OPTN Kidney Transplantation Committee
Meeting Summary
September 16, 2024
Teleconference

Jim Kim MD, Chair
Arpita Basu, MD, Vice Chair

Introduction

The OPTN Kidney Transplantation Committee (the Committee) met via teleconference on 9/16/2024 to discuss the following agenda items:

1. Public Comment Presentation: Continuous Distribution of Pancreata Update
2. Public Comment Presentation: Require Reporting of HLA Critical Discrepancies and Crossmatching Events to the OPTN
3. Public Comment Presentation: Update Histocompatibility Bylaws

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

1. Public Comment Presentation: Continuous Distribution of Pancreata Update

The Chair of the OPTN Pancreas Transplantation Committee presented the *Continuous Distribution of Pancreata* update.

Summary of Presentation:

The purpose of this update is to inform the community on the progress to date on the Continuous Distribution of Pancreata project and share updates on the Committee's work in efficiency. The update paper:

- Describes progress on medical urgency discussions
- Provides updates on the Scientific Registry of Transplant Recipients (SRTR) data request
- Outlines conversations on promoting efficiency in procurement and allocation of pancreata

Medical Urgency

The OPTN Pancreas Transplantation Committee (the Pancreas Committee) decided to consider the addition of a medical urgency attribute, noting that this would provide a pathway for medically urgent pancreas patients to receive increased priority. Furthermore, the development of a Pancreas Review Board can support improved data collection regarding pancreas medical urgency.

The Pancreas Committee identified impaired awareness of hypoglycemia as a preliminary marker of increased medical urgency, and collaborated with endocrinologist subject matter experts to discuss potential characteristics for Review Board evaluation. These characteristics include metrics for reporting severe hypoglycemic events, alignment with Kidney medical urgency definition to remain consistent for KP access, cardiac autonomic neuropathy, and diabetic ketoacidosis.

The Pancreas Committee is in the process of developing and reviewing potential guidelines for Pancreas Medical Urgency.

Efficiency and Utilization

The Pancreas Committee recent discussed and submitted a request to the SRTR to assess the feasibility of including utilization as a modeled outcome for pancreas allocation. The request asked future analyses to support understanding of how proposed policies may impact several potential areas:

- Utilization and non-use of deceased donor pancreata, overall and by donor characteristics (age, BMI, DCD status)
- Recovery rates of pancreata
- Sequence number at final acceptance
- Timing of final acceptance relative to donor recovery
- Cold ischemic time
- Allocation by center aggressiveness

The Pancreas Committee has also discussed the increased non-use of pancreata being attributed in part to the logistics related to procurement and transplantation. The Pancreas Committee identified a potential project developing a guidance document that would provide awareness and share best practices for consideration as it pertains to procurement of pancreata and organ offer acceptance. The Pancreas Committee is seeking feedback on a variety of questions related to center and OPO procurement, with the objective to better understand barriers to procurement and devise potential solutions.

The Pancreas Committee is seeking feedback on the following questions:

- How might encouraging OPOs to have procurement teams for all abdominal organs, including pancreas, impact procurement?
- What innovative strategies could be implemented to enhance fellowship training and cultivate greater interest in pancreas transplantation among medical professionals?
    - And what range of skills and experiences might contribute to a professional's readiness to participate in organ procurement procedures?
- In what ways might encouraging programs to have a dedicated pancreas directors, separate from kidney, influence outcomes and growth of the programs?

Summary of Discussion:

The Chair remarked that the Pancreas and Kidney Committees have had similar discussions related to efficiency. The Chair asked if the Pancreas Committee plans to have medical urgency exceptions be reviewed prospectively. The Pancreas Committee Chair explained these exception requests would be reviewed prospectively, so the patient would not receive additional priority until the Review Board had made a determination on the case. The Pancreas Committee Chair continued that this will also provide a pathway for the Pancreas transplantation community to demonstrate cases where medical urgency priority may be necessary, which can help optimize medical urgency criteria.

The Chair asked if pancreas medical urgency will include strict criteria, noting that even hypoglycemic unawareness can be subjective. The Pancreas Committee Chair agreed and explained that the Pancreas Committee has deliberated on the subjectivity of potential criteria, but ultimately would like to develop an objective list. The Pancreas Committee Chair continued that for patients on a continuous glucose monitor or pump, time and range would be considered, and for those not on pump, hospital admissions for hypoglycemia may be considered. The Pancreas Committee Chair continued that the Pancreas Committee has consulted and will continue to consult endocrinologist subject matter experts regarding criteria and impaired awareness of hypoglycemia.

A representative from the Scientific Registry of Transplant Recipients (SRTR) noted that the modeling request submitted to the SRTR may not be able to inform on the challenges that impact pancreas utilization, particularly related to specialized procurement expertise. The SRTR representative explained that nearly every OPO has challenges finding a recovery surgeon who is comfortable procuring pancreata. The SRTR representative continued that it is difficult to model local recovery and other aspects of procurement with minimal data collection. The Pancreas Committee Chair agreed, and noted that behavior drives many elements of utilization, but that the Pancreas Committee hopes to glean some information about utilization and efficiency, particularly related to more marginal pancreata, that could guide policy development. The Chair agreed and noted it would be difficult to model local versus program recovery, and that elements of trust are required when local recovery is employed to recover pancreata. The Chair added that OPOs have begun to hire their own recovery surgeons, but that there currently isn't standardization to ensure pancreas recovery expertise. The Chair remarked that it's difficult to encourage programs to accept pancreata that are locally recovered, highlighting the trust required. The Chair of the Pancreas Committee agreed, noting that this is especially true for programs accepting pancreas from further away, and when local recovery information is limited. The Pancreas Chair explained that there can be a significant difference between a liver surgeon recovering a pancreas than a trained recovery surgeon with significant pancreas recovery experience.

One member pointed out that although Pancreas transplantation rates have seemingly declined, waitlist volume and transplant volume for kidney-pancreas has remained relatively consistent. The Pancreas Chair agreed, noting that the waiting list has been relatively stable, although recovery may be declining. The member responded, noting that pancreas transplants may be concentrated at those centers that have high volumes, and that it may be more difficult for smaller programs to maintain or increase volumes. The Pancreas Chair agreed, adding that this could similarly present challenges for patient access.

2. Public Comment Presentation: *Require Reporting of HLA Critical Discrepancies and Crossmatching Events to the OPTN*

A representative of the OPTN Histocompatibility Committee presented the Histocompatibility Committee's proposal to *Require Reporting of HLA Critical Discrepancies and Crossmatching Events to the OPTN*.

Summary of Presentation:

The purpose of this proposal is to require reporting of critical discrepancies in Human Leukocyte Antigen (HLA) to gain insight about root cause and develop prevention strategies to reduce the number of these cases. This proposal will also update the definition of critical discrepancies to focus required reporting of what is most immunologically significant and align with the required HLA typing resolution.

This proposal will require HLA critical discrepancy reporting to the OPTN Patient Safety Reporting Portal within 24 hours of discovery. This proposal will also update the definition of HLA critical discrepancy. Finally, the proposal will also require reporting of incorrect specimens or typings used for physical or virtual crossmatch.

Currently, critical discrepancies are voluntarily reported to the OPTN. Reported events may lead to root cause analyses (RCA) and corrective action plan (CAP) to prevent errors from recurring. Histocompatibility labs are required to report critical discrepancies to OPOs and transplant programs.

Required reporting would provide system-wide information to inform future policy and prevention efforts. When caught after transplant, critical discrepancies are a patient safety concern due to

their potential to have an immunologic reaction in the recipient(s). Reducing HLA critical discrepancies would increase patient safety and system efficiency.

The current critical discrepancy definition includes discrepancies in the same split antigen group. The proposed definition excludes discrepancies within the same split antigen group. For example: A*01:01 is currently critically discrepant from A*01:02, however with this proposal, it will no longer be considered critically discrepant because it will be within the same split antigen group.

There is also potential for incorrect donor or recipient samples to be used in a physical or virtual crossmatch. This error could cause a potential immunologic reaction between the recipient and potential donor to go undetected. This should be required to report.

This proposal will require histocompatibility labs to report critical discrepancies to the OPTN within 24 hours of discovery. Upon review of the reported incident, this may involve performing root cause analyses to determine the cause of the HLA critical discrepancy and implementing corrective action plans as needed.

The Histocompatibility Committee is seeking feedback on the following questions:

- Is 24 hours an appropriate time frame for the initial report of a critical HLA discrepancy to the OPTN?
- Do you agree with the modified definition of a critical HLA discrepancy?
- Should incorrect donor or recipient samples for crossmatch be included in required reports?

Summary of Discussion:

The Chair asked what the scope of the concern is with critical discrepancies, particularly related to volume currently and expected volume. The presenting member responded that, based on the last pull of data from the donor histocompatibility forms, critical discrepancies occurred in about 0.3 percent of the donor population, equating to approximately 100 or so incidents out of 40,000 donors. The presenting member remarked that this could be underreported, particularly in cases where the donor is not retyped.

The Chair noted trends in increasing virtual crossmatching and asked if it is becoming more frequent for donors to be retyped as well. The presenting member remarked that retyping is common practice, and shared that they felt retyping was becoming more common, particularly as many laboratories have implemented next generation sequencing high resolution typing as routine. The member explained that, in order to get a higher resolution of typing for deceased donors, programs and histocompatibility labs will retype these donors. The member continued that many programs additional retype for confirmatory purposes, and to achieve higher resolution typing for donor specific antibodies post-transplant.

A member remarked that errors and incorrect reports should be included in final documentation, noting that this will help in understanding where the error occurred and how to prevent it in the future. The member continued that it is important to ensure documentation is correctly and clearly labeled, expressing support for a paper trail.

3. Public Comment Presentation: Update Histocompatibility Bylaws

A representative of the OPTN Histocompatibility Committee presented the Histocompatibility Committee's proposal *Update Histocompatibility Bylaws*.

Summary of Presentation:

The purpose of this proposal is to clarify and update the OPTN histocompatibility bylaws to align with upcoming Clinical Laboratory Improvement Amendments (CLIA) changes.

This proposal will:

- Allow multiple OPTN-approved laboratory directors at a histocompatibility lab
- Update laboratory director education and training requirements to align with CLIA
    - Laboratory directors must already follow CLIA requirements for qualifications; must be certified by a board approved by the U.S. Department of Health and Human Services (HHS)
- Clarify and expand requirements for laboratory agreements with transplant programs and OPOs
    - Proposed changes organize requirements into four named categories: HLA typing requirements, crossmatching requirements, antibody screening, and blood type verification
- Modify required personnel and add primary data coordinator to act as OPTN point of contact (POC)
- Update laboratory subcontracting requirements
- Remove requirement for the laboratory director to review and approve all subcontracting results before release
- Expand inactivation and withdrawal notification requirements
- Remove or clarify requirements that are redundant to existing regulatory requirements for labs

In 2020, a Histocompatibility Subcommittee developed proposed changes to Bylaws. The Histocompatibility Committee supported the proposed changes, and the OPTN Membership and Professional Standards Committee (MPSC) endorsed the initial draft language. In 2023, Centers for Medicare and Medicaid Services (CMS) published a final rule updating CLIA. These updates will be effective on December 28, 2024.

This proposal will require histocompatibility labs to evaluate their transplant hospital and OPO agreements to ensure they meet new requirements. Laboratories may choose to submit additional laboratory director applications but are not required to do so. OPOs and transplant programs may need to adjust contracts with their laboratories if they do not meet the new requirements.

The Histocompatibility Committee is seeking the following feedback:

- Are there any suggestions regarding metrics that should be considered beyond CLIA requirements?
- Are the components required within the transplant program and OPO laboratory agreements sufficient and clear?

Summary of Discussion:

There were no comments or questions from the Committee.

Upcoming Meetings

October 8, 2024 (in person)
October 21, 2024

Attendance

- **Committee Members**
  - Jim Kim
  - Christine Hwang
  - Eloise Salmon
  - Jason Rolls
  - Jesse Cox
  - John Lunz
  - Leigh Ann Burgess
  - Kristen Adams
  - Tania Houle
  - Toni Bowling
- **HRSA Representatives**
  - James Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Bryn Thompson
  - Grace Lyden
  - Jodi Smith
  - Jon Miller
- **UNOS Staff**
  - Kayla Temple
  - Shandie Covington
  - Kaitlin Swanner
  - Sarah Booker
  - Lauren Motley
  - Thomas Dolan
  - Stryker-Ann Vosteen
- **Invited Guest**
  - Oyedolamu Olaitan