

## **OPTN Pancreas Transplantation Committee**

### **Meeting Summary**

**January 6, 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 01/06/2025 to discuss the following agenda items:

1. Update: Pancreas Continuous Distribution Review and Next Steps
2. Update: Guidance Document Outline
3. Update: TRR and TRF Preliminary Evaluation

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

#### **1. Update: Pancreas Continuous Distribution Review and Next Steps**

The Committee received an update and a refresh on previous continuous distribution work and anticipated next steps.

##### Summary of presentation:

OPTN Contractor staff (staff) shared the previous work the Committee has done on continuous distribution and past updates sent out for public comment. The Committee was able to review previous attributes decided upon and the anticipated weights of those attributes given past modeling. The November 2024 update from the Scientific Registry of Transplant Recipients (SRTR) was shared again as well as their insights on future simulation modeling options for the Committee. The Committee was reinforced that the SRTR does not recommend simulation modeling for future attempts at pancreas allocation policy modeling, and recommends using different formats such as match run analysis. The OPTN Contractor research staff indicated that work is being done to develop a match run analysis dashboard to aid the Committee with this work and will be available in the spring of 2025.

##### Summary of discussion:

No decisions made, discussion only.

The Chair sought clarification on whether the SRTR meant for the Committee to no longer use simulation modeling at all for allocation policy modeling. Staff indicated that feedback from the SRTR at the time of the report was that it is feasible and adequate to build off the previous simulation modeling and attribute weights that reflect that modeling, however, future simulation modeling is not recommended. A member asked what the anticipated timeline is for the Continuous Distribution public comment. Staff shared the current tentative date of January 2026 public comment. It was highlighted that both the Kidney Committee and the Pancreas Committee would put out their documents together and this might have an impact on timelines.

Next steps:

The Committee will continue working on developing CD throughout the next several months, finalizing attribute weights and determining final decisions for medical urgency based on feedback from public comment.

**2. Update: Guidance Document Outline**

The Committee reviewed the proposed outline for the guidance document in anticipation of project presentation to the Policy Oversight Committee in February.

Summary of discussion:

No decisions made, discussion only.

In discussion regarding which organizations to involve in this work, the Chair asked whether the American Diabetes Association (ADA) should be asked regarding their view on pancreas transplantation in diabetes management. A member offered that their chief endocrinologist, also the scientific chair of the ADA, does not support pancreas transplantation alone (PTA) as a viable treatment for Type 1 diabetes, though they recognize the benefits of simultaneous pancreas-kidney transplant (SPK). Other members indicated similar sentiments regarding the ADA and lack of acknowledgement for PTA as diabetes management. The Chair acknowledged the difficulty of engaging the ADA, suggesting a focus on bridging gaps rather than forcing collaboration, and the Vice Chair chimed in confirming the lack of historical engagement with the ADA, recommending inclusion in the discussion but with realistic expectations.

The Vice Chair highlighted the ADA's prioritization of broader diabetes management while the transplant community and this Committee sees a subset of patients who benefit from PTA. It was suggested to seek common ground where the ADA could acknowledge that some patients benefit from alternative treatments such as transplantation, emphasizing the importance of patient access to a variety of treatment options as the primary focus. The Chair assented, indicating that it might be more productive to engage with ADA later in the process after having identified those patients who benefit from PTA in the guidance document. It was also recommended to prioritize patient and provider perspectives when possible, to encourage broader comprehension on the topic of PTA benefits.

Other members agreed and advised other organizations such as the American Association of Clinical Endocrinology, the Breakthrough T1D organization, the American College of Physicians, and the American Medical Association. The diversity of outreach could aid in ensuring insight is received from providers as well as patients.

Staff provided an outline of the proposed timeline, sharing the expected Policy Oversight Committee (POC) review date is February 13<sup>th</sup>, and should the project be approved, work could commence then officially. Members were advised that there would not be a workgroup started for this and that those who choose to participate would meet during some leadership calls and on Committee calls. Staff asked if there are any members initially interested in writing this document to identify themselves. Several members responded.

Next steps:

The project will go to the POC for approval in February, and if approved work could then commence.

### 3. Update: TRR and TRF Preliminary Evaluation

The Committee reviewed the Transplant Recipient Registration (TRR) and the Transplant Recipient Follow-Up (TRF) form for adult pancreas candidates to determine some preliminary forms that would require review in a greater data project.

#### Summary of discussion:

No decisions made.

The Committee was informed that though the weight and Body Mass Index (BMI) fields were previously removed, in June of 2020 the insulin dosage field was updated to include kilograms/day (kg/day). The Committee was asked whether that adjustment was sufficient or whether a new data field needed to be added back in asking for weight specifically. The Chair advised that it would be necessary to include the weight field again and other members agreed.

A key issue with the form that was previously highlighted was the many fields left blank or with the status “unknown” or “not entered”. Members wondered whether it would be possible to make the form thus that it cannot be submitted unless the form is filled out in completeness. This was advised as being difficult as the fields are already required fields and the status options are necessary as it might not always be possible to retrieve specific information from patients.

Members discussed the role and benefit of A1C versus C-Peptide in diagnosing graft failure. Some viewed A1C as unreliable due to the possibility of anemia being present in a patient and does not provide sufficient insight, and thus only C-Peptide should be requested. Others found that including A1C still has its value despite limitations. Other members voiced that including both options is beneficial as both are still used to assess pancreatic function post-transplant, depending on the physician. There were additional questions whether insulin dosage alone would be sufficient, however, for Type 2 diabetic patients it was determined this is insufficient in determining graft failure.

The Committee agreed that a clear definition of graft failure is essential, however, there are a variety of limitations and variations depending on the patient, and though the current definition is imperfect, it is sufficient, should the form be filled out to its fullest. It was voiced that ensuring C-Peptide values are filled out would be beneficial as it is valuable information pre- and post-transplant in defining graft failure for both Type 1 and Type 2 diabetic patients. Time in range for glucose control was also suggested as a meaningful metric for those patients who use a continuous glucose monitoring (CGM) device.

Members agreed that fields such as C-Peptide and A1C values should be compulsory and required to fill out, however, there was concern on how to ensure compliance with this as it has already been identified as a field that is frequently missed, even though it is currently required on the forms.

Other members highlighted the need to have objective data to define when a graft has failed, as there is some subjectivity still. Though members agreed that this is complicated by the variability of patient conditions and the differences in patient needs when it comes to post-transplant care and treatments. A standardized approach was highlighted, despite the challenges in collecting the data, to ensure equitable application across the board for all patients, though members acknowledge the difficulty they might have in developing this.

#### Next steps:

The Committee agreed that refining the TRR and TRF forms could improve both clinical practice and enhance data collection on pancreas transplantation and outcomes but recognized the difficulties in a

project of this size. Additionally, the Committee highlighted the eventual need for a new definition of pancreas graft failure. The Committee will continue discussions and possibly pursue a new project should the capacity be available.

Staff indicated the need to also confer with the Data Advisory Committee should a data project move forward.

#### **Upcoming Meetings**

- February 3, 2025

## Attendance

- **Committee Members**
  - Asif Sharfuddin
  - Colleen Jay
  - David Lee
  - Diane Cibrik
  - Dean Kim
  - Jason Morton
  - Jessica Yokubeak
  - Mallory Boomsma
  - Muhammad Yaqub
  - Neeraj Singh
  - Oyedolamu Olaitan
  - Patrick McGlone
  - Stephanie Arocho
  - Todd Pesavento
  - Ty Dunn
- **HRSA Representatives**
  - Marilyn Levi
- **SRTR Representatives**
  - Bryn Thompson
  - Jon Miller
- **UNOS Staff**
  - Stryker-Ann Vosteen
  - Dzhuliyana Handarova
  - Cole Fox
  - Kristina Hogan
  - Kaitlin Swanner
  - Keighly Bradbrook
  - Kevin Daub
  - Asma Ali
  - Lauren Motley