

OPTN Pancreas Transplantation Committee

Meeting Summary

October 2, 2023

Conference Call

Dolamu Olaitan, MD, Chair

Ty Dunn, MD, Vice Chair

Introduction

The OPTN Pancreas Transplantation Committee (the Committee) met via Citrix Webex teleconference on 10/02/2023 to discuss the following agenda items:

1. Follow-Up and Discussion: Organ Registration
2. Post-Public Comment Review: Efficiency and Utilization in Kidney and Pancreas Continuous Distribution

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

1. Follow-Up and Discussion: Organ Registration

The Committee continued their discussion on the organ registration attribute. In previous meeting discussions, there were concerns about assigning a 10% weight for the organ registration attribute due to the overlap presented among whole organ and islets. With a 10% weight for the organ registration attribute, 40% of islet candidates would have scores that overlap with whole pancreas scores for donors who are less than or equal to 45 years of age and with a body mass index (BMI) of 30 or less. This significant overlap of 40% for islet candidates is of concern because it does not align with the Committee's original modeling goals, resulting in less priority for whole pancreas candidates for donors who are less than or equal to 45 years of age and with a BMI of 30 or less.

The Committee reviewed alternative weight options remodeled at a 20% and 30% weight to help determine the most appropriate weight assignment for the organ registration attribute. The Committee was asked the following:

Which weight assignment does the Committee agree with for organ registration?

- 10%
- 20%
- 30%

Summary of discussion:

Decision #1: There was consensus among the Committee to consider a 20% weight assignment for the organ registration attribute.

The Chair commented that there is no significant difference in overlap between whole organ and islet candidates when modeling the organ registration attribute with a 20% and/or 30% weight. Members voiced that 20% weight seems most appropriate for the organ registration attribute due to the modeling demonstrating minimal overlap between islet and whole pancreas candidates. A member recommended

maintaining the 10% weight for organ registration because if the weight changes, it will impact the weight of the other attributes.

A straw poll was taken. The Committee was made aware that the purpose of poll was to gather the Committee's consensus on the weight assignment for the organ registration attribute but was not a final decision. The Committee was asked the following:

Which weight assignment does the Committee agree with for organ registration?

Straw Poll: 10%: 1, 20%: 7, 30%: 0

There was consensus among the Committee to consider a 20% weight assignment for the organ registration attribute.

Next Steps:

Further discussions are forthcoming where final decisions will be made on the weight assignment for this attribute at that time.

2. Post-Public Comment Review: Efficiency and Utilization in Kidney and Pancreas Continuous Distribution

The Committee reviewed public comment feedback on the August 2023 Efficiency and Utilization in Kidney and Pancreas Continuous Distribution request for feedback (RFF), relevant to the medical urgency attribute. This request for feedback required additional input on pancreas medical urgency to determine the following:

- Does the community support the inclusion of an exception-based medical urgency attribute for pancreas?
- What clinical considerations should be considered in defining increased medical urgency among pancreas and kidney-pancreas candidates?

The following themes were identified:

- Mixed sentiment on including pancreas medical urgency as an attribute:
 - Support:
 - Agreement that there should be an exception pathway for candidates.
 - Oppose:
 - Medical urgency is not seen as relevant for pancreas transplantation.
 - There must be clarification on guidelines to avoid burden on the Review Board members.
- Clinical Considerations for Medical Urgency:
 - Hypoglycemia unawareness
 - Medical urgency for patients suffering from hyperglycemia unawareness, particularly if they have diabetes and had hospitalizations for self-injury from hyper and hypoglycemia.
 - Medical urgency for a pancreas transplant should only be for some documented cases of hypoglycemic unawareness.
 - Medical urgency should be considered as a scale vs. binary attribute.
 - Criteria for islet transplant as a basis for criteria for medical urgency for pancreas.

The Committee was asked the following:

Which option for pancreas medical urgency does the Committee recommend to move forward?

- Include medical urgency as an attribute.
- Do not include medical urgency as an attribute.

Summary of discussion:

Decision #2: There was consensus among the Committee to include medical urgency attribute in the pancreas continuous distribution framework.

A member commented that if a patient nearly dies of hyperglycemia unawareness, they should be considered medically urgent. He further commented that while there is mixed sentiment about including medical urgency as an attribute, the attribute should be considered in the continuous distribution framework. A member asked if technology, such as a continuous glucose monitor (CGM), should be utilized for hyperglycemia unawareness patients before a patient is considered medically urgent. A member replied that CGMs are helpful, but they are not available to everyone in the country. If a candidate suffers from hyperglycemia unawareness and does not have access to a CGM device, there should be a pathway to help that candidate.

Regarding clinical considerations for hyperglycemia unawareness, a member asked if patients with type 2 diabetes will also be considered medically urgent. Staff replied that the criteria for medically urgent candidates are still being discussed; a list of criteria can be reviewed to better understand what criteria should be prioritized to deem a patient as medically urgent. She further explained that potentially developing a pancreas review board is an opportunity to collect data and get additional information for medical urgency. Another member agreed and stated that it may be helpful to use the expertise of an endocrinologist to help with developing pancreas medical urgency criteria. Another member suggested simultaneous pancreas and kidney (SPK) candidates who have hyperglycemia unawareness, should be considered as criteria for medical urgency.

Next steps:

The Committee recommend including medical urgency as an attribute in the pancreas continuous distribution framework and will continue discussions on developing pancreas medical urgency criteria.

Upcoming Meetings

- October 12, 2023 (Teleconference)
- November 6, 2023 (Teleconference)

Attendance

- **Committee Members**
 - Mallory Boomsma
 - Dolamu Olaitan
 - Colleen Jay
 - Grish Mour
 - Dean Kim
 - Nikole Neidlinger
 - Todd Pesavento
 - Asif Sharfuddin
 - Neeraj Singh
 - Shehzad Rehman
 - Muhammad Yaqub
 - Jessica Yokubeak
- **HRSA Representatives**
 - Marilyn Levi
- **SRTR Staff**
 - Bryn Thompson
 - Jon Miller
- **UNOS Staff**
 - Joann White
 - Tamika Watkins
 - Krissy Laurie
 - Sarah Booker
 - Kayla Temple
 - Carlos Martinez
 - Kristina Hogan
 - Laura Schmitt
 - James Alcorn