OPTN Pancreas Transplantation Committee
Continuous Distribution Workgroup
Meeting Summary
October 23, 2020
Conference Call

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

Introduction

The Continuous Distribution Workgroup (the Workgroup) met via Citrix GoToMeeting teleconference on 10/23/2020 to discuss the following agenda items:

1. Overview of Project – Review of 10/09 Meeting
2. Review and Discussion of Attributes
3. Next Steps

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

1. Overview of Project – Review of 10/09 Meeting

The Workgroup reviewed the purpose and goals of the Continuous Distribution project. Continuous Distribution will change allocation from a classification-based system to a points-based system in order hard boundaries such as geography and ABO Typing.

The Workgroup is currently in the first phase of the project, which is identifying and categorizing attributes.

During the Workgroup's last call, they discussed attributes specific to pancreas that are currently in policy. The following were new attributes introduced during the 10/09 meeting:

- Facilitated pancreas – avoid organ wastage
- Pancreas after kidney (PAK) transplant – candidate biology
- Prior living donor – patient access

Summary of discussion:

No discussion.

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:

Avoid organ wastage

Attributes: Islets, Facilitated Pancreas

A member inquired whether most other members are familiar with the facilitated pancreas policy. A member stated that it would be helpful to review the policy before having further discussion. A member explained that, in pancreas transplantation, the best use of the pancreas is often local; however,

pancreas allocation sometimes takes a long time. So, when it gets to the point in pancreas allocation where the donor is ready to go to the OR and it's within an hour of incision time, the OPO that is in charge of allocating or the United Network for Organ Sharing (UNOS) Organ Center can switch the allocation pattern to a facilitated pancreas allocation system. At the moment, the facilitated pancreas allocation system is comprised of a certain number of centers that have performed five transplants in the past two years. These centers have a history of importing pancreata and transplanting them successfully. This facilitated system can also only be applied after all local candidates have been exhausted.

A member inquired whether the Committee has data on how many pancreas were allocated using this facilitated system in the past couple of years. A member stated that it was maybe less than 40 pancreas per year.

A member stated that initially when facilitated pancreas was being discussed, the initial requirement was four hours prior to incision. However, there was concern that a large number of pancreas would move to the facilitated pancreas system and that would usurp the normal pancreas allocation system. The member explained that this concern didn't occur, so it may be worthwhile to reconsider the time requirement since it's difficult to mobilize resources within that hour.

A member highlighted another reason to include facilitated pancreas, which is if pancreas allocation is going to be operating from a larger distribution circle, more aggressive programs may have patients who may have been listed for longer. A member stated that, pre-COVID, the recipient teams went out to procure the pancreas for aggressive centers, but that's ruled out in a facilitated system currently.

Members agreed to keep islets and facilitated pancreas as attributes for this category.

Candidate Biology: Increase transplant opportunities for patients who are medically harder to match

Attributes: Blood type, CPRA, HLA Matching (0-ABDR), KP Transplants (biologically need both organs), Pancreas after kidney (PAK) transplants

A member stated that, for HLA Matching, the Workgroup should at least align with what the Kidney Continuous Distribution does and mentioned that the real discussion will be about the order for priority. With kidneys, there are so many candidates on each list that some blood group compatible transplants are discouraged or prohibited by the deceased donor regulations in order to give more equity to different blood group candidates based on waiting time. That may not be as relevant for pancreas.

A member mentioned that kidneys get two points for the DR match and suggested there could be additional points for that specific matching. A member stated that this could be combined with other factors in the future as well, for example, a patient that needs a pancreas alone and is quite young may develop renal failure over time. So it may benefit the community to try to match them so they won't be terribly sensitized if they need a kidney in the future.

A member inquired whether the Workgroup was discussing pancreas after living donor kidney or pancreas after deceased donor kidney in regards to the PAK attribute. UNOS staff explained that PAK is in regards to living donor kidney. A member stated that this attribute was added because the Workgroup didn't want to disincentivize living donor kidney transplants if the PAK wait times are longer than the simultaneous pancreas kidney (SPK) wait times.

A member mentioned that pancreas transplant alone (PTA) candidates with diminishing kidney function need to receive a pancreas offer sooner since that may save them from kidney transplant. The same might apply for deceased donor PAK patients since they may have been disadvantaged by receiving a transplant from a center that didn't offer pancreas transplant. A member questioned whether these

candidates should also receive some type of priority because PTA patients shouldn't suffer from longer wait times than SPK patients.

A member suggested giving the living donor an advantage that rewards the finding of the living donor, but also give some credit to those patients who went through a deceased donor kidney transplant already.

A member noted that a PTA patient with hypoglycemic unawareness has a higher mortality rate than a diabetic patient with a functioning kidney transplant and no hypoglycemic unawareness. A member emphasized the importance of including hypoglycemic unawareness in the Workgroup's continuous distribution model because, if the Workgroup doesn't include it, then it disadvantages some PTA candidates in relation to others.

A member suggested separating PAK into three different categories:

- Pancreas transplant alone (PTA)
- PTA with hypoglycemic unawareness
- Pancreas after living donor kidney
- Pancreas after deceased donor kidney

Members agreed that this is a good idea to separate PTA and pointed out that there may be overlap with how well donors match and CPRA.

A member inquired about the possibility of creating a safety net for the kidney for PTA patients marginal kidney function so they can still get a pancreas transplant if they have life threatening hypoglycemia. Members agreed that patient access may be a good place for this safety net. A member suggested looking where the liver safety net was put in their continuous distribution model.

A member brought up the distinction between Type I vs. Type II diabetes. A member inquired whether this was in regards to solitary pancreas or SPK candidates. The member stated this question was referring to both. A member explained that SPK transplants are usually done after a patient has had long standing diabetes and, by that time, Type II candidates usually have burn out and don't make much more insulin after that. A member noted that there could be overlap with low C-peptides in this situation.

Members agreed that it is hard to create strong definitions to distinguish between Type I and Type II diabetes, and it's almost easier to come up with a hypoglycemic unawareness score.

A member inquired about precedence for using a subjection score or scale in allocation for any organ type. Members explained that one example was the liver Pugh score and, for islets, they use a combination of the Clark and Gold score in the UK. A member also mentioned that there's a new trend in endocrinology that concludes patients on CGMs have hypoglycemic unawareness if they spend a certain amount of time between a certain range; however, not all patients have continuous glucose monitors.

A member stated that patients who fear hypoglycemia will let their A1C run high and use suboptimal insulin. The caveat is that hypoglycemic unawareness doesn't become apparent until a patient tries to control their sugar. A member suggested adding CGMs as an alternative attribute to hypoglycemic unawareness, since not everyone has CGMs. A member also inquired how surgeons would document candidates that need to have a high A1C and noted that, long-term, these patients don't have great outcomes due to high blood sugars.

UNOS staff explained that the Workgroup decided to put Type I and Type II diabetes in the miscellaneous category since it may not be in the purview of the continuous distribution project, but could be discussed in the Medical Urgency Workgroup.

A member stated that, in the past, the Pancreas Committee never categorized candidates as Type I or Type II diabetics, but instead included characteristics that are indicative of Type I or Type II. A member suggested taking out BMI and leaving C-peptides if the Workgroup considers that to be reasonable. The member explained that the reasonable value could still be 2 since a Type I candidate wouldn't be anywhere close to 2 C-peptides.

A member agreed with getting rid of BMI and using C-peptide, since that's one of the best attributes the Workgroup has to distinguish between Type I and Type II. The member suggested getting more priority for having C-peptides less than 2 since they have more risk.

A member inquired whether the Workgroup would need to introduce the idea of collecting C-peptide levels. A member noted that C-peptides are in the UNOS surgery form; however, it's not mandatory to input that data. Members agreed that once the Workgroup's continuous distribution model becomes operational the C-peptide field will need to become a required field.

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

Attributes: Waiting time, Age, Prior living donor

A member suggest putting the safety net under this goal, after discussing with the Liver and Kidney Committee. A member also pointed out the potential problem of a candidate having a kidney only transplant at a kidney only center – should these candidate get priority for a pancreas since their center didn't offer access to pancreas. A member stated that as long as the Workgroup has some priority for having a previous pancreas deceased donor transplant, it will be hard to determine which transplants were done in a center that provided it, or done in a center that didn't provide it.

The Workgroup decided to leave the safety net as they are currently discussing it.

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

Attributes: KP vs. Pancreas vs. Islets

A member suggested adding medical urgency workgroup as an attribute so there's evidence the Workgroup is working on components of medical urgency for pancreas.

Post-transplant survival: Prioritize candidates who are expected to survive for at least one year after receiving a transplant

Attributes: Ischemic time

A member stated that ischemic time depends on so many factors and may not be practical to include in the continuous distribution model. A member suggested using surrogates of ischemic time like distance or travel time, even though travel time could be hard to model too.

A member pointed out that ischemic time is not documented until after the transplant is complete, so the Workgroup would have to use other surrogates that predict ischemic time. The member stated that facilitated pancreas allocation is indirectly a surrogate of ischemic time because centers transition to facilitated pancreas allocation when they're having difficulty placing organs.

Members agreed to add distance and travel as attributes in order to predict ischemic time.

Placement efficiency: Consider resource requirements required to match, transport, and transplant an organ

Attributes: Travel efficiency metrics, costs

There was no additional discussion.

Donor Characteristics

Attributes: BMI

A member stated that, for donors, the Workgroup wants to consider BMI because a high BMI donor may be a candidate to donate islets, but not the best donor for pancreas. A member suggested also included age as an attribute, since, currently, younger donors are routed toward pancreas donation and older donors are routed toward islet donation.

Members agreed to keep the status quo for age and BMI – a donor 50 years or older with a BMI greater than 30 would be eligible for islet donation after exhausting all local pancreas candidates. A member suggested giving these islet candidates some type of priority so they can easily match with the potential islet donors.

3. 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 Kidney Continuous Distribution Workgroup UNOS staff.

Upcoming Meeting

- November 6, 2020 (teleconference)
- November 20, 2020 (teleconference)

Attendance

- **Workgroup Members**
  - Silke Niederhaus
  - Rachel Forbes
  - Ajay Israni
  - Parul Patel
  - Pradeep Vaitla
  - Raja Kandaswamy
  - Tarek Alhamad
- **HRSA Representatives**
  - Raelene Skerda
- **SRTR Staff**
  - Bryn Thompson
  - Jonathan Miller
- **UNOS Staff**
  - Joann White
  - Matt Prentice
  - Nang Thu Thu Kyaw
  - Rebecca Brookman
  - Kerrie Masten