OPTN

Thank you to everyone who attended the Region 8 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: 3 strongly support, 9 support, 8 neutral/abstain, 0 oppose, 0 strongly oppose
- Comments: Region 8 supports this proposal and an attendee recommend the committee add tracking non-utilization of lungs to the post-implementation monitoring. Another attendee commented that this proposal makes perfect sense.

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

- Sentiment: 2 strongly support, 13 support, 2 neutral/abstain, 2 oppose, 3 strongly oppose
- Comments: The majority of Region 8 members support this proposal with some members in opposition. During the discussion, an attendee commented on his support of safe transplants, he believes the addition of strongyloides and T. cruzi is not advantageous nationally applied. It is not endemic in all regions. The proposed requirement to screen the entire donor population adds additional burden that is not appropriate in regions without significant prevalence. In addition, the laboratory burden is prohibitive to sweeping requirements. There is no FDA approved assay for strongyloides. There is no standard approved assay for the confirmatory testing for T. cruzi. Its' institution does not have the equipment available for testing and would have to incur additional costs. It would have to assess staffing capacity to determine the need for additional staff, to perform the additional testing. And this will likely increase donor screening turn-around times and will increase donor screening costs. Another attendee expressed concern about national testing availability and increases turn-around time for testing. An attendee pointed out that it will be important to ensure adequate ID consultation and/or education, at the time of organ offer, to be sure that organs are not turned down even when prophylactic treatment for these diseases is available. An attendee thought it would be helpful for the committee to provide guidance on the testing. An attendee pointed out that the incidence is so small that they don't see the need to test every donor.

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

- Sentiment: 2 strongly support, 12 support, 5 neutral/abstain, 2 oppose, 0 strongly oppose
- Comments: Region 8 mostly supports this proposal, but some members were in opposition. An attendee said that its' institution supports the alignment of blood type matching and annual re-evaluation (the latter in concept). And recommends the committee consider reducing the burden of re-evaluation on both potential donors and transplant centers by performing virtual re-evaluation, rather than in-person. It also recommends deferring any ID testing that is unlikely to change.

Discussion Agenda

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

- Sentiment: 0 strongly support, 1 support, 2 neutral/abstain, 8 oppose, 12 strongly oppose
- Comments: The majority of Region 8 members opposed this proposal. During the discussion, an attendee explained the proposal must mandate the use of the two different tests, otherwise the discrepancy will not be eliminated. Another attendee believes the proposal will put a strain on staff and needs more information for justification. Some labs won't have two different test methods, which will be a burden for labs. Members indicated that this proposal could slow down allocation for some donor cases, which could increase organ non-use. A member suggested to update UNET HLA reporting needs before addressing discrepant typing issues, otherwise the data could be incorrect. An attendee said the proposal should be opposed from the clinical side. The member pointed out the risk is 0.3% for potential errors. The final cross-match is the safety net for preventing hyperacute rejection, and this proposal is unhelpful because it does not provide better methodology than cross-match. Several attendees said this proposal would further increase the associated costs with HLA lab personnel and sample supplies. Several members suggested to establish and require API for the elimination of manual entry interpretation errors. An attendee said the data doesn't support the proposal and that centers are doing confirmatory typing when the organ/blood sample reaches the center. An attendee pointed out that it seemed, from the discussions, that this project is still in development, and there are too many concerns to move forward, as proposed, at this time. An attendee had concern that manual entry would be a problem and that it would put further strain on an already strained system. The member believes this may lead to more errors in general. However, from a patient point of view, patients may feel more comfortable with confirmatory typing, and would have more trust in the system. But, at the same time, the member thinks for the greater good of the patient and donor families, they would understand the limitations of this type of testing.

Ethical Evaluation of Multiple Listings, *OPTN Ethics Committee*

- Sentiment: 0 strongly support, 9 support, 5 neutral/abstain, 5 oppose, 2 strongly oppose
  Comments: Region 8 mostly supports this proposal, but some members were in opposition. An attendee pointed out that multiple listing is an important topic to consider and multiple listing can be effective for difficult to match candidates. An attendee inquired about the implications of continuous distribution on multiple listing. An attendee commented that the white paper doesn't address how the need for multiple listing will be affected by implementation of continuous distribution which also intends to address difficult to match candidates. Discussion suggested that both continuous distribution and multiple listing seem to have the same objective of equitable matching. Attendees suggested to wait and see how continuous distribution implementation impacts multiple listing before making change to the multiple listing policy. An attendee pointed out that two thirds of all double listed liver patients in the U.S. are due to a centers' practice of double listing all patients at two programs. The member said this has to be taken into account in the data analysis.

  An attendee explained that he was troubled by the fact that candidates have the ability to multiple list – he thinks that multiple listing shows disparity in means, access, information, etc. And this needs to be handled on a national level because transplant programs will always operate in silos. An attendee cautioned that the data in the paper is from peak pandemic and should be cautiously interpreted.

  An attendee pointed out that travelling will still exist even if multiple listing doesn't – and candidates with financial means can and will travel to areas where there are lower waiting times. Regarding equity in listing versus access to listing – there is no part in paper showing how many candidates are multiple listed. Several attendees pointed out that the paper limits candidate access where the candidate has parents in multiple locations. The paper also limits people who seasonally live in different locations. The member said there will still be limits in populations who need to be able to list across different locations. For medically sick patients, they get better care with more access. Several attendees said the option to multiple list should be available to all candidates, irrespective of whether or not they can do it. Several members said the transplant centers' goal should be helping candidates get transplanted at the earliest point possible, even if it is not at their center.

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

- Sentiment: 1 strongly support, 8 support, 8 neutral/abstain, 4 oppose, 0 strongly oppose
- Comments: Region 8 mostly supports this proposal, but some members were in opposition. An attendee expressed concern for wasting resources in light of poor outcomes on multivisceral transplant (MVT) recipients. Another member questioned if this proposal will have a benefit. An attendee recommended the committee include guidance to ensure there is sufficient information, regarding why the kidney is needed, in the MVT. She also pointed out the NLRB needs to have access to renal expertise when evaluating exception requests for MVT, when a kidney will be involved in the MVT. An attendee requested as much guidance as possible in

order to eliminate miscommunication or differences of opinion, regarding how to proceed, between the OPO and the transplant center.

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

- Comments: An attendee indicated that she agrees with equity, but there is an absurd implementation cost for this project. An attendee asked how it should account for the knowledge gap between coordinators and candidates and requested the committee provide structured language to help the coordinators in communication with candidates. An attendee inquired about how points will be given to pediatric candidates. An attendees' institution indicated that it was surprised that C-statistics in the 0.6 range were used to exclude post-transplant models. The member said that the SRTR report, used in the development of lung continuous distribution, indicates the C-statistics from the 5-year survival models were below 0.6. An attendee said that he supports moving beyond mileage as the only consideration after MELD.

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

- Comments: Region 8 appreciates the update and supports how this project is developing. An attendee said that she supports reviewing the various models available. Another attendee commented that this is very meaningful work but the committee needs to keep in mind that continuous distribution is rationing an already limited resource. A member requested an exercise that determines which of the factors are weighted by most of the community, both by the allocation exercises in OASIM and also explicit (competing risk) surveys. An attendee pointed out that some aspects of the model impact candidates >98%; these candidates should be at the top of the list. An attendee inquired whether urgency is going to be a static assignment for every candidate, or if urgency is going to be variable, and whether a candidate can be more urgent.

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

- Sentiment: 1 strongly support, 5 support, 2 neutral/abstain, 8 oppose, 4 strongly oppose
- Comments: Region 8 mostly opposes this proposal, with some in support. An attendee said this is a valid concept but premature in process. The attendee suggested the committee move in incremental steps – the first step being that every member designates an IT contact. Several attendees commented on the need for more clarity about accessing UNet from personal devices. There was concern about how aggressive implementation of security controls may affect members' ability to field offers from outside the hospital while using personal devices. There was discussion that there could be too many unintended consequences and that the policy shouldn't be implemented until there is a complete understanding amongst all members.

Several members said that the proposed policy is an over-reach and that this is too much all at once, but support the notion of heightened security. Another member explained that its' IT department believe this proposal is an overreach. That they would expect these types of requirements from a risk management consultant, but not a clinical partner. An attendee explained that the proposed requirements are not unreasonable and are likely in place at most institutions, but feels it is unreasonable for the OPTN to audit members security. An attendee cited a concern for small OPOs and the associated implementation expense.

In addition to the financial costs that a member will incur, an attendee pointed out that most institutions already have internal security measures in place. Several members pointed out the financial burden this proposal will cause and questioned whether that cost is worth the benefit when security measures already exist – even when those members support having secure IT systems. An attendee expressed concern that this proposal may impede members' ability to do their jobs. The member pointed out that they need to be able to access donor information in an efficient, yet safe, manner.

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

- Sentiment: 4 strongly support, 15 support, 0 neutral/abstain, 0 oppose, 1 strongly oppose
- Comments: Region 8 supports this proposal. An attendee said that his kidney program uses the filters and has had positive results. He expressed concern that this proposal, as written, is not clear on whether programs will have notification when filters reapply. He suggested that programs should be told what the suggested filters are, before they're implemented so they can be involved in the decision of whether to apply them or not. Regarding timeline for review, he suggested somewhere between a week and a month. And he emphasized that programs need to have the right of refusal. An attendee questioned whether a program could feasibly manage a 90 day re-set; and noted that human behavior doesn't change that fast. An attendee pointed out that depending on the system, there is a possibility for human error to limit the organs available to recipients. The member believes programs should have the ability to determine the filters for its program. From the OPO perspective, this proposal will increase allocation efficiency. An attendee suggested that the committee consider periodic re-evaluation or reset to ensure the filters are not impairing change in acceptance criteria. An attendee explained that centers who manage their filters well and have strong offer acceptance outcomes should not be penalized in terms of maintenance mandates. An attendee suggested that it might be useful to offer more granular filters in order to accurately identify which donors a candidates might accept.

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

- Comments: An attendee commented it would be unethical, from a utilitarian perspective, to transplant a kidney with another organ, other than a pancreas. He supports the idea to adjust with EPTS depending on which organ the kidney is allocated with. He suggested that kidney extra renal could be transplanted based on the kidney match run, and that the kidney should allocated by the list, regardless of the multi-organ transplant (MOT). Attendees pointed out the

local programs tend to get preference on the choice of kidney, which doesn't seem equitable. And both kidneys should not be allocated to the MOT unless the kidneys were not allocated on the kidney list. An attendee commented that if a kidney-alone and heart-alone have already been allocated, OPOs won't offer the primary to the kidney program because an MOT candidate is behind the heart-alone candidate. Attendees requested a policy to determine when the kidney-alone can be placed primary on the kidney list.

In support of the project, an attendee commented that the proposal incorporating kidney allocation in MOT with kidney-alone is an optimal path forward (utilizing composite allocation score). An attendee suggested that eligibility for a kidney should be based on need for a kidney, regardless of whether there is another organ. The member further suggested that the committee develop a composite score that gives some priority for MOT candidates, but also weighs other factors of MOT and kidney-alone candidates (dialysis time, kidney disease severity, CPRA, etc.). An attendee commented the focus should be on getting organs transplanted and pointed out the non-used organ numbers. An attendee pointed out that candidates with high CPRAs or who are very sick should be preferentially given a kidney along with the other needed organ. There was a suggestion that candidates should be evaluated on a need basis. An attendee said this project addresses a challenge of bias in favor of MOT recipients and against kidney-alone candidates. Attendees suggested that consistency is important and there needs to be clear guidance to support transplant professionals. A member pointed out there is a perception that the best kidneys are "lost" to MOT candidates.

From a pediatric candidate perspective, an attendee commented that it is still difficult when a MOT takes a kidney over a candidate who is first on the kidney-alone wait list. The member suggested that the choice of kidney also need to be identified. If a program can only use one kidney, where both are available and the program has to share the other kidney with a MOT candidate, then the program should have the ability to identify which kidney it wants to use.

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

- Sentiment: 0 strongly support, 7 support, 7 neutral/abstain, 4 oppose, 1 strongly oppose
- Comments: The majority of Region 8 members support this proposal but there was some opposition. An attendee commented that it is highly likely there will only be a small increase in MOTs, but each kidney in the MOT is an optimal kidney that would otherwise been allocated to a kidney-alone candidate. The member said that this is not an unintended consequence, it's a known one. An attendee suggested to readjust heart down to 250 Nautical Miles (NM) to account for MOT rather than offering the SLK to eligible candidates beyond the 250 NM. Another member commented that the expansion of SLK to 500 NM makes the allocation process more complex which means the allocation process take significantly more time. The member suggested to put limits on the number down the list, to make all multi-organ allocation less confusing and more efficient. In support of utilizing more kidneys with livers, an attendee also pointed out that this should not take away from dual organ heart/kidney candidates, since those

candidates are very sick as well. The member did not support decreasing the heart/kidney allocation to 250 NM. An attendee slightly favored the 250 NM limit for all, as opposed to the 500 NM, but believes that consistent alignment seems reasonable. An attendee explained that at first it makes sense to align SLK sharing policy with other MOT policies – but said its institution is concerned there will be a negative effect for kidney-alone candidates, including pediatric kidney-alone candidates. Another attendee said this proposed policy will delay organ offers and increase organ ischemic time. Currently, its institution is already receiving SLK offers after cross-clamp. An OPO member requested as much clear guidance and information as possible for when and where a kidney should be allocated with another organ.

Updates

OPTN Predictive Analytics

- Comments: Attendees discussed how to assess the impact of different pieces of allocation in isolation, if it was possible to track the usage of predictive analytics tool, and the timeline for other organs.

OPTN Patient Affairs Committee Update

- Comments: No comments.

OPTN Membership and Professional Standards Committee Update

- Comments: An attendee suggested to create a list of criteria to initiate an expedited pathway for when OPO staff have to allocate out of sequence. An attendee suggested the following criteria for expedited pathway: creatinine over 2 or 3 at cross-clamp, or BMI (because OPOs know those organs will not remain local). An attendee suggested to leverage the collaborative structure between OPO and transplant center, with surrounding transplant centers, in order to improve outcomes. An attendee suggested to create continuous quality improvement networks on a “regional” or local basis in order to instill continuous improvement practices.

OPTN Executive Committee Update

- Comments: An attendee inquired about offer filters for other organs. Staff explained there will be offer filters for other organs but there is no timeline for it now.