

Meeting Summary

OPTN Pancreas Transplantation Committee Meeting Summary September 19, 2022 Conference Call

Rachel Forbes, MD, Chair Oyedolamu Olaitan, MD, Vice Chair

Introduction

The OPTN Pancreas Transplantation Committee (the Committee) met via Citrix GoToMeeting teleconference on 09/19/2022 to discuss the following agenda items:

- 1. Housekeeping/Updates
- 2. Public Comment Presentation: Modify Waiting Time for Candidates Affected by Race-Inclusive Estimated Glomerular Filtration Rate (eGFR) Calculations
- 3. Public Comment Presentation: Enhancements to OPTN Donor Data and Matching System Clinical Data Collection
- 4. Update/Review: Kidney-Pancreas (KP) Continuous Distribution Timeline

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

1. Housekeeping/Updates

The Committee received the following updates:

Kidney-Pancreas (KP) Continuous Distribution Project

In preparation for the next phase of the KP Continuous Distribution project (modeling and analysis), there will be primers on the KPSAM and MIT analyses. Additionally the Pancreas Committee meetings will extend by half an hour to accommodate for the next steps of this project: review/discussion of the data reports, adjust the framework as needed, and development of the second data request.

Pancreas Committee in person meeting

The Committee was reminded of the in person meeting scheduled for Tuesday, November 1st in Chicago, IL. In order to hold the in person meeting, there will need to be 50% or more members attending the meeting in person. A survey will be sent to the Committee to indicate if they plan to attend in person, attend virtually, or not attending. The meeting will be confirmed once attendance is evaluated from the survey responses.

Summary of discussion:

There was no discussion.

2. Public Comment Presentation: Modify Waiting Time for Candidates Affected by Race-Inclusive Estimated Glomerular Filtration Rate (eGFR) Calculations

The Committee received a presentation on the OPTN Minority Affairs Committee's *Modify Waiting Time for Candidates Affected by Race-Inclusive Estimated Glomerular Filtration Rate (eGFR) Calculations* proposal.

Summary of discussion:

The Vice Chair commented that this policy should be made mandatory in some form because a significant number of patients may not be in a position to advocate for themselves. There is uncertainty if all programs would be willing to go through the efforts of reviewing their lists and identifying those patients to correct these values, so they may still be at a disadvantage despite these efforts. The Vice Chair continued by suggesting that apart from the usual education that is done, there should be something built into the OPTN Donor Data and Matching System where patients are identified within the system and can document whether or not any modification to the eGFR is needed.

A member agreed with support in having this modification mandatory and suggested that there should be a responsibility of the OPTN to automate this update. UNOS staff stated that one of the challenges is that the OPTN system today does not collect information on what eGFR calculation was used, therefore is not able to determine which candidates may have been affected by a race-inclusive calculation.

Another member agreed in this policy being mandatory as it would help with the process; having a timeline would help encourage this policy being mandatory. The member suggested there should also be a pathway for candidates who have already received a transplant to gain wait time back as well.

A member commented if the policy were mandatory, it may be difficult for programs to complete the requirements due to staff turnover. Other members agreed the pathway as outlined would be burdensome on transplant program staff. One member commented they would not know what candidates are listed pre-emptively without conducting a holistic review of their full candidate list.

Other members also suggested a recalculation of eGFR based on a candidate's creatinine level included in their original calculation.

Next Steps:

The comments received by the Committee will be drafted into a formal statement that will be submitted for public comment.

3. Public Comment Presentation: Enhancements to OPTN Donor Data and Matching System Clinical Data Collection

The Committee received a presentation on the OPTN Organ Procurement Organization (OPO) Committee's *Enhancements to OPTN Donor Data and Matching System Clinical Data Collection* proposal.

Summary of discussion:

A member suggested having a donation after cardiac death (DCD) page and allowing the graphing of some of this data. The member also commented that a category for controlled or uncontrolled classification would be helpful as well.

The OPO Committee representative that there have been similar feedback received. Additionally, there has been some feedback in also including a normothermic regional perfusion (NRP) question and a few pediatric questions related to this, such as duration of extracorporeal membrane oxygenation (ECMO). The member voiced support for these inclusions.

Another member asked if this data collection would be in real-time data upload or if it would be something that would be seen after the donor has progressed. The OPO Committee representative stated that this would depend on the OPO practice; several OPOs collect capture the data in real time into their electronic donor records and then are able to upload it sooner. Other OPOs capture this information on paper during the withdrawal of life sustaining treatment interval, and then enter the data into the electronic donor records later after the fact. At a minimum, this data will give better retrospective data, but it will depend on OPO practice.

The member continued by asking how this data collection would be different from what is currently collected in the OPTN Donor Data and Matching System. The OPO Committee representative stated that currently, there is a scan or PDF in the record and that with this proposal, there will be actual data fields; the attachments that are included in the system now are not searchable data fields.

Another member added by asking if on the front page, when looking at a donor offer, for example, warm ischemic time being reported there next to cross clamp time. The OPO Committee representative stated that this could be calculated through the system and would be determined by how warm ischemic time is defined. The member continued by asking if there has been discussion on a universal agreement to how warm ischemic time is calculated as this varies across OPOs. The OPO Committee representative stated that the historical definition that has been mostly agreed upon has been a BP systolic below 80 or a saturation below 80. There is variation on this definition across transplant programs; OPOs provide the vitals and the transplant programs make a determination from there.

The Committee Vice Chair commented in agreement to having a separate page for DCD progression information. The Committee Vice Chair also agreed with using with using the Maastricht Classification as there has been current data that has been able to correlate this with survival, which will be important to evaluate. It was added that defining the different parameters will be important. For example, routine cessation of circulation is not clearly defined. Clarification and further defining this information would be helpful.

The Committee Chair commented by agreeing that standardization of DCD reporting would be helpful as there are more types of DCDs.

A member suggested, in thinking of ways to implement this easier for OPOs, after a certain timeframe, usually 45 minutes to an hour after extubation if the interval needs to be every minute to collect vitals. The member continued by stating believe that OPOs tend to space this documentation out when there is less organs to consider due to warm time. Would this data collection require every minute until the donor is declared deceased? The OPO representative stated uncertainty if this is the requirement of every minute in the non-agonal phase but believes it is every minutes in the agonal phase.

There were no additional comments or questions.

Next Steps:

The comments received by the Committee will be drafted into a formal statement that will be submitted for public comment.

4. Update/Review: KP Continuous Distribution Timeline

The Committee received an update of the KP Continuous Distribution (CD) project timeline. In the next phase of the project, the Committee will be reviewing the KPSAM and MIT modeling results, make adjustments to the framework as needed and prepare to develop a second modeling request. The KP CD proposal is targeted to go out for public comment in August 2023 with review and approval by the Board targeted for December 2023. Is no

The Committee reviewed the proposed changes in the Committee and KP CD Workgroup schedules. Beginning in November, the Pancreas Committee will extend the regularly scheduled Committee calls by 30 minutes and the KP CD Workgroup calls will be reduced to once a month. The KP CD Workgroup will be updated on the Kidney and Pancreas Committees discussions and will provide cross committee stakeholders the opportunity to provide feedback for consideration. The goal will be to have a second modeling request developed and submitted by January 13, 2023.

The Committee will receive updated meeting invitations to reflect these changes.

Summary of discussion:

There was no discussion. The meeting was adjourned.

Upcoming Meetings

- October 3, 2022 (Teleconference)
- November, 1, 2022 (In person, Chicago, IL)
- November 7, 2022 (Teleconference)

Attendance

• Committee Members

- o Rachel Forbes
- o Oyedolamu Olaitan
- Antonio Di Carlo
- o Colleen Jay
- o Dean Kim
- o Diane Cibrik
- o Jessica Yokubeak
- o Maria Friday
- o Muhammad Yaqub
- o Nikole Neidlinger
- o Parul Patel
- o Rupi Sodhi
- o William Asch
- o Todd Pesavento

• HRSA Representatives

- o Jim Bowman
- o Marilyn Levi
- SRTR Staff
 - o Bryn Thompson
 - o Jonathan Miller
 - o Raja Kandaswamy
- UNOS Staff
 - o Joann White
 - o Lauren Mauk
 - o Alex Carmack
 - o Sarah Booker
 - o Carol Covington
 - Lauren Motley
 - o Lindsay Larkin
 - o Robert Hunter
 - Sara Moriarty
- Other Attendees
 - o PJ Geraghty