

OPTN Pancreas Transplantation Committee

Meeting Summary

June 22, 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 06/22/2022 to discuss the following agenda items:

1. Removal of Donation Service Area (DSA) and Region from Pancreas Allocation: 1 Year Report
2. Continuous Distribution of Kidneys and Pancreata: Facilitated Pancreas Allocation

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

1. Removal of Donation Service Area (DSA) and Region from Pancreas Allocation: 1 Year Report

The Committee reviewed the results of the one-year post-implementation monitoring report of the Removal of DSA and Region from Pancreas Allocation proposal, which was implemented on 3/15/21. This proposal replaced DSA and regions with a 250 nautical mile (NM) circle and assigned proximity points based on distance between the donor hospital and transplant hospital.

Data summary:

The following is a summary of the results:

- Kidney-pancreas and pancreas transplant volumes remained stable
- More pancreata were distributed outside the donor hospital DSA, but most stayed within 250 NM
- Overall pancreas discard rate increased from 22.7 percent to 26.5 percent
- No difference in six-month post-transplant patient or graft survival

Summary of discussion:

The Chair inquired if the distribution of preservation time for kidney-pancreas (KP) transplants includes the cold ischemic time (CIT) for kidney or for pancreas. Staff stated that CIT is collected for kidneys and preservation time for pancreas, so this data is specific to pancreas. Staff also noted that kidney CIT was included in the monitoring report, and it was very similar to pancreas preservation time.

The Chair noted that, unfortunately, these results are not the best in terms of metrics the Committee is interested in. Although volume stayed relatively stable, transplant rates decreased, discards increased, efficiency decreased (more offers but fewer acceptances), and the use of facilitated pancreas allocation decreased.

The Chair stated that this is something the Committee needs to watch, since these results are not aligning with the goals of pancreas transplant.

A member agreed that these results are somewhat disappointing. The member suggested that it may be helpful for the Committee to see what sequence on the match run the discarded organs were initially

accepted in the two-year monitoring report. The member wondered if the increase in discards may be related to more marginal pancreas offers that were provisionally accepted and then resulted in non-utilization of pancreata.

The Chair inquired if there is information regarding donor quality for discards. Staff mentioned that the monitoring report does include discard reasons during the pre- and post-policy eras and the top reasons for discards in both eras were:

- “Other, specify”
- “Anatomical abnormalities”
- “No recipient located due to exhausting the list”

Staff suggested it may be helpful to review the text responses for the “other, specify” discard reason.

A member stated that, to be sure about the cause of the increase in discard rates, the Committee needs to look at donor characteristics, such as age and whether the pancreas was procured by other teams.

A Scientific Registry of Transplant Recipients (SRTR) representative stated that a helpful analysis for the Committee would be to look at local procurement team discard rates versus (vs.) remote procurement team discard rates to determine if the increase in discards is a result of the pancreas travelling further distances or another factor.

A SRTR representative stated that the graft survival rate for pancreas alone transplants seemed low and inquired how many pancreas alone transplants there were in the post-policy era. Staff stated that there were 92 pancreas transplants and 18 pancreas graft failures in the post-policy era. The SRTR representative mentioned that this was a high rate of graft failure and it may be due to the small number of pancreas transplants; however, graft failure is something the Committee should continue to monitor.

A SRTR representative stated that if the pancreas discard rates keep increasing, then the incentive for organ procurement organizations (OPOs) to procure pancreata goes down. The SRTR representative explained that this was because the intent to transplant is counted in the Medicare cost calculation for reimbursement, so discard rate might be a significant number for the Committee to monitor.

A member stated that, on a positive note, pancreas transplant seems to be allocated closer to the donor hospital and that might be because of the circles-based allocation of KPs. The member also mentioned that the 250 NM distance that the Committee agreed to use as a threshold in the proximity efficiency attribute for the pancreas continuous distribution framework is supported by this data.

A SRTR representative also mentioned that it may be worthwhile to look at what percentage of procurement teams are local vs. remote procurement teams once pancreas allocation transitions to continuous distribution.

The Chair agreed but noted that concerns with circles-based allocation are different between pancreas and kidney.

A member stated that pancreas transplants may need more educational resources or championship because relying on local procurement teams that have ambivalence towards pancreas may impact the reported quality of the pancreas. The Chair agreed and mentioned that there must be a belief and an understanding that pancreas transplants benefit patients for pancreas transplants to sustain volume.

The Chair stated that it is probably not just the change in allocation causing these changes in pancreas transplant trends but may be some sentiment towards choosing an alternative to pancreas transplant

for diabetic patients. The Chair emphasized that members should look out for pancreas initiatives within societies, such as American Society of Transplantation, to get involved.

A member noted that, if the Committee reviews the goal of circles-based allocation, broader distribution was the goal; however, not at the expense of reducing total transplant volume. The member inquired how the Committee would move forward to analyze whether the 250 NM threshold in the proximity efficiency attribute is appropriate for the pancreas continuous distribution framework. The Chair stated that one of the models the Kidney and Pancreas Continuous Distribution Workgroup submitted to SRTR had significant priority for proximity, so it would be important to see what that modeling shows.

The Chair stated that the use of facilitated pancreas (FP) allocation had decreased post-policy and mentioned that one of the concerns is the hindrance to OPOs caused by so many centers being within the 250 NM now. If there is a hindrance, the Committee should also consider how they can improve FP even when there is no longer a 250 NM threshold.

A SRTR representative stated that it will be important to understand what stage of allocation FP was initiated pre- and post-policy. If most are occurring in the operating room (OR) then that is a different issue and needs to be handled slightly different from if most of the FP offers happened three hours prior to procurement (when facilitated pancreas allocation can be activated).

The Chair inquired if there is a way for the Committee to review data at that granular of a level. A SRTR representative stated that staff could create a density scatter plot for FP allocation commencement, pre- and post-allocation, that will show the number of allocations that were sent out and the time period. Staff mentioned that they would have to follow up with the Committee on what data is available.

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

The Committee reviewed previous discussions and feedback that they had received regarding facilitated pancreas.

During the 5/16/22 Pancreas Committee call, the Committee discussed the following:

- Keep facilitated pancreas operationalized as outlined in policy
 - 250 NM distance would remain
 - OPOs permitted to make facilitated pancreas offers three hours prior to scheduled donor organ recovery (acknowledgement that three-hour timeframe can be challenging for OPOs)
- Leadership recommendation
 - Use distance, but decrease to 100 NM
 - Consider removing exception for high calculated panel reactive antibodies (CPRA), 0-ABDR mismatch after 100 NM

The OPTN Organ Procurement Organization (OPO) Committee provided the following feedback:

- Facilitated pancreas is not frequently utilized
- Challenges with timeframe (three hour prior to scheduled donor organ recovery) due to recovery logistics (coordinating a recovery team willing and able to procure pancreata)

The Committee was asked to discuss the following questions:

- Who should not be bypassed?
 - Candidates based on distance
 - Within 250 NM (most similar to current policy)

- Within 100 NM (leadership recommendation)
- Candidates based on sensitization/mismatch:
 - 0-ABDR mismatch/greater than 80 percent CPRA candidates and greater than 80 percent CPRA candidates (in current policy)
 - Ignore sensitization/mismatch and bypass all candidates at non-facilitated programs (discussed by leadership)

Summary of discussion:

A SRTR representative inquired if the current exception for high CPRA and 0-ABDR mismatch is combined or if they are separate criteria. Staff stated that the high CPRA and 0-ABDR mismatch criteria are combined for the current exception. The SRTR representative pointed out that a 0-ABDR mismatch is the best result a patient can have for CPRA, so that is the one situation where a center may feel comfortable performing a transplant without a crossmatch.

A SRTR representative stated that it is a rare situation that a patient would have a 0-ABDR mismatch for a high CPRA and that in those cases, they should not be bypassed.

The Chair emphasized that the goal of revising FP is to decrease any burden that facilitated pancreata may go through at such a late stage of allocation. The Chair stated that, at the initiation of FP, the pancreas is probably already a somewhat marginal pancreas, and the goal is to get it placed at FP centers rather than taking the time to work through half of the match run that can't be bypassed. The Chair inquired if there are ways the Committee can increase the efficiency or utilization of FP allocation.

A SRTR representative stated that the window of time could be manipulated. With three hours to procurement and the pancreas is hard to place, it's possible a distant center does not have a procurement team that is 100 percent invested in the procurement of the pancreas.

The Chair agreed and mentioned that the 250 NM decreases efficiency since there are many centers in high density areas, so making the NM distance smaller once FP can be initiated may work as well. The Chair mentioned that, within 5 hours of OR, they would not want to lose an offer within 250 NM to FP; however, the Chair is not sure what the right time window would be for FP. A SRTR representative pointed out that the pancreas would still have to be offered to all candidates within 250 NM before being offered to FP centers.

The Chair inquired if there should be a time point where centers do not have to offer to all candidates within 250 NM before making an FP offer or should the Committee make the NM distance smaller. A SRTR representative stated that there could be a tiered system approach. For example, five to six hours before OR, OPOs can start a facilitated allocation but they cannot bypass candidates within 250 NM and FP bypasses can be applied to centers outside of 250 NM. Then, at two hours before OR, OPOs can solely use FP allocation and bypass candidates within 250 NM. The two time windows apply to (1) initiation of FP with candidates within the 250 NM distance and (2) exclusion of all candidates at non-FP centers, regardless of distance.

The Chair stated that this tiered approach would come down to what is considered "local" now. The Chair suggested that 250 NM is too far to be considered "local" at this time.

A member stated that something their OPO tried for kidneys was having backups. The member emphasized that there are three places where the Committee can make changes and create criteria for FP:

- Geographic distance
 - The member thought that 100 NM makes sense

- Increasing the amount of time prior to procurement necessary to initiate FP
- Creating a threshold based on pancreas offer number – the pancreas has been offered a certain number of times and can now be offered using FP allocation.
 - Use data from Removal of DSA and Region from Pancreas Allocation one-year monitoring report

The member stated that, initially, the FP allocation will be like backup – wherever the pancreas is accepted, the pancreas will be available earlier instead of last minute. The Chair inquired if there was something the Committee would write in policy or is that something OPOs choose to do.

A SRTR representative stated that currently backups can be offered at any point and OPOs can send out as many backup offers as they want, but the Committee could require OPOs to send out backup offers. The SRTR representative cautioned the Committee because backups are approached differently between kidney and pancreas. Backup offers for kidneys are more effective because centers do not receive kidney offers as frequently as they do pancreas offers.

Next Steps:

Staff will follow-up with Committee members by email to gather their feedback on the discussion questions and the Committee will continue the facilitated pancreas discussion at their next meeting.

There was no further discussion. The meeting was adjourned.

Upcoming Meeting

- July 11, 2022 (Teleconference)

Attendance

- **Committee Members**
 - Rachel Forbes
 - Oydolamu Olaitan
 - Antonio Di Carlo
 - Dean Kim
 - Diane Cibrik
 - Maria Helena Friday
 - Jessica Yokubeak
 - Mallory Boomsma
 - Muhammad Yaqub
 - Parul Patel
 - Rupi Sodhi
 - Todd Pesavento
- **HRSA Representatives**
 - Shelley Grant
- **SRTR Staff**
 - Ajay Israni
 - Bryn Thompson
 - Jonathan Miller
 - Raja Kandaswamy
- **UNOS Staff**
 - Joann White
 - Rebecca Brookman
 - Carol Covington
 - Lauren Motley
 - Sarah Booker