

**OPTN Pancreas Transplantation Committee
Meeting Summary
November 15, 2021
Conference Call**

**Rachel Forbes, MD, Chair
Oyedolamu Olaitan, MD, Vice Chair**

Introduction

The Pancreas Transplantation Committee (the Committee) met via Citrix GoToMeeting teleconference on 11/15/2021 to discuss the following agenda items:

1. Project Update and Discussion: Continuous Distribution of Kidneys and Pancreata Concept Paper
2. Medical Urgency Project Update

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

1. Project Update and Discussion: Continuous Distribution of Kidneys and Pancreata Concept Paper

The Committee reviewed an overview of the progress of the continuous distribution project and an update on the analytical hierarchy process (AHP) exercise.

- Workgroup's progress
 - Finishing up phase 2, which is converting attributes into points
 - Second concept paper going out for January 2022 public comment cycle
 - Will include AHP exercise/community exercise

The Committee also resumed conversations regarding the islets and facilitated pancreas attributes and rating scales.

- Pancreas-specific attributes and rating scale recommendations
 - Islets
 - Binary (Yes/No) rating scale based on current criteria/classification outlined in policy
 - Facilitated pancreas
 - Binary (Yes/No) rating scale under placement efficiency goal
 - Additional points (boost points) for facilitated pancreas

Summary of discussion:

Islets

A member noted that there's not much utilization of pancreata when the donor is both over 35 years old and has a body mass index (BMI) over 30, so it would be more efficient to allow those pancreata to be allocated to islet candidates.

A member mentioned that there could be more discussion regarding how to prioritize kidney-pancreas (KP), pancreas, and islets. A member suggested that pancreas and KP priority in current policy should stay the same and continue to be based on wait time; the Committee agreed that pancreas candidates

should not wait too long after their kidney transplant. Another member agreed and added that, from experience, isolated pancreas transplants are not performed as often as sequential pancreas transplants.

A member inquired how many islets infusions have been performed in 2020 and how many islet candidates are currently on the national wait list. Members noted that the numbers are in the single digits. It was explained that 3 islet candidates were added to wait list in 2020 and by the middle of 2021 there were 67 total islet candidates.

A Scientific Registry for Transplant Recipients (SRTR) representative inquired about what the intent is of changing the age cut off to 35 years old when the utilization of islets at that donor age is equally as low as the utilization of pancreata. The SRTR representative emphasized that a policy change to 35 years old may be too sudden and suggested that the Committee consider the ramifications of that change.

A SRTR representative explained that, currently, waiting times are low for kidney-pancreas (KP) candidates, which allows programs to be very selective of the pancreata that they accept. This means that, currently, data may not accurately show the utility of the pancreata from donors between the ages of 35 and 40. If the waiting time for KPs begins to increase, then most programs would start using kidneys and pancreata from 40 year old donors to offset the increase in waiting time; however, right now they don't need to. The SRTR representative cautioned the Committee on using practice patterns to justify policy change because practice patterns can change very quickly.

Members noted that KP and pancreata alone candidates are still allocated before islet candidates for all donors except donors older than 50 years old or donor with a BMI greater than 30. A SRTR representative stated that they do not agree with all pancreata from donors over 35 years old being first allocated to islets because it may cause pancreas waiting time to increase when islets aren't approved by the U.S. Food and Drug Administration (FDA) yet.

A member suggested that 40 may be a better age cutoff than 35, since the catchment for pancreas should go up to at least age 50.

A member also highlighted that, in the continuous distribution framework, there doesn't need to be an age cutoff. Instead, there can be an age scale or BMI scale which can assign points that gradually increase from 30 years old up to 50 years old in order to increase priority for islets. A member inquired if these attributes would be categorized under donor biology. Staff confirmed this to be correct and explained that the Committee could decide to add "donor age" and "donor BMI" as attributes under donor biology in the pancreas continuous distribution framework.

A SRTR representative also mentioned that there can be an interplay between the age and BMI attribute. For example, pancreata from a donor aged 40 with a BMI of 25 has a much higher likelihood of being allocated to an islet candidates than pancreata from donors with a BMI of 32. The SRTR representative explained that pancreata from donors who are 40 years old or older and have a BMI greater than 30 could have a stronger priority to be preferentially allocated to islets, as opposed to receiving priority for either age or BMI. Staff explained that this is possible within continuous distribution; however, it gets significantly more complicated to implement.

Members agreed that it makes the most sense to preferentially allocate to islets when both criteria are met, since donors aged 35 with a BMI of 30 are rarely used for whole organ pancreas transplant and the islet yield seems to be even higher than lower in that situation. A member, again, noted that 40 is the preferred age criteria, since some pancreata may get used from donors between the ages of 35 and 40.

A member suggested that it would be helpful to review data on how many KPs are used from donors between the ages of 30 and 50 and from donors with a BMI above 30 in order to see at what age KPs

aren't being used at all or not being considered. The member emphasized that if there's any chance the pancreas could be utilized at an age then that should be used as the cutoff.

A SRTR representative noted that five year data is colored by the new pancreas allocation and, since then, the waiting time for KP has been dropping dramatically to where it's now down to 12 months. Currently, with KP waiting times being so low, one would expect utilization at the fringes of the criteria to be low; however, current situations may change and it shouldn't be used to make projections for the future.

The Chair inquired if changing the criteria for islet priority counts as a policy change and whether it needs to go through a different process than continuous distribution. Staff explained that this could be adjusted within the continuous distribution project.

The Chair inquired if the calculated panel reactive antibody (cPRA) attribute for pancreas is more aligned with the kidney attribute rather than the 80 percent cPRA that is currently in policy. Staff explained that that is up to the Kidney Committee and Kidney Pancreas Continuous Distribution Workgroup to decide. Members agreed that there is an advantage in mirroring what the Kidney Committee decides for cPRA because patients are often dually listed for KP and kidney transplants.

A SRTR representative explained that, for example, a KP candidate is allocated a kidney based on a 99.4 percent cPRA, but the pancreas cannot come with it because the cPRA allocation does not match the threshold for KP allocation. In this situation, the program typically calls the donor hospital to ask if the pancreas can be allocated to the KP candidate; however, most of the time the donor hospital declines them the pancreas either because policy doesn't allow it or the pancreas has already been allocated. The SRTR representative continued by stating that this creates a disadvantage for the KP recipient who is trying to get a kidney offer.

The SRTR representative further explained that the reverse (withholding the kidney instead of pancreas) could happen in a local situation – the kidney may not get offered to the KP candidate unless the Committee preserves the policy that one kidney goes to a KP candidate unless it goes to a kidney heart or kidney liver candidate.¹ The SRTR representative emphasized that the Committee needs to be determine that the ground rules set forth in policy are maintained in the new allocation because, if they aren't, that may change the approach for prioritizing attributes.

A member mentioned that they haven't heard the above policy being discussed by the Multi-Organ Transplantation (MOT) Committee.

In summary, the Committee agreed on the following:

- Prioritize whole organs ahead of islets
- Consider changing the age cutoff in policy to 40 years old
- Consider increasing islet priority for pancreata from donors that meet both the age and BMI criteria

Facilitated Pancreas

Staff explained that there has been internal discussion about putting more utility into the system when first allocating, so getting the organ to the right candidate at the right time. This would shift a bit from equity to utility at the beginning of the match run.

¹ OPTN Policy 11.5.A

Staff continued by stating that facilitated pancreas identifies hospitals that are more likely to accept an import offer and suggested that it would be possible to apply this identification concept at the beginning of the match run. Certain criteria could be used, such as the BMI and age criteria discussed with islets, to identify those centers and then prioritize them on the match run so they are then more likely to place the pancreas and reduce discards.

Staff introduced this concept of awarding priority at the beginning of the match run based on center behavior as likelihood of acceptance and noted its critical importance in allocation in order to increase the number of transplants.

A member expressed concern that awarding points to facilitated pancreas programs at the beginning of the match run will advantage recipients that are listed at very easily accepting organ centers. The member preferred having standards for organ acceptance that are applied across the country to all transplant programs. If the facilitated pancreas is standard acceptance and a center, which is within the 250 nautical mile (NM) distance, routinely discards or turns down the organ for reasons other than sound medical judgement reasons, then there should be further education for those centers.

A member explained that the behavior of transplant programs might look similar from the outside; however, there are factors that differentiate them, such as the surgeon on call or how busy the program currently is. This boost at the beginning of the match run may disadvantage medium to small sized programs.

Staff mentioned that, if the Committee goes down this path, they have to be careful of (1) qualification criteria on the candidate side, (2) qualification criteria on the donor side, and (3) how much weight to apply to the priority when the criteria is met. Staff highlighted that, since this is still a novel concept, they would not suggest applying much weight to the priority so centers aren't gaining a huge amount of points but would receive enough to reorder the list a little bit.

The Chair inquired if the points would be awarded to all candidates on the list at centers that qualified for facilitated pancreas once the pancreas has been turned down by all centers within the 250 NM distance. Staff explained that that would be correct if the Committee decided to maintain the same qualifications that are currently in policy. The Chair stated that that would be reasonable since most KPs of any type are hard to place once outside of that 250 NM radius.

Another member countered by stating that they understood this idea to be, rather than waiting for those hard to place organs to be turned down within the 250 NM distance, centers are given some booster points at the beginning of the match run based on characteristics of their previous performance of accepting these hard to place organs. Staff explained that that is another way facilitated pancreas can be incorporated into continuous distribution.

The Chair clarified that the preference would be awarded within the 250 NM distance. Staff explained that there's a time limit in facilitated pancreas policy currently, so, if that limit is discounted when the match offer is made in the beginning, then criteria for donors and programs is left in policy. So, what if the criteria for donors and programs is used to give boost points to candidates at the beginning of the match run when both criteria is met. For example, there are two hospitals both at 300 NM and their pancreas candidates are identical, but one hospital has a history of accepting organs and one does not. The boost points could be given to the hospital that has experience at the beginning to try to decrease the chances of getting into the situation at the 3 hours before procurement mark where the match needs to start screening off a lot of centers.

Staff further explained that the qualifications for these boost points can change, for example, the points may not need to be awarded to all candidates at those centers and centers should offer within 150 NM

distance instead of the current 250 NM distance. The concept is that, when sending out the initial match run, centers that are more likely to accept this offer have already been identified and given a small boost.

The Chair stated that they would only recommend giving boost points to facilitated centers outside of a certain distance away from the donor hospital. The Chair emphasized that they wouldn't want a local center to be bypassed by a center that is 350 NM away and received a boost.

A member noted that distance is something that would need to be negotiated because the likelihood of acceptance concept is trying to replace time with distance. The member explained that years down the road there should be more data available that would provide more information on which organs are unlikely to be accepted and at which point in time to appropriately award those boost points; however, that data isn't available currently.

A SRTR representative stated that the current system kicks in when it's 3 hours before procurement and policy doesn't mention distance, so, if a center is a facilitated pancreas center, then they get that offer because (1) it's assumed that the offer process would have played out by that time and (2) if it hasn't, it's so close to procurement that the center has to go for an emergency procurement of some sort and doesn't have time to go through the whole offer process.

The SRTR representative explained that distance could be put in as a criteria and it could be combined with time to procurement. In that instance, if a center has 24 hours until procurement, then it would seem unfair for a center further away to bypass a local center. The SRTR representative noted that the booster points could then gradually increase for facilitated centers as the donor hospital gets closer to procurement.

Staff explained that this is referred to as a dynamic match run and is significantly more complicated to implement than what is currently being proposed, although it is more effective long term.

A SRTR representative noted that, when considering distance as a qualification in facilitated pancreas, the multitude of attributes in the continuous distribution framework will also prioritize some candidates further away ahead of others that are closer. This complicates putting distance as a criterion, since a candidate who is far away can be ahead of someone closer because of other attributes.

The Chair highlighted, however, that organ procurement organizations (OPOs) can only access the facilitated list after they've run through all the centers on the 250 NM list. The Chair mentioned that the Committee needs to be critical of awarding boost points to facilitated centers too early because lower volume centers rely heavily on local offers due to not having access to teams that can procure the organs or not having access to teams that can fly.

Staff mentioned that they are starting to hear some value-based conversations and that there has been an appetite from the transplant community to put more weight on utility since there's typically a lot of weight placed on equity; so, use the match run to better place organs.

A member mentioned that prioritizing larger programs with more resources to transplant the harder to place organs hurts patients that only have access to programs with lesser resources. This prioritization could disadvantage already challenged patients.

A member emphasized that continuous distribution is nice in the way the Committee can decide to maintain how facilitated pancreas currently works and when they have more data can add boost points in another iteration.

A member explained that facilitated pancreas was created when donation service areas (DSAs) were still being used, so it might have been practical then to run through the whole list of centers within 250 NM;

however, offering to all those centers within 3 hours before procurement is no longer practical. The member suggested that the 250 NM distance may need to be shortened in regards to how much time there is before procurement.

Staff mentioned that they have not looked at facilitated offers by distance, although they know that there's been a very small number of offers made since the policy was implemented. A member suggested that it may be worthwhile for the Committee to review that data before making a decision regarding the distance qualification.

In summary, the Committee agreed on the following:

- Concern with awarding booster points at beginning of the match run
 - Maintain how facilitated pancreas works in the current system
- 250 NM distance should be shortened instead of extended (wait on data for that)

2. Medical Urgency Project Update

The Committee reviewed the progress of the Medical Urgency Workgroup, which is still in the evidence gathering phase of the policy development process, and the medically urgent criteria that the Workgroup has discussed.

Summary of discussion:

Committee members were asked whether they thought it would be worthwhile to either include pancreas after kidney (PAK) discussions in the Medical Urgency Workgroup discussions or create a new workgroup specifically for PAK.

Members agreed that PAK, specifically pancreas after living donor kidneys, dealt more with patient access than they did with medical urgency. A SRTR representative noted that a patient with kidney failure and diabetes can choose to get listed for a KP and they will have access within 12 months; however, if they choose to go find a living donor kidney, which is better for the system, then there should not be a disincentive for access to the pancreas.

A SRTR representative stated that pancreas transplant alone (PTA) patients were also discussed. Those were the patients with marginal glomerular filtration rate (GFR) who will not have access to KP transplants because they don't have a qualifying GFR although they have significant hypoglycemic unawareness. The SRTR representative inquired whether these patients should have priority points for KPs despite have a GFR greater than 20 or should there be a safety net for if they end up on dialysis after their PTA.

The Chair stated that there has been some concern about prioritizing candidates for deceased donor organs who have already received living donor organs, especially since those who can find living donors probably already have good access or have a higher socioeconomic status and are now getting priority in the deceased donor pool.

Members stated that the PTA discussion makes sense to have in the Medical Urgency Workgroup since any patient with hypoglycemic unawareness should have increased medical urgency priority. A SRTR representative mentioned that the PTA issue also has an access component— PTA candidates meet the medical urgency criteria since they have hypoglycemic unawareness; however, have an access issue for kidneys due to their marginal GFR.

The Committee agrees there should be a PAK/PTA workgroup solely focused on access and the medical urgency component of PTA can be discussed in the Medical Urgency Workgroup.

3. Wrap Up & Next Steps

Committee members should review the Transplant Recipient Follow-up (TRF) form before their discussion during the next meeting.

Upcoming Meetings

- December 13th, 2021 (teleconference)

Attendance

- **Committee Members**
 - Rachel Forbes
 - Oyedolamu Olaitan
 - Silke Niederhaus
 - Antonio Di Carlo
 - Dean Kim
 - Maria Friday
 - Megan Adams
 - Nikole Neidlinger
 - Parul Patel
 - Pradeep Vaitla
 - Randeep Kashyap
 - Todd Pesavento
 - Ty Dunn
- **HRSA Representatives**
 - Marilyn Levi
- **SRTR Staff**
 - Bryn Thompson
 - Jonathan Miller
 - Raja Kandaswamy
- **UNOS Staff**
 - Rebecca Brookman
 - Anne McPherson
 - James Alcorn
 - Kerrie Masten
 - Lauren Motley
 - Leah Slife
 - Sarah Booker