

Thank you to everyone who attended the Region 10 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: 5 strongly support, 9 support, 8 neutral/abstain, 0 oppose, 0 strongly oppose
- Comments: None

Improve Deceased Donor Evaluation for Endemic Diseases

OPTN Ad Hoc Disease Transmission Advisory Committee

- Sentiment: 3 strongly support, 16 support, 2 neutral/abstain, 1 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 expressed their support of the project as long as the necessary testing assays are available. Another member stated that while this may marginally improve recipient safety, the risk of losing transplantable organs is expected to significantly increase due to the inherent false positives with any serological testing. The cost of donor workup will continue to rise, and the complexity of organ allocation will further increase with the need to juggle 14 different infectious disease tests with different time and reflex requirements.

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

OPTN Kidney Transplantation Committee

- Sentiment: 1 strongly support, 12 support, 8 neutral/abstain, 1 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 committee is encouraged to review what would be required for re-evaluation.



Discussion Agenda

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

- Sentiment: 4 strongly support, 2 support, 5 neutral/abstain, 9 oppose, 2 strongly oppose
- Comments: Members in the region were mostly opposed to the proposal. One attendee expressed their support as it does not seem overly burdensome and hopefully will encourage growing confidence in the use of virtual crossmatches. However, many attendees noted that the discrepancies identified in the proposal were most likely due to clerical errors and requiring additional typing would not address the issue. Many were in support of the committee developing a guidance document to address best practices in HLA typing but are opposed to a policy change. Without a guarantee that the proposal will reduce the number of discrepancies, it only seems to be more burdensome for laboratory staff and increases costs and allocation time. An attendee suggested more emphasis should be placed on the upstream process, like collection of donor material and labeling. Most HLA discrepancies may have to do with training and interpretation of test results, and not mitigated by performing additional testing. Another attendee noted that obtaining two samples could be problematic for unstable donors when timing is limited. Another attendee added that several labs would not be able to type both specimens concurrently and suggested that the first typing be completed and entered into the OPTN computer system for match run purposes. The lab would then immediately complete the second typing within 2-3 hours. In the event that there was a discrepancy, the local OPO would promptly address the issue. That may be more practical from an operations standpoint. Other attendees noted that when there are discrepancies, typing the donor again using the same method would result in the same discrepancy. In order to better address discrepancies, the proposal should require two separate testing methods.

Ethical Evaluation of Multiple Listings

OPTN Ethics Committee

- Sentiment: 5 strongly support, 8 support, 4 neutral/abstain, 4 oppose, 1 strongly oppose
- Comments: Overall, members in the region were supportive of the white paper. An attendee noted that the white paper addresses another way to improve equity in the transplant system. Another attendee added their support of considering how to minimize the impact of policies that allow for better access to healthcare for some, and by default, restricting access for others. Another attendee stated that the principles explored in the white paper are important. In practice, multiple listing is a tool of the socioeconomically advantaged and health literate, and probably exacerbates disparities in access to transplant. Restricting multiple listing would need to be considered from a patient autonomy and legal point of view it seems like it may be difficult. The paper should provide some clarity on what is defined as "medically complex" if that is going to be the criteria for multiple listing. Another member added that the white paper makes sense since each state's Medicaid will not pay for care in a different state. The fix might be that patients should have access to national insurance. Alternatively, if every transplant program has similar waiting time to transplant, there is less reason for patients to be multiple listed with the exception of difficult to transplant patients (immunologic or anatomic).



However, we should not prevent patients from multiple listing. Single center listing would help programs keep patients, but if patients have access to a center outside the DSA where the wait time is shorter, the patients should have that opportunity. Getting patients transplanted earlier has greater patient benefit rather than waiting longer for a transplant, which may ultimately preclude patients from getting transplant at all due to severity of illness. Another attendee noted that encouraging ways to multiple list for harder to match candidates is sensible, but we cannot ethically stop others who are not hard to match. It is the patient's choice, and education matters. Lastly, another attendee noted their strong support for the white paper, with the caveat that poorly performing OPOs be held accountable, as that is a large part of wait time discrepancies.

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

- Sentiment: 5 strongly support, 6 support, 10 neutral/abstain, 0 oppose, 0 strongly oppose
- Comments: Members in the region were supportive of the proposal. It was noted that this guidance is a good first step and the data needs to be reassessed regularly as to whether MVT patients should have more points. Another attendee noted that Region 10 has the most MVT programs in the nation and were included in the committee's deliberations. The attendee added that although they believe MVT candidates deserve more priority, the proposal is sufficient. The committee should consider placing the MVT candidates at the top of the list, similar to kidney/pancreas allocation because it will be difficult to identify these candidates when they are mixed in with all other liver candidates.

Update on Continuous Distribution of Livers and Intestines

OPTN Liver and Intestinal Organ Transplantation Committee

Comments: Members in the region offered several suggestions for the committee to consider as they continue towards Continuous Distribution. An attendee who was heavily involved in developing Continuous Distribution for Lung suggested that the Liver community should apply future proposed attribute weights to their patient population to see if the new allocation score makes sense. If things seem off base, then the committee will have time to adjust attribute weights before finalizing a proposal. Another attendee noted that moving away from MELD will allow for anatomical differences in the patient population. The committee should add attributes for various binary anatomical differences like portal vein thrombosis, retransplantation, or hepatocellular carcinoma. It may be more difficult to accommodate other attributes that are more complex and not a yes/no answer. Another attendee added, as the community transitions to a continuous distribution system it needs to take into consideration utilization and placement efficiency along with the added cost of organs being transported across the country. In addition, there was a request for more of a financial analysis as costs have gone up substantially because organs are flying more, and local offers are leaving the DSA. Another attendee noted support for utilizing other attributes, especially population density, along with deleting attributes for post-transplant survival. Universally, the OPTN needs to shift allocation policies to find ways to rule organs "in" vs. ruling organs "out". Another member



added the committee needs to remember that transportation is fluid and affected by the time of day, weather, and access to airports. Lastly, an attendee recommended the OPTN provide programs the opportunity to look at their individual lists with currently policy and the new proposed Composite Allocation Score, prior to public comment. That way programs will be able to see how it affects their list before it gets fully implemented. Then additional modeling can be done if there are unintended consequences.

Continuous Distribution of Kidneys and Pancreata

OPTN Kidney Transplantation Committee and Pancreatic Transplantation Committee

 Comments: An attendee recommended that each program should be given an individual report on how their list would look for any proposed Composite Allocation Score before it goes for approval, so if needed, additional modeling could be done. Another attendee added, that although the Committee is getting input from the Pediatrics committee, they would encourage the group to consider the unintended consequences of moving to Continuous Distribution. It appears that the pediatric wait time will decrease based on modeling, but many pediatric centers may be discouraged from accepting organs that travel a greater distance, which may increase the likelihood for delayed graft function. Another attendee noted that the concept of continuous distribution makes sense, but distance should remain a significant factor, to reduce cold time, expedite transport, reduce transportation failures, and reduce organ non-utilization. Allocation scores don't matter if the organ is not transplanted. In regard to Pancreas Continuous Distribution, several attendees noted concern with allocating pancreata more broadly. An attendee noted that when the Pancreas committee was developing Facilitated Pancreas Allocation, data showed that many pancreas programs were unwilling to accept pancreata from long distances and that were recovered from unfamiliar surgeons. The number of pancreas transplants has gone way down across the country. Another attendee added that the concerns with pancreas utilization might be improved by more local priority. This could have a large impact on small programs and likely little impact on large aggressive programs as their access to transplant will likely remain significant as they use organs others may not. Another attended noted that if broader sharing leads to fewer transplants, then it is defeating the purpose. The OPTN needs to ensure that the new allocation system results in more pancreas transplants.

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

OPTN Network Operations Oversight Committee

- Sentiment: 1 strongly support, 17 support, 2 neutral/abstain, 1 oppose, 1 strongly oppose
- Comments: Members in the region were supportive of the proposal. An attendee noted that it
 is important to ensure security of all data and having a multi-stakeholder group is essential.
 However, it is important that it is not too cumbersome to adhere to the recommendations or
 future requirements of the OPTN. Another attendee added that it quite common in the OPO
 world to have these items in place, but the community can always do better. Another attendee



noted their support, but obviously the devil is in the details. Safe personal device use is essential for transplant professionals. Another attendee voiced concern with the amount of work burden placed on institutions to complete this work. A questionnaire of compliance would be reasonable, but to require IT changes will be a real challenge across institutions. The attendee added that most transplant hospitals already have very secure spyware and infrastructure in place. Another attendee added that this is an important goal, but high risk for creating cumbersome barriers to efficient organ offer and acceptance, as well as robust waitlist management processes.

Optimizing Usage of Offer Filters

OPTN Operations & Safety Committee

- Sentiment: 3 strongly support, 13 support, 2 neutral/abstain, 3 oppose, 1 strongly oppose
- Comments: Overall, members of the region were supportive of the proposal but there was some opposition. An attendee noted their full support of all avenues that result in more efficient organ acceptance and placement. The offer filters have been underutilized, and there has to be tough decisions made to use the filters as intended. There also has to be consequences for those who do not use the filters properly. In those instances, the OPTN should have the leeway to adjust a program's filters if the acceptance data does not support the range of filters the transplant program inputs itself. There is too much time wasted in placing organs due to not using the filters in the proper way. Others noted their support in offer filters for adult programs but would oppose mandatory filters for pediatric programs. Pediatric programs should be educated about the offer filters but allow them the choice to turn on offer filters. Others suggested changing the re-evaluation period from three months up to six months. Another attendee noted that they are not in favor of mandatory filters. Instead, they support better scrutiny/oversight of organ offer acceptance, as is occurring, which hopefully will drive use of filters and associated behavior change. Another attendee added before moving to mandatory filters, please consider requirements based on offer acceptance rates. If above a certain threshold, filters would be optional. If below the threshold, mandate certain minimum filters, and if rates are in the lowest percentiles, mandate stronger filters. An attendee requested access for OPOs in the OPTN computer system to see the full list of available filters. Another attendee noted that their program was an early adopter of offer filters, but mandating usage may not be the right direction to go. With the large number of offers programs are receiving, as well as increased scrutiny of organ offer acceptance rates, programs will start using filters organically. For those programs that have moved to third-party vendors to handle organ offers, there is a financial incentive to use offer filters and stop paying for the third-party vendors. Another attendee added that by using filters, it decreases the workload and allows the importing coordinator the opportunity to focus on offers the program is more likely to accept. It also provides an opportunity for OPOs to bypass programs not interested, so that after cross clamp they are able to get to programs willing to accept an organ more quickly.



Identify Priority Shares in Kidney Multi-Organ Allocation

OPTN Ad Hoc Multi-Organ Transplantation

Comments: Several attendees noted that kidney/pancreas transplants should not be considered a multi-organ combination. Kidney/pancreas candidates should be considered kidney candidates who also need a pancreas. Including kidney/pancreas in the multi-organ shares will result in fewer pancreas transplants. Another attendee noted that more data is needed to evaluate the number of times both kidneys from one donor went to multi-organ candidates versus when at least one kidney went to a kidney alone candidate. An attendee noted that, to the degree possible, criteria for multi-organ transplant needs to be standardized and uniform across all multi-organ combinations. The attendee would favor a small subset of kidney-alone candidates that would be allocated first choice of one kidney above multi-organ candidates. Reasonable kidney-alone candidates for such a policy could include prior living donors and kidney candidates without vascular access. There needs to be a policy providing appropriate allocation order among multiorgan candidates, but it needs to be based on acuity or need, not just category of organ. For example, a heart/kidney shouldn't always have priority over a lung/kidney. Another attendee added that highly sensitized, medically urgent, and pediatric kidney-only candidates should receive priority over multi-organ candidates in some situations. Lastly, an attendee implored the committee to ensure representation from all involved stakeholder organizations, including OPOs.

Expand Required Simultaneous Liver-Kidney Allocation

OPTN Ad Hoc Multi-Organ Transplantation

- Sentiment: 2 strongly support, 5 support, 6 neutral/abstain, 5 oppose, 1 strongly oppose
- Comments: Overall, members in the region were split on their sentiment for this proposal. One attendee noted that this is an important step towards making multi-organ allocation criteria similar across all organ types. Conversely, another attendee stated that this proposal will need to be addressed further once more data is available; increasing allocation distance does not necessarily result in more organ transplants. Other attendees expressed concern with sharing SLKs out to 500 nautical miles, noting it results in increased logistical challenges, increased costs, and an increase in organ non-utilization. An attendee suggested that OPTN policy needs to move away from allocation based on nautical miles since there is high geographical variation across the country. Population density would be a better basis for allocation. Another attendee added that allocating SLKs out to 500 nautical miles and still allowing liver programs the ability to accept two livers for the same candidate will lead to more late turndowns and organ nonutilization. Another attendee noted concern that the proposed allocation expansion could result in fewer offers for pediatric, highly sensitized, and medically urgent kidney-only candidates. Perhaps this would be mitigated if the priority shares in kidney multi-organ allocation concept paper is implemented in a manner which addresses this concern. Lastly, an attendee suggested that instead of offering SLKs out to 500 nautical miles to mirror heart-kidney allocation, heart-kidney allocation should be changed to mirror current SLK allocation policy.



Updates

OPTN Predictive Analytics

• Comments: An attendee commented that consideration should be given to smaller programs in terms of Predictive Analytics given their smaller transplant volumes. Another attendee suggested adding Predictive Analytics to the desktop version of DonorNet in addition to DonorNet mobile. Also, there should be consideration given to post-transplant outcome measures such as graft survival for a given organ. The attendee also requested the ability to view Predictive Analytics in a group or list view that would allow programs to compare a patient's Predictive Analytics to others, since they review offers for groups of patients instead of one by one. Another attendee requested clarity regarding if the analytics are performed on candidate registration information or does it change with time because a candidate's CPRA changes regularly. Lastly, another attendee suggested that this project should be rolled out to all organs because it appears to be a useful tool in placement efficiency.

OPTN Patient Affairs Committee & Regional Councillor Updates

• Comments: None

OPTN Membership and Professional Standards Committee Update

Comments: One attendee expressed surprise in the number of kidney programs that have been flagged under the new offer acceptance rate ratio criteria. From the OPO perspective, the number of programs seems low given their experience with organ non-utilization. Another attendee spoke very highly of the OPTN Offer Acceptance Collaborative; it was very well organized and was a wonderful opportunity to share knowledge with programs from across the country. In regard to reporting of patient safety events, another attendee noted concern with two aspects of the process. Some hospitals and OPOs have opted to use third party call centers as their patient safety contact, which makes the process more burdensome. Often times, those third-party entities are not familiar with the patient safety reporting process and communication can be difficult. Their second concern is that after reporting a patient safety incident, there is rarely follow up from the OPTN on the outcome of the event. They would like to see more transparency after an event has been resolved. As the MPSC works to update the OPO performance metrics, an attendee noted that they would be in favor of eliminating the eligible death definition and would encourage the MPSC to work with the OPO community while developing new metrics. Several attendees offered comments and suggestions in regard to the Allocations Monitoring Subcommittee. One attendee noted support in developing criteria where OPOs may place organs out of sequence for traditionally difficult to place organs. This should be transparent to both the OPO as well as to the transplant centers. The MPSC should not be burdened to review all OPOs who do place organs out of sequence. In addition, reviewing programs that consistently decline organs late might be challenging, especially with kidney allocation. Many kidney programs use pump numbers and biopsies prior to accepting or declining organs. Another attendee noted that it is troubling that many OPOs are having to circumvent OPTN Policy in order to place organs. In their experience, most late declines occur in liver allocation due to liver programs being able to accept two organs for the same patient. The logistics to try to find back up candidates is onerous, and the two-acceptance policy should be



reconsidered. In regard to broader sharing and having to make more kidney offers outside of the 250 nautical mile circle, another attendee expressed interest in allowing OPOs the option to make national kidney offers instead of being forced to turn allocation over to the UNOS Organ Center.

OPTN Executive Committee Update

• Comments: An attendee noted that the recently implemented race neutral eGFR wait time modifications policy only allows for wait time modifications for Black or African American candidates due to late referral based on the use of race inclusive eGFR calculations. The OPTN should look to address late referrals and access to transplant across all patient populations. In regard to the Normothermic Regional Perfusion (NRP) Workgroup, an attendee commends the formation of the workgroup, as evidence-based and rational discussions about NRP will help to educate the community of the practice. They suggested that the workgroup add a member from the American Hospital Association or someone similar to bring the donor hospital voice to the discussions. Policy discussions about when OPOs are allowed to approach families about DCD donation, palliative care, and withdrawal of life sustain therapy are very relevant to NRP. Often times those discussions with potential donor families occur too late and thus limits donation.