OPTN Pancreas Transplantation Committee
Meeting Summary
March 3, 2025
Conference Call

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

Introduction

The OPTN Pancreas Transplantation Committee (the Committee) met via Cisco Webex teleconference on 03/03/2025 to discuss the following agenda items:

1. Welcome and Updates
2. Public Comment Presentation: Establish Multi-Organ Allocation Policy Request for Feedback
3. Public Comment Presentation: Continuous Distribution of Kidneys Update
4. Waiting Time Modification Request Review

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

1. Welcome and Updates

The Committee was informed that the in-person meeting originally scheduled for April 7th in Detroit has now been moved to virtual. The Committee will receive updated invites shortly.

2. Public Comment Presentation: Establish Multi-Organ Allocation Policy Request for Feedback

A representative from the OPTN Multi-Organ Transplantation (MOT) Committee presented their request for feedback on proposed allocation tables for multi-organ allocation.

Summary of presentation:

Currently, no clear policy directs OPOs on how to prioritize organs for different candidates, leading to inconsistencies. The proposal, set for public comment in summer 2025 and potential approval by year-end, introduces multi-organ allocation tables to create a structured, transparent framework.

Key Decisions and Considerations:

- Prioritization Factors:
  - Medical urgency (e.g., Status 1A liver > Status 1 heart due to lack of support devices).
  - Access to transplant (e.g., highly sensitized kidney candidates given priority).
  - Organ utilization (e.g., ensuring pancreas recipients have access to kidneys when needed).
- Allocation Table Framework:
  - Tables categorize donors by age, donation type (DBD/DCD), and kidney quality (KDPI).
  - Orders organ allocation systematically across all organ match runs.
  - Continuous distribution integration is planned for future updates.

- Policy Impact:
    - Standardized approach reduces OPO variation and improves efficiency.
    - Ensures equitable organ distribution without disadvantaging single-organ candidates.
    - Does not yet include high KDPI donors or some DCD donors, but further refinements are expected.

Summary of discussion:

The Committee will submit a public comment response.

The Chair highlighted their concerns that a classification shift for donors age 11-17, KDPI 0-34% shifted Kidney Class 6 candidates (registered prior to 18 years old, 250 nautical miles) ahead of pancreas candidates Classification 4, meanwhile, this category of donors makes up around 50% of pancreas donors. They highlighted that this could have a significant impact on pancreas candidates.

A member questioned how allocation distinguishes between pancreas-alone and kidney-pancreas (KP) offers. It was clarified that existing organ-specific match runs remain unchanged and will be followed according to policy, these tables simply indicate levels of prioritization that OPOs will follow.

Another member queried whether simulation models had been used to determine these tables. Additionally, though medical urgency was cited as a factor, they wondered where other factors such as access, time to offer, and efficiency featured in the proposed tables. It was confirmed that no simulation modeling had been run, historical data was used to develop these tables. It was also acknowledged that a simulation model could be a potential outcome of this public comment period, though there could be some technical or timing challenges. The presenter emphasized that allocation was structured around medical urgency, access, difficult populations, and organ utilization, with the system itself aims to balance efficiency and equity.

A member asked how prioritization might change for a KP patient with medical urgency compared to a routine KP patient. The presenter indicated that without special designation, the system will not differentiate, so they are unsure how pancreas allocation might change. It was affirmed that though currently there is no pancreas medical urgency, it is in the works and will be implemented with continuous distribution. The presenter highlighted that cutoff points would need to be established, similar to how the Lung Committee developed thresholds.

A member indicated that in cases like liver-kidney or heart-kidney allocation, mortality comparisons can be misleading. The primary organ (e.g., heart or liver) is life-saving, while the kidney provides incremental survival improvement rather than a drastic difference. The MOT presenter acknowledged this concern, explaining that eligibility criteria for multi-organ listing play a key role in addressing such issues, rather than the proposed system itself. The member reiterated that the discussion should distinguish between receiving the primary organ alone versus receiving both.

A member queried whether there was data on the number of kidneys allocated with hearts and livers and whether it was known how many pancreata were left un-utilized. It was indicated that the largest affected groups were liver-kidney, simultaneous pancreas kidney (SPK), and pancreas only patients that

saw the greatest impact from these allocation table changes, with heart-kidney seeing fewer changes to allocation by comparison.

Next steps:

The Committee feedback will be summarized and submitted as a public comment response.

3. Public Comment Presentation: Continuous Distribution of Kidneys Update

The Chair of the OPTN Kidney Transplantation Committee presented the update on Kidney CD and the Kidney Committee's work on developing a definition of hard-to-place kidneys and kidney expedited placement policy.

Summary of presentation:

The update provides a status report on the Continuous Distribution (CD) of kidneys, focusing on efficiency, non-use modeling, and policy development. Key efforts include defining hard-to-place kidneys, improving expedited placement pathways, and ensuring alignment with the OPTN Board of Directors' goals (non-use reduction, allocation efficiency, and expedited placement).

In February 2024, the committee requested the Scientific Registry of Transplant Recipients (SRTR) to evaluate the feasibility of incorporating non-use and efficiency metrics into the OASIM (Organ Allocation Simulation Model).

- Key non-use and efficiency metrics being analyzed include:
    - Utilization rates of deceased donor kidneys.
    - Timing and sequence number at organ acceptance.
    - Cold ischemic time (CIT) and its impact on kidney function.
    - Equity and access metrics, particularly for recipients of high KDPI (Kidney Donor Profile Index) kidneys and those identified as hard-to-place.

In November 2024, the SRTR successfully modeled non-use factors alongside previously requested equity, access, and outcomes metrics. The partners at MIT are now working to incorporate these non-use models into the optimization process for continuous distribution.

The committee is also developing a data-driven definition for kidneys that are at higher risk of non-use, aiming to establish an evidence-based standard for allocation adjustments. A multi-pronged approach is being used, combining:

- Pre-recovery (predictive) criteria – to anticipate potential non-use risks.
- Post-recovery (identified) criteria – to classify kidneys in real-time during allocation.

Key proposed criteria for defining hard-to-place kidneys include:

- KDPI ≥ 50% (Kidneys with a higher KDPI are generally less desirable and more likely to be discarded).
- Cold ischemia time ≥ 6 hours (Longer storage times reduce viability).
- Sequence number ≥ 100 (Organs that have been declined multiple times).
- Donor factors:
    - Hypertension history > 5 years

- Age > 60 years
- Diabetes > 5 years
- Donation after circulatory death (DCD)
- Glomerulosclerosis > 10% on at least one biopsy
- Use of continuous renal replacement therapy (CRRT) before donation

These criteria will help identify kidneys that require special allocation pathways to increase utilization.

The committee is refining this definition by analyzing historical data and reviewing real-world allocation thresholds. There is recognition that adjustments to criteria may be made based on further data reviews and public comment feedback. The goal is to ensure efficient and equitable allocation while reducing organ non-use and improving transplant outcomes. This work will inform the kidney expedited placement project that being revisited following previously paused work on the variance policy. The committee is now pursuing a national kidney expedited placement policy within the current system, with modifications planned for CD integration. Public feedback is being solicited on the hard-to-place kidney criteria, expedited placement participation, and efficiency improvements for kidney allocation.

Summary of discussion:

The Committee will submit a public comment response.

The Chair asked whether the Kidney Committee would consider including pediatric en bloc kidneys as a predictive factor due to their longer cold ischemic times and varying acceptance rates. Additionally, the Chair proposed using AI to predict donor-recipient matches based on historical data. This idea was met with support but acknowledged as a complex task.

Concerns were raised about the recent OPTN letter in response to a New York Times article on out-of-sequence allocation. The article focused on KDPI, but it was noted that KDPI alone is an imperfect predictor of hard-to-place kidneys. Members stressed the need for a standardized definition and pathway for hard-to-place kidneys to enhance transparency and consistency. The importance of tracking out-of-sequence allocations and improving decision-making transparency was highlighted as a response to criticisms of organ allocation practices.

A member sought clarification on whether meeting just one criterion, such as a KDPI greater than or equal to 50%, would be sufficient, or if multiple factors would be required. It was noted that the Kidney Committee found a high non-use rate for kidneys meeting two or more criteria, particularly when KDPI exceeded 75-85%. However, the Kidney Committee is seeking public input before finalizing the approach.

Concerns were also raised about the lack of standardization in how OPOs allocate hard-to-place kidneys. Currently, OPOs often favor programs based on relationships rather than proximity. There was broad agreement that a standardized allocation process would improve fairness and transparency.

Another member inquired about including pump parameters in the criteria and sought clarification on the definition of cold ischemia time. It was explained that not all OPOs use pumps, and their impact on allocation is still under discussion. It was offered by the Kidney Chair that regarding cold ischemia time, a six-hour threshold was identified as critical, based on data showing that non-use rates increase after this period. This time is measured post-cross-clamp, not at the time of offer. Additionally, while non-use rates significantly rise when glomerulosclerosis (GS) exceeds 20%, the Kidney Committee's focus is on identifying kidneys that are difficult to place, rather than those unlikely to be used at all.

A member raised a concern that glomerulosclerosis might not be as important as vascular disease, as kidneys with significant vascular disease are often declined due to poor outcomes. This concern was acknowledged, with the Kidney Chair noting that other criteria could be considered and that some biopsy findings were already excluded.

The Vice Chair expressed concerns about using a KDPI cutoff of 50%, as many of the factors contributing to KDPI are already included in the proposed criteria. They suggested that this threshold might be counterproductive, as some kidneys with a KDPI less than 50% are also hard to place. It was recommended that multiple factors be considered, rather than relying solely on KDPI. The Vice Chair also raised concerns about the six-hour cold ischemia time threshold, noting that variability between OPOs—such as waiting for pump numbers and biopsy results—could lead to inconsistent practices. It was suggested that weight-on-sequence or other factors might require further consideration to address these issues.

The Kidney Chair acknowledged these concerns and emphasized the need for rules to ensure consistency. They clarified that the six-hour cold ischemia time was based on the availability of information and its transmission to centers. Regarding KDPI, they explained that the 50% threshold was based on data showing a high non-use rate for kidneys with a KDPI over 75%. However, it was agreed that additional factors could be considered for kidneys with a KDPI under 50%, and the committee would continue to explore this possibility.

Next steps:

The Committee will submit a public comment response.

4. Waiting Time Modification Request Review

The Committee reviewed a centers request for their patient to receive backdated waiting time for a pancreas alone listing.

Summary of presentation:

The Committee reviewed a request to modify the waiting time for a patient who was mistakenly listed for a kidney transplant instead of a pancreas-alone transplant in 2021 due to a clerical error. To prevent similar mistakes in the future, the transplant center implemented a corrective action plan requiring a two-person verification process for both initial listings and status changes. The request before the committee sought to retroactively adjust the patient's waiting time for pancreas-alone listing to reflect the original intended listing date.

Summary of discussion:

The Committee agrees with the patient receiving the backdated time for the pancreas alone listing and offered additional suggestions to the transplant center regarding their documentation.

Some members expressed concerns about inconsistencies in the documentation. It was noted that the patient had end-stage renal disease (ESRD) and type 1 diabetes, making them eligible for a simultaneous kidney-pancreas (SPK) transplant. However, the request focused solely on pancreas-alone listing, raising questions about why SPK had not been considered at the time. Some members speculated that ESRD may have been mistakenly included due to the use of a templated document, rather than being an accurate reflection of the patient's condition. Others pointed out conflicting information regarding dialysis, with some records indicating that the patient tolerated dialysis well, while a later note suggested the opposite.

The committee also debated the potential implications of approving the request. A key concern was whether the patient had already received a kidney transplant—either from a living or deceased donor—which could affect the fairness of granting retroactive waiting time for pancreas-alone listing. If the patient had already undergone kidney transplantation, members cautioned that granting backdated waiting time for pancreas-alone status could be perceived as gaming the system. The Committee considered whether additional information was needed, however, it was confirmed that a prior transplant would have been documented.

Some members suggested asking the transplant center whether they intended to request backdated waiting time for SPK rather than just pancreas-alone, given the patient's clinical profile. Others noted that while the pancreas-alone backdating request seemed reasonable on its own, future requests to also backdate a kidney listing could present fairness concerns.

Despite the documentation inconsistencies, there was broad support for approving the request to backdate pancreas-alone listing, provided the transplant center corrected any errors in the patient's records. The Committee emphasized that accurate documentation is essential to ensuring fairness and transparency in the transplant system.

Next steps:

Ultimately, the group agreed to move forward with a vote on the pancreas-alone waiting time adjustment while also offering the transplant center additional notes on how to improve documentation practices.

Upcoming Meetings

- April 7, 2025

Attendance

- **Committee Members**
  - Asif Sharfuddin
  - Colleen Jay
  - Diane Cibirk
  - Dean Kim
  - Mallory Boomsma
  - Muhammad Yaqub
  - Neeraj Singh
  - Oyedolamu Olaitan
  - Piotr Witkowski
  - Shehzad Rehman
  - Stephanie Arocho
  - Girish Mour
  - Todd Pesavento
  - Ty Dunn
- **HRSA Representatives**
  - Marilyn Levi
- **SRTR Representatives**
  - Bryn Thompson
  - Jon Miller
  - Peter Stock
  - Raja Kandaswamy
- **UNOS Staff**
  - Stryker-Ann Vosteen
  - Dzhuliyana Handarova
  - Carly Rhyne
  - Kaitlin Swanner
  - Keighly Bradbrook
  - Asma Ali
- **Other attendees:**
  - Chris Sonnenday
  - Jim Kim