

OPTN Pancreas Transplantation Committee

Meeting Summary

August 1, 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 08/01/2022 to discuss the following agenda items:

1. Updates
2. Continuous Distribution of Kidneys and Pancreata: Facilitated Pancreas Allocation

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

1. Updates

The Committee was informed that the Kidney and Pancreas continuous distribution project timeline has been updated based on Committee leadership and Kidney and Pancreas Continuous Distribution Workgroup feedback.

The following is the updated timeline for the continuous distribution project:

- Continuous Distribution Proposal: August 2023
- Proposal goes to OPTN Board of Directors for consideration: December 2023

The Committee was also informed that their in-person meeting in Chicago will be on 11/01/22.

Summary of discussion:

There was no discussion.

2. Continuous Distribution of Kidneys and Pancreata: Facilitated Pancreas Allocation

The Committee received an overview of the continuous distribution project, which aims to change kidney and pancreas allocation from a classification-based system to a points-based system, and continued discussions regarding facilitated pancreas (FP) allocation. The Committee also received a demonstration of how FP allocation works in the OPTN computer system.

During the 7/11/22 Pancreas Committee call, the Committee finalized the following recommendations:

- Organ procurement organizations (OPOs) and the OPTN are permitted to make FP offers if no pancreas offer has been accepted five hours prior to the scheduled donor organ recovery
- Apply facilitated pancreas bypasses to candidates registered at transplant hospitals greater than 100 nautical miles (NM) from the donor hospital

The Committee's discussion on 8/1/22 was framed by the following questions:

- Should FP bypasses apply to kidney-pancreas (KP) candidates and pancreas candidates, or just pancreas candidates?
 - Currently, FP bypasses apply to pancreas candidates only

- A separate button allows OPOs to bypass all KP candidates if a kidney is not available
 - Committee leadership feedback
 - For efficiency purposes, when initiating FP, FP bypasses should apply to KP candidates and pancreas candidates, not just pancreas candidates
- Who should not be bypassed based on sensitization/mismatch?
 - Committee leadership feedback
 - Consider decoupling calculated panel reactive antibody (CPRA) and zero antigen (0-ABDR) mismatch (making exceptions for both high CPRA candidates and cases of 0-ABDR mismatch)
 - Data from circles monitoring report
 - About seven percent of KP and pancreas registrations added in the year post-policy were for highly sensitized candidates (CPRA greater than or equal to 80 percent). Most candidates are not sensitized (CPRA zero percent).
 - Very few KP or pancreas transplants are 0-ABDR mismatch (less than five a year).
- How should programs qualify to receive FP offers in continuous distribution?
 - Current qualifying criteria
 - Programs qualify if they have transplanted at least two pancreata from donor hospitals greater than 250 NM from the transplant program in the previous two years
 - Multi-organ pancreas transplants (including KP) count towards this total

Summary of discussion:

Should FP bypasses apply to KP candidates and pancreas candidates, or just pancreas candidates?

The Chair inquired why FP bypasses only apply to pancreas candidates in the current system. A Scientific Registry of Transplant Recipients (SRTR) representative stated that FP was implemented in the early 2000s, when the proportion of pancreata transplanted as KP was much lower than it is now. Nationally, about half of pancreata were used for pancreas alone transplants and the other half were used for simultaneous pancreas-kidney (SPK) transplants. At that point, to improve pancreas utilization it was sufficient to for FP to only impact pancreas. Additionally, at that time, SPKs were allocated from the kidney match run, not the pancreas match run. However, with SPKs currently counting for 80 percent of pancreas utilization, a pancreas alone FP program accepting a FP offer will only affect 20 percent of the pancreas match, which will probably not have a profound effect on overall utilization.

The Chair stated that this stresses the importance of bypassing KP candidates more, in addition to pancreas candidates.

A member stated that, with the background provided, they would favor bypassing KP candidates since increasing the utilization of pancreata, no matter the organ it is being allocated with, should be the goal of the Committee. A SRTR representative stated that, at the time FP was initiated, it was procedurally easier because the pancreas list was separate from the KP list, but now pancreas and KP candidates are on a combined list. The SRTR representative noted that having a policy for only a fraction of patients on the pancreas list does not make much sense.

A member highlighted that FP allocation could get delayed prior to the operating room (OR) due to extrarenal organs, which would undo the intent of this policy. A SRTR representative stated that that is a good point; however, from an analytical point of view, the center is committing to accepting the KP and it's hard to find accepting centers that late in allocation. The SRTR representative mentioned that they

believe this will be an underlying issue no matter what the Committee decides. The SRTR representative stated that the capture rate, using FP for pancreas alone, will be so minimal that not bypassing KPs would be difficult.

A member stated that things have changed a lot since FP was implemented and that they would be supportive of bypassing KP candidates in FP.

A member stated that, from an OPO perspective, delays in allocation do occur because of extrarenal organs. The great donors who are likely to donate a KP may have a lot of multi-visceral complications and when this happens the KP offer becomes primary. So, if there is a heart-kidney and a liver-kidney both on that match run, then the program must select that there is “no kidney available”.

The Chair inquired if the FP time range (five hours prior to procurement) applies to high-quality donors, since those organs are straightforward to place if the KP is available. The member stated that it is straightforward if the KP is available, but often it is not available. If there is a heart-kidney and a liver-kidney, then there would be no kidney available for the KP candidate and the recovery center could only offer the pancreas. Or a liver-kidney candidate is at sequence two on the match and it is assumed that the solitary liver candidate is going to accept the liver, but they decline in the OR. The member explained that, in that situation, the KP was allocated 5 hours prior, and the kidney cannot be allocated to the liver-kidney candidate at sequence two.

A SRTR representative explained that centers would not be able to bypass the multi-visceral candidates with FP. The problem of multi-visceral complications is applicable whether it is facilitated allocation or it is a timely allocation. The SRTR representative stated that FP is trying to solve the problem of not having allocated the KP and, when approaching the procurement time, allowing OPOs to bypass centers that are unlikely to accept that offer. The SRTR representative stated that what is being suggested is that the KP offer becomes primary under FP, meaning the kidney would become unavailable for multi-visceral organ offers, and that would be difficult to gather support for from other organ-specific committees.

The SRTR representative emphasized that just because centers are using FP allocation does not mean that the offer is locked in. Centers will still have to follow the match run as if the organ was being allocated 20 hours prior to procurement, except they will be able to find FP centers quicker and have a commitment from them.

A member stated that a nice OPO practice would be to have a backup pancreas alone FP center available and ready in case something like that happened.

Staff also noted that the Committee is working with the Multi-Organ Transplantation (MOT) Committee to discuss how mandatory KPs will be incorporated into continuous distribution and the Committee should have more information once the kidney and pancreas simulated allocation modeling (KPSAM) results are ready.

The Committee voted on the recommendation to either apply FP bypasses to both KP and pancreas candidates or just to pancreas candidates.

- Apply bypasses to pancreas candidates only (current policy) - 0 votes
- Apply bypasses to KP and pancreas candidates - 11 votes

Who should not be bypassed based on sensitization/mismatch?

The Chair stated that current policy applies to a small number of candidates and, previously, members expressed interest in the highly sensitized candidates having some type of priority and not being bypassed. However, the Chair noted that that would decrease efficiency closer to procurement.

The Committee was asked to discuss and vote on the following options:

- A. Candidates who are both highly sensitized (CPRA greater than or equal to 80 percent) and a 0-ABDR mismatch with the donor (current policy)
- B. Candidates who are highly sensitized (CPRA greater than or equal to 80 percent), regardless of 0-ABDR mismatch
- C. Bypass all candidates at non-facilitated programs, regardless of CPRA or 0-ABDR mismatch

A SRTR representative stated that a 0-ABDR mismatch candidate can often go without a crossmatch; however, centers are doing prospective crossmatches for high CPRA candidates. The SRTR representative mentioned that there is a decreasing tolerance for prolonged pancreas ischemia time, regardless of CPRA, so centers may not accept the FP offer for high CPRA candidates anyway due to having to do a crossmatch and it being a late offer.

A member inquired if both options A and B are patients that are at non-facilitated centers. The Chair explained that option A is the candidates who are not bypassed currently. A 0-ABDR mismatch and highly sensitized candidate will not be bypassed, regardless of the center's facilitated status, within the five-hour time frame. The Chair also noted that option A applied to about five patients last year.

The Chair inquired if the Committee is comfortable bypassing the highly sensitized candidates unless they are a 0-ABDR mismatch. The Chair noted that centers would have to have time to perform a prospective crossmatch and the offer may go to a center that is not used to importing last minute.

A member noted that, for efficiency purposes, even facilitated programs may be less likely to accept the FP offer for a highly sensitized candidate.

A member suggested adding a fourth option, 0-ABDR mismatch candidates at non-facilitated programs, because those candidates would not require a crossmatch. The Chair stated that the Committee has mentioned that before, but it has come up in discussions that 0-ABDR mismatch priority may be going away for kidney in the continuous distribution framework. The Chair stated that they were not sure there was justification for giving so much priority at the end of allocation to 0-ABDR mismatch candidates.

A SRTR representative stated that the Committee would not decrease FP efficiency by not bypassing 0-ABDR mismatch candidates because there are so few of them. However, if a non-facilitated center were to accept an offer last minute, it would be for a 0-ABDR mismatch.

The Committee voted on the recommendation of who should not be bypassed based on sensitization/mismatch.

- A. Candidates who are both highly sensitized (CPRA greater than or equal to 80 percent) and a 0-ABDR mismatch with the donor (current policy) – 5 votes
- B. Candidates who are highly sensitized (CPRA greater than or equal to 80 percent), regardless of 0-ABDR mismatch – 0 votes
- C. Bypass all candidates at non-facilitated programs, regardless of CPRA or 0-ABDR mismatch – 5.5 votes
- D. 0-ABDR mismatch at non-facilitated programs – 0.5 votes

How should programs qualify to receive FP offers in continuous distribution?

The Committee was asked to discuss and vote on the following options:

- Option 1 (current policy): Programs qualify if they have transplanted at least two pancreata from donor hospitals greater than 250 NM from the transplant program in the previous two years

- Option 2 (align distance with how bypassed are applied): Programs qualify if they have transplanted at least X pancreata from donor hospitals greater than 100 NM from the transplant program in the previous two years
 - Can adjust number of transplants needed to qualify based on what the Committee thinks would be an appropriate percentage of programs to qualify for FP allocation

The Chair stated that this criterion is also trying to balance utilization with efficiency close to OR time. The Chair also noted that 100 NM is not a very far distance for a center to claim that they have imported a pancreas.

The Chair inquired if there is data on how many pancreata are transplanted outside of 250 NM. Staff stated that 46 programs (39 percent) currently qualify for FP allocation out of the 118 programs that transplanted pancreata from July 1, 2020 to June 30, 2022.

A member stated that option 2 seems too generous and if essentially every program qualifies for FP then there isn't facilitation. The member advocated using a greater distance to delineate between the programs that are truly aggressive and willing to accept an organ and the programs that accept offers at 101 NM from the donor hospital. Another member agreed.

The Chair inquired if the Committee feels that 40 percent of programs qualifying for FP allocation is reasonable. A SRTR representative explained that, in the first iterations of FP policy, the goal was to have about 25 percent of programs qualify as facilitated. When the percentage of qualifying programs started shrinking, that was when the Committee decreased the number of transplants needed to qualify. When the current circles-based allocation was implemented, it was thought that that was a broader area and the numbers were shrinking in terms of overall pancreas transplant, so the Committee decreased the number of pancreas transplants to qualify as facilitated to two.

Staff explained that, if the Committee wanted to pursue different distances for FP bypasses and FP qualifying criteria, in the current system a center can qualify as a FP program by accepting FP offers. However, if those distances are different then that would no longer be true. For example, there may be a FP offer sent to a center 150 NM away and if the center accepts and transplants the pancreas, then it would not count toward that qualifying total. Staff noted that this could cause confusion in the pancreas transplant community.

A member stated that they think the 250 NM distance aligns nicely with the pancreas rating scale for proximity efficiency in continuous distribution. The member thought keeping the qualifying distance at 250 NM would not cause much confusion.

A SRTR representative explained that, in FP placement, candidates under 100 NM are not bypassed because of their distance. If the qualifying distance criteria is not until 250 NM, then there are centers that would have accepted FP offers between 100 and 250 NM and not have that FP transplant count toward qualifying as a facilitated center.

The SRTR representative mentioned that that could cause some awkwardness for programs accepting FP offers but not qualifying as a facilitated center. The SRTR representative stated that an option would be to make the qualifying distance as 100 NM but increase the number of pancreas transplants needed to qualify to account for that potential discrepancy.

A member inquired if transplant centers might expect to be grandfathered in with their past performance. A SRTR representative mentioned that those centers who accept FP offers between 100 and 250 NM may question why they no longer qualify as a facilitated center.

A member noted that that discrepancy could disadvantage programs that are willing to accept offers between 100 and 250 NM, but not willing to fly. The member suggested that it may be better to keep the distance consistent.

A member suggested that the qualifying criteria could be two-fold. For example, a program would qualify if they have transplanted at least two pancreata from donor hospitals greater than 250 NM from the transplant program or at least X pancreata from donor hospitals between 100 and 250 NM from the transplant program. Staff mentioned that this idea has come up in the past and the focus for this iteration of continuous distribution is translating over the current system into the new framework.

The Committee voted on the recommendation of how programs should qualify to receive FP offers in continuous distribution.

- Option 1 – 11 votes
- Option 2 – 0 votes

A member inquired how FP will work if it can't be used until every candidate in 100 NM receives an offer, but the candidates will not be listed in order of their distance. For example, there may be a candidate at sequence 1000 on the match run with short waiting time and is ABO compatible who is only 5 miles away? The member stated that they would like to understand that better and hopefully it can be explained during the next meeting.

Next steps:

There are two new workgroups for Committee members to participate on: the Operational Considerations Workgroup (which will also discuss FP) and the Review Board Workgroup. All Workgroup recommendations will be reviewed by the Kidney and Pancreas Committees for endorsement.

There was no further discussion. The meeting was adjourned.

Upcoming Meetings

- September 19, 2022 (Teleconference)

Attendance

- **Committee Members**
 - Rachel Forbes
 - Oyedolamu Olaitan
 - Dean Kim
 - Diane Cibrik
 - Jessica Yokubeak
 - Maria Friday
 - Muhammad Yaqub
 - Nikole Neidlinger
 - Parul Patel
 - Rupi Sodhi
 - Todd Pesavento
 - Ty Dunn
 - William Asch
- **HRSA Representatives**
 - Jim Bowman
 - Marilyn Levi
- **SRTR Staff**
 - Bryn Thompson
 - Jonathan Miller
 - Peter Stock
 - Raja Kandaswamy
- **UNOS Staff**
 - Joann White
 - Rebecca Brookman
 - Carol Covington
 - Lauren Mauk
 - Lauren Motley
 - Matt Belton
 - Sarah Booker