**OPTN Pancreas Transplantation Committee**
**Continuous Distribution Workgroup**
**Meeting Summary**
**September 25, 2020**
**Conference Call**

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

**Introduction**

The Pancreas Transplantation Committee Continuous Distribution Workgroup (the Workgroup) met via Citrix GoToMeeting teleconference on 9/25/2020 to discuss the following agenda items:

1. Overview of Project
2. Review and Discussion of Attributes

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

**1. Overview of Project**

The Workgroup reviewed the scope of the Continuous Distribution project as well as the objectives of the first phase of the project (identifying and categorization of attributes).

Summary of discussion:

Continuous Distribution will change allocation from a classification-based system to a point-based system. For the first phase of the project, the Workgroup is being tasked to identify and categorize pancreas specific attributes that relate to the OPTN's goals in the OPTN Final Rule.

There were no comments or questions.

**2. Review and Discussion of Attributes**

The Workgroup reviewed and discussed proposed attributes and their categorization related to pancreas transplantation for consideration in the Continuous Distribution project.

Summary of discussion:

The Workgroup provided input on proposed attributes and their categorization as follows:

*Medical Urgency: Prioritize sickest candidates first to reduce waiting list mortality.*

Attribute: Kidney-Pancreas versus (vs.) Pancreas vs. Islet

The Workgroup Chair stated that in pancreas transplantation, medical urgency and determining the sickest candidate is challenging and has not been done. Candidates who need a kidney-pancreas transplantation may have somewhat more urgency than a pancreas alone transplantation. It will be challenging to prioritize among these patients.

A member stated that when listing patients for pancreas alone candidates, hypoglycemia unawareness and severe diabetes are present indications that are used in listing. For Kidney-Pancreas candidates, those patients are already on dialysis and waiting for two organs. It may be difficult to make one type of transplant more prioritized than the other.

Another member stated that there should be consideration for Type I diabetics vs. Type II diabetics and whether there should be prioritization of Type I diabetics. In regards to hypoglycemic unawareness, it may be hard to quantify to develop any type of criteria. If there were prioritization, it is thought that Type I diabetics would be favored in being prioritized for pancreas alone transplants as they would be more likely to have hypoglycemic unawareness. As far as defining this, there may need to be a review of C-peptide level as a potential surrogate for this determination.

*Post-Transplant Survival: Prioritize candidates who are expected to survive for at least one year after receiving a transplant.*

Attribute: HLA Matching (0-ABDR), Ischemic Time

The Workgroup Chair stated uncertainty that these may not be good prioritization points unless there is some sort of calculator for likelihood to survive a year. The selection process may not be relevant for pancreas.

A member agreed with this and stated that there is not any criteria or objective number to quantify post-transplant survival for pancreas, as seen in liver and kidney. There may be a need to refer to the Scientific Registry of Transplant Recipients (SRTR) to see if there is some criteria that could be established, but there may not be a tool for pancreas transplantation. The member continued by suggesting that the proposed HLA Matching (0-ABDR) attribute may be better categorized in Candidate Biology. For pancreas, it is challenging to categorize this as post-transplant outcomes and factors to help prioritize based on this. From previous discussions with SRTR, HLA Matching was discussed and it was determined that 0-DR mismatch was a benefit. There could be more research to get more information on how much of a benefit this is, although it is not a factor that is looked into when accepting or declining a pancreas offer.

SRTR staff stated that in terms of pancreas transplantation, there is not a huge problem on inequities in organ allocations. It is based upon programs and how aggressive they are. The number of transplants for pancreas are already low and while embracing the idea of making this a fair and equitable system, there is a risk of over tuning the system and maybe causing a detrimental effect in allocation. There are a few things to consider:

- Inequities as far as high CPRA patient in KP; if there is a high panel reactive antibody (PRA) KP patient, they may come up for kidney alone, but not a KP because there is no allocation preference for a high CPRA and a KP.
- A 0 mismatch does not receive any preference. This can add onto waiting time and continuous distribution of distance rather than concentric circles. Other than 0 mismatch, the rest of the matching can become more challenging. This would be something that should be modeled to see what the recent data shows and determine if there is any value in adding matching to it.
- In terms of mortality risk pre-transplant, for any type of diabetic, the biggest risks are (three things that affect mortality):
  - Hypoglycemic unawareness - This is tougher to assess as it is based on surveys and may be hard to evaluate)
  - Cardiac autonomic neuropathy – any patient who is chronically Type I diabetic and enters the phase of cardiac autonomic neuropathy, their 5-year survival is about 40%. The data related to pancreas transplantation is not well documented.
  - Kidney Failure
- When looking at organ utilization and waiting time, the pancreas transplant alones are waiting twice as long as simultaneous pancreas kidney transplantations (SPKs) on the waiting list. This imbalance should be taken notice.

A member suggested the possibility of using donor risk index. Similar to kidney donor profile index (KDPI), donors with low donor risk index could be utilized for recipients with low transplant survival. This has not been established in pancreas but it may be able to be factored in with the characteristics that are being discussed.

SRTR staff clarified that pancreas donor risk index (PDRI) has been discussed previously by the Committee and there were some challenges identified. The PDRI's effect and its correlations with outcomes is greatly driven by one variable: pancreas preservation time. Cold preservation time is the only variable that changed that lead to permanent outcomes. This does not pertain to allocation as it happens after the fact.

The Vice Chair added that using post-transplant to assign candidates can limit some of their options. When programs accept organ offers, they are thinking of these factors and what is appropriate for the patient. Candidates may not get offers if these factors are already being assumed.

*Candidate Biology: Increase transplant opportunities for patient who are medically harder to match.*

Attribute: Blood Type, CPRA, KP Transplants

A member stated that HLA Matching (0-ABDR) should be added to this category. Any HLA matching should be included. A 0 mismatching from a Kidney-Pancreas or Pancreas transplant separates out from the rest.

The Workgroup Chair agreed with this and stated that it would be valuable to be included to this category. Additionally, for the suggested KP transplant attribute, it was suggested that input from the Kidney Committee would be valuable to determine if this is the appropriate categorization.

A member stated that if there was a way to quantify hypoglycemic unawareness and autonomic neuropathy, it would make sense to include these as attributes but as there is no data to support this, it would be challenging to include them into this model.

The Workgroup Chair stated that pediatric age should be included to this category, since there are a few pediatric pancreas alone and pediatric kidney-pancreas candidates. The Workgroup Chair continued by explaining that part of what can come out of this project is to identify attributes for prioritization and later on, develop a scored based on this model to help in collecting the data to evaluate the impact.

*Patient Access: Increase transplant access for patients under the age of 18 and patients who previously donated an organ or part of an organ.*

Attribute: Wait Time

The Workgroup Chair stated that pediatric age would be appropriate for this category as Patient Access is defined by patients under the age of 18. Patient access is difficult for patients who live a greater distance from a program and would be a controversial topic to discuss on the advantages and/or disadvantages for patients.

The Workgroup Chair continued by stating that for now, waiting time may need to be included, but should not play a big role in this category because patients are referred along their course of diabetes. Some patients are referred early because their endocrinologists is transplant-aware and educated while others are referred late, due to factors that are not the patients doing.

An SRTR staff stated that for kidney-pancreas patients, wait time is an important factor and goes back to the patient's dialysis start date. For pancreas alone, waiting time may be challenging. There are questions of when to begin the wait time – does it begin when the patient started having hypoglycemic unawareness or after so many years of diabetes? These details can become inexact; there is not an ability to apply hypoglycemic surveys retrospectively to determine when it first started.

The Workgroup Chair agreed with this and added that waiting time for pancreas alone is a tricky variable to think about. Time of listing can always be used, with recognizing the advantages and disadvantages. There is not any other good variables to use for waiting time for pancreas alone; the time of listing then use a fraction of how long they've had diabetes/how long they've been on insulin (this may be more trackable). This can be an option if the Workgroup feels waiting time is not the right attribute.

The Workgroup Chair continued by stating that for kidney-pancreas patients, waiting time is fair for those who started dialysis at a set time. However, there are different listing procedures for different programs to be considered; patients may be equally sick, but have different waiting times based on what their respective programs decided to do.

Another member stated that this does depend on how a patient is referred. For pancreas alone patients, the waiting time is not as long, but agreed that waiting time is still a crude tool for pancreas alone.

SRTR staff stated that other things to keep in mind is that there are other factors that should be considered. The median wait time for pancreas alone patients is 24 months and depends on a number of factors. For blood type, type A blood types match quickly, while type O blood types and high CPRA patients wait longer. Additionally, kidney-pancreas patients have priority as well.

A member asked that if a patient had a prior living donor transplant, would it be fair to give them priority in terms of access to a pancreas after this versus other candidates. This subset of patients should be considered. There is also a biological need as well; if a patient received a living donor kidney and a pancreas sooner, in theory, the patient may be suppressed much less. The Workgroup Chair agreed with this idea.

SRTR staff stated that from a previous study, it was shown that early pancreas transplants associated with living donor kidney transplants had better outcomes. As a patient waits after a transplant, there can be a gradual accumulation of calcineurin inhibitor (CNI) toxicity, where the patient would be unable to tolerate a second transplant. There are a number of resources available that can account to this.

_Placement Efficiency: Consider resource requirements required to match, transport, and transplant an organ._

Attribute: Travel Efficiency Metrics, Costs

A member stated that this is important to pancreas in terms of having local donors, local recovery teams, decreasing cold ischemic time, and being able to plan more readily. It is not believed there are many cost or travel efficiency metrics, but this is an important attribute.

The Workgroup Chair agreed with this and added that there is a good number of pancreata that are not recovered because there is not a recovery team that has resources willing to travel greater distances. This varies from each program, but it is essential to include this. Many transplant programs may have one surgeon who does both the recovery and transplants; to send them across the country would not be feasible and would delay allocation.

SRTR staff asked if distance was a subset of travel efficiency metrics as it is not listed as an attribute. Is distance being taken away as a variable and using travel efficiency metrics attribute to be more comprehensive? UNOS staff confirmed that this was correct.

SRTR staff continued that if there is an attribute put in for travel efficiency metric, distance alone does not calculate the efficiency of travel. If an organ is chartered in, the efficiency soundly improves tremendously. The concept of chartering for pancreas transplantation is something that is being embraced by a number of programs over the last few years. For this Workgroup, it is something that could be considered and factored in. The Workgroup should consider cost sharing for traveling to improve travel efficiency.

The Workgroup discussed additional attributes and categories as followed:

*Donor Characteristics*

Attribute: BMI

A member opposed to BMI as an attribute as it is believed that programs should evaluate and decide on what they feel is a reasonable donor based on this characteristic.

The Workgroup Chair asked that if there was an islet candidate listed at an islet program, should potential donors with a BMI over 28 possibly be prioritized to the islet recipient over the pancreas group.

The member stated that if there is a program willing to accept a pancreas from a donor with a BMI of 30 because the distribution is muscular, wouldn't this be more favorable?

SRTR staff stated that BMI alone is not a contraindication although in looking at overall statistics, the use of patients with a BMI over 30 has dropped (about 5% of pancreas utilization at this point). After going through local offers of pancreas and there are no acceptances, it would then go for islets.

The Workgroup Chair agreed with this and stated that in many cases, BMI is not a consideration when looking at pancreas offers. It is a good point to make that when a pancreas is not accepted locally, to provide an opportunity for an islet candidate rather than placing the offer on the national list.

A member stated that this is a good point and may need to be revisited. Going to a national listing may not work every time and this would be a good alternative to ensure that the pancreas is utilized.

*Avoiding Organ Wastage:*

Attribute: Islets

There were no comments or questions.

*Miscellaneous:*

Attributes: Age, Prior Living Donor

The Workgroup discussed that both pediatric age and prior living donor should be attributes considered in the model. In regards to prior living donor, the Workgroup Chair voiced concern that currently, if a donor donated a kidney, they would have prioritization on the kidney list but not necessarily on the liver wait list or another list. The Workgroup Chair commented that for prior living donor, there should be a requirement outlined that any prior living donor should have priority on any other list they are placed on.

There were no additional comments or questions. The meeting was adjourned.

Next Steps:

- UNOS staff will synthesize the information from the meeting and revise the working attribute table for pancreas which will be shared with the Workgroup to review and discuss further during the next Workgroup meeting.

**Upcoming Meetings**

- October 9, 2020 (Teleconference)

**Attendance**

- **Committee Members**
    - Silke Niederhaus
    - Rachel Forbes
    - Parul Patel
    - Pradeep Vaitla
    - Tarek Alhamad
- **HRSA Representatives**
    - Chris McLaughlin
- **SRTR Staff**
    - Bryn Thompson
    - Jonathan Miller
    - Raja Kandaswamy
- **UNOS Staff**
    - Joann White
    - Jennifer Wainwright
    - Nang Thu Thu Kyaw
    - Rebecca Brookman
    - Ross Walton
    - Kerrie Masten
    - Nicole Benjamin