OPTN

Thank you to everyone who attended the Region 5 Winter 2023 meeting. It was great being back in person and still having an option for you to join virtually. We plan to continue providing both options.

Regional meeting presentations and materials

Public comment closes March 15! Submit your comments

The sentiment and comments will be shared with the sponsoring committees and posted to the OPTN website.

Non-Discussion Agenda

Modify Heart Policy for Intended Incompatible Blood Type (ABOi) Offers to Pediatric Candidates, *OPTN Heart Transplantation Committee*

- Sentiment: 9 strongly support, 13 support, 7 neutral/abstain, 0 oppose, 0 strongly oppose
- Comments: Region 5 supports the proposal.
- A member commented that this proposal will better align pediatric heart allocation policy with current evidence and allow centers to choose more appropriate offers for pediatric candidates waiting for a heart transplant. The member further noted that the proposal has the potential to decrease pediatric waitlist mortality.
- A member suggested there should be follow up monitoring to see if the proposal causes an increase in ABOi pediatric transplants and transplant outcomes.

Improve Deceased Donor Evaluation for Endemic Diseases, *OPTN Ad Hoc Disease Transmission Advisory Committee*

- Sentiment: 8 strongly support, 21 support, 3 neutral/abstain, 1 oppose, 0 strongly oppose
- Comments: Region 5 supports the proposal.
- A member commented that currently donors are being correctly evaluated and that more testing will increase the complexity of allocation, further delay and perhaps even preclude some donors. The member will only support the proposal if there is compelling data that shows an increase in disease transmission.
- A member institution noted that while it recognizes the prevalence of Chagas is significantly lower than that of strongyloidiasis, given the subjective nature of donor screening histories, the significant increase in individual travel and migration as well as the substantial morbidity and mortality in the post-transplant setting particularly for heart transplant recipients, it urges the Committee to require universal testing for both Strongyloides and T. Cruzi. If the Committee does not agree there is sufficient evidence to support universal testing, it argues that, at minimum, the criteria for testing should be expanded to include those with travel history, those that lived in an endemic area for greater than 6 months, close relatives of people previously diagnosed, and those with clinical indications of potential infection. Given the anticipated false positive rate (1- specificity), it also supports requiring two initial samples as recommended in the testing protocol published in the 2021 Journal of Infectious Disease, Recommendations for Screening and Diagnosis of Chagas Disease in the United States.

Align OPTN Kidney Paired Donation Blood Type Matching Policy and Establish Donor Re-Evaluation Requirements, *OPTN Kidney Transplantation Committee*

- Sentiment: 8 strongly support, 19 support, 2 neutral/abstain, 0 oppose, 0 strongly oppose
- Comments: Region 5 supports the proposal.
- A member commented that there are many requirements for donor re-evaluation, and pointed out there have been potential KPD chains broken due to donor issues, and that this will significantly increase costs associated with KPD.
- A members' institution explained that it supports the concept but opposes the requirement that centers obtain a written signature from the donor for every annual re-evaluation. It explained that informed consent is an evolving process that occurs over the course of the donation journey and should be documented by providers. And noted that requiring a signature is an antiquated and burdensome practice with little positive impact on patient safety.

Discussion Agenda

Require Human Leukocyte Antigen (HLA) Confirmatory Typing for Deceased Donors, *OPTN Histocompatibility Committee*

- Sentiment: 4 strongly support, 12 support, 2 neutral/abstain, 9 oppose, 5 strongly oppose
- Comments: Some Region 5 members support this proposal and some Region 5 members oppose this proposal. Some members supported the requirement for additional testing and encouraged doing what is the safest for candidates. However, several members questioned whether the additional time and cost was worth the burden, and if it would solve the root cause of the issue. A member explained that there is resistance, regarding the costs, from the HLA community.
- A member supported the proposal and suggested the tests be performed simultaneously to minimize the time period for receiving results.
- In support of the proposal a member stated that this proposal is critically important for centers that have moved to virtual cross-matching.
- A member pointed out that the majority of errors cited were clerical errors that have been addressed. And the impact of the errors is questionable. The member opined if the proposal creates a greater harm by increasing time required for testing and increasing costs. The member suggested that these additional requirements could reduce the availability of viable organs for transplant.
- A member explained that patient safety is important; however, the proposal is predicated upon a .24% error rate, of which 12 reported events are related to "sample switching" and it is unclear what the actual adverse impact of these errors resulted in, which leaves this to be a somewhat theoretical problem. The member recommended the committee consider incorporating improved lab standards to limit sample switching. Further, the proposal does not address what an OPO is to do if there are discrepant results (if typed twice), which sample would be the "correct" sample? The member had the following suggestions: consider applying this to living donation; and perform a true cost analysis to determine the financial impact prior to implementation.
- Several members asked for a cost analysis and additional data before deciding whether additional testing is needed.

- A member commented that this proposal creates a substantial operational and financial burden for HLA labs (and, subsequently, for OPOs) to address a problem that is not well-documented by data.
- A members' institution recommended, instead of this proposal (that will likely add additional delay cost and complexity to organ offer review and the matching process), for the committee to consider a proposal that requires the OPOs to perform high resolution donor typing for kidney deceased donors. The member pointed out that the current technology is cost efficient, accurate, available, and timely. Further, the member explained that this is the standard of care for the largest kidney paired donation program in the country and matching based on the virtual process has been accurate and efficient with rare discordance between visual and physical cross-matches.

Ethical Evaluation of Multiple Listings, *OPTN Ethics Committee*

- Sentiment: 4 strongly support, 9 support, 6 neutral/abstain, 7 oppose, 3 strongly oppose
- Comments: Some Region 5 members support this white paper and some Region 5 members oppose this white paper.
- A member suggested that there will be significant unnecessary consequences if a candidate cannot be evaluated and listed at more than one center.
- Several members pointed out that there is wider sharing as a result of multiple listing. The member explained the impact is nowhere near the disparity, since waiting time is so high in his area, candidates list at other centers but that removes a candidate from his centers' wait list, as a result. So, there ends up being a benefit for candidates listed on longer wait time list because of multiple listing. The member thought that multiple listing evens the playing field to some extent.
- A member institution supported the paper and analysis; but suggested that the Board of Directors not act on it until after continuous distribution allocation models have been implemented across all organs. The transplant process is incredibly complex and candidates face multiple challenges to simply being approved for listing at a single center, let alone the right center or multiple centers. Proposing solutions such as creating scholarships to cover housing or other expenses, redistributing resources to promote with health literacy, waiving residency criteria, and lobbying insurers to cover additional transplant evaluations these are individually focused solutions that will not necessarily solve the systems problem. While it may seem simplest to put the onus of increasing opportunities for transplant by multiple listing on the individual, we would argue this is actually the responsibility of the community and the system which we create. If the intent of continuous distribution is to, "get the right organ to the right patient at the right time," and cPRA has been included as an attribute for the new lung continuous distribution model composite allocation score (presumably, other organs are following suit), should the committees not seek to define "medically complex patients" and incorporate these attributes into the allocation algorithms? The removal of hard boundaries and prioritizing these hard to match and medically complex candidates can and should eliminate the need for the multiple listing policy.

- A member suggested that the committee consider that the best deceased donor center and the best living donor center might be different centers. We don't want to dis-incentivize candidates from secondary listings at living donor centers (thereby discouraging living donation).
- A member suggested for the committee to consider older patients and areas of high wait time – does the committee consider older candidates in areas with long waiting time in the "exceptionally hard to match" category for multiple listing since the older candidates might not live long enough to be transplanted in their state.
- A member commented that eliminating multiple listing without addressing the large topic of geographic disparities in organ availability is unreasonable. Organ preservation techniques have improved to the extent that distant sharing should be a reality. The member pointed out that there are candidates who reside in states without transplant programs, and those candidates utilize multiple listing in order to get access to transplant.
- A member suggested that the committee provide patient education resource as a part of this white paper – especially a consistent, overarching, educational, national resource from the OPTN. The patients need to know this option and be educated on it.
- A member commented that multiple listing allows patients to have informed decision making by having several evaluations. Several members inquired about how to define the “exceptionally difficult to match” population, and pointed out that this definition could be different based on organ and age.
- A member institution said they support the objective of reducing disparities in access to transplant but feel that the analysis creates more questions and does not address critical components such as how we would set criteria for the “exceptionally difficult to match”. They pointed out that as allocation continues to change making the system more equitable as a whole, there will be a reduction on the impact/advantage of multiple listing for those patients who have the resources.
- A member pointed out that multiple listing should be available to more candidates, regardless of the candidates’ socioeconomic status.
- From a pediatric perspective, a member advised caution when putting restriction on multiple listing. The member inquired about the impact on pediatric patients and the socioeconomic demographics for pediatric alone.
- When inquiring about how to define "exceptionally difficult to match?" a member pointed out that all small children could be considered exceptionally difficult to match based on the percentage of the total donor pool that would be appropriate for them. For liver, in particular, they may benefit from evaluation and listing at centers that are more likely to offer living donor, split liver, or ABOi transplants than their "home center". The member inquired if insurance companies support multiple evaluations – particularly after a patient is already listed at a center. The member expressed concern for candidates with public insurance, especially across state lines, and if they will not have the opportunities for multiple evaluations – which will cause disparities to continue.

National Liver Review Board (NLRB) Guidance for Multivisceral Transplant Candidates, *OPTN Liver and Intestinal Organ Transplantation Committee*

- Sentiment: 9 strongly support, 12 support, 8 neutral/abstain, 1 oppose, 0 strongly oppose
- Comments: Region 5 supports the proposal.
- A member commented that there are probably only two or three multivisceral transplants in this region so this proposal will not greatly impact liver transplant.
- A member commented that it's society will not oppose the proposal due to the compelling evidence that shows how MVT candidates are disadvantaged.
- A member suggested that the committee consider giving MVT candidates a MELD of 40.

Update on Continuous Distribution of Livers and Intestines, *OPTN Liver and Intestinal Organ Transplantation Committee*

- Comments:
- A member commented that there is a need for ample objective data to support each bracket.
- In support of the principle of continuous distribution, a member commented that the process for developing guidelines is critical. The member also suggested that the committee consider forming a focus group for both pediatric and adult candidates in order to develop the metrics and factor that need to be measured and utilized.
- Another member commented that the shift to continuous distribution is a good change. The member inquired how will placement efficiency be determined – will centers that answer donor offers quickly, have fewer reversals, have fewer late turn downs and therefore, be rewarded with more offers?

Continuous Distribution of Kidneys and Pancreata, *OPTN Kidney Transplantation Committee and Pancreatic Transplantation Committee*

- Comments:
- A member commented that in an effort to increase organ availability and encourage donation - the committee should look at living versus deceased donors, and whether consideration has been given for weighting proximity with local OPOs, efficiency, and recovery rates.
- A member expressed concern about kidneys having lower transplant rates in 35-50 year old candidates, increased graft failure rates in older kidney recipients, and decreased transplant rates for black candidates.
- Another member commented that more equitable access to renal transplant across regions is a good benefit. Currently, the patients with sensitization and prior transplant appear to have an advantage over other candidates.

Establish Member System Access, Security Framework, and Incident Management and Reporting Requirements, *OPTN Network Operations Oversight Committee*

- Sentiment: 4 strongly support, 20 support, 4 neutral/abstain, 1 oppose, 0 strongly oppose
- Comments: Region 5 supports the proposal.
- A member commented that PHI is more at risk – that this project is timely and needed.
- A member requested a more robust definition for "Security Framework".
- A member commented that we must ensure the safety of patient data to prevent disruption of organ allocation. However, the member noted that excess complexity to access to the network may decrease safety. In addition, dual factor authentication without frequent password changes is an acceptable method.
- Several members inquired about funding for implementation costs associated with this proposal. And a member suggested that the OPTN absorb the implementation cost.
- In support of the proposal a member institution expressed its support of the concept but noted there need to be more work on the logistics, operations, etc.

Optimizing Usage of Offer Filters, *OPTN Operations & Safety Committee*

- Sentiment: 8 strongly support, 21 support, 0 neutral/abstain, 0 oppose, 0 strongly oppose
- Comments: Region 5 supports the proposal. A member commented that mandatory offer filters will be a big improvement for OPO efficiency in organ placement.
- A member noted her support for the offer filters as long as programs retain the right to opt out/modify the filters at any time.
- As a suggestion, a member said that centers should receive continuous feedback on filter modifications that could help increase allocation of hard to place kidneys.

Identify Priority Shares in Kidney Multi-Organ Allocation, *OPTN Ad Hoc Multi-Organ Transplantation*

- Comments:
- A member commented that there should be uniformity and that OPOs could disadvantage candidates if they are inconsistent. The member suggested to look at the data.
- Another member pointed out that when there is an increase in the size of a particular resource there is a corresponding increase in behavior. The member suggested to look at the modeling to determine the impact on the increase of the availability of these organs. The member also reminds the committee that it is taking the kidney from a single kidney candidate.
- A member commented that providing more guidance to OPOs will decrease variability in practice is an important goal. Pediatric kidney candidates should be prioritized to receive offers of appropriate kidneys prior to multi-organ candidates with lower medical urgency. The member explained that this is particularly applicable to adult kidney-pancreas candidates, who should not be prioritized above pediatric candidates for kidneys, where the kidney would be appropriate for the child. The number of pancreas-kidney adult candidates is small relative to the adult waitlist but is a significant number relative to the pediatric waitlist. There needs to be consideration for prioritizing multiple organ candidates differently based on the candidates' risk of waitlist mortality.

- As a pediatric center, it would be great to see guidelines in place for multi-organ allocation. It would be nice to limit multi organ so both kidneys do not go to multivisceral. The member asked to see multivisceral in the match run so that it could help with planning and save time communicating with the OPO.
- A member pointed out that there are times when the kidneys are released from mandatory share, and then the center is on standby until the organ is placed.
- A member noted her strong support of the creation of allocation priorities in kidney multi organ transplants.
- A member suggested the committee to consider living donor kidney transplantation in the group of candidates. In high-risk candidates, delayed renal transplantation should be considered so that the low KDPI kidneys are not automatically allocated to patients with a high risk death or graft failure.

Expand Required Simultaneous Liver-Kidney Allocation*, OPTN Ad Hoc Multi-Organ Transplantation*

- Sentiment: 7 strongly support, 14 support, 4 neutral/abstain, 2 oppose, 0 strongly oppose
- Comments: Region 5 supports the proposal.
- A member commented that there has been confusion on the differences in nautical miles, and that it should be standardized to eliminate the confusion. The member said that having some patients that are 250 nautical miles for liver and kidney is okay.
- From a pediatric candidate perspective, a member commented that this proposal will adversely impact pediatric kidney candidates, who repeatedly lose offers to multi-organ candidates.
- A member institution expressed its strong support of the proposal to expand required simultaneous liver-kidney allocation from the current limit of 250 nautical miles to 500 nautical miles. It commented that the change better aligns the simultaneous liver-kidney policies with those of other mandatory multi-organ shares and will promote more equal access (nationally) for these transplant candidates. And that it is an appropriate next step as the community moves away from rigid geographical boundaries and towards continuous distribution.
- A member suggested that delayed kidney transplantation needs to be considered more frequently to reduce the excessive kidney graft failure in MOT population.

Updates

OPTN Predictive Analytics

- Comments: Region 5 members were supportive of the Predictive Analytics app.
- A member suggested that using UAs would be a helpful tool for the exceptionally sensitized population, and that seeing DP antibodies would be useful.
- A member explained that it is helpful to view the mortality rate when allocating kidneys and asked for a visual the shows the benefits of a candidate not being on dialysis.
- A member suggested adding recipient cPRA to the analytics.
- Members inquired about future plans for:
    - Highly sensitized population
    - KDPI over 85
    - Pediatrics
    - Other organs, specifically, liver

OPTN Patient Affairs Committee Update

- Comments: Region 5 did not have questions or comments after this update.

OPTN Membership and Professional Standards Committee Update

- Comments: A member applauded the MPSC for their work, and suggested that the Wakefield requirements be clearly communicated if they are going to be used for evaluation.
- It was pointed out that there is a plan for SRTR to remove eligibility reporting from OPO metrics for the July 2023 reports, and that the CMS metrics will be included in those reports.

OPTN Executive Committee Update

- Comments: A member inquired about the status of redefining the geographic regions. UNOS staff explained that there was not consensus, amongst members, in whether nor how to geographically change the regions. Therefore, the Board of Directors decided to re-visit the topic of potentially changing geographic regions in 2025.