OPTN Pancreas Transplantation Committee
Meeting Summary
August 5, 2024
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 08/05/2024 to discuss the following agenda items:

1. Update on Continuous Distribution
2. Update on Current Work
3. Closing Remarks

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

1. Update on Continuous Distribution

The Committee received an overview of work thus far on continuous distribution, as a refresher on decisions made and what decisions are still outstanding.

Summary of discussion:

Members discussed methods to assess the urgency of impaired awareness of hypoglycemia (IAH), considering various patient scenarios and data collection challenges. The Committee emphasized the need for further expert consultation in finalizing medical urgency criteria.

A member inquired about the attribute of Proximity Efficiency in the finalized allocation objectives. They questioned why the goal only referenced minimizing distance traveled for pancreas alone, suggesting it should also apply to simultaneous kidney-pancreas (SPK) transplants. It was clarified that the proximity efficiency attribute will use the same weight for both kidney and pancreas. The member suggested clarifying the goal language to say "minimize distance traveled for pancreas and SPK," and other members agreed with this suggestion.

The Chair offered additional insight, explaining that when these discussions were initially held, the primary concern was the distance most pancreata travel for transplant. However, updating the language to include both pancreas and SPK seemed appropriate.

A member also asked whether it was possible to obtain further data on patient outcomes beyond 2 years. OPTN Contractor staff confirmed that this should be attainable.

The Vice Chair clarified that the four characteristics—metrics, dialysis, cardiac autonomic neuropathy, and diabetic ketoacidosis—are not methods for assessing impaired awareness of hypoglycemia (IAH) itself. Rather, they are used to assess the urgency of IAH and, consequently, a patient's medical urgency.

A member pointed out that these metrics would require significant documentation, potentially disadvantaging some patients. For instance, those who don't use Continuous Glucose Monitors (CGMs) or glucagon, but simply seek out sugary items during IAH episodes, might be at a disadvantage. The member suggested that Emergency Medical Services (EMS) calls and documented Emergency Department (ED) admissions for IAH could also serve as potential characteristics. The Chair acknowledged that these possibilities had been considered in past discussions. They noted that work is still ongoing to determine which characteristics play a significant role and the weight of medical urgency as an attribute. They further emphasized that a variety of subject matter experts had been consulted and were present during the most recent discussion on medical urgency. It was with their expertise that the Committee ultimately decided upon these characteristics.

The Vice Chair highlighted a previous comment that not every patient will have CGM data or ED admissions. They suggested adding a bullet point to include consideration of other forms of patient documentation.

The Committee discussed the characteristic of severe hypoglycemic events, considering what timeframe and/or number of events would serve as a quantifiable metric for assessing medical urgency. The Vice Chair proposed that a severe hypoglycemic event recorded in the past 6 or 12 months might be adequate. Members agreed that 6 months would be reasonable, as it would ensure contemporary data. It was emphasized that even one severe hypoglycemic event can be lethal, and that these events vary in severity. Members concurred with this assessment.

One member raised concerns about patients using CGMs or insulin pumps, noting that these patients often experience more hypoglycemic events and are typically prescribed glucagon as a preventative measure. They felt that attempting to further define this could prove problematic. The member added that their primary concern arises when patients can no longer feel their low blood sugars and have no symptoms, suggesting that in such cases, a pancreas should be urgently obtained for the patient.

The Chair sought clarity on next steps and what was still necessary to finalize these discussion points. They recommended further consultation with endocrinologists and subject matter experts to ensure final decisions are based on sound medical judgment. It was noted that for CGM data, it might be necessary to collect the percentage of "out of range" data, which can be easily obtained. Additionally, it was suggested that an updated hypoglycemic severity score could be used to capture data for those who do not use a CGM. The Chair recommended further discussion with subject matter experts to finalize these points.

The Chair highlighted an additional point relating to dialysis access for Kidney-Pancreas (KP) patients, as it is currently listed as a possible characteristic for IAH and in assessing medical urgency. The Chair agreed that consistency with the Kidney Committee's work in this area is critical and would ensure continuity across the board for all patients.

The Chair recommended continuing work on finalizing the Pancreas Review Board process, ensuring that once medical urgency discussions are completed, the Review Board structure is also finalized, allowing the Committee to avoid sequential work.

Next steps:

The Committee will continue this discussion with subject matter experts at the in-person meeting. In addition to finalizing medical urgency, the Committee will also aim to finalize the Pancreas Review Board framework.

2. Update on Current Work

The Committee received a brief overview of their previous discussions on developing a guidance document as well as the questions the transplant community is considering as a part of the Continuous Distribution of Pancreata Summer Update out for Summer 2024 public comment.

3. Closing Remarks

A member sought clarity on when the Committee can expect results from the Scientific Registry of Transplant Recipients (SRTR) on the modeling data request submitted March 2024. An SRTR staff member affirmed they have been working continuously on developing a model to assess non-use and non-utilization of both kidneys and pancreata, and expect to have it finalized within a couple of months.

Upcoming Meetings

- September 9, 2024
- October 10, 2024 (In-person)

Attendance

- **Committee Members**
  - Ty Dunn
  - Colleen Jay
  - Jason Morton
  - Dean Kim
  - David Lee
  - Diane Cibrik
  - Mallory Boomsma
  - Muhammad Yaqub
  - Neeraj Singh
  - Dolamu Olaitan
- **HRSA Representatives**
  - Marilyn Levi
  - Jim Bowman
- **SRTR Representatives**
  - Bryn Thompson
- **UNOS Staff**
  - Stryker-Ann Vosteen
  - Dzhuliyana Handarova
  - Cole Fox
  - Laura Schmitt
  - Lauren Motley
  - Sarah Booker