

Thank you to everyone who attended the Region 5 Summer 2024 meeting. Your participation is critical to the OPTN policy development process.

Regional meeting <u>presentations and materials</u>

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: 3 strongly support, 21 support, 2 neutral/abstain, 0 oppose, 0 strongly oppose

• Comments: Region 5 supported the business membership requirement, and they emphasized that there needs to be individual training as well as organization training available. A member suggested that access to data for research should be considered whenever changes are made. Another member commented there needs to be more details about the process for "developing an ISA" with OPTN. They were supportive of increasing security associated with third party vendors however they don't want the process to make it more difficult to maintain existing agreements. Current institutional agreements with these vendors already include sections regarding IT security. They said it was challenging to complete a data use agreement due to institutional requirements for HECVAT survey.

Promote Efficiency of Lung Donor Testing

Lung Transplantation Committee

Sentiment: 3 strongly support, 10 support, 12 neutral/abstain, 0 oppose, 0 strongly oppose

• Comments: Region 5 supports this proposal but suggests obtaining more OPO perspective feedback, evaluation, and input on operational feasibility. Specifically, an attendee commented that it would be helpful to assess the additional work this might impose on the OPO and the timing consequences. A member commented that "recruitment maneuver" is too broad and needs a more specific definition. Another member explained they rely on the hospital availability for draws, so timing may be out of the OPO's control. They also agreed with adding "if performed" for echocardiograms or catheterizations. Regarding the more frequently challenging cases, a member commented there's a concern for donor stability (hemodynamic stability). An organization said that the lung donor testing must be more consistent and protocolized. They explained OPOs tend to operate under their own protocols such as only getting at CT chest if requested or obtaining ABGs every 8 hours versus every 6 hours, etc.

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

Histocompatibility Committee

Sentiment: 2 strongly support, 19 support, 4 neutral/abstain, 0 oppose, 0 strongly oppose

• **Comments:** Some attendees thought the 24 hours from discovery seemed like an appropriate time frame for reporting the discrepancy. But many other attendees thought the 24 hours was

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too short and suggested 48 to 72-hour timeframe. A member explained that when a critical discrepancy is identified, the lab will often perform an internal investigation and may repeat testing to ensure reproducibility. In order to allow time to do this, especially when a lab may be understaffed (for example, on the weekends), a 48 to 72-hour timeframe is more feasible.

- A member said that currently, the critical discrepancies only count HLA-A, B DR in TIEDI. They
 asked the committee to clarify if the proposed critical discrepancies include other loci, such as
 DP and DQ.
- A member explained their lab already has policies in place to report any discrepancies to transplant programs immediately after they are found. They thought it was unclear how the committee plans to utilize the data and why they need it and asked for clarity on the data's purpose. They said their lab enters HLA typing Tiedi after transplant; including high resolution typing for import donors (which is where they sometimes find discrepancies with the originating lab). They said they would benefit from making the data entry process easier by allowing for high resolution typing entry, allele level entry, and development of import tools that interface with the LIS (which labs use to eliminate complex manual data entry). They thought integration or elimination of manual data entry will improve patient safety. And that they generally support the concept of accurate and timely reporting of discrepancies but not without an import process to reduce manual data entry of lab data.

Update Histocompatibility Bylaws

Histocompatibility Committee

Sentiment: 1 strongly support, 21 support, 4 neutral/abstain, 0 oppose, 0 strongly oppose

• **Comments:** Region 5 supported this project. An attendee suggested the committee collaborate with the MPSC to verify they support the proposed personnel changes.

Continuous Distribution Updates

Continuous Distribution of Hearts Update, Summer 2024

Heart Transplantation Committee

- Comments: Online feedback showed agreement with the general priority of attributes as identified by the VPE results. An attendee commented that post-transplant survival should be more heavily weighted, since that is the ultimate purpose of the transplant. Virtual attendees provided mixed responses to the relatively low prioritization of the proximity efficiency attribute. An attendee suggested that the committee provide organ non-use rates associated with cold ischemia time due to long distance.
- A member commented that distance may need to be a little higher due to the associated cost and burden related to increased travel and pointed out that not all centers will have the technology available to implement.
- A member suggested that biologically difficult to match should receive more points.
- An attendee asked the committee to ensure that there is pediatric priority for pediatric candidates. Also commented that the OCS system is limited for pediatric programs as well as cost prohibited for smaller programs.
- A member provided a general comment that is applicable to all organs in continuous distribution. They asked that the committee keep in mind directly and indirectly related increased costs associated with continuous distribution implementations.



Continuous Distribution of Kidneys Update, Summer 2024

Kidney Transplantation Committee

- **Comments:** Online feedback showed the majority did not agree that cold ischemic time (CIT) threshold alone should be used to define a kidney as "hard to place" or at increased risk of nonuse. Attendees commented that CIT should be a factor, but not the only factor, and that it is just one attribute that makes kidney hard to place. Other factors include age of donor, biopsy findings if TMA, chronicity, AKI IN donor, etc. Another attendee suggested that factors identifying potentially hard to place organs could be captured earlier in the process. Regarding specific anatomy characteristics or considerations that should be included in a definition of a "hard to place" kidney, or a kidney at increased risk of non-use, attendees suggested multiple vessels, capsular tear, en - bloc, dual kidney, pediatric en-bloc, and 95-100% KDPI. Regarding whether there is a specific number of candidate or program declines at which an organ could be considered harder to place or at risk of non-use, attendees suggested candidate declines over 250, or 100 candidates and 2 program declines. Another attendee commented that she didn't have a specific number but she supports the idea and leans toward the number of programs declining. Another member said that if 5 centers turn down the organ then that is a good indication that the organ is "hard to place". A member said that it is difficult to define "hard to place" and commented that it is all so multifactorial.
- An attendee commented that it's crucial to ensure that pediatric priority is retained for pediatric donors in the ongoing organ distribution system.
- A member said that it is important to consider transportation logistics in the continuous distribution model in order to mitigate loss of organ due to transplantation.
- A member provided a general comment that is applicable to all organs in continuous distribution. They asked that the committee keep in mind directly and indirectly related increased costs associated with continuous distribution implementations.

Continuous Distribution of Livers and Intestines Update, Summer 2024

Liver and Intestinal Organ Transplantation Committee

- Comments: Region 5 supported the liver continuous distribution model and concepts, with a lot of feedback on geographic factors, travel logistics, and pediatric liver candidates. The region felt it was important for the committee to spend time looking into travel logistics when developing the liver continuous distribution model. They also confirmed that travel distance does affect allocation. Several attendees commented that their organization opts to fly a liver when it is more than a 2-3 hour drive away or is out of state. Another member pointed out that driving distance will vary depending upon the rural versus suburban area and the season. The member suggested that it would be helpful to evaluate current data and the distance between transplant center and donor center. An attendee pointed out that geographic equity needs to be highlighted for states with greater rural populations (for example, Idaho and Montana). Regarding exceptions, an attendee said that certain organs might not be suitable to ship long distances, and the committee should keep this in mind in an additional effort to reduce organ non-use.
- There was a lot of support for the committee to focus on pediatric liver candidates. They
 believed it was important to retain pediatric priority for pediatric donors and suggested to
 create a process to identify quality livers that can be split. A pediatric liver team pointed out that
 if children are not eligible for additional priority related to their BSA, it will be essential to

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consider how BSA-related prioritization will compare to pediatric prioritization to ensure that children are not under-prioritized compared to small adults. They agreed with the concept of a donor modifier and suggested that BSA priority be used for small donors. But if applied in pediatric match runs, there needs to be a system in place to ensure children are highly prioritized for pediatric organs. They agreed with the inclusion of priority for initiating a split transplant, but strongly encouraged the committee to consider a more meaningful variable than "willingness to accept a split liver". The committee should pay attention to how this variable is actually defined. They also agreed with continued use of PELD to determine medical urgency for now; and said if moving to OPOM, it will be essential to further develop the pediatric version. In simulation phase, it will be important to track transplant of pediatric donors into pediatric recipients. An attendee inquired whether there would be a different score for pediatric candidates.

- A member suggested that donors in remote areas, and donors with forced late reallocation should probably be considered complex unless NMP is being used. There was a suggestion for the committee to consider whether there will be significant changes in the near future on the degree to which an older or DCD liver is really a "high risk" liver considering NRP and machine perfusion is available. An attendee said that large livers and livers with steatosis are challenging to allocate. These characteristics are generally known at the time of organ offer. Those variables should be included in the definition of medically complex livers. In order to allocate small livers to recipients that need them, recipients with a small capacity need to be identified, and this is not reliably identified by BSA, BMI, height or weight. Frequently the candidate's CT scan must be used to make the determination on the appropriate liver size. They inquired if it was possible for centers to designate waitlist candidates who need an exceptionally small liver.
- A member suggested that the committee confirm that MELD 3.0 addressed sex disparity.
- A member provided a general comment that is applicable to all organs in continuous distribution. They asked that the committee keep in mind directly and indirectly related increased costs associated with continuous distribution implementations.

Continuous Distribution of Pancreata Update, Summer 2024

Pancreas Transplantation Committee

• Comments: Online feedback showed support for encouraging OPOs to have procurement teams for all abdominal organs, including pancreas, and a member suggested to know the organ acceptance rates for transplant centers. Regarding cultivating strategies and range of skill set for pancreas transplant professionals, attendees suggest workshops, pointed out that fellows need to rotate at high volume centers to gain experience along with increasing training for procurement, and requiring specific hours with identified focus. For how to encourage programs to have dedicated pancreas directors, separate from kidney, in order to influence outcomes and growth of the programs, an attendee suggested a separate FTE efforts for Pancreas Directorship may help. Another thought that having a dedicated director would support growth but explained that that would be allocating a lot of resources for very little gain. Another attendee said they don't believe a dedicated pancreas director will make a difference unless the transplant center is vested in pancreas transplantation and has the requisite personnel to do so. A member shared that their program has designated pancreas directors. And having the designated pancreas director is helpful because their program receives the necessary attention.



Updates

Councillor Update

No comments

OPTN Patient Affairs Committee Update

No comments

OPTN Executive Update

• Comments: Region 5 appreciated the update. The region felt strongly that experts working in transplantation should develop transplantation policy. Another attendee commented that they are not optimistic about future changes and expressed concerns about the impact of available false narratives. An attendee commented that a big issue amongst patients is whether they know if they are active or inactive on the waitlist.

Update from the Expeditious Task Force

• **Comments:** Region 5 appreciated the informative update and thanked the Expeditious Task Force for sharing their exciting work.

HRSA Update

- **Comments:** Region 5 appreciated the presentation. An attendee commented that it's important to hear from HRSA on the modernization initiative. Another attendee expressed concern from the community on transparency. They asked the following:
 - o How will the contracts process work?
 - How do you envision HRSA keeping the community informed on how the new contracts unfold and how will HRSA keep new contractors accountable?
 - o How can HRSA keep members aware of new data changes sooner?
 - How are new positions assigned and what does the process look like for selecting the contractors? What about conflicts between two contractors, how will HRSA address if there are issues?
 - o How will HRSA ensure patient safety with all the changes?
 - What are the plans to assess disparities in organ transplant amongst patients active on the waitlist?
 - Regarding the ventilated patient form, a member inquired about the plan to access affected patients who have been on the waitlist a long time.