

OPTN Pancreas Transplantation Committee

Meeting Summary

April 7, 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 4/7/2021 to discuss the following agenda items:

1. Request for Feedback: Operations & Safety Committee Broader Distribution Data Collection
2. Research Update & Discussion: Graft Failure Data
3. OPTN Policy Oversight Committee Update
4. Project Update: Medical Urgency
5. Project Update: Continuous Distribution
6. New Project Ideas

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

1. Request for Feedback: Operations & Safety Committee Broader Distribution Data Collection

The Committee was provided an overview of the Operations & Safety Committee's (OSC) Broader Distribution data collection project and was asked to provide feedback regarding additional data elements specific to pancreas or kidney-pancreas that should be included in this project.

Goals & Objectives: Broader Distribution Data Collection Project

Goal: Develop a data collection proposal that will promote effective data collection in evaluating the logistical impact of broader distribution as it pertains to travel.

Objectives: Comprehensive review and proposed recommendations for current data elements related to broader distribution (specifically as it related to travel)

- Focus being on relevancy to members and what would be helpful information to assess broader distribution (as it pertains to travel)

Data Elements

Data elements were reviewed related to the following:

- Cold ischemic time
- Machine perfusion
- Recovery teams
- Organ disposition

The following new data elements were proposed:

- Transportation mode
 - Air; commercial
 - Air; charter

- Ground; courier
- Ground; staff
- Transport time (when organ leaves donor hospital to when organ arrives at transplant hospital)
- Data to reflect coordination time/allocation (late turndowns)
 - Will be addressed by the Data Advisory Committee (DAC) in separate project

Summary of discussion:

The Chair stated that they would be interested in including travel modalities, ideally as multiple fields, because many organs have a combination of travel modalities.

The vice-chair inquired if pancreas ischemic time is being included as one of the data elements and if it is only related to machine perfusion. Staff stated that “Total ischemic time” for left kidney and right kidney is included, but if total ischemic time is collected for pancreas then that can be added. The vice-chair stated that cold ischemia time for pancreas will probably be increased as travel increases.

Next steps:

This project will be presented to the OSC, including the feedback received from stakeholder Committees, for review and additional feedback on 4/15/21 and is slated to go out for public comment in August 2021.

2. Research Update & Discussion: Graft Failure Data

The Committee reviewed the results of the two year post-policy monitoring report for the pancreas graft failure definition.

Pancreas Graft Failure Definition

February 2018, OPTN Board approved policy went into effect clarifying definitions for when a pancreas graft has failed.

Pancreas graft failure occurs when any of the following occurs:

- A recipient’s transplanted pancreas is removed
- A recipient re-registers for a pancreas
- A recipient registers for an islet transplant after receiving a pancreas transplant
- A recipient’s total insulin use is greater than or equal to 0.5 units/kg/day for a consecutive 90 days
- A recipient dies

Data summary:

The following conclusions were presented to the Committee:

- One year pancreas graft survival was lower in kidney-pancreas recipients post policy
- Issues with required data elements reported via Status field and clinical values such as insulin level
- Issues with pancreas graft failure definition threshold
 - 1 or more missing data elements make it unable to calculate
 - Recipient (adult) weight no longer on Transplant Recipient Follow-up (TRF) forms

Summary of discussion:

The Chair stated that the previous definition of pancreas graft failure focused on whether the graft was failed or functioning based on individual center's definition of functioning. The Chair continued by stating that the Committee wanted a standard graft failure definition to collect more accurate data.

The Chair voiced uncertainty on whether this definition has improved or not, and that part of the problem is that not many pancreas transplants are done.

The Chair inquired about what the Committee can address to decrease the amount of missing/unknown data in order to learn more about those recipients who have encountered graft failure. Staff stated that there may be a need for education on how to fill out these forms.

A Scientific Registry of Transplant Recipients (SRTR) representative pointed out that pancreas did not have a graft failure definition that was enforced prior to 2018; however, pancreas transplants prior to 2018 were utilized for improvements. The SRTR representative also mentioned that there were clear guidelines from the OPTN that was used in this new definition.

An SRTR representative inquired if the total insulin dose per day or dose per kilogram is shown in the "Insulin Dosage Reported at 6 months and One Year" graphs. Staff stated that total dose is being presented and, although OPTN help documentation states insulin must be entered as unit/kilogram/day, it seems that centers are entering total dosage. The SRTR representative states that one can't assume that all centers are entering total insulin dosage and not unit/kilogram/day, which makes this hard to analyze.

The Chair stated that coordinators are being asked to input complicated values so its possible different values are being entered. The Chair also explained that another challenge is that the form no longer requires the collection of the recipient's body mass index (BMI), so now the only weight collected is weight at transplant, which may not be reflective of the recipient's weight one year after transplant. The Chair inquired if the Committee should try to modify the definition of graft failure again.

The Chair wondered if it would be worthwhile for the Committee to pursue more clarification on how they want the insulin dosage entered and how to ask for a follow-up BMI to be entered at the time these forms are filled out. A member agreed that asking for follow-up BMI would be helpful.

A member inquired if the Committee could remove the unknown or missing options, so then coordinators would have to put in the insulin dosage. An SRTR representative stated that the problem with taking out the unknown option is that then the default answer would be no if nothing is entered. The SRTR representative continued by mentioning that coordinators are more likely to feel comfortable selecting unknown when they don't know the type of insulin or insulin dosage rather than definitively selecting no.

Staff noted that the insulin dosage field has a limitation, which is that the insulin dosage units must be between 1 and 1000. Values for units/kg/day would probably be less than one, so maybe centers are entering total dosage because they can't enter doses less than 1.

The Chair stated the insulin dosage should range from 0 to 1000. The other question is, if the Committee tries to tackle the help documentation in the future, should the Committee give programs the option of either entering total insulin dosage in units/kg/day or entering total insulin dose per day and the patient's weight. The Chair explained that giving an option would allow coordinators to determine what data they have and then enter it.

The Chair inquired if the Committee would need to change the insulin dosage data field and whether it would need to go through OMB approval. Staff explained that changes to data elements would need

OMB approval, but if the Committee is changing the help documentation then there wouldn't need to be OMB approval. For example, to add the weight data element back into the form then that would need OMB approval.

A member stated that everything about the paragraph in the help documentation suggests that its total amount of insulin given per day that should be inputted except in the average total insulin dosage per day section where it states the dosage should be in units/kg/day. The member stated that the Committee would want to know the total insulin per day and weight. For example, if a patient's insulin dosage changes from 50 to 100 units and their weight increased, the units/kg/day wouldn't demonstrate a significant weight gain or that the insulin usage doubled. The member suggested that total insulin dosage per day and corresponding weight would give the Committee the most optimal use of the data for analysis.

The Chair agreed that the definition of graft failure should be revisited so it will be useful for Committee's in the future.

A member agreed to have the data granularity that was just mentioned; however, a member noted that over half of the values entered are not being calculated, resulting in inaccurate data. The member emphasized that a large focus of revisiting the graft failure definition should be to make it as easy as possible for members to input the data.

Staff explained that a frequent question they have received about this data field is how to answer this field when a patient is coming on and off of insulin post-transplant in the first 90 days. What date should be collected for when insulin use resumed? How would the duration of insulin use be entered for those patients?

An SRTR representative stated that they think the policy document is clear – if someone came off of insulin and started back on it later, the date of the most recent start should be entered. There's one hole in the auditing data collection form, which is that the form asks for date of last insulin resumption and the current dose.

A member questioned if it would be easier to change the values range of the total insulin dosage field and have coordinators reflect on what can actually be entered. The Chair stated that the Committee should look at this suggestion, but it hinges on whether that change would need OMB approval or not.

A Health Resources & Services Administration (HRSA) representative inquired if the data collected on oral hypoglycemic medications post-transplant is clear or if that also needs to be adjusted. The Chair inquired if staff knows how well the oral insulin use was reported and if the forms ask what insulin patients are taking or if they're just taking any oral insulin.

Staff stated that the Transplant Recipient Follow-up (TRF) form asks if the patient is on oral medication to control blood sugar and the response options are yes, no, or unknown. Staff continued by explaining that, at 6 months post-implementation, 5% of the forms submitted had been marked unknown for whether a patient was using any method of blood sugar control.

A HRSA representative inquired if the use of oral insulin is included in the definition of graft failure or if this data element is additionally being collected. The Chair explained that oral insulin use was just being collected. The Committee consider it graft failure if the patients are back on insulin because it's required as a qualification for pancreas transplant. It is believed that if a transplant patient who is diabetic and with a high BMI, there may be some weight gain after transplant. These patients may have a new onset post-transplant Type II diabetes, even if they had Type I beforehand, so the Committee included this data because they wanted to see how many patients may be on oral medications.

An SRTR representative stated that the Committee should also consider that non-insulin medications are not restricted to oral medications today. There are injectable non-insulin medications that are being used, so that may need to be accounted for as well.

The Chair stated that the TRF form has been a difficult form to fill out, so this may be a good time to start forming a Workgroup to review the graft failure definition, the data fields collected, and the help documentation.

Staff stated that the process for forming a Workgroup can be discussed.

3. OPTN Policy Oversight Committee Update

The Committee reviewed the purpose of the Policy Oversight Committee (POC) and the projects that they are currently working on.

Summary of discussion:

A member inquired if the Multi-Organ Transplant Workgroup is going to be one workgroup with all of the organs represented or if it will be a separate workgroup for each organ type. Staff explained that this will be one workgroup with representative for each organ.

The vice-chair inquired if this Multi-Organ Transplant Workgroup is separate from the desire to move forward with heart-kidney allocation or if that's a sub-project of the workgroup. Staff explained that heart-kidney allocation would be a sub-project of this workgroup. The multi-organ proposal that went out for the Winter 2021 public comment cycle was sponsored by the Organ Procurement Organization (OPO) Committee; however, staff felt that it would be more beneficial to create an Ad Hoc Multi-Organ Committee to work on these issues so the various organs involved could be represented, but also to ensure that there are consistent principles and approaches across the organ types.

A member inquired if there are anticipated changes in how kidney-pancreas allocation would occur independent of continuous distribution. The vice-chair stated that the next changes related to kidney and pancreas will be related to continuous distribution.

A member stated that, in the past, they have heard concerns raised by the pediatric community and other groups regarding the utilization of pancreata and wanted to emphasize the importance of including the Committee in the multi-organ work.

4. Project Update: Medical Urgency

The Committee reviewed the goal of this Workgroup and was presented with the list of medical urgency criteria the Workgroup discussed.

Goal: Evaluate and discuss criteria that should be considered medically urgent as it pertains to pancreas candidates

Criteria

- Hypoglycemic unawareness
- Type I vs. Type II diabetes
- Pancreas Donor Risk Index (PDRI)
- Cardiac Autonomic Neuropathy
- Total duration of diabetes
- Pediatrics
- Accessibility to technology
- Diabetes ketoacidosis (DKA)

- Sever hypoglycemic events
- Gastroparesis
- Impaired Awareness of Hypoglycemia (IAH)

Next Steps

Resume project after Board of Directors Meeting: December 2021

- Consider any additional feedback provided from the Kidney and Pancreas Continuous Distribution concept paper
- Present project plan/timeline to Policy Oversight Committee

Summary of discussion:

There was no discussion.

5. Project Update: Continuous Distribution

The Committee reviewed the goal of this Workgroup, attributes, and the current progress that has been made.

Goal: Change allocation from a classification-based system to a points-based system

Progress to Date

- Phase I of identifying attributes has been completed
- Phase II: Assigning Values to Attributes
 - Workgroup began discussion on Phase II in January
 - Workgroup has submitted data requests focused on the following attributes:
 - ABO/calculated Panel Reactive Antibodies (cPRA)
 - Pediatrics
 - HLA Matching
- Concept paper for Kidney and Pancreas Continuous Distribution are scheduled to be released for public comment in August 2021

Summary of discussion:

A member inquired if the broader community understands this continuous distribution model and what their thoughts or beliefs are about how this system should look. The Chair stated that they aren't aware if public comment is greatly known by the broader community, but public comment is open to all of the broader community for them to share their thoughts. Staff stated that a lot of outreach had been done with the transplant community at large, as well as patient groups.

6. New Project Ideas

The Committee brainstormed new project ideas and reviewed the OPTN Strategic Goals to make sure these ideas were in alignment.

Potential Project Ideas

- Evaluating outcomes of organ retrieval for pancreas allocation
 - Organ loss due to damage from recovery process
- Promote increase in pancreas utilization
 - Ex: Collaborative Innovation and Improvement Network (COIIN) project
- Review Islet Wait Time Transfer Request process (OPTN Policy 11.3.D.ii: *Criteria to assign Islet Waiting Time to Pancreas*)

- Reworking pancreas graft failure definition

Summary of discussion:

A member stated that COIIN project would be exciting. They were involved in COIIN for kidney and they thought it was a big success. This would be a good approach for the Committee to address potential quality improvement process for listing patients, organ offers, and management of patients post-transplant.

The vice-chair inquired if there is any staff that can speak to the feasibility of a COIIN project for kidney-pancreas. Staff will reach out to the team that works on these projects for additional information to determine potential next steps for this project idea.

Staff mentioned that one of the pieces of COIIN for kidney was sharing best practices and inquired if the Committee believes that one of the driving forces for pancreas utilization is a need to share best practices for wait list management and donor interaction or is there more that needs to be addressed to increase pancreas utilization.

The vice-chair stated that they do think that a lot of it is in comfort with patient selection, organ selection, and what happens after transplantation – the collaborative nature of COIIN is key.

A member stated that, when low volume and high volume centers are collaborating, there are reasons for centers being low volume other than waitlist management and donor interaction. These reasons include low number of candidates identified, inappropriate turndowns, lack of staff, and lack of resources.

Members are very interested in getting more information on the COIIN project and agreed that it would be a worthwhile project, especially due to the success of the project with kidney.

The vice-chair inquired what staff think is a good number of projects to move forward with. Staff stated that currently members are working on continuous distribution and medical urgency, so it would be appropriate to look at 1-2 projects. If there's a list of projects, the Committee can prioritize them based off of what needs to be done and the other current projects being worked on.

The vice-chair inquired if the changes to the TRF form and the changes to graft failure are a similar project. The Chair stated that they think that they are the same. Members agreed that it's reasonable for the Committee to start working on that and can send out an email for members to express interest.

The vice-chair inquired if, for pancreas retrieval, that is something that could be discussed with the OPO committee or other interested Committees. Staff stated that the Committee could discuss collaborating with the OPO committee. The vice-chair expressed concern that this project would be telling OPOs what they can and can't do and whether it's even possible to make policy regarding that. Staff stated that this the Committee can bring this to the OPO Committee to get their input.

The vice-chair inquired if members are interested in working on the pancreas retrieval project as well or if members would rather limit the Committee's projects to hearing about COIIN, reworking the graft failure definition, and continuous distribution. A member stated that the pancreas retrieval project is important; however, they are concerned that it would be a lot of effort that may not be accepted.

Staff stated that this pancreas retrieval idea could be brought to the OPO Committee to gauge their acceptance of this project and then, based on the sentiment of the OPO Committee, the Committee can decide whether this project should be a policy change or should be a guidance document. Staff also suggested presenting this idea to the Policy Oversight Committee (POC), since POC members represent all of the policy developing Committees.

The vice-chair stated that the islet wait time transfer request project may not be a lot of work for the Committee. It seems like the review process of islet wait time transfer requests could be changes to be more efficient. The Chair agreed that this wouldn't be a major change since the review process doesn't affect many patients. The Chair stated that it comes down to whether the Committee wants to continue dedicating their time to the review process as it is now or dedicate their time to changing this process.

Members agreed to prioritize the following projects:

- 1) Promote increase in pancreas utilization – COIIN project
- 2) Reworking pancreas graft failure definition
- 3) Reach out to POC during their May meeting to get thoughts about the pancreas retrieval project
- 4) Table the islet wait time transfer request project – process is currently working efficiently enough

Upcoming Meetings

- May 19, 2021 (teleconference)

Attendance

- **Committee Members**
 - Silke Niederhaus
 - Rachel Forbes
 - Antonio Di Carlo
 - Daniel Keys
 - Ken Bodziak
 - Luke Shen
 - Nicolae Leca
 - Pradeep Vaitla
 - Randeep Kashyap
 - Todd Pesavento
- **HRSA Representatives**
 - Jim Bowman
 - Marilyn Levi
- **SRTR Staff**
 - Bryn Thompson
 - Jon Miller
 - Nick Salkowski
 - Raja Kandaswamy
- **UNOS Staff**
 - Joann White
 - Rebecca Brookman
 - Ross Walton
 - James Alcorn
 - Julia Chipko
 - Kerrie Masten
 - Leah Slife
 - Matt Prentice
 - Nang Thu Thu Kyaw
- **Other Attendees**