

OPTN Pancreas Transplantation Committee

Meeting Summary

April 1, 2024

Conference Call

Oyedolamu Olaitan, MD, Chair

Ty Dunn, MD, MS, FACS, Vice Chair

Introduction

The OPTN Pancreas Transplantation Committee (henceforth the Committee) met via WebEx teleconference on 4/1/2024 to discuss the following agenda items:

1. Follow Up and Discussion: New Project Ideas

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

1. Discussion/Report Outs: New Project Ideas

The Committee discussed and identified potential new projects ideas. In follow up to some of the project ideas, there were projects within each category identified as either a potential project for the Committee to move forward with or a project that is currently in progress:

Group 1: Focus group on improved offer acceptance rates

- Quality assessment in the operating room (OR) – should be standardized; increase use of NRP (helping OPOs with training)
- Transportation – geography is important
 - Collaborating with OPO Committee – potentially develop guidance around this

Group 2 – Optimize Organ Use

- Addressing procurement of pancreata
 - OPOs with procurement surgeons
 - Education/outreach – addressing resistance to pancreas transplantation (education for American Diabetes Association (ADA))
 - Training
 - Possible safety net
 - Wait time (selective of organ offers)

Group 3 – Enhancing OPTN efficiency

- Offer Filters
 - Education on how to use
 - Policy – requirement that all transplant programs use offer filters

Committee leadership reviewed the list prior to the meeting and provided the following recommendation for the Committee to consider and discuss further:

Development of a guidance document that would bring awareness and share best practices for consideration related to procurement of pancreata. Combining the topics suggested by the Committee as summarized above, the guidance document would include (but not limited to) the following:

- OPO procurement team – having discussions of these processes and an expertly trained person available
- ASTS fellowship (deprioritizes training for pancreas)
- Training - programs should have separate training from liver
- Education – outreach to endocrinologists
- Encouraging programs to have separate director rather than Kidney-pancreas
- Requirement/training (OPO Committee)

Summary of discussion:

The Committee will review and further outline the potential new projects identified and determine the sequence of projects.

A member suggested the Committee do further work on defining pancreas allograft (graft) failure. Currently in the field, there are more medications available in treating diabetes and it is being observed that more Type II diabetics are being transplanted in comparison to a decade ago. Due to these changes, there may be a need to revisit the definition of allograft failure.

The Committee Vice Chair replied that the Committee's work on this is unfinished and that this effort ties into issues related to (the burden of) data collection; as the Committee thinks about collecting pre-transplant data on medical urgency, there also needs to be consideration on other data collection opportunities. The Committee Vice Chair agreed that this is an important potential project for the future. There is a lot of knowledge to be gained about long-term outcomes for Type II diabetes that could be an added factor to the discussion.

Staff stated that reevaluation of the pancreas graft failure definition is on the list of project ideas previously discussed by the Committee and could potentially be worked on at the same time as the guidance document if the Committee were interested in doing so.

A representative from the Scientific Registry of Transplant Recipients (SRTR) agreed with the Committee Vice Chair and stated that the pancreas graft failure definition is limited by the amount of data available. The first iteration that came out was far from ideal, but it was limited by what data was collected at that time. Moving forward with this project, the Committee will need to identify what data points are needed. The SRTR representative suggested the Committee think about the ideal definition for pancreas graft failure in the modern era and from there, determine what data points are necessary. The SRTR staff then provided their personal thoughts (not speaking on behalf of the SRTR), that the biggest question facing pancreas transplant today is where does pancreas transplant stand; it would be important to address the current landscape and future outlook for pancreas transplant, projected outcomes with new therapies available today, and whether or not technology will make pancreas transplant obsolete? The SRTR representative suggested prefacing this guidance document that would address these questions.

The Committee Vice Chair agreed with this suggestion and stated that technology and scientific advancements are outstripping the ability to develop a policy that defines success. There is an opportunity to establish what would be meaningful outcomes and revisiting these discussions and thinking about how data could be captured on these points so that it could be applicable to all forms of beta replacement therapies; these are the types of conversations the Committee should start to have across the community.

The Committee Chair suggested that this effort could be done in conjunction with review of the Transplant Recipient Follow Up Form (TRF) for data collection to better support defining pancreas graft failure. The Committee Vice Chair added that this project should include engagement and input from the subject matter experts (SMEs) the Committee has engaged with in the past who could help with a definition on pancreas graft failure.

A member voiced support for the list of topics that would be included in the guidance document but noted that some of the topics may have a different focus. For example, the member asked if the suggestion of encouraging programs to have a separate pancreas director may be more suited for consideration by the OPTN Membership and Professional Standards Committee (MPSC). The member suggested the Committee break down the topics to determine how to address them (either including them in the guidance document or propose a separate project).

Staff replied that the topics listed were a compilation of the Committee's brainstorming ideas at this point and that this list could evolve as the Committee continues to discuss and develop an outline of this guidance document. It is possible for the list of topics to change as far as what would be included in the final guidance document and what topics the Committee may decide are better placed elsewhere (i.e., addressed in a separate project).

Another member stated that the fellowship training and the separate director boils down to numbers. If a transplant program is not doing enough pancreas transplants a year, there may not be enough opportunity in terms of training at those respective programs. The member voiced support in reaching out to endocrinologists and commented that in the curriculum for endocrine training, pancreas transplants are hardly taught. There is a need for collaboration with endocrinologists to further discuss and get to a place where pancreas transplant should be in the future.

The Committee Vice Chair asked the Committee to consider how the conversation may change if islets were available today. This may change how work with endocrinologists may be and a need to think about that as well.

A member stated that pancreas transplantation is currently not included in guidelines for endocrinologists. From their own experience, the member stated that they had not received referrals from an endocrinologist. There is a place for pancreas transplantation, but more clarity and awareness is needed.

The Committee Chair voiced agreement in thinking about what the landscape of pancreas transplant will be in the next 5-10 years; once more informed of what exactly the future state of pancreas transplantation will be, the Committee should then include endocrinologists more in the discussion. The Committee is already engaging with endocrinologist SMEs, which is a good first step; as the Committee's discussions and projects progress, there will be opportunities to get them more involved in defining pancreas transplantation in the future. The Committee Chair then commented on the pancreas graft failure project idea and stated that rather than looking at pancreas graft failure, it's more of islet failure of diabetes and having the endocrinologist SMEs involved in those discussions as well.

Another member asked if outreach to endocrinologists should be considered as a separate project. The member continued by voicing agreement that input from endocrinologists fits in with the question posed of what the future state of pancreas transplantation will be, however, the other topics listed don't seem to mesh with this point as much and seems like it could be its own project. The member added that once the future state of pancreas transplantation is defined, outreach to leadership within the American Diabetes Association (ADA) may need to be considered as well.

An SRTR representative stated their opinion that in the past, there have been attempts to engage endocrinologists as well as with the American Diabetes Association (ADA). The SRTR representative noted that there had been previous published papers where pancreas transplantation was not mentioned as an option for Type II diabetics; it is uncertain how much more outreach can be done and the success of recruitment of endocrinologists, however, it is still worth to continue engagement with endocrinologists as much as possible. It is important to get the message out about where pancreas is positioned in the next few years and discuss the advantages and limitations. The SRTR representative added that there are 40 plus years of data on the durability of a simultaneous pancreas-kidney (SPK) transplant; additionally, there is a need to get the message out among nephrologists too.

The Committee Vice Chair commented that it seemed like the endocrine society disregards pancreas transplant as an option. There was reference of an article that was recently published, titled "Generating strategies for a national comeback in pancreas transplantation: A Delphi survey and United States (U.S.) conference report"¹, which could potentially help inform and give the Committee on some direction on how they can move forward.

The Committee Chair commented on a previous point made on training being dependent on the number of pancreas transplants being done by a program. Although there is truth to this, there are high volume pancreas transplant programs and those that do large volumes of kidney and liver transplants that train their fellows in all three organs; there should be a refocus in training for pancreas transplantation. The ASTS fellowship training does not prioritize or have pancreas listed as an organ for transplant, but rather, as a subdivision and categorized with dialysis access.

¹ Ronald F. Parsons *et al.* Generating strategies for a national comeback in pancreas transplantation: A Delphi survey and US conference report. American Journal of Transplantation, 2024.
<https://www.sciencedirect.com/science/article/abs/pii/S1600613524002065?via%3Dihub>

Staff summarized the Committee discussion in the new project ideas discussed moving forward with a guidance document; the Committee would need to further discuss which topics outlined (or not mentioned) should be included. Additionally, the Committee will look further into the Committee's previous project idea of redefining pancreas graft failure and determining what data may need to be collected to further inform/define pancreas graft failure. Staff continued by asking the Committee to identify which stakeholders may want to be included in the development of the guidance document.

The Committee Chair suggested collaboration with the OPTN Membership and Professional Standards (MPSC) Committee, Organ Procurement Organization (OPO) Committee, and the Multi-Organ Transplantation (MOT) Committee.

An SRTR representative suggested rephrasing the Committee project as a white paper rather than a guidance document. A guidance document would provide guidance on how things should be; there would be input needed from a lot more stakeholders. A white paper, on the other hand, is more like a "wish list"; the Committee would address what is felt to be the right approach to the topics outlined, and then it would be at the discretion of others if they want to adopt those practices/approaches or not.

Staff clarified that there have been misconceptions on guidance documents in the past and there has been work by the OPTN on clarifying the purpose/intent of these documents. There has been concern voiced in the past that guidance documents become policies which is not necessarily the case in most instances. Staff further defined white papers as those documents that are more research-based while guidance documents are advisory and bringing awareness to certain topics; guidance documents are not prescriptive.

The Committee Chair asked if the guidance document would need to go through public comment. Staff confirmed that the guidance document would need to go through public comment.

An SRTR representative asked if a white paper is a peer reviewed publication that is submitted to journals.

Staff clarified that a white paper would also need to go through the public comment process as other documents. White papers can be published to journals but are still required to go through the public comment process. Upon this realization, the SRTR representative withdrew their previous suggestion due to their definition of a guidance document versus white paper differs from the definition established by the OPTN. Staff will provide a list of the various documents and their definitions to further clarify and to better inform the Committee on their next steps for the proposed project.

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

Next steps:

The Committee will review and further outline the potential new projects identified and determine the sequence of projects.

Upcoming Meetings

- May 6, 2024 (Teleconference)

Attendance

- **Committee Members**
 - Oyedolamu Olaitan
 - Ty Dunn
 - Asif Sharfuddin
 - Colleen Jay
 - Diane Cibrik
 - Jason Morton
 - Mallory Boomsma
 - Muhammad Yaqub
 - Nikole Neidlinger
- **HRSA Representatives**
 - Jim Bowman
 - Marilyn Levi
- **SRTR Staff**
 - Jon Miller
 - Bryn Thompson
 - Raja Kandaswamy
- **UNOS Staff**
 - Joann White
 - Stryker-Ann Vosteen
 - Cole Fox
 - Houlder Hudgins
 - Kristina Hogan
 - Lauren Motley