

Thank you to everyone who attended the Region 4 Winter 2023 meeting. Although we didn't get to meet in person due to the bad weather, we had a great virtual turnout with 268 people in attendance.

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: 4 strongly support, 14 support, 5 neutral/abstain, 0 oppose, 0 strongly oppose
- **Comments**: Region 4 supported this proposal with no comments.

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

- Sentiment: 3 strongly support, 19 support, 1 neutral/abstain, 0 oppose, 1 strongly oppose
- Comments: This was not discussed during the meeting, but OPTN representatives were able to submit comments with their sentiment. The proposal was generally supported by the region. One attendee commented that the proposed required test is not endemic or reported with any frequency in many areas of the country. They went on to comment that this testing may not be readily available in a timely fashion. They added that there is no analysis of the additional cost to OPOs or the impact on donor process delays, and really no cost-benefit. Given the fact that literally thousands of donors are recovered in this country for which this parasite is not a problem, continuing to test for known risk or endemic locations makes infinitely more sense.

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

- Sentiment: 2 strongly support, 19 support, 4 neutral/abstain, 0 oppose, 0 strongly oppose
- **Comments:** Region 4 supported this proposal with no comments.

Discussion Agenda

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

- Sentiment: 2 strongly support, 7 support, 3 neutral/abstain, 6 oppose, 6 strongly oppose
- **Comments:** Region 4 had mixed support for this proposal. Several attendees commented that while the fundamental goal of the proposal is important, the committee has not provided data that this change would correct the small number of cases in which HLA typing issues are reported. Two attendees went on to comment that unless the proposal includes a requirement



for a second, unique, vendor or typing method to be utilized in the confirmatory typing, mistyping due to a reagent issue will likely not be caught. One attendee suggested that it would be more beneficial to use two different vendor kits or two different methods which would not add any cost to the typing. Another attendee commented that a simpler solution may be to require samples be verified by more than one person. One attendee commented that the proposal needed more clarity regarding what would happen when a discrepancy is noted between two typing's. Several attendees were concerned about the cost of the additional testing commenting that there was very little data about increased cost, or if the extra typing would fix the problem. Several attendees expressed concern about the additional time the extra typing would take adding that it would require labs to increase staff and equipment. Two attendees commented that many accepting centers already re-type for kidneys and having the donor lab do confirmatory typing would double the charge. Another attendee suggested that the committee should focus on the 0.3% of typing's that have a critical discrepancy.

Ethical Evaluation of Multiple Listings, OPTN Ethics Committee

- Sentiment: 3 strongly support, 5 support, 8 neutral/abstain, 6 oppose, 3 strongly oppose
- Comments: Region 4 had mixed support for this white paper. Several attendees were not supportive of taking away access for patients to multiple list and did not agree that it would be more equitable. They went on to comment that patients should have the autonomy to make this decision for themselves. One attendee commented that there is no way to equalize center behavior or solve for sociodemographic issues. Another attendee commented that medically complex patients are not the group you want to have travel further if multiply listed. One attendee commented that we should not restrict access for those who multi-list but work on improving access and education for the underserved. Several attendees noted that limiting patient access could lead to lawsuits.

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

- Sentiment: 3 strongly support,12 support, 7 neutral/abstain, 0 oppose, 1 strongly oppose
- Comments: Region 4 generally supported this proposal. One attendee was concerned about
 allocating more high-quality kidneys to multi-visceral candidates ahead of kidney alone
 candidates and commented that this needs to be monitored for patient and graft survival for
 multi-visceral recipients versus kidney alone recipients.

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

• Comments: Two attendees commented that this system is very complicated and adds more complexity to an already complex system. They added that the financial impact of changing the system should be considered and weighed against the benefit. One attendee commented that the community should re-evaluate the time frame placed on the prioritization exercise and development of a new system until the impact of the Acuity Circle system can be evaluated. Another attendee commented that the attributes and weighting will be critical to determine the success of continuous distribution. Another attendee commented that replacing MELD/PELD with OPOM in the continuous distribution without prior evaluation of OPOM as an independent measure of candidate priority would complicate the development of the system. They



recommend independently evaluating OPOM prior to considering it for use in continuous distribution. Another attendee commented that the community needs to exercise a thoughtful approach and balance between developing a comprehensive framework to prioritize patients and also not to create something that is too complex for people to understand or implement.

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

• Comments: One attendee commented that the initial models do not seem to show any benefit to moving to continuous distribution for kidneys. Another attendee commented that continuous distribution should only move forward if there is data to support that it is better than the current system. One attendee commented that under the current distribution model, kidney export and import activity has become extremely costly and moving to an even broader model such as continuous distribution seems imprudent until we understand the impact, cost, and outcomes of the current system.

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

- Sentiment: 3 strongly support, 17 support, 2 neutral/abstain, 2 oppose, 0 strongly oppose
- Comments: Region 4 generally supported this proposal. One attendee commented that adding additional training requirements without evidence that user activity is increasing network vulnerability seems to be an overreach. They added that there needs to be evidence for network vulnerabilities and suggested corrections rather than adding more barriers to accessing the system. Another attendee recommended interfacing with members' IT teams. One attendee commented that all members should strive for excellent data and system security, not only for the national database, but for their own systems and patients.

Optimizing Usage of Offer Filters, OPTN Operations & Safety Committee

- Sentiment: 5 strongly support, 11 support, 4 neutral/abstain, 3 oppose, 1 strongly oppose
- Comments: Region 4 generally supported this proposal. Several attendees supported default filters but had concerns about moving to mandatory filters. One attendee commented that programs should proactively manage their acceptance patterns and filters. They added that automatically applying default offer filters for kidney transplant programs based on their previous acceptance puts undue burden on transplant programs to have to go and make sure the filters are correct every 3 months. They recommended that alternatively, data should be provided to help programs choose their own filters. One attendee recommended that patients should have the ability to update preferences and communicate to their programs what type of kidney they are willing to accept. Another attendee commented that centers should be required to report to patients what filters are in place and if they change. They added that the re-evaluation window should be no more than 90 days. Another attendee commented that they did not think adding filters helps with transparency and could be confusing to patients. Another attendee commented that programs are not being good stewards of the freedom their allowed under the current system. They added that programs often list with the broadest criteria, but never accept organs within those criteria and OPOs can't get kidneys to the centers who will transplant them. One attendee commented that the committee should look at the possibility of developing centralized labs and pair them with donor procurement centers to allow calls to centers knowing which recipients cross match negative and allowing the center to accept or



decline. Another attendee recommended the committee take into consideration the expanding use of NRP and extended warm ischemic times under current definitions.

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

Comments: Several attendees were supportive of the work of the Multi-Organ Transplant committee and commented that one kidney should go to a kidney-alone candidate and the other kidney to a multi-organ recipient. They went on to comment that we need to prioritize offers to multi-organ candidates based on medical urgency. One recommendation was to establish a scoring system that put all multi-organ transplants on a single list, adding that this may help OPOs and allow more low KDPI kidneys to be allocated to the kidney-alone list. Two attendees supported giving priority to kidney/pancreas candidates to improve the utilization of pancreata. Several attendees supported giving priority to pediatric candidates ahead of multiorgan transplants. One attendee added that data shows that pediatric transplant rates vary based on how close pediatric kidney candidates are to multi-organ transplant centers. They went on to comment that the increase in multi-organ transplant allocation disadvantages children and kidney alone candidates. One attendee was concerned about limiting options for Heart/Kidney candidates as these candidates don't have great options without a kidney. They went on recommend getting more data about outcomes for these recipients before proceeding. There was also a request for data showing: The relationship between KDPI and multi-organ transplant patients and graft survival, the volume and timing of offers for multi-organ transplants stratified by KDPI, waiting times for SLKs vs. pediatric and other renal recipient groups, patient and graft survival for multi-organ transplant vs. kidney alone (peds, prior living donors, etc.) recipients, multi-organ transplant patient survival on the list vs. post-transplant. They went on to comment that we may have reduced death on the waiting list but increased post-transplant mortality.

Expand Required Simultaneous Liver-Kidney Allocation, *OPTN Ad Hoc Multi-organ transplantation*

- Sentiment: 2 strongly support, 12 support, 6 neutral/abstain, 2 oppose, 0 strongly oppose
- Comments: Region 4 generally supported the proposal. Several attendees supported
 consistency with other multi-organ allocation systems but were concerned that increasing the
 number of kidneys going to multi-organ transplants was disadvantaging pediatric and kidney
 alone candidates. One attendee was concerned about the utility of low KDPI kidneys going to
 high EPTS candidates.

Updates

OPTN Predictive Analytics

Comments: During the discussion, one attendee recommended bringing this tool to DonorNet
desktop, noting that it is currently only on Mobile. Another attendee commented that the time
to next offer feels too fast and they would like the group to explore different ways to stratify
time to next offer rather than just KDPI – more risk aware criteria, likely modeling against offers



with reasonable cold ischemic time. Several attendees noted concerns that the tool could be used as a metric for evaluating how programs are accepting kidneys.

OPTN Patient Affairs Committee Update

• Comments: No comments.

OPTN Membership and Professional Standards Committee Update

• **Comments:** During the discussion one attendee commented that offers should go to local patients if they are allocated out of sequence.

OPTN Executive Committee Update

• Comments: During the discussion, one attendee commented that prior to moving forward with continuous distribution, there should be data to support that continuous distribution will be better than the current system. Another attendee was supportive of the MPSC sharing lessons learned with the community. One attendee expressed concerns that the liver continuous distribution values exercise did not include outcomes and commented that from the patient's point of view, outcomes are as important as wait list deaths.