

Meeting Summary

OPTN Pancreas Transplantation Committee Meeting Summary April 17, 2023 Conference Call

Rachel Forbes, MD, Chair Dolamu Olaitan, MD, Vice Chair

Introduction

The OPTN Pancreas Transplantation Committee (the Committee) met via Citrix GoToMeeting teleconference on 04/17/2023 to discuss the following agenda items:

1. Continuous Distribution of Kidneys and Pancreata: Medical Urgency

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

1. Continuous Distribution of Kidneys and Pancreata: Medical Urgency

The Committee heard an update on medical urgency and discussed whether this attribute should be incorporated into the continuous distribution (CD) of Pancreas framework and in the review board process.

A Medical Urgency Workgroup (the Workgroup) was developed in November 2020 to help evaluate and discuss criteria that should be considered medically urgent regarding pancreas candidates. The Workgroup determined that additional evidence gathering is needed to develop criteria for medical urgency policy. The Workgroup then reconvened in March 2023 to explore a definition of medical urgency for pancreas transplant candidates and focused on hypoglycemic unawareness as a potential initial definition for pancreas medical urgency. The Committee was asked to determine if medical urgency should be included as an attribute in the CD framework and the pancreas review board.

Summary of discussion:

A member asked for clarity on potentially establishing a Review Board. Staff replied that the Committee is trying to determine what the Review Board would examine if it was established. The Committee has not approved a Review Board, which is still being determined. Another member asked if this discussion is focused on the pancreas only or both kidney and pancreas. The Chair clarified that the scope of this project is candidates registered on the pancreas and kidney-pancreas (KP) waitlist and further explained that while the Committee is still determining the final attributes for the CD framework, currently, there is nothing to denote a sicker pancreas patient.

Staff noted that when considering what is deemed as medical urgency, the Committee can consider other factors; it is not limited to only hypoglycemia unawareness. A member shared that one year after their KP transplant, their A1C levels went from 13.9 Mg/dL to 5.1Mg/dL. Therefore, looking at severity trends of A1C may be helpful evidence to contribute.

A member asked if there was data on the justification of the cause of death for pancreas and KP patients on the waitlist. Staff replied that the cause of death is usually reported as unknown. A member commented that it's essential to define what is considered medically urgent so that there are some guidelines for the Review Board to discuss the exception request further. Without any guidelines, it would be challenging for any Review Board. Another member agreed that the Committee should define

these parameters for the Review Board. Members expressed concerns that if there are no guidelines for the Review Board, it would be free for all and confusing and overwhelming for the Review Board to determine the outcome of these potential cases.

Another member pointed out that there is much ambiguity with some of these parameters, such as A1C, which is affected by anemia and end-stage renal disease. The member noted that a lot of these criteria could be very subjective. Considering who should have medical urgency for a pancreas transplant is essential. The member further explained that hypoglycemic awareness could be life-threatening, which indicates medical urgency for a pancreas. What constitutes hypoglycemic awareness should be defined. Another member agreed and argued that hypoglycemic awareness should be the main focus. The member explained that with A1C, there are many factors, and it's only an average and does not paint a complete picture. The Vice-Chair favored incorporating medical urgency in the project's first iteration and suggested establishing broad guidance for the review board.

Does the Pancreas Transplantation Committee support medical urgency as an attribute?

Straw Poll: Support- 16 Abstain- 0 Neutral- 0

Does the Pancreas Transplantation Committee support collecting data within the system to further assess medical urgency?

Straw Poll: Support- 16 Abstain- 0 Neutral- 0

Next steps:

The Committee will move forward with medical urgency as an attribute and further discuss guidelines for the Review Board. The Committee will also determine which data should be collected to further assess medical urgency.

Upcoming Meeting

May 1, 2023

Attendance

• Committee Members

- o Rachel Forbes
- o Dolamu Olaitan
- o Dave Weimer
- o Dean Kim
- o Diane Cibrik
- o Jessica Yokubeak
- o Mallory Boomsma
- o Maria Helena Friday
- o Muhammad Yaqub
- o Parul Patel

HRSA Representatives

- Shelly Grant
- SRTR Staff
 - o Bryn Thompson

UNOS Staff

- o Joann White
- o Carol Covington
- o Colleen Jay
- o James Alcorn
- o Joel Newman
- o Jonathan Miller
- o Kayla Temple
- o Krissy Laurie
- o Lauren Mauk
- o Lauren Motley
- o Lindsay Larkin
- o Sarah Booker

Other Attendees