OPTN Pancreas Transplantation Committee
Meeting Summary
February 17, 2021
Conference Call

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

Introduction

The Pancreas Transplantation Committee (the Committee) met via Citrix GoToMeeting teleconference on 2/17/2021 to discuss the following agenda items:

1. Public Comment Proposal Presentation: 2021-2024 Strategic Plan
2. Feedback Requested: Data Advisory Committee (DAC) Refusal Codes Project
3. Public Comment Proposal Presentation: Update Key Personnel Training and Experience Requirements

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

1. Public Comment Proposal Presentation: 2021 – 2024 Strategic Plan

The Committee was provided an overview of the OPTN Executive Committee 2021 – 2024 Strategic Plan request for feedback. Members provided feedback and voted on their sentiment of the proposal.

Summary of discussion:

The Committee Vice Chair questioned what the Executive Committee meant by increasing numbers of transplants, in terms of metrics. The discussion around that were wanting to improve OPO metrics that provide an accurate assessment of OPO performance and can be leveraged as a tool to identify actionable improvement opportunities. Thinking of developing a dashboard of transplant center metrics that go beyond one year post-transplant outcomes and avoid creating disincentives to transplant to include measures that can be utilized to identify strategies for improvement.

The Committee vice Chair mentioned previous discussions in regards to pancreas procurement surgeons being present at the time of transplant to increase the yield of usable transplantable pancreata and suggested that this could be an idea from the Committee that aligns with the goal of increasing the number of transplants.

A member mentioned that the goal of improving duration of transplant only accounted for 10% of the Strategic Plan. The member inquired if the OPTN is potentially sacrificing medium to long-term outcomes in order to increase the number of transplants. A Chair agreed that this is a bigger question of utility in the system. A member suggested that this needs to be emphatically stated. For example, if we know what the pancreas or kidney graft half-life is, but only measuring 3 year statistics then there is almost no accountability for time after 3 years.

Members agreed that the goals are very straightforward and the proposed performance metrics are a good starting point.

2. Feedback Requested: Data Advisory Committee (DAC) Refusal Codes Project

The Committee received an update on the OPTN Data Advisory Committee (DAC) Refusal Codes Project. Members provided feedback on the proposed changes.

Summary of discussion:

The Committee provided the following feedback:

Candidate Specific Reasons

A member stated that the reasons "candidate's condition improved, transplant not needed" may be interesting because was the candidate's diabetes cured. A Chair countered by stated that some candidate's, if their kidney function improved significantly, they may want to wait for a transplant.

A member inquired how often "candidate's condition improved, transplant not needed" is used. This reason accounted for a total of 407 responses out of under six million total refusals, so it was less than 1%.

The Committee Vice Chair inquired if DAC is trying to maintain consistency across all organ offers or if they are alright with making the refusal codes organ-specific. Staff explained that the refusal code list is going to be available for all organs, but if the Committee sees one that doesn't make sense for pancreas it can be hidden for pancreas organ offers. The Committee Vice Chair mentioned that the reason "candidate's condition improved, transplant not needed" would be rarely used for active patients, but it may be used for candidates with a dual kidney-pancreas (KP) offer.

A member stated that this reason may be used if a candidate's glucose variability stabilized with a pump to an extent that they was no longer an urgency for a pancreas transplant. Members agreed to keep the "candidate's condition improved, transplant not needed" as a pancreas refusal reason.

The Committee Vice Chair inquired whether the DAC looked into why the candidate refused. Staff mentioned that they didn't want to get too granular and impact the user experience by having too many codes to scroll through. The Committee Vice Chair mentioned that usually the "why" is used for quality purposes, so it may be more helpful to include why it was refused. Staff explained that the organ specific reasons category would go more into detail about the quality reasons as to why the organ was refused.

A member noted that some candidates have turned down organs because of the U.S. Public Health Service (PHS) risk status. Staff explained that there are refusal reasons for PHS risk criteria under the disease transmission risk category.

Crossmatch Related Reasons

Members agreed the refusal reasons in this category were reasonable and straightforward.

Disease Transmission Risk

Members agreed the refusal reasons in this category were reasonable.

Donor and Candidate Matching

Staff inquired whether the Committee thought the refusal reasons made sense in this category, primarily "number of HLA mismatches unacceptable". Staff explained that the reason this was originally put into this category was because it's typically on the matching side, but there has been feedback that it would be helpful to put this under the crossmatch related reasons category in order to bundle all the HLA related reasons together. Members agreed to moving "number of HLA mismatches unacceptable" to the crossmatch related reasons category.

A member inquired if the reason “DCD donor” should be moved to the donor specific reasons category. Members agreed to make this change.

A member explained that they were having difficulty understanding this category because the donor is either good or not, and they don’t try to match the sizes of the donor and recipients for pancreas. The Committee Vice Chair mentioned that some centers are transplanting pediatric donors and recipients, so they could imagine a center not wanting to use a small donor for a higher body mass index (BMI) candidate. Staff explained that, currently in production, the reason is “donor size/weight” and it was utilized about 1.5% of the time (85,000 responses). Staff mentioned that DAC had wanted to split that reason into “donor size – height” and “donor size – weight” because sometimes the refusal is due to height or weight. Staff inquired if it makes more sense for “donor age”, “donor size –height”, and “donor size – weight” under the donor specific reasons category.

The Committee Vice Chair mentioned that, if it’s a high quality pancreas it would be used for most candidates, but they could see instances where it wasn’t ideal to transplant on the extremes of age or size. Members agreed to keep “donor age”, “donor size – height”, and “donor size – weight” under the donor and candidate matching category.

Donor Specific Reasons

The Committee Vice Chair inquired about how the text box will work for the “donor medical history, specify” reason. Staff explained that when this reason is selected, a text box will pop up where the end user will have to input additional details as to why they're selecting this reason.

The Committee Vice Chair inquired whether the Committee thought it would be worthwhile to include things like insulin, hemoglobin A1c, or hyperglycemia in this category, even though it is more of a medical situation than medical history. A member explained that they like the suggestion of these categories, especially for research purposes. Staff explained that if those reasons are important for pancreas, they can be included in this category just for pancreas. Staff inquired whether those reasons would fit better under the organ specific reasons category or under the donor specific reasons category.

A member stated that they would like to know if the donor was acceptable, but the organ wasn’t acceptable.

Organ Specific Reasons

The Committee Vice Chair suggested that the reasons previously mentioned (insulin, hemoglobin A1c, hyperglycemia) might fall under the “unsatisfactory organ specific test results” reason in this category. A Committee Vice Chair inquired if it’s worth creating more sub-reasons for “unsatisfactory organ specific test results”.

A member stated that these reasons would be interesting in order to have some more data that is very pancreas specific to analyze usage and outcomes in the future. The member mentioned that other granular reasons to include for pancreas offers would be a previous splenectomy, trauma splenic laceration, pancreatic laceration, peripancreatic hematoma.

A member mentioned that they have never been offered a biopsy for pancreas. The Committee Vice Chair mentioned that a biopsy may have been offered with a KP. The member stated that it would be interesting to know the refusal reason for pancreas only. Staff explained that they can hide “biopsy not available” and “organ biopsy results unsatisfactory” reasons for pancreas only offers.

A member inquired if, when a KP offer is turned down due to the kidney, would two separate refusal codes need to be filled out or are they combined together for the kidney and the pancreas. Staff

explained that, currently, they don't think it would be possible to specify whether the refusal code was for the kidney or the pancreas in KP offers.

A member suggested adding "KP – Kidney not acceptable" as a reason under the organ specific reasons category.

3. Public Comment Proposal Presentation: Update Key Personnel Training and Experience Requirements

A representative from the OPTN Membership and Professional Standards Committee (MPSC) presented their Update Key Personnel Training and Experience Requirements request for feedback to the Committee. Members provided feedback and voted on their sentiment of the proposal.

Summary of discussion:

The Committee provided the following feedback:

The Committee Vice Chair stated that the process is onerous and programs change over quickly. Making this process easier and standardized would be important for physicians and surgeons.

The MPSC representative asked the Committee their thoughts on keeping logs on transplants performed and the reliance of transplant programs to keep this log.

The Committee Vice Chair agreed with this being a good idea, but that it is sometimes harder in practice. When someone leaves an institution, they should be able to obtain a log of everything they've done at that time so they would have those records going forward.

The MPSC representative stated that at their respective program, there is an exit interview with fellows to discuss what they would require to become primary surgeons and physicians. A part of the education curriculum and the curriculum on how to become an effective primary surgeon or physician is important to have.

The Committee Vice Chair stated that some of the requirements (particularly the 10 years requirement) is a long time and is hard to train pancreas primaries. There should be more recognition for on the job learning pathways.

The MPSC representative stated that there have been some experiences where a fellow takes a transplant fellowship, has met their criteria, and then decide to not pursue an academic or transplant career. That individual may decide years later to come back to a transplant program – would the criteria they met as part of their application as a primary physician used?

A member stated that a challenge faced is the issue of showing currency in procurements from moving from one center to another. If the criteria has been met at one center in the past, is this still relevant? For procuring alone, this should be reconsidered.

The member continued by asking for clarification on foreign physicians and surgeons – is one of the criteria that the physician is board certified as a transplant surgeon? The MPSC representative confirmed that this was correct along one of the pathways. The member continued by stating that if a physician is coming from Europe, they would not be board certified as they would not be coming from a training program from the United States (U.S.) or Canada. This should be made aware.

The member also added by asking who would be determining if one country's training is as vigorous as the U.S.? The programs can vary from one country to the next and may or may not be comparable to training the U.S.

The MPSC representative stated that each case is different and that the certification is placed on the criteria.

The Committee Vice Chair stated that for the on-site requirements, there is some concern for surgeons who are not on site in a particular city, and that there are outlets among programs over wide geographic spaced to allow those surgeons to travel last minute. There would be some unintended consequences if off site surgeons were allowed to run these transplant programs.

The MPSC representative stated that the MPSC is aware of this issue and will be looking in this closely.

A member stated that there is going to be a reality in maintaining good outcomes, but at the same time, the less programs or the harder it is to access a pancreas program, the less likely the pancreas transplant will happen. There is data that demonstrates this. Priorities should be established to address this.

The member continued by suggesting that that for physicians and surgeons who move from one program to the other, there should be a way for there to be a primary certification that can be taken to show some activity as opposed to going back to a center years letter to ask for a fellowship director to write a letter.

The MPSC representative stated that this is being suggested by looking at a window of clinical experience and the certification to be accepted. This is one of the proposed changes that is being considered.

There were no additional comments or questions. The meeting was adjourned.

Upcoming Meetings

- March 17, 2021 (teleconference)

Attendance

- **Committee Members**
  - Rachel Forbes
  - Antonio Di Carlo
  - Ken Bodziak
  - Maria Friday
  - Pradeep Vaitla
  - Randeep Kashyap
  - Todd Pesavento
- **HRSA Representatives**
  - Marilyn Levi
- **SRTR Staff**
  - Bryn Thompson
  - Jonathan Miller
  - Nick Salkowski
  - Raja Kandaswamy
- **UNOS Staff**
  - Joann White
  - Rebecca Brookman
  - Adel Husayni
  - Leah Slife
  - Nang Thu Thu Kyaw
  - Sally Aungieer
  - Sharon Shepherd
- **Other Attendees**
  - Ian Jamieson