OPTN

Thank you to everyone who attended the Region 10 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: **5 strongly support, 12 support, 2 neutral/abstain, 0 oppose, 0 strongly oppose**
Comments: Members of the region are supportive of the proposal. There was concern about how the proposed requirements might affect STAR files and whether a new process would be necessary. It was noted that all data procured is subject to the new requirements, though the specific impact on STAR files remains uncertain. The conversation also touched on the definition of a "business member," questioning if at least a year of business activity is required. Proposed changes are intended to lower entry barriers for newer businesses. There was support for separating STAR files from other data reports, emphasizing the need for the IT system to be both secure and user-friendly. The responsibilities of third-party contractors were discussed, with an emphasis on them following the same security standards as other members. These contractors play a significant role in the transplantation process, and support was expressed for them maintaining "business member" status without facing unreasonable hurdles. Security concerns were raised, emphasizing that the system's security is only as strong as its weakest link. Therefore, exceptions to security policies were discouraged, even for small businesses. There was also an understanding that any changes should not slow down existing or new processes. Additionally, there was a request for more information regarding the inclusion of new business partners with less than a year of operation and the specifics of Data Use Agreements (DUAs).

Promote Efficiency of Lung Donor Testing

Lung Transplantation Committee

Sentiment: **2 strongly support, 10 support, 6 neutral/abstain, 1 oppose, 0 strongly oppose**
Comments: Overall, members of the region are supportive of the proposal. Several concerns were raised about the proposed changes to donor testing and organ offer processes, particularly regarding the clarity of requirements and potential challenges in specific situations. The term "initial offer" needs clarification, and there are concerns about requiring an echocardiogram or right heart catheterization (RHC) before an organ offer. The challenges associated with DCD donors were highlighted, especially the limited control over the donor in such situations and potential complications like lung recruitment loss, which could lead to atelectasis and the loss of viable lungs. It was noted that while the policy aims to standardize processes, there should still be room for communication between donor hospitals, OPOs, and transplant programs in unique situations. There was support for additional testing if it helps get

more organs to transplant, but there is caution that an increase in required procedures, such as catheterizations, could lead to more doubts and late declines for lungs that could otherwise be usable. DCDs, in particular, require careful consideration due to family consent, hospital capabilities, and staffing constraints. Further clarity is needed on when testing cannot occur and access to timely testing, particularly in DCD situations that may require a right heart catheterization. Concerns were also raised about the proposed mandate for a chest X-ray (CXR) every 4 hours in DCD patients, with some suggesting a time range around O2 challenges and recruitment maneuvers. Additionally, the availability of Echo and Cath procedures at donor hospitals is a concern. There were also suggestions to include patient positioning (supine or prone) in arterial blood gas (ABG) testing requirements. Overall, while the proposed changes are viewed as an improvement over the current state, they are considered a first step toward standardizing and enhancing donor testing. More rigid requirements for the data posted by OPOs and for programs to respond to available data were suggested to prevent endless additional data requests.

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

Sentiment: **5 strongly support, 14 support, 0 neutral/abstain, 0 oppose, 0 strongly oppose**
Comments: Members are supportive of the proposal. Two attendees noted that the proposed 24-hour reporting requirement is too tight of a timeframe. Suggestions were made to change the reporting timeframe to 48 – 72 hours or by the end of the next business day to account for weekends and holidays.

Update Histocompatibility Bylaws
Histocompatibility Committee

Sentiment: **4 strongly support, 14 support, 1 neutral/abstain, 0 oppose, 0 strongly oppose**
Comments: None

Continuous Distribution Updates

Continuous Distribution of Hearts Update, Summer 2024
Heart Transplantation Committee

Comments: The discussion centered around the prioritization of attributes in the Value Prioritization Exercise (VPE) for heart transplant allocation, revealing mixed opinions among attendees. Some were surprised by the results, particularly the lower emphasis on post-transplant outcomes, a topic of significant concern within the heart transplant community. It was noted that prior living donors were given a higher weight than post-transplant outcomes and biological factors, which many found unexpected. However, the lower prioritization of proximity efficiency was generally accepted, especially given the availability of machine perfusion technologies, which makes proximity less critical. There were differing opinions on whether the VPE results accurately reflect the priority of attributes. Some participants disagreed, feeling that the questions were unclear and did not allow for a fair comparison, particularly regarding left ventricular assist device (LVAD)-related topics. Others agreed with the results but expressed concerns about the interpretation of urgency for LVAD patients. Some participants were

uncertain and felt they needed more information to provide a definitive answer. There was also a suggestion that having the VPE results in a written format would help stakeholders better understand and absorb the information. Concerns were raised about the increased use of intra-aortic balloon pumps (IABP) since allocation has prioritized their use. Additionally, the weighting of specific diagnoses within heart failure, such as congenital disease and the need for re-transplant, as well as the integration of current exceptions and time on LVAD, were highlighted as areas needing further consideration. While the heavy weighting of medical urgency was generally supported, some felt that patients who are biologically difficult to match should receive higher priority, given the limited availability of suitable offers for them. The discussion also touched on the importance of focusing on post-transplant survival as a critical consideration in the allocation process.

Continuous Distribution of Kidneys Update, Summer 2024

Kidney Transplantation Committee

Comments: The discussion focused on defining "hard to place" kidneys and the factors influencing their placement and utilization in transplant programs. Attendees agreed that cold ischemic time (CIT) should be considered as a significant factor in evaluating kidneys for transplant, especially once the organ is outside the body. However, it was emphasized that CIT should not be the sole determinant for defining a kidney as "hard to place" or at risk of non-use. Other factors, such as anatomy characteristics (e.g., horseshoe kidneys, plaques, short or multiple arteries and veins), donor age, function, biopsy results, pump numbers, and surgical damage, should also be considered. There was consensus that CIT, when combined with other characteristics, could be more useful in determining risk and guiding decisions. The conversation touched on the skewing of data from programs with high offer acceptance rates and discussed potential thresholds for defining a "hard to place" kidney. Suggestions included defining a "hard to place" kidney based on non-acceptance by all centers within 250 nautical miles or using criteria like 3 or more program declines, 200 candidate declines, or 350 candidate declines. Other considerations include surgical or procurement damage, more than two arteries or veins, hard plaque, multiple cysts, hematoma, discoloration, or a shortened or less-than-optimal ureter. There was also a suggestion that the OPTN should consider reducing outcome requirements for "hard to place" kidneys meeting specific criteria to encourage more risk-neutral behavior among transplant centers. This would help increase the acceptance of these kidneys. It was noted that increased costs and adverse outcomes (e.g., delayed graft function, longer hospital stays) are associated with harder-to-place kidneys, which necessitates careful consideration of these financial and clinical impacts. Attendees agreed that more modeling and data analysis are needed to better define "hard to place" kidneys and to optimize the continuous distribution model for kidneys. The use of offer filters by individual transplant centers was recommended to minimize late declines and reduce CIT, thereby potentially improving the placement process.

Continuous Distribution of Livers and Intestines Update, Summer 2024

Liver and Intestinal Organ Transplantation Committee

Comments: The discussion covered several key topics related to liver and intestine allocation priorities and efficiencies, particularly for post-transplant survival, travel, and donor categorization. Post-transplant survival is currently given a lower priority in the allocation system, and it was noted that the liver allocation process lacks a reliable metric to predict post-transplant survival. The group also discussed travel efficiency, weighing the benefits of flying versus driving for organ transport. This is an

evolving area due to technological advancements, but there was a consensus that broad guidelines based on cost and efficiency should be established. Utilization efficiency was another focus area, particularly the idea of incorporating a center-based aspect into the allocation score. However, participants struggled with the ethical implications of this approach. Placement efficiency, especially concerning late turndowns of organs, was highlighted as a persistent issue. It was suggested that policy changes could help address these inefficiencies. There was also discussion about how to handle exceptions in the allocation system and the need for more modeling to develop fair and effective scoring mechanisms. DCD donors were debated as a "special category." While the relevance of DCD donors to placement efficiency is recognized—given rapidly changing technology and the unique challenges they pose—it was argued that their categorization should remain distinct in the continuous distribution model. Regarding travel logistics, most organ transport now involves air travel due to changes in allocation policy. Liver transportation also predominantly relies on air travel because of greater distances involved. The issue of late declines for liver transplants continues to be a problem for OPOs. This is sometimes linked to local recovery processes where the initially accepting center bears no cost because it does not send a plane, potentially contributing to inefficiency in placement. Overall, the discussions highlighted the need for continued improvements in the allocation process, with an emphasis on addressing efficiency and fairness while considering evolving medical and logistical factors.

Continuous Distribution of Pancreata Update, Summer 2024

Pancreas Transplantation Committee

Comments: The discussion centered on strategies to enhance pancreas transplant programs and improve outcomes. A key point is the role of training programs in driving innovative strategies, particularly the potential benefits and challenges of appointing dedicated pancreas directors. While having a dedicated director could focus more attention on pancreas transplants, there is concern that such positions might be used as steppingstones to other roles, which would require institutional support to be truly effective. The group also discussed the small size of the waiting pool for pancreas transplants and whether enough is being done to identify and funnel appropriate candidates. The potential reimbursement for islet transplants was noted as a factor that could increase interest in the field. With advancements in diabetes technology providing good quality of life for many patients, there is a question about whether pancreas transplants are justified, given the risks associated with immunosuppression. The suggestion was made to consider a more regional approach to pancreas transplantation due to the limited number of specialists. Logistics around the recovery and distribution of pancreata are challenging because of the lack of expertise, and these logistics need to be carefully considered. The need for a clear definition of medical urgency was also highlighted, along with the role of ASTS and the OPTN in monitoring procurement processes carried out by OPOs and their staff. Reducing cold ischemic time was mentioned as a factor that could help increase pancreas offers. There was recognition that while it is helpful for transplant programs to receive organs with varied anatomy or surgical damage, this also encourages programs to procure organs themselves to ensure they meet their standards. Engaging with the community, referring doctors, and endocrinologists, as well as developing specific criteria for Type 2 diabetes mellitus, were suggested as ways to improve patient selection and engagement. Some felt that additional overhead, such as increased coordination and logistics for pancreas transplants, may not be practical for most hospitals. While some participants were unsure about the need for certain changes, the overall focus remained on finding effective ways to enhance pancreas transplant practices, with a specific emphasis on collaboration, logistics, and training.

Updates

Councillor Update

- *Comments*: Several patients and family attendees shared their stories.

OPTN Patient Affairs Committee Update

- *Comments*: There was a question about how to involve families and patients in the public comment process for organ transplant policy. It was highlighted that anyone can provide feedback on proposals through the OPTN website. Additionally, patients have the opportunity to apply to serve on OPTN committees, where they can actively participate in developing and shaping policy.

OPTN Executive Update

- *Comments*: The discussion centered around upcoming changes in the organ transplant system, focusing on several critical areas such as data handling, system efficiency, third-party membership, financial oversight, patient advocacy, and education within the OPTN. Concerns were raised about how potential changes might impact data management for transplant centers. It was clarified that HRSA is responsible for ensuring that transplant programs retain access to their data, and there should not be significant changes in this respect. However, there is some anxiety about the efficiency of the transplant system given increasing government intervention. While organ allocation processes may not slow down, there is concern that committee processes could face delays due to this increased oversight. It was also noted that directives from the Secretary of Health are designed to accelerate changes within the system, especially those that have community support. However, only a few such directives have been issued so far. The discussion also included whether third-party groups should be considered members of OPTN, particularly in relation to meeting security requirements. The complexity of this issue was acknowledged, and it is under active consideration to determine if these third parties should be held to the same standards and regulations as existing members. Regarding financial management, the OPTN Board of Directors is responsible for setting budgets and proposing registration fees, but HRSA must approve these fees. The process of transitioning the allocation system to a more modern state will be gradual, and HRSA will play a crucial role in setting priorities and managing resources. This transition brings forward concerns about maintaining system efficiency, particularly given HRSA's role in prioritizing tasks and allocating resources. There was a strong emphasis on the need for greater transparency in how transplant programs decide who receives an organ. Many people get involved in the transplant system because of personal experiences, and there is hope that the modernization process will bring improvements. Furthermore, questions were raised about how data modeling and management would work under the new system. It remains essential for the OPTN and SRTR (Scientific Registry of Transplant Recipients) to manage data effectively to support these changes. The conversation also highlighted the importance of better onboarding processes to help new members of the transplant community understand OPTN's policies and procedures. Improving education around these areas could help foster greater involvement and understanding among community members. Overall, the discussion reflected a period of transition focused on maintaining efficiency, ensuring effective data management, and enhancing transparency and engagement in the organ transplant system.

Update from the Expeditious Task Force

- *Comments*: There were concerns about the current risk-averse behavior of many transplant centers when accepting kidneys, particularly those from older donors. It was suggested that the Task Force consider providing more leeway or incentives to help centers become more risk-neutral and increase the acceptance of kidneys with a higher Kidney Donor Profile Index (KDPI). The Task Force acknowledges the importance of aligning incentives and disincentives across the transplant system to encourage organ utilization. There was also a discussion about the issue of underreporting surgical damage and anatomical reasons that are often not included on the anatomy sheet, which can affect the perception of organ quality and the decision not to use a particular organ. There is a need for granular and accurate data to capture behaviors and factors that truly reflect the work being done. Lastly, there was concern about the number of patients who never make it onto the transplant waitlist, despite there being many unused organs. It was suggested that the Task Force investigate why some patients are unable to get on the waitlist and how to address this issue. The importance of including the patient voice to ensure practices are patient-centered was emphasized.

HRSA Update

- *Comments*: None