

Meeting Summary

OPTN Pancreas Transplantation Committee Meeting Summary August 16, 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 8/16/2021 to discuss the following agenda items:

 Public Comment Presentation: Enhance Transplant Program Performance Monitoring System (Membership & Professional Standards Committee)

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

1. Public Comment Presentation: Enhance Transplant Program Performance Monitoring System (Membership & Professional Standards Committee)

The Committee reviewed the public comment proposal, Enhance Transplant Program Performance Monitoring System, from the Membership & Professional Standards Committee (MPSC).

The following is the purpose of the proposal:

- Develop a holistic review of member performance throughout all phases of transplant
 - Current performance monitoring evaluates only 1-year post-transplant patient and graft survival
- Identify real-time patient safety issues
- Provide support and collaboration to transplant programs for identified opportunities for improvement
- Evaluate and modify any system of review to ensure maximum support for increasing the number of transplants, promoting equitable access to transplantation and fostering innovation

Summary of discussion:

A member inquired about the offer acceptance for pancreas transplants, since only four programs would be potentially flagged, and whether that was the baseline for all organs. The member explained that they think most centers would get flagged since they got offered so many pancreata that aren't transplantable. The presenter explained that the goal of offer acceptance, as a metric, is to identify true outliers in performance. The presenter emphasized that it's the observed acceptances to the expected acceptances. For example, if a center declines a pancreas that would likely be accepted by their peers, then that would count significantly against the center. If a center declines an organ that is unexpected to be accepted by the center's peers, then it doesn't count against the center. The presenter highlighted that it has to be an organ that is accepted for transplant for it to count as an organ offer.

The Chair inquired if there are many offer filters for pancreas. The presenter stated that the new offer acceptance filters come online in September 2021, but they are unsure of how many filters there are. A

member noted that centers can put in what they want and the presenter emphasized that filtering out an offer is not an offer, so there is no demerit.

The presenter mentioned that the goal for the offer acceptance ratio is for a center to be comparable to itself and what they would accept, not comparable to their peers.

The Chair thanked the presenter for reviewing the proposal with the Committee and applauded the MPSC for continuously looking at ways to improve transplants and minimize flagging centers.

The Chair inquired if the MPSC will be using the new definition of pancreas graft survival in the upcoming models for the patient survival hazard ratios of 1.75. The presenter stated that when this proposal is implemented, patient survival is what is being used instead of graft survival. The presenter stated that, to incorporate pancreas graft survival as a metric, the MPSC would need to (1) collect cohorts of data on the new graft failure definition to make sure it is performing how it should and, (2) have a discussion with the Committee to determine next steps.

The Chair inquired if, even in kidney-pancreas patients, the MPSC will be solely looking at patient survival of anyone who has received a pancreas. The presenter explained that these initial metrics are not going to include multi-organ transplants.

Staff explained that the MPSC, in the past, looked at pancreas post-transplant results based on both pancreas alone and kidney-pancreas transplants due to the fact that the majority of pancreas transplants are done through kidney-pancreas transplants.

A member stated that there's a wide variety of what constitutes an acceptable candidate between programs. For example, some kidney programs do not accept patients who smoke or patients who are beyond a certain body mass index (BMI). The member inquired if there is some pre-transplant metric that would bring more conservative programs to a more reasonable stance. The member emphasized this would focus more on the candidate, as opposed to the outcomes and criteria set by the program.

A member stated they strongly support having good outcomes because it helps the patients, the program, and society; however, asking programs to take control of patients beyond one year is unfair to the program. The member didn't support longer monitoring, but mentioned they support having good outcomes long term.

The presenter stated that if programs are being conservative because they don't understand the waitlist mortality ratio, the MPSC is making a big educational push to improve this. However, the presenter emphasized that it's not the MPSC's role to tell programs how to practice.

A member stated that the offer acceptance rate ratio could improve allocation efficiency because, then, programs will limit the distance from which they will accept offers so they don't keep turning offers down; however, it could also make programs limit how much they want to go outside of their programs. The member stated a way to resolve this may be to limit the range at which the MPSC penalizes programs.

The presenter stated that the organ offer acceptance ratios account for things such as distance traveled. The presenter emphasized that, as a program, it's their choice to decide what they will and won't accept; however, programs need to start thinking in a larger community sense.

The presenter mentioned that, for example, a program was still interested in these broader range organ offers. If the program turned down an organ that would be highly sought after, then that organ would hold a lot of weight on the program's offer acceptance rate ratio because the offer would be expected to be accepted. However, as the program continues working down the match run, the pancreas offers within 250 to 500 nautical miles (NM) of cold ischemic time aren't expected to be accepted. So, it is true

that the program will receive a minor demerit if they pass on the organ offer and another program accepts it farther down the match run. However, it is also true that just one acceptance of an organ that would be unexpected to be transplanted can wipe out the impact of those organ offers the program declined. The presenter summarized that the organ offer acceptance rate ratio doesn't limit a program from still trying to be a good advocate for their patient.

A member inquired about whether the MPSC did any modeling in terms of what percentage of those programs that the MPSC would consider to be in the yellow zone would eventually move on to being flagged by the MPSC. The presenter stated that modeling hasn't been done regarding that percentage, but the concept of the yellow zone was really to make sure the MPSC was still attending to their patient safety responsibility and bringing concerns to the attention of programs. The presenter mentioned that, with the yellow zone, the MPSC hopes to foster an environment where programs can evaluate what they are doing, since they know best what should be fixed, and then improve their performance.

A member inquired about the rationale for sticking with the pre-transplant mortality metric, since no programs were flagged for this metric and programs don't usually have influence over patients at that phase. The presenter explained that no kidney programs had been flagged for that metric, but there had been heart and liver programs that were flagged for the pre-transplant mortality metric. The presenter mentioned that kidney programs don't really actively manage or intervene on their list and, because of this, the numbers are so large that there are no outliers in performance.

The Chair inquired how Coronavirus disease 2019 (COVID-19) is going to affect some of these cohorts. The presenter explained that a death from COVID-19 would be factored in as any other death. An Scientific Registry of Transplant Recipients (SRTR) representative stated that COVID-19 is complicated and the MPSC is making decisions on a cycle by cycle basis. The representative stated that, at least for post-transplant outcomes, the cohorts are restarting in the middle of June 2020 due to COVID-19. Currently, there doesn't seem to be a lot of variability between the post-COVID-19 era and the pre-COVID-19 era to provide oversight.

A member stated they were intrigued by the organ offer acceptance metric and inquired if the reason to include that metric is to increase acceptance or incentivize filter use. The presenter explained that the main reason is to make the system more efficient. Some other pros of this metric are that it's a patient-centric metric, it's a metric the program can control, and it holds programs accountable to their larger community. The presenter also stated that this metric allows programs to learn from each other.

A member stated that, from the organ procurement organization (OPO) perspective, they think this metric is great and think OPO's will really appreciate it.

There was no further discussion.

Upcoming Meetings

• September 20th , 2021 (teleconference)

Attendance

• Committee Members

- o Rachel Forbes
- Oyedolamu Olaitan
- Dean Kim
- Maria Friday
- Megan Adams
- o Nikole Neidlinger
- o Parul Patel
- o Pradeep Vaitla
- o Silke Niederhaus
- o Todd Pesavento

• HRSA Representatives

- o Jim Bowman
- Marilyn Levi

SRTR Staff

- o Bryn Thompson
- o Jon Miller
- Nick Salkowski
- Peter Stock
- Raja Kandaswamy

UNOS Staff

- o Joann White
- o Rebecca Brookman
- o Anne-Marie Leary
- Lauren Motley
- o Leah Slife
- o Nicole Benjamin
- Sally Aungier
- o Sarah Booker
- Sharon Shepherd

• Other Attendees

Richard Formica