end up
 - Have a limit for cold ischemic time on an organ that would trigger a clear protocol for OPOs to follow to ensure the organ is placed
 - Many challenges for OPOs when working with families to obtain consent for donation when a patient is not a registered donor – it might be helpful to create a coalition to get all impacted parties on the same page, especially with donor hospital staff. Sometimes donor hospital staff feel uncomfortable with the conversations OPO staff have with potential donor families. Educating and working with donor hospital staff would improve the process for everyone.
 - Provisional yes is essentially a "maybe" improving some of the data provided for an offer would allow programs to more quickly navigate offers
 - Use artificial intelligence to better determine when a candidate could become primary on an offer
 - Create a meter that takes in information about an organ and shows when an organ becomes at risk for non-use and would trigger a rescue pathway.
 - Have a separate match run for double kidney allocation
 - o Acknowledge that some organs just should not be transplanted

HRSA Update

 Comments: A member stated that the OPO community is pleased with the data directive and hopes that enough information will be captured to make a meaningful impact. They added that the community is anxious to hear more information about the roll out of the independent OPTN Board of Directors and expressed concern with the potential for a for-profit contractor to be in charge of OPTN policy making.