OPTN

Thank you to everyone who attended the Region 4 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 Forms, *OPTN Histocompatibility 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 virtual crossmatch data collection needs to be better defined to specify what needs to be captured in this field. They added that various labs define a negative/positive virtual crossmatch in different ways.

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

- Sentiment: 2 strongly support, 8 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. One attendee commented that they appreciated the committee's work to promote efficiency and agreed that it should be a primary concern.

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

- Sentiment: 1 strongly support, 9 support, 4 neutral/abstain, 0 oppose, 0 strongly oppose
- Comments: No comments

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

- Sentiment: 2 strongly support, 8 support, 4 neutral/abstain, 0 oppose, 0 strongly oppose
- Comments: No comments

Discussion Agenda

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

- Sentiment: 1 strongly support, 9 support, 1 neutral/abstain, 2 oppose, 1 strongly oppose
- Comments: During the discussion several attendees supported revising the language to recommend Patient Safety Contacts be employed by the transplant center but not make it a requirement. They added that having third party vendors as Patient Safety Contacts is essential to avoid overburdening individuals and programs. One attendee added that leaving the requirement in the policy is too prescriptive particularly since the transplant center is ultimately responsible for performance of vendors they hire to serve in this role. One attendee commented that if third party vendors are allowed to serve as Patient Safety Contacts, the OPTN should have standards for the vendors as well as a statement of responsibility. Several attendees supported the requirement that Patient Safety Contacts be employed by the centers, adding that it is crucial to avoid delays. They went on to comment that members need to be accountable for safety and communication. One attendee recommended including language requiring the use of the Patient Safety Contact information provided in UNet. They added that sometimes the transplant center or OPO use the institution's main number which causes delays in reaching the appropriate Patient Safety Contact. One member recommended allowing a "generic" email or phone number that is monitored 24/7 by a qualified team to avoid gaps in the system updates between the member and the OPTN. Several members supported the proposal and are happy to see the removal of duplicate reporting.

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

- Comments: Members in the region offered several suggestions for the committee to consider as they address this very important issue. Several attendees supported prioritizing kidney alone candidates who were highly sensitized, medically urgent, pediatric and prior living donors. Another attendee commented that the policies need to consider the relative benefit to recipients of receiving a multi-organ transplant, versus the relative benefit to the two (or more) individuals who would otherwise receive the multi-organ transplant. They added that the allocation system has not historically considered the loss of benefit to the other potential recipients and as a system it seems that that focus on potential benefit to multiple individuals vs. a single multi-organ transplant candidate should be considered. Several attendees supported one kidney being allocated to a multi-organ transplant and one to a kidney/pancreas or kidney alone candidate. One attendee supported increasing utilization of low KDPI kidneys under a safety net policy adding that the allocation system should be modified in a way that high quality kidneys don't just go to multi-organ transplant candidates. One attendee commented that the threshold for heart/kidney varies from center to center, adding that the committees need to continue to monitor the safety net criteria to determine if the policy needs to be updated. One attendee commented that if we remove race and HCV from the KDPI calculation there may be more kidneys available with lower KDPIs. One attendee recommended a Values Prioritization Exercise (VPE) for multi-organ allocation to get a better idea of how the community prioritizes allocation across the organs, as well as medically urgent kidney alone and pediatric versus adult. One attendee recommended that the committee consider the racial breakdown of multi-organ

transplant candidates versus kidney alone candidates to make sure we are not creating a racial bias or access issue with allocation policy.

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

- Sentiment: 3 strongly support, 6 support, 4 neutral/abstain, 0 oppose, 0 strongly oppose
- Comments: The region supported this proposal. During the discussion one attendee recommended adding a timeframe for OPOs to clarify when the kidneys can be offered to the kidney alone candidates making them no longer available for allocation to a multi-organ candidate. Another attendee commented that the definition of organ acceptance needs to be clarified so that the OPO and center know when the acceptance is binding. One attendee recommended that the committee consider moving toward more transparency so that candidates understand why they are not being offered the kidney. Another attendee commented that candidates have expressed a desire to centers to know what offers have been declined for them. They added that the goal would be to refine hospital screening criteria to match patient preferences. One attendee recommended requiring all multi-organ allocations to have a back-up for the kidney in the event that the multi-organ allocation has a late decline.

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

- Sentiment: 2 strongly support, 10 support, 2 neutral/abstain, 0 oppose, 0 strongly oppose
- Comments: Region 4 supported this proposal. One attendee said it will be important to ensure that the goals in the strategic plan are adhered to during the modernization initiative. They added that this will be important if there are multiple vendors and contracts.

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

- Comments: Members in the region offered several suggestions for the committee to consider as they move forward with continuous distribution. Two attendees recommended including post-transplant survival as a variable. They added that overall medical care of the patient is important, and the most medically urgent candidate should not always be prioritized if they are going to have a bad outcome. Another attendee said the data for post-transplant mortality will never be as good as we want, but there is an opportunity to think about it as we move forward. They added that this is an opportunity to improve how we care for patients, and we need to accommodate post-transplant outcomes, especially if we use devices to prioritize people. Devices are a decision we make, not a marker of urgency or illness.

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

- Sentiment: 0 strongly support, 9 support, 5 neutral/abstain, 0 oppose, 0 strongly oppose
- Comments: Region 4 supported this proposal. During the discussion one attendee commented that it is a great start for transplant oncology. They added that the only concern is that treatment varies from center to center and even from oncologist to oncologist so the guidance should not be too prescriptive.

Refit Kidney Donor Profile Index without Race and Hepatitis C Virus, *OPTN Minority Affairs Committee*

- Sentiment: 5 strongly support, 7 support, 0 neutral/abstain, 1 oppose, 0 strongly oppose
- Comments: During the discussion one attendee supported the proposal and commented that changing that removing race and Hepatitis C from the KDPI calculation will help African American and recipients with Hepatitis C with their transplant outcomes. Another attendee supported the proposal but commented that if KDPI remains "indexed" such that the number of donors in each category will remain similar, it is not clear that this will actually increase utilization. They added that it may increase utilization of donor organs with hepatitis C or of African American race, but there may be a corresponding decrease in other categories if centers continue to use KDPI cut-offs.

Updates

Councillor Update

- No comments

OPTN Patient Affairs Committee Update

- No comments

OPTN Membership and Professional Standards Committee Update

- No comments

OPTN Executive Committee Update

- During the discussion one attendee commented that there are candidates willing to accept hard-to-place organs, understanding the challenges, and centers should not be penalized for doing what the candidates want and transplanting the organs. Several attendees agreed and added that the biggest impediment with hard-to-place organs is that centers are flagged if they have poorer outcomes. They went on to recommend that there needs to be discussion about developing a pathway for programs that take recommended risks. Another attendee commented that there are many barriers to achieving a 58% increase in the number of transplants, many of which are outside of the OPTNs control. They added that this will require changes in allocation policies, procurement procedures, efficiencies and outcome measures. One attendee commented that hospitals are already dealing with information security and the OPTN should require that any CMS approved transplant institutions annual security training should meet the OPTN transplant security training expectations. They added that there will be poor compliance amongst physicians if they have to log into UNet. Another attendee commented that the transplant community needs CMS and HRSA to come together with uniform policies on DCD, NRP, etc. They added that we have the best transplant system in the world, and we need to improve, but we really need to be careful and smart about it and not get bogged down in bureaucracy. One attendee was concerned about how multiple contractors will work together to smoothly move the transplant program and OPTN initiatives forward.

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

- During the discussion there were several recommendations from attendees about how to increase the number of successful transplants and improve organ allocation efficiency:

- The need for requirements for DCD and NRP, and real accountability for donor hospitals
- Improvements for crossmatching including not doing physical crossmatches
- Determine what type of organs should be allocated to centers closest to the donor hospital so that transportation does not add cold ischemic time.
- Less broad allocation should be considered as a possible strategy
- Kidney biopsies read/interpreted by a regional or centralized group of skilled transplant pathologists
  - Feasible to adopt standardized digitization of kidney biopsies at site of donor read and then secondary read by program pathologists
  - Biopsies should be used to rule-in, not rule-out
- Hold regional conferences to discuss improvements in standards and best practices
- Improve user interface for DonorNet to minimize distractions and empower the end users with decision-support analytic data
- Need to find out what is important to Payors
- Need to educate the community about what is important to patients
- It is important to understand why the organs aren't being used. Liver non-use may be due to an increase in livers being pumped to see if they could be transplanted, when before they wouldn't have been recovered
- One idea to reduce the number of allocations out of sequence is to use a sequence number on the match run or cold ischemic time on the organ, after which OPOs can allocate to centers they know will accept
- Using AI is an option that should be investigated
- Patient support groups within dialysis centers and hospitals would be a great way to engage the kidney patients who are not familiar with the OPTN
- Use pilot programs in high performing transplant programs or OPOs to try new processes or ideas
- Given the increase in DCD donation and organ donors over age 50, changes in utilization may be more due to the changing environment than to policies

HRSA Update

- During the discussion there was concern raised about the funding for the modernization initiative and how the community will be assured that the funding will always be available. There was also concern about allowing for-profit companies to hold portions of the OPTN contract which could result in increased costs for patients and the community. Another attendee commented that every new thing that comes to transplant costs money and we need to consider the new costs of transplantation once we implement continuous distribution. They went on to comment that we need to be sure we are not ignoring the finances of what we are doing and how this will impact access to transplantation, which is the ultimate goal. Another attendee commented that the community is concerned not just the what but the how. As we transition, how do we ensure there is no disruption of care with data systems, matching process, etc. Another attendee commented that as access to transplantation is explored, they urged HRSA to ensure referral data is collected in such a way that it is understood regardless of selection criteria They added that referrals are initially limited by centers with whom the patient's insurance is contracted and this can be limited via primary payor and/or secondary payor. They went on to comment that our community is also mindful of the expected 380

million dollar loss should CMS's reform of the transplant center's cost report pass. They added that while there is not an active proposal, CMS continues to review feedback with a pledge that the system will be reformed.