OPTN Pancreas Transplantation Committee
Meeting Summary
January 8, 2024
Conference Call

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

Introduction

The OPTN Pancreas Transplantation Committee (the Committee) met via Cisco WebEx teleconference on 01/08/2024 to discuss the following agenda items:

1. Follow-Up and Discussion: Pancreas Medical Urgency

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

1. Follow-Up and Discussion: Pancreas Medical Urgency

The Committee continued their discussion on clinical considerations and guidelines for pancreas medical urgency.

Data summary:

The Committee refined a list of potential clinical considerations down to those they felt were most relevant for medical urgency. These included:

- Hypoglycemic unawareness

- Severe hypoglycemic events

- Cardiac autonomic neuropathy

- Diabetic neuropathy (concerns raised about potential influx of patients)

There were a few considerations outstanding that the Committee wanted to further discuss:

- Pediatrics

- Accessibility to technology

- Whether diabetic neuropathy could be merged with cardiac autonomic neuropathy

Summary of discussion:

The Committee decided that further input is needed from endocrinology experts on whether to merge diabetic neuropathy with cardiac autonomic neuropathy.

The Committee decided to pursue a scaled approach for determining medical urgency, depending on further input and feedback from endocrinology experts.

The Committee will, in conjunction with expert input, finalize a narrowed list of considerations along with severity criteria guidance for the review board.

The discussion was initiated with an affirmation that there will be opportunity for collaboration with the Kidney Committee as they also continue their discussions of kidney medical urgency. The Vice Chair voiced agreement in collaborating with the Kidney Committee, but noted that the overlap between pancreas and kidney medical urgency might be quite small. It was asked whether there are lessons learned from the Lung Committee's construction of exception points. Staff supplemented that public comment feedback to the Lung Committee's work indicated the need to be as detailed and clear as possible with in definitions and criteria that are developed.

The Committee engaged in extensive debate regarding whether to merge diabetic neuropathy with cardiac autonomic neuropathy (CAN), and have it included as part of the medical urgency criteria. Committee members cited diabetic neuropathy's prevalence among the diabetic patient population. With so many potential transplant candidates affected, including it could dramatically expand the medical urgency criteria beyond what the Committee felt was manageable or intended.

However, there were mixed opinions regarding the more severe manifestation - cardiac autonomic neuropathy. Some members argued CAN has a greater impact on mortality and could justify higher waitlist prioritization. But others noted CAN is still highly prevalent in long-term diabetic patients, making it difficult to use as definitive criteria for medical urgency. Concerns were also raised around the complexities of clearly defining diagnostic cut-offs and standards for CAN.

To address the open questions around CAN, suggestions were made to further engage experts in endocrinology and diabetes care. In particular, the Committee seeks guidance on whether pancreas transplantation has demonstrated effectiveness in improving long-term CAN outcomes. If so, this could strengthen the case for prioritizing CAN patients. Committee members also asked if there are certain age groups or pediatric populations where early transplantation could curb progression of neurologic damage from ongoing diabetes. The Committee agreed that additional input from subject matter experts (specifically endocrinologists) would help inform final decisions around incorporating CAN - whether as an absolute indication or tiered by severity benchmarks yet to be delineated.

The Committee explored different approaches to setting the medical urgency criteria thresholds - either as definitive, absolute indications or scaled relative to severity benchmarks. Hypoglycemic unawareness was cited as a prime example of needing unambiguous and objective guidelines for determining its prevalence in transplant candidates.

Other members noted many potential considerations like CAN manifest along a spectrum, with implications for transplant urgency relative to severity, variability in presentation, and interaction with other comorbidities. For such complex or subjective measures, they advocated for graded criteria thresholds as opposed to binary yes/no indicators. Suggested approaches included numeric scoring systems, tiered classifications levels, or other structured rubrics to help quantify urgency. Review board members could then apply these frameworks to weigh medical evidence, lab values, test results, and clinical indicators on a case-by-case basis.

An example was raised in creating a grid or matrix that assigns points based on the presence and extent of select criteria. The totals would essentially index patients along an acuity scale - the higher the cumulative score, the greater justification for heightened transplant urgency due to medical risk. This kind of relative system with scalar criteria cut-offs could assist reviewers in delineating elevated priority cases across a range of considerations. However structured, greater clarity around medical urgency evaluation protocols will aid reliability and consistency in review decisions.

The Committee highlighted hypoglycemic unawareness as needing clear, quantified definitions. Some considerations around assessment were raised as needing further clarification, such as the role of advanced monitoring technology and insurance coverage limitations. The Committee discussed how to

best include advanced monitoring technologies as a criteria, due to the potential disadvantage it could present to those populations who may not have access due to limitations, such as insurance coverage.

The Committee acknowledged hypoglycemic unawareness as a priority area needing both refined eligibility criteria and clear procedures for consistent, evidence-based review decisions. They underscored urgency around expert consultation and data review to establish best practices on characterizing and responding to this critical driver of mortality risk.

Next steps:

The Committee will seek further input from endocrinology SMEs on the outstanding questions and continue discussion and refining the list of considerations for medical urgency and development of criteria around the clinical considerations identified.

Upcoming Meetings

- January 31, 2024
- February 5, 2024
- February 26, 2024
- March 8, 2024 (in-person)

Attendance

- **Committee Members**
  - Oyedolamu Olaitan
  - Mallory Boomswa
  - Todd Pesavento
  - Dean Kim
  - Ty Dunn
  - Colleen Jay
  - Neeraj Singh
  - Asif Sharfuddin
  - Shehzad Rehman
  - Nikole Neidlinger
  - Muhammad Yaqub
  - Dianne Cibrik
  - Rupi Sodhi
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Bryn Thompson
  - Jon Miller
  - Raja Kandaswamy
- **UNOS Staff**
  - Joann White
  - Stryker-Ann Vosteen
  - Sarah Booker
  - Kaitlin Swanner
  - Houlder Hudgins
  - Cole Fox
  - Kayla Temple
  - Carlos Martinez
  - James Alcorn