OPTN

Thank you to everyone who attended the Region 2 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*: **7 strongly support, 14 support, 1 neutral/abstain, 1 oppose, 0 strongly oppose**
- *Comments*: Members of the region are, overall, supportive of the proposal. The discussion emphasized the need to prioritize security of the OPTN Computer System, though concerns were raised about the potential complexity and inconvenience of repeated logins during critical work. If the proposed policy is approved, it is crucial for the OPTN to allow ample time for business members, including transplant centers, OPOs, and HLA labs, to align their membership status and establish secure interconnection agreements. This alignment is essential for maintaining the efficiency and reliability of donation and transplant systems, which ultimately benefits patients. There was also a call for a mechanism that allows necessary access without being overly restrictive. Any changes should avoid being overly burdensome, recognizing that third-party companies often assist with organ offers due to the complexities of the current 24/7/365 organ allocation system. Simplicity in Data Use Agreements is encouraged to reduce administrative burdens, and while security and data protection are acknowledged as top priorities, the overall administrative load on users should be minimized to maintain system efficiency.

Promote Efficiency of Lung Donor Testing

Lung Transplantation Committee

- *Sentiment*: **9 strongly support, 11 support, 3 neutral/abstain, 0 oppose, 0 strongly oppose**
- *Comments*: Members of the region were supportive of the proposal. There was strong support for the proposed changes to transplant practices, with several suggestions to further enhance the process. One attendee suggested including peak and plateau pressure measurements alongside arterial blood gases (ABGs) in the OPTN Computer System, as many centers frequently request this data when receiving organ offers. Blood gas data is seen as a valuable addition, though there was debate about whether certain requirements, like making X-ray images available, should be mandatory rather than just guidelines, considering the operational capacities of OPOs. Another attendee noted concern that chest X-rays may not always reveal underlying lung pathologies, which can be detected by CT scans. It was suggested that chest CT scans should be required in certain cases. The burden on transplant centers and patients, including the stress of extensive traveling and testing, should be minimized as much as possible. Standardization across the transplant process was emphasized as crucial for success. There was

agreement on the importance of adding peak and plateau pressure information from mechanical ventilation. However, concerns were raised about the practicality of requiring fungal culture results, which can take over 28 days to obtain; one attendee suggested that only preliminary results should be required. Overall, the attendees highlighted the importance of requiring documentation, particularly for chest CT scans to catch issues that X-rays might miss. Additionally, the discussion underscored the need for balancing thoroughness in the organ evaluation process with the practical limitations faced by OPOs and the stress placed on donor families and patients.

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

Histocompatibility Committee

- *Sentiment*: **7 strongly support, 14 support, 1 neutral/abstain, 1 oppose, 0 strongly oppose**
- *Comments:* Members of the region were supportive of the proposal. Attendees noted the importance of matching organs to the best candidates, as it is believed to improve outcomes and increase the longevity of transplants. There was some uncertainty about whether the 24-hour window is sufficient and whether earlier knowledge of HLA matching could enable more effective interventions, such as reallocation or intensified induction for already transplanted organs. Several attendees suggested increasing the 24-hour reporting requirement either to 36-48 hours or by the next business day to account for weekends and holidays. An attendee noted that HLA experts need to provide input on this proposal and that the committee should consider all public comments before finalizing the proposal. Lastly, one attendee highlighted the importance of prioritizing HLA matching for children in organ transplants, emphasizing that better matching could significantly reduce transplant failures and the development of donor-specific antibodies. It was suggested that children should receive additional priority for HLA matching, similar to practices in Europe, to improve long-term transplant success.

Update Histocompatibility Bylaws

Histocompatibility Committee

- *Sentiment*: **5 strongly support, 12 support, 4 neutral/abstain, 2 oppose, 0 strongly oppose**
- *Comments*: Overall, the region was supportive of the proposed changes to the Histocompatibility Bylaws. One attendee noted that by correctly setting the bylaws will standardize the overall procurement and transplantation process. Another attendee added that histocompatibility bylaws are difficult to understand for those outside of the histocompatibility field, despite how clear they bylaws are written. Of the opposition noted, one attendee suggested that the American Society for Histocompatibility and Immunogenetics (ASHI) or the College of American Pathologists (CAP) should undertake these changes, not the OPTN.

Continuous Distribution Updates

Continuous Distribution of Hearts Update, Summer 2024

Heart Transplantation Committee

- *Comments*: Feedback submitted online highlighted concerns and support for the new organ allocation system, particularly regarding its impact on smaller transplant centers and rural communities. While there is general support for the inclusion of additional factors in the

continuous allocation model, one attendee expressed concern that too much emphasis is being placed on prior living donors, suggesting that more weight should be given to biologically difficult-to-match candidates. There was also apprehension about the financial burden the new system might impose, especially on smaller centers. As seen with the lung allocation transition to a Continuous Allocation Score (CAS), there has been an increase in travel distances and upfront costs, which could force smaller centers—particularly those serving rural communities with limited financial means—out of the system. This raises concerns about how the transplant community will support these centers and ensure equal organ distribution for all patients. Overall, there is acknowledgment that helping those on the waitlist should be a priority, as it would ultimately benefit both costs and health outcomes. However, there is a need for careful consideration of the potential inequities the new system could create.

During the meeting, 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 feedback on the VPE results was generally supportive and in line with expectations. However, concerns were raised about the negative impact of the current attribute list on stable LVAD (Left Ventricular Assist Device) patients, as it fails to consider the duration of mechanical circulatory support. While the new system is seen as more equitable and patient-centric—similar to the lung allocation model—there is worry that not everyone fully understands the implications of their prioritization choices. One significant concern is the low emphasis placed on post-transplant outcomes. The fear is that this could lead to a system where patients with a longer potential survival suffer poorer outcomes due to extended wait times, while others receive transplants but with significantly worse long-term results. Such extreme outcomes could ultimately be unacceptable to all involved.
- Do you agree with the relatively low prioritization of the proximity efficiency attribute suggested by the VPE results?
    - The discussion on Placement Efficiency raised concerns about equitable access to organs, particularly when some programs have the resources to facilitate long-distance travel, potentially disadvantaging others. The inefficiency of organs crisscrossing the country was highlighted as a poor use of resources. There was acknowledgment of the increasing use of organ perfusion systems like TransMedics, which could improve the ability to transport organs over longer distances. However, the true impact on organ procurement and outcomes is still uncertain and may need to be reassessed in the future.
- 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?
    - An attendee noted that the videos and graphics on the OPTN website are simple and easy to understand, which is a good thing.

Continuous Distribution of Kidneys Update, Summer 2024

Kidney Transplantation Committee

- *Comments*: Feedback submitted online highlighted the need to limit penalties for transplant centers that accept organs with unadjusted risks, emphasizing that many donor organs now carry significant risks not accounted for in standard SRTR risk adjustments or KDPI. Examples include donors on dialysis before donation or with a history of acute kidney injury/renal failure. Once an organ is deemed "hard to place" after multiple centers decline it, it should not be scrutinized under standard SRTR criteria, and recipients of such organs should receive priority if the organ fails early. Additionally, there was support for giving patients a greater role in decision-making and transparency regarding organ preferences, as well as agreement on the importance of optimizing outcome modeling for hard-to-place organs.

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

- Should a cold ischemic time threshold alone be used to define a kidney as “hard to place” or at increased risk of non-use?
    - Cold ischemia time (CIT) should not be the sole factor in decision-making for kidney transplants, as there are many other important considerations, such as medical comorbidities, the reliability of virtual crossmatch, and biopsy results, especially for hard-to-place organs. While some agreed that CIT is important, they noted that its definition varies, and for some, CIT should ideally be less than 24 hours from cross-clamp to departure from the OPO.
- 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?
    - The discussion highlighted key anatomical and medical factors that can make a kidney difficult to place, including multiple vessels, suspicious cysts or nodules, and specific vascular anomalies or damage, such as renal artery surgical injuries and poor flush quality. Additionally, medical comorbidities like a history of diabetes (DM), hypertension (HTN), and the use of continuous renal replacement therapy (CRRT) or hemodialysis (HD) during admission were noted as new challenges in kidney placement.
- 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?
    - The discussion emphasized that the allocation of kidneys should consider not only the number of declines but also the specific centers that decline them, as surgeon behavior can significantly impact placement. Geographic factors and reasons for declines were acknowledged as driving influences in the process. A kidney should not be deemed hard to place based solely on decline numbers; rather, if five different programs decline offers to standard adult single organ candidates—excluding high CPRA, pediatric cases, or other organ transplant priorities—the organ should be flagged as at risk. The proposed distance for evaluating placements was noted as 150 to 200 nautical miles. Overall, both the quantity and reasons behind declines are critical in assessing a kidney's placement challenges.

Continuous Distribution of Livers and Intestines Update, Summer 2024

Liver and Intestinal Organ Transplantation Committee

- *Comments*: Feedback submitted online touched on several points of interest including MELD exception calculations, with curiosity expressed about the outcomes of these calculations. There was also a call for better ways to describe anatomical size, such as height or anteroposterior (AP) diameter, noting that AP diameter is commonly available for both candidates and donors and should be utilized more effectively. Improved organ distribution was highlighted as a key factor that could lead to higher success rates, lower costs, and overall better patient health outcomes.

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.
    - The discussion focused on the limitations of using nautical miles (NM) as the sole factor in deciding whether to fly or drive for organ transport. It was emphasized that cold ischemia time (CIT) and overall travel time, including potential delays like traffic, are more critical considerations. While some teams typically fly for rapid recovery, others suggested that time estimates, accounting for rush hour traffic in major cities, should be prioritized over just measuring distances.
- 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.
    - The discussion highlighted the importance of internal practices aimed at maximizing the success rate of liver transplants by carefully matching organs to suitable patients. This involves a detailed framework for grading both livers and patients, including assessing biopsies and pump data to ensure the best possible outcomes. There is interest in expanding these practices to other programs to improve access to organs and consider MELD exception points. Additionally, the use of modifiers for donors by some programs and the potential of MELD 3.0 to award candidate points were mentioned as important considerations.
- 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.
    - No comments

Continuous Distribution of Pancreata Update, Summer 2024

Pancreas Transplantation Committee

- *Comments*: Feedback submitted online emphasized the importance of setting standards to improve the chances of successful transplant outcomes. An attendee, who is a simultaneous kidney and pancreas transplant recipient, expressed a wish that they had been given the option for a pancreas transplant 25 years earlier. This could have potentially prevented complications from Type 1 Diabetes and preserved their kidneys. There was also agreement on the value of metrics and modeling in the Continuous Distribution update.

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

- What innovative strategies could be implemented to enhance fellowship training and cultivate greater interest in pancreas transplantation among medical professionals? What range of skills and experiences might contribute to a professional's readiness to participate in organ procurement procedures?
    - The discussion highlighted the rarity of pediatric pancreas transplants, particularly for adolescents who often face challenges in accessing adult programs due to the specialized skills required for pancreas surgeries. The need for adult programs to gain expertise in treating younger patients was emphasized, especially as advancements in diabetes care, such as Dexcom and insulin pumps, are transforming treatment options. Concerns were raised about the future of training for pancreas transplant surgeons, including the potential reduction of required surgical fellowship years and the removal of mandatory transplant rotations, which could impact the quality of training. The idea of utilizing simulation labs to enhance surgical practice and better prepare fellows and donor surgeons for pancreas transplants was proposed. Additionally, it was noted that, with limited pancreas donor resources, it is essential to ensure that all transplant surgeons are adequately trained and qualified. There was some uncertainty expressed about the relevance of pancreas transplants given the advancements in insulin technology, indicating a need for ongoing discussion in the transplant community about these issues.
- How might encouraging OPOs to have procurement teams for all abdominal organs, including pancreas, impact procurement?
    - The discussion focused on the potential benefits of moving towards local recovery of pancreata from an OPO perspective. Local recovery could improve the training of procurement staff and ensure that centers are more inclined to utilize pancreata, as they would have the capability to procure them directly. This approach aims to control the recovery narrative and reduce declines attributed to inadequate recovery staff or the challenges of traveling long distances for pancreas retrieval. Overall, enhancing local recovery practices could increase the number of available pancreata for transplantation.
- In what ways might encouraging programs to have dedicated pancreas directors, separate from kidney, influence outcomes and growth of the programs?
    - While there was some skepticism about whether simply appointing a pancreas director would lead to significant improvements, it was noted that having someone solely focused on pancreas transplants could enhance interest and outcomes. Dedicated pancreas directors may not be influenced by the demands of kidney or liver transplants, allowing for a more concentrated effort in this area. It was acknowledged that having specialized staff could improve outcomes, although there are questions about the overall demand for pancreas transplants, especially regarding the inclusion of type 2 diabetics. The conversation also highlighted the high costs associated with pancreas transplantation, raising concerns about the financial feasibility of expanding programs focused solely on pancreas transplants.

Updates

Councillor Update

- *Comments*: An attendee highlighted the growing challenge of managing an aging population in need of kidney retransplants. As patients who received their first transplant decades ago are now reaching advanced ages, there is a need to develop treatment plans that address the unique needs of older patients requiring a second transplant. This issue is becoming increasingly urgent as the number of candidates in this demographic rises, especially in the context of an ongoing organ shortage. Another attendee noted the difficulties faced by teenage kidney recipients, particularly with issues of nonadherence to treatment protocols and financial burdens, such as the inability to afford copayments. To address these challenges, there was a suggestion to organize an online conference that would bring together recipients and donors to share experiences and support each other, potentially helping younger patients navigate these struggles more effectively.

OPTN Patient Affairs Committee Update

- *Comments*: None

OPTN Executive Committee Update

- *Comments*: An OPTN Board member in attendance expressed gratitude for the dedication and hard work of transplant professionals and the bravery of patients involved in the transplant system. The OPTN acknowledges and appreciates their contributions and looks forward to continued collaboration in the modernization efforts. An attendee raised concerns from the pediatric transplant community regarding the additional burdens that new rules impose. Pediatric programs, which often have fewer patients and staff, face significant challenges in meeting OPTN requirements. A specific example mentioned was the eGFR wait time modification process, which was mandated for pediatric programs despite eGFR not being used for pediatric patients. This situation underscores the need for more pragmatic approaches within the OPTN, particularly in how policies are applied to pediatric programs. In regard to the OPTN Modernization Initiative, an attendee expressed a desire for the OPTN to be involved in the contractor selection process to the extent possible, recognizing that it is a government process and not solely an OPTN initiative.

Update from the Expeditious Task Force

- *Comments*: The discussion focused on the importance of balancing standardization with the need for specialized care in transplantation, particularly for pediatric and complex cases. One attendee emphasized that while standardization is important, it should not hinder the expertise of certain programs in managing specific conditions, especially rare or complex disorders. This is especially relevant in pediatrics, where end organ disease can be more esoteric and require specialized management. A suggestion was made to develop a comorbidities index to better match pediatric patients with suitable kidneys, potentially including marginal kidneys that may be more appropriate for patients with life-limiting conditions. The current systems, like MELD and EPTS, were acknowledged for being imperfect in assessing patient acuity, particularly in cases where a patient's condition, such as cancer remission, isn't fully reflected. There was some disagreement regarding the uniformity of transplant practices. One attendee argued that while

uniformity is crucial, it should not disadvantage patients who might find better outcomes at specialized programs, especially in pediatric cases. It suggested that uniformity should be applied as much as possible across age groups but acknowledged that pediatrics often involves rare cases that require specialized care. The conversation also touched on the future of transplantation, including the potential for xenotransplantation and the need for broad standards that prevent patients from being turned down solely based on age. The importance of timely transplants to avoid the grueling experience of dialysis was highlighted, along with a call for increased financial investment in drug research and development to prevent the need for re-transplantation.

HRSA Update

- *Comments*: The discussion began with a question regarding the role of the OPTN and its Board of Directors in selecting contractors. The response clarified that a hybrid approach will be used due to federal acquisition rules. Since the contracts are HRSA contracts funded by appropriated dollars, they must follow legal requirements. However, the OPTN Board of Directors will be consulted regularly, with their feedback incorporated into decisions. Another attendee raised concerns about the financial implications of the modernization efforts, particularly the potential chaos if organ allocation processes were abruptly changed. HRSA emphasized a cautious approach, ensuring that no harm will come to patients waiting for transplants. Congress has supported the modernization efforts, providing additional funding, and HRSA is committed to scaling the process responsibly. A representative from the pediatric community expressed concerns about the unique needs of pediatric patients, who have different medical conditions and referral processes compared to adults. They stressed the importance of early feedback from pediatric experts to ensure that the reforms are appropriate and effective for children. There was also a discussion about the importance of transparency and uniformity in practices, particularly in the referral process for kidney patients. Concerns were raised about the current system, where many patients are only referred for transplants after starting dialysis, indicating a failure to identify and act on their needs earlier. Questions were asked about the recruitment of an executive director for the modernization effort, the budget required to accomplish the goals, and the timeline for implementation. The response indicated that a multi-vendor environment would be used, with an iterative process expected to take three to five years. The recruitment process for the interim director will be a joint effort between OPTN leadership and HRSA. Another attendee also raised concerns about the impact of the year-to-year federal budget on contracting with vendors. HRSA acknowledged that while there is a risk of budget cuts, Congress has typically provided consistent funding, which should allow for the continuation of contracted work. Regarding the OPO data collection process, it was noted that while input has been received from OPTN members, the next round of feedback would occur after the form is sent out for public comment, expected in August or September. An attendee noted concern about the potential delay in selecting the next class of committee volunteers. It was suggested that current committee members might be asked to extend their service. Lastly, it was noted that the modernization initiative was affirmed to have broad bipartisan support, indicating that it will likely continue regardless of potential changes in government leadership.