

Thank you to everyone who attended the Region 2 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 <u>presentations and materials</u>

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: 6 strongly support, 13 support, 6 neutral/abstain, 0 oppose, 0 strongly oppose
- Comments: This was not discussed during the meeting, but OPTN representatives were able to submit comments with their sentiment. One member noted that the proposal is a valuable opportunity to expand the availability of donor organs. Additionally, it will allow research to better understand the pre- and post-transplant ABO antibody profiles, giving further support to the ABO incompatible transplants in older patients.

Improve Deceased Donor Evaluation for Endemic Diseases

OPTN Ad Hoc Disease Transmission Advisory Committee

- Sentiment: 8 strongly support, 13 support, 1 neutral/abstain, 1 oppose, 1 strongly oppose
- comments: This was not discussed during the meeting, but OPTN representatives were able to submit comments with their sentiment. It was noted that both Chagas and Strongyloides should be required across the board. Limiting to those born in an endemic country and for only six months in an endemic country, leaves a gap for a potential missed diagnosis. Chagas can be passed down from mother to child, so if a child is born in the US, but the parents lived in the endemic country that is a potential missed diagnosis. Getting information from historians is challenging at best and relying on their information regarding travel can lead to a potential missed diagnosis. Another member noted their strong support given that the local community has a fair amount of people who are from nations where Chagas and Strongyloides are endemic, and this proposal will help the community be vigilant in early diagnosis and treatment. Strongyloides within the US is predominantly in the Southeastern states (especially rural Appalachia) so screening all donors would be significantly beneficial for centers in Region 2. One attendee did note opposition to the proposal given the inability to perform Strongyloides at their local OPO, which requires testing kits to be sent out of state for reading.

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

OPTN Kidney Transplantation Committee

- Sentiment: 9 strongly support, 12 support, 2 neutral/abstain, 1 oppose, 0 strongly oppose
- Comments: None



Discussion Agenda

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

- Sentiment: 0 strongly support, 12 support, 3 neutral/abstain, 4 oppose, 6 strongly oppose
- Comments: Members in the region were split on this proposal. There were a few comments in support of the proposal acknowledging that, although it may increase workload, this will address a potential patient safety issue. The number of identified discrepancies is small, but those discrepancies were important to the patients effected by them. The remaining comments were more critical, identifying pain points with the proposal and offering suggestions for the committee to consider. One attendee commented that patient safety is at the forefront of the community, but the percentage of error is extremely low to implement a policy change that will drastically impact Histocompatibility lab operations and be a cost burden to OPOs, Labs, and Transplant Centers. One attendee commented that the OPTN needs to review the data closer to see if most discrepancies are due to reporting high-resolution vs. low-resolution testing. It would be important to break out the data of the errors to better understand whether they are data entry errors, med tech errors, switched samples, etc. Another attendee identified concerns that the proposal does not address instances where donor management timing does not allow for two typings to be completed. One attendee suggested that in these instances where donor typing cannot be performed twice, transplant programs should be required to do a prospective crossmatch. Several attendees noted that by requiring two HLA samples, it will only lead to more discrepancies, and there needs to be direction on how OPOs address those discrepancies. Additionally, if a discrepancy is found, is a third HLA typing required? Others noted that this proposal will increase the amount of time it takes to allocate and transplant organs, which may result in greater organ non-utilization. One attendee suggested that transplant programs should be able to run a preliminary virtual crossmatch based on the first donor typing results in order to not cause a delay while waiting for confirmatory typing. Another attendee commented that many transplant programs are utilizing virtual crossmatches and the committee should consider developing educational best practices for virtual crossmatches. It was also suggested that the proposal needs to address whether labs are supposed to perform the HLA testing on the same testing kit, or should two kits be used. Finally, several attendees noted that instead of implementing this proposal nationally, the committee should consider doing a pilot study with a handful of OPOs to better understand the effects this may have on the organ allocation process. The Regional Councillor did comment that this proposal should be viewed in a similar fashion to the requirement to dual blood typing for donors and candidates awaiting transplant. The Councillor also noted that for shipped national kidneys allocated to the very broadly sensitized that this proposal might decrease unexpected positive cross matches and thus could be beneficial for allocation and preventing non usage of kidneys.



Ethical Evaluation of Multiple Listings

OPTN Ethics Committee

- Sentiment: 2 strongly support, 7 support, 6 neutral/abstain, 8 oppose, 2 strongly oppose
- Comments: Overall, members in the region did not support the Ethics Committee's white paper. A recipient attendee spoke to their experience navigating the transplant system and there were only three programs in the country willing to list them. The attendee added that there needs to be more options for patients in similar situations. Several attendees noted this is a controversial topic, but removing the ability for patients to multiple list would be a detriment to the overall system and would restrict patient's autonomy. Another attendee added that patients with a lower socioeconomic status, have public insurance, or live in underserved areas have less access to multiple listing, but these are problems that require a larger public policy response beyond multiple listing. It was also noted that there is a need for guidelines to define medical complexity, and the impact of multiple listing on propagating social inequities needs to be addressed promptly. Another attendee added that many disparities and barriers are the result of insurance coverage. The community needs to initiate discussions with CMS with respect to candidates with Managed Medicare or Medicaid plans. Access to care is determined by commercial payor rules, which could limit access to multiple listing. The Regional Councillor did ask why this is an area where the OPTN Ethics Committee decided to focus. There does seem to be better areas for this Committee's focus. There is an understandable sympathy for candidates who multiple list even though it might disadvantage other single program listed candidates.

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

- Sentiment: 5 strongly support, 12 support, 7 neutral/abstain, 0 oppose, 0 strongly oppose
- Comments: The proposal was supported by members in the region. One attendee noted that it would be important to review data on the impact to adult candidates receiving the MVT organs and how it compares to different regions where the MVT programs are located. Additionally, it is not a fair comparison to compare MVT candidates to all liver candidates. It is important to understand how adults with high MELD scores will be affected. Another attendee noted that it seems to make sense to add points to MELD scores of older candidates. Typically, those candidates are very sick and would benefit from receiving an organ earlier.

Update on Continuous Distribution of Livers and Intestines

OPTN Liver and Intestinal Organ Transplantation Committee

• Comments: One attendee noted that placement efficiency should be the highest weighted attribute. There has been a large increase in workload and overall efficiencies with liver acuity circles, and continuous distribution is an opportunity to address those issues. Another attendee added that geographical differences across the country have different effects on allocation. This attendee encouraged the OPTN to consider that distance is not the only aspect of placement efficiency being considered by the committee. Transplant hospital density, along with population density, are very important attributes for the committee to consider. Another attendee noted that local organ availability is the most efficient. One attendee suggested that the committee should consider consulting with a geographic sciences expert to analyze overlapping geographic parameters through computer modeling. Lastly, another attendee



stated that the goal of the project should be to maximize the number of successful transplants and the committee should assess the impact of attribute selection on the transplant rate.

Continuous Distribution of Kidneys and Pancreata

OPTN Kidney Transplantation Committee and Pancreatic Transplantation Committee

• Comments: An attendee suggested that having access to test match runs would be a useful tool in helping to determine attribute weights. Being able to see the distribution of potential candidates could help with determining placement efficiency. Another attendee noted that placement efficiency should be of the highest priority. Another attendee stated that in an effort to share organs more broadly and increase equity in allocation, the system has neglected placement efficiency. Donation Service Areas were created as means to allow for quick placement of organs. Without a national transport system the non-utilization rate will only continue to increase. The attendee noted apprehension with moving towards Continuous Distribution without taking the time to address non-utilization and the lack of a national transport system. Lastly, another attendee noted that the OPTN has done a good job with equity and social responsibilities, but there is room for improvement in regard to financial responsibilities. Organ acquisition costs are rising at a rapid rate. Additionally, flying more organs all over the country is not environmentally sound.

Establish Member System Access, Security Framework, and Incident Management and Reporting Requirements

OPTN Network Operations Oversight Committee

- Sentiment: 4 strongly support, 9 support, 3 neutral/abstain, 5 oppose, 3 strongly oppose
- Comments: There was mixed support for the proposal. One attendee noted that data security is important, but the committee should consider users workload when developing additional security measures and training modules. Complicating the ability for users to access the system could impede patient care. Another attendee noted that care providers already spend a lot of time on training modules and would encourage the OPTN to partner with member institutions to utilize existing modules in order to prevent duplication. It was also mentioned that this poses a potential financial burden to member institutions. The proposed measures seem extreme, as there is no way to be 100% secure from infiltration. Lastly, one attendee noted that there needs to be additional information on how this will apply to personal devices and home networks.

Optimizing Usage of Offer Filters

OPTN Operations & Safety Committee

- Sentiment: 6 strongly support, 12 support, 3 neutral/abstain, 3 oppose, 0 strongly oppose
- Comments: Overall, the region supports the proposal, with some noting that offer filters need to be required at all kidney programs. It was also noted that programs should retain the ability to modify their filters. An attendee suggested the need to add more granular filters for the process to be effective. Offer filters need to be expanded before mandating usage by transplant programs. The attendee suggested adding filters for donor/recipient age or EPTS/KDPI parity. Lastly, an attendee suggested that the committee should determine a minimum set of filters that transplant programs must use.



Identify Priority Shares in Kidney Multi-Organ Allocation

OPTN Ad Hoc Multi-Organ Transplantation

Comments: One attendee suggested educating programs that list a candidate for multi-organ, when the second organ is not medically necessary. It is not just a problem for kidney alone candidates, but also for liver alone candidates. Such education efforts may help to reduce the number of unnecessary multi-organ transplants. Additionally, it is important to ensure balance of access based on need of transplant. Another attendee noted that any future limitations on multi-organ transplants need to be organ combination specific. Rule outs for heart/kidney transplants may not be the same for heart/liver transplants. The Regional Councillor added that the community needs to see more data around the kidney after liver safety net as well as how much access to quality kidney transplantation the EPTS candidate population is obtaining. This data is needed so that the community can best identify kidney priority shares. In terms of allocation, an OPO attendee noted that the OPO community would welcome more direction and less flexibility with multi-organ sharing. It is difficult for OPOs to make decisions regarding priority of allocation. Another attendee suggested that when allocating kidneys, one should be allocated to multi-organ candidates and the other kidney should be offered to kidney alone candidates. There is data that shows outcomes are better for single organ recipients compared to multi-organ recipients. Another attendee noted that more needs to be done to show that multi-organ recipients who receive a kidney do satisfy demonstrable medical need for the kidney, and that they receive a kidney commensurate with their age and EPTS score. Lastly, an attendee noted concern with focusing solely on KDPI as criteria to allocate kidneys. KDPI is not really accurate for pediatric donors, so you could be diverting very good kidneys with a >20 KDPI from a child/adolescent because we are applying an adult measure to pediatric donors.

Expand Required Simultaneous Liver-Kidney Allocation

OPTN Ad Hoc Multi-Organ Transplantation

- Sentiment: 3 strongly support, 9 support, 5 neutral/abstain, 2 oppose, 2 strongly oppose
- Comments: Although supported by the region, several members raised concerns about the proposal. Most notably, there was concern that sharing SLKs more broadly will negatively affect kidney alone candidates. There needs to be an assessment on the impact of this proposal to potential kidney alone candidates. Additionally, this proposal should not be implemented until after the safety net for heart/kidney candidates goes into effect. Without a safety net option for both organ combinations, then the two policies will never be aligned. There was additional feedback that this proposal will only delay the allocation process which could lead to an increase in out of sequence allocation. The proposal also has the potential to increase organ non-utilization.



Updates

OPTN Predictive Analytics

Comments: Meeting attendees had several comments about Predictive Analytics. One attendee noted that there needs to be more patient engagement when a program uses Predictive Analytics. The patient should be part of the decision making process. To a patient, minor differences in KPDI are not of much importance, their biggest concern is their quality of life. Predictive Analytics should also include more patient focused models like the risk of staying on dialysis versus the risk of being transplanted with a specific organ being offered. Another attendee noted that the OPTN should consider presenting this information at larger events like ATC and ASTS in order to increase the community's awareness to the tool. Additionally, Predictive Analytics needs to incorporate delisting characteristics into the models. The Regional Councillor added that some of the data used in Predictive Analytics is super robust, whereas other data is less well defined and needs further elaboration. An attendee also agreed that delisting characteristics are important to patients. Multiple OPO attendees suggested that OPOs should be involved in the Predictive Analytics process, as they have a wealth of knowledge in allocation which can help improve the models. It was also suggested that programs should have the ability to use Predictive Analytics to identify the best candidate at their program for a given organ offer. Several attendees noted that they would like to see Predictive Analytics expanded to other organs and not just for kidney offers. Lastly, an attendee noted that the long term goal of Predictive Analytics could help standardize acceptance practices or help identify best practices for transplant hospitals.

Regional Councillor & OPTN Patient Affairs Committee Update

• Comments: An attendee expressed that the patient voice must always matter.

OPTN Membership and Professional Standards Committee Update

• Comments: In regard to transplant programs being monitored for offer acceptance rate ratio, one attendee noted that the models do not predict real world behavior of programs and the models do make some assumption in regard to programs accepting organs. Once this is implemented there will need to be frequent re-evaluation of the models. Another attendee stated that there needs to more emphasis on improving offer acceptance rates. Another attendee noted that as the MPSC looks to revise the OPO performance metrics to center around the CMS metrics, any revisions need to be a collaborative effort with OPOs. Lastly, on the topic of allocations out of sequence, it was noted that the focus of the Allocations Monitoring Subcommittee should be to focus on what is the root cause of the allocations out of sequence and to work towards a solution. The subcommittee should not focus on monitoring data. Another attendee highlighted that out of sequence allocations occur in an effort to utilize more organs, which is a symptom of an inefficient system. The subcommittee needs to focus on improving the system. Another attendee stated that making organ offer filters mandatory will help improve allocation efficiency, which may help alleviate out of sequence allocations.

OPTN Executive Committee Update

Comments: None