

Meeting Summary

OPTN Pancreas Transplantation Committee Meeting Summary July 8, 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 07/08/2025 to discuss the following agenda items:

- 1. Welcome and updates
- 2. Allocation out of sequence
- 3. Community concerns & potential new projects

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

1. Welcome and updates

OPTN Contractor staff (staff) shared the update regarding the temporary pause to continuous distribution (CD) due to concerns of allocation out of sequence (AOOS) and the impact CD could have on AOOS.

Summary of discussion:

No discussion.

2. Allocation out of sequence

Staff presented information available on allocation out of sequence and the critical comments and subsequent directives from HRSA regarding addressing this concern.

Summary of presentation:

In August 2024, the OPTN received a critical comment letter and data request regarding allocation out of sequence. From September 2024 to February 2025, HRSA and the OPTN discussed necessary relevant information needed. March 2025, the OPTN submitted a draft plan for allocation out of sequence and this plan is currently under review by HRSA.

In May, efforts expanded to include website development, member compliance assessments, and promotion of awareness and policy adherence. In June the OPTN submitted an analytical and operational definition which HRSA accepted and was published to the webpage.

Operational definition: AOOS is when an organ is offered or accepted or transplanted into a transplant candidate or potential transplant recipient (PTR) that deviates from the match sequence and is not consistent with OPTN policy.

Analytical definition: AOOS is identified through the use of one or more of the following organ offer bypass codes:

- **861:** Operational Organ Procurement Organization (OPO)
- **862:** Donor medical urgency
- 863: Offer not made due to expedited placement attempt
- 887: Not Offered expedited placement
- **799:** Other (specify)

The Committee was provided clarification that the bypass code for facilitated pancreas is not included in the analytical definition and do not currently fall under the definition of AOOS.

Summary of discussion:

No decisions made.

The Chair proposed requesting data on the regional breakdown of allocation out of sequence (AOOS) to assess whether significant differences exist across regions. While uncertain about the prevalence of AOOS in pancreas transplantation, the Chair emphasized the need for more data and deeper analysis.

A committee member asked for clarification on whether kidney transplantation has ceased all instances of AOOS or if the focus is on gathering additional data to better understand the issue. Staff responded that, ideally, allocations that deviate from the established allocation plan should not occur. They noted that the OPTN Kidney Committee is currently developing an expedited kidney placement policy to address concerns related to AOOS in kidney transplantation. Staff also confirmed that data analysis is still underway.

Another member commented that kidneys are often allocated out of sequence due to concerns about potential non-utilization. They highlighted the role of facilitated pancreas allocation in placing non-ideal or complex organs with transplant centers equipped to use them appropriately, suggesting that AOOS may serve a similar purpose. While acknowledging the potential for misuse, the member stressed that comprehensive data collection is essential to fully understand the scope of the issue.

The Chair agreed that it is important to distinguish between facilitated pancreas allocation and AOOS in pancreas transplantation. Other members expressed support for this distinction. One member asked whether the committee is expected to provide specific feedback on AOOS in pancreas transplantation at this time or comment more broadly on the allocation process. Staff clarified that this is an initial discussion and no formal feedback is required at this stage. The goal is to identify potential projects the Committee may wish to pursue.

The Chair reiterated that once the requested AOOS data becomes available, the Committee will be able to conduct further evaluations. Staff added that the OPTN Data Advisory Committee (DAC) and the Membership and Professional Standards Committee (MPSC) will be responsible for collecting and reviewing the data.

A committee member asked whether pancreas-alone transplants fall under the scope of AOOS, or if simultaneous pancreas-kidney (SPK) transplants are also included. Staff clarified that facilitated pancreas transplants are not considered AOOS, as the bypass code associated with facilitated pancreas was excluded from the analytical definition. When the data is compiled and reviewed, instances involving the facilitated pancreas bypass code can be separated out, allowing for potential identification of AOOS in pancreas transplantation.

The Vice Chair suggested that framing new project discussions through the lens of AOOS could be beneficial, noting that projects aligned with AOOS-related efforts may have a greater chance of advancing. The Chair agreed, indicating that initiatives connected to AOOS should be prioritized. The

Vice Chair also shared the view that AOOS may not be a major issue in pancreas transplantation, but emphasized that data will provide a clearer picture.

Another member recommended analyzing AOOS beyond the regional level, suggesting that evaluations at the OPO and transplant center levels could offer more insight. They also stressed the importance of distinguishing facilitated pancreas offers from AOOS to avoid confusion in the analysis. The member asked what steps would follow if the data revealed significant AOOS activity in pancreas transplantation. Staff explained that, according to the OPTN plan submitted to Health Resources and Services Administration (HRSA), the initial data review, based on the analytical definition, will be conducted by the MPSC and DAC. Once HRSA approves the plan, the next phase of data review can begin.

Another member raised the question of whether the committee already knows what data will be collected or if specific requests should be made. Staff responded that while the OPTN plan outlines areas for further review and research, the committee is encouraged to flag any pancreas-specific data elements that DAC and MPSC may not be aware of.

A member reiterated the importance of examining AOOS at the OPO level and questioned whether AOOS is inherently problematic. They noted that while misuse is possible, AOOS might also contribute to improved center performance. The member suggested correlating AOOS activity with OPO performance tiers, though acknowledged that such data may not be available in the OPTN Computer System. They also proposed examining how OPOs manage aggressive center lists, noting that variation and limited oversight likely exist. They added that aggressive centers might be inferred by identifying those that consistently receive out-of-sequence offers.

The Chair referenced kidney data from the OPTN AOOS site, which indicated that AOOS did not improve organ utilization. The member questioned the control group used in that analysis, suggesting that if an organ is not allocated out of sequence, its discard rate would be 100%, making any utilization preferable. They shared findings from their own center, where out-of-sequence recipients tended to be older, had less dialysis exposure, and were more likely to be preemptive transplant candidates. They also observed increased access among non-white recipients. While acknowledging that the system should ideally function without workarounds, the member noted that positive outcomes can still emerge from a flawed process.

The Chair expressed agreement and surprise at the OPTN AOOS site's conclusion that AOOS does not improve utilization. Another member added that the HRSA-referenced paper is informative and reflects similar demographic patterns, such as age and preemptive status, as previously discussed.

A representative from the Scientific Registry of Transplant Recipients (SRTR) emphasized the importance of understanding the scope and frequency of AOOS in pancreas transplantation. While noting that their perspective was personal, they suggested AOOS may offer benefits in certain pancreas cases. They recommended that specific nuances be communicated to the MPSC and others involved in data review. For example, they pointed out that pancreas transplant wait times are generally shorter than those for kidney, which may reduce the impact of AOOS in this context.

The representative highlighted the need to examine cases that fall just outside the facilitated pancreas policy window, typically in the 4 to 8-hour range, as distinct from those occurring much earlier, such as 24 hours before procurement. They noted that if most AOOS cases cluster within that narrower time frame, it may represent a different issue than broader deviations. Another nuance they raised involves the pancreas-alone list: when no kidney is available for a kidney-pancreas (KP) transplant, a bypass code allows allocation to a pancreas-alone candidate, which is not considered AOOS. However, if a kidney is technically available but deemed poor quality and bypass codes are used to skip KP candidates, that may

warrant further scrutiny. These distinctions, they noted, are specific to pancreas and should be considered during data analysis.

The Vice Chair shared a prior experience in which their center's top-ranked KP candidate did not receive an offer, while the second-ranked pancreas-alone candidate did. The OPO indicated that a bypass code would be used due to the absence of a kidney, which was allocated for a planned multivisceral transplant. The Vice Chair noted that such situations can be confusing, especially in the critical hours before and after allocation, and suggested that the facilitated pancreas model might be worth expanding.

The SRTR representative agreed that the facilitated pancreas policy was a positive initiative and that demonstrating its effectiveness would be valuable. They expressed disagreement with HRSA's assertion that AOOS does not improve utilization, citing the lack of a control group to support such a conclusion. They noted that randomized allocation would be necessary to validate that claim. Additionally, they cautioned against conducting center-level data reviews prematurely, as such data becomes public once published and could have significant implications. They recommended treating center-level analysis as a secondary step.

The Vice Chair asked whether the forthcoming data review could help inform potential changes to the current offer limit policy. The Chair responded that this presents an opportunity to finalize the committee's work on facilitated pancreas. They suggested it would be helpful for HRSA to review the data in collaboration with the committee. The Chair also supported a previously raised idea to compare OPOs that utilize AOOS—specifically facilitated pancreas—with those that take a more conservative approach, to assess differences in utilization. They agreed that examining OPO-level data and analyzing the use of bypass codes for both facilitated pancreas and KP bypass scenarios are critical to understanding the broader implications of AOOS.

Next steps:

The Committee will continue discussions regarding AOOS, the Committee will also discuss potential new projects that could align with the AOOS initiative.

3. Community concerns & potential new projects

The Committee heard a community concern and briefly discussed potential new projects but ran short of time to have an in depth discussion regarding prioritizing projects.

Summary of presentation:

A community concern had been recently submitted regarding vessel sharing and vessel splitting. The community member detailed a recent issue involving a multi-organ procurement intended for a liver split where a simultaneous pancreas-kidney offer was also accepted. The plan agreed upon prior to procurement designated which team would take which arteries, however, at procurement, the left liver team requested one of the iliac vessels which the right liver team maintained their claim on the other iliac vessel. This left the pancreas without the necessary iliac vessel.

Another issue detailed included concerns about aberrant right hepatic arteries, where a pancreas transplant may be forfeited due to the liver taking priority. This puts pancreata at an increased risk of non-use and non-utilization.

It was noted there is currently no OPTN policy on vessel sharing or splitting. Potential next steps include requesting feedback from the broader community and sending memos to the Multi-Organ Transplantation and Liver & Intestine Committees to obtain their insight.

Staff shared a list of project ideas from before continuous distribution work was prioritized that could be reviewed again:

- Vessel sharing
- Pancreas offer filters (potentially tied to allocation out of sequence)
- Revision of Policy 3.6.B.2 (waiting time reinstatement for non-functional pancreas transplants)
- Efficiency improvements in pancreas procurement
- Waiting time modification for pancreas after kidney candidates
- Review of pancreas program membership requirements
- Revisions to the transplant recipient registration and follow-up forms
- Pancreas safety net

Summary of discussion:

No decisions made.

A representative for the SRTR suggested that vessel sharing in multi-organ transplants is solvable as there are plenty of vessels available. They acknowledged that aberrant right hepatic arteries is a different challenge requiring cooperation and problems arise when external liver teams are unfamiliar with pancreas needs. They highlighted that communication is key. The Vice Chair voiced their agreement that communication is critical. The Chair agreed that the vessel sharing should be easily resolved, as it is common practice for the pancreas to have priority for the internal and external iliac confluent (Y graft), and typically the liver and intestine teams need only a straight vessel. Should the liver team reject the pancreas teams need for the Y-graft, that is what policy can address. The Vice Chair added that this would align with promoted transparency and filling a recognized policy gap. They suggested that clear guidance would be beneficial for the OPO community.

A representative of the SRTR suggested examining a previous policy created a decade ago that addressed pancreata being sacrificed during an intestine procurement. They suggested revisiting that directive and considering similar guidelines for aberrant right hepatic arteries. The Chair agreed that even should the Committee not address the vessels concern right now, it is prudent to resolve as it could continue to recur.

The Chair suggested adding facilitated pancreas as a potential new project. The Chair also recommended for the following Committee call to review each of the project ideas in greater detail, so that the Committee can appropriately prioritize projects. Additionally, the Chair brought up another community concern regarding provisional yes and offer limits. Staff shared that there is no data currently available on how many pancreata or kidneys were affected by the offer limit policy change as they were not included in the post-monitoring report.

Next steps:

The Committee will continue their discussion on project prioritization and selection on the next Committee call. Staff will check to see if there is data available on concurrent pancreas offers or related to offer limits.

Upcoming Meetings

August 12, 2025

• September 9, 2025

Attendance

• Committee Members

- o Asif Sharfuddin
- o Colleen Jay
- o Diane Cibirk
- o Ty Dunn
- o Muhammad Yaqub
- o Neeraj Singh
- o Oyedolamu Olaitan
- o Stephanie Arocho
- o Rupi Sodhi
- o Todd Pesavento

• SRTR Representatives

- o Bryn Thompson
- o Peter Stock
- o Raja Kandaswamy

UNOS Staff

- o Stryker-Ann Vosteen
- o Dzhuliyana Handarova
- o Cole Fox
- o Lindsay Larkin
- o Ross Walton