OPTN

Thank you to everyone who attended the Region 8 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:** 6 strongly support, 13 support, 0 neutral/abstain, 1 oppose, 0 strongly oppose
- **Comments:** The region supports the proposal to allow third party vendors a pathway to OPTN membership. An attendee pointed out that more OPTN support is needed for the ISA process. They explained that transplant centers must bear the cost of resources, time, and expertise to complete an ISA, so they requested more information on what resources they need to complete the ISA and be in compliance with policy. An attendee commented that this proposal does not seem to significantly impact clinical research but recommended reassurance to the community that the process is not significantly more cumbersome with the proposed changes.
- An attendee provided the following suggestions based on review of the current DUA with UNOS. The DUA should:
  - set expectations about data integrity/accuracy
  - ensure PHI is handled consistent with HIPAA requirements
  - set expectations about privacy authorized users will have while using the system
  - set parameters for system use (including limitations on 3rd party use)
  - set requirements for notification related to data breach
  - provide clarity on data ownership
  - make clear consequences for violating terms and dispute resolution / governing law.
- Another member pointed out that the revision of reporting systems leaves the potential for communication gaps that could not only lead to inefficiencies but also may unintentionally exclude certain groups from providing input. For example, the effort to extend data collection into the pre-waitlist period. Forms will be submitted for community feedback through a pathway that is different than the long-established system of OPTN public comment. This could lead to a decrease in healthcare, transplant hospital, and hospital administration engagement. Which bolsters the concern in the healthcare community that transplant professionals hold a diminishing voice with a shift toward greater legislator management at the exclusion of medical professionals.

Promote Efficiency of Lung Donor Testing

Lung Transplantation Committee

- **Sentiment:** 5 strongly support, 9 support, 3 neutral/abstain, 3 oppose, 0 strongly oppose
- **Comments:** The region supported the proposal with the following requests for clarity and language changes. Several members suggested the x-ray should be within three hours, and

there needs to be clarification on the “initial offer”. They suggested changing the policy language to “upon starting allocation”. They explained a program may mistakenly expect an x-ray within three hours because it’s *their* first time seeing the offer. Regarding the echo – rural areas may not be able to get an echo if the OPO is not pursuing heart donation. Smaller hospitals may not have the ability and the OPO must decide where to push to keep allocation moving.

- A member pointed out that the proposal needs to consider the impact of the donor hospital limitations in the wording of the requirements. Even though the OPTN states these must be required the OPO can't force a hospital to complete them especially with a DCD donor or if there are limited resources. There should be language in the proposal that provides leeway for the OPO that cannot complete the testing.
- Several members recommended changing language to clarify the timing of ABGs/CXR on primary offer time. They proposed the language should be, within three hours of lung allocation and every 24 hours after, or with patient status change. They also recommended consideration of donor type in the language and to remove the requirement of echo or right heart catheterization, since that is not possible at every hospital.
- In response to the question on whether the proposed guidance for fungal and bacterial cultures, chest CT scans, chest x-rays, and RHCs are appropriate recommendations – attendees confirmed they are appropriate, overall. But an attendee emphasized that, when providing CXR images, photos of a CXR on a computer monitor should be avoided.
- The pediatric community had concerns about 0-11 candidates not having the same increase in access, and suggested the committee consider giving points if the donor is pediatric. They also suggested requiring X-ray images <u>and</u> interpretation. Regarding the imaging language, when providing a chest x-ray and chest CT scan results, there should be a preference for images in DICOM readable format as opposed to photographs or videos of computer display screens (which could be added to any guidance document).
- In response to the question on whether community members support the use of the NHLBI ARDS Network formula for IBW or prefer to use a different formula when calculating IBW – an attendee said the NHLBI ARDS Network formula is as follows: Male: PBW (kg) = 50 + 2.3 (height (in) – 60), Female: PBW (kg) = 45.5 + 2.3 (height (in) – 60). And commented that these formulas are validated for adults. And that the OPTN should determine the most appropriate IBW calculation for children.
- An attendee requested clarification on the range for PEEP for O2 challenge prior to initial offer. They appreciated the option for CXR to be image or interpretation prior to initial offer, since this allows the OPO to meet the time requirements. And allows the OPO to be able to continue to provide the information available to meet timing requirements without delaying the process.
- A member pointed out that it’s important to remember that OPOs are guests in donor hospitals. Particularly in the case of DCD donors, where OPOs must work with the patient's doctor and may not be able to order tests as frequently as this guidance suggests. Further, right-heart catheterization, or even echocardiograms may not be available on demand.
- Another said that more data is great as long it doesn't create additional burden on timing of offers by OPOs to transplant centers. Notably, several donor hospitals in Region 8 are rural and have limited or no ability to provide cardiac catheters, etc. (especially on demand and 24 hours).

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

Histocompatibility Committee

- **Sentiment:** 4 strongly support, 15 support, 1 neutral/abstain, 0 oppose, 0 strongly oppose
- **Comments:** The region agreed on the modified definition of a critical HLA discrepancy and pointed out that errors that don't have a clinically significant impact may be a near-miss (which warrants investigation and consideration in implementation). Another attendee commented that this has long been an area of concern for the community and the new language aligns with the current technological capabilities of our testing methods and will reduce the number of incorrectly assigned "discrepancies".
- In agreeance with the discovering lab being responsible for reporting critical HLA discrepancies to the OPTN, an attendee also added that ideally both the discovering lab and the original testing lab should be involved in reporting discrepancies via the Patient Safety Portal to ensure the most comprehensive information is provided for the occurrence.
- Regarding the time frame questions, an attendee suggested that the effort would be better spent determining the root cause of the error and implementation of corrective actions, with subsequent notification to the OPTN notification within 48 hours.
- Attendees agreed that incorrect donor or recipient samples used for crossmatch should be included in required reports, and that incorrect donor HLA typings or incorrect candidate HLA antibody test should be used for virtual crossmatch in required reports. An attendee commented that this data is critical to determining members' opportunities as a community for improving patient safety and optimizing organ allocation.

Update Histocompatibility Bylaws

Histocompatibility Committee

- **Sentiment:** 5 strongly support, 13 support, 2 neutral/abstain, 0 oppose, 0 strongly oppose
- **Comments:** The region supported this proposal and provided the following responses to community questions. They supported allowing multiple OPTN-approved laboratory directors at a histocompatibility lab, with one primary laboratory director responsible for OPTN operations. (But noted that the OPTN should save its volunteer resources for other key issues instead of reviewing laboratory director case portfolio submissions.) The OPTN has recognized laboratory accreditation organizations which are already used for laboratory site surveys/inspections and are key regulatory partners ensuring OPTN compliance for laboratories under their jurisdiction. These organizations have thorough processes for approving laboratory directors including a case portfolio review. The attendee commented that we should utilize these partners for director approval rather than duplication of the work for OPTN volunteers.
- For the question on whether OPTN laboratory director education and training requirements should be more stringent than CLIA, or align with CLIA regulations as proposed, an attendee said "no" and that all OPTN laboratory personnel requirements should align with CLIA regulations and not be more stringent.
- On whether the components required within the transplant program and OPO laboratory agreements sufficient and clear, an attendee explained: the process and timing for laboratory testing turn-around-time should be left to the parties involved. Currently, the proposal language implies that notification of extended testing time should occur prospectively on every test that goes over. Resources at the laboratory, transplant programs, and OPOs would better be utilized
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if the agreeing parties set the terms for communication of TAT (for example, a monthly or quarterly report of TAT).
- For the potential future proposal of General Supervisor qualifications, an attendee reiterated that the OPTN shouldn't require anything more than CLIA requires.
- Regarding whether the Committee should consider proposing a minimum number of cases a laboratory director must review per year as a future proposal, an attendee commented that only if the MPSC has found repeated instances where lack of sufficient case experience has led to HLA laboratory performance issues.

Continuous Distribution Updates

[Continuous Distribution of Hearts Update, Summer 2024]

Heart Transplantation Committee

- **Comments:** Online feedback showed agreement with general priority of attributes as identified by the VPE results. However, an attendee said except the case in which a recipient has been waiting a long time since those recipients are more likely to die waiting on a heart organ. There was some agreement with the relatively low prioritization of the proximity efficiency attribute suggested by the VPE results. But one attendee disagreed with the low prioritization of the proximity efficiency attribute suggested by the VPE results. The attendee explained they believed the thoracic organ offers distance is important, with the understanding that as new preservation technologies are available and become standardized, distance should be less of a deciding factor.
- An attendee requested clarification on multivisceral requirements in allocation. Another attendee pointed out that continuous distribution framework requires more transparency in candidate rating, and explained how factors like religious beliefs affecting medical choices are weighted for unbiased evaluation. They said clarification is needed on how to handle special populations, such as Jehovah's Witnesses refusing blood transfusions, and addressing growing concerns about their acceptance rates. They said it would help to share simulation data on the impact on different patient groups, including those requiring bloodless transplantation. The framework should explain the balance of ethical considerations of equity and utility, reflecting OPTN Ethics Committee recommendations. Additionally, information on the system's adaptability to incorporate advancements in bloodless transplantation and address disparities over time is crucial. And developing patient education materials on fair access regardless of religious beliefs would enhance understanding and potentially contribute to increasing overall transplant numbers.
- For pediatric recipients, attendees recommend constructing a mechanism to retain pediatric priority for pediatric donors, at least to some degree. If the outcomes of continuous distributions of hearts mirrors the outcomes for lung (i.e. traveling further distances for organs), they had concerns about limited access to donor organs in pediatric programs. Further, pediatric programs do not have as much access to organ preservation devices which limits their ability to travel further for organs.
- An attendee implored the committees to consider allocation efficiency in developing equitable organ allocation in relation to the impact of donor families. With the implementation of the lung continuous distribution allocation, the allocation process is extended, adding time required to facilitate gifts given by donor family. On average, donor cases are taking 50-60 hours prior to going to the operating room, which is hard on donor families. The clarification of the multi-

organ priorities should help. The attendee explained that as we improve the system, we need to consider the needs of the donor families.

During the meeting, in-person attendees participated in group discussions and provided feedback on the following questions:

- Do you agree with the general priority of attributes as identified by the VPE (Value Prioritization Exercise) results?
  - The group agreed with medical urgency and pediatric priority but felt that candidate biology should have more priority than prior living donor. They also felt that being located close to the donor should have more priority than in the exercise.
- Do you agree with the relatively low prioritization of the proximity efficiency attribute suggested by the VPE results?
  - A lung colleague described their lung continuous distribution experience and recommended prioritizing pediatric donors for pediatric candidates due to better outcomes.
- The Committee is very interested in hearing from those with a personal connection to organ donation and transplantation and would like to know if there is any additional information the OPTN could provide to help you better understand the concepts associated with the continuous distribution of hearts allocation framework?
  - Recipients agreed with VPE but felt that knowing they are active on the list and offers are coming in is more important and want to consider how to keep families aware of what is happening with organ offers.

Continuous Distribution of Kidneys Update, Summer 2024

Kidney Transplantation Committee

- **Comments:** Online members pointed out that as more centers decline a kidney, others become skeptical. A member suggested the number of 50 declines is the number at which an organ should be considered “hard to place” or at risk of non-use. The number of transplant center programs that have declined for all recipients is a very good indicator of kidney non-use. More specifically kidney centers who have been deemed "aggressive", if they decline it is more likely for non-use.
- An attendee explained there are many factors that make a kidney difficult to place. Kidney biopsy being one large factor in non-utilization.
- For specific anatomy characteristics or considerations that should be included in the “hard to place” kidney or kidney at increased risk of non-use, attendees suggested the following: plaque, stripped or multiple ureters, and biopsy results.
- An attendee commented that they did not recommend reducing the pediatric weight (even slightly) to reduce median travel distance.
- Another attendee commented how continuous distribution has greatly increased transportation logistics. For organs such as lungs, hearts, and even livers, charter jets are more mainstream. For kidneys, there is a real risk of increased non-use due to extended CITs by using commercial aircraft unless CMS makes an announcement that charter jets can be used as standard of care in transportation logistics over longer distances.

During the meeting, in-person attendees participated in group discussions and provided feedback on the following questions:

- Should a cold ischemic time (CIT) threshold alone be used to define a kidney as "hard to place" or at increased risk of non-use?
    - The group reported that no, we should not use CIT threshold alone. Twenty hours of CIT may mean something very different in one donor than another. They suggested to consider factors in conjunction with CIT.
- Are there 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?
    - Regarding specific anatomy characteristics - not biopsy but gross anatomy inspection, i.e. multiple arteries, presence of plaque in arterial veins, and overall kidney size.
- Allocation thresholds are based on the progress of allocation, specifically in terms of increasing numbers of declines. For example, allocation efforts reaching sequence number 200 means that the organ offer has been declined for 199 candidates. Alternatively, another allocation indicator under consideration could be the number of programs who have declined for all of their candidates. Is there a number of candidate or program declines at which an organ could be considered harder to place or at risk of non-use?
    - Programs may be more reflective of when a kidney is getting harder to place. For example, if five programs pass, then OPOs may start getting nervous. It also depends on where you are/transplant program density.

Continuous Distribution of Livers and Intestines Update, Summer 2024

Liver and Intestinal Organ Transplantation Committee

- **Comments:** Online attendees submitted the following feedback on flying versus driving and travel logistics - anything more than one hour driving the centers' team will fly (sometimes within their own state if the travel times are increased and weather is a factor), at more than 250 miles, and at more than two hours travel time. Online attendees did not submit feedback on the Utilization Efficiency attribute. And there was support for specific donor modifiers.

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

- Please provide feedback on when your organization begins to fly rather than drive for organ procurement as well as any feedback on travel practices.
    - There was not a clear consensus on the fly versus driving question but there were a lot of considerations taken into account, including FAA restrictions or non-approvals.
- Please provide feedback on the Utilization Efficiency attribute including input on the options for how to award candidates points and the definition of a medically complex liver offer.
    - Attendees in the group were very uncomfortable with individuals getting points for a specific attribute based on center behavior that they are unable to control.
- Please provide feedback on how to incorporate exceptions into the continuous distribution framework, including Hepatocellular carcinoma (HCC) stratification, and whether any specific donor modifiers are necessary.
    - Regarding donor modifiers, the group had pediatric representation at their table and reported the biggest recent impact on pediatric waitlist was prioritizing pediatric donor organs to pediatric candidates as designed in current allocation.

- Regarding split livers, the group requested reassurance, when possible, organs originally allocated to pediatric patients that are split be allocated to pediatric candidates since pediatric surgeons may be more comfortable splitting livers.

Continuous Distribution of Pancreata Update, Summer 2024

Pancreas Transplantation Committee

- **Comments:** During the meeting, attendees participated in group discussions and provided feedback in-person and online, on the following questions:
- For innovative strategies that could be implemented to enhance fellowship training and cultivate greater interest in pancreas transplantation among medical professionals and what range of skills and experiences might contribute to a professional's readiness to participate in organ procurement procedures – attendees suggested the following:
  - Volume, experience, and exposure to pancreas transplants are really important
  - More funding to promote training in pancreas transplants
  - Train at centers that do the procedure
  - Personal mentorship by experienced surgeon
  - Focus on comprehensive skill development, including advanced surgical and blood conservation techniques crucial for patients like Jehovah's Witnesses. (This aligns with the OPTN Ethics Committee's 2021 White Paper encouraging unbiased evaluation.) Fellows should rotate through related specialties, participate in research on bloodless surgery techniques, and engage in simulation-based training for complex scenarios. Cultural competence training should emphasize consistent, transparent criteria application to avoid discrimination. Mentorship programs with surgeons experienced in bloodless transplantation and interdisciplinary collaboration can advance innovative techniques. These strategies ensure a well-rounded skill set addressing diverse patient needs and could increase overall transplant numbers.
- For encouraging OPOs to have procurement teams for all abdominal organs, including pancreas, impact procurement, attendees suggested the following:
  - Make it more efficient and economical
  - If the surgeons are highly skilled, it would be positive; if not, it would have negative impact
  - Noted support for OPOs having procurement teams
- For encouraging programs to have dedicated pancreas directors, separate from kidney, influence outcomes and growth of the programs, attendees provided the following feedback?
  - A dedicated person that can focus on increasing pancreas transplant would be ideal.
  - There could be a decrease in volume since pancreas transplant is a specialized field.

Updates

Councillor Update

- **Comments:** No comments.

OPTN Patient Affairs Committee Update

- **Comments:** No comments.

OPTN Executive Committee Update

- **Comments:** Region 8 appreciated the update and had asked and answered questions about what constitutes an OPTN member, the Interim Executive Director selection process, and representation from all contractors on committees.

Update from the Expeditious Task Force

- **Comments:** No comments.

HRSA Update

- **Comments:** Region 8 appreciated the update from HRSA and had the following, asked and answered, questions:
  - As you move forward to multi contract support, how will HRSA ensure institutional memory as much is not written down?
  - As we move to multiple contractors, if we have a question for the Board of Directors, do we go to board contract support with questions or will there be others to assist?
  - Where is the provision in bylaws or Final Rule that allows for special election of Board members?
  - What do you expect the timeline to be for the membership bylaws? For example, pancreas is tied with membership bylaws and there is ultimately a negative impact on patients.