OPTN Pancreas Transplantation Committee
Meeting Summary
December 11, 2023
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 12/11/2023 to discuss the following agenda items:

1. Welcome and Updates
2. Follow-Up and Discussion: Pancreas Medical Urgency

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

1. Welcome and Updates

Staff introduced the afternoons discussion items as well as updates regarding changes to the CPRA calculator made December 2023.

Summary of discussion:

No decisions made, discussion only.

The Committee heard plans on how to make Committee calls more transparent to the public through a new Open Forum process. Meetings will start being live-streamed and 5 minutes will be allotted at the end of the meeting for Public Forum, which would allow the Committee to answer discuss any questions from the public submitted to the Committee.

The Committee also heard about a recent fix to the Calculated Panel Reactive Antibody (CPRA) calculator, which determines transplant priority. Back in January 2023, the calculator was updated, but an error was recently discovered in how DQ Alpha 1 antigens were being grouped by the calculator. This caused some candidates' CPRA scores to calculate lower than they should have based on policy. The error impacted over 2000 candidates to some degree.

Specifically for kidney-pancreas (KP) and pancreas candidates, 35 and 48 registrations were affected. After the fix, 5 candidates (2 KP and 3 pancreas) saw their CPRA score increase - bumping some into the highest 99-100% priority tier. The median CPRA was 5.58% lower across affected candidates. So while some changes were minor, others were significant in terms of potentially missing opportunities for transplant.

Next steps:

The Committee will be kept apprised of any additional changes that might occur due to the error in the CPRA calculator.

2. Follow-Up and Discussion: Pancreas Medical Urgency

The Committee continued their discussion on pancreas medical urgency while awaiting further guidance on continuous distribution from the Expeditious TaskForce.

Summary of discussion:

The Committee made the decision to include these items for consideration for Pancreas Medical Urgency:

> Hypoglycemic unawareness; cardiac autonomic neuropathy (CAN); and severe hypoglycemic events.

The Committee made the decision to remove these items from consideration for Pancreas Medical Urgency:

> Pancreas Donor Risk Index (PDRI); EAGLES criteria; gastroparesis; Type 1 vs. Type 2 diabetes; total duration of diabetes; diabetic ketoacidosis

The Committee decided to continue reviewing the following items further:

> Pediatrics; and accessibility to technology

The Committee discussed considerations for medical urgency for pancreas transplant candidates. One member suggested removing the Pancreas Donor Risk Index (PDRI) and EAGLES graft assessment criteria, as they relate more to donor organ quality rather than candidate medical urgency. Other members agreed with this sentiment.

There was agreement to remove gastroparesis as it is not typically acutely life-threatening. Some members proposed including severe diabetic retinopathy that is leading to vision loss, but others noted that would qualify many simultaneous KP candidates who may already meet other urgency criteria.

The Committee engaged in discussion around potentially including hypoglycemic unawareness as criteria for urgent need for a pancreas transplant. Several members noted that the definition can vary between providers. Some doctors apply the term broadly, to ensure that underserved patients struggling with severe hypoglycemic episodes don't get overlooked if proper terminology isn't used. There is also interplay with accessibility to diabetes management technology like continuous glucose monitors. Patients without access or for whom the technology proves ineffective may get labeled as having unawareness.

The Committee grappled with how to account for these nuances around diagnosing hypoglycemic unawareness in under-resourced patients, while still capturing those truly at an urgent risk level. There was a suggestion to use a quantified measurement scale as criteria, as well as requiring proof that all appropriate available treatments have been exhausted before a patient could qualify based on this condition. Setting thresholds could help mitigate disadvantages due to uneven healthcare accessibility.

Several members voiced concerns about patients with severe diabetes complications who face disadvantages in obtaining optimal treatment technology and expertise. Especially those in rural areas or with inadequate insurance coverage. There was agreement that access issues stopping short of patient fault should not disqualify someone from priority status.

There were suggestions to categorize considerations based on physiology versus availability of interventions. The members aimed to craft careful criteria that encapsulate mortality risks linked to diabetes progression itself, apart from what societal realities may exacerbate them.

The committee touched briefly on including cardiac autonomic neuropathy as criteria for urgent need of a new pancreas. Two members described it as carrying mortality risk on par with, if not exceeding, hypoglycemic unawareness. There seemed to be awareness among some members of cardiac autonomic neuropathy's severe implications. But uncertainty lingered around its appropriateness and workability as criteria for medical urgency qualification. Members gravitated toward conditions with better defined parameters and treatment exhaustion markers. It was also noted that diabetic neuropathy should merit discussion, however, caution should be considered as without proper definition there could be an influx of diagnoses since many patients suffer without being symptomatic.

Members also debated making distinctions between type 1 and type 2 diabetes and ultimately decided against making any distinctions between the two types for discussions of medical urgency.

The Committee talked through scenarios about patients listed for both kidney alone and KP. There was agreement that if the kidney review board approves a patient for kidney transplant medical urgency, that determination should carry over to the Pancreas Review Board as well. In instances when a potential KP patient has already received medical urgency approval from the Kidney Review Board, to reduce burden the Pancreas Review Board could adopt the medical urgency decision without conducting a separate review.

Overall, the members aimed to focus urgency criteria on factors directly tied to mortality risk versus those impacting general quality of life. It was suggested to categorize considerations into two columns: lack of insulin production and complications from diabetes. The considerations will inform guidelines but are not intended as a limiting definitive list.

Next steps:

Staff will summarize the discussion and provide a revised document for Pancreas Medical Urgency. The conversation will continue at the next meeting.

Upcoming Meetings

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

Attendance

- **Committee Members**
  - Colleen Jay
  - Neeraj Singh
  - Todd Pesavento
  - Oyedolamu Olaitan
  - Sohail Yaqub
  - Asif Sharfuddin
  - Jessica Yokubeak
  - Dean Kim
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Jon Miller
  - Peter Stock
  - Raja Kandaswamy
  - Bryn Thompson
- **UNOS Staff**
  - Joann White
  - Kristina Hogan
  - Stryker-Ann Vosteen
  - Houlder Hudgins
  - James Alcorn
  - Sarah Booker
  - Lauren Motley
  - Alex Carmack
  - Carlos Martinez
  - Susan Tlusty