OPTN Pancreas Transplantation Committee
Meeting Summary
October 12, 2023
Conference Call

Oyedolamu Olaitan, MD, Chair
Ty Dunn, MD, MS, FACS, Vice Chair

Introduction

The OPTN Pancreas Transplantation Committee (the Committee) met via Cisco WebEx teleconference on 10/12/2023 to discuss the following agenda items:

1. Post-Public Comment Review: Efficiency and Utilization in Kidney and Pancreas Continuous Distribution
2. Multi-Organ Transplantation Committee Update
3. Update: OPTN Task Force on Efficiency

The following is a summary of the Committee's discussions.

1. Post-Public Comment Review: Efficiency and Utilization in Kidney and Pancreas Continuous Distribution

The Committee heard the feedback from post-public comment and discussed it. There were 85 public comments received with 30 total written comments. The feedback also addressed Kidney Continuous Distribution as this was a joint paper.

There were three items the Committee discussed during this meeting: Facilitated Pancreas; Released Organs; and Mandatory Kidney-Pancreas.

Facilitated Pancreas

The Committee reviewed current Facilitated Pancreas (FP) policy 11.7:

- OPOs and the OPTN are permitted to make FP offers if no pancreas offer has been accepted 3 hours prior to the scheduled donor recovery surgery.
- Apply FP bypasses to candidates registered at transplant hospitals > 250 nautical miles (NM) from the donor hospital.
- Apply bypasses only to isolated pancreas candidates.
- Bypass all candidates at non-facilitated programs.
    - Due to classifications, high CPRA and 0ABDR candidates are not bypassed.
- Qualifying criteria: programs qualify if they have transplanted at least 2 pancreata from donor hospitals > 250NM from the program in the previous 2 years.

The Committee made recommended changes that went out as part of the Efficiency and Utilization Request for Feedback (RFF):

- OPOs and the OPTN are permitted to make FP offers if no pancreas offer has been accepted **5 hours** prior to the scheduled donor recovery surgery.
- Allow bypasses for **kidney-pancreas (KP) and pancreas** candidates.

- Bypass all candidates at non-facilitated programs, **regardless** of CPRA or ABDR mismatch level.
- Qualifying criteria: programs qualify if they have transplanted at least **4** pancreata from donor hospitals **> 250NM** from the program in the previous 2 years.

Summary of discussion:

No decisions made, the Committee discussed at length and will continue reviewing the feedback.

The proposed changes received public support, but there were concerns raised. One opposition was that bypassing patients at non-facilitated centers could result in unequal access to donor organs, disadvantaging waitlisted patients at those centers who need a pancreas transplant. Comments focused on the qualifying criteria, suggesting that raising the transplant requirement would decrease the number of facilitated programs. Some recommended further review of the current threshold of 2 transplants, as increasing the threshold to 4 could reduce the number of facilitated centers overall. The OPO perspective is that increasing the time and distance requirements for participation is not advisable.

The Chair opened the floor for Committee members to address the feedback. The Chair brought up that clarification of the Committees recommendations might help assuage some concerns relating to the window increasing from 3 to 5 hours for facilitated pancreas. A member brought up that Organ Procurement Organizations (OPOs) sometimes face challenges related to the recovery of pancreata, and so increasing the window of time can allow for more time to make arrangements as needed.

One member posed the question of how the current policy, based on available data, would be affected by the proposed change in transplant requirements. According to the data, under the existing policy, 46 programs qualify for facilitated pancreas transplantation. The Chair explained that, if the transplant requirement were increased to 4, the number of qualifying programs would decrease to 25% of the current total.

The member then sought clarification on a comment made during the public comment, suggesting that only 2-3 centers would meet the new qualification criteria. The Chair acknowledged that some of the comments received might indicate a misunderstanding of the proposed policy. This comment prompted a sense that not all stakeholders fully comprehended the changes under consideration.

A member expressed their support for the idea of increasing the transplant requirement, but voiced concerns about the limited number of programs that would meet the new criteria. They emphasized the importance of considering the geographical context of the country and how some centers might no longer be eligible due to the proposed changes. The member also discussed the potential impact on the transplantation scheduling, highlighting the possibility of a surge in transplants in certain months followed by periods of inactivity, with concerns about the 2-year qualification period being insufficient for some programs.

Another member sought to understand whether the critiques and concerns raised during the meeting represented the majority of the feedback or if there was more support for the policy change. Staff clarified that the critiques and concerns discussed during the meeting constituted the majority of the written comments received from stakeholders.

A member's next query focused on the data regarding centers that qualified for facilitated pancreas offers and their acceptance rates. They stressed the need to ensure that offers were made to centers that were likely to accept pancreas transplants, especially within the 250NM radius. A research staff member provided insight into the data, indicating that currently, nine transplant centers were participating in the facilitated pancreas program. They mentioned that there had been 300 match runs for facilitated pancreas, resulting in nine successful transplants.

One member then requested information about the geographic distribution of the qualifying centers to gain a better understanding of where facilitated pancreas centers were located. Another member echoed concerns related to the geographical distribution, particularly on the west coast, where fewer centers might meet the eligibility criteria due to the increased distance from donor organs.

The Chair suggested extending the qualification period beyond the existing 2-year timeframe, potentially considering a 3-year qualification period. It was reasoned that a longer qualification period could address concerns about limited time for programs to meet the criteria. In response, a member underlined the Committee's reasoning of increasing the transplant requirement from 2 to 4, emphasizing that it was intended to ensure that offers were made to centers with a higher likelihood of accepting pancreas transplants and to minimize the non-use of donor organs.

The Chair explained that the facilitated pancreas program would only come into effect after local centers had responded to the offers. They clarified that facilitated pancreas allocation is not permitted until local centers had the opportunity to accept or decline offers (as outlined in policy), adding that this approach could be advantageous for programs with limited local access to pancreas transplants. The Chair also highlighted the potential benefits of facilitated pancreas for programs in regions with limited pancreas transplant activity.

A member commented that most decisions regarding pancreas transplantation were influenced by the visual assessment of the pancreas. They explained that centers typically made decisions once they had seen the organ, if located outside the 250NM radius.

The discussion then delved into the efficiency and logistics of the pancreas transplantation process, with a particular emphasis on the balance between inclusivity and efficiency. A member explained the importance of identifying target centers for pancreas transplantation and the challenges related to organ placement. It was inquired about the nine centers that had accepted transplants under the current policy, suggesting that perhaps their aggressive approach had influenced their high acceptance rates. Further discussion on this topic had members raising concerns about the potential impact of increasing the requirement from 2 to 4 on program acceptance rates, highlighting that it might be more a question of program behavior than the criteria themselves. It was proposed that reducing the number of phone calls to centers might increase the acceptance rate. A member emphasized the importance of geographical inclusivity, ensuring that aggressive transplant programs were available across the country.

Another member clarified that the 9 programs (according to the available OPTN data) that had accepted transplants were based on the previous policy, which required a 3-hour travel radius. Increasing the travel radius to 5 hours could potentially lead to more centers meeting the criteria. There was some agreement amongst the members that this could have such an impact.

One member pointed out that the discussion about geographic disparities was not unique to this policy and had been an issue in organ allocation for a long time. They emphasized the importance of identifying centers that could accept the organs and highlighted the logistics of getting the pancreas to the right center.

The Chair emphasized the potential benefits of reducing the number of centers that the OPOs needed to contact outside the 250NM radius. This could streamline the process and facilitate quicker pancreas placements. They pointed out that some centers already reached out to inquire about organ acceptance. One member proposed a change in the eligibility criteria, allowing centers to apply for changes more frequently and consider a longer timeframe for meeting the required number of transplants. The Chair concurred, recommending that perhaps annual reviews could be beneficial for this policy change.

Next steps:

The Committee agreed to conduct further discussions on the proposed changes to policy, specifically the qualification criteria and the 2 vs. 4 pancreata transplantation requirement.

Released Organs

No decisions made, the Committee discussed at length and will continue reviewing the feedback.

Summary of Discussion:

The Committee recommended to maintain current OPTN policy for released organs and as such little feedback on this portion of the RFF.

There was mostly public comment support for this with most comments relating to kidney on this topic. Some feedback recommended to track organ releases by center and report that data out. A member asked if it was possible to track this data. A research staff member that some of this data was reported on the DSA Circles Monitoring Report, highlighting that there has been few pancreata released via this policy, 6 over the past 2 years.

Next steps:

The Committee will continue reviewing feedback and finalize their recommendation as the project continues to develop.

Mandatory Kidney Pancreas (KP)

No decisions made, the Committee discussed at length and will continue reviewing the feedback.

The Committee recommended transitioning the classification-based threshold to a composite allocation score (CAS) threshold. The Committee will review data/continue discussions in the future to determine specific CAS after weights for the final policy proposal are determined as well as other characteristics that should be considered within the mandatory KP offer threshold. The Committee agreed to maintain candidate profile for the candidate profile for KP sharing to mirror current policy (candidates within 250NM).

The Committee received significant public comment feedback regarding Multi-Organ Transplants (MOT). Recommendations surfaced proposing that Kidney-Pancreas (KP) transplants should encompass other organs with mandatory sharing. The Pediatric and Pancreas communities advocated strongly for the principle that only one kidney should accompany any double organ combination. Additionally, public concerns were raised about the potential consequences of mandatory KP sharing, including possible delays in kidney allocation and disruptions to pancreas recovery. Addressing logistical issues, there was a call for emphasizing local placement for pancreas transplants. The idea of utilizing efficiency matching to prioritize patients closer to the hospital was also voiced.

To enhance priority consideration with KP, a suggestion was made to incorporate the median wait-list waiting time. This recommendation is aimed at optimizing efficiency and ensuring that patients in proximity to the hospital receive prompt attention.

The Committee discussed the current KP policy and the potential transition into a CAS. The Chair sought clarification on the current policy and the decision-making process for KP patients beyond 250NM, emphasizing the 250NM distance threshold for OPOs to couple and decouple KP allocation. Staff

confirmed the current process but noted the need for determining future thresholds using CAS instead of a classification-based decision tree. It was also explained that current policy allows decoupling of KP after 250NM, contingent on meeting specific criteria. Research staff highlighted the challenge posed by the absence of a hard boundary in distance with CAS, especially for candidates near the end of a match run within 100NM. A member inquired about the allocation process for Heart-Kidney and Liver-Kidney, questioning whether CAS or absolute radius was used. A staff member explained there is ongoing exploration of CAS for Liver-Kidney and Heart-Kidney.

One member raised a point about the potential scoring conflicts between KP and Kidney alone patients. The Chair suggested awaiting the implementation of a future iteration of the Kidney classification system to address these concerns. A member asked about the shift from a distance cutoff to a CAS cutoff, prompting discussions on determining future CAS cutoffs.

Another member suggested extending the uncoupling distance to 500NM to avoid discarding pancreases traveling long distances. The Chair suggested using the MIT sensitivity score to assess patient distribution around 250NM. A staff member explained the algorithmic approach to calculating scores, considering a subset of patients and marrying CAS with the current policy. A member raised concerns about using proximity efficiency in CAS, complicating the determination of the 500NM cutoff.

A staff member shared insights from lung transplantation data, emphasizing the multifaceted considerations in CAS beyond distance.

Next steps:

The Committee will continue discussions about transitioning the current policy to CAS, addressing distance thresholds, and ensuring a seamless integration of the new system.

2. Multi-Organ Transplantation Committee Update

The Committee received updates about the Multi-Organ Transplantation (MOT) Committee discussion.

No decisions made, the Committee discussed at length and the Chair will return to the MOT with the Committees feedback.

The Chair raised a question to the Committee about the allocation of Kidney-Pancreas (KP) transplants, specifically discussing whether KP should maintain its historical priority due to higher mortality. Some members expressed concerns about potentially categorizing KP patients with Multi-Organ Transplants (MOT), emphasizing the urgency of identifying high-mortality KP patients.

One member pointed out that KP patients might not always be the sickest, highlighting the complex decision-making involved. Another member suggested that while pediatric patients already receive substantial priority, extreme situations could warrant a case-by-case review. Concerns were raised about potential conflicts between prioritizing pediatric patients and the historical mortality data of KP patients. The Chair urged caution in defining "sicker" KP and pediatric patients, considering the subjective nature of such assessments. One member advocated for prioritizing pediatric patients, emphasizing historical practices due to their unique needs beyond medical considerations. The Chair acknowledged the Pediatric Committee's viewpoint and proposed exploring a threshold for pediatric priority.

Another member cautioned against prioritizing pediatric patients first, suggesting it might lead to longer wait times for KP patients. Other members agreed that such prioritization could increase pancreas non-use rates. One member suggested separating simultaneous pancreas-kidney (SPK) cases based on

diabetes type, and the Vice Chair emphasized the need to keep pancreas separate from kidney allocation due to potential complications.

The Committee leaned towards maintaining KP priority, considering the concerns raised by the Pediatric committee. Members agreed on focusing on allocation and utilization rather than determining who is "sicker." Another member added that MOT candidates may not need inclusion in KDPI less than 35%.

Next steps:

The Committee expressed a preference for not including KP in the MOT list, maintaining KP priority over pediatric patients, and avoiding stratification based on sickness but focusing on utilization. The Chair will be bringing this feedback back to the MOT Committee at their next meeting.

3. Update: OPTN Task Force on Efficiency

The Committee discussed their thoughts on efficiency and how to promote utilization in pancreas transplant and the transplant system in general.

No decisions made, the Committee discussed at length and decided on different items to prioritize in future discussions on efficiency. These items include increasing the number of credentialed pancreata recovery surgeons, logistics of transporting organs, one year graft survival outcomes, and offer filters for pancreas and kidney-pancreas.

Members acknowledged the difficulty in recovery pancreata as there is a lack of qualified pancreas recovery surgeons.

A member pointed out that while much of the concerns were considered in the Continuous Distribution (CD) work, logistical aspects such as resources, manpower, and equipment still posed challenges. One member shared observations from a regional meeting, noting a vocal resistance to prioritizing pancreas transplantation in the broader community, emphasizing the need for better understanding of the vital role pancreas transplants play, especially in addressing hypoglycemic unawareness.

Another member identified what seemed to be an apathy issue within the transplantation community, emphasizing the responsibility to train more fellows proficient in pancreas recovery surgeries. Members agreed with this sentiment, with the discussion leaned towards addressing this by intentionally training surgeons to recover all abdominal organs, including the pancreas.

A member brought up the impact of donor recovery centers on cold ischemia time, suggesting that localizing transplantations could enhance efficiency. The Chair expressed support for the move toward recovery centers, acknowledging both positive and potential challenges.

One member emphasized the need to consider poor graft function and longer hospital stays when discussing organ pumps and the potential increase in cold ischemia time. This concern also affects other organs and staff suggested forwarding information on these aspects to the Expeditious TaskForce for consideration.

The Committee also discussed issues surrounding the allocation change, including concerns about the efficiency of allocation leading to higher discard rates. Members considered various factors contributing to these challenges, such as longer cold ischemia times, increasing delayed graft function (DGF), and the impact of focusing on allocation efficiency. The Chair highlighted instances where the pancreas might be sacrificed for the liver or vice versa due to conflicts of interest, prompting a member to share the concerns raised by surgeons regarding insufficient vessels for pancreas recovery.

Another member raised the potential contradiction in encouraging local recovery centers while also considering the utilization of marginal kidneys. Additionally, the shift in outcomes with increased DGF since the allocation change was emphasized. A member suggested focusing on the data related to one-year graft survival outcomes and the impact of changes in allocation. The Chair proposed concentrating on reducing cold time to improve DGF. The inefficiency of current offer filters for pancreas and kidney-pancreas transplants was highlighted, emphasizing the need for more precise and effective filters.

Ultimately, the Committee expressed a consensus on the need for more granular data on factors contributing to cold time and the necessity of addressing logistical challenges, especially in the procurement and recovery processes for pancreas transplantation.

Next steps:

Staff will ensure that the Committee ideas are recorded and relayed to the TaskForce. The Committee will continue discussing these items on future calls as well.

Upcoming Meetings

- November 6, 2023 (Teleconference)
- December 11, 2023 (Teleconference)

Attendance

- **Committee Members**
  - Todd Pesavento
  - Oyedolamu Olaitan
  - Dean Kim
  - Asif Sharffudin
  - Ty Dunn
  - Girish Mour
  - Mallory Boomsma
  - Neeraj Singh
  - Shehzad Rehman
  - Colleen Jay
  - Diane Cibrik
  - William Asch
  - Nikole Neidlinger
  - Jessica Yokubeak
  - Muhammad Yaqub
  - Rupi Sodhi
  - Rachel Allen
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Jon Miller
  - Bryn Thompson
  - Raja Kandaswamy
  - Peter Stock
- **UNOS Staff**
  - Joann White
  - Cole Fox
  - Stryker-Ann Vosteen
  - Sarah Booker
  - Laura Schmitt
  - Kristina Hogan
  - Carlos Martinez
  - James Alcorn