

Meeting Summary

OPTN Pancreas Transplantation Committee Meeting Summary May 19, 2021 Conference Call

Silke Niederhaus, MD, Chair Rachel Forbes, MD, Vice Chair

Introduction

The Pancreas Transplantation Committee (the Committee) met via Citrix GoToMeeting teleconference on 5/19/2021 to discuss the following agenda items:

- 1. Project Update: Continuous Distribution
- 2. Follow Up: New Project Ideas
- 3. Discussion: New Allocation Policies for Kidney and Pancreas

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

1. Project Update: Continuous Distribution

The Committee reviewed the progress of the Continuous Distribution project and the outline of the concept paper going out for the August 2021 public comment cycle.

Progress to Date

Completed phase 1 of the project, which is to identify and categorize attributes.

Developed Data Requests for:

- Blood Type reviewing results
- Calculated panel reactive antibodies (cPRA) reviewing results
- Pediatrics
- HLA Matching

Outline of Concept Paper

Purpose: inform community of project progress; provide opportunity to receive feedback throughout development of project

- Background high level overview of Continuous Distribution framework
 - List of possible "enhancements"
 - Including request for feedback questions
- Project purpose and plan description of project in context of kidney, pancreas, and kidneypancreas allocation
- Progress so far summary of phase 1 of project and next steps

Summary of discussion:

There was no discussion.

2. Follow Up: New Project Ideas

The Committee reviewed the new project ideas that were suggested during their April 2021 meeting and received follow-up information and next steps.

Project Idea #1: COIIN Project

Idea: Promote increase in pancreas utilization (similar to kidney COIINC project)

Status: Pending more information

- Staff working on processes and prioritization of projects
 - Will include this project idea to present to department leadership for further review and recommendations
- Project is led by COIIN team wouldn't be sponsored by the Committee

Project Idea #2: Modifications to Transplant Recipient Follow-Up (TRF) Form

Idea: Modifications to TRF Form to improve data collection efforts to evaluate/monitor impact of pancreas graft failure definition

- a) Revisions to help documentation regarding insulin
 - Status: Pending/Under internal review
- b) Modifications to total insulin dosage units
 - Status: Pending/IT is aware and currently working to fix issue
- c) Adding Weight data element back on TRF Form
 - Recommendation: Comprehensive review of TRF Form

Project Idea #3: Evaluating Outcomes of Procurement of Pancreata

Idea: Addressing/outlining requirements of recovery teams in procurement of pancreata

Status: Pending

 Internal review and determining next steps to gather feedback from the Policy Oversight Committee (POC)

Project Idea #4: Review/Modify Islet Wait Time Transfer Request Process

Idea: Modifications to current policy (OPTN Policy 11.4.D.ii: *Criteria to assign Islet Waiting Time to Pancreas*) outlining islet wait time transfer request process

Status: On hold for now

- Process is currently working efficiently
- Will consider re-evaluation if requests become more frequent

Summary of discussion:

A member stated that they would be interested in working on the modifications to the TRF form project and agreed with the comprehensive review. A member inquired if the TRF form could be sent out to the Committee so they can review it in its current iteration.

Staff encouraged members to reach out if they are interested in participating in the work for any of these projects.

A member inquired if the pancreas graft failure definition is accepted by the Committee or if the definition is still evolving and that could be a new project idea. Staff explained that, from the past two

research updates, there isn't enough data to come to a conclusion – the Committee wanted to review more data before making a decision on whether the pancreas graft failure is acceptably working in practice. The Chair emphasized that the first part of developing a more comprehensive definition would be to gather more in-depth data. It was also noted that it's going to take several years to collect data on graft failures from the beginning of the time of transplant because pancreas graft failure doesn't occur frequently.

3. Discussion: New Allocation Policies for Kidney and Pancreas

The Committee was presented the following question and was asked to provide discussion on their experiences:

• Since the implementation of the new allocation policies for kidney and pancreas, what changes are you seeing?

Summary of discussion:

A member noted that they have seen an increase in the number of donation after cardiac death (DCD) donors since the implementation of these policies and they are going to have a meeting with their center's organ procurement organization (OPO) to gauge how these policies have affected overall allocation in the area. Another member also noted that they have seen an increase in DCD donors and an increase in delayed graft function (DGF) rates, so their center's imports have increased dramatically.

A member inquired what the national data shows in terms of cold ischemia time and DGF. Staff explained that there's a monitoring report being worked on by research and that should be available the end of June 2021.

The Chair stated that they have been completely inundated with organ offers for kidneys and kidney-pancreas (KP). In this inundation, the Chair's center has had to tighten their criteria for organ acceptance and the workload is falling on on-call coordinators and the HLA lab because OPOs are asking if the patient is ready for transplant and if their cross match is negative. There seems to be an interest in keeping organs local unless there's a guarantee that they will be used elsewhere.

The Chair also mentioned that local backup is very rarely given and biopsy results are very variable and often inaccurate. It would be nice to have a standardized way to upload biopsy images that can be reviewed in a pathology viewer system, like there is for CT scans.

A member mentioned that they've been doing virtual cross matches, but they only do it for low to medium risk patients, and their HLA team is telling them that they can't get blood samples to do a physical cross match so they're having to bypass offers at times.

A member stated that they see a similar pattern of less backup being called and more local kidneys going to centers outside of their area, but at the same time their center is getting kidneys from other areas. The member noted that the following changes applicable to both kidney and pancreas: the volume of organ offers is pretty much the same, increase in receiving shipped organs, increase in DGF, and increase in shipping organs to other centers.

Staff inquired if there were any specific data elements that the Committee wanted to include in the monitoring report. Members suggested looking at the following:

- Number of transplants
- Number of virtual cross match transplants
- Number of flow cross match transplants
- Number of organ offers

- How far down a match run centers are going to place an organ
- DGF incidence
- Cold ischemic time
- Local OPO vs. non-local OPO offers and transplants
- Stratify by kidney donor profile index (KDPI) higher KDPI kidneys are probably used more locally
- Declines for reasons other than biopsy

The Chair stated it's really important to look at the number of organ offers because, at the moment, the amount of organ offers isn't helping with efficiency of allocation.

A member stated that they are getting a lot of organ offers on any given day, but no organs. They're doing multiple virtual cross matches, so this is impacting work in the lab.

A member inquired if the OPTN has offered any guidance on how to use race in determining glomerular filtration rate (GFR) for listing criteria. Staff explained that the Minority Affairs Committee is working with the Kidney Committee on a request for feedback that will go out for public comment in August 2021 to get additional information. The goal would be for the two committees to create a proposal from the request for feedback, so there is discussion surrounding this topic. A member stated that the OPTN does not specify a particular GFR, either with or without the race coefficient, so the program can pick what is best for that particular patient. The member suggested that the Committee should advocate for their patients and switch to using the lowest number at their centers.

A member suggested that it would be helpful for the OPTN to send out a communication regarding this information.

Upcoming Meetings

• June 16, 2021 (teleconference)

Attendance

• Committee Members

- Silke Niederhaus
- o Daniel Keys
- o Ken Bodziak
- o Maria Friday
- o Nicolae Leca
- o Oyedolamu Olaitan
- o Parul Patel
- o Piotr Witkowski
- o Pradeep Vaitla
- o Tarek Alhamad
- o Tracy McRacken
- o Ty Dunn

• HRSA Representatives

o Marilyn Levi

• SRTR Staff

- o Bryn Thompson
- Nick Salkowski
- Raja Kandaswamy

UNOS Staff

- o Joann White
- o Rebecca Brookman
- o Anne McPherson
- o Leah Slife
- Nang Thu Thu Kyaw
- o Sarah Booker