OPTN Pancreas Transplantation Committee
Meeting Summary
July 11, 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 07/11/2022 to discuss the following agenda items:

1. Welcome to New Members
2. Continuous Distribution of Kidneys and Pancreata: Facilitated Pancreas Allocation

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

1. Welcome to New Members

The Committee introduced and welcomed new members whose term started on 7/1/2022.

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.

During the 6/22/22 Pancreas Committee call, the Committee discussed the following:

- The timeframe of 3 hours prior to procurement necessary to initiate FP allocation may not provide enough time
    - Logistics of coordinating recovery team to recover the pancreas
- A potential solution to this would be to increase the timeframe in which organ procurement organizations (OPOs) can initiate FP
    - Pros
        - Increase in time may allow OPOs opportunity to coordinate recovery team
    - Cons
        - Increased time could make FP utilization more common, resulting in inequitable prioritization of FP
        - Time increase recommendation would be more arbitrary than data driven
        - Availability of programs/recovery teams

The Committee's discussion on 7/11/22 was framed by the following questions:

- Should the timeframe in which OPOs can initiate FP allocation remain as currently outlined in policy or should the timeframe be increased?
- Who should not be bypassed in FP allocation?

- Leadership recommendation
  - Use distance, but decrease to 100 nautical miles (NM)
  - Consider removing exception for high calculated panel reactive antibody (CPRA), 0-ABDR mismatch after 100 NM

Summary of discussion:

Timeframe in which OPOs can initiate FP allocation

A member inquired if FP allocation is just for pancreas alone candidates or for both pancreas and kidney-pancreas (KP) candidates. Staff explained that FP allocation applies only to pancreas alone candidates and KP candidates are not bypassed.

A member stated that increasing the timeframe would be better because it is challenging to mobilize a team to procure the pancreas within three hours, especially when a program receives an offer in the middle of the night. The member suggested that increasing the timeframe to five hours seems reasonable.

A member mentioned that they have noticed it is very hard to reallocate a pancreas the closer it gets to time of procurement, especially when the donor is already in the operating room (OR). The member noted that it is a problem, from the OPO side, when a program is interested in the pancreas, but they cannot get a team there in enough time. Then, typically, the liver procurement team does not feel qualified or is not certified to recover the pancreas. The member emphasized that having more time would be helpful to get a pancreas certified surgeon there to perform the recovery of the pancreas.

Staff inquired if there were any concerns from the Committee with an increase in the timeframe to five hours. A member inquired if an OPO would be able to offer to KP candidates once FP allocation is initiated at the five-hour mark, or if offers could only be made to pancreas alone candidates. Staff explained that the KP candidates would still receive offers and would not be bypassed once FP allocation is initiated.

The Chair mentioned that they were confused because they thought FP allocation could be used to bypass KP candidates. A member stated that they had thought the same – FP allocation bypasses applied to both pancreas and KP candidates.

Staff explained that, when FP is initiated, the KP candidates will not be bypassed regardless of their program's transplant history, so just the pancreas alone candidates at non-facilitated centers are bypassed. The Chair inquired if that is just within the current 250 NM distance. Staff stated that KP candidates are not bypassed, no matter the distance.

A member summarized that, when FP is initiated, if a non-facilitated program has a KP candidate then that candidate is not going to be bypassed, so inefficiencies would remain in FP allocation. The member suggested that, if the goal is to make FP allocation more efficient, it makes sense to apply FP to both pancreas alone and KP candidates. The member stated that, in their region, their patients do not wait very long for a pancreas, so their concern is more about underutilization rather than patients not having access to a pancreas transplant.

Staff also highlighted that qualifying criteria to be considered a facilitated program are distinct from how FP bypasses are applied.

The Chair inquired how many FP offers were to pancreas alone candidates. Staff explained that data on use of FP allocation is based on when the OPO initiated FP allocation and, since pancreas and KP candidates are on the same match run, they are combined in contributing to the total number of uses of FP.

The Chair inquired if the Committee had discussed bypassing KP candidates outside of the 250 NM distance in FP allocation. Staff stated that the Committee had not discussed that.

Staff summarized that the Committee seems to be in support of increasing the timeframe in which OPOs can initiate FP to 5 hours and inquired if there was any opposition. There was no opposition.

Who should not be bypassed in FP allocation?

The Chair stated that the goal of FP is to increase efficiency in the system and posed the following questions to the Committee:

- Does the Committee feel that it is reasonable for OPOs not to bypass candidates within 100 NM (instead of the current 250 NM distance) in the five-hour timeframe?
- How comfortable does the Committee feel about bypassing the high CPRA and 0-ABDR mismatch candidates outside of that 100 NM distance?

A member explained that the reasoning behind the suggestion to change the distance to 100 NM was to not disadvantage those centers close to the donor hospital and to ensure that OPOs do not wait until the last minute to offer an essentially good quality pancreas.

A member stated that they think changing the distance to 100 NM makes sense. Most programs would not use the FP pancreata, so the member also thought that bypassing the high CPRA and 0-ABDR mismatch candidates makes sense as well.

A member inquired about the rationale for choosing 100 NM as the distance. The member mentioned that they would be concerned about the candidates who were within the 100-250 NM distance. The member also mentioned that they would be concerned about bypassing the candidates with a CPRA greater than 80 percent and a 0-ABDR mismatch, especially if the Committee changes the distance to 100 NM.

The Chair stated that the concern was that FP allocation is not efficient and 100 NM, especially in high density areas, can still be two or three hours of travelling by car, which was about the time it was thought to take to mobilize a team to travel to recover the pancreas. With the current 250 NM, it can sometimes result in seven to eight hours of transportation.

A member also emphasized that all these decisions are always open to revisit and stated that they are in favor of making these changes to see the impact it may have.

A member inquired if there is any modeling that can be done to see the impact of changing the distance to 100 NM on the amount of FP offers. The member stated that another goal of FP allocation, in addition to increasing efficiency, is to increase the volume of pancreas transplants.

A Scientific Registry of Transplant Recipients (SRTR) representative stated that they are not sure modeling would be a useful tool because transportation efficiency cannot be modeled well. The SRTR representative stated that it might be possible to model how many more FP offers there would be between 100-250 NM; however, that would not show how many of those FP offers would be transplanted within the five-hour timeframe. The SRTR representative stated that it seems this will need to be an iterative decision rather than modeling.

A member also noted that, if pancreata begin to be shipped using commercial flights (similar to kidneys) and the Committee maintains the 250 NM distance, the Committee may run into similar issues with cargo holds which would result in lost pancreata.

The Chair stated that it seems the Committee agrees that they should not bypass the high CPRA candidates and should change the distance to 100 NM. A member stated that any opportunity to transplant high CPRA candidates should be taken, so the Committee should not bypass them.

Members were in favor of not bypassing high CPRA candidates. A member inquired if the 0-ABDR mismatch candidates should not be bypassed as well.

Staff clarified that the existing classification in policy is for candidates that are both 0-ABDR mismatch and high CPRA, which is a small number of candidates. If the Committee wanted to make an exception for high CPRA candidates who aren't a 0-ABDR mismatch then that would be a change. A member stated that that makes sense, so 0-ABDR mismatch candidates should not be bypassed as well.

Staff summarized that the Committee supports changing the timeframe in which OPOs can initiate FP allocation to five hours, changing the distance to 100 NM, and not bypassing the high CPRA and 0-ABDR mismatch candidates.

A member cautioned the Committee about changing too many variables because then they will not be able to know what to attribute any differences in efficiency of FP allocation to.

Staff clarified that the Committee is also not adding any preferential behavior for candidates with just a high CPRA. The Chair stated that priority isn't given to only high CPRA pancreas candidates currently, but inquired if the Committee would want to consider expanding priority for high CPRA patients outside of the 100 NM distance within the five hour window. A member stated that they would support that.

Next steps:

Staff will finalize the recommendations that the Committee has discussed today and will plan to discuss any outstanding items during the next Committee meeting.

There was no further discussion. The meeting was adjourned.

Upcoming Meeting

- August 1, 2022 (Teleconference)

Attendance

- **Committee Members**
  - Rachel Forbes
  - Oyedolamu Olaitan
  - Antonio Di Carlo
  - Colleen Jay
  - Dean Kim
  - Diane Cibrik
  - Jessica Yokubeak
  - Maria Friday
  - Megan Adams
  - Muhammad Yaqub
  - Nikole Neidlinger
  - Parul Patel
  - Pradeep Vaitla
  - Ty Dunn
  - William Asch
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Bryn Thompson
  - Jonathan Miller
  - Peter Stock
- **UNOS Staff**
  - Joann White
  - Rebecca Brookman
  - Carol Covington
  - Krissy Laurie
  - Lauren Mauk
  - Lauren Motley
  - Sarah Booker