OPTN

Thank you to everyone who attended the Region 5 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: 10 strongly support, 20 support, 7 neutral/abstain, 0 oppose, 0 strongly oppose
- Comments: Region 5 supports this proposal and commented that it eliminates a largely unnecessary clerical task and decreases the workload.

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

- Sentiment: 5 strongly support, 25 support, 7 neutral/abstain, 0 oppose, 0 strongly oppose
- Comments: Region 5 supports this proposal and an attendee suggested there should be more attention given to allocation for pediatric candidates.

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

- Sentiment: 6 strongly support, 20 support, 10 neutral/abstain, 0 oppose, 0 strongly oppose
- Comments: Region 5 supports this proposal. An attendee pointed out that it provides an objective measure of frailty for the potential recipient. But noted that if the potential recipient performs well, then they might not have as high a priority as a more frail recipient.

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

- Sentiment: 12 strongly support, 22 support, 1 neutral/abstain, 1 oppose, 0 strongly oppose
- Comments: Region 5 supports this proposal and commented that there is a need for a standard procedure and protocol for transparency and consistency purposes. There was significant support for standardizing the processes, and providing clear requirements and guidelines, surrounding the pronouncement of death in DCD donors. There was support for clarifying both policies and having consistent language especially when referencing pronouncement of death. An attendee supports a simple clarification that ensures separation of duties. A member commented that in DCD situations, many physicians are uncomfortable with the five-minute time period between initial determination of death and the second confirmation, which is time

of death. They explained that they personally have seen many physicians strongly express frustrations that an outside team, who are not their academic peers, request them to veer against their own personal practice for determination of death. To prevent this conflict, they suggested the committee draft clear guidelines that are standardized nationally and that can be clearly incorporated into a hospital's own DCD internal protocol.

Discussion Agenda

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

- Sentiment: 13 strongly support, 18 support, 1 neutral/abstain, 2 oppose, 0 strongly oppose
- Comments: Region 5 supports this proposal. Specifically, an attendee supported the requirement for designating a specific transplant professional at a center, as the point person. And suggested that it could be optional for transplant programs to complete electronic recording of cultures and associated work. A member suggested that communication could be via computer systems, using the enhancement to communicate any potential donor derived transmission. Another pointed out that centers may not have the capacity nor resources to hire or assign additional staff to support, and the committee needs to mindful to not require additional onerous regulatory rules. There was support for the implementation to be as simple as possible. A member commented that this initiative will go a long way to potentially increase the efficiency in information transfer. A member institution agreed with reducing duplicate work but disagreed on having only one listed patient safety contact. They explained that this responsibility is typically given to a staff member who works Monday through Friday, and most of the critical information regarding a donor result is sent to the person on-call. They believe that a full-time patient safety contact will be a staff burden for the transplant program.

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

- Comments: Region 5 supported this concept paper and offered the following feedback. There was a lot of support for allocating one kidney to a multi-organ (MOT) candidate and the other kidney to a kidney-alone candidate. There was differing opinion on whether a kidney-pancreas candidate should be categorized as an MOT candidate. A member commented that it will be disadvantageous for kidney-pancreas candidates to be included amongst the MOT candidate pool, since pancreas donors are rare and for someone to be a pancreas donor there will have to have a low KDPI, and heart, liver, etc. candidates may not need a low KDPI kidney. For each donor, at least one kidney should be allocated to kidney-alone candidates and potentially both kidneys for the difficult to transplant candidates: pediatric, high PRA, previous living donor.
- Another attendee commented that pediatric patients only receive offers from 0-34% donors, it's a limited donor pool, and in their experience the low KDPI kidneys go to MOTs instead of pediatric candidates. Several members and a small pediatric center commented that they are heavily impacted by MOT's and support policy change in this area. They support one kidney being allocated to a MOT candidates (including kidney-pancreas candidates) and one kidney being allocated to kidney-alone list. They explained that they need the kidney's with KDPI 0-34%, which limits their pool, and if those kidneys are always allocated to MOT candidates, then

it would be a significant disservice to their small patient population and extends dialysis time which in turn increases morbidity and mortality. A member supported the pediatric, prior living donor, and high PRA to be before the MOT in the allocation sequence.

- An attendee suggested that the Committee consider if the kidney alone patients should take priority on the list. They support a proposal that states which high priority kidney alone candidates should receive priority over MOT candidates, includes policy allocation order, and that kidney-pancreas should be considered a MOT transplant.
- An attendee commented that kidney-pancreas patients more aligned with kidney alone patients (no one would accept kidney alone for heart/kidney but would consider kidney alone for a kidney-pancreas candidate), while another attendee disagreed with this comment.
- A member explained that kidney-pancreas allocation needs to be further discussed since technically it is a MOT allocation but more like kidney allocation. They noted that the wait time benefit of kidney-pancreas allocation would be diminished if not considered MOT. And requested survival date related to wait time for each of the MOT recipients to make final allocation and policy decisions.
- A member supported one kidney going to the MOT candidates and one kidney to the kidney-alone candidate, and when there is an individual heart candidate at the top of the list (i.e. status 1), then the two kidneys should go to single organ candidates.
- Another attendee commented how challenging this area of policy is, and that in their individual practice area, there isn't enough broad experience since they are only familiar with their own patient populations, which makes it difficult to make policy decisions. They suggested the committee investigate mortality data on MOT patients and provide this data in future policy proposals.
- A member suggested creating a waitlist for the following MOT combinations: lung/kidney, heart/kidney and liver/kidney candidates. An attendee suggested that the committee create an allocation order for MOT candidates based on medical urgency, mortality on wait list, and post-transplant survival benefit. And should also include the same factors for kidney alone. So, for example, a highly sensitized who is also medically urgent kidney alone candidate should be placed higher than kidney-pancreas candidate. A member commented that allocation of a kidney going to the kidney MOT candidate will be driven by heart, liver, or the lung list. With regards to which kidney MOT candidates (heart versus liver versus lung) should be prioritized in the allocation of the kidney, the order should be based on pre-transplant mortality risk. From an OPO perspective, an attendee commented that these concepts could increase the number of times OPOs need to make allocation decisions for MOT candidates.

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

- Sentiment: 10 strongly support, 19 support, 4 neutral/abstain, 1 oppose, 0 strongly oppose
- Comments: Region 5 supported this proposal and offered the following feedback. They requested clarification on what constitutes a MOT candidate and more information on a back-up scenario and a definition for a back-up offer. There was support for the concept of addressing back-ups and suggested a MELD threshold for these situations. Another member suggested addressing the back-ups in Policy and require OPOs to honor the back-up. An attendee commented that although this may be challenging, back up offers for simultaneous

liver-kidney waitlisted candidates should be considered since their mortality is high. A member commented that an OPO should never take back an organ that has been allocated. Another suggested the committee include a provision to not disadvantage backup MOT candidates. If there is an immediate backup MOT candidate, that candidate should be offered the organs prior to offering the kidney to the kidney alone candidates. In support of this proposal, a member commented that this proposal will improve allocation efficiency by allowing OPOs to offer kidneys without fear of having to revoke an offer due to a late allocation of an extra-renal organ. An attendee explained that it is important to not "take away" a kidney from patients who had been allocated off the normal match run especially for pediatrics or for the highly sensitized. They believe that there is the potential that as currently written, the OPO can still "make up" their own rules. And part of the challenge is weighing mortality at the top of the list versus the isolated kidney need.

- It was commented that this will allow pediatrics and high CPRA patients to receive kidneys in a more time efficient manner and that there should be exceptions for pediatric candidates. Another attendee commented that they are very interested in allowing hard to transplant and pediatric candidates who need a kidney to not be bypassed by MOT candidates. Several members commented that hard too transplant kidney candidates should be taken into consideration when allocating kidneys to MOT candidates. A member inquired about how this proposal would affect heart-lung candidates.

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

- Sentiment: 5 strongly support, 25 support, 1 neutral/abstain, 3 oppose, 0 strongly oppose
- Comments: Region 5 supported and appreciated the strategic plan presentation. An attendee suggested removing consent requirements for high KDPI kidneys and explained that the longer a candidate is on the wait list their preferences could change. An attendee suggested holding a national, public, campaign to help establish the goals to counter-balance negative media. A member institution said they support the initiatives to increase organs for transplant. They suggested changes in risk stratification for centers that accept marginal organs, so they are not overtly penalized for accepting such organs. An attendee asked if there has been progress in having centralized pathology (via digitalized images). They commented that the transplant field would benefit from an organ specific pathologist interpreting donor biopsy to reduce inter-observer availability and increase confidence to accept organs. In support of the current plan, an attendee suggested including information on how to achieve the goals with descriptions of interventions that will be implemented to meet the objectives and goals. A pediatric program supported the effort towards granularity and specificity, but noted there remains concern amongst the pediatric population that some of the transplant community's core values, such as equity and access, are not a focus of the proposed strategic plan.

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

- Comments: Region 5 appreciated the update on Heart Continuous Distribution and offered the following feedback on the committee's work thus far. A member encouraged all attendees to participate in the values prioritization exercise and suggested including post-transplant survival (even if rudimentary/low weight) as part of first iteration and a category for waiting time. He explained it was important for medically urgent patients. An attendee commented that she agreed with exclusion of post-transplant survival from this first iteration. While another

attendee suggested the committee include some component of post-transplant survival, and several members suggested to include HLA sensitization for allocation (cPRA especially and similar to CAS lung allocation). A member suggested the committed consider continuous medical urgency score rather than status. Another member commented on proximity – the willingness to travel a longer distance reflects on program infrastructure particularly in the era of improved storage strategies of organs. Proximity criteria will limit visibility to programs that are able to travel negatively. An attendee commented that lung CAS lead to increased distances to procurement, high costs, less access, and more dry runs. As a result, they believe that CAS will be difficult to maintain. While several members were in support of continuous distribution, and an attendee commented that the committee's progress is a big step forward to moving toward continuous distribution.

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

- Sentiment: 9 strongly support, 22 support, 4 neutral/abstain, 0 oppose, 0 strongly oppose
- Comments: Region 5 supported this update and offered the following feedback. In support of this update an attendee commented that it all sounded reasonable with the minor caveat with the CRLM. He explained that 15 points is difficult. He suggested the committee consider a point increase after a period of time. In regard to oncology review board, he suggested establishing the review board, then see how much they have to review and whether it becomes a burden. He commented that he believes there has been a reduction in HCC review and its mostly cholangiocarcinoma and associated items. He believed the review board would receive nuanced tumors but thinks that its helpful to have all the information in one place for standardization efforts. Several members said they are worried about the workload for this review board after patients are added.
- An attendee strongly supported the idea of transplanting highly selected cases of CRC mets or iCCA. But doesn't think the proposed MELD point is reasonable. They explained that for both categories, it might make more sense to grant MMaT-10, which will likely be a MELD of ~20-25 in most areas. This way, organs that are not likely used otherwise would be used for these patients who have slightly lower post-LT 5-year survival compared to non-cancer patients. The other suggestion was to clarify the "stability of disease for 6 months" for iCCA cases. They suggested the guidance should specify the absence of a new lesion after the initial lesion has been treated. The development of a new iCCA lesion is consistent with disease progression and more aggressive behavior in the case of cholangiocarcinoma. Another member agreed with the discussion about CRC metz and commented that exception points up to 20 will not make a patient competitive in this region. While another commented that MMAT - 20 for CRC mets seems appropriate, and they should not supersede patients with chronic liver disease or other standard indications for liver transplantation with MELD 15-25.
- Another commented that the committee should collect data on the new diagnoses transplanted with regards to outcomes versus current HCC patients who have been transplanted. A member commented that it will be important to follow up with data on outcomes in the expanded criteria tumor patients. An attendee explained that the field of transplant oncology is growing and with the possibility of the increased availability of liver donors it could help expand the field. An increased utilization of NMP and NRP will likely lead to an increase in liver allograft availability for such endeavors. A member suggested that the OPTN provide additional guidance to transplant centers regarding MELD/PELD exceptions, which could help with the uncertainty

surrounding the process. Transplant centers would be able to better identify patients who are likely to be approved for the exception and determine other treatment options for the rest.

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

- Sentiment: 14 strongly support, 19 support, 1 neutral/abstain, 1 oppose, 0 strongly oppose
- Comments: Region 5 supported this proposal and offered the following feedback. An attendee suggested that this should be split apart, where there is KDPI without race, and KDPI and hepatitis C. They noted that pediatric patients only receive priority for KDPI kidneys of 0-34%, and current drugs for hepatitis C are only approved for children three years old and up. They inquired about insurance covering medication for a child less than three years old or a liquid compound for a child that cannot swallow pills. A member commented that the decrease in the KDPI percentage will more correctly represent the true quality of the renal allograft. Another member commented that hepatitis C may need to be left in the KDPI formula as a risk factor. An attendee encouraged donor APOL1 testing when feasible. And if it is not incorporated into the KDPI, it should be available during the organ offer as with all other donor risk factors and test results.

Updates

Councillor Update

- Comments: Region 5 did not have any comments or questions.

OPTN Patient Affairs Committee Update

- Comments: Region 5 appreciated the Patient Affairs Committee's update and did not have any comments or questions.

OPTN Membership and Professional Standards Committee Update

- Comments: Region 5 did not have any comments or questions.

OPTN Executive Committee Update

- Comments: Region 5 supports the Executive Committee's update and appreciated the presentation. An attendee commented that while he supports the three pillars he pointed out that the end goal should be to perform the most transplant ever; rather, it should be to save more lives. Region 5 inquired about Board separation and when future Board Meetings will occur.

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

- Comments: Region 5 appreciated and supported the Expeditious Task Force (Expeditious) update and interactive tablework session. After the tablework session attendees identified the following as barriers to transplant:
    - Availability of pronouncing physicians
    - Availability of ICUs
    - Helping hospitals to recognize that donor operating room time is a high priority (especially in light of allocation changes)

  - Lack of availability to get procedures done for organ utilization i.e. echocardiograms, bronchs, repeat tests, or pre-OR biopsies for DCD livers
  - Standardizing biopsy
  - Holding members accountable to policies (they may place an organ in the evening and the next team comes in in the morning and codes out, which creates a late decline)
  - Travel logistics
  - Difficulty lining up backup organs (Notably, a group explained that establishing a back-up offer is more challenging with continuous distribution. They suggested that with lung continuous distribution, placement efficiency should be more heavily weighted because they are seeing that some of their first offers out of California can be for a candidate in Florida.)
  - Local recovery and late turndowns
- An attendee suggested Expeditious identify incentives for transplant surgeons and physicians to review offers and be heavily involved in the offer/acceptance stage.
- Regarding managing the volume of non-expeditious organ offers, a member suggested to have the surgeons begin their day by reviewing the offers that came in overnight and providing a response. Another member offered that their OPO pauses allocation at a certain time of night (i.e. 9-10 pm), then performs a check-in in the morning with all those offers to keep them moving.
- Regarding ideas on allocation, an attendee suggested reducing variation. There should be the same expectations across the country: pre-OR liver biopsies, centralized pathology via someone who has experience with these biopsies, real-time changes in KDPI for cold kidneys to better facilitate placement, allocation during the day, address PHS criteria (they haven't seen a patient sero-convert after NAT testing), overcome language barriers (speaking through an interpreter is tough and usually results in a declined offer), for kidney default filters – they suggested to set up an algorithm that would allow centers that take marginal organs and allocate those kidneys to them quickly.
- An attendee suggested that donors with high KDPI should be eligible for the rescue pathway, members should be able to proceed further down the candidate list and should be used for hard-to-place kidneys and when reallocation is needed.
- Regarding the expedited placement pathway, another group explained there should also be increased communication transparency for DCD donors to help transplant programs with decision making on whether to pursue and offer. Especially because it takes 6-8 hours to set up machine perfusion. Identifying donors with high neuro status, questionable progression – figuring out pathways to recover those organs even if they aren't immediately accepted, maybe they'd just go to local centers but then they'd still get used. There shouldn't be a cross-clamp prior to acceptance if a member is still waiting on biopsy results – accrue CIT and more likely to get declined. They suggested that at 15 hours of cold time for a kidney (and 4-6 hours for a liver), then the organ should be locally placed. They suggested establishing thresholds for transitions to expedited placement.
- Another group pointed out that there should be a change to the culture of the risk falling on the transplant center or transplant team. They shared that they feel there are patients who are willing to take rescue pathway organs, and there could be a separate match run for patients who are willing to take those high-risk organs. There should also be positive incentive or risk mitigation for a program willing to accept rescue organs, and if a rescue organ fails, that patient should be able to move up the list.

- An attendee suggested the Expeditious be mindful of costs associated with all their ideas.
- Members noted that sometimes it is difficult to find information they are looking for in the OPTN Donor Data and Matching System, requested updated tools, and commented that they spend most of their offer evaluation time consolidating information for physicians/surgeons to review. Another group listed the following challenges: transportation and limitations with commercial flights and cargo holds, availability and cost of pumps, reimbursement for pumps, getting blood to do crossmatching ahead of time, centralized pathology, monitoring trends in increasing declines, shared decision-making with patients and ongoing discussions about patient preference.

HRSA Update

- Comments: An attendee pointed out that the patient population wants continuity of the system; that separation between end of contract and RFP timeframes is concerning; and that they want to see independent oversight of all the changes that will be made with the modernization plan. Another attendee inquired about the creation of a legally independent OPTN corporation.