OPTN

Thank you to everyone who attended the Region 1 Summer 2024 meeting. Your participation is critical to the OPTN policy development process.

Regional meeting presentations and materials

Public comment closes September 24th! Submit your comments

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

Revise Conditions for Access to the OPTN Computer System

Network Operations Oversight Committee

Sentiment: 1 strongly support, 3 support, 4 neutral/abstain, 2 oppose, 0 strongly oppose
Comments: Overall, the region supports the proposal. A member noted that ISAs would need to be executed between centers and business members. An attendee requested information and guidance for hospital information securities teams to complete the questionnaires and understand the requirements, especially those newer to supporting the transplant and HLA programs. One attendee agreed with the suggestion to increase the categories of people allowed to access the data and to make their access contingent on their role.

Promote Efficiency of Lung Donor Testing

Lung Transplantation Committee

Sentiment: 1 strongly support, 5 support, 4 neutral/abstain, 0 oppose, 0 strongly oppose
Comments: Overall, the region supports the proposal. One attendee advised against the committee basing the fungal blood culture policies on older technologies when new ones exist. An attendee asked if the committee had considered different ABG settings when a donor is DCD versus DBD, as it is harder to change ventilator settings for DCD donors. A member requested the committee consider the testing requirements when EVLP is used because some of the tests might not be able to be done in an EVLP scenario. Another attendee commented that with donor hospital staffing issues, testing results could quite often fall outside the 4 hour timeframe. They continued to say they worry about how closely this would be audited as it's less a measure of OPO willingness to have timely results, and more a reflection of donor hospital staffing issues. A comment was made supporting the proposal but requesting that some flexibility be incorporated into the policy to account for issues, as mentioned above, that are out of the OPOs control. They expressed this should be a balance between providing needed information and not inhibiting OPOs from allocating lungs when required testing is not available. Lastly, they suggested adding a requirement in policy that programs review all donor information before requesting additional testing. Additionally, an attendee asked that there be a requirement that another member wondered if there would be any consequences if the testing requirements weren't met and recommended the committee consider adding some enforcement language. An attendee questioned whether this proposal has the potential to disproportionately disadvantage smaller hospitals who may not have the resources to complete this testing.

Require Reporting of HLA Critical Discrepancies and Crossmatching Event to the OPTN

Histocompatibility Committee

Sentiment: 3 strongly support, 6 support, 1 neutral/abstain, 0 oppose, 0 strongly oppose
Comments: Overall, the region supports the proposal. A member commented that they were in favor of the proposal overall but wondered if the 24 hour timeframe might be a little too short. An attendee suggested that the committee consider recommending that OPOs designate someone to receive these reports, to help streamline communication. An attendee requested that the committee clarify that the policy is referring to using the wrong patient's antibody information, not using an older sample versus a newer one. A member commented that the 24 hour timeframe is ample and expressed uncertainty as to why split antigens are excluded if they are immunologically significant. Another attendee stated that patient safety is paramount and there should be no delays in reporting potentially dangerous events. The attendee recommended having one reporting mechanism for all parties to receive this information, to reduce burden.

Update Histocompatibility Bylaws

Histocompatibility Committee

Sentiment: 2 strongly support, 5 support, 3 neutral/abstain, 0 oppose, 0 strongly oppose
Comments: Overall, the region supports the proposal. Two attendees commented that aligning requirements with CLIA makes sense.

Continuous Distribution Updates

Continuous Distribution of Hearts Update, Summer 2024

Heart Transplantation Committee

Comments: A comment was submitted supporting the results of the Values Prioritization Exercise (VPE) and the work of the committee. Another online comment requested the committee consider a higher level of priority on proximity efficiency than what came out of the VPE. They also believe that post-transplant survival should factor into heart continuous distribution, as it is an important part of utility. The commented also noted that thoracic NRP may have an impact on survival and allow hearts to be allocated to more distant candidates.

During the meeting, attendees participated in group discussions and provided the following feedback:

- Regarding proximity efficiency, traveling further distances and new preservation technology result in higher and higher costs for programs, which can impact access and equity. Some programs are not able to keep up with these costs, which could jeopardize the survival of small programs.
- The group had several heart patients participating in the discussion, and they appreciated having the patient perspective.

Continuous Distribution of Kidneys Update, Summer 2024

Kidney Transplantation Committee

Comments: A comment was submitted stating that kidney allocation should be based on best use and efficiency, since kidney transplants are not as life-saving as heart or liver transplants. The commenter supports exhausting the list of patients who are "local" before considering any patients at further distances. They added that the single largest barrier to kidney allocation is programs who express interest in a kidney, only to turn it down after cross-clamp and that this must be addressed. Another comment suggested looking at kidney offer filters to help define "hard to place". A virtual attendee stated that programs differ in their tolerance to cold ischemic time limits, so using that alone to define a "hard to place" kidney would not be useful. The attendee also does not believe there are specific anatomy characteristics that should be included in a "hard to place" definition.

During the meeting, attendees participated in group discussions and provided the following feedback:

- Cold ischemic time (CIT) should be major factor in defining hard to place kidneys. Attendees commented that their OPO allocates kidneys 12-24 hours pre-recovery, so if these were "easy to place" they should be accepted right after recovery.
- A member suggested that if programs thoroughly review the offers, there might not be a need for expedited or rescue pathways. Creatinine, age of donor are examples of things to be evaluated related to offers.
- An attendee remarked that many times their program doesn't hear about kidney until 12-15 hours post-procurement. CIT is a major consideration but not the only one – they would also consider factors like KDPI and location of donor. For example, if there is a high KDPI kidney in New York and the program is notified it at 12 hours, they may not take it. Other important factors to consider would be biopsy, pump pressure, and anatomy.
- The group felt that determining allocation thresholds for defining "hard to place" is difficult. They remarked that it would be helpful to see the data within each KDPI group to see how far it goes. They said that once a kidney starts getting turned down, it develops a reputation based more on assumptions than actual organ quality, so attendees felt initially that "hard to place" should be stringently defined.

Continuous Distribution of Livers and Intestines Update, Summer 2024

Liver and Intestinal Organ Transplantation Committee

Comments: A virtual attendee commented that regarding the decision to drive versus fly, their program uses ground transportation up to 2-3 hours, anything more than that would be a helicopter or airplane. The attendee also supports fulminant hepatic failure being prioritized over all other medical urgency states. Another comment suggested looking at offer filters data to help identify "hard to place" livers.

During the meeting, attendees participated in group discussions and provided the following feedback:

- Defining when programs decide to fly versus drive is difficult – it's a nebulous number, dependent on program, whether the liver is being pumped, etc., so group could not settle on an answer.
- There was significant concern that the increased prevalence of machine perfusion, any efficiency metrics established for liver continuous distribution may be out of date by implementation.
- Regarding medically complex liver offers, attendees suggested adding large livers. They also again stated that with perfusion and pumping, these definitions may not be applicable in the future.
- Participants commented that if you're getting down to sequence 200 on the match, pre-recovery, that might be around the point when expedited placement should be considered.
- The group expressed support for making it easier for conversations between local OPOs and programs for decision-making and expedited placement

Continuous Distribution of Pancreata Update, Summer 2024
Pancreas Transplantation Committee

Comments: One attendee commented that part of the reason their program no longer does pancreas transplants was because their pancreas surgeon felt that oftentimes, how the liver was recovered resulted in damage the pancreas anatomy, so it is highly important to consider issues related to pancreas recovery. Another member said that only efficiency and patient matching should be considered for pancreas continuous distribution, and that the only time a pancreas is transported should be if the list of local candidates is exhausted.

During the meeting, attendees participated in group discussions and provided the following feedback:

- The group agreed there's need for improved training and dedicated pancreas directors, but ultimately questioned whether it should be a goal to increase the number of pancreas transplants.

Updates

Councillor Update
- Comments: No comments.

OPTN Patient Affairs Committee Update
- Comments: No comments

OPTN Executive Committee Update
- Comments: A member asked about how out of sequence allocation is defined, and the response was that it is multi-layered. The MPSC reviewed instances of out of sequence allocation and found that it mostly applied to kidneys late in allocation, with cold ischemic time rising, and the

OPO decides they need to do something to ensure the kidney is placed, rather than a scenario where the OPO immediately decides to allocate out of sequence before even trying to go down the match run. An attendee noted that while these instances were cases where the OPO was trying to avoid non-utilization, it still results in allocation that does not reflect the priorities that the community has already agreed upon. A member noted that the need for a corporate structure for the OPTN is about more than just needing to be able to purchase insurance – it also means there will be well defined legal duties that are relevant, like duty of care and duty of loyalty. The member also stated that there is a fundamental misalignment with the new OPO metrics and that the OPTN needs to consider the potential disruption to the system that could be caused by large numbers of OPOs being decertified by CMS. An attendee suggested that the OPTN Computer System could be improved with the addition of more discrete data fields. For example, for a TA-NRP heart, the cross clamp time that is listed is for the abdominal organs. There was discussion on the variety of initiatives being considered to improve organ utilization, such as rescue pathways or modifying outcomes metrics for programs participating in the PDSAs being proposed by the Expeditious Task Force.

Update from the Expeditious Task Force

- Comments: An attendee expressed appreciation for Task Force's deeper dive into understanding late declines, as the reasons behind them can be complex. There was discussion of the CMS IOTA initiative and how the metrics of success for transplant programs and OPOs are not aligned. A member thanked the Task Force for its efforts, but remarked that there isn't enough representation from donor hospitals. They also hoped for more representation from different members in Region 1 and more opportunities for engagement rather than twice a year. An attendee requested that business members also be engaged with the work of the Task Force.

HRSA Update

- Comments: An attendee stated that a number of leaders across the country, including many in Region 1, had signed a letter expressing concern about perceived censorship of OPTN volunteers at the American Transplant Congress this past June. The attendee wondered if there were any plans to handle the potential disruption of the transplant system if many OPOs are decertified due to the new CMS OPO metrics. The presenter responded that censorship was a strong characterization, as HRSA has not restricted any access to data to do analysis, it was more related to contracting and resources. Regarding the new OPO metrics, the presenter shared that the Organ Transplant Affinity Group continues to review and discuss these issues, and while HRSA is involved in these discussions, they ultimately will be lead by CMS. There was discussion clarifying that HRSA will be responsible for awarding the final contracts for any OPTN work, but that HRSA is engaged with the community and OPTN leadership to get feedback to help inform their decisions.