**OPTN Pancreas Transplantation Committee**
**Meeting Summary**
**May 16, 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 05/16/2022 to discuss the following agenda items:

1. Research Update: Three Year Pancreas Graft Failure Definition Post-Policy Monitoring
2. Continuous Distribution of Kidneys and Pancreata

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

**1. Research Update: Three Year Pancreas Graft Failure Definition Post-Policy Monitoring**

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

The goal of this policy change had been to establish a consistent definition for pancreas graft failure. The new definition implemented on 2/28/2018 was:

"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"

The policy implementation also created new status fields to collect data about insulin dosage and duration, HbA1c, and C-peptide on the Transplant Recipient Registration (TRR) and Transplant Recipient Follow-up (TRF) forms.

Data summary:

The following is a summary of the results:

- Optional data collection fields are not utilized in the majority of cases
- Graft failure cannot be determined based on the new definition for the majority of recipients on insulin due to missing data
- Of candidates whose graft status can be calculated under the new definition, very few meet the definition of graft failure
- Recipients continue to be reported as having failed grafts despite not meeting the definition
- Significant difference in graft survival seen only at two years

Summary of discussion:

The Chair stated that it's not surprising the optional fields aren't being filled out and mentioned the Committee may need to consider revising the collection form so there are more mandatory fields.

A member stated that there are several areas for the Committee to look at: (1) ease of filling out the data collection form from a logistical standpoint and (2) review of the pancreas graft failure definition. The member emphasized that having 98 percent missing data for insulin dosage field is concerning as this provides information to help provide insight to graft failure.

A member mentioned that the definition is public knowledge and something that can be reinforced; however, if the Committee does not mandate the definition they won't have an accurate understanding of the graft losses.

A member stated that the definition is still liberal and suggested that the Committee consider incorporating glycated hemoglobin (A1c) into the definition. A member agreed and noted that the data gap is so large that, when looking at the definition, others have advocated changing the definition to simply whether the recipient is on insulin or not.

Another member noted that, as more Type II diabetics are receiving transplants, a proportion of those patients will gain a significant amount of weight afterwards and may still be on insulin; however, the pancreas graft is still making insulin but it's not sufficient for the recipient. The member stated that they aren't entirely sure if that should be considered graft failure.

A member explained that there are some individuals who agree that mitigating the effects of the disease equates to a successful pancreas graft, which is why they are comfortable with transplanting Type II diabetics and having them experience weight gain or insulin resistance. A member highlighted that chronic kidney disease (CKD) has multiple stages, and suggested that multiple stages of pancreas graft failure is something the Committee should consider.

A member stated that this is complicated and it seems the goal is to stabilize the glycemic state and, if that can be done with insulin and the recipients aren't experiencing hypoglycemic unawareness, then recipients aren't going to have microvascular disease. The member agreed that A1c would be a key metric in doing this.

A member inquired if the Committee is asking for this data from programs that have already determined the recipient is experiencing graft failure or if they are requiring programs to say the recipient is experiencing graft failure based on the insulin use data field. The Chair stated that, typically, programs make a determination themselves, while the Committee wanted a more unified approach to graft failure. The Chair mentioned that it appears this definition may not be granular enough, though, so the Committee will need to re-evaluate some of these considerations.

The Chair inquired about how important it is to have this standardized definition or should the Committee trust the programs to make a determination of failed or functioning.

A Scientific Registry of Transplant Recipients (SRTR) representative mentioned that, prior to the onset of this definition, there was no policy for pancreas graft failure, but there was a TIEDI definition. The TIEDI definition alluded to "partial function" as a recipient being on insulin and the insulin requirements were less than 50 percent of the basal requirements. If the recipient's insulin requirements were greater than 50 percent of the basal requirements, then it was considered "total graft failure". Partial graft failure and functioning grafts were considered functioning. The SRTR representative stated that there were reporting issues with that definition as well.

The SRTR representative explained that the discussion around the new graft failure definition was that there would still be a lot of imperfections (Type II diabetics, onset of diabetogenic drugs, and onset of

weight gain) and reasons why there may be insulin usage without endogenous loss of beta cell function. The SRTR representative stated that the Committee had inquired if these would be considered failure of the graft or failure of the process, if the goal is not insulin independence.

The SRTR representative continued by stating the Committee had wanted to be inclusive of graft failure patients – set a low threshold and anything above that is undoubtedly graft failure. The SRTR representative also noted that the important data to capture are the recipients whose grafts are still functioning and whether or not they are on insulin; however, that is where there is missing data and insulin dosage is difficult to calculate at that point in time.

The SRTR representative mentioned that SRTR did stop publishing pancreas graft failure data around 2011 in anticipation of a new graft failure definition. Only recently has SRTR collected enough data to publish again, but with a lack of data related to insulin dosage as previously mentioned.

A member stated that when they have pancreatic failure at their program, they perform an oral glucose tolerance test to assess function and get the recipient's C-peptide at time zero and C-peptide two hours after. The member stated that, if they can demonstrate that the pancreas is making insulin in response to a glucose challenge, then it could be an indicator that the patient has Type II diabetes. The member emphasized that it's difficult to discern if that is pancreatic transplant failure or just insulin resistance.

A member stated that, in order to decide the best definition for graft failure, the Committee should define the purpose of collecting data on graft failures. The member agreed with the suggestions of incorporating A1c and having multiple stages to the definition.

A member stated that, as a patient, they looked at the success and failure rate when deciding what program to register at and never once considered a partial failure as a partial success. The member stated that the patient perspective should be considered as well when determining this definition because it can be used to educate the general population as well. The Chair inquired where the member found the pancreas outcomes data when looking by programs because it's difficult to find data on pancreas outcomes. The member stated that they believe it was a state report where they found this information.

A member mentioned that, as a community, we should want to know the pancreas graft failure rate. The member mentioned that kidney graft failure is nebulous in itself and it's not as easy to define pancreas graft failure as the recipient is on insulin or a certain amount of insulin. The member stated that they have seen Type I diabetics who have gained 100 pounds and required insulin as well, so it's not just Type II diabetics that have insulin insufficiency. The member suggested that the Committee should have some standard definition so the whole pancreas community is on the same page.

Staff mentioned that this has been brought up as a potential project idea, in addition to modifications to the Transplant Recipient Follow-Up (TRF) form.

There was no further discussion.

**2. Continuous Distribution of Kidneys and Pancreata**

The Committee discussed facilitated pancreas allocation in regards to how it can be incorporated into the continuous distribution framework. The Committee had previously decided to keep facilitated pancreas as an operational component and keep it as similar to current allocation as possible.

Currently, organ procurement organizations (OPOs) and the OPTN are permitted to make facilitated pancreas offers if the pancreas has not been placed within three hours prior to the scheduled donor organ recovery. OPOs also only have access to facilitated pancreas allocation after all pancreas offers made to transplant programs within 250 nautical miles (NM) have been declined.

The following questions were posed to the Committee:

- How should programs qualify to receive facilitated pancreas offers?
    - Is distance still a good mechanism to identify "aggressive" pancreas programs?
    - Could consider alternatives:
        - Number of previously refusing programs
        - Example: programs who have transplanted X pancreata that were previously declined by Y centers in the previous 2 years would qualify to receive facilitated pancreas offers
- When should OPOs be able to make facilitated pancreas offers?
    - Should OPOs be required to exhaust a certain number/percentage of offers before they can initiate a facilitated pancreas match run?

Staff noted that they are posing these same questions to the OPTN OPO Committee to gather their feedback and recommendations.

Summary of discussion:

The Chair stated that they don't think distance was ever a mechanism of aggressiveness. The intent of using 250 NM was so that small programs had priority for the pancreata that were close to them, since those are the centers that would most likely utilize the pancreas. The Chair mentioned that they think all centers, within a certain proximity, should have access to these offers before they are offered to more aggressive centers that are further away.

The Chair inquired if a new match run can be created within three hours of the pancreas procurement. Staff stated that that would be something different than what is currently being done in policy and may be too complex for the first iteration of continuous distribution. The Chair stated that, currently, it seems there is a bypass run that occurs within three hours of the operating room (OR). Staff stated that that is correct. The Chair inquired if there could be a bypass continuous distribution run. Staff stated that that would be the most similar to current policy; however, the order of the match run for that bypass run does not change.

Staff explained that if the Committee maintains the requirement for OPOs to offer to all candidates within 250 NM of the donor hospital before they may apply facilitated placement bypasses, this will reduce the effectiveness of facilitated pancreas allocation once the distance-based classifications are removed in continuous distribution. The Chair stated that there would still have to be programs that qualified for facilitated pancreas allocation and they would be prioritized.

A member inquired how facilitated allocation works for other organs. Staff mentioned the only other facilitated allocation they can think of is expedited liver allocation, but it is a bit different than facilitated pancreas. The member stated that, in their experience, expedited liver isn't as formal.

A member stated that expedited liver is very specific (the donor has to be in the OR), but they don't think there are other organs that have a facilitated process for allocation.

The Chair stated that the utilization of pancreata is important – if the OPO has started ahead of time and the pancreas is still not placed within three hours then all that matters is getting the pancreas placed. The Chair stated that it would be great to have a way to turn on facilitated pancreas allocation within three hours, whether it's a new run and OPOs just look at who the FP programs are or not.

Staff summarized that it seems distance is still a good mechanism to help with identifying those programs and allocation. The Chair stated that, even at three hours, they'd want the pancreas to be

allocated closer than further away and to a program that has experience transplanting pancreata from outside of 250 NM.

Staff also summarized that it seems the Committee agrees that OPOs should allocate in the same way that is currently outlined in policy. The Chair agreed and stated that, for equity, the OPO should still try to offer according to the match run prior to three hours before OR.

A member stated that, from an OPO perspective, switching to facilitated three hours before OR is challenging because of the need for an available surgeon who is capable of recovering the pancreas. The member explained that, very commonly, the OPO will be challenged with the liver team being ready to recover the liver but they are uncertified to recover the pancreas.

The Chair inquired, for a pancreas quality donor, how much time is there usually before OR. A member stated that 3 hours is challenging but it's possible. The Chair inquired if it's common that the liver team is finds difficulty in recovering the pancreas. A member stated that it's common, especially if the liver team is all fellows or they are from a center that doesn't do pancreas transplant.

Staff summarized the Committee's decision in wanting to maintain what is currently in policy in regards to distance and the parameters around when OPOs can use facilitated pancreas allocation.

Next Steps:

Staff mentioned that they will pose these questions to the OPTN OPO Committee for their input and will share their feedback via email.

There was no further discussion. The meeting was adjourned.

**Upcoming Meeting**

- June 22, 2022

**Attendance**

- **Committee Members**
  - Rachel Forbes
  - Collen Jay
  - Dean Kim
  - Antonio Di Carlo
  - Diane Cibrik
  - Jessica Yokubeak
  - Luke Shen
  - Mallory Boomsma
  - Muhammad Yaqub
  - Nikole Neidlinger
  - Parul Patel
  - Ty Dunn
  - Todd Pesavento
- **HRSA Representatives**
  - Marilyn Levi
  - Raelene Skerda
- **SRTR Staff**
  - Bryn Thompson
  - Jonathan Miller
  - Raja Kandaswamy
- **UNOS Staff**
  - Joann White
  - Rebecca Brookman
  - Kaitlin Swanner
  - Kelsi Lindblad
  - Lauren Motley
  - Sarah Booker