OPTN Pancreas Transplantation Committee
Meeting Summary
August 12, 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 08/12/2025 to discuss the following agenda items:

1. Welcome and updates
2. OPTN Updates
3. New Project Discussion
4. Closing remarks

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

1. Welcome and updates

The Committee members discussed and briefly shared their recent experiences at World Transplant Congress 2025. OPTN Contractor staff (staff) shared that the meeting platform will be transitioned to Teams from Webex and to expect the updated meeting invites soon.

2. OPTN Updates

Staff shared updates regarding recent decisions impacting OPTN work.

Summary of presentation:

Staff updated the Committee on the new public comment dates of August 27 – October 1. Staff shared further information regarding critical comments sent to the OPTN and related directives from the Health Resources and Services Administration (HRSA).

Normothermic Regional Perfusion:

- HRSA directed the OPTN to develop a plan to propose policies, policy definitions, data collection, technical and quality standards, and standard practices that address patient safety for organ procurement organizations using NRP in patients from whom organs may be procured, and OPTN data collection regarding the attempted and/or successful use of NRP in patients from whom organs may be procured.

Donation after Circulatory Death (DCD) Policy Development:

- HRSA directed the OPTN to develop policies to improve safeguards for potential DCD patients and increase information shared with patient families regarding DCD organ procurement.
- OPTN Organ Procurement Organization (OPO) Committee leading development of proposed policies, utilizing work group with representatives from impacted stakeholders.

Rabies Transmission:

- HRSA directed the OPTN to propose improvements to policy to reduce the risk of donor-derived rabies.
- OPTN Disease Transmission Advisory Committee (DTAC) has reviewed relevant data with CDC and HRSA and is actively considering appropriate data and policy changes.

Allocation Out of Sequence (AOOS):

- HRSA directed the OPTN to:
    - Establish an AOOS Workgroup, with representatives from across the OPTN Committees, and associated RACI roles for Workgroup members.
    - Establish an execution plan to include finalized task list for the first 90-day project phase, including:
        - Evaluate member compliance in the aggregate by OPTN member and identify members with patterns and/or large volumes of AOOS. (MPSC)
        - Send notices and/or direction to members to mitigate non-compliance. (MPSC)
        - Send a notice to OPTN members highlighting applicable OPTN policies and definitions, including appropriate application of the wastage provision. (OPTN)
        - Develop an administrative definition for the "offer" of an organ by an OPO to a transplant center, including minimum requirements for notification and information accuracy. (AOOS Work Group)
        - Review OPTN policies for possible updates to the term “offer” and its related policies. (AOOS Work Group)

Staff informed the Committee that additional information is available on the OPTN website regarding all of these directives and initiatives. They also shared that a couple of Committee members are on the Workgroup that has been established by the OPTN Board of Directors contractor, American Institutes of Research (AIR).

Summary of discussion:

There were no decisions made.

A member asked whether the DCD policy development was in response to the New York Times article or whether this was work already in progress. Staff clarified that the OPO Committee had already begun developing policy changes regarding DCD and the HRSA directive builds on that and responds to various patient safety concerns that have arisen in the transplant community.

Another member added that they are also on the AOOS Workgroup, as a representative of the Veterans Affairs (VA) perspective. Other members expressed interest in hearing more updates from the workgroup members as the project progresses. A member asked the Committee whether it would be possible to gather opinions from other members as their center is not particularly aggressive nor have they seen reallocations occur frequently. One member requested staff to share previous facilitated pancreas policy discussions as those could inform their work on the AOOS workgroup. The Chair advised to continue the conversation during the next meeting.

Next steps:

Staff will share relevant information regarding facilitated pancreas to Workgroup participants.

3. New Project Discussion

Staff presented the current OPTN strategic goals and the Policy Oversight Committee (POC) benefit scoring process. Staff also shared brief details regarding each of the potential new projects. Project ideas being discussed include:

- Pancreas offer filters
- Vessel sharing and splitting
- Revise policy 3.6.B.ii
- Improving efficiency in pancreas procurement
- Waiting time modification for PAK candidates
- Review pancreas program membership requirements
- TRR and TRF form review and revision
- Pancreas safety net
- Facilitated pancreas
- Pancreas medical urgency

Summary of discussion:

No decisions made.

A member asked whether each of the POC scoring categories are weighted the same or differently. Staff clarified that each one is weighted differently, and together it all totals 100.

One member asked for clarification whether the Committee is required to focus on a particular project per direction from POC. Staff clarified that the project ideas being discussed are up for Committee decision on how they should be prioritized. Providing the additional insight of the strategic plan and how POC scores projects for benefit is to aid Committee members making informed decisions regarding which project to pursue. The Vice Chair added that there are many projects from which the Committee can choose, some in greater alignment with the strategic plan and POC benefit scoring than others. They highlighted that though it won't be possible to get everything done, it would make sense to focus on projects "that are more likely to succeed."

A member asked if there was a limit on how many projects the Committee could pursue at a time, as even with a ranking it would probably only be feasible to move forward with a few of them at a time. Staff clarified that it would depend on the nature of the project/s and the Committee's bandwidth as there is no formal limit, it depends on what can be accomplished during the once monthly meetings. The Vice Chair added that for a number of the projects, a bit of the work has already been completed on them, so it would be best to identify which projects align with goals and have a solid chance of being approved, so as to maximize impact.

The Vice Chair sought clarification on the formal process for a request for feedback and what would happen should they pursue that option for a project. Staff clarified a request for feedback is often seen as a precursor to policy or data collection, to solicit additional feedback from the community. The Vice Chair sought further detail as to why a request for feedback is preferrable to a guidance document, and staff clarified that guidance documents are not enforceable and therefore are not subject to monitoring by the Membership and Professional Standards Committee (MPSC) and OPTN.

The Vice Chair highlighted a project idea to update policy for waiting time modifications for pancreas-after-kidney (PAK) candidates as having strong alignment with the strategic goals. They voiced that patients who are not educated about pancreas transplant during kidney transplant evaluation would have to restart their waiting time after a kidney transplant. Additionally, providing candidates with a mechanism to preserve their pancreas waiting time, they will not be penalized for staying with their local kidney center. Another member agreed and expressed their support of the project idea.

Members discussed another project on developing a pancreas safety net that would prioritize candidates who have already received a pancreas and now need a kidney. A member stated they see these types of cases often, patients with glomerular filtration rates around 30, with Type 1 diabetes, and potentially even with a living donor lined up. The Chair agreed, voicing that this is a challenge, and pancreas-alone transplants (PTA) should also come with an assurance that if the kidney fails, then the patient will get priority for a kidney, like liver, heart, and lung recipients do. Another member shared their experience with a patient who had received a kidney-alone transplant and was being evaluated for a PAK, however there was concern that a PTA would push her into renal failure. They shared that because the candidate also does not qualify for a simultaneous pancreas-kidney transplant (SPK), they have listed them as status 7 to monitor their GFR. They voiced that "a safety net would have encouraged us to move forward more confidently."

A member emphasized that they viewed this more as a primary need, not a safety net, for candidates, "the pancreas is the priority, and if the GFR is 30, that should qualify for a kidney, just like it does for liver recipients with chronic renal failure." They agreed with needing to address this, stating pancreas policy should align with the other organ policies in this instance. The Vice Chair voiced their agreement as well, stating that with diabetes being a primary cause of kidney failure, the pancreas should also be prioritized. The Chair agreed, highlighting that a safety net policy would encourage pancreas transplants for patients with marginal kidney function. The Vice Chair also noted that it could be argued these are a vulnerable subset of pancreas candidates who might never get listed.

A member queried how the facilitated pancreas project idea is different from allocation out of sequence. Staff clarified that facilitated pancreas currently exists in policy and has a specific bypass code, one which does not fall under the technical or analytical definition of out of sequence allocation as defined and accepted by HRSA. The Vice Chair added that in current policy, the 3-hour pre-OR window when organ procurement organizations (OPOs) can begin making facilitated offers is very short, making it hard for centers to send teams in time for the procurement. They highlighted that this could lead to instances of non-utilization of pancreata and that extending the window to 5 hours as previously discussed by the Committee could salvage more pancreata. Additionally, they noted that it should not negatively impact local patients since the 250 nautical mile radius must first be exhausted before facilitated pancreas allocation can occur. They indicated that this would be a relatively simple project and might be a good focus of the Committee's time and efforts. The Chair voiced agreement stating that it would align with both allocation out of sequence concerns and strategic plan goals. They also noted that since the length of the CD pause is unknown, "it makes sense to pick a straightforward [project] that we can complete before [CD] work resumes."

The Chair asked how long it might take to finalize the medical urgency policy language and proposal as a whole and when it might be able to go to public comment. Staff advised that it might be a 7-8 month process yet as though the clinical portion has been finalized, the Pancreas Review Board would need to be finalized as would other specifics around the operationalization of the proposal and system enhancements, including possible data collection needs which would necessitate conversations with the OPTN Data Advisory Committee (DAC). The Vice-Chair added their sentiment that it would be beneficial

to have the medical urgency mechanism in place before CD work resumes, in addition, the project aligns with supporting vulnerable populations and they would be sad to see it left in limbo.

Next steps:

Staff will send out a project prioritization survey that all members can fill out to identify which projects to focus on.

4. Closing remarks

A member raised an issue regarding offer acceptance limits. They noted that under the current system, an OPO might move on from the provisional yes (PY) stage to offer acceptance before a final confirmation, thereby "locking" that candidate into the offer as the primary, and they can no longer be primary on any other offers. They highlighted that pancreas offers pre-OR are often filled with uncertainty, with a high chance of being told the organ is unusable; fatty, too firm, or cannot be split. The member articulated that it would be a disservice for a pancreas candidate, who has high priority as well, to be bypassed for other offers especially if the first one does not work out but that is known so late in the process. They indicated that "there should be no formal offer acceptance for pancreas pre-OR that disqualifies a patient from being primary on other offers, or the system should allow them to be primary on more than one offer."

Staff confirmed that the *Modify Organ Offer Acceptance Limit* policy which went into effect 5/29/2024 did reduce the number of concurrent offers from two to one. They noted that the first year post-implementation monitoring report did not include pancreas or kidney as the number of concurrent acceptances is extremely low. Additionally, during the development phase of the project, the OPTN OPO Committee was unable to find instances of pancreas or kidney concurrent offers. Staff sought clarification on whether there was a particular issue in distinguishing between provisional yes and formal offer acceptance or something further. The member clarified that their candidate had two possible offers and the next patient on the list was also at their center, however, the OPO informed the member that because the first candidate had accepted the offer they could no longer be primary for any other offers. The ORs ended up being delayed as well and the first pancreas ended up not being viable for the candidate, however, they were able to pivot since their 2nd candidate was next and so they were able to transplant a pancreas ultimately. They highlighted that if another center had had the 2nd place candidate, this would have prevented them from being able to transplant at all. The Vice Chair added that the timelines are often shifting and that the system seems to incentivize centers going after local donation after cardiac death (DCD) donors that look good, rather than a donation after brainstem death (DBD) candidate who might be further away, but when the second donor option ends up not being good, then nobody is able to get a pancreas and it could lead to non-utilization.

The Chair asked whether it would be possible to get access to the research the OPO Committee used to review it from a pancreas perspective, and that if DCD is being disadvantaged then that is worth exploring further. The member agreed and highlighted that there is a spectrum of sincerity when it comes to provisional yes'. Staff noted that there could be an opportunity to discuss these concerns with the OPO Committee leadership.

Next steps:

Staff will follow up on OPO leadership availability for further discussion on the concerns regarding provisional yes and organ offer acceptance limits.

Upcoming Meetings

- September 11, 2025

Attendance

- **Committee Members**
  - Asif Sharfuddin
  - Colleen Jay
  - David Lee
  - Diane Cibrik
  - Dean Kim
  - Jason Morton
  - Jessica Yokubeak
  - Mallory Boomsma-Kempf
  - Muhammad Yaqub
  - Patrick McGlone
  - Neeraj Singh
  - Oyedolamu Olaitan
  - Shehzad Rehman
  - Stephanie Arocho
  - Todd Pesavento
  - Ty Dunn
- **SRTR Representatives**
  - Bryn Thompson
  - Jon Miller
- **UNOS Staff**
  - Stryker-Ann Vosteen
  - Dzhuliyana Handarova
  - Lindsay Larkin
  - Asma Ali